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ATTD 2023 Invited Speaker Abstracts

IS001 / #171

OPENING CEREMONY

OPENING LECTURE - THE NEW FACE OF DIABETES

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Since the first clinical use of insulin, more than one hundred years ago, the face of diabetes has dramatically changed. Diabetes turns out to be a 'hydra' with many faces, with many pathophysiological routes, with many diagnostic paths and more importantly with many therapeutic opportunities. The last 20-30 years have seen an explosion in our knowledge and in our therapeutic approach of people living with diabetes, ranging from the introduction of novel insulins and novel technologies for measuring glucose and administering insulin, to the availability of direct organ protecting agents and disease modifying therapeutics, in particular in type 2 diabetes, but more recently also in type 1 diabetes. Research is moving on rapidly, with the promise of precision medicine for all just around the corner. In the whirlwind of progress, it will remain important to stay focused on what really matters: the quality of life of the person living with diabetes. For people to live longer and healthier lives, not only tools and techniques are important, but even more so education, motivation, accompaniment of the person living with diabetes. Making the person with diabetes a member of the multidisciplinary team will ultimately determine success. The way we communicate all the novelties and make them matter, really matter for those with diabetes, is crucial and we should never forget that there are as many faces to diabetes as there are people living with this disease. Importantly, we need to strive for an all-inclusive strategy in diabetes care: access to care should be there for all… independent on age, gender, where you are born in the world, your socio-economic status…. And probably that is the greatest challenge to be faced in the next years. A challenge however this community can and WILL overcome.

IS002 / #172

PLENARY (1) – CGM USE IN TYPE 2 DIABETES AND BEYOND

USE OF CGM WITH PEOPLE WITH DIABETES TYPE 2 NOT TREATED WITH INSULIN

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***Today's Headlines for CGM use in T1D*:**
''CGM-First,'' ''CGM-Standard of Care,'' ''CGM- Most significant advance in diabetes management since the discovery of insulin!''

***Today's Headlines for CGM use in T2D non-insulin users*:**
Amer. Board Internal Med- *Choosing Wisely campaign* promotes clinician-patient conversations about avoiding unnecessary care … like this example, **"**Don't routinely recommend daily home glucose monitoring for patients who have Type 2 diabetes and are not using insulin.''

What is the nature of the data we have today on CGM use in T2D non-insulin users?

I*ntriguing* - **survey** data; ''they say it helps…

I*nteresting* - **pilot** data; ''I think'' it might help…

I*nnovative* - technology **programs;** CGM ''seems to'' help patients…

I*ncomplete* - **registry** data, hints at populations of PwD who do better, so ''maybe it does'' help...

I*nformative* - ***trials*** *using CGM in T2D patients on insulin resulted in glycemic improvement compared to using SMBG, but minimal insulin dose changes were made, with the concluding summary, ''It must have been CGM guided lIfestlye changes.''*

I*nsistent* - powerful **anecdotes**, and voices of people with diabetes not on insulin, saying *''F*OR SURE IT HELPS!'' ''Please - Listen to me.''

What do we need to do for CGM to become a standard of care in T2D non-insulin users?

Determine - **how A1C and CGM data align/coexist** in the management of diabetes

Define - **the outcome(s)** we are trying to achieve with the help of CGM

Decide - if CGM data and profiles can **facilitate healthy lifestyle choices**

Deliberate - on the role of CGM in helping the **selection of high value diabetes drugs**

Decipher - CGM user **registry data** by separating out and evaluating T2D non-insulin users

Design - **RCT's and robust real-word** evaluations to demonstrate the value of CMG in non-insulin users

My prediction is that after we **I**nvestigate and **D**iscuss the "$\mathbf{I}_s$" and "$\mathbf{D}_s$" above we will want to r**ewrite a headline f**or people with T2D not using insulin that reads something like: ***"Of Course CGM Should Be Part of Diabetes Education, Management and Support for All People Living with Diabetes."***

IS003 / #173

PLENARY (1) – CGM USE IN TYPE 2 DIABETES AND BEYOND

USE OF CGM WITH PEOPLE WITH DIABETES TYPE 2 TREATED WITH BASAL INSULIN ONLY

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Glucose monitoring is central to safe and effective management for individuals with type 2 diabetes using insulin. It is estimated that approximately 30% of people living with type 2 diabetes in the USA are treated with insulin, with about two-thirds using basal insulin without prandial insulin. However, only about one-third of those individuals using insulin achieved HbA1c of less than 7.0%. Recent data also suggest there had not been much improvement in glycaemic outcomes in the USA between 2005 and 2016. Real-time (rtCGM) and intermittently scanned continuous glucose monitoring (isCGM), by providing frequent glucose measurements, low and high glucose alerts, and glucose trend information can better inform diabetes management decisions compared with episodic self-monitoring with fingerstick glucose. Studies have demonstrated that CGM improved glycaemic control in individuals with type 1 diabetes and with type 2 diabetes using insulin regimens with basal plus prandial insulin. However, the role of CGM in individuals with type 2 diabetes using less-intensive insulin regimens is not well defined. Key Objectives of this lecture include: Understand the status of current glycaemic control in people with type 2 diabetes Glycaemic profiles of patients with type 2 diabetes using basal insulin HbA1c, sensor-based and other outcomes from studies investigating the efficacy and safety of continuous glucose monitoring in people with T2DM only on basal insulin Impact of CGM on patient-reported outcomes and quality of life Use of SGLT2 inhibitors and GLP-1 in studies investigating CGM Mechanisms underpinning the improved outcomes Cost-effectiveness Gaps in evidence-based and future studies

IS004 / #174

PLENARY (1) – CGM USE IN TYPE 2 DIABETES AND BEYOND

USE OF CGM IN THE CYSTIC FIBROSIS POPULATION

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Cystic fibrosis related diabetes (CFRD) affects up to 20% of adolescents and 50% of adults with cystic fibrosis (CF). Although CFRD shares some characteristics of type 1 and type 2 diabetes, it is a unique form of diabetes caused primarily by insulin deficiency from progressive islet cell dysfunction and destruction related to underlying pancreatic exocrine disease and fibrosis. At present, the oral glucose tolerance test (OGTT) is recommended annually in adolescents and adults with CF to screen for CFRD, but screening rates have historically been suboptimal, particularly among adults. Insulin is the only recommended treatment for CFRD, but this can add substantial treatment burden to an already medically complex patient population. Continuous glucose monitoring (CGM) has been validated in people with CF, and CGM measures have been correlated with important clinical outcomes such as pulmonary function and nutritional status. Emerging data suggest that CGM may identify people at risk for the future development of CFRD and may be a promising approach for the diagnosis of CFRD, but prospective longitudinal studies investigating this as a tool for CFRD screening are greatly needed. Although data are very limited, CGM may also have a beneficial effect on the management of CFRD, including in combination with hybrid closed loop insulin pumps, offering the potential for improved glycemic control and decreased diabetes treatment burden. In summary, CGM technology may be particularly useful for addressing current challenges unique to CF, but further studies are needed to investigate the use of this tool in the screening, diagnosis, and management of CFRD.

IS005 / #175

PLENARY (1) – CGM USE IN TYPE 2 DIABETES AND BEYOND

THE VISION OF THE FUTURE OF CGM IN TYPE 2 DIABETES

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With the increasing number of people diagnosed with both type 1 and type 2 diabetes and related healthcare costs, it is imperative that we find easier ways to manage diabetes remotely and empower self-diabetes management. Recently, the JDRF launched Type 1 Diabetes (T1D) Index where they revealed stark disparities in T1D life expectancy by countries. They also project a 66-116% increase in the prevalence of T1D by 2040. Over the last three years, many new continuous glucose monitors (CGMs) have been approved in Western Europe and the USA. We have come a long way in the past 28 years from the first CGM being iPro, developed and launched by MiniMed (now Medtronic MiniMed, Northridge, CA, USA). Many CGM terminologies have been used, such as retrospective vs real-time, real-time vs isCGM, and adjunctive vs non-adjunctive. Now most CGMs are standalone factory-calibrated devices lasting for 10-14 days. At the time of this writing, about 8 million people are using a CGM for their diabetes management, and this number is likely to exponentially grow to more than 15-20 million in the next 5-10 years. Also, in the near future, we might see another electrolyte or a ketone measurement being measured continuously through the same device (CGM + CKM, etc.). The majority of the available CGMs have a MARD of <10%; and thus, are pretty accurate for their interoperability with other devices like insulin pumps. Just like many years ago, Louis Monnier, et al. had

shown that fasting blood glucose (FBG) values relate better in individuals with higher A1c and post-prandial blood glucose (PPBG) values correlate better with individuals with lower A1c values. Similarly now, Time In Range (TIR) correlates to the contributions by FBG and PPBG. The research data has clearly documented that use of CGM improves glucose control, TIR, reduces hypo- and hyperglycemia, and a higher TIR reduces the risk of micro- and macrovascular complications. Since the insulin need in patients with T2D has continued to increase, it is likely that the use of CGM will become the standard of care for people with both T1D and T2D. It is also likely that many people with pre-diabetes (T1D and T2D) could be detected before overt deterioration of glucose control and the risk of diabetic ketoacidosis (DKA). One wonders if glucose could be considered a vital sign just like blood pressure and heart rate.

IS006 / #180

PARALLEL SESSION - DECISION SUPPORT SYSTEMS

INCORPORATING EXPLAINABILITY AND INTERPRETABILITY INTO AI-ENABLED DECISION SUPPORT SYSTEMS

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Artificial intelligence (AI) and the sub-field of machine learning (ML) are yielding powerful tools that are beginning to impact the field of diabetes in a number of ways. ML algorithms are being trained to forecast glucose, to predict meal and exercise events, and utilized in decision support systems to make insulin dose recommendations. Larger data sets are now becoming available because of the ubiquity of commercial sensors and these data sets are being used to train new ML algorithms. A challenge in the use of ML algorithms in healthcare, is that the algorithms are oftentimes not interpretable or explainable. An algorithm with high interpretability means that the algorithm is adept at indicating the cause and effect relationship between an input and an output of the algorithm. An algorithm with high explainability is designed in such a way that it is possible to easily understand how an algorithm works and therefore why it provides a specific forecast or recommendation. In this talk, I will discuss how we are incorporating interpretability and explainability into an AI-driven app-based decision support tool called DailyDose that is used to provide insulin dosing and behavioral suggestions to people with type 1 diabetes using multiple-daily-injection therapy. Specifically, I will review several decision support approaches: (1) a rule-based system, (2) a k-nearest-neighbor approach and (3) a digital twin approach. I will discuss the strengths and weaknesses of each of these approaches as they relate to interpretability and explainability. I will show results from a recent clinical study on DailyDose that showed that glucose outcomes could be improved (6.3% increased time in range), but only when participants followed the recommendations provided by the app. A rule-based and an AI-based exercise decision support module within DailyDose will also be described with regards to interpretability and explainability. I will finally describe how the recommender engine in DailyDose compares with physician recommendations and how often the two agree.

IS007 / #181

PARALLEL SESSION - DECISION SUPPORT SYSTEMS

ARTIFICIAL INTELLIGENCE AND DECISION SUPPORT SYSTEMS

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Designing an integrated, scalable decision support and coaching platform for multiple daily injection therapy Artificial Intelligence (AI) based decision support tools offer great promise to improve the care for people with type 1 diabetes who use multiple daily injections. We designed and tested in a clinical study a smartphone app decision support tool, DailyDose. This system makes insulin dose adjustment recommendations once weekly driven by an AI-based algorithm. In the pilot clinical study, we found some participants did not accept recommendations even when clinically indicated based on glucose patterns. We conducted interviews with participants at the completion of the study which indicated involvement of clinical diabetes care and education specialists and behavioral health experts may improve uptake and interactions with the decision support system. However, this type of care is costly and resource intensive. In order to ensure scalability of the decision support system, we have designed a follow-up study whereby those participants not achieving glycemic goals with decision support app use alone would receive diabetes education and behavioral health support tailored to their needs. This approach may allow for greater scalability and effectiveness. This presentation will include discussion of (1) qualitative results from post-study interviews with participants, (2) incorporation of these findings into the decision support-app to improve usability and explainability, (3) development of a web portal for interaction of diabetes educators, behavioral health and diabetes providers with app users. These system updates are important to ensure people with type 1 diabetes are able to benefit fully from AI-based decision support systems. Lastly, the design of the next phase multi-site clinical study with DailyDose will be presented.

IS008 / #182

PARALLEL SESSION - DECISION SUPPORT SYSTEMS

PATIENT REPORTED OUTCOMES IN CLOSED LOOP STUDIES

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Closed loop (CL) automated insulin delivery leads to glycemic improvements yet there are mixed findings with regard to

patient reported outcomes (PROs). PROs refer to the subjective experience of the person using CL and often include topics such as quality of life, satisfaction, and diabetes distress. Common methods for obtaining PROs are validated surveys and structured interviews or focus groups. This presentation covers the results from CL studies and real-world publications with regard to PROs, why there are mixed findings (e.g., some studies show PROs improvements while others show no change), and how we can improve methods for PROs data collection in clinics and future studies.

IS009 / #186

PARALLEL SESSION - TECHNOLOGY USE IN PREGNANCY

AUTOMATED INSULIN DELIVERY IN TYPE 1 DIABETES PREGNANCY - ARE WE NEARLY THERE YET?

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Despite increasing use of continuous glucose monitoring (CGM) and insulin pumps, the pregnancy glucose targets of >70% time in range (TIR 3.5-7.8 mmol/L, 63-140mg/dl)) and mean glucose 6.0-6.5mmol/L (108-117mg/dl) is often only reached in the third trimester, which is too late for optimal neonatal outcomes. Outside pregnancy, hybrid closed-loop (HCL) insulin delivery systems are associated with improved glucose levels and early data for T1D pregancy suggest feasibility of use at home and in hospital settings, including after corticosteroids, and during labour/birth. The Cambridge adaptive MPC, is the first interoperable HCL android app (CamAPS® Fx) compatible with several insulin pumps (mylife YpsoPump®, DANA Diabecare RS® DANA-i®) and with Dexcom G6 sensors (G6, G7). It offers customizable personal glucose targets which can be tightened to keep pace with gestational changes in insulin pharmacokinetics and variations in insulin sensitivity and/or resistance. Randomised controlled trials are underway evaluating this and the Tandem t:slim X2®, and Medtronic 780G® HCL systems. Case reports on other systems including Diabeloop® (Dexcom G6 with Kaleido® insulin pump) and do-it-yourself artificial pancreas systems (DIY-APS) are available. This session will summarize the progress of ongoing HCL studies and translation into antenatal care.

IS010 / #189

PARALLEL SESSION - EXERCISE IN DIABETES

EXERCISE WITH AUTOMATIC INSULIN DELIVERY

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Physical exercise with type 1 diabetes is a challenge, regardless of whether the insulin is given as multiple daily insulin injections or insulin pumps. Current consensus guidelines for avoiding hypo- and hyperglycemia during and after exercise are available. Recent advances in diabetes technology have led to the development of automated insulin delivery (AID) systems for glycemic management of people with type 1 diabetes. However, little is known about their safety and efficacy around exercise, which can cause significant and often worrisome disruptions in acute glycemic control. Although consensus recommendations exist for exercise management with AID, the guidance is based on first-generation AID systems. Therefore, it is unknown how best to use the latest diabetes technologies around exercise.

In this presentation, data from new and ongoing studies that have investigated different glucose management strategies for training with the different generations of AID systems will be discussed. In addition, possible future management options for spontaneous exercise during AID treatment will be discussed.

IS011 / #190

PARALLEL SESSION - EXERCISE IN DIABETES

IS TECHNOLOGY USEFUL FOR BREAKING DOWN BARRIERS TO EXERCISE IN DIABETES?

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Clinical exercise guidelines recommend that children should aim to achieve at least 60 minutes of moderate-to-vigorous physical activity (MVPA) daily, but many youths with type 1 diabetes (T1D) are falling short of these recommendations. For individuals with T1D, exercise and physical activity can lead to disturbances in glycemia without proper preparation and implementation of these strategies. Some common strategies include insulin dose adjustments and/or carbohydrate feeding to reduce the risk of hypoglycemia during exercise. In addition to barriers such as lack of motivation to exercise and fear of hypoglycemia, exercise interventions in adults with T1D have been shown to be acceptable and feasible to deliver. Our team at Stanford is currently implementing a structured telehealth exercise education program in newly diagnosed youth with T1D. The exercise pilot study is part of the larger Teamwork, Targets, Technology, and Tight Control 4T Study that started youth with new-onset T1D on continuous glucose monitoring (CGM) technology, physical activity trackers, and exercise education approximately 1-month after diagnosis. This study also examined the potential association between physical activity and glycemia on active days in youth with T1D. We present data from focus groups aimed at understanding the parental and youth experiences in exercise education after T1D diagnosis and also benefits and challenges with real-world use of physical activity trackers.

IS012 / #191

PARALLEL SESSION - EXERCISE IN DIABETES

PHYSICAL ACTIVITY WITH LONG AND ULTRA-LONG-ACTING BASAL INSULINS

L. Bally

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The use of long and ultra-long acting basal insulins exposes people who are physically active to insulin levels that are entirely different from normal physiology. Consequences involve exercise-induced hypo- and hyperglycaemic excursions, alterations in substrate utilization and post-exercise metabolism. Large variations in individual clinical needs (e.g. purpose for engagement in exercise) introduces additional complexity. However, several pro-active strategies, including variation of exercise intensity, use of digital tools, pharmacological agents and nutritional strategies can help people on long and ultra-long acting basal insulins achieving maximal benefits from being physically active.

IS013 / #192

PARALLEL SESSION - EXERCISE IN DIABETES

AUTOMATED DETECTION OF MEALS AND EXERCISE EVENTS IN PEOPLE WITH DIABETES

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Background and aims The occurrence of several factors that disturb glucose homeostasis must be detected In real time to develop fully-automated insulin delivery (AID) systems. Meals, physical activities (PA) and acute psychological stress (APS) events should be detected and their characteristics should be determined to compute the optimal insulin doses to be infused by the AID system or suggested to a user in an advisory system. **Methods** Machine learning techniques ranging from support vector machines and decision trees to qualitative trend analysis and deep neural networks, along with systems engineering and multivariate statistical techniques can detect the occurrence of specific events, discriminate between different types of events and estimate the characteristics of the specific event (carbohydrates in a meal, intensity of PA, type of APS). Processing of signals from CGMs or wearable devices to filter out signal noise and motion artifacts, imputation of missing data, generation of features from measured variables and pruning of features to minimize collinearity in information improve detection and diagnosis accuracy. **Results** Various techniques can infer events that have occurred from CGM values reported (yielding feedback information) or from wearable device data as the event is occurring, well before it affects CGM readings (feedforward disturbance information that will affect glucose levels). Estimates of carbohydrates in a meal based on CGM data can provide miniboluses of insulin during a meal, Detection of physical activity type and estimates of energy expenditure inform the control algorithm of the AID system to enable adjustments of insulin infusion doses. Discrimination between PA and APS prevent incorrect dosing of insulin based on erroneous assumption that an increase in heart rate would always indicate PA. **Conclusions** The quest for fully-automated AID systems benefit from leveraging real-time data provided by wearable devices such as activity wristbands. Signal processing, systems engineering and machine learning techniques that can work with data generated in free living must be used for generating reliable information for use by the AID system.

IS014 / #198

PARALLEL SESSION - RESOLVING HYPOGLYCEMIA

LEARNINGS FROM THE HYPO-RESOLVE PROJECT

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Therapeutic insulin is lifesaving for many people with diabetes. However, despite 100 years of experience and many innovations, its use is still associated with elevated risks of hypoglycaemia, the burden of which impacts considerably on many aspects of daily life with diabetes. Hypoglycaemia remains a major barrier to achieving optimal glucose control, reduces quality of life, increases health care demand and costs, and is associated with cardiovascular events, cognitive decline and death. The Hypoglycaemia REdefining SOLutions for better liVEs (Hypo-RESOLVE) project is a public-private partnership that aims to increase our understanding of hypoglycaemia through a comprehensive multilevel approach in order to reduce the burden of hypoglycaemia. One of the activities is the construction of the Hypo-RESOLVE database, which contains data on hypoglycaemia from 98 clinical trials on insulin treatment among 60,000 participants with type 1 or type 2 diabetes, analysis of which will reveal better insight into the consequences of and risk factors for different levels of hypoglycaemia. In addition, the embedded 10-week Hypo-METRICS study will examine the psychological, clinical and health-economic impact of sensor-detected low interstitial glucose values and its relevance as compared to patient-reported hypoglycaemia. A large hypoglycaemic glucose clamp study, conducted among over 100 people with type 1 or type 2 diabetes, aims to reveal potential mechanisms underlying the association between hypoglycaemia and cardiovascular disease, focussing on inflammatory parameters and cardiac function. Qualitative research and a quantitative survey examine the widespread impact of hypoglycaemia on various aspects of quality of life, diabetes distress and related aspects in people with or affected by diabetes Finally, the basic science component of the project will reveal novel pathways of hypoglycaemia sensing, so as to better understand the pathophysiology of impaired awareness of hypoglycaemia. Data from Hypo-RESOLVE will provide the evidence needed to solidify the current and widely adopted International Hypoglycaemia Study Group (IHSG) 3-level classification of hypoglycaemia. Collectively, the outcomes of Hypo-RESOLVE will advance our understanding of hypoglycaemia, so as to alleviate its burden and improve the lives of people with diabetes.

IS015 / #230

PARALLEL SESSION - EMERGING TREATMENT OPTIONS FOR OBESITY AND TYPE 2 DIABETES

GLP-1 ANALOGS FOR THE TREATMENT OF OBESITY

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The classic approach to obesity treatment is a ''treat to failure'' model. If patients fail to lose weight or regain lost weight, they progressively escalate in a stepwise fashion to more intensive therapies, from lifestyle/behavioural therapy to pharmacotherapy and bariatric surgery.

Weight loss that is associated with clinically impactful outcomes for most adiposity based chronic disease (ABCD) is 10 to 20%. The marked increment in efficacy of modern anti-obesity medications (AOMs) permits the weight loss within this range of magnitude as a new treatment target. The first AOM that fully enables such ''treat to target'' approach is GLP-1 receptor agonist (RA) semaglutide 2.4 mg.

The safety and efficacy of semaglutide was evaluated in The Semaglutide Treatment Effect in People with Obesity (STEP) Phase 3a clinical development program. STEP 2 enrolled patients with overweight or obesity with type 2 diabetes (T2D), while the remaining STEP studies (STEP 1, 3 and 4) enrolled patients with overweight and at least one weight-related comorbidity or obesity without T2D. Semaglutide safely produces ≥10% placebo subtracted weight loss in 69.1-75.3% of patients without T2D and in 45.6% of patients with T2D. The estimated treatment differences for semaglutide versus placebo were 10.3 to 17.4%. More than half of patients lost ≥15%, up to 35% of patients were able to achieve ≥20% weight loss as an adjunct to lifestyle. In STEP 5 semaglutide led to clinically impactful and sustained weight loss of 15.2% at week 104 in adults with obesity without T2D, along with improvements in weight related cardiometabolic risk factors. The ongoing study SELECT was designed to see if semaglutide may reduce the risk of having cardiovascular events in patients with prior cardiovascular disease and will be completed in 2023.

Significantly more females than males in STEP 1, 3 and 4, while in STEP 2, a distribution between females and males was more even. Understanding some inter-sex related difference in efficacy and some sex-specific effects of GLP-1 RAs is important to further improve therapeutic approaches in obesity care. GLP-1 RAs is being studied in women with obesity and polycystic ovary syndrome (PCOS). The ovulation rate and menstrual frequency improved with GLP-1 RAs exenatide and liraglutide. Short-term preconception intervention with exenatide resulted in an increase of natural pregnancy rates in overweight and obese women with PCOS. A pilot study showed that preconception treatment with liraglutide increased pregnancy rates for patients with PCOS undergoing in vitro fertilization who responded poorly to first line reproductive treatment. In another pilot study liraglutide was superior to testosterone replacement therapy in improving an overall health benefit in men with obesity-associated functional hypogonadism after lifestyle intervention failed.

The great advances are being seen in the use of GLP-1 receptor agonists in combination with multi-agonist unimolecular peptides, such as glucose dependent insulinotropic polypeptide (GIP), gastrin, amylin analogue, and others. GLP-1 RAs and other developing therapeutic tools will change the way clinicians approach obesity and the prognosis of many ABCDs.

IS016 / #231

PARALLEL SESSION - EMERGING TREATMENT OPTIONS FOR OBESITY AND TYPE 2 DIABETES

UNIMOLECULAR MULTIAGONISTS (DUAL AND TRIPLE) FOR THE MANAGEMENT OF OBESITY AND CARDIORENAL RISK – AN UPDATE

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The selective glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., semaglutide, dulaglutide) have gained an ever-increasing prominence in the management of type 2 diabetes (T2D) and obesity, and several agents in the class have proven cardiovascular (CV) benefits. We are now moving into an era of incretin-based multiagonists. These so-called unimolecular multiagonists are single molecules that bind to and agonize 2 or more receptors. Recently, tirzepatide, a dual agonist of the glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 receptors was approved by regulatory agencies in the U.S. and Europe. In the T2D phase 3 SURPASS clinical development program, tirzepatide at 5, 10 and 15 mg once weekly demonstrated unprecedented glycemic and weight control across the spectrum of the disease, exceeding that seen with once-weekly semaglutide 1.0 mg (SURPASS-2) and titrated insulin degludec (SURPASS-3). In these studies, tirzepatide-treated patients exhibited a dose-dependent reduction in body weight exceeding a mean reduction of 10% in each trial, with up to approximately 60% of patients achieving ≥10% weight loss. In the recently published SURMOUNT-1 study, assessing tirzepatide for weight management in persons with overweight or obesity (without T2D), participants lost an average of over 20% body weight at 72 weeks, with approximately 40% achieving greater than 25% weight reduction. The tirzepatide CV outcomes trial (SURPASS-CVOT) is underway and scheduled to complete in 2024. A prespecified meta-analysis of 7 randomized-controlled trials assessing tirzepatide CV safety was recently published, demonstrating a 20% reduction in 4-point MACE for tirzepatide versus comparators thereby indicating its cardiovascular safety. Other GIP/GLP-1 receptor dual agonists as well as GLP-1/glucagon receptor agonists are currently in clinical development for T2D, obesity and/or non-alcoholic fatty liver disease. Additionally, a triple agonist (GIP/GLP-1/glucagon receptor) recently reported encouraging 12-week data in patients with T2D, with significant improvement in glycemic control and a mean reduction in body weight of approximately 10% at 12 weeks. It will be entering late stages of clinical development. As we look into the future, these important agents that address obesity and its many complications (including dysglycemia) should gain increasing prominence in our management of metabolic diseases. We await further weight loss data as well as data demonstrating potential cardiorenal benefits.

IS017 / #233

PARALLEL SESSION - EMERGING TREATMENT OPTIONS FOR OBESITY AND TYPE 2 DIABETES

BARIATRIC SURGERY: AN UPDATE

W. Pories

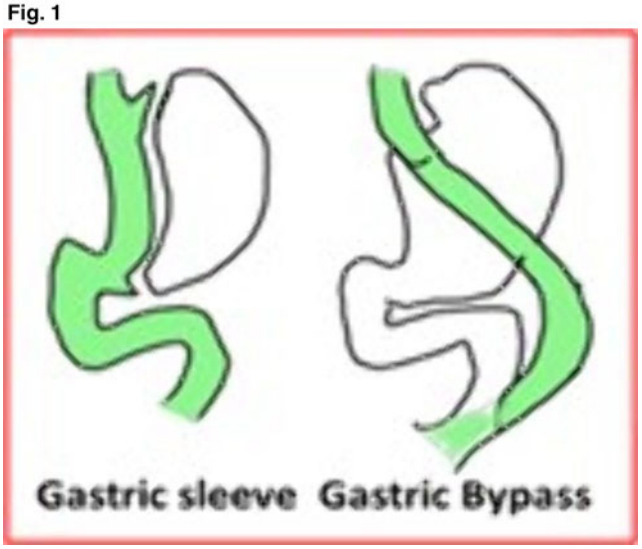
FACS, Md, Colonel, United States of America

Background: The classic description, I.e., that Type 2 Diabetes (T2D)is an incurable, unique and progressive disease due to insulin resistance, no longer holds true.

Methods: Basic and clinical studies as well as literature review

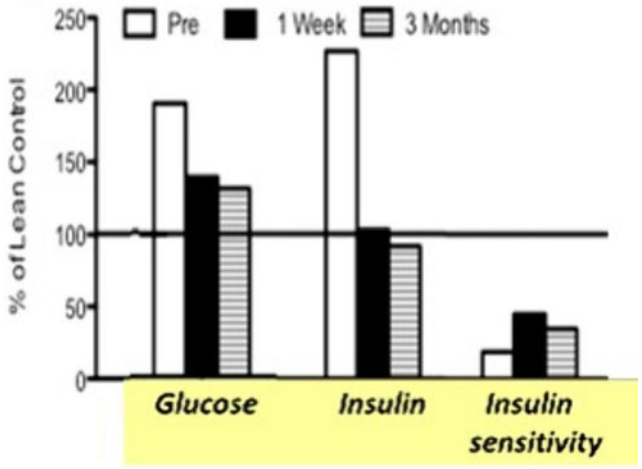
Results: The world-wide epidemic of obesity, T2D and hypertension and the dramatic effects of bariatric surgery and the newer medications call for a reassessment of our traditional beliefs about these diseases. The first challenge came from geriatric surgery. How could the two most commonly performed bariatric surgical operations, i.e. the gastric sleeve and bypass (Fig. 1),

Fig. 1



lead to full normalization of glucose, insulin and lactate levels in less than a week, before there is any significant loss of adiposity? If insulin resistance is directly related to T2D, why, as shown in Fig 2, did it remain unchanged for three months in our studies?

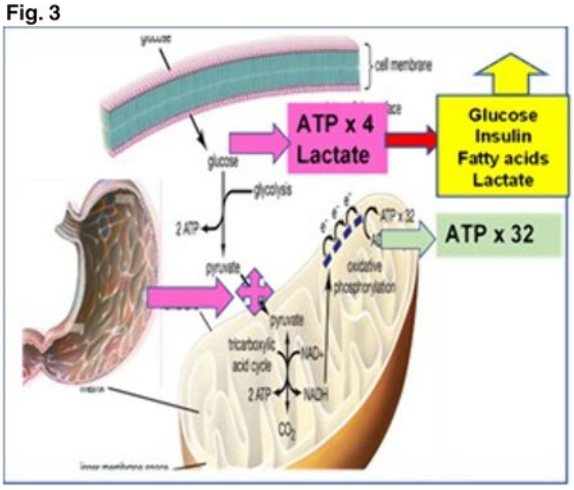
Fig. 2



Further, how does the traditional dogma explain the broad response to the surgery with the rapid and durable remission of T2D (83%), other expressions of metabolic disease also show long-term correction: hypertension (52%), dyslipidemia (63%), non-alcoholic steatotic hepatitis (NASH) 37%,, polycystic ovary syndrome (79%), migraine (57%), obstructive sleep apnea (74%), asthma 82%, cardiovascular disease (82%). stress urinary incontinence (44%), degenerative joint disease (41%), venous stasis disease (95%), gout (77%), improvement in cognition, reduction in the prevalence of cancer within five years and an 89% reduction in all-cause mortality? The durability of these effects is also remarkable. We have two patients, operated on 32 and 33 years ago, still free of T2D.

Conclusions: The key to understanding these effects, lies in the high lactate levels, reflecting only partial utilization of glucose by mitochondria, in patients with the metabolic syndrome**.** Because all of these effects follow a highly specific and limited intervention, i.e., decreasing contact between food and the stomach with rapid correction of glucose, insulin and lactate, a likely explanation is that this portion of the foregut sends a dysmetabolic signal to mitochondria that limits the utilization of glucose and fatty acids in most if not all organ systems as shown in Fig. 3.

Fig. 3



Instead of full utilization of glucose to produce 32 ATP, the signal limits energy production to 4 ATP with conversion of the remainder to lactate, glucose and fat.

While this mechanism that limits the conversion of glucose to ATP by mitochondria may be injurious today at a time of ready access to food, it could be an ancient adaptation that facilitated storage of fat in times of plenty. It could also be an underlying process in hibernation.

Based on these observations, our approach to T2D, obesity and the other expressions of the metabolic syndrome deserve review. Insulin resistance is not the cause of T2D.

IS018 / #210

PARALLEL SESSION - JDRF SESSION - CONTINUOUS KETONE MONITORING FOR TYPE 1 DIABETES

CLINICAL NEED FOR CONTINUOUS KETONE MONITORING INTEGRATED INTO CGM DEVICES (I.E. CGM-CKM)

D. O'Neal

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In people with type 1 diabetes, diabetic ketoacidosis (DKA) is a medical emergency and a major threat to life. While a failure in insulin delivery would also be signalled by increasing glucose levels, there are other causes of elevated glucose levels which are less likely to be associated with ketosis e.g. carbohydrate ingestion covered by an inadequate bolus, or emotional stress. In addition, DKA can also present without hyperglycaemia. Therefore, ketone levels should be checked in the face of significantly elevated glucose levels or if the person has nausea or vomiting. The current standard of care is measurement of capillary blood ketones using a ketone-capable meter. However, some people with type 1 diabetes may not check their ketones in a timely manner as not all meters have a ketone measuring function, and many people do not have in date ketone testing strips with them. Continuous glucose monitors are now the standard of care for glucose monitoring in people with type 1 diabetes in advantaged countries. These devices currently sense a single analyte only (interstitial glucose). Evidence indicates that interstitial ketone levels closely mirror those in blood. Incorporating a ketone sensor as part of a multianalyte platform which also senses glucose would overcome some of the limitations associated with our current approach to the early detection and management of ketosis. An ideal device would not increase the user's physical, emotional, or financial burden. The ketone component of the multianalyte sensor should act analogously to a car's airbag, sitting unobtrusively in the background for most of the time, and becoming evident and lifesaving under those (hopefully exceptional) circumstances when needed. A continuous glucose/ ketone sensor would be relevant to the general type 1 diabetes population and of particular importance for those with recurrent DKA; during an acute illness; those who are pregnant; those on an SGLT2 inhibitor; those on a low carbohydrate diet; or those undertaking high intensity exercise.

IS019 / #211

PARALLEL SESSION - JDRF SESSION - CONTINUOUS KETONE MONITORING FOR TYPE 1 DIABETES

SGLT INHIBITORS IN T1D: DKA RISK AND DKA RISK MITIGATION STRATEGIES, ESPECIALLY CGM-CKM, TO ENABLE THERAPY USE FOR HEART AND KIDNEY HEALTH

R. Busui

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Despite continous progress in the development and implementation of diabetes technologies (including automated insulin delivery systmes) into the clinical care for people with type 1 diabetes (T1D), only 20% T1D individuals meet the evidence-based A1c target shown to prevent chronic complications such as renal and cardiovascular disease (CVD). Additionally, a solley intensive insulin management regimen is associated with residual challenges such as overweight/ obesity, high disease self-management burden, substantial diabetes-related emotional distress, fear of hypoglycemia. Diabetic kidney disease (DKD) remains the leading cause of end-stage kidney disease (ESKD) in the USA and developed world despite improvements in glycemia management and the use of renin-angiotensin system blockade, with incidence rates of 30-40% in T1D. Also, heart failure has emerged as the most prevalent CVD complication in people with T1D, while DKD markedly increases the risk of CVD and heart failure, leading causes of increased mortality in T1D. For people with type 2 diabetes, sodium-glucose cotransporter-2 inhibitors (SGLT2i) have emmerged to effectively prevent CVD and DKD progression and associated severe outcomes including death. Whether similar results can be achieved in T1D remains unknown because traditionally people with T1D were excluded from the larger CVD and CKD outcome trials. Add-on to insulin SGLTi therapy was shown to associate with significant glycemic, weight loss, and blood pressure benefits in several randomized clinical trials , and have been approved in Europe and in Japan for use in T1D. However, there are concerns about a causally increase in risk of diabetic ketoacidosis (DKA) with SGLT2i therapy in T1D. Background risk of DKA in the contemporary T1D population remains high, estimated at 5-7%**.** Furthermore, DKA is substantially more common in the underprivileged (lower socioeconomic class, certain ethnicities), among those struggling the most with self-management, younger age, and higher A1c. SGLTi is designated a component cause as it is neither necessary for the occurrence of DKA (the outcome is known to occur from other factors in the absence of SGLTi), nor sufficient (the outcome requires another precipitating factor in addition to the SGLTi such as illness, infection, starvation, or insulin pump malfunction). Mitigation strategies created by expert clinician and researcher panels have been published, though their implementation in clinical practice and their acceptatbility to patients and healthcare providers is not known. Data on the prevalence and risk of DKA in contemporary populations with T1D, the risk with SGLT2i as well optimal mitigation strategies will be dicussed.

IS020 / #212

PARALLEL SESSION - JDRF SESSION - CONTINUOUS KETONE MONITORING FOR TYPE 1 DIABETES

PRE-CLINICAL DEVELOPMENT OF CGM-CKM

I. Tamir

QuLab Medical, R&d, Herzliya, Israel

The unmet need for ketone monitoring in the diabetic population is underscored by the rising incidence of Diabetic Ketoacidosis (DKA). Current solutions for ketone monitoring are expensive and cumbersome, mostly involving serial measurements of capillary blood. These solutions are insufficient for real-time monitoring of ketone levels, which is required for reducing DKA incidence. Continuous Ketone Monitoring (CKM) wearable patches are under development by several groups, employing different approaches to measure levels of the most prominent ketone - beta-hydroxybutyrate (BHB) - in the interstitial fluid (ISF). Most of these approaches rely on the enzyme BHB-dehydrogenase to specifically oxidize BHB to pyruvate while generating the co-factor NADH in the process, which is then electrochemically sensed. QuLab Medical has developed a novel minimally-invasive intradermal patch platform for continuously monitoring multiple metabolites in parallel. We are in the process of developing a novel non-enzymatic sensor for BHB sensing. Combining this sensor with a CGM in a single patch device is expected to greatly benefit T1D patients, providing

them with multiple additional treatment options and empowering them to better monitor their condition and improve their overall health and well-being.

IS021 / #213

PARALLEL SESSION - JDRF SESSION - CONTINUOUS KETONE MONITORING FOR TYPE 1 DIABETES

FEASIBILITY AND PERFORMANCE OF A CONTINUOUS KETONE MONITORING SENSOR

S. Alva

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Current methods of ketone measurement using urine or blood ketones do not indicate the onset of ketosis or ketoacidosis, rather confirm if it is already in progress. In the case of diabetes ketoacidosis (DKA), alerting the patient about an impending DKA would reduce the complications of DKA, including hospitalization or even prevent it.

Feasibility of a subcutaneous continuous ketone monitoring (CKM) sensor was demonstrated using β-hydroxybutyrate dehydrogenase enzyme with a proprietary mediation chemistry in a FreeStyle Libre 2 sensor form factor. The in vitro performance of the sensor has been demonstrated up to 8 mmol/L, showing that the sensor responds linearly to the change in the concentration of ketone and with minimal variation between sensors. The first human study with participants on low carbohydrate diet demonstrated that subcutaneous ketone can be measured with these sensors, which tracks the capillary ketone levels over a 14-day period with a single retrospective calibration. The ketone levels generated with low carbohydrate diet were limited to 2mmol/L.

For the CKM sensor to be viable, the sensor needs factory calibration, as the fingerstick calibration is impractical. Performance of a factory calibrated sensor in the FreeStyle Libre 2 form factor was evaluated in a clinical setting where the study participants (without diabetes) consumed exogenous ketone to generate elevated ketone levels. The sensor results were compared to venous blood ketone using Precision Xtra ketone test strips. The sensor responded quicky to the changing ketone concentrations and the lag time was about 4 minutes. The mean absolute difference between the sensor and the reference results was 0.3 mmol/L.

The integrated continuous glucose – ketone monitoring will leverage the FreeStyle Libre 3 form factor. This dual analyte sensor system is designed to continuously monitor glucose and ketones levels every minute, in one sensor.

Funding: This study was funded by Abbott Diabetes Care, Alameda, CA.

IS022 / #215

PARALLEL SESSION - AID EXPERIENCE IN THE REAL-WORLD

– IN FRENCH CHILDREN

E. Renard

Montpellier University Hospital, University of Montpellier, Department Of Endocrinology And Diabetes, Montpellier, France

A cohort of 120 pre-pubertal French children, aged 6-12 years, 45%F/55%M, with Type 1 diabetes since 5.1+/-2.2 years treated by continuous subcutaneous insulin infusion since 4.4+/-2.4 years, with HbA1c of 7.8+/-0.6%, were included in a 18-week randomized control study to assess 24/7 vs. evening and night Automated Insulin Delivery (AID) using Control-IQ algorithm and were further followed-up with free-life 24/7 AID for up to 83 to 101 weeks. Under 24/7 AID with a mean of 94.1% of time in closed-loop, the time in 70-180 mg/dl target range (TIR) reached 67.5+/-5.6% after 18 weeks (+12.5% vs. baseline), while time below 70 mg/dl (TBR) was 2.6% (95%CI 1.9-3.6) (reduction by 41% from baseline) and mean HbA1c was reduced by 0.5%. TIR at night-time was 77.2 +/-7.7% and TBR 2.2% (95%CI 1.0-3.7). During the follow-up after 36 and 83-101 weeks, similar glucose metrics were sustained with no occurrence of severe hypoglycemia or ketoacidosis. Meanwhile, 45% of children entered in puberty with no impact on glucose control. During a 13-week period of closed-loop interruption, TIR and TBR went back to baseline levels, whereas a later 13-week confinement due to the COVID-19 pandemic while Control-IQ was active had no impact on TIR and TBR levels. Our data shows that AID using active Control-IQ in free-life provides sustained improvement of glucose control with no safety concern in children, including during the pubertal period.

IS023 / #216

PARALLEL SESSION - AID EXPERIENCE IN THE REAL-WORLD

AUTOMATED INSULIN DELIVERY IN BELGIUM IN REAL WORLD: A SPECIFIC MODEL COMING FROM THE PARADOX COUNTRY

R. Radermecker

CHU Liège, Liège University, Diabetes, Nutrition And Metabolic Disorders, Liège, Belgium

In Belgium, we have 3 Automated Insulin Delivery (AID) systems: the Minimed Metronic 780G system, the Tandem Basal or Control IQ and the Diabeloop.

The Belgian federal health authorities have allocated a specific fixed budget for new technologies in the management of diabetes.

This budget covers the reimbursement of some of these technologies but only through specific centers recognized as experts in the field and designated by these same authorities.

Reimbursement of these AID devices is only available to people with type 1 diabetes and according to certain criteria.

These devices are only implemented in the hospital setting (either during hospitalization or as an outpatient). Education is also provided by these hospital teams and the equipment is provided by the hospital.

There is therefore no intermediary service provider, as in some countries. The budget allocated by the authorities therefore covers the purchase of the equipment by the hospital, as well as the multidisciplinary staff required for education, according to a fixed reimbursement.

Finally, the reimbursement of these technologies by the authorities is conditioned by the obligation to carry out a real-life study in order to judge the relevance of this type of treatment and to ensure the sustainability of the reimbursement in the future.

The objective of these studies will be briefly discussed. Translated with www.DeepL.com/Translator (free version).

IS024 / #217

PARALLEL SESSION - AID EXPERIENCE IN THE REAL-WORLD

– IN THE UNITED KINGDOM

E. Wilmot[1,2], T. Crabtree[1], T. Griffin[3], Y. Yap[4], P. Narendran[5], G. Gallen[6], N. Furlong[7], I. Cranston[8], A. Chakera[9], C. Philbey[10], M. Karamat[11], S. Saraf[12], S. Kamaruddin[13], E. Gurnell[14], A. Chapman[15], S. Hussain[6], J. Elliott[16], R. Ryder[17], P. Hammond[18], A. Lumb[19], P. Choudhary[20]

[1]University Hospitals of Derby and Burton NHS Trust, Department Of Diabetes & Endocrinology, Derby, United Kingdom, [2]University of Nottingham, Translational Medical Sciences, Nottingham, United Kingdom, [3]University Hospital of Leicester NHS Trust, Leicester Diabetes Centres, Leicester, United Kingdom, [4]Liverpool University Hospitals NHS Trust, Department Of Diabetes & Endocrinology, Liverpool, United Kingdom, [5]University Hospitals Birmingham NHS Trust, Department Of Diabetes, Birmingham, United Kingdom, [6]King's College London, Diabetes, London, United Kingdom, [7]St Helen's Hospital, Diabetes, Merseyside, United Kingdom, [8]Portsmouth Hospitals University NHS Trust, Diabetes, Portsmouth, United Kingdom, [9]University Hospitals Sussex, Diabetes, Brighton, United Kingdom, [10]Harrogate and District NHS Trust, Diabetes, Harrogate, United Kingdom, [11]Heartlands Hospital, Diabetes, Birmingham, United Kingdom, [12]Good Hope Hospital, Diabetes, Birmingham, United Kingdom, [13]County Durham and Darlington Foundation Trust, Diabetes, Durham, United Kingdom, [14]Cambridge University Hospitals NHS Trust, Diabetes, Cambridge, United Kingdom, [15]Manchester University Hospitals NHS Trust, Department Of Diabetes, Manchester, United Kingdom, [16]Sheffield Teaching Hospitals NHS Trust, Department Of Diabetes, Sheffield, United Kingdom, [17]Sandwell and West Birmingham Hospitals NHS Trust, Department Of Diabetes & Endocrinology, Birmingham, United Kingdom, [18]Harrogate and District NHS trust, Department Of Diabetes, Harrogate, United Kingdom, [19]Oxford University Hospitals, Department Of Diabetes & Endocrinology, Oxford, United Kingdom, [20]University of Leicester, Leicester Diabetes Centre, Leicester, United Kingdom

AID experience in the real-world in the United Kingdom Background Hybrid closed loop (HCL) technology automates insulin delivery and improves outcomes in people living with Type 1 diabetes. We report real-world outcomes from adults with Type 1 diabetes with raised HbA1c despite insulin pump therapy and flash glucose monitoring. Methods A national clinical audit programme collected routine, anonymised clinical data submitted to a secure online tool. Reported outcomes include HbA1c, key glucose sensor metrics; Diabetes Distress Score; Gold Score; event rates (hospital admissions, paramedic callouts and severe hypoglycaemia) and user opinion of HCL. Results Follow up data were available from 520 HCL users; median age 40 (IQR 29-50) years, 67% female, mean diabetes duration of 21 (IQR 15-30) years, 85% white British. Baseline HbA1c 78.9 ± 9.1mmol/mol [9.4 ± 0.8%] reduced to 62.1 ± 9.1mmol/mol [7.8 ± 0.8%] at 5.1 (IQR 3.9-6.6) months median follow up. Mean adjusted HbA1c reduced by -18.1mmol/mol (95% CI -16.5, -19.6; $P < 0.001$) [1.7% (95% CI 1.5, 1.8, $P < 0.001$)]. Time in range (3.9-10mmol/l) increased from 34.2% to 61.8% ($P < 0.001$), time below range (<3.9mmol/l) reduced from 2.1% to 1.6% ($P < 0.001$). The proportion reporting diabetes-related distress reduced from 69.0% to 22.5%($P = 0.001$). Gold score reduced from 2.2 to 1.6 ($P < 0.001$). Almost all (96.3%, 549/570) would recommend HCL to others with diabetes; 94.7% (540/570) reported that the system had a positive impact on their quality of life. No significant increases in hospital admissions/paramedic callouts were found. Conclusion The NHS England pilot of HCL therapy led to substantial improvements in HbA1c, time in range and time below range over 5 months of follow up. The prevalence of diabetes related distress improved. Almost all reported a positive impact on quality of life and would recommend the use of HCL system to other people living with diabetes.

IS025 / #218

PARALLEL SESSION - AID EXPERIENCE IN THE REAL-WORLD

– REAL-WORLD ROLLOUT OF AUTOMATED INSULIN DELIVERY IN TYPE 1 DIABETES PREGNANCY

H. Murphy[1,2,3]

[1]Cambridge University Hospitals NHS Foundation Trust, Norwich, Cambridge, United Kingdom, [2]Norfolk and Norwich University Hospitals NHS Foundation Trust, Diabetes And Antenatal Care, Norwich, United Kingdom, [3]University of East Anglia, Norwich Medical School, Bob Champion Research And Education Building, Norwich, United Kingdom

Over the past 5 years there has been an unprecedented acceleration of diabetes technology use before and during pregnancies complicated by type 1 diabetes (T1D). The CONCEPTT trial established the benefit of Continuous Glucose Monitoring (CGM) for improving maternal glucose and reducing neonatal morbidity in T1D pregnancy. However, many women struggled to achieve and maintain the mean CGM glucose and time in range (TIR) targets required for optimal obstetric and neonatal outcomes. Automated insulin delivery systems have the potential to support women to safely achieve the pregnancy glucose targets from early pregnancy. This session will review the experimental and real-world experience of using hybrid closed-loop systems during T1D pregnancy. It will examine which commercially available systems are suitable for use during pregnancy and explore the opportunities and barriers to rolling out closed-loop in routine antenatal care. It will report on healthcare professionals' views about the training needed for hospital teams to support effective rollout of closed-loop systems including management of diabetic ketoacidosis (DKA) by emergency and maternity department staff, as well as inpatient hospital use following corticosteroids, and continuing closed-loop during and after labour/birth. We will report on how pregnant women engage with closed-loop and how its use

during pregnancy affects their diabetes self-management, pregnancy experiences, interactions with healthcare teams and quality-of-life.

IS026 / #221

PARALLEL SESSION - CLOSED-LOOP IN ACTION

CLOSED-LOOP WITH ADJUNCT THERAPIES

A. Haidar

Research Institute of the McGill University Health Centre, Experimental Medicine, Montreal, Canada

Automated insulin delivery systems improve glycemia in type 1 diabetes but daytime control remains suboptimal and carbohydrate counting is still needed. Glucose control could be improved and carbohydrate counting burden could be reduced with the addition of adjunct therapies such as pramlintide, SGLT2i, and GLP-1. The amylin analogue pramlintide delays gastric emptying, suppresses nutrient-stimulated glucagon secretion, and increases satiety in people with type 1 diabetes. Adjunct use of pramlintide with closed-loop therapy improves glucose control during the day and has the potential to alleviate carbohydrate counting. SGLT2i inhibits glucose reabsorption in the kidney, which allows more glucose to be excreted in the urine and thus lowers blood glucose levels in an insulin-independent manner. Adjunct use of SGLT2i with closed-loop therapy improves glucose control during the day and night but increases ketone concentration and ketosis compared to placebo. Data on the adjunct use of GLP-1 with closed-loop therapy is lacking.

IS027 / #223

PARALLEL SESSION - CLOSED-LOOP IN ACTION

LEVERAGING BEHAVIORAL AND PHYSIOLOGIC PATTERNS COLLECTED FROM WEARABLE SENSORS AND A SMART-HOME TO AUGMENT NEXT-GENERATION CLOSED-LOOP ALGORITHMS

P. Jacobs[1], T. Kushner[1], C. Mosquera-Lopez[1], R. Dodier[1], W. Hilts[1], D. Branigan[2], D. Chen[2], J. Eom[2], E. Wan[1], J. Leitschuh[1], J. Pinsonault[1], L. Wilson[2], J. Castle[2]

[1]Oregon Health & Science University, Department Of Biomedical Engineering, Portland, United States of America, [2]Oregon Health & Science University, Harold Schnitzer Diabetes Health Center, SW Pavilion Loop, United States of America

Wearable sensors and smart-home based sensors are becoming ubiquitous but they have not yet been integrated into automated insulin delivery (AID) or decision support systems (DSSs). We present a new algorithm called BlockRQA that is used to identify patterns from multi-variate, multi-modal data collected from both wearable sensors and smart-home sensors to identify behavioral patterns that can lead to negative health outcomes or other events important for glucose management. A total of 30 people with type 1 diabetes were recruited to be monitored for 4 weeks while wearing a CGM, an insulin pump, an Apple Smart Watch, and using a custom food and exercise tracking app while having their movement tracked with a beacon-based smart home monitoring system called MotioWear (MotioSens, Portland OR). Twenty-four participants had data that were usable for analysis of patterns. We found that BlockRQA was able to identify patterns that led to 61% of low glucose (<70 mg/dL) events on average. We found that meals could be anticipated 30-60 minutes in the future when utilizing movement data from the smart home along with other physiologic data within the BlockRQA algorithm whereby an average of 46.2% of meals could be anticipated. We derived a *hypoglycemia risk score* that is defined as a prior-conditioned ratio of likelihood of a pattern leading to low glucose (<70 mg/dL) relative to likelihood of a pattern leading to high glucose (>180 mg/dL). We also derived a *meal anticipation score* that is defined as a prior-conditioned ratio of likelihood of a pattern leading to a meal relative to likelihood of the pattern leading to low glucose. The *hypoglycemia risk score* and the *meal anticipation score* may ultimately be used to increase the aggressiveness of insulin delivery for an AID algorithm in anticipation of a meal, or may be used to decrease insulin aggressiveness in anticipation of a behavioral pattern that has led to a problem event like hypoglycemia.

IS028 / #225

PARALLEL SESSION - DERMATOLOGY IN DIABETES

SKIN AND THE INSULIN PUMP: NEW FINDINGS

I. Hirsch

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Insulin pump infusion set failure is a common problem in all age groups, yet many with long-standing pump use have more problems with insulin flow. Skin pathology with insulin infusion has been studied with short-term animal models, but never with long term human use. Our group assessed non-invasive optical coherence tomography (OCT) and skin biopsy of 30 subjects using insulin pump therapy. OCT showed both dermal inflammatory changes and increased vascularity. Pump sites where the infusion set was removed immediately prior to biopsy, and 3-day old infusion sets showed no differences compared to control skin with inflammation, fibrosis, vascularity, fat necrosis, and IGF1, and TGFβ binding. Eosinophilic inflammation was also common with pump sites, but not seen with the controls. We also saw a positive relationship between inflammation and insulin dose, and a negative correlation between inflammation and time-in-range on continuous glucose monitoring. This single study has numerous implications. First, we have shown it is possible to study skin pathology both non-invasively and invasively in type 1 diabetes. Next, the implications of the findings need further study, particularly as they pertain to site failures and skin health after years of insulin infusion. The etiology of these findings need study, as insulin, the infusion set, or both could be involved. More skin data are needed for pediatric patients, multiple injections, and sensors.

IS029 / #226

PARALLEL SESSION - DERMATOLOGY IN DIABETES

SKIN INTEGRITY, TIPS, TRICKS AND HACKS FOR SUSTAINED DEVICE USE

L. Messer

University of Colorado School of Medicine, Barbara Davis Center For Diabetes, Aurora, United States of America

Diabetes device components including insulin infusion sets, patch pumps, and continuous glucose sensors all involve adhesive patches adhered to the user's skin. Wear is often for an extended amount of time (3-14 days), and requires continued, repeated exposure to chemical and mechanical agents. As a result, exposure to adhesives lead to acute and chronic skin problems that may impede comfortable use of diabetes devices. Skin complications from device use can range from contact irritation to contact allergy. Contact irritation causes direct damage to skin via chemical or mechanical agents, and results in a non-immune inflammatory response. Contact allergy is a hypersensitization of the immune response to a chemical agent in the adhesive. It can be immediate (Type 1 hypersensitivity, IgE mediated) or delayed (Type 4 sensitivity T-cell mediated). Contact allergy has been documented in response to isobornyl acrylate, colophonium, ethyl cyanoacrylate and N,N-dimethylacrylamide. Different devices contain different agents in their adhesives. To minimize complications from contact dermatitis, clinicians should discuss prophylactic strategies with users, including site rotation, skin preparation and chemical/physical barriers. Insufficient adhesion can be addressed with overpatches and tackifiers. Sensor removal agents and techniques are important for healing. For contact allergy, it may be possible to use a skin protecting layer between the native adhesive and skin, however complete avoidance of the offending agent is often indicated. Overall careful skin care before, during, and after device application may reduce incidence of complications.

IS030 / #227

PARALLEL SESSION - DERMATOLOGY IN DIABETES

LONG TERM SOLUTIONS FOR IMPROVING INFUSION SITE CHALLENGES FOR INSULIN PUMPS

S. Pennathur

American Institute for Medical and Biological Engineering, University Of California, Santa Barbara, United States of America

Background: Phenolic compounds that are used for stabilizing or preserving insulin formulations may cause harmful side effects within the human body. Specifically, it may explain ''site loss'' or unexplained hypoglycemia for type 1 diabetes patients using continuous subcutaneous insulin infusion (CSII). In this work, I will present our research to date on a bioinspired polyelectrolyte-modified carbon electrode for effective electrooxidative removal of phenol from insulin and eventual incorporations into an infusion set of a CSII device.

Methods: To electrooxidize the phenol, we used a screen printed carbon electrode (SPE) that we modified with poly-L-lysine (PLL) to avoid passivation due to polyphenol deposition while still removing phenolic compounds from insulin injections. We characterized these electrodes using scanning electron microscopy (SEM) and electrochemical impedance spectroscopy (EIS) and compared their data with data from bare SPEs. We performed electrochemical measurements to determine the extent of passivation, and high-performance liquid chromatography (HPLC) measurements to confirm both the removal of phenol and the integrity of insulin after phenol removal.

Results: Voltammetry measurements show that electrode passivation due to polyphenol deposition is reduced by a factor of 2X. HPLC measurements confirm a 10x greater removal of phenol by our modified electrodes relative to bare electrodes.

Conclusion: Using bioinspired polyelectrolytes to modify a carbon electrode surface aids in the electrooxidation of phenolic compounds from insulin and is a step toward integration within an infusion set for mitigating site loss.

IS031 / #235

PARALLEL SESSION - WEEKLY INSULINS

ONCE WEEKLY INSULINS IN TYPE 1 DIABETES: SAFETY, EFFICACY AND DOES IT ADDRESS AN UNMET NEED?

S. Edelman

University of California, Division Of Endocrinology And Metabolism, San Diego, United States of America

Once weekly basal insulin is being developed for both type 1 and type 2 diabetes. Although most of the studies with weekly basal insulin are looking at type 2 diabetes , there are a few studies looking at the effects of weekly basal insulin in type 1 diabetes treated with a multiple daily injection regimens. Both Lilly's BIF and NovoNordisk's Icodec appear to be safe and effective comparted to insulin glargine and/or insulin degludec in clinic trials (details will be shown and discussed at the presentation). The promise of once weekly basal insulin comparted to once daily basal insulin includes greater convenience, better adherence, improved quality of life, reduced burden of self-management and easier for individuals in need of self-care assistance. Is there an unmet need in type 1 diabetes? For individuals on ''dumb'' pumps and hybrid closed loop systems there Is no obvious need unless an individual feels the technology is burdensome and stressful. For many on multiple daily injections regiments currently doing well on the second generation basal insulins supported by a CGM may or may not enjoy the need for one less injection per day. There will be a subset of T1Ds were adherence with their current daily basal insulin is poor leading to an elevated A1c and TIR in which weekly basal insulin may help. The successful use of weekly basal insulin in T1D, as well as T2D will require an intensive education program to the people living with diabetes and their HCPs for the proper switching, initiation, titration and long term monitoring. Education and protocols will also be needed for acute situations where the dose of basal insulin must be significantly reduced or increased.

IS032 / #236

PARALLEL SESSION - WEEKLY INSULINS

ONCE WEEKLY BASAL INSULIN FC (BIF): AN UPDATE ON THE TYPE 2 DIABETES CLINICAL DEVELOPMENT PROGRAM

J.P. Frias

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Basal insulin Fc (BIF) is a once-weekly basal insulin currently in phase 3 of clinical development. BIF is a fusion protein that combines a novel single-chain variant of insulin with a human IgG2 Fc domain and is designed for once weekly administration. It has a half-life of approximately 17 days due to slow absorption from the subcutaneous space, Fc-Rn-mediated recycling, reduced renal clearance, and reduced insulin receptor affinity (reducing receptor-medicated endocytosis). Importantly, it has low mitogenicity potential and low immunogenicity risk. In phase 1 pharmacokinetic (PK) and pharmacodynamic (PD) studies, BIF demonstrated dose-proportional PK with low between-day and -subject variability and a flat peak-to-trough ratio (1.14) throughout the week after administration. PD results in these studies demonstrated dose-dependent reductions in fasting glucose concentrations, consistent with PK results and with a once-weekly dosing regimen. Two phase 2 studies in patients with type 2 diabetes (T2D) have been reported to date; one in patients previously treated with basal insulin (32-week study) and one in in insulin naïve patients previously treated with oral agents (26-week study). Both studies compared once-weekly BIF to once daily insulin degludec, with change in HbA1c as the primary endpoint (non-inferiority). Both trials demonstrated significant HbA1c reductions from baseline for both insulins, which were non-inferior between BIF and insulin degludec. Rates of hypoglycemia were lower or similar with BIF versus insulin degludec and both insulin formulations were well tolerated with similar incidences of treatment-emergent adverse events. Based on these positive data, BIF has entered phase 3 of clinical development. The phase 3 program, called QWINT, is assessing BIF in patients with T2D who are insulin naïve as well as patients previously treated with insulin. It is anticipated that initial phase 3 results will be available in late 2023 or early 2024.

IS033 / #237

PARALLEL SESSION - CARDIOVASCULAR DIABETES

CARDIOVASCULAR OUTCOME TRIALS (CVOT): WHICH ROLE FOR RISK FACTORS CONTROL?

A. Ceriello

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Several studies suggest that, together with glucose variability, the variability of other risk factors, as blood pressure, plasma lipids, heart rate, body weight, and serum uric acid, might play a role in the development of diabetes complications. Moreover, the variability of each risk factor, when contemporarily present, may have additive effects. However, the question is whether variability is causal or a marker. Evidence shows that the quality of care and the attainment of the target impact on the variability of all risk factors. On the other hand, for some of them causality may be considered. Although specific studies are still lacking, it should be useful checking the variability of a risk factor, together with its magnitude out of the normal range, in clinical practice. This can lead to an improvement of the quality of care, which, in turn, could further hesitate in an improvement of risk factors variability.

IS034 / #239

PARALLEL SESSION - CARDIOVASCULAR DIABETES

CAUSES OF CARDIOVASCULAR DISEASE AND INSULIN RESISTANCE IN TYPE 1 DIABETES

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Despite remarkable progress in newer therapeutics and diabetes technologies for the management of type 1 diabetes (T1D), mortality in people with T1D still remains elevated. On average, the life-span of people with T1D is reduced by 10 years in developed nations (unfortunately, life-span is much shorter for people with T1D in developing nations); this is largely attributed to a higher burden of cardiovascular diseases (CVD). A number of large prospective studies have highlighted the importance of optimal glycemic control to reduce CVD risk in people with T1D. Besides glycemic control, optimal blood pressure and lipid management are paramount to CVD risk reduction in T1D. Studies have also shown that despite optimal control of three major factors (A1C, blood pressure, and lipids), CVD risk is still elevated in people with T1D, especially in overweight and obese individuals. The prevalence of overweight and obesity is increasing among T1D and it is associated with insulin resistance and heightened risk for cardio-renal complications. Moreover, insulin resistance in normal-weight individuals with T1D has been shown to have a higher prevalence of coronary artery calcification (CAC) score and progression of that CAC score. Mounting evidence is now implicating insulin resistance as an important and independent risk factor for CVD and CVD mortality in people with T1D. How can we reduce CVD risk in people with T1D? Clinicians must encourage all people with T1D to optimize A1C, blood pressure, lipids, and other CVD risk factors (e.g. smoking). Studies have documented clinical inertia in treating blood pressure and lipids, especially in adolescent and young adults with T1D. For example, in a recent study from the T1D Exchange Clinic Registry (USA) and German/Austrian Registry (DPV), only 4-6% of young adults with T1D were receiving anti-hypertensive or lipid-lowering treatment despite elevated blood pressure and lipids. Recent clinical trials with GLP-1RAs (glucagon-like peptide-1 receptor agonists) and SGLT-2 (Sodium glucose transporter-2) inhibitors have been shown to reduce CVD events and mortality in people with type 2 diabetes. Moreover, GLP-1RA and a newer dual incretin agonist (Tirzepatide) has been shown to reduce weight significantly. However, these agents are currently not approved by the US FDA (Food and Drug Adminisration) and EMA (European Medical Agency) for managing T1D and reducing CVD risk in people with T1D. Hopefully in future, these agents will be evaluated in randomized controlled trials to establish their glycemic and non-glycemic effects in people with T1D.

IS035 / #240

PARALLEL SESSION - NON-INVASIVE GLUCOSE MONITORING: REALITY VS. HYPE

NON-INVASIVE GLUCOSE MONITORING: BREATH, A REALISTIC OPTION?

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Non-invasive glucose monitoring (NIGM) refers to the measurement of glucose levels in the human body without puncturing the skin, drawing blood, causing trauma or pain. NIGM has become a desire of patients with diabetes ever since the search for a successful technique began about 1980 and has continued to the present time. Approaches that have been tried includes spectroscopic technologies like fluorescence, near-infrared, mid-infrared, stimulated emission/stimulated Raman, bio impedance, terahertz, and photoacoustic. It also includes other technologies like microwave/Radio frequency sensing, reverse iontophoresis and ultrasound. However, most of these NIGM approaches try to measure glucose levels in the skin and not in other compartments of the body. Measurement of Volatile Organic Compounds (VOCs) in breath has gained interest as an alternative approach. VOCs in exhaled breath are correlated to many disease areas, like diabetes (e.g. glucose, ketones), gastrointestinal related diseases (e.g. lactose intolerance), COPD and oncology. For the first product, we correlate VOCs concentrations in breath with glucose levels. The number of publications for diabetes and breath has grown throughout the years from 2 in 1995 to 342 in 2022. An accurate VOC breath analyzer would be a breakthrough in glucose monitoring as this solution would be non-invasive, gentle, affordable, user-friendly, less stigmatizing and would produce significantly less waste compared to existing finger-stick blood glucose or continuous glucose monitoring systems. Several challenges must be overcome for a successful development of a miniaturized VOC breath analyzer to enable glucose monitoring. For instance, VOCs that are highly correlated to glucose levels/changes must be properly identified, measured with sufficient accuracy and precision and their biological relevance must be verified. The cost and size of such a VOC analyzer must be optimized since GC-MS, the golden standard for chemical detection of VOCs, is a too costly and cumbersome method for a personal use. Additionally, an effective noise reduction system, working at the levels of the sampling module, the sensor and the algorithms must be developed to separate exogenous VOCs from endogenous VOCs. For regulatory agencies, measurement of VOCs in breath is a novel approach as well. Verification and validation of the breath analyzer that we have developed must include not only research studies, but also validation and longitudinal clinical studies. In view of these challenges, it is not surprising that no breath analyzer to monitor glucose has come to market yet. Nevertheless, a new and promising development of a breath analyzer is in clinical trials right now, most recently in a clinical study in patients with type 2 diabetes. The presentation will give an overview on breath VOC sensing, analyzer development and will discuss potentials and challenges.

IS036 / #241

PARALLEL SESSION - NON-INVASIVE GLUCOSE MONITORING: REALITY VS. HYPE

CONTINUOUS KETONE MONITORING

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Continuous glucose monitoring has improved diabetes care, showing beneficial effects on time in range (70-180 mg/dl), time below range, HbA1c, hospitalisations for acute complications, and quality of life. Monitoring of additional biomarkers such as ketones may offer further advantages. Ketones are being produced in conditions of insulin deficiency (e.g. in case of inadequate bolus/basal dosing, pen or pump failure), starvation or insufficient intake of carbohydrates (very low calorie diet), increased alcohol intake, during sick days, or when using sodium-glucose co-transporter-2 inhibitors (SGLT2-i). Treatment with SGLT2-i has shown cardiorenal benefits in people with type 2 diabetes and in those without diabetes. However, in people with type 1 diabetes (T1D) increased ketone levels appear in up to 3-4%. Even in people with T1D using a hybrid closed loop system, the danger of DKA is present, probably related to a reduction in total insulin delivery. Monitoring ketones is advised in these conditions, but in reality many at-risk patients do not have ketone test strips at home. Continuous ketone monitoring (CKM) may facilitate earlier detection of ketones, thereby possibly reducing hospitalisations for diabetic ketoacidosis (DKA) in high-risk people. In those developing DKA, CKM may potentially help to resolve this condition faster, and reduce in-hospital length of stay. However, this remains to be proven. In people using hybrid closed loop (HCL) systems, successful integration of a CKM into an automated insulin delivery device will require novel algorithms also integrating data on ketone levels. Ketone-specific alarms for high ketone levels, and predictive alarms and trend information will be useful features. The first-in-human results obtained in 12 volunteers of a CKM device were published in 2021 by Alva et al. The electrochemical sensor used wired enzyme to measure β-hydroxybutyrate (BHB), the major pathologic analyte. This sensor delivered a linear response over the 0-8 mM range with good accuracy and stability, both in vitro and in vivo, for 14 days. With a single retrospective calibration the mean absolute difference (MAD) for BHB concentrations <1.5 mM was 0.129 mM and 91.7% of the sensor results were within ±0.3 mM of the reference. For BHB ≥1.5mM the mean absolute relative difference (MARD) was 14.4%. Teymouran et al. reported data of a new real-time CKM microneedle platform based on the electrochemical monitoring of BHB alongside with glucose. This sensor detects BHB based on the NAD-dependent dehydrogenase enzyme and a selective low-potential fouling-free anodic detection of NADH using an ionic liquid-based carbon paste transducer electrode. In vitro data showed that the sensor had a high sensitivity (with low detection limit, 50 μM), high selectivity in the presence of potential interferences, along with good stability. We performed an early feasibility study (NCT04782934), including 4 participants with T1D and 3 healthy volunteers investigating the safety of the YANG near-infrared (NIR) spectroscopy multimetabolite sensor (developed by Indigo Diabetes nv, Belgium) which was implanted for 28 days. Exploratory data on accuracy were collected. Different protocols were performed to induce a broad range of glucose levels (glucose drink, from 40-400 mg/dL, 2.2-22.2 mmol/L) and ketones (ketone drink, up to 3.5 mM). NIR spectra for glucose and BHB levels analyzed with partial least squares regression were compared with blood values for glucose (Biosen EKF) and BHB (GlucoMen LX Plus). The implanted YANG sensor proved to be safe, well tolerated, and did not cause any infectious or wound healing complications. Six out seven sensors remained fully operational over the entire study period. Glucose measurements were sufficiently accurate (overall mean absolute (relative) difference MARD of 7.4%, MAD 8.8 mg/dL). MAD values were 0.12 mM for BHB levels. In summary, there is a compelling need for a device that can

continuously monitor not only glucose, but also ketones. However, so far only limited data (in vitro, in healthy volunteers, but also in T1D) is available. In the future, CKM exerts great potential to reduce the risk of DKA, and potentially also allow people with T1D to be able to use SGLT2-i for cardiorenal benefits.

IS037 / #242

PARALLEL SESSION - NON-INVASIVE GLUCOSE MONITORING: REALITY VS. HYPE

RAMAN NI-BGM FROM CONCEPTION TO REAL WORLD CLINICAL DEVICE; ARE WE THERE YET?

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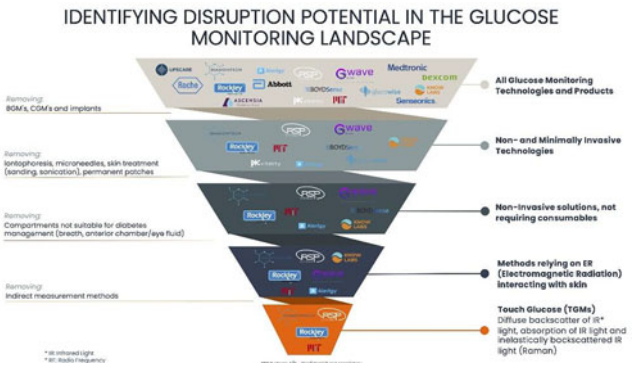
The quest for non-invasive Blood Glucose Monitoring (NI-BGM) intensifies: people/patients and their caterers want improved convenience, lower expense and less waste and in order to grow the industry needs ways of expanding the use of Glucose Monitoring. Years of failed attempts have disappointed stakeholders and thereby raised the barriers for realising a genuine solution.

To be successful, a NI-BGM solution must now offer clear advantages over CGM, which use is currently expanding, both as a stand-alone device, and increasingly integrated with insulin delivery.

Most attempts, broadly characterized as non-invasive BGM, does not promise such advantage, and when applying more stringent criteria (good accuracy, stable calibration, touch only and no waste), only a few approaches appear relevant as depicted below:

Of those, Raman spectroscopy clearly leads. An often overlooked feature is, that a practical device must be be stably calibrated. To surpass CGM in that respect, calibration should be stable for two weeks or more. Stable calibration has recently been demonstrated by NI-BGM devices using Raman spectroscopy. While Raman based devices have demonstrated the required performance and calibration stability, the associated low photon yield necessitates high yielding photonics, which currently limits applications due to cost. High power integrated VCSEL lasers and microspectrometers are about to change that, and next generation Raman devices are poised to rival CGM in performance, and surpass them in affordability, while delivering the ultimate convenience.



IS038 / #243

PARALLEL SESSION - ADVANCES IN FULLY AUTOMATED CLOSED-LOOP

AUTOMATED CONTROL MEETS BEHAVIOR: HUMAN-MACHINE CO-ADAPTATION OF THE ARTIFICIAL PANCREAS

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The first attempts to automatically regulate blood glucose levels in type 1 diabetes (T1D) via exogenous insulin were made between the 1960s and 1970s. Due to technological limitations of the time, applicability of all these pioneering efforts was rather limited, confining their use to inpatient settings. With the advent of less invasive and more accurate glucose sensors and insulin delivery methods, wearable automated insulin delivery (AID) systems were possible. After years of gathering clinical evidence and testing of system components and algorithms, the idea of a commercial product became a tangible reality. Now, more than 6 years after the U.S. Food and Drug Administration approved the first commercial AID system — the Medtronic Minimed^{TM} 670G, we can claim that AID solutions are becoming standard of care. However, all systems on the market still represent hybrid closed-loop (HCL) solutions that work best with premeal insulin doses. To understand why full closed-loop (FCL) designs remain in early stages, we should consider that in health, glucose metabolism is tightly controlled by a hormonal network that rapidly compensates for any physiological and behavioral disturbance. This fast response cannot be achieved with a minimally invasive AID system where glucose measurement and insulin infusion are both performed subcutaneously. In such setup, there are significant delays in insulin absorption and action that make impossible to match physiological plasma insulin profiles. Under these conditions, an aggressive design can increase the risk for hypoglycemia due to controller-induced insulin stacking. In control-engineering terms, a way to circumvent these structural limitations is through feedforward actions, or in other words, to anticipate the effect of important disturbances and take preventive actions. Off-the-shelf AID systems recognize the need for anticipation, but the burden falls on the users who are expected to assess the total amount of carbohydrates for every meal and prompt prandial boluses. This naturally links system's performance to user's behavior since the achieved glycemic control will rely on user adherence to manual doses. This presentation will revolve around two approaches that aim to compensate for the current slow response to fast biobehavioral disturbances. We will introduce an Adaptive Biobehavioral Control (ABC) strategy that recognizes the need for bi-directional human-machine co-adaptation. In this regard, ABC assists the person's adaptation to the AID system via information and risk assessment provided to the user while it adapts the AID system to the co-dynamics of physiological and behavioral disturbances. Also, focusing on FLC, we will discuss how we can design an AID system that can anticipate user's behaviors by injecting data-driven patterns of glycemic disturbances into its formulation. Insulin timing is the key, and timely biobehavioral adaptation can represent a viable means to take another step forward into the next generation of more effective AID solutions.

IS039 / #244

PARALLEL SESSION - ADVANCES IN FULLY AUTOMATED CLOSED-LOOP

CLOSING THE LOOP ON EXERCISE

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Many individuals living with diabetes are now on automated insulin delivery (AID) systems for the maintenance of their glycemia. While AID can effectively improve overall time in range and reduce hypoglycemia exposure relative to multiple daily insulin injections or standard pump therapy, management during times of increased physical activity remains a challenge with the current AID systems. This session will highlight current research programs that evaluate the efficacy and safety of current AID systems during and after exercise and will also provide evidence-informed strategies to help maximize AID control during exercise. The evolution of possible future ''exercise smart'' AID systems, including the use of glucagon, will also be discussed.

IS040 / #245

PARALLEL SESSION - ADVANCES IN FULLY AUTOMATED CLOSED-LOOP

ULTRA-RAPID INSULIN AND ANTICIPATORY ALGORITHMS

K. Dovc

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Glucose-responsive automated insulin delivery has improved the management of type 1 diabetes. Several clinical studies evaluating different automated insulin delivery systems have demonstrated safety and efficacy of these devices in individuals with type 1 diabetes in all age groups. Users of automated insulin delivery systems, however, still experience the everyday burden of constant engagement with the device, including meal or exercise announcement. Premeal insulin dosing bolus is required to prevent postprandial glycemic excursion due to the pharmacokinetic and pharmacodynamic delay and comparatively slow insulin absorption from subcutaneous administration of insulin. Ultra-rapid insulin formulations are continuously being developed and have the potential to further improve the efficacy and safety of automated insulin delivery systems, with the aim towards fully glucose-responsive insulin delivery. Data from clinical trials have demonstrated encouraging glycemic outcomes with ultra-rapid insulin formulations using various hybrid automated insulin delivery systems in adults and less in youth with type 1 diabetes. In this presentation, we will present contemporary data regarding ultra-rapid insulin formulations use with automated insulin delivery systems in individuals with type 1 diabetes.

IS041 / #246

PARALLEL SESSION - ADVANCES IN FULLY AUTOMATED CLOSED-LOOP

FULLY-AUTOMATED CLOSED-LOOP CONTROL: CHALLENGES AND POTENTIAL SOLUTIONS

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All contemporary automated insulin delivery (AID) systems are ''hybrid,'' in that the user is expected to announce meals and initiate meal boluses, or anticipate physical activity and attenuate insulin delivery in advance. Fully-automated Closed Loop is defined as an AID system that does not require meal or exercise announcements. While the most advanced hybrid AID systems have consistently shown improvements in overnight control, all studies to date point out that achieving optimal control during the day is still a challenge. This is a direct result of behavioral disturbances typically occurring during the day, e.g., meals or exercise that contribute to unexpected glycemic fluctuations. Moreover, the current speed of insulin action, even with modern ultra-rapid acting analogs, is still too slow to enable adequate AID response – it is simply too late to automatically inject insulin when CGM indicates a post-prandial BG excursion, or to discontinue insulin delivery when exercise is detected. In this presentation, we review various studies attempting to devise potential solutions for the Fully-AID problem: While studies comparing AID with ultra-fast vs. rapid insulin found little difference in achieved glucose control, inhaled insulin and adjuvant hormones, e.g., amylin or SGLT-2 inhibitors have been tried with better success and continue to be tested to mitigate the meal-excursion problem. New algorithms trying to anticipate the timing of the next meal or activity, have been tested in pilot or in-silico studies. Additional signals, such as motion sensing or heart rate, were tested to mitigate the effects of exercise. In conclusion, while promising ideas exist, reliable automated prediction of behaviorally-driven disturbances, and thereby full closed loop control, are still in infancy.

IS042 / #250

PARALLEL SESSION - TIMES IN RANGES

TIR AND OTHER TIMES IN RANGES ARE BETTER THAN HBA1C AS METRICS FOR QUALITY OF GLYCEMIC CONTROL

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Subtitle: Mean Glucose, *Time Above Range* (*%TAR*), and *Time In Range* (*%TIR*) are superior to HbA1c for assessment of *Therapeutic Efficacy* Aim: Evaluate CGM metrics as alternatives to **HbA1c** when evaluating therapeutic Efficacy. **Background**: **HbA1c** is subject to multiple sources of error that are difficult or impossible to overcome (e.g., RBC lifetime,

glycation rate). **Mean Glucose** is generally accepted as the main pathogenetic mechanisms underlying long-term complications of diabetes. **Method**: We re-analyzed correlations among ***%TAR***, ***%TIR***, **Mean Glucose,** and **A1c** reported by multiple studies (1-9), including 545 people with T1D (1-6), 5,910 people with T2D (7), 98 people with T1D during pregnancy and the postpartum period (8), among others (10). **Results**: Three CGM metrics, **Mean Glucose**, *Time Above Range* (***%TAR$^{>180\ mg/dL}$***), and *Time In Range* (***%TIR$^{70\text{-}180\ mg/dL}$***) are correlated with **HbA1c** and provide metrics that can be used to evaluate therapeutic *Efficacy*. **Mean Glucose** shows the highest correlation with ***%TAR*** (r = 0.98 in T1D, 0.97 in T2D) but substantially weaker correlations with ***%TIR*** (r = -0.73 in T1D, -0.83 in T2D) and **HbA1c** (r = 0.78 in T1D). ***%TAR*** and ***%TIR*** are highly correlated (r = -0.96 in T1D, -0.91 in T2D). Following an intervention (six-months use of rtCGM) by people with T1D, *changes* in **Mean Glucose** were more highly correlated with ***%TAR*** (r = 0.95) than with *changes* in ***%TIR*** (r = -0.85) or with *changes* in **HbA1c** (r = -0.47) (1). These metrics can be combined with metrics of hypoglycemia and/or glycemic variability to provide a comprehensive assessment of overall quality of glycemic control (11). **Conclusion**: **Mean Glucose, *%TAR,*** and ***%TIR*** are very highly correlated among themselves but relatively poorly correlated with **A1C**. ***%TAR*** shows a consistently better correlation with **Mean Glucose** than does ***%TIR***. Thus, **Mean Glucose** is the best metric, followed by ***%TAR*** and finally***%TIR***. Clinicians and patients can use **Mean Glucose** as the principal metric to evaluate quality of glycemic control and for evaluation of changes in response to therapeutic interventions. There should be no need to convert **Mean Glucose** into an estimate of **HbA1c** such as **GMI.** Regulatory agences should should modify and expand criteria currently based on **HbA1c** and instead preferably utilize **Mean Glucose**, ***%TAR, or %TIR,*** as measured by CGM. Additional metrics are available to combine *Efficacy* with *safety* (e.g., risk of hypoglycemia) (11). References 1. Beck RW, Bergenstal RM, Cheng P, Kollman C, Carlson AL, Johnson ML, Rodbard D. J Diabetes Sci Technol. 2019 Jul;13(4):614-626. doi: 10.1177/1932296818822496. Epub 2019 Jan 13.PMID: 30636519Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial. *JAMA*. 2017;317: 371-378. Crossref. PubMed.12. 2. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med*. 2008;359:1464-1476. Crossref. 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IS043 / #252

PARALLEL SESSION - FEAR OF HYPERGLYCEMIA

UPDATE ON GLYCEMIC TARGETS IN THE ICU

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We don't have evidenced-based glycemic targets in the ICU for as the data to date has been unclear (except for cardiac surgery). Society recommendations suggest all patients, with or without diabetes, maintain glucose in the 140-180 mg/dL range. These pragmatic targets consider glycemic safety (hypoglycemia) and concerns for hyperglycemia resulting in worse infection, wound healing, and inflammation. It has been noted repeatedly since 2002 (including with COVID patients) that those without diabetes have higher ICU mortality rates with hyperglycemia than those with diabetes. The reason for this is unclear. In 2020, Krinsley et al published a retrospective study where HbA1c levels were measured on each ICU patient starting in 2011. With over 5500 patients, it was shown those with HbA1c levels benefited from glucose levels 80-140 mg/dL and had a 3.5X higher mortality with glucose levels above 180 mg/dL. However, for those with admission HbA1c levels >8%, those with glucose levels 80-140 mg/dL had a 3X greater mortality than those with glucose levels above 180 mg/dL. A future study reported the exception to these observations were those with HbA1c levels less than 6.5% receiving insulin. For this population, mortality was almost twice as high with the well-controlled glucose levels of 80-140 mg/dL. While the etiology of these findings is not known, there are several speculatory hypotheses, including brain adaptation to pre-admission glycemia. This also explains why those with, compared to without diabetes appear to be protected in the hospital from hyperglycemia. While the

impact of these findings could result in ''precision glycemia'' for those admitted to the ICU, it is time to consider an appropriate randomized controlled trial to test these findings.

IS044 / #253

PARALLEL SESSION - FEAR OF HYPERGLYCEMIA

AVOIDING HYPERGLYCEMIA FROM DIABETES ONSET

N. Bratina

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It is well known that children are more sensitive to dysglycemia and that hyperglycaemia in youth is associated with decreased executive functions, possibility to learn and remember. But even nowadays talking about diabetes is discussing hypo/hyperglycaemia. Usually more time is spent discussing hypoglyceamia and the danger of severe hypoglycamia and the use of glucagon already at diagnose, but also later in out patient clinic or other opportunityies We have many questionnaires discussing the fear of hypoglycamia, but almost never ask patients how much they know about the danger of hyperglyceamia. But on the other hand - goals for good metabolic control are clear for all age groups - we discuss time in range above 70% (glucose values from 3,9 - 10 mmol/l) next to HbA1c of less than 7% (53 mmol/mol) or bellow also for children and adolescents, emphasising that glucose values should not exceed 14 mmol/l frequently (less than 5% daily), next to less than 1% of time spent bellow 3 mmol/l. Can we reach these goals? With modern therapy - newest insulins, insulin pumps, continuous glucose monitoring, the percentage of children and adolecents reaching those goals is increasing in the last 20 years. Times of frequent severe hypoglycaemia belong to history. But still - we know that parents carry the decisions about diabetes management for their children and this on short or long term can be related to anxiety, stress and depression and severe fear from hypoglyecemia and lead to metabolic detoriatation. Education is a powerfull tool for families of newly diagnosed childrenand later in life, so we must change the setting - more and earlier in the first days should be discussed about hyperglycaemia. Putting the hypo on the second place can also reduce the fear of hyperglycaemia.

IS045 / #254

PARALLEL SESSION - FEAR OF HYPERGLYCEMIA

FEAR OF HYPERGLYCEMIA IN PARENTS OF CHILDREN WITH TYPE 1 DIABETES

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Abstract OBJECTIVE: This study aimed to: (1) develop and validate a novel questionnaire for measuring fear of hyperglycemia among parents of children with type 1 diabetes (T1D) – the Hyperglycemia Fear Survey – Parent version (FoHyper-P); (2) investigate correlations between parental fear of hyperglycemia and objective measures of glycemic control. RESEARCH DESIGN AND METHODS: A multi-center, multi-national study of 152 parents of children with T1D was conducted in three large diabetes clinics from Israel, Poland, and Greece. Inclusion criteria were parents of children aged 6-16 years, at least 6 months from diagnosis, at least 3 months of CGM use and parental involvement in care. Parents filled the FoHyper-P and the Hypoglycemia Fear Survey - Parent Version (HFS-P). Patient data were obtained via electronic medical records and informative questionnaires. RESULTS: Significant correlations were found between our new FoHyper-P and the HFS-P including total questionnaires scoring (r = 0.747, p<0.001), worries subscales (r = 0.735, p<0.001), and behavior subscales (r = 0.532, p<0.001). Significant correlations were also found between time in range (TIR) (r = -0.18, p = 0.029) and time above range and parental fear of hyperglycemia (r = 0.192, p = 0.02). Correlations were found between worry subscales, and HbA1C in the past year (r = 0.198, p = 0.014) and percent of hyperglycemia (r = 0.236, p = 0.004). A negative correlation was found between the worry subscale and TIR (r = -0.219, p = 0.008). CONCLUSIONS: The FoHyper-P is a novel, validated tool for assessing parental fear of hyperglycemia which also correlates with objective measures. Integrating it into clinical practice can address an underestimated aspect of parental diabetes management, thus enabling better care for children with T1D.

IS046 / #255

PARALLEL SESSION - TECHNOLOGY FOR THE HEALTHY AGING OF OLDER PEOPLE WITH DIABETES

WHY HEALTHY AGING WITH DIABETES IS A CHALLENGE?

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There has been a significant evolution in technology to improve diabetes management over the past decade. Studies have shown that when used in appropriate patients, technology can ease the burden of self-care and provide a sense of security in all adults with diabetes. With successful aging in both type 1 and type 2 diabetes, there is an increased opportunity and need to use technology for better and safer diabetes management in the older population. However, there are several age-related factors that can act as barriers to the successful use of technology in older adults. Multiple medical comorbid conditions, including cognitive and physical decline, can make technology use challenging in this population. In addition, older adults with diabetes are a heterogeneous group with varying degrees of clinical, functional, and psychosocial characteristics that require individualized considerations. Finally, older adults at different stages of their life have different overall goals for health and quality of life, and require input from, not only patients, but also caregivers, to choose the appropriate technology. Thus, the barriers to successful technology use in older adults might be related to a combination of factors, including the patients themselves, their caregivers, their clinicians, and their healthcare system as a whole. To achieve optimal benefits while using technology and avoiding harm, it is

imperative to choose the right technology with a targeted, but holistic, approach for older patients with diabetes.

IS047 / #256

PARALLEL SESSION - TECHNOLOGY FOR THE HEALTHY AGING OF OLDER PEOPLE WITH DIABETES

ADVERSE OUTCOMES OF HYPERGLYCEMIA & HYPOGLYCEMIA IN OLDER PEOPLE WITH DIABETES- HOW SHOULD THE RECOMMENDED TARGET % TIR BE DETERMINED?

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The prevalence of diabetes increase with age. It is estimated that 25-30% of the population over the age of 65 have diabetes. As in the younger age group diabetes treatment aims at preventing the short and long term complications of the disease. However, in older age maintenance of cognitive function, physical capacity and prevention of dementia and disability become important treatment targets also. The lecture will present the data regarding the relationship between hyperglycemia, hypoglycemia and these diabetes complications that are important in older age. It will discuss the heterogeneity that exists in functional state and present current guidelines that recommend treatment targets be determined according to the health status of the individual. Using this data a framework for determining TIR in older individuals will be proposed.

IS048 / #258

PARALLEL SESSION - TECHNOLOGY FOR THE HEALTHY AGING OF OLDER PEOPLE WITH DIABETES

THE USE OF HYBRID CLOSED SYSTEMS IN OLDER PEOPLE WITH DIABETES

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The number of older people living with type 1 diabetes is increasing. In an advantaged country such as Australia there are three times as many people aged 60 years or older living with this condition than aged 20 years or less. Older people are faced with unique challenges in managing their glucose levels. They vary widely in their functional state and have a higher prevalence of impaired hypoglycaemia awareness. Regardless, glucose control remains important because the adverse impact of both hypoglycaemia and hyperglycaemia are particularly pertinent to the older person living with type 1 diabetes. While Automated Insulin Dosing (AID) systems have been shown to improve glucose control in the general diabetes population and age has not impacted outcomes there have been few randomised-control trials targeting older people with type 1 diabetes. Data from available studies indicate that use of AID systems results in a significant increase in time in range in older adults without an increase in hypoglycaemia risk, with real world observational data providing supporting evidence. However, these data are derived largely from older high-functioning adults. Further AID trials are needed, including studies with more advanced systems that are tailored to address the needs of older people across the full spectrum of health including reduced vision, reduced manual dexterity, and impaired cognition.

IS049 / #942

SOME MORE HIGHLIGHTS IN DIABETES

WHY DO CGM PERFORMANCE ASSESSMENTS NEED MORE STANDARDIZATION?

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Systems for continuous glucose monitoring (CGM) have become an essential tool in the therapy of people with diabetes that provides information to the patent and allows to calculate CGM derived parameters like TiR etc. Accuracy of CGM systems has since become a topic of discussion, promoting the mean absolute relative difference (MARD) as one of the key characteristics of a CGM system. Experiences from practice as well as from structured head-to-head studies, however, have shown that different CGM systems may exhibit considerable variations in clinically relevant accuracy parameters even if they claim similar MARD values. On the one hand, this shows that the MARD alone is inadequate to fully characterize the accuracy of CGM system, which has led to the proposal of several alternatives. On the other hand, it shows that the apparent accuracy of a CGM system can be highly dependent on various factors related to the design and evaluation of the respective performance study. Among these factors are the selection of study participants as well as the characteristics of the comparator measurements (e.g. range and rate of change) and their traceability. This leads to a broad range of reported accuracy and makes comparison of different systems indeed difficult because all aspects of the respective study design have to be taken into consideration which requires extensive background knowledge that cannot be expected from practitioners or users.

Given the importance of CGM in current diabetes therapy, reliable and transparent performance declaration is essential which can be reached by standardized and scientifically reasonable study procedures. In his talk, Dr. Freckmann will provide an overview on past and current efforts, including the work of the IFCC working group on CGM, to achieve this goal of standardization.

IS050 / #943

SOME MORE HIGHLIGHTS IN DIABETES

CAN HYBRID CLOSED LOOP AND/OR VERAPAMIL PROLONG ISLET SURVIVAL IN NEW ONSET TYPE 1 DIABETES? RESULTS FROM THE JDRF CLVER TRIAL

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Background: Thioredoxin-interacting protein overexpression induces pancreatic beta cell apoptosis and is involved in glucotoxicity-induced beta cell death. Calcium channel blockers, like verapamil, reduce these effects and in a small pilot study in adults with newly diagnosed type 1 diabetes (T1D) was found to preserve pancreatic beta cell function. Near-normalization of glucose levels instituted immediately after T1D diagnosis has been postulated to also preserve beta cell function by reducing glucotoxicity. Previous studies have been hampered by an inability to achieve tight glycemic goals. **Methods**: We conducted a double-blind factorial-design trial at six pediatric endocrinology centers across the United States. Using a balanced factorial design, each participant was randomly assigned to the verapamil group or placebo group and also to receive either intensive diabetes management with an automated insulin delivery (AID) system or standard care diabetes management. Eligible participants were 7 to <18 years old with type 1 diabetes diagnosed within 31 days of randomization who had at least one positive islet autoantibody, and for verapamil only weighed ≥30 kilograms and had no contraindication to use of verapamil. The primary outcome for both arms was mixed-meal-tolerance test-stimulated C-peptide area under the curve (AUC) 52 weeks from diagnosis. **Results**: For the drug-therapy arm, 88 participants were randomly assigned to the verapamil group (N = 47) or placebo group (N = 41). Participant age ranged from 8.5 to 17.9 years (mean 12.7 ± 2.4); 74% of the participants identified as non-Hispanic White, 3% as non-Hispanic Black, 17% as Hispanic White, and 5% as another or more than one race or ethnic group. The trial was completed by 44 of the 47 (94%) participants in the verapamil group and 39 of the 41 (95%) in the placebo group. For the intensive management arm, 113 participants were randomly assigned to the intensive-management (N = 61) or standard-care groups (N = 52). Participant age ranged from 7.0 to 17.9 years (mean 12 ± 3); 76% of participants identified as being non-Hispanic White, 4% as non-Hispanic Black, 14% as Hispanic White, and 4% as another or more than one race or ethnic group. The trial was completed by 60 of the 61 (98%) participants in the intensive-management group and by 48 of the 52 (92%) in the standard-care group. **Conclusions**: We will present the results of change in islet function as assessed by C-peptide AUC at 52 weeks in both arms of this multicenter randomized controlled trial.

IS051 / #945

SOME MORE HIGHLIGHTS IN DIABETES

THE USE OF SAP IN PREGNANCY: COMPARISON OF THE INITIATION OF THE TREATMENT BEFORE AND AFTER CONCEPTION

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Previous studies showed that achieving and maintaining optimal metabolic control remain a challenge during pregnancy complicated with type 1 diabetes (T1D). The International Consensus on Time in Range recommends increasing time in range (TIR) in pregnancy with T1D promptly and safely with a target glycaemia range of 3.5-7.8 mmol/L and TIR >70%.

However, CONCEPTT, a large multicenter randomized controlled trial of real-time continuous glucose monitoring (CGM) before and during pregnancy with T1D, indicate that women only achieved these targets towards the end of the third trimester.. However, it is suggested that even a 5% increase in TIR is associated with clinically relevant improvements in neonatal health.

Previous trials demonstrated the safety of sensor-augmented insulin pump therapy (SAP), and its potential to improve glucose control in pregnancy, without increasing maternal hypoglycemia. Also, recent trials conducted in women with T1D who started SAP before pregnancy, including our study, showed an earlier significant reduction of HbA1c and improvement in TIR all over from prepregnancy to third trimesters.

Hybrid closed-loop insulin pumps with automated insulin delivery based on CGM readings have not been approved for use in pregnancy. However, many women use it in preconception and during pregnancy, after discussion of risks and benefits. Recently, use of artificial pancreas (AP) with a model-predictive control algorithm, in pregnancy with T1D, was associated with comparable glucose control and significantly less hypoglycemia than SAP therapy. Further trials are needed to identify suitable candidates for CGM, SAP and AP technology in pregnancy.

IS052 / #259

PARALLEL SESSION - REMOTE TREATMENT OF DIABETES

POPULATION HEALTH MANAGEMENT IN THE DIGITAL DIABETES ERA

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Few diabetes centers have implemented risk-based approaches to differentiating care in the clinic. Yet clinicians and researchers recognize that individuals with diabetes do not all respond equally to various medical therapies (e.g., glucometer or CGM use; insulin delivery via pen, smart pen, insulin pump or automated insulin delivery system; non-insulin medications for type 2 or type 1 diabetes, etc.). Psychologists also recognize that individuals with diabetes do not all respond equally to behavioral interventions

designed to promote engagement with medications, glucose monitoring, physical activity or dietary interventions. Remote monitoring and mHealth tools for the first time allow clinicians to interact with patients' data and with the patients themselves between scheduled clinic visits. mHealth tools further allow clinicians to deliver behavioral interventions that are less time consuming, less expensive, and- in many cases- just as effective as in-person interventions. Thus clinics have the opportunity to create an entire toolkit of interventions that, along with population health management software, can be used to deliver personalized care that drives precision engagement at population scale. The speaker will review the essential ingredients for delivering a scalable, flexible population health management program in the clinic: quality improvement methods, software that integrates data from many sources and highlights patients at risk, clinic-owned mHealth app(s) that serve as a ''clinic in the pocket'' or a digital front door to the clinic, advanced predictive analytics, and a care delivery model that supports clinical micro-encounters via telehealth. Examples of such systems for diabetes and neighboring chronic will be provided from the research literature.

IS053 / #261

PARALLEL SESSION - REMOTE TREATMENT OF DIABETES

ECHO STUDY - DELIVERING TELE-EDUCATION ON DIABETES TO PRIMARY CARE PHYSICIANS IN UNDERSERVED AREAS

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Many people with diabetes do not receive care at a diabetes center. The ECHO model is a tele-education program developed at the University of New Mexico. Teams at Stanford University and the University of Florida developed an ECHO Diabetes program to improve care provided by primary care providers to people with T1D and intensively managed T2D in California and Florida. Goals included addressing disparities and the urgent needs of complex patients across the lifespan. In this presentation, data will be reviewed on experiences with recruitment (with a focus on reaching those people with diabetes under-represented in research), disparities experienced by people with diabetes in our study, primary care provider perspectives, use of diabetes coaches, and financial considerations of starting an ECHO Diabetes program.

IS054 / #263

PARALLEL SESSION - REMOTE TREATMENT OF DIABETES

OUTCOMES OF CONTINUOUS REMOTE CARE IN PRE-DIABETES AND TYPE 2 DIABETES

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Although telehealth existed and was widely implemented in the past, its potential and necessity was amplified in 2020 with the onset of the COVID pandemic. Many providers and patients shifted from periodic office visits to the use of episodic computer and telephone-based contacts. Although somewhat useful, these interactions cannot take the place of data and laboratory assessments, and always preclude direct patient examination. The true potential for telehealth requires data inputs from the patient to the provider, including anthropometrics and personal device data, with subsequent provider assessment, support, and follow-up therapeutic recommendations. Telehealth provides the opportunity to shift from an episodic encounter system (every 3-6 months) for chronic disease management to a continuous remote care paradigm in which data are continuously collected and reviewed, and patient support and education, together with therapeutic interventions may be instituted as rapidly and as often as needed. Diabetes serves as an ideal intervention to be managed by this continuous remote care telehealth model. This presentation will describe one model of diabetes care delivery using nutrition as the primary intervention through telehealth with data on sustainability, durability and patient outcomes, in a research setting over 5 years and in a real world setting over 2 years.

IS055 / #265

PARALLEL SESSION - NUTRITION AND FOOD TECHNOLOGIES

STRATEGIES FOR MITIGATING GLYCEMIC EXCURSIONS FOLLOWING UNANNOUNCED MEALS WITH EXISTING TECHNOLOGIES

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Post-prandial hyperglycemia can occur frequently, and it is still a challenge also in (advanced) hybrid closed loop (A-HCL) systems users, both children and adults. Usually, meal announcements are manual inputs to the A-HCL system, and to date no system in the market is able to manage unannounced boluses autonomously.

Some experiences exist using either larger or smaller amounts of carbohydrates. For example, a recent study from Italy found that children and adolescents with type 1 diabetes using an A-HCL (MiniMed 780G) system can tolerate an unannounced snack containing 20 g of carbohydrate without excessive blood sugar fluctuations. This may be particularly helpful for young children who are still not autonomous in providing insulin boluses through the pump when not assisted by an A-HCL skilled caregiver (e.g., grandparents, schoolteachers, and babysitters).

We investigated the efficacy of another A-HCL system (Control IQ) to contain post-snack glycemia in 42 children and adolescents with type 1 diabetes. Participants underwent two 2-h interventions involving midafternoon snacks (15 gr CHO and 25 gr CHO, respectively) eaten in random sequence without bolusing. Glucose values were significantly lower after 15 gr CHO snack (baseline vs. 2-h, 161 ± 52 mg/dl vs. 136 ± 45 mg/dl, $p = 0.008$ with one-sample Kolmogorov-Smirnov test), while after the 20 gr CHO snack a significant increase was observed (152 ± 57 mg/dl vs. 172 ± 73 mg/dl, $p = 0.028$). Correction

boluses were used in 21/43 patients (15 gr CHO snack) and in 30/42 patients (25 gr CHO snack). Although there is always the need to reinforce the importance of bolusing before meals, in selected circumstances, actual A-HCL systems pediatric users can eat unannounced snacks up to 15-20 g of carbohydrate, without causing a glycemic excursion.

Further studies are needed in larger cohorts for bigger unannounced meals, with any starting glycemia, and with other A-HCL systems.

IS056 / #266

PARALLEL SESSION - NUTRITION AND FOOD TECHNOLOGIES

COMPLEX MEAL HANDLING WITH ADVANCED HYBRID CLOSED-LOOP SYSTEM

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Background: Meal management is a major challenge for people with type 1 diabetes (PWD), especially of complex meals, containing high amount of protein and fat. More recently, advanced hybrid closed loop systems are available for diabetes management which reduce the daily burden of diabetes management. Yet, it is unclear how these systems respond to complex meals, and patient guidance for managing complex meals using these advanced technologies is lacking.

Objective: To explore 3 approaches of high-fat, high-protein (HFHP) meal management for people with diabetes (PWD) from most comprehensive scheme using the current standard of care (an open loop [OL] system), to a simplified, carbohydrate (CHO) counting-free approach using an advanced hybrid closed loop (AHCL) system.

Research Design and methods: An open label trail, among 15 adults with T1DM using AHCL system. The outcomes compared were postprandial glycemic control after consuming a controlled pizza meal across 3 study conditions: **1)** Standard of care bolus using OL therapy with sensor augmented pump therapy with predictive low glucose management feature on. **2)** Meal bolus using AHCL system with accurate CHO counting (CL). **3)** Meal bolus using AHCL system with CHO-free predefine bolus (CLP).

Results: Thirteen Participants, mean age 46.8 ± 12.8 years and baseline hemoglobin A1C (HbA1c) of $6.1 \pm 1.2\%$ completed the study. No differences were observed in time spent in target range (TIR) of glucose 70–180 mg/dL (3.9–10 mmol/L) between the groups during 5.0-hr post meal, but a significant higher TIR overnight was observed using either CL or CLP compared to OL (86.8 ± 13.4 and 81.8 ± 20.1 vs. 68.4 ± 22.6 , $p < 0.0001$ and $p = 0.023$, respectively). During a 12.0-hr post meal period, OL mean sensor glucose (MSG) and TIR were significantly inferior in comparison to CL and to CLP with a tendency for higher rates of hypoglycemia.

Conclusions: Our results indicate that glycemic control following a HFHP meal challenge by automated insulin system with or without accurate CHO counting is superior when compared with the highly burdensome meal management using OL and with less tendency for hypoglycemia. Thus, complex meal management using AHCL systems may improve glycemic outcomes and alleviate disease burden for PWD.

IS057 / #267

PARALLEL SESSION - NUTRITION AND FOOD TECHNOLOGIES

WHAT HEALTHCARE PROFESSIONALS AND END-USERS NEED IN IMAGE-BASED NUTRITION APPS

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Digital technologies have advanced rapidly in recent years and smartphones apps are increasingly used for different purposes, including health monitoring. Dietary assessment is critical for the prevention and treatment of nutrition-related diseases, including diabetes. There are numerous nutrition and diet apps available, and some of them are very popular in terms of user downloads, indicating a trend towards digital diet monitoring and assessment. However, the opinions of users and healthcare professionals (HCPs) who recommend nutrition apps have not been studied in detail. Preferences for nutrition app features, current use, and predictors of adoption from the perspectives of HCPs and end-users will be shared in this presentation. One interesting finding is that nearly a quarter of HCPs who have not yet recommended a nutrition app to their clients/patients are unaware of such apps' existence. Easy to use, free, validated apps that can automatically estimate calorie and macronutrient content are highlighted as important factors for recommending an app for HCPs. The use of inaccurate food composition databases, lack of local food composition database, and tech-savviness. were significant barriers for HCPs. The respective barriers for end-users were incorrectly estimated portion size, and nutrient content and the usage of database that does not include local foods. Although smartphone penetration is increasing and mobile health research is progressing, there is still room for improvement in HCP's recommendations and end-users' selection criteria of nutrition apps. Understanding user needs will assist researchers in the fields of digital dietary assessment and nutrition-related behavioral change, as well as computer scientists and AI experts who design, develop, or optimize such apps.

IS058 / #268

PARALLEL SESSION - NUTRITION AND FOOD TECHNOLOGIES

MOBILE APPLICATIONS FOR PERSONALIZED NUTRITION

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Preventing postprandial glucose elevations in people with diabetes (PWD) is critical in achieving tight glucose control. Treatment with an insulin pump and continuous glucose monitoring (CGM) or with automated insulin delivery systems enables tighter glucose control, trying to reach the goal of 70% of the time in the range of 70-180 mg/dl. However, both treatment modalities demand premeal bolusing by the patient according to the meal content.

Since carbohydrates are the macronutrient that primarily affects blood glucose, guidelines for diabetes treatment recommend carbohydrate counting as an effective strategy for achieving glucose control. Therefore, nutritional education given to PWD focuses on counting carbohydrates and dosing insulin accordingly. Nonetheless, most people with diabetes underestimate the amount of carbohydrates they eat and do not account for other food composites such as protein, fat, and fibers. Therefore, prandial insulin doses are usually inaccurate.

Smartphone apps can aid with meal insulin dosing. Nutritional apps for PWD are mainly food journals and food composition databases. More advanced apps use artificial intelligence to analyze a meal photo to collect information about its composition, while others suggest personalizing nutrition according to the person's microbiome. This data and data from insulin pumps and CGM devices may help understand the effects of different food and meals on blood glucose levels. Such applications are needed and should be an integral part of nutritional consultation, helping to personalize the diet for PWD.

IS059 / #271

PARALLEL SESSION - DESPAIR AND SELF-HARM & DIABETES TECHNOLOGY

UNDERSTANDING CLINICAL RELEVANCE ON A PRO

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It has long been recognized that a biopsychosocial approach to diabetes management is required for optimal health outcomes. In 1948, the World Health Organization (WHO) defined health beyond the absence of disease or infirmity to include 'a state of complete physical, mental and social well-being' [who-definition-of-health-1.jpg (888×665) (publichealth.com.ng)]. Furthermore, the WHO constitution states the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition [Constitution of the World Health Organization (who.int)] The challenge lies in the delivery of healthcare that achieve these goals. Many patient-reported outcome measures have been developed for use in diabetes, however their quality is variable. Furthermore, some measures are designed for use in clinical trials rather than in clinical practice and it is often not possible to determine what represents a meaningful difference of improvement or otherwise. In 2020, the FDA qualified the first PRO for use specifically in diabetes. This milestone represented an achievement of parity of esteem between standardized, rigorous assessment of a physical health outcome and a mental health outcome. Translating that standard into routine clinical care is necessary to enable healthcare professionals to effectively support their patients in optimal self-management of their diabetes. This presentation will provide clarity on what represents a patient-reported outcome, why that is important, what the underpinning science is pertaining to PROs, including mechanism of action and improvements in physical or mental health outcomes.

IS060 / #276

PARALLEL SESSION - PRACTICAL ISSUES IN DAILY LIFE OF PEOPLE WITH DIABETES

THE ISSUES WITH USING CE MARK AS A VALID PROXY FOR CONTINUOUS GLUCOSE MONITORING SYSTEMS ACCURACY FOR PEOPLE WITH TYPE 1 DIABETES

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In March 2022, the National Institute for Clinical Excellence (NICE) updated the United Kingdom (UK) diabetes guidance for adults (1) and paediatrics (2). The updates will make real-time continuous glucose monitoring and intermittently scanned continuous glucose monitoring (defined as CGM forthwith) accessible for all people living with type 1 diabetes. The NICE guidance lays out multiple factors when choosing a CGM device. Prudently, accuracy is the first factor; however, there are no internationally recognised design or performance criteria for accuracy studies, and NICE has called for a review (2). The updates also state, 'if multiple devices meet their needs and preferences, offer the device with the lowest cost' (1,2), making the UK market attractive to manufacturers with existing or prospective CGM devices with a range of prices and varied sensor accuracy, reliability and user-friendliness. The UK Medical Device Regulations (MDR) 2002 (3) brought into effect the Conformité Européenne (CE) marking regulations from the 1993 European Union (EU) Directive 93/42/EEC (4). Therefore, CE marking indicates the medical device is fit for purpose and no pre-market assessment is required by the UK patient safety regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) (3). Therefore, evaluating the robustness of the CE marking process is essential. This lecture starts by outlining the landscape of CGM accuracy detailing the available CGM performance metrics and explaining the rationale for focusing on manufacturer sponsored studies submitted for CE marking. The lecture goes on to describe the current regulatory framework for CE marking in the EU, in contrast to the United States of America (USA) Food and Drug Administration (FDA) and Australian Therapeutic Goods Administration (TGA) processes. Furthermore, the review highlights the limitations of the CE marking system compared to the FDA and TGA approval processes by appraising the clinical data requirements. The lecture discusses the acceptance of a representative sample of clinical data and studies using a device of equivalence for CE marking, resulting in wide-ranging indications for use that stretch beyond the available clinical data. Also, the review identifies the challenge in verifying if data 'on file' submitted by manufacturers is robust, considering the data misses the peer-review process required for a scientific journal publication. In contrast, the lecture references FDA and TGA approval documents showing the

approved indications for use mirror the available clinical data. The FDA published the integrated CGM (iCGM) study design and performance criteria to speed up approval and allow interoperability in 2018. The iCGM criteria define the standards required for CGM approval with manually operated digital technologies and automated insulin delivery systems (AID). Evaluating the CGM devices available in the UK against the iCGM criteria identifies several studies that used protocols that minimise glucose variability. Performance in the hypoglycaemic range did not meet the standards or was missing for many devices. The lecture discusses the inadequacy of using full glucose range accuracy metrics such as mean absolute relative difference (MARD. Finally, the lecture discusses opportunities and risks for UK medical device safety from 2025 because of leaving the EU. The main finding is the USA FDA and Australian TGA approvals are valid proxies of CGM device accuracy for the indicated populations due to the using the highest risk classification with specific assessment criteria that requires comprehensive product-specific clinical data. The CDRH of the FDA and Advisory Committee of the TGA complete conformity assessments against regulatory requirements as governmental entities, ensuring consistency without conflicts of interest. However, the time taken to receive FDA and TGA approval risks hindering innovation. In contrast, CE marking does not appear to be a valid proxy for the accuracy and performance of CGM devices. Multiple Notified Bodies perform conformity assessments against EU regulations without standardised criteria risking inconsistency of assessment, and their employment by the manufacturer introduces a potential conflict of interest. Publication and transparency in the clinical data that justified the CE marking would be welcome. CE marking for AID requires an urgent appraisal. The CGM-specific study design and accuracy criteria for iCGM approval offer a starting point for the standardisation of CGM Accuracy. However, more work is required to develop clear design verification standards and performance metrics depending on the CGM device category, for which the IFCC working group on CGM may provide. In the absence of standardised assessment criteria, the lecture offers an overview of considerations for the critical appraisal of study design, reporting, and performance of a CGM accuracy study to support stakeholders involved in the decision-making process. If unable to complete a full critical appraisal, when presented with a MARD of $\sim$10%, one could enquire, 'Did the study include participants in sufficient numbers with demographics similar to those I look after, did the protocol induce glycaemic variability on the test days, and what is the percentage of readings withing 15/15 agreement rates in the different glucose ranges?' If the UKCA marking system tightens regulation, there are justified grounds to suggest more stringent standards will hinder innovation and slow access to the latest technologies. Fro example, in the USA and Australia, where regulation is more robust than CE marking, the time required to gain approval is estimated to be double that of CE marking. Also, the CE marking system supports commercialisation of markets that can drive down prices and increase optionality for users and health care professionals. A solution could be for the UKCA marking system to implement study design criteria that apply to all CGM devices, with varying accuracy performance standards for different CGM device categories.

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IS061 / #277

PARALLEL SESSION - PRACTICAL ISSUES IN DAILY LIFE OF PEOPLE WITH DIABETES

HELPING ADULTS CHOOSE A SAFE AND EFFECTIVE CGM IN LIGHT OF NEW NATIONAL GUIDANCE

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There is growing evidence to support the use of continuous glucose monitoring in people living with diabetes. As such, in the UK the National Institute for Clinical Excellence (NICE) now recommend that all people living with Type 1 diabetes, and subgroups of people with insulin treated Type 2 diabetes should have access to interstitial glucose monitoring. In those with Type 1 diabetes the choice should ideally be based on individual preferences, considering the needs, characteristics, and functionality of the devices. Some of the factors to be considered for individuals with Type 1 diabetes include device accuracy, predictive alerts/alarms, dexterity, hypoglycaemia fear, psychosocial factors, need for use as part of a closed loop, calibration, data sharing, hypoglycemia awareness and cost. This lecture will consider the practical considerations above, alongside available evidence to support informed, collaborative decision making when deciding on the optimal continuous glucose monitoring solution.

IS062 / #278

PARALLEL SESSION - PRACTICAL ISSUES IN DAILY LIFE OF PEOPLE WITH DIABETES

IS IT EASY TO USE TIME IN RANGE (TIR) FOR DAILY MANAGEMENT OF DIABETES?

R. Ajjan

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This presentation attempts to compare and contrast two key glycaemic markers: the old and the new, represented by glycated haemoglobin (HbA1c) and time in range (TIR), respectively.

HbA1c has been used as the gold standard for assessing glycaemic control in diabetes, given the wealth of data linking this glycaemic marker to future vascular complications. While HbA1c served us well, this glycaemic marker is not without limitations as accuracy can be affected by factors that influence

red blood cell lifespan. Moreover, HbA1c fails to provide information on hypoglycaemic exposure and glycaemic variability, which are both associated with adverse outcome. HbA1c is also slow at assessing response to new glycaemic therapies, which can delay optimisation of glucose levels.

These were accepted limitations for HbA1c in the absence of a credible alternative. However, with the increased use of continuous glucose monitoring, additional glycaemic markers have surfaced that can address the shortcomings of HbA1c.

One of these modern glycaemic markers is TIR, depicting the time spent in glucose levels between 3.9 and 10 mmol/l (70-180 mg/dl) each day, and showing an inverse relationship with the risk of diabetes complications. While use of TIR is not as widespread as HbA1c, it is easy to understand and well accepted by health care professionals as well as individuals with diabetes. Importantly, TIR gives an unbiased account of glucose levels, and, unlike HbA1c, is not affected by red blood cells changes, while rapidly assessing response to the introduction of new glycaemic therapies.

Despite the clear advantages of TIR, HbA1c will continue to serve the diabetes community for a while. However, this old friend will need help from the new generation of glycaemic markers for optimal glucose management in people with diabetes.

IS063 / #284

PARALLEL SESSION - FIGHTING DISPARITIES

FIGHTING DISPARITIES: DIFFERENT WORLDS

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Diabetes care has continued to progress around the world-with an explosion of new drugs, insulin, technology etc. Yet a big challenge continues to be access to those who need it most-whether it be based on deprivation or ethnicity In this session-w e will look at 2 different funded health systems- namely UK and India- and see where the similarities end- yet also are quite close to each other. we will explore means to try and bridge gaps, methods being used-as well as ideas about taking things forward.

IS064 / #285

PARALLEL SESSION - FIGHTING DISPARITIES

BRIDGING DISPARITIES IN TYPE 1 CARE IN THE US

D. Maahs[1], D. Zaharieva[2], P. Prahalad[2], D. Scheinker[2], K. Hood[2], F. Bishop[2], A. Addala[2]

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The American Diabetes Association and the International Society of Pediatric and Adolescent Diabetes advocate (evidence grade level A) for the use of automated insulin delivery for all people with type 1 diabetes and other types of insulin-deficient diabetes who are capable of using the device safely. Data from programs designed to identify and reduce disparities in care for people with type 1 diabetes in the US will be reviewed.

IS065 / #286

PARALLEL SESSION - FIGHTING DISPARITIES

ADVOCACY AND ADOPTION OF TECHNOLOGY AND DISPARITIES IN INDIA

V. Mohan

Madras Diabetes Research Foundation & Dr. Mohan's Diabetes Specialties Centre, Diabetology, Chennai, India

The number of people with diabetes globally, is rising at an alarming rate. South Asia is one of the hot spots of the diabetes epidemic. In India alone, there are over 74 million people with diabetes today. Unfortunately, 70% of the doctors in India practice in urban areas while 70% of India's population lives in rural areas. This mismatch between the availability of health care professionals and the rapid spread of diabetes in rural areas, provides an opportunity to use technology to deliver the diabetes care to remote rural areas. The first part of this presentation will talk about a model of successful delivery of diabetes health care in rural India. The Chunampet Rural Diabetes Program was carried out in a group of 42 villages in Kancheepuram District in Tamilnadu. Using a Mobile van, a population of 27,014 individuals (86.5% of the adult population) were screened for diabetes. All those detected with diabetes were offered a follow up care at a rural diabetes centre which was set up during the project. The results were very impressive and led to good improvement in A1c levels using low cost generic drugs. The second use of technology was during the COVID – 19 pandemic and the lock down which was enforced in India and many other countries. Thankfully, Telemedicine was also legalized in India at that time. Using technology, a system was created whereby the doctor and the patient stayed at home but blood tests were arranged at home for the patient. With the results, teleconsultation was done by doctors using the Electronic Medical Records which were made available on their mobile phones. Thus, despite the lockdown, patients managed to get their tests and diabetes consultations done remotely. The third use of technology is through our network of diabetes clinics across India. Even at centres where there was no ophthalmologist, retinal photographs were obtained using a low-cost retinal camera and were uploaded for centralized diabetic retinopathy grading unit where the images were read by trained retina specialists. The eye reports were sent back to the peripheral clinics in real time. Over one year period, 25,316 individuals with diabetes could have their eyes screened for diabetic retinopathy. Only 11.4 % needed referral to an ophthalmologist for further management. Finally, the use of mobile Apps has revolutionized diabetes treatment. Recently, we have developed three diabetes related tools. **'DIA'** – an AI powered chatbot to assist people through automated digital conversations, '**DIALA'** – a patient-friendly mobile app and '**DIANA'** - a healthcare application for precision diabetes care. The details of these three tools are briefly described below : **DIA** : The Conversational AI Virtual Assistant **'DIA'** can interact in English with its unique conversational AI technology and intuitive interface, it has proved to be a useful solution for patients, providing complex dialogues, with quick response time and offers comprehensive solutions for patients with diabetes. DIA's uses range from scheduling appointments and reminders for visits, lab tests and teleconsultation, to addressing enquiries on available medicines, treatments, and facilities. During an emergency, health crisis or in pandemic situations, it connects with caregivers and patients to take proper action as per the seriousness of their conditions. Further, it shares notifications, updates patient engagement and special offers. In addition to this, DIA can

assist patients through reminders on their medicine refill via WhatsApp or SMS notifications and even facilitate purchase and tracking of medicine orders. **DIALA : 'DIALA'** is a **DIA**betes **L**ifestyle **A**ssistant Mobile Application. This app helps deliver superior and positive patient outcomes with weight tracking, step counts, diet plan adjustment, prescription refilling, availing reports of tests done, glucose monitoring data, scheduling appointments and sends reminders. It can help to monitor one's health and manage diabetes effectively. It is currently available in Android. **DIANA** : An advanced machine learning tool **DIANA (DIA**betes **N**ovel subgroup **A**ssessment) is used to classify individuals with newly detected type 2 diabetes into specific subgroups such as insulin deficient or insulin resistance forms. This tool also gives the estimates of the risk for developing diabetes complications like eye or kidney disease. This machine learning approach has been developed based on published real world clinical data and will help the clinician offer individualized care for people with diabetes. In conclusion, judicious use of technology can help to bridge the socioeconomic and geographical challenges in delivering diabetes health care in developing countries.

IS066 / #794

PARALLEL SESSION - JDRF SESSION - MONITORING PRE-SYMPTOMATIC TYPE 1 DIABETES: WHICH TECHNOLOGY FOLLOWS AUTOANTIBODY DETECTION?

THE STRENGTHS AND LIMITATIONS OF MONITORING VIA OGTT

M.J. Haller

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We will review the strengths and limitatoins of monitoring progression to Stage 3 T1D via OGTT.

IS067 / #795

PARALLEL SESSION - JDRF SESSION - MONITORING PRE-SYMPTOMATIC TYPE 1 DIABETES: WHICH TECHNOLOGY FOLLOWS AUTOANTIBODY DETECTION?

THE EVIDENCE FOR ALTERNATIVE MONITORING TECHNOLOGIES

C. Mathieu

University Hospitals Leuven - KU Leuven, Endocrinology, Leuven, Belgium

When it comes to monitoring glucose, the last 50 years have seen a revolution, in particular when it comes to allowing people living with diabetes to measure their glucose levels themselves. It was only in the 1980's that self-monitoring of blood glucose became available broadly with the home blood glucose meters. These have seen increasing accuracy, but most importantly increasing user friendliness, with reduction of the size of the capillary blood volume needed, with the improved lancets for sampling, and with greater affordability, increasing thus the accessibility of the technology and allowing people with diabetes around the world to perform capillary blood glucose measurements. This is of the utmost importance those using insulin, as they need the guidance of blood glucose levels in their day to day decisions on insulin doses, but also for those not on insulin, having the data on blood glucose levels is important for guidance and motivation, provided the data are part of educational programs. The field was revolutionized with the arrival of systems allowing continuous glucose measurements, measuring glucose levels in subcutaneous tissue and recalculating them to blood glucose values. But it was only when the Abbott system Libre™ became available that this technology truly revolutionized the way glucose is measured in those living with diabetes. This system with intermittent scanning allowed a 14day sensor use, with great accuracy and most importantly greater affordability compared to the previous continuous glucose monitoring systems was a key moment in diabetes care. Democratization of sensor use lead to worldwide uptake and importantly pushed the field forward on thinking about new ways to express overall glucose control. The availability of 24h glucose curves, with many more data, drove to new concepts: times in ranges, coefficients of variability etc.. These turn out to be important additional inputs on top of the traditional concepts like HbA1c and are even overtaking HbA1c in daily practice and clinical trials. It will hopefully not be long before also regulators will embrace these new parameters. The good news is that the field does not stand still! For a revolution to become a persisting reality, evolution is needed: linking sensor and pen data, linking sensors to pumps with artificial intelligence, creating (hybrid) closed loop systems, apps assisting those using sensors for glucose measures in decision making on insulin doses, food intake, exercise etc. and most importantly, increase affordability and user friendliness. But new revolutions are on the horizon: not only glucose monitoring is being targeted, but also other metabolites come into the picture: lactate, ketones and others. And integration of all these values together with information on exercise, heart rate, food intake and even geography (person in the kitchen versus the bathroom…) will lead to completely different sets of information allowing artificial intelligence systems to assist those living with diabetes even better in therapeutic decision making, but particularly guiding them how to integrate diabetes better in their life, with less disruption and improved quality of life.

IS068 / #796

PARALLEL SESSION - JDRF SESSION - MONITORING PRE-SYMPTOMATIC TYPE 1 DIABETES: WHICH TECHNOLOGY FOLLOWS AUTOANTIBODY DETECTION?

WHAT'S FEASIBLE IN THE CLINICAL CARE SETTING?

K. Simmons

University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America

The natural history of type 1 diabetes is well defined, and early stages of type 1 diabetes are defined by the presence of multiple type 1 diabetes associated autoantibodies (glutamic decarboxylase antibody, insulinoma antigen-2 antibody, insulin antibody, and zinc transporter 8 antibody). Internationally, the number of programs screening for early stages of type 1 diabetes through the measurement of type 1 diabetes associated autoantibodies continues to increase. In addition, all four major type 1 diabetes associated

autoantibodies can be measured commercially in many countries. With increased screening and detection of individuals who are in early stages of type 1 diabetes, there is a need to provide routine clinical follow up to keep patients medically safe, reduce the risk of diabetic ketoacidosis, counsel on risk of disease progression and identify individuals who may be eligible for interventions. In a research setting, oral glucose tolerance tests, metabolic risk scores, HbA1c measurement, blood glucose testing and continuous glucose monitors may be used to monitor disease progression. It is unknown whether these tools used during follow-up visits in a research setting will be technically, economically or operationally feasible in a clinical setting. Whether our current monitoring strategies are feasible in a clinical setting is also dependent on the demand for such follow-up, which hinges on the successful implementation of screening individuals for early stages of type 1 diabetes. We will review experience from our general population screening program in Colorado, the Autoimmunity Study in Kids, as well as our Early Type 1 Diabetes Clinic to examine the acceptability, implementation, practicality and integration of the use of various monitoring tools in the clinical setting. We will also discuss how current monitoring strategies may be adapted to improve feasibility in a clinical setting.

IS069 / #289

PARALLEL SESSION - DATA SCIENCE IN DIABETES

IMPROVED DATA COLLECTION: MOVING CGM REPORTS FROM THE PATIENT DIRECTLY TO THE EMR

A. Criego

International Diabetes Center, Pediatric Endocrine, Minneapolis, United States of America

International Diabetes Center (IDC) has spent the last 15 years working with the diabetes technology community to establish an effective way to present glucose data that allows both the patient and the clinician a way to identify actionable patterns of hyperglycemia and hypoglycemia to increase time in range. The result of the multiple consensus meetings and publications has been the refinement of the ambulatory glucose profile (AGP) report to display continuous glucose monitoring (CGM) and blood glucose monitoring (BGM) data in a standardized and clinically meaningful way. The AGP Report has been accepted by the International Consensus Committee on Time in Range and the American Diabetes Association's (ADA) Standard of Medical Care for Diabetes as a recommended example of a standardized method to represent CGM data. With increasing options for virtual diabetes care, the ability to integrate CGM data directly into the Electronic Health Record (EHR) efficiently for clinical care has become more necessary. The Integration of Continuous Glucose Monitoring Data into the Electronic Health Record (iCoDE) Project, completed in 2022, recognized the importance of consistent and secure data integration and has developed guidelines for loading and integration of continuous glucose monitor (CGM) data into the EHR. Since May 2020, our healthcare organization (IDC, HealthPartners Institute & HealthPartners Care Group) has been able to integrate Abbott's CGM data from LibreView directly into our Epic EHR using the application programming interface (API) supplied by Redox. We have created a patient flowsheet in Epic to review CGM glucose metrics over time to identify areas of improvement for the individual patient with diabetes providing the foundation to track diabetes population health metrics in the future. Patients with diabetes use different CGM devices and are seen for diabetes in primary and specialty care with a need to establish scalable processes to bring discrete CGM data from all devices directly into the EHR wherever patients receive diabetes care. Work has now begun to integrate data from other CGM systems, connected insulin delivery devices and on standardizing the associated data reports needed for efficient and effective use of these technologies that are transforming diabetes care. Automated access to CGM data, fully integrated into the EHR, is a key step toward precision diabetes care.

IS070 / #290

PARALLEL SESSION - DATA SCIENCE IN DIABETES

ALGORITHM-ENABLED RPM FOR T1D; LESSONS FROM THE 4T STUDY FOR A CONTINUOUSLY LEARNING HEALTH SYSTEM

D. Scheinker

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The 4T (Teamwork, Targets, and Technology for Tight Control) Study seeks to set and maintain tighter glucose management targets in patients with newly diagnosed T1D, with the use of continuous glucose monitoring and telemedicine. Timely Interventions for Diabetes Excellence (TIDE) facilitates this new technology-enabled, telemedicine-based care model. TIDE identifies patients with deteriorating glucose management and the data most relevant for providers to help patients reastablish control, through the analysis of CGM data. The 4T program and TIDE are a continuously learning, algorithm-enabled model for personalized care at population scale. The algorithms that identify patient needs are continuously improved based on historical CGM data collected through TIDE, the messages sent to patients by the care team, and the resulting changes in patient glucose management. The TIDE interface is continuously improved based on feedback from the care providers who use it. The initiation of TIDE reduced provider screen time by 47%. A year later, the first major round of improvements to the algorithms and interface reduced provider screen time by 86%. Within the 4T study, patients monitored with TIDE saw greater reductions in HbA1c and higher TIR than patients not monitored with TIDE. We present the development of TIDE, lessons learned from its iterative improvements, and ongoing projects to further expand its functionality.

IS071 / #291

PARALLEL SESSION - DATA SCIENCE IN DIABETES

DATA OWNERSHIP AND USE OF DATA AGGREGATORS IN CLINICAL CARE

G. Forlenza

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Type 1 diabetes (T1D) is increasingly becoming a ''digital disease'' for which persons with diabetes (PwD) generate hundreds of continuous glucose monitoring (CGM), insulin dosing, carbohydrate intake, exercise, sleep, and other physiological datapoints per day. These data have value to the PwD themselves in addition to the providers giving medical advice, companies looking to improve algorithms and products, and third-party researchers aiming to better understand T1D care. The desire to share data and grow knowledge is counter-balanced against the

need to secure protected health information, prevent breeches in privacy, and obstruct malicious actors. Digital data is generally available to PwD and their providers via manufacturer-based websites and uploaders. These platforms, however, require individual providers to learn and maintain a growing number of accounts, a process which is prohibitive outside specialty diabetes centers. Third-party data aggregators hold the potential to homogenize data sharing and visualization among PwD, providers, and researchers, but move data control outside of the companies creating and improving the devices. In this talk we will discuss data ownership and the pros and cons of data aggregators getting at the question, ''Whose Data Is It Anyway?''

IS072 / #292

PARALLEL SESSION - DATA SCIENCE IN DIABETES

DEEP LEARNING TO PREDICT DIABETES OUTCOME

M. Clements

Children's Mercy Hospital, Endocrinology And Diabetes, Kansas City, United States of America

Deep learning is a special form of machine learning that uses algorithms inspired by the structure and function of the human brain. Deep learning methodologies are now being tested in automated insulin delivery systems, where other machine learning methodologies are already widely used. But deep learning also has the potential to positively impact the structure diabetes care delivery overall. Deep learning models can be used to classify patients and to predict clinical outcomes like hospital admission for diabetic ketoacidosis, rising hemoglobin A1c, falling time in range for sensor glucose, predicting the onset of type 1 and type 2 diabetes, nudging individuals toward increased physical activity or other behaviors, and even the optimal choice of the next therapy for type 2 diabetes. Deep learning models have even been applied to voice recordings to predict health outcomes. In this presentation the speaker will survey the literature on the applications of deep learning in diabetes care, and he will review some of the concepts critical to evaluating this literature. The speaker will specific applications of deep learning in detail, as well as issues of concern that are raised by deep learning models such as barriers to implementation across healthcare institutions, disparities in model performance across patient subgroups, lack of explainability impacting clinician trust in Artificial Intelligence, model overfitting, and the need to tune or retrain models over time or across different populations. The presenter discuss potential a potential model for accelerating the implementation of machine learning and deep learning in diabetes care.

IS073 / #294

PARALLEL SESSION - GLUCOSE MANAGEMENT IN THE PEDIATRIC AND ADULT FEMALE POPULATION

TECHNOLOGICAL GADGETS: WHAT IS AVAILABLE TO GIRLS AND WOMEN WITH DIABETES

E. Cengiz

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Women have unique diabetes care needs that encompass a range of areas. Technology plays a fundamental role in delivering progress on personalized diabetes care. And now, new technologies are making it possible for women to manage their diabetes care and well-being on a more precise and personalized level than ever before. Female Technology (''Femtech'') is a term applied to a category of software, diagnostics, products, and services that use technology often to focus on women's health. As gender becomes more widely addressed in conversations about health disparities, so does Femtech's power to advance women's health. During this talk, we dive into women's health and the technologies disrupting the space, with a specific focus on diabetes technology. We will present evidence based diabetes technology gadgets that have transformed treatment of diabetes in women and discuss potential diabetes technology tools and systems to enhance lives of women with diabetes.

IS074 / #295

PARALLEL SESSION - GLUCOSE MANAGEMENT IN THE PEDIATRIC AND ADULT FEMALE POPULATION

GENDER DIFFERENCES IN CARDIOVASCULAR RISK MARKERS IN YOUNG POPULATION WITH TYPE 1 DIABETES

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Overall, life expectancy is shorter in people with type 1 diabetes (T1D) compared to the general population, and cardiovascular diseases (CVD) are the leading cause of morbidity and mortality in persons with T1D. Hyperglycemia is considered the primary mediator of atherosclerosis in T1D. However, it cannot explain all CVD risks associated with T1D. Even individuals who achieved HbA1c levels of 6.9% or lower still had a chance of death from CVD twice as high as the risk in the general population. Several other modifiable risk factors such as hypertension, dyslipidemia, obesity, insulin resistance, lack of exercise, smoking and psychosocial factors further influence the CVD risk. Women with T1D have a greater excess risk of all-cause mortality and fatal and nonfatal vascular events compared with men with T1D. Therefore, sex-related protection from CVD seems to be lost in women with diabetes. Why diabetes confers a higher risk for CVD in women than men is not entirely understood. It is also unclear when excess CVD risk in women with T1D begins. Intima-media thickness of the carotids and aorta shows that vascular damage and atherosclerosis start from the first years after the onset of T1D. A higher prevalence of multiple CVD risk factors in adolescent girls than in boys may contribute to a more atherogenic risk profile and, thus, less favourable CVD morbidity and mortality outcomes in women with T1D compared to men. Early identification of CVD risk factors and possibly also sex-specific intervention would potentially reduce later CVD morbidity and excess mortality in women with T1D. Further studies and more precise clinical guidelines are needed to address the role of sex-related differences in CVD risk profiles in the pediatric population.

IS075 / #296

PARALLEL SESSION - GLUCOSE MANAGEMENT IN THE PEDIATRIC AND ADULT FEMALE POPULATION

SEX DIFFERENCES IN THE MANAGEMENT OF EXERCISE IN THE PEDIATRIC AND ADULT POPULATION

D. Zaharieva[1], V. Ding[2], V. Ritter[2], M. Desai[2], P. Prahalad[1], D. Scheinker[3], K. Hood[1], F. Bishop[1], A. Addala[1], M. Tanenbaum[4], D. Maahs[1]

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Regular physical activity and exercise can lead to numerous health benefits for individuals with type 1 diabetes (T1D). However, glycemic disturbances in individuals with T1D can also occur depending on various factors including, but not limited to, time of day, type, intensity, and duration of exercise. There is well-established literature suggesting differences in sex-related responses to exercise in individuals without T1D, but fewer studies have focused on this topic related to T1D. A large percentage of the existing literature around exercise and glycemic management with T1D has been conducted on mostly male participants. This presentation will be reviewing the current literature on sex-related differences that may impact glycemic responses to exercise in youth and adults with T1D. In addition, we will be exploring the potential sex-differences of newly diagnosed youth with T1D in 4T Exercise Study that have been started on physical activity trackers and involved in exercise education within the first month of diabetes diagnosis. This work in new-onset T1D youth will highlight potential sex-differences and acute glycemic responses to exercise (24 hours post-exercise) in the 4T Exercise cohort.

IS076 / #297

PARALLEL SESSION - GLUCOSE MANAGEMENT IN THE PEDIATRIC AND ADULT FEMALE POPULATION

INSULIN DOSING IN WOMEN WITH T1D: IS THERE A NEED FOR TAILORED SOLUTIONS?

C. Fabris

University of Virginia, Center For Diabetes Technology, Charlottesville, United States of America

Correctly tuning insulin replacement therapy in type 1 diabetes (T1D) is a challenging task because insulin requirements are modified by multiple metabolic and psycho-behavioral factors – eg, meals, physical activity, psychological stress. In women, hormonal changes happening over the life span further influence insulin needs, making the task of dosing insulin even more strenuous for the female population. Among the factors complicating insulin replacement for women, a relevant role has been documented to be played by the menstrual cycle. According to several studies, women with T1D may experience a decrease in insulin sensitivity during the second half of their menstrual cycle (ie, the luteal phase), which is oftentimes accompanied by an increased exposure to hyperglycemia. Also, increased occurrence of hypoglycemia has been documented during the initial days of the menstrual cycle, as women transition from luteal to follicular phase. During this talk, we will review aspects unique to the physiology of women that impact insulin needs and complicate insulin dosing – with particular attention to the menstrual cycle. Further, the talk will discuss how technology in the form of open-loop decision support systems or closed-loop automated insulin delivery systems can be tailored to support challenges in the management of T1D specific to women.

IS077 / #298

PARALLEL SESSION - GLUCOSE MANAGEMENT IN THE PEDIATRIC AND ADULT FEMALE POPULATION

PSYCHO-BEHAVIORAL BARRIERS TO OPTIMAL GLUCOSE MANAGEMENT IN WOMEN WITH T1D ACROSS THE AGES

K. Barnard-Kelly

Spotlight-AQ Ltd, R&d, Fareham, United Kingdom

There are many factors affecting glucose management at different stages in life for girls and women with type 1 diabetes. From puberty through to menopause, sexual health and reproductive function present considerable challenges for many with both physical and mental health consequences. Female sexual health remains a much-neglected area in diabetes clinical medicine, however it is important for psychological and social well-being. Sexual health issues for women go beyond preconception care and pregnancy. The risk of sexual dysfunction is 2.5 times higher for women with type 1 diabetes with contributing factors spanning interpersonal, social, psycholgoical and biological issues. Given the complex nature of type 1 diabetes, its management and its complications it is unsurprising that female sexual health is markedly affected by the condition. This presentation will explore some of the factors affecting women with type 1 diabetes across the ages in the context of barriers to optimal glucose management and how these can be overcome.

IS078 / #348

PARALLEL SESSION - DIABETES INDIA

PERSONALIZED MEDICINE TO PRECISION MEDICINE: INDIA IS CHANGING

A. Gupta

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Personalized medicine is well established in management of diabetes and patient centric approach is now at the core of all the global recommendations and guidelines . Person centered approcah takes into consideration the choices and preferences of the person living with diabetes but it still does not considers the fact that each individual is genetically and metabolically unique. Advent of Big Data, omics and Artificial intelligence looks promising but precision medicine is yet to find its way into routine clinical practice in case of diabetes. India is uniquely placed as it represents the second largest population of persons

living with diabetes. Asian Indian Phenotype is characterized by earlier onset of diabetes, higher insulin levels and greater degree of insulin resistance , abdominal obesity, higher visceral fat despite lower BMI along with certain other unique biochemical and clinical markers in comparison to Caucasian counterparts. Precision diabetes is still in its infancy and most of the work is with monogenic diabetes however it has a great potential for use in prevention, diagnosis and treatment of other forms of diabetes. Researchers in India are now looking at the unique population characteristics through genome wide studies, DNA sequencing, application of microRNA techniques, Big DATA and omics measurements.

IS079 / #349

PARALLEL SESSION - DIABETES INDIA

DIABETES TECHNOLOGY - THE MAKE IN INDIA STORY

R. Parikh

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The latest IDF atlas puts India at second position in the list of top 10 countries with highest prevalence of type 2 diabetes in adults (20-79 years) and also of those with undiagnosed diabetes. India also has highest estimated prevalence of type 1 diabetes. With such huge burden, India spends only 3% of its GDP on healthcare. There have been several developments in the field of diabetes technology like insulin pumps and continuous glucose monitoring. Although majority of Indians cannot afford these. India is also known for frugal innovations like the Mars Orbiter Mission. Govt of India launched make in India initiative in the 2014 to transform India into global design and manufacturing hub. In the year 2015 Startup India was launched by Govt of India. Over last one decade India has given over 100 unicorns. Currently there are 11738 startups in the field of healthcare registered with startup India, out of which 2632 are working in the field of healthcare IT and healthcare technology. Several startups have launched their diabetes care products incorporating flash glucose monitoring system and wearable devices into their mhealth apps. Ultrahuman is dedicated to improving metabolic health of people at risk of diabetes. Startups like SugarFit and TwinHealth are focused on reversal of diabetes. Efforts are on to launch indigenous continuous glucose monitoring system. BeatO has launched a connected glucose meter along with diabetes care programs. Some startups also claim to have developed non-invasive glucose monitoring systems, although they are yet to establish their validity. Sensing self is working on saliva based non-invasive glucose monitoring. 7Sugar has launched a program that helps people get calorie distribution of their meal by uploading a photo of their meal plate on the app. A cost-effective insulin pump is being developed that can potentially bring down the cost of insulin pumps by 90%. Various startups are working on improving metabolic health by the use of wearable devices and machine learning programs. Artificial intelligence is being used in fundus cameras. Artificial intelligence based multispectral wound imaging cameras that can differentiate between gram positive and gram-negative bacteria have been developed. The story of India's progress in the field of Diabetes Technology with special reference to few frugal innovations that can potentially change the lives of millions of Indians with diabetes will be presented.

IS080 / #350

PARALLEL SESSION - DIABETES INDIA

DIABETES MANAGEMENT IN INDIA - CHALLENGES & TECH SOLUTIONS

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India has the second largest number of people with diabetes in the world today (74.2 million). There are many a challenges faced – delayed diagnosis, presence of complications at time of diagnosis, lack of insurance support for ambulatory care, lack of support programmes to engage and motivate individuals with chronic diseases, high cost of monitoring, poor availability of test strips, many unvalidated monitoring devices , social and cultural beliefs like religious fastings and walking bare feet, early onset of typ2 DM, poor screening of complications and follow up visits, poor adherence to lifestyle modification and poor medications compliance. Some of the other challenges in Diabetes management are the high patient burden with poor physician to patient ratio and geographical barriers to accessing optimum care. Technology has come to the forefront in overcoming some of these challenges. Use of locally available connected meters, training on structured smbg including 3/21 concept, mobile apps and applications for diet adherence, exercise regularity, insulin dosing algorithms, carbohydrate counting etc are gradually being used regularly by patients with diabetes especially the younger individuals. The use of cgm too has gradually improved especially in type 1 DM , but largely continues to be intermittent with smbg used in between. Use of telemedicine and teleconsultation too has improved the access to diabetes specialists especially for patients in rural areas. Technology advancements in point of care testing are resulting in better monitoring of metabolic parameters and screening for complications including those for retinopathy and neuropathy and some of these devices make use of artificial intelligence for correct interpretation and reporting. Technology is helping in development of digital tools to identify at risk foot, grades of foot ulceration along with technology driven solutions for protective footwear and insoles. Though there continue to be many a challenges in diabetes management in India, technology is slowly and steadily helping physicians, patients and health care companies find simple solutions towards earlier diagnosis , monitoring , treatment and screening and prevention of complications. The wide use and availability of mobile phones with cheap data and internet availability have been a boon towards this.

IS081 / #351

PARALLEL SESSION - DIABETES INDIA

OPPORTUNITIES AND THREATS ANALYSIS (SWOT) OF BLOOD SUGAR MONITORING IN INDIA

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'' Is the Glass half full or half empty? '' It depends on your outlook.

India is a diverse country with wide geographical variation in knowledge, financial capability and exposure .In Diversity lies its strength and the opportunities to thwart the weakness and threats.

Strength

Fasting and PP system
Screening camps
Pharmacies
Cheap health packages
Diabetes centre packages
Pharma driven CME

Weakness

Intermingling of Tier system
Pharma dependent training
Johari window unawareness

Opportunities

Converting the strength into Assets
Neutralising weakness by online modules, credit points, new NMC rules
encouraging startups
Streamlining fasting and PP concepts

Threats

''Who moved my cheese''
Funding
Half training
Chinese whispers

Blood sugar monitoring has evolved enormously. As Robert Frost said '' I have miles to go ,miles to go before I sleep '', there is still a lot of work to do .

IS082 / #352

PARALLEL SESSION - DIABETES INDIA

DO IT YOURSELF ARTIFICIAL PANCREAS: THE AFFORDABLE INDIAN EXPERIENCES

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Jothydev's Diabetes Research Centre, Diabetes, Trivandrum, India

In spite of a robust decline from 55.1% to 16.4% over the past 15 years, India still has the highest number of poor people in the world. Though poverty among children has declined at a faster rate, India still has the highest number of poor children (97 million, 21.8%) implying that one in every three children lives in poverty, while one in seven adults lives in poverty. It is a frustrating experience for adolescents with TID in India, to live a miserable life, despite technological advances in diabetes. In India, currently, there is no established support for T1D with either CGM, insulin pumps, or automated insulin delivery (AID) devices. The Do-it-yourself artificial pancreas (DIYAP), which is popular in developed countries is slowly catching up in the Indian T1D community and is experimenting with affordable options. DIYAP combines the sensor data from a CGM together with other specifications such as basal rate, insulin sensitivity factor, & carb ratio and subsequently, calculates the insulin dose required to maintain the blood glucose level within the target range. Unfortunately, in India, we don't have many options either for insulin pumps or CGMs, including integrated CGM (CGM that can be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin dosing systems, insulin pumps, blood glucose meters or other electronic devices used for diabetes management). In a country like India, where 16.4% of the population, as mentioned earlier, is in multidimensional poverty, the cost is the major limitation to the use of technologies. A commercial hybrid-close loop costs around 600,000 INR (73467 USD) followed by a monthly cost of approximately 30,000 INR (370 USD) making it difficult to afford by self-funding. The only commercial hybrid-close loop AID available in India is MiniMed 780G. Though in some states like Kerala, the government provides free insulin pumps and AIDs to some patients, these are only very few numbers compared to the magnitude of the T1D population in the country. In India, currently, there are approximately 860,423 people living with T1D who are finding every option to optimize the use of currently available affordable devices. This reiterates the need for DIYAPs. As per the users, the initial investment is around 250,000 INR (3061 USD) followed by a monthly cost of approximately 10,000 INR (122 USD). The majority of DIY users in India use AndroidAPS (Android users) and loop (for IOS) as open-source closed-loop systems. Out of limited options, the compatible insulin pumps they mostly use are old Medtronic pumps including, Medtronic Minimed 712,715,&722. Unlike many other developed nations insulin pumps are not reimbursable and no insurance policies are available in India. Since the options are limited the users are re-engineering the available pumps so as to work with the open-source closed-loop system. For old Medtronic pumps, an additional communication device is needed to ''translate'' the radio signal from the pump to Bluetooth. The additional communication devices that are used by most of the users here in India are Rileylink and Orange link. The Orange link is preferred by the larger population as it is compact, lightweight, and designed using an all-new nRF52810 Bluetooth 5.2 System on Chip. With regard to CGM, we have Guardian Sensor 3 and Guardian Sensor 4 (factory calibrated) currently available as real-time CGM in India that provide predictive alerts up to 60 minutes in advance of high and low glucose events. Guardian sensor though available as a real-time device in India is not affordable to a majority of the tT1D population and is also not an integrated CGM. Freestyle Libre is the isCGM available in India. The professional CGM (Libre Pro) is comparatively affordable to the majority of the T1D population. One of the alternate affordable ways to get real-time data is to use a professional CGM like Libre Pro with a transmitter like Miao Miao or NightRider. Consequently, the users also reuse the sensor with the help of certain apps and restart the sensor. As per the users, the readings are quite accurate. To display the glucose data, they use the xDrip+ app or the Nightscout website[Table 1]. That is the one side of the story where people are trying to convert available devices into user-friendly and affordable options. The average time-in-range [TIR] with a commercial hybrid close loop system is 70-80%. When using DIYAP, the average TIR is about 85-90%, as per the users. Though there are more than two dozen known users successfully

Table 1. Summary of Components of DIYAP Used in India

Insulin Pump	Medtronic MiniMed 712	Medtronic MiniMed 715	Medtronic MiniMed 722
Sensor + Transmitter	Libre pro with Miao Miao 3		
Data Display	Nightscout	xDrip+	
Open Source	Android APS	Loop for IOS	
Additional Communication Device	Riley Link	Orange Link	

using DIYAP, one of the difficulties that the users face is regarding troubleshooting, which can be difficult at times. Patient stories also suggest that the procurement of compatible devices to initiate the DIYAP is the most difficult part. The setting up of algorithms can be time-consuming and requires technical know-how. The configuration can be tricky and complicated which can discourage the patients from choosing these systems. The users need to be engaged, activated, and committed to allocating time to understand and set up the system. The chance of insulin pump failure is very low when used by tech-savvy users, but it can be the other way when less-expert individuals start managing the older pumps. A very small percentage (<1%) of users get support from their clinics to use DIYAP. The patient community themselves support each other in every step. They research and train each other. The loopers community is equipped with 24-h, global online support and makes consistent efforts to increase its radical transparency and accountability. Like in other parts of the world, DIYAP is not approved for use in India as well. But, as American Diabetes Association (ADA) states, we never discourage users. These affordable options are providing them with profound quality of life (QoL). Diabetes technology advancements in the past years made possible the development of DIYAPs that lead to ''closing the loop'' integrating CGM, insulin pumps, and smartphone technology to run openly shared algorithms to achieve appreciable glycemic control and QoL without burning their pockets too much!

IS083 / #299

PARALLEL SESSION - EMERGING TECHNOLOGIES FOR DIABETES

REPLACING PUMPS WITH LIGHT CONTROLLED INSULIN DELIVERY

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We have developed a new way of delivering insulin that uses light to stimulate insulin release from a patient-injectable depot. We call this approach the Photoactivated Depot (PAD) approach. This allows for the continuous variability of an insulin pump, without the numerous problems associated with the physical connection that a pump requires. These problems include infection, cannula crimping, bio-fouling and occlusion. We designed and synthesized a range of materials that are injectable into the skin using a standard insulin syringe and have shown that these release insulin both in-vitro and in-vivo. The amount of insulin released is proportional to the amount of light applied to the skin using a compact LED light source. In addition, we have demonstrated that these materials release fully bioactive insulin which results in blood glucose reductions that are also proportional to the amount of irradiation. In this presentation we will discuss the strategies that we have used to achieve multiple design aims. One of these design aims is Efficiency. This refers to the proportion of the material that is insulin, as opposed to carrier or polymer. First generation materials were based on polymers to achieve depot insolubility. This resulted in materials that contained <10% insulin by dry weight. Our second generation design strategies allow materials that are ~90% dry weight insulin, allowing for greater duration of action and ease of release. In addition, we will describe potential therapeutic advantages of photoactivated insulin over pump delivered insulin. The principal of these advantages is speed. We observe insulin in the blood 5 minutes after irradiation of a PAD, which makes photoactivated insulin as fast or faster than the fastest insulins commercially available. This begins to rival the performance of the pancreas itself, and can lead to better control of post-prandial blood glucose excursions, with attendant health benefits. Finally we will discuss some of the operational issues associated with the PAD approach. The skin based light source used to stimulate insulin release is entirely solid state with significantly lower energy requirements compared to a pump. This can lead to a smaller, lighter form factor. In addition, the lack of moving parts compared to an insulin pump should lead to greater physical robustness, and lower costs to manufacture and purchase. This latter factor can potentially expand the range of patients who are able to access and use an artificial pancreas.

IS084 / #300

PARALLEL SESSION - EMERGING TECHNOLOGIES FOR DIABETES

CONTINUOUS LACTATE MONITORING (CLM) – A NEW PARADIGM FOR MONITORING HIGH-RISK DIABETIC PATIENTS

I. Tamir

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As wearable healthcare monitoring systems advance, there is great potential for multi-metabolite sensing to enhance the management of type 1 diabetes (T1D). Improvements in wearable sensor technology, specifically the introduction of additional analyte monitoring capabilities, are believed to ultimately lead to improved glycemic control. Defective glucose metabolism and low tissue oxygenation have been linked to enhanced lactate levels in diabetic patients with acute myocardial infarction (AMI). High lactate levels indicate increased risk for poor outcome in this population. The rise in blood lactate concentration in diabetics with AMI was previously shown to be associated with increased incidence of heart failure, severe arrhythmias, cardiogenic shock, and high mortality rate. QuLab Medical has developed a novel minimally-invasive intradermal patch platform for continuously monitoring multiple metabolites in parallel. Specifically, we have focused on the development of a Continuous Lactate Monitor (CLM) and combining it with a CGM in a single path device. We believe that the combined CGLM solution will help T1D patients better manage their life, on both wellness and disease fronts.

IS085 / #301

PARALLEL SESSION - EMERGING TECHNOLOGIES FOR DIABETES

BEYOND THE GLUCOSE-CENTRIC DIABETES MANAGEMENT: THE PATH TO MULTIPLE SENSING

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Whereas continuous monitoring of *glucose* has served as the main guidance for the development and use of automated insulin

delivery systems (AID) in type 1 diabetes (T1D), major limits still halt the achievement of a fully AID able to self-adaption to different daily life activities as well as to optimize glycemic control in other conditions than T1D. Glucose is part of a complex energetic cellular balance that involves other two key metabolites – *lactate* and *ketones (beta-hydroxybutyrate[BHB]*) – that have been recently the target of continuous sensing. Recently, investigational devices that allow continuous lactate and BHB sensing have shown promising results in small clinical studies. The clinical relevance of lactate and BHB stands in their ability to early detect metabolic shifts during unannounced activities (e.g. physical activities, fasting) as well as in their role as alternative metabolic fuels for critical organs as brain and hearth. The ability to real time monitor lactate and BHB paves the way to a new generation of AID able to minimize the need for user announced activities and to broaden the use of AID to other clinical settings. We will propose three experimental case studies: the use of lactate during physical activity in those living with T1D ; the potential benefit of monitoring lactate and BHB in preterm neonates to adjust glucose and insulin infusion in order to meet the metabolic need of neonatal; the enhanced safety of BHB continuous monitoring as a tool for early detection of ketosis in those with T1D.

IS086 / #302

PARALLEL SESSION - ISPAD SESSION

GLOBAL REGISTRY DATA: DIABETES TECHNOLOGY IMPACT

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Global registries reflect the current status of type 1 diabetes and the real-life impact that the adoption of diverse diabetes therapies have beyond randomized clinical trials. With the rapid adoption of diabetes related-technology worldwide, firstly continuous glucose monitoring and more recently closed-loop systems, it is expected a drastic change in the achievement of recommended targets for children and adolescents with type 1 diabetes. International registries such as SWEET (Better control in Pediatric and Adolescent diabetes: Working to create centers of reference) or large national prospective registries like DPV (Diabetes-Patienten-Verlaufsdokumentation; Germany and Austria), T1D Exchange (US), ADDN (Australasian Diabetes Database Network (Australia) or the SWEDIABKIDS (Swedish Childhood Diabetes) registries have reported a drastic increase in technology use. The SWEET registry has shown a significant decrease in HbA1c on a background of increasing pump and sensor use for 10 years within this registry. Nevertheless, there is still room for improvement as only 21% of children and adolescents with type 1 diabetes achieved the current ISPAD/ADA HbA1c<7.0% (53 mmol/L) target in another description within the SWEET Registry from 2021 (with data for the period 2017-2019) while 37% achieved the former ISPAD/ADA HbA1c<7.5% (58 mmol/L) target. This percentage is however significantly higher that the one described by the T1D Exchange for the period 2017-2018, where only 17% of youth with diabetes achieved the ISPAD/ADA HbA1c<7.5% (58 mmol/L). Reports from the different registries associate a positive effect of technology use (pump and/or sensor) on HbA1c. The decrease in HbA1c in large registries have been accompanied by a lower number of diabetes ketoacidosis and severe hypoglycemic episodes. During the next few years a potential improvement in diabetes outcomes is also expected in parallel with an increasing use of closed loop systems. On the other hand, there is still a paucity of registry-derived data regarding other parameters such as time in range, economic measurements/analyses and quality of life/patient-reported outcomes (PROs) which might help to visibilize the impact of technology in pediatric diabetes.

IS087 / #303

PARALLEL SESSION - ISPAD SESSION

PSYCHOLOGICAL IMPACT OF TECHNOLOGY: WHAT IS MOST RELEVANT?

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The clinical benefits to using diabetes technology are now well established. However, to optimise these clinical gains, user 'buy in' and engagement are essential. The psychological impacts of using diabetes technology can both motivate and hinder effective and sustained technology use. Hence, alongside clinical trials to assess efficacy, it is vital to draw upon users' perspectives to better understand acceptability. With a focus on closed-loop technology, this presentation will showcase how qualitative methodology can help illuminate and understand how diabetes technology can impact users' quality of life in ways which cannot be captured through questionnaire designs. Drawing upon findings from interviews with a diversity of user groups (young people, parents of children with type 1 diabetes and pregnant women), the presentation will highlight the transformative impact closed-loop technology can have on users' sense of self and their confidence and ability to undertake everyday activities and engage in meaningful relationships with others. The presentation will also highlight how qualitative methods can capture unintended psychological consequences to technology use, such as excessive anxiety leading to over interaction with the system in certain individuals. Hence, it will be argued that consulting users and learning about their lived experience can help inform decisions about technology rollout and support identification of those who might benefit from bespoke input and psychological support to make optimal use of technology in everyday life.

IS088 / #304

PARALLEL SESSION - ISPAD SESSION

DIABETES TECHNOLOGY ACCESS IN LOW AND MIDDLE LOW-INCOME COUNTRIES: NOW OR LATER

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Emerging diabetes technologies, including insulin pumps, continuous glucose monitors, and automated insulin delivery systems, can improve the quality of life and glycemia of people living with diabetes mellitus. Diabetes technologies are not available to all people living with diabetes across the globe secondary to issues with manufacturing, marketing and registration, pricing and reimbursement, procurement and supply, prescribing, dispensing, and patient use. There are also well described socioeconomic and racial disparities in the use of diabetes technology even in high income countries with access to these devices. Given the continued challenge of access to blood glucose meters, blood glucose strips and insulin in low and middle income countires, is now the time to make access to diabetes technologies in low and middle income countries a priority? Benefits of using diabetes technology on quality of life and glycemia (HbA1c and time in range) and current access to and use of diabetes technology in low and middle income countires will be reviewed in the context of the 2022 ISPAD Clinical Practice Consensus Guideline Chapter on the management of the child, adolescent, and young adult with diabetes in limited resource settings.

IS089 / #306

PARALLEL SESSION - MIND THE FOOT!

MONITORING OF DIABETIC FOOT DISEASE

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Diabetic foot syndrome is a complication of diabetes mellitus and is defined as the infection, ulceration, or destruction of the deep tissues of the foot. Diabetic neuropathy and/or peripheral vascular disease in the lower extremities are factors that contribute to the occurrence of diabetic foot syndrome. To diagnose diabetic neuropathy other causes of neuropathy have to be ruled out; neuropathies not associated with diabetes mellitus may be present in patients with diabetes and may be treatable. In up to 50% diabetic peripheral neuropathy can be asymptomatic. If diabetic peripheral neuropathy is not recognized and preventive foot care thus is not implemented, patients are at risk to develop diabetic foot syndrome due to their insensate feet. Loss of protective sensation (LOPS) is a sign of distal sensorimotor polyneuropathy and is a risk factor to develop foot syndrome. The following diagnostic tests are useful to assess small- and large fiber function and protective sensation: pinprick and temperature sensation for small-fiber function, vibration perception and 10-g monofilament for large-fiber function and 10-g monofilament for assessment of protective sensation. The incidence of diabetic foot syndrome lies between 15 and 25%. Diabetic foot syndrome is a frequent cause of hospitalization and could lead to major complications, like lower limb amputations, sepsis and death. In up to 80-85% of cases with diabetes who have to undergo lower limb amputations have previously had a foot ulcer. The mortality rate in patients with diabetic foot syndrome is more than double than in the general population. As diabetic neuropathy with loss of protective sensation is associated with a high risk to develop (recurrent) ulcerations, different methods to (continuously) monitor diabetic feet and diabetic foot disease are in development. (Remote) monitoring of diabetic foot syndrome can be applied in three domains using technologies to support triaging high-risk patients, technologies to support care at the site of the care provider, and technologies an enabling self-management. These technologies include digital health solutions, smart wearables, telehealth technologies, and ''hospital-at-home'' care delivery model. Minor injuries are often unnoticed and may result in subsequent infection and ulceration may end in a foot amputation. Some studies have shown an association between increased skin temperature and asymmetries between the same regions of both feet. A smart device to assess the temperature patterns might indicate the risk to develop diabetic foot syndrome. Pressure sensors could compensate for the loss of pain sensation and enable the early detection of inadequate pressure patterns and thus prevent diabetic foot syndrome. These sensors can be incorporated in socks or insoles. Apps to recognize infections and wounds, and to empower self-care might also be useful in the management of diabetic foot syndrome. Most of these innovative technologies are still in early phases of development and have not been widely adopted in routine care. However, they do have the potential to revolutionize management of diabetic foot syndrome in the near future.

IS090 / #308

PARALLEL SESSION - DIABETES TECHNOLOGY AND WASTE: HOW TO TURN GREENER?

THE GREENING OF DIABETES CARE IN AMERICA

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In the United States (U.S.), 7 million Americans use insulin each day and an increasing number are being prescribed other types of injectable therapies. Similarly, a growing proportion of the 1.6 million individuals living with type 1 diabetes, change their continuous glucose monitoring sensor every 2 weeks including the majority of the 350, 000 insulin pump users. Going forward, the market for CGM among adults with non-insulin treated diabetes and pre-diabetes is set to increase, perhaps exponentially. From an environmental perspective, the downside of the ubiquitous use of technologies, in addition to established therapies such as insulin, is the negative impact that this can have from the associated waste. The waste associated with diabetes care can be stratified according to the type of materials (e.g., recyclable versus non-recyclable) and the risk to human health (e.g., from needlestick injuries or exposure to bodily fluids). In the U.S., reducing risk from hazardous waste varies by State – for example in California, the Dept of Public Health regulates medical waste. The cost of dealing with medical waste in the U.S., has been estimated to contribute to 5 to 16% of healthcare spending. With the increasing concerns about environmental change, stakeholders in diabetes care have a vested interest in developing creative new approaches to reducing the impact of all forms of waste. These stakeholders include the pharmaceutical and medical device industries, health professionals, payers, policy makers and people living with diabetes. To be successful, this may also require new thinking on the transparency of the environmental burden of different approaches to diabetes care and ensuring that environmental progress comes with meaningful rewards and not additional costs to the end-user.

IS091 / #309

PARALLEL SESSION - DIABETES TECHNOLOGY AND WASTE: HOW TO TURN GREENER?

DIABETES TECHNOLOGY AND WASTE: HOW TO TURN GREENER? - THE EU POINT OF VIEW

L. Heinemann

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Diabetes Technology (DT) is widely used in the EU, with rapid increases in the usage of certain medical products, e.g. systems for continuous glucose monitoring. The well-known pros of doing so, concerning improvements in glucose control, are associated with cons like an increase in the economic burden for the healthcare systems, but also with a lot of (plastic) waste. In the EU it is the political will to reduce plastic waste drastically. The EU Commission has issued several respective regulations, which currently mainly address plastic disposable items like bags; however, in the end also the situation with medical products (which are often exempt from such considerations) has to be improved. For example, in the Medical Device Regulation (MDR) it is clearly stated that the design of medical products should be so, that waste production is reduced or even avoided. One can envisage that such conditions will become even more rigid soon, the MDR is in constant ''development''. Many manufacturers of products used for diabetes therapy are located outside the EU; however, also these will have to fulfill EU requirements. Given the long periods needed to change production lines/develop new products, it is obvious that the manufacturers are already considering and implementing such changes. In addition, patients with diabetes and diabetologists are becoming rapidly more sensitive to environmental aspects of diabetes therapy, with certain differences between countries in the EU. This also exerts pressure on manufacturers to reduce waste and recycle wherever this is meaningful and possible. Several country-specific aspects/activities do exist at the country level, driven by regional diabetes associations; however, to my knowledge, there is no EU-wide initiative in the diabetes arena. A coordinative activity by, e.g., by the EASD is missing. This also holds true for patient associations like the IDF-Europe. What can be done immediately on a practical level is to provide appropriate information/training to patients with diabetes about how to handle the (plastic) waste generated. Because of the activities in the US (i.e. the Green Diabetes Declaration, in which specific tasks are given to all parties involved), we should adjust this declaration to the EU situation and establish a Task Force which pushes a change in the EU ahead.

IS092 / #310

PARALLEL SESSION - DIABETES TECHNOLOGY AND WASTE: HOW TO TURN GREENER?

DIABETES TECHNOLOGY AND WASTE: HOW TO TURN GREENER? - THE MANUFACTURERS' POINT OF VIEW

M.A. Schweitzer

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Take the question ''How to turn greener'' and split it in several ''sub-questions'', the resulting sub-questions might be: ''Is there a problem?'' … ''Is the problem understood and addressed?'' … ''Are there strategies for how to turn greener?'' … ''Are there any tangible and concrete goals set and even controlled?'' and finally … ''Is progress being made and what expectation can we have for the future?'' The good message at the beginning, the topic is deeply understood and broadly addressed. Today, there isńt barely any pharmaceutical or medical device company that doesńt understand and agree that sustainability and the ecological footprint is important, change is necessary and actions need to be taken, holistically, to improve current situation and transform organizations into greener and ecologically more responsible parts of society.

In January 2020 at Davos, ''Sustainable Market Initiative'' (SMI) *(1)* was launched by his Royal Highness the Prince of Wales. His Majesty King Charles III, hosted several task forces which invite and involve companies to develop strategies and collaborations for more sustainability. In SMI, there is a ''Health Systems Task Force'' which is also a partner of the WHO's Alliance on Transformative Action on Climate and Health (ATACH), a platform that over 60 countries have committed to at the Minister of Health level to strengthen climate resilience and lower the emissions of health systems. To fill this Task Force with life and focusing on environmental strategies and actions of the health industry , CEOs of 7 major global pharmaceutical companies (AstraZeneca, GSK, Roche, Merck Germany, Novo Nordisk, Sanofi and Samsung Biologics) released - at the recent COP27 at Sharm el-Sheikh - collaborations and goals for the future to achieve a near-term emission reduction and accelerate the delivery of net zero health systems *(2)*.

Even if recently published studies *(3)* relativize - to a certain extent- the quantity of negative ecological footprints of the pharmaceutical and medical device industry in comparison to other industries, e. g. in regard to waste production, they are by far not heading the list but are rather midlevel in ranking.

Pharmaceutical and medical device companies are aware of the need to act on the ecological footprint and do aim at getting greener and more sustainable. Clear strategies have been developed and are in implementation, about what to do, how and until when. The core of sustainability strategies focuses on CO2 emission, on (renewable) energy consumption, on resource consumption (e.g. [toxicity and amount of] raw materials or water) and for sure specifically also on waste. Avoiding waste and mange waste as end-of-life challenge of medical products. One example for a broad environmental strategy is Novo Nordisḱs strategy ''Circular for Zero''. It has been developed and implemented soon after the turn into the new millennium with the ambition: zero environmental impact. It addresses ''circular supply'', including supplier footprint and circular procurement, ''circular company'', including operations and transport, elimination of energy-, water- and material waste and green affiliates and ''circular products'', including circular product design and solving end-of-life challenges. This strategy includes near, mid- and long-term goals, e.g. for the year 2030: ''all supply based on 100% renewable power'', ''zero CO2 from operations and transportation'' and ''50% of Novo Nordisk products to be reused or recycled until that year''. An already existing result of ''Circular for Zero'' is the use of 100% renewable energy in all Novo Nordisk production facilities worldwide since 2020. *(4)*

Getting greener is understood, agreed on and actions are taken. However, the way to full sustainability is multifaceted, challenging and quite complex. To cover a zero environmental impact and, in particular, to reduce waste, it requests sustainable mindset from the beginning of the value chain until the end-of-life solution. It requests innovation, creativity and many partners to collaborate with, such as regulators, interdisciplinary scientists and experts from many areas and industries, also politicians. Prolonged half-lives of medications changing from daily to weekly use or from injections to tablets can reduce waste significantly. Political support for an innovation friendly environment is needed for materialisation of related benefits. More robust and compatible medical devices, smaller, next generation medical devices and those made of less different materials, like plastics, can reduce waste in many ways. Packaging and blister materials based on organic, recyclable, even eatable materials are other examples to change and reduce waste from designing products to the use at patienťs level. Collecting back medical products in a systematic manner to reuse or recycle, in ''take-back'' programs, request learning, partnering and intelligently covering evolving details, in order not to solve problems at one end and create new environmental problems at another end. Pilots are needed and strategies how to deal and proceed with the acquired knowledge. Piloting take-back programs in one country by one company, then scaling up to different countries, then collaborating with different companies in different countries on the same (medical) product and finally scaling up to a global approach across different countries and industries involving different medical products could be one strategy that indeed already exists for insulin pen devices *(5).* Innovation is often the key to solving problems. Even so to reduce waste and improve the quality of treatment in the same approach. Injection devices and needles can be collected in internet linked boxes not only to prepare products for recycling but also addressing poor adherence and reminding patients on missed injections. While counting the number of devices put into the boxes and assessing the treatment adherence level, the internet connection of the boxes allows messages to patients in case therapies have been missed. Getting greener and reducing the ecological footprint is understood and being addressed. Strategies are in place and deliver results. There is no doubt that it is still a long way to become entirely green with zero footprints and, unfortunately, such improvements need time. Nothing shall be glossed over. However, pharmaceutical and medical device companies must and will continue to lead this development.

Preventing diseases, providing better treatments or even cures that avoid acute and chronic care also in hospitals are the core and finest tasks of pharmaceutical and medical device companies. This by itself leaves a greener footprint in society as all medical care that is needed significantly contributes to waste, energy and material consumption. (1) White Paper, ''ACCELERATING THE DELIVERY OF NET ZERO HEALTH SYSTEMS''. Sustainable Markets Initiative Health Systems Task Force, in collaboration with BCG, November 2022. https://www.sustainable-markets.org/health-systems-taskforce-whitepapers/ (2) European Pharmaceutical Review https://www.europeanpharmaceuticalreview.com/news/175981/seven-pharma-ceos-unite-to-achieve-emission-targets/ November 2022 (3) FORSCHUNGSBERICHT OKTOBER 22, „SEE-Impact-Study der deutschen MedTech-Branche''. WifOR Institut & BVMed – Bundesverband Medizintechnologie e.V. . October 2022. https://www.bvmed.de/de/branche/standort-deutschland/branchenstudien (4) Novo Nordisk https://www.novonordisk.com/sustainable-business/zero-environmental-impact.html November 2022 (5) Novo Nordisk. Returpen™. https://www.novonordisk.com/sustainable-business/zero-environmental-impact/can-you-recycle-an-insulin-pen.html

IS093 / #311

PLENARY (3) SCREENING AND PREVENTION OF TYPE 1 DIABETES

SCREENING OF GENERAL POPULATION – CURRENT STATUS AROUND THE WORLD

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Until recently, screening programs identifying children and adults at risk of type 1 diabetes (T1D) focussed on those with first degree relatives with the disease. This has been an efficient approach for recruitment into prevention trials, as individuals with a first degree relative have a ~15-fold increased relative lifetime risk of T1D compared to the general population. However, this approach identifies only the minority (10-15%) of individuals who will progress to T1D. The success of improved technology to identify at-risk individuals, and the development of drugs aiming to delay onset of the disease, has seen a rise in programmes around the world which target screening in the general population. These programmes utilise diabetes autoantibody testing at various different ages, alone, or in conjunction with genetic testing. The benefit of general population screening is in identifying a wider group of individuals suitable for drugs or trials to delay T1D onset, such as the anti-CD3 monoclonal antibody, teplizumab, which has recently been approved by the USA's Food and Drug Administration, and to prevent life-threatening diabetic ketoacidosis, and to prepare individuals for a smoother transition to insulin therapy. Here we will discuss the breadth of programmes around the world and highlight their achievements and potential hurdles, which will need consideration, before rollout into clinical practice is possible.

IS094 / #312

PLENARY (3) SCREENING AND PREVENTION OF TYPE 1 DIABETES

EMERGING BIOMARKERS OF RESPONSES TO IMMUNOTHERAPIES

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Therapies to augment the immune response in type 1 diabetes will become an important part of the early management of the disease. Several therapies have been successful, albeit transiently, in preserving C-peptide in clinical trials. This often manifests clinically as a significant and prolonged 'honeymoon', or partial relapse, period. Such times of lower glycemic variability and increased time-in-range reduce diabetes-related complications, both acute and chronic. However, challenges remain regarding the use of immunotherapies as a future standard

of care in type 1 diabetes. Firstly, there is vast heterogeneity in regard to the immunopathogenesis of type 1 diabetes, affecting multiple cell types including T cells (effector and regulatory), B cells, dendritic cells, and more; thus, a myriad of immunotherapeutics with differing mechanisms of action have been studied to interdict in this destructive process. Next, the role of the beta cell in its own demise requires further elucidation, and measures of beta cell function, used as clinical trial endpoints, continue to evolve. Chief among the challenges of implementing precision medicine-directed immunotherapy is the variability in response and how it is defined. While a specific therapy may work for some individuals, termed ''responders'', it may not work for all who receive it. This phenomenon is seen in other autoimmune diseases. Even among successful clinical trials, meeting their primary endpoint, there can be a subpopulation that has a C-peptide response similar to that of the placebo group (i.e., ''non-responders''). Therefore, a one-size-fits-all mentality will not be sufficient for the use of immunotherapeutics in early type 1 diabetes. Determination of the appropriate time to treat with the appropriate immunotherapy is a major hurdle. Statistical modelling could aid in this query and has been used to determine immune signatures of slow and fast progressors from multiple autoantibody positivity to type 1 diabetes. To identify biomarkers of immune therapy ''responders'', in-depth characterization is required, not only via immunophenotyping but also transcriptomics, genomics, epigenomics, and demographics. Currently, we have limited knowledge of markers that differentiate ''responders'' from ''non-responders''. Study teams are performing mechanistic and responder-based analyses and are uncovering exhausted T cell subsets, HLA frequency variation, and the presence of specific autoantibodies in association with responders. In the future we hope to identify a biomarker for the *prediction* of these ''responders''. Other autoimmune diseases can be a powerful example for the field of type 1 diabetes in their use of precision medicine-directed treatment pathways. We are working towards increasing the number of immune therapies receiving regulatory approval. This, along with the validation of current and future biomarkers, would allow a personalized, biomarker-driven recommendation for the treatment of the underlying pathology in type 1 diabetes.

OP001 / #424

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

SEPSIS-ASSOCIATED HYPOGLYCEMIA ON ADMISSION IS ASSOCIATED WITH INCREASED MORTALITY IN CRITICALLY ILL PATIENTS, BASED ON REAL-WORLD EVIDENCE

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Background and Aims: The frequency and cause of hypoglycemia in various categories of septic patients have not been adequately explored. In this study, we focused on sepsis-associated hypoglycemia in the early phase of critically ill patients and evaluated the impact of hypoglycemia on mortality.

Methods: We performed a retrospective cohort study using the Medical Information Mart for Intensive Care IV, anonymised database (MIMIC-IV), based on the data of Intensive Care Unit (ICU) admissions between 2008 and 2012 at Beth Israel Deaconess Medical Center, USA. The study protocol was approved by the respective Institutional Review Boards.

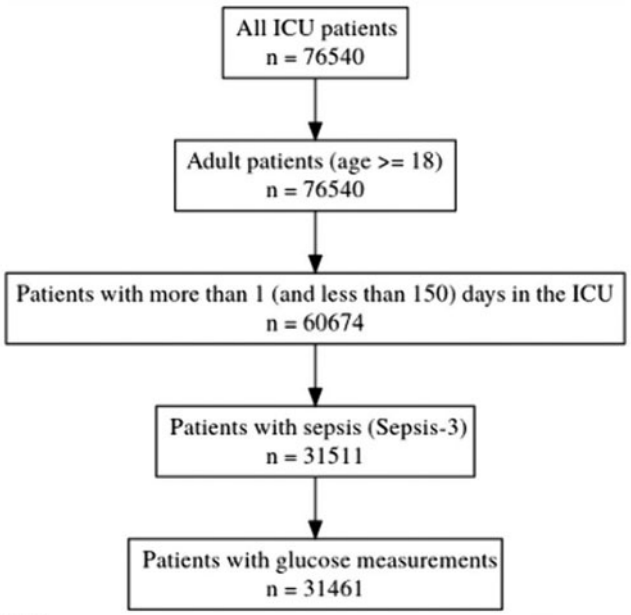

Figure 1.

We selected 31461 patients with Sepsis-3 criteria from the MIMIC-IV database for the analysis. Figure 1 depicts the stages of patient inclusion in the study.

Results: We performed survival analysis with ICU mortality as the target, stratified per glucose level. Figure 2 shows the Kaplan-Meier curves.

Figure 2. Kaplan-Meier survival curves for patients with sepsis in the five categories of blood glucose levels. The following table shows the results of a Cox proportional hazards model, per glucose category, after adjusting for age, sex, OASIS (Oxford Acute Severity of Illness Score) and SOFA (Sequential Organ Failure Assessment) scores.

Conclusions: The survival curves for severe and mild hypoglycemia seem to be quite below the curve for euglycemia, indicating lower survival rates, as is also the case for severe hyperglycemia, although less prominently. The proportional

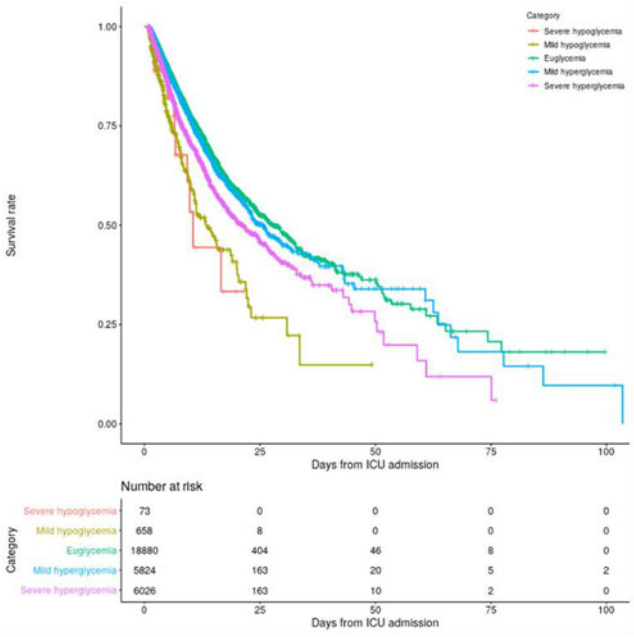

Figure 2. Kaplan-Meier survival curves for patients with sepsis in the five categories of blood glucose levels. The following table shows the results of a Cox proportional hazards model, per glucose category, after adjusting for age, sex, OASIS (Oxford Acute Severity of Illness Score) and SOFA (Sequential Organ Failure Assessment) scores.

Category	Hazard ratio	95% confidence interval	p-value
Severe hypoglycemia	2.02	1.23-3.30	**0.01**
Mild hypoglycemia	1.97	1.68-2.30	**p < 0.005**
Euglycemia	1.00	-	-
Mild hyperglycemia	1.01	0.93-1.09	0.81
Severe hyperglycemia	1.24	1.16-1.34	**p < 0.005**

hazards model suggests that severe and mild hypoglycemia are significantly ($p < 0.05$) associated with increased mortality rates for septic patients, as is also severe hyperglycemia.

OP002 / #466

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

A SCORING SYSTEM FOR PERSONALIZED AND STREAMLINED DIABETES MANAGEMENT IN CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: The abundance and complexity of CGM-data constitute a challenge. Therefore, we created a composite score combining all aspects of glucose control in order to maximize its use. By using real-world data, we evaluated how our score correlates with traditional CGM-metrics.

Methods: CGM-data was collected from 194 pediatric type 1 diabetes subjects (age 13.8 ± 4.2, disease duration 5.2 ± 3.6), corresponding to approximately 5200 patient-weeks. Correlations between our score and CGM-metrics for a 14-day period were computed. The latest 14-day period of each patient was categorized into three groups based on the median score (low <60, medium 60-75 and high >75; maximum score = 100).

Results: We observed a positive correlation between our score and time in range (TiR) ($r = 0.84$, $p < 0.001$). A negative correlation was observed for eHbA1c ($r = -0.77$, $p < 0.001$), time above range ($r = -0.77$, $p < 0.001$), coefficient of variation ($r = -0.39$, $p < 0.001$). Also, the number of severe hyperglycemic- ($r = -0.49$, $p < 0.001$) and severe hypoglycemic- ($r = -0.11$, $p < 0.001$) episodes correlated negatively with our score. The three different groups differed both for eHbA1c (72 ± 15 vs. 53 ± 7 vs. 45 ± 7 mmol/mol, $p < 0.001$) and TiR (41 ± 12 vs. 63 ± 10 vs. 77 ± 11 %, $p < 0.001$). However, it should be noted that also in the group with the lowest score there was a wide range of eHbA1c (49-124 mmol/mol) and TiR (10-65%).

Conclusions: Our composite score can be used to rapidly assess several aspects of CGM-data. By grouping patient-weeks we can stratify patients while still accounting for several aspects of glycemic control.

OP003 / #922

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

INVESTIGATING THE EFFECT OF DIFFERENT TREATMENTS ON EXERCISE-INDUCED HYPOGLYCEMIA IN TYPE 1 DIABETES

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Background and Aims: In people with type 1 diabetes (T1D), physical activity (PA) affects blood glucose (BG) concentration during exercise and for up to 12 to 24 hours in recovery [1]; therefore, it is essential to design appropriate treatment decisions to prevent PA-induced hypoglycemia in T1Ds.

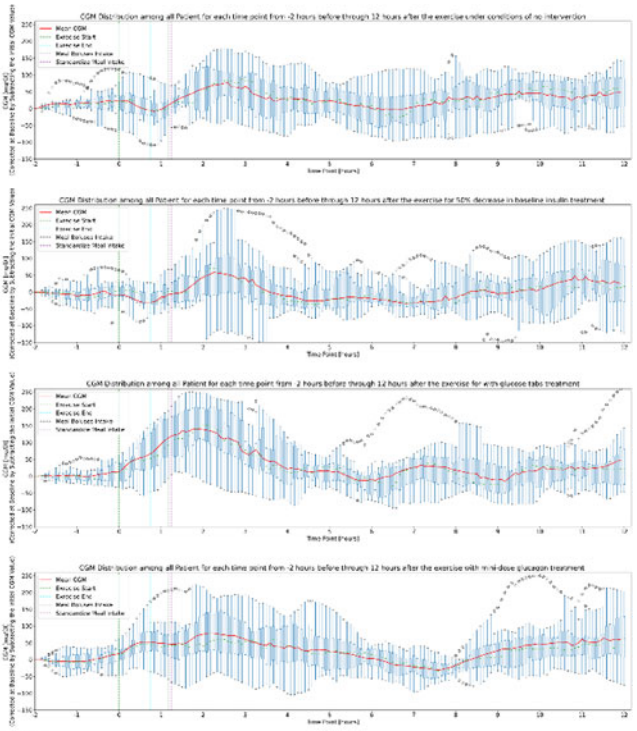

Figure.1

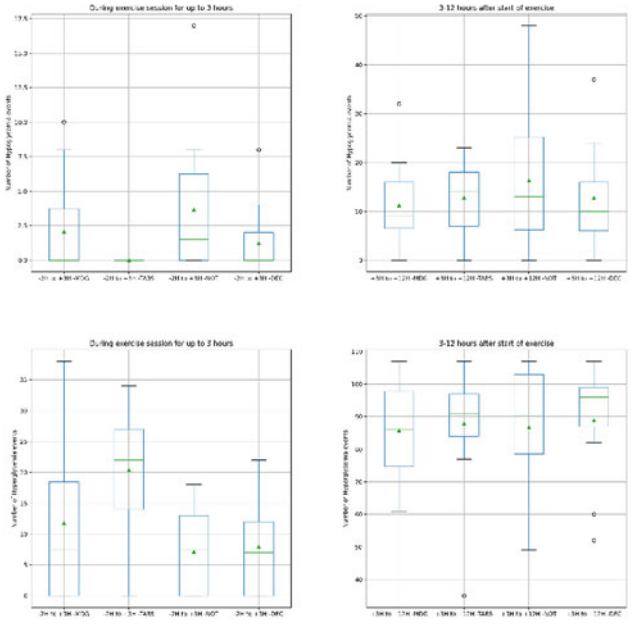

Figure.2

Table 1. Dataset Description

Strategy	Description
Control	No reduction in basal rate
DEC	50% reduction in basal rate 5 minutes before exercise, by the end of the exercise
TABS	No basal adjustment + pre-exercise glucose tabs (buccal route-40 grams in total
MDG	No basal adjustment + pre-exercise mini-dose glucagon

Methods: We utilized a publicly available dataset [2] to examine the effect of various strategies on a group of T1Ds who participated in four 45-minute fasted aerobic exercise sessions as described in Table 1. We examined the effect of each treatment on post-exercise glycemic stability by analyzing the total number of hyperglycemia and hypoglycemia events across all participants.

Results: Each exercise session contained fourteen participants. Figure 1 depicts the glucose profiles measure by continuous glucose monitoring (CGM) sensor for all patients receiving various treatments. Fig.2 depicts the total number of hyperglycemia and hypoglycemia events for 0-3 hours (during exercise and early recovery) and 3-12 hours after exercise.

Conclusions: In conclusion, we observe that during the exercise session and early recovery, all treatments function adequately; however, for the time interval of 3 to 12 hours after the experiment, mini dose glucagon treatment can reduce the number of both hypoglycemia and hyperglycemia events in T1Ds.

OP004 / #633

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

VARIABILITY OF INSULIN DOSE AND BASAL/BOLUS INSULIN RATIO ACCORDING TO USE OF DIABETES TECHNOLOGIES: DATA FROM SURVEY AND SWEET DIABETES REGISTRY

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Background and Aims: As of today,the optimal basal to total insulin(BD/TD) has not yet been determined,and also there is no consensus how to determine basal insulin dose with using diabetes technology.The aim of this study is to determine the variability of insulin doses and basal/bolus insulin ratios according to insulin treatment modality and diabetes technologies from the Better Control in Pediatric and Adolescent Diabetes:Working to Create Centers of Reference(SWEET)registry.

Methods: The study cohort included the patients in SWEET database with Type 1 diabetes onset <18 years with at least one clinic visit between June 2010 and June 2021 and Type 1 diabetes for at least 2 years.

Results: In this study; 38,889 patients included.48.6% were female, median age was15.2(11.9;17.2)years, and median diabetes duration was 5.9(3.7; 9.0)years. The distribution of treatment modality was as follows: multiple daily injection (MDI) without continuous glucose monitoring(CGM), 32.8%; MDI with CGM, 18.0%; subcutaneous insulin infusion(CSII) without CGM,11.7%; and CSII with CGM37.3%. Data of the participants were analyzed for each treatment modality separately. In unadjested data, a significant association with BD/TD was shown in all analyses, regardless of treatment modality:male gender, younger age group, and lower HbA1c were all related to decreased BD/TD (all $p < 0.05$). After adjustment for age, sex, and diabetes duration, there is no association remained between BD/TD and using diabetes technologies.

Conclusions: This study shows that similar basal to total insulin proportion is associated with using diabetes technologies,after adjustment for sex, age, and diabetes duration.On the other hand it remains to be investigated in a large prospective long-term study if reducing BD/TD insulin will improve metabolic control in children with type 1 diabetes.

OP005 / #530

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

PARAMETERS OF TYPE 1 DIABETES CONTROL BY TREATMENT MODALITY IN CHILDREN WITH TYPE 1 DIABETES: POPULATION-BASED STUDY

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Background and Aims: To assess the association of the key parameters of type 1 diabetes (T1D) control with treatment and monitoring modalities including the newly introduced hybrid closed-loop (HCL) algorithms in children with T1D (CwD) using the data from the national pediatric diabetes registry ČENDA.

Methods: CwD younger than 19 years with T1D duration >1 year were divided according to the treatment modality and type of CGM used: multiple daily injections (MDI), insulin pump without (CSII) and with HCL function, intermittently scanned continuous glucose monitoring (isCGM), real-time CGM (rtCGM) and intermittent or no CGM (CGM-). HbA1c, times in glycemic ranges and glycemia risk index (GRI) were compared between the groups.

Results: A total of 3251 CwD data (mean age 13.4 years) were analyzed. 2187 (67.3%) were treated with MDI, 1064 (32.7%) with insulin pump, 585/1064 (55%) with HCL. The HCL users achieved the best CGM-derived parameters results with median

TIR 75.4% and GRI 29.1 ($p < 0.001$ compared to the other groups), followed by MDI rtCGM and CSII groups with TIRs 68.8 and 69.0%, GRIs 38.8 and 40.1, respectively (non-significant p-values). These three groups did not differ in the HbA1c medians (51.8, 50.7, and 52.7 mmol/mol, respectively). The poorest T1D control was observed in CGM non-users (defined as CGM use <70% of the time) regardless of the treatment modality.

Conclusions: This population-based study shows that HCL technology is superior to other treatment modalities in a pediatric population.

OP006 / #875

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

REMISSION OF TYPE 2 DIABETES AND REGRESSION OF MICROALBUMINURIA WITH THE WHOLE-BODY DIGITAL TWIN TECHNOLOGY: A MULTICENTRIC, RANDOMIZED, CONTROLLED TRIAL

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Background and Aims: The prospective study was designed to determine the effect of Twin Precision Treatment Technology (TPT) on change in A1C and T2DM remission and regression of microalbuminuria. The TPT intervention uses the Whole-Body Digital Twin Platform, with AI and Internet of Things, to integrate multidimensional data to give precision nutrition and health recommendations via the TPT app and by coaches.

Methods: We analysed the data for 6 months (intervention n = 206, control n = 71).Microalbuminuria was defined as urinary albumin excretion of 30-300 mg/day.

Results: No. of patients with microalbuminuria (MIC) and macroalbuminuria reduced from 42 to 6 (-85.7%) and 4 to 1 (-44.4%), $p < 0.001$, respectively. 151 patients who did not have microalbuminuria at baseline increased to 191 (26.5% increase). Mean duration of diabetes was 3.6 years (±2.6, 95% CI 3.3 to 4.04). Mean age was 43.3 years (±8.8, 95% CI 42.1 to 44.4). Based on ADA criteria, 83.4% (n = 172/206) achieved diabetes remission vs 71.4% (n = 10/14) in MIC group and 84.3% (n = 161/191) without MIC; $p = 0.257$ (ns). One patient had macroalbuminuria. There was significant change in HbA1c and cardiometabolic parameters (Table). The changes noted were: mean HbA1c % (9.2 to 6), HOMA2B % (54.04 to 81.26), HOMA2IR % (1.9 to 1.13), body weight kg (79.06 to 67.09), hsCRP mg/dL (3.21 to 2.53), SBP mmHg (130 to 118.5), DBP mmHg (87 to 79.3), ASCVD risk score % (10.46 to 4.29).

Conclusions: A significant number of patients achieved regression of microalbuminuria and improvement in metabolic markers. TPT is useful for mitigating the incipient renal complications attributed to T2DM.

Table: Change in HbA1c and Cardiorenal and Metabolic Parameters

		N	Mean	Std. Deviation	Std. Error	95% Confidence Lower	95% Confidence Upper	Minimum	Maximum	p value
D0 HbA1C (%)	Normal	191.00	9.00	1.87	0.14	8.73	9.27	5.50	16.20	
	Microalbuminuria	14.00	9.24	2.32	0.62	7.90	10.57	6.00	12.90	
	Overall	205.00	9.01	1.90	0.13	8.75	9.27	5.50	16.20	
D180 HbA1C (%)	Normal	191.00	5.65	0.49	0.04	5.58	5.72	4.70	7.60	<0.001
	Microalbuminuria	14.00	5.97	0.64	0.17	5.60	6.34	5.00	7.50	<0.001
	Overall	205.00	5.67	0.50	0.03	5.60	5.74	4.70	7.60	<0.001
D0 Homa2B (%)	Normal	191.00	50.71	30.80	2.23	46.32	55.11	7.80	161.90	
	Microalbuminuria	14.00	54.04	27.65	7.39	38.08	70.01	15.40	116.30	
	Overall	205.00	51.21	30.71	2.14	46.99	55.43	7.80	161.90	
D180 HOMA2B (%)	Normal	191.00	87.65	30.72	2.22	83.27	92.04	23.90	199.50	<0.001
	Microalbuminuria	14.00	81.26	40.07	10.71	58.13	104.40	34.80	169.40	0.019
	Overall	206.00	87.36	31.36	2.18	83.05	91.67	23.90	199.50	<0.001
D0 HOMA2IR	Normal	191.00	1.93	0.91	0.07	1.80	2.06	0.39	6.21	
	Microalbuminuria	14.00	1.90	0.69	0.18	1.50	2.30	1.06	2.82	
	Overall	205.00	1.93	0.90	0.06	1.81	2.06	0.39	6.21	
D180 HOMA2IR (%)	Normal	191.00	1.02	0.47	0.03	0.95	1.09	0.30	3.27	<0.001
	Microalbuminuria	14.00	1.13	0.52	0.14	0.83	1.43	0.49	2.15	0.002
	Overall	206.00	1.03	0.48	0.03	0.96	1.09	0.30	3.27	<0.001
D0 weight (kg)	Normal	191.00	78.34	13.49	0.98	76.41	80.26	54.50	127.82	
	Microalbuminuria	14.00	79.06	23.97	6.41	65.22	92.90	42.24	132.54	
	Overall	205.00	78.41	14.33	1.00	76.44	80.38	42.24	132.54	
D180 Weight (kg)	Normal	191.00	67.91	11.14	0.81	66.32	69.50	45.32	110.43	<0.001
	Microalbuminuria	14.00	67.09	18.77	5.02	56.25	77.93	39.38	107.52	<0.001
	Overall	205.00	67.86	11.72	0.82	66.25	69.47	39.38	110.43	<0.001
D0 hsCRP (mg/L)	Normal	191.00	2.87	4.53	0.33	2.22	3.51	0.05	29.30	
	Microalbuminuria	14.00	3.21	5.31	1.42	0.15	6.28	0.05	19.40	
	Overall	205.00	2.89	4.56	0.32	2.27	3.52	0.05	29.30	
D180 hsCRP (mg/L)	Normal	191.00	1.30	2.71	0.20	0.91	1.69	0.02	28.90	<0.001
	Microalbuminuria	14.00	2.53	4.57	1.22	-0.11	5.16	0.05	16.30	0.047
	Overall	205.00	1.39	2.87	0.20	0.99	1.78	0.02	28.90	<0.001
D0 SBP (mmHg)	Normal	191.00	127.36	11.48	0.83	125.72	129.00	98.20	176.80	
	Microalbuminuria	14.00	130.00	10.30	2.75	124.05	135.95	115.80	152.00	
	Overall	205.00	127.54	11.37	0.79	125.98	129.11	98.20	176.80	
D180 SBP (mmHg)	Normal	191.00	116.97	10.36	0.75	115.49	118.45	94.00	142.11	<0.001
	Microalbuminuria	14.00	118.55	10.85	2.90	112.28	124.81	102.36	136.44	<0.001
	Overall	205.00	117.11	10.36	0.72	115.69	118.54	94.00	142.11	<0.001
D0 DBP (mmHg)	Normal	191.00	84.63	7.14	0.52	83.61	85.65	63.00	106.80	
	Microalbuminuria	14.00	87.04	7.57	2.02	82.67	91.41	77.20	106.80	
	Overall	205.00	84.77	7.16	0.50	83.79	85.76	63.00	106.80	
D180 DBP (mmHg)	Normal	191.00	78.11	6.95	0.50	77.12	79.10	59.00	98.00	<0.001
	Microalbuminuria	14.00	79.30	8.07	2.16	74.64	83.96	70.00	97.60	<0.001
	Overall	205.00	78.24	7.02	0.49	77.27	79.20	59.00	98.00	<0.001
D0 ASCVD (%)	Normal	191.00	8.10	7.83	0.57	6.95	9.18	0.35	48.41	
	Microalbuminuria	14.00	10.46	11.09	2.96	4.05	16.86	1.26	41.51	
	Overall	205.00	8.21	8.06	0.56	7.11	9.32	0.35	48.41	
D180 ASCVD (%)	Normal	191.00	3.00	2.89	0.21	2.59	3.41	0.09	16.19	<0.001
	Microalbuminuria	14.00	4.29	4.74	1.27	1.55	7.03	0.36	16.07	0.004
	Overall	205.00	3.10	3.05	0.21	2.68	3.52	0.09	16.19	<0.001
D0 eGFR (mL/min/1.73m2)	Normal	191.00	111.81	12.44	0.90	110.03	113.58	67.83	152.33	
	Microalbuminuria	14.00	111.44	17.71	4.73	101.21	121.66	79.52	140.76	
	Overall	205.00	111.53	13.29	0.93	109.70	113.35	59.73	152.33	
D180 eGFR (mL/min/1.73m2)	Normal	191.00	107.90	11.96	0.87	106.20	109.61	55.84	140.57	<0.001
	Microalbuminuria	14.00	108.59	13.52	3.61	100.78	116.39	77.73	124.50	0.159 NS
	Overall	205.00	107.76	12.31	0.86	106.07	109.45	55.84	140.57	<0.001

OP007 / #668

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

Q-SCORE: A COMPOSITE METRIC FOR EVALUATION OF SHORT-TERM QUALITY OF GLYCEMIC CONTROL

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Background and Aims: Composite metrics are potential screening tools for quality of glucose profiles. Q-Score has been constructed using main factors of the glucose profile, which are central glycemic tendency, hyperglycemia, hypoglycemia, intra- and inter-daily variability. Here, Q-Score was further developed for assessment of short-term glycemic control and identification of glucose profiles requiring therapeutic action.

Methods: CGM-profiles were from non-interventional, retrospective cross-sectional studies. The Q-Score-parameter, time above target range' (TAR) was adjusted from 8.9 to 10 mmol/l using 3-day-sensor profiles (n = 1,562). Profiles with 21 days of recording, obtained from 251 people with diabetes using the flash-glucose monitoring (FM) system, were applied to investigate time to Q-Score stability as well as correlation of Q-Score with fructosamin, Glucose management indicator % (GMI) and time in range % (TIR) as parameters of short-term metabolic control.

Results: The linear relation between the Q-Scores applying both TARs was $Q\text{-Score}_{10} = -0.03 + 1.00\ Q\text{-Score}_{8.9}$ ($r = 0.997$,

$p < 0.001$). Q-Score was stable after 11 days prior to TIR with 12 and variability given as % CV within 14 days. The Q-Score components reached stability between 12 and 13 days. Hypoglycemia was the slowest with 15 days. Q-Score had a correlation to fructosamin, GMI and TIR of $r = 0.715$, 0.884 and -0.869, respectively. Q-Score indicated insufficient glycemic control in 218/251 profiles, mostly belonging to insulin-treated people with diabetes. Q-Score components responsible were variability plus hypoglycemia in type 1 and hyperglycemia in type 2 diabetes, respectively.

Conclusions: Q-Score is a potential metric for short-term glycemic control and can be used for personalized evaluation of glucose profiles by quantifying Q-Sore components.

OP008 / #1041

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

EFFICIENCY AND TIME SAVING IN TREATMENT OF PEOPLE WITH DIABETES

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Background and Aims: Rapidly improving diabetes device technology offers great promise for improving diabetes care. However, the patient data necessary for evidence based medical management exist outside the EMR and creates a massive burden for providers to access and evaluate. Meaningful care plans depend on assessing glycemic control over time and pulling this data involves multiple steps and inefficiencies. Various technologies have been deployed to address this problem. To date, however, these have been deployed mostly outside the EMR workflow, and only address the challenge acquiring data, with limited functionality to automatically import the data into the EMR and process clinical data into a meaningful treatment decision support.

Methods: Data was collected during routine clinical care at three sites of Yale Health and North East Medical Group (NEMG) endocrinology centers. Time it takes clinical staff members in treating patients with diabetes on an intensive insulin regimen was captured before and after integration of the technology into the Yale Health EMR system. Number of ''clicks'' in the process was also analyzed.

Results: Medical assistants and providers from three clinical sites were included in this study, before and after integration of the technology into the EMR. Data collected compared time it takes for the complete patient flow and time it takes to perform each step. Results to be presented.

Conclusions: Results to be presented.

OP009 / #464

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

EFFECTIVENESS OF SMART PHONE APP BASED MONITORING SYSTEM SYNCRONIZED WITH EMR IN ACHIEVING BETTER GLYCAEMIC CONTROL BEYOND STANDARDS OF CARE IN DIABETES MANAGEMENT

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Background and Aims: The OneGlance® EMR and Smart Phone App is a unique platform customised for diabetes care. The app is synchronized with EMR and enables direct connectivity between patients and doctors. The patient can record and share their SMBG readings, receive timely treatment using the available chat option. The study aims to evaluate the effectiveness of the app based connectivity in helping the patients to achieve a better individualized glycaemic targets, minimize hypoglycaemic episodes, with a better adherence to treatment regime.

Methods: A retrospective data analysis over five years, with selection criterion of 18 months treatment. The selected 731 patients were classified as App users (288) and non-app users (443) and then app users subclassified as insulin users and insulin non-users. The primary outcome was the glycaemic control measured by HbA1c, FBS, SMBG before and after using the app, while secondary outcomes included reported hypoglycemia events.

Results: In the study population of 288 app users (137 males, 151 females), they have mean age 53.1 ± 13.1 years, baseline HbA1c $7.2 \pm 1.9\%$ and FBS 139.6 ± 57.7 mg/dl. Before and after using the app mean difference in their HbA1c was 0.44 ($p < 0.0001$), FBS was 18.53mg/dl ($p < 0.0001$) respectively, amongst them the insulin takers had a mean difference of 0.76 in HbA1c($p < 0.0001$). Average monthly incidence of reported hypoglycaemia reduced from 0.82 to 0.47 in the app users. Patients using the app had 3.3% overall better glycaemic profile on a like for like comparison to the non-users.

Conclusions: OneGlance® app is effective tool helping patients achieve better individualised glycaemic control with minimum hypoglycaemic episodes.

OP010 / #610

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

IN SILICO REPLAY OF PHASE 3 INSULIN DEGLUDEC CLINICAL TRIAL

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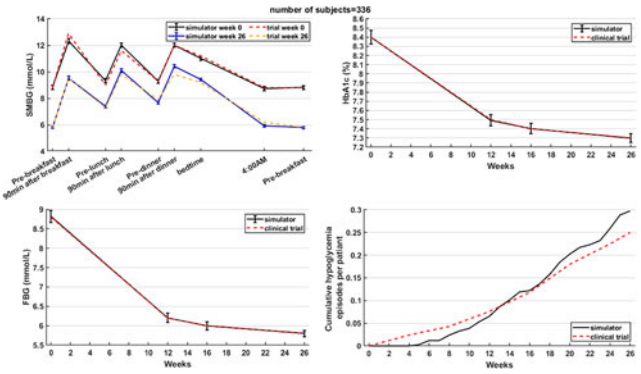
Background and Aims: The UVA virtual lab (UVlab), equipped with a population of 6156 in-silico type 2 diabetes (T2D) subjects (avatars), accounts for the heterogeneity and different subtypes of T2D. We aim to demonstrate the capacity of UVlab to reproduce the results of a previously published efficacy clinical trial of insulin degludec (NCT01006291).

Methods: Published data were used, and the trial's protocol was applied to the virtual population. Each avatar received a fixed ratio of 0.3/0.3/0.3/0.1 of their total daily carbohydrate for breakfast, lunch, dinner, and bedtime snack, respectively. A subpopulation of avatars was selected to match the available mean and standard deviation of body weight, 9-point SMPG profiles, and insulin delivery. HbA1c and hypoglycemia events were compared to the clinical trial for validation.

Results: The selection method found a subpopulation of 336 avatars. The selected virtual sub-population well matched the available clinical data, with a median percent difference between clinical data and simulated outcomes of 0.2% (IQR, 0.06-3.2, Figure 1). This sub-population had an HbA1c of 8.4% at week 0 and 7.3% after simulating the trial protocol at week 26. This sub-population also reproduced patterns of hypoglycemia observed in the clinical trial (0.3 *vs.* 0.25 events per patient).



Conclusions: The outcomes of a phase 3 insulin degludec clinical trial were reproduced closely in simulation by a subpopulation curated from the UVA virtual lab T2D population. Considering these data were never used to construct the virtual lab, this demonstrates the capacity of this platform to predict the impact of basal insulin use in T2D.

OP011 / #803

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

INFERRING CAUSE FROM EFFECT: TOWARDS A PERSONALISED NUTRITION ADVISOR TO REACH BODY WEIGHT TARGETS

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Background and Aims: We aim to develop a system enabling personalised weight prediction and providing data-based personalised nutrition advice for weight management.

Methods: We developed an interpretable weight prediction model based on the energy balance equation (energy intake is a function of recorded calorie consumption and a latent part dependent on observed weight changes, whereas energy expenditure is a function of weight and physical activity). We modelled the change in the caloric intake rate as random walk. Weight measurement errors and uncertainty of caloric intake were assumed to be independent and normally distributed. Parameters were estimated using Bayesian inference across weight, meal and activity data of 9500 users undergoing App-based nutrition and lifestyle coaching.

Results: The model proved useful in revealing preceding cause, i.e. caloric deficit or excess, from the observed body weight. This facilitates early detection of unwanted dietary habit shifts. The model also informs about main drivers of weight change by attributing it to quality and frequency of meals and activities. The causal design of the model allows estimating the effect of candidate dietary interventions on body weight. The predicted likelihood of achieving predefined weight targets (e.g., 73% accuracy predicting ≥5% weight loss at week 4 of 12) further supports tailored counselling.

Conclusions: The developed interpretable model empowering dietitians to individually tailored nutritional advice may facilitate the application in public health care, a sector otherwise cautious when adopting AI systems. Moving forward, we will further tailor the model output to fit in with clinical workflows, end users and therapeutic decisions.

OP012 / #786

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

IRTA, A DECISION SUPPORT APPLICATION FOR INSULIN THERAPY COUPLED WITH THE CONTINOUS GLUCOSE MONITORING: IMPACT ON GLYCEMIC CONTROL AND SATISFACTION OF TYPE 1 DIABETIC PATIENTS

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Background and Aims: Despite information delivered by Continuous Glucose Monitoring (CGM), few patients achieve glycemic targets defined by ATTD in 2019. This study evaluates the impact of IRTA (Insulin Real-Time Advisor), an application developed to help insulin therapy from FreeStyle Libre (FSL) data, on glycemic control as well as the level of satisfaction of type 1 diabetic patients using FSL.

Methods: We performed an interventional, prospective, monocentric and before-after study which included a first phase without IRTA and a second one with IRTA that delivered personalized advice. Data from 64 patients followed at Rennes University Hospital and trained to use FSL have been analyzed to try to show an improvement of 5% of time spent in the glycemic target 70-180mg/dL (Time In Range, TIR). The primary end point was the percentage of time spent in TIR during the last month of each period. Secondary end points evaluated HbA1c, indirect glycemic data and items scores to specific satisfaction questionnaires.

Results: IRTA did not show any efficacy in improving glycemic control on TIR (from 55.5% to 53.1%, $p = 0.0332$) in a heterogenous population with old diabetes. The other data were not statistically and significatively modified, including among high users. Scores to questionnaires showed an excellent level of satisfaction with FSL and a good level of satisfaction with IRTA.

Conclusions: IRTA is of little benefit on glycemia with experienced and educated patients with diabetes. Additional studies are needed to define the subpopulations in which IRTA would be the most relevant.

OP013 / #374

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

ASSESSMENT OF DRUG THERAPY EFFECTIVENESS IN TYPE 2 DIABETES USING CONTINUOUS GLUCOSE MONITORING SYSTEMS

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Background and Aims: The increasing use of continuous glucose monitoring (CGM) devices in individuals with type 2 diabetes (T2D) opens the door for monitoring glucose control in outpatient conditions. The key parameter quantifying the quality of glucose control is the disposition index (DI), usually assessed from plasma glucose (G), insulin (I) and C-peptide (CP) measurements collected after an IVGTT or OGTT performed in hospitalized subjects. Recently, we proposed a method to calculate DI from CGM data obtained in free-living conditions. We validated it against the Oral Minimal Model (OMM) using the virtual population of the Padova T2D Simulator. Here we aim to validate it using in vivo T2D data.

Methods: Twelve subjects with T2D (mean±SD: age = 53 ± 8 years; BMI = 34 ± 6kg/m^2) underwent a randomized, double-blind, placebo-controlled crossover study receiving either 50mg DPP-4 inhibitor (treatment) or placebo before breakfast and dinner over a 10-day period with a 2-week washout. On day 9, they consumed a mixed meal containing 75g glucose 30min after the morning dose. G, I and CP concentrations were measured for 5h after the meal and used to estimate the DI with the OMM (DI^{MM}), while CGM data were used to calculate DI with the sensor-based method (DI^{SB}).

Results: DI^{SB} correlated with DI^{MM} and both were able to detect the significant improvement in DI attributable to treatment (Fig. 1).

Conclusions: The DI^{SB} can be used to assess therapy effectiveness in subjects with T2D wearing CGM and, potentially, in decision support systems for T2D management.

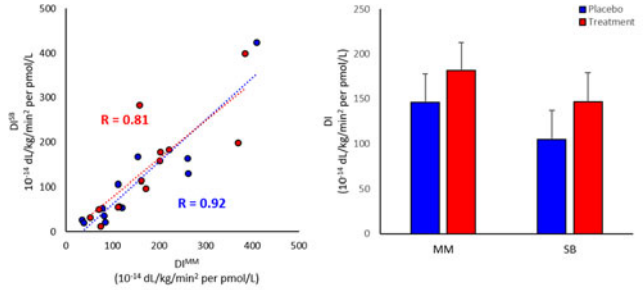

Fig 1. Regression (left) and mean±SE (right panel) of DI measures obtained with the Oral Minimal Model (MM) vs Sensor-Based method (SB) in the placebo (blue) and treatment (red) arms. Differences between treatment and placebo are statistically significant (p<0.05) with both methods.

Background and Aims: Determining user profile settings is an important part of insulin pump initiation and long-term use. We designed and evaluated an automated system to initialize and adjust insulin pump settings.

Methods: Adults with type 1 diabetes (N = 29, mean age 35.4 (10.1) years, 62.1% female, diabetes duration 20.7 (11.2) years), completed 2 weeks of CGM run-in with multiple daily injections, then 13 weeks of Control-IQ technology use. Initial basal rate, carbohydrate ratio, and correction factor were determined by an algorithm based on prior insulin use, with follow-up settings adjusted weekly by the automated system. Providers could override the automated settings changes for safety concerns.

Results: Time 70-180 mg/dL (3.9-10 mmol/L) improved from 45.7% during run-in to 69.1% during the last 30 days of Control-IQ use. This improvement was evident after just one week (median improvement 18.8%, p < 0.001, 95% CI 13.6 to 23.9). However time <70 mg/dL (<3.9 mmol/L) gradually decreased from 1.8% during run-in to 1.0% over 6 weeks and then stayed stable (p = 0.03) (Table 1). Percentage of participants achieving HbA1c <7% (<53 mmol/mol) went from zero at baseline to 55% at study end (p < 0.001). Only six of the 318 automated settings adaptations were manually overridden.

Conclusions: Automated therapy settings initialization and adaptation, implemented with Control-IQ technology, reduced hypoglycemia over time while showing immediate and sustained improvement in time in range. Use of this simplified technology may allow primary care and other providers, less comfortable with pump technology, to improve outcomes and reduce burden of care by increasing uptake of insulin pump use.

Table 1. Median [IQR] CGM run-in metrics with MDI (2 weeks) compared to the last 30 days of Control-IQ technology use with automated settings initialization and adaptation. Central Lab HbA1c was collected at end of MDI run-in and after 13 weeks of Control-IQ technology use.

	MDI Run-In (14 Days)	Control-IQ Technology with Automated Initialization and Adaptation (Last 30 days)	p value
Percent Time < 54 mg/dL (< 3.0 mmol/L)	0.3 [0.1, 0.7]	0.2 [0.1, 0.3]	0.06
Percent Time < 70 mg/dL (<3.9 mmol/L)	1.8 [1.1, 2.8]	1.0 [0.8, 1.4]	0.03
Percent Time 70-180 mg/dL (3.9-10 mmol/L)	45.7 [40.5, 56.7]	69.1 [61.8, 73.1]	<0.001
Percent Time > 180 mg/dL (>10 mmol/L)	51.9 [42.3, 57.1]	29.5 [26.2, 36.5]	<0.001
Percent Time > 250 mg/dL (> 13.9 mmol/L)	21.8 [12.9, 26.3]	7.7 [6.1, 10.7]	<0.001
HbA1c %	7.9 [7.6, 8.4]	6.9 [6.5, 7.2]	<0.001
(mmol/mol)	62.8 [59.6, 68.3]	51.9 [47.5, 55.2]	

OP014 / #166

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

AUTOMATED THERAPY SETTINGS INITIALIZATION AND ADAPTATION WITH THE TANDEM T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ TECHNOLOGY REDUCES HYPOGLYCEMIA WHILE MAINTAINING HIGH TIME IN RANGE

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OP015 / #467

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

GLYCEMIC RESPONSES AND PATIENT REPORTED OUTCOMES (PROS) IN PEOPLE WITH DIABTES FOLLOWING 4 WEEKS USAGE OF AN INSULIN INJECTION SUPPORTING APP: A FEASIBILITY STUDY

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Background and Aims: Lipohypertrophy, poor insulin injection technique and missed boluses are well-known issues in the management of diabetes. This study evaluated whether use of

an app with digital training on correct injection routines, site rotation and injection related behaviors will change glycemic control, adherence, or empowerment.

Methods: In this prospective, open label, 2-period study patients injected at least one bolus per day, had a HbA1c ≥7% and wore a continuous glucose monitoring device. A 4-week period without was followed by a 4-week period with the use of the injection supporting app. Four PROs (Diabetes Distress Scale (DSS), Diabetes Empowerment Scale (DES-SF), Diabetes Self-Management Questionnaire (DSMQ), and the Adherence Scale for Diabetes (ARMS-D)) were answered three times by patients.

Results: 58 patients (37 male, 21 female) completed the study (mean age 52.0 ± 14.6y, diabetes duration 19.2 ± 12.5y, HbA1c 8.0 ± 0.8%, 35 T1DM, 23 T2DM). The DDS Total score and the DDS Emotional Burden subscale showed significant differences ($p < 0.05$). There were significant differences ($p < 0.001$) between baseline and intervention for mean glucose (190.2 (39.2) vs 186.0 (42.0)), time in range (49.9 (17.1) vs 52.6 (18.3)) and time >180 mg/dl (48.2 (17.3) vs 52.6 (18.3)). No significant differences in % of values in the hypoglycemia range (<70 mg/dl) were observed.

Conclusions: This feasibility study demonstrates that use of an insulin injection supporting app for 4 weeks leads to improvements in diabetes distress and several glycemic measures. A larger randomized controlled study of longer duration is planned for confirmation.

OP016 / #812

Topic: ***AS03 Closed-loop System and Algorithm***

REAL LIFE RESULTS OF DBLG1 SYSTEM IN EUROPE

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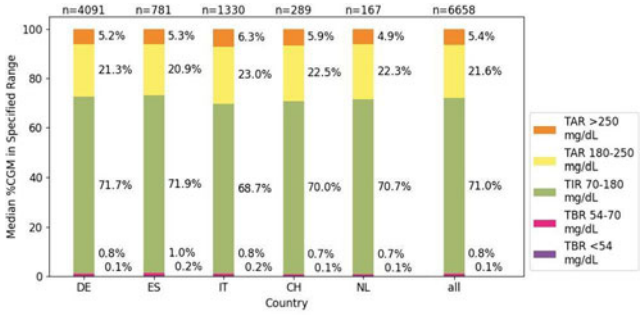
Background and Aims: This study aims to assess the performance of DBLG1 System (Closed Loop) on patients equipped with DBLG1 System in Switzerland (CH), Germany (DE), Spain (ES), Italy (IT) and the Netherlands (NL). 6658 patients gave their consent to join the study.

Methods: The glycemic data of the patients are analyzed between April 2021 and April 2022. For each patient, the Time In Range 70-180 mg/dL (TIR), time below range 70 (TBR70) and 54 mg/dL (TBR54) and time above range (TAR) 180 and 250 mg/dL are computed. For comparison, the baseline TIR is estimated using the HbA1c measured before using the device (available for 4162 patients). The statistics are then aggregated by country and overall.

Results: For the 4162 patients, the overall median TIR is 71.79% [65.3, 78] – with a baseline TIR of 54.88% [40.2, 67.0]. For the 6658 patients, we observe a median TIR of 71% [63.8, 77.7]. The median TBR70 and TBR54 are 0.98% [0.5, 1.8] and 0.14% [0.06, 0.3] respectively. The results are similar across all the countries as shown in Fig. 1.

Conclusions: The use of DBLG1 system in real life in Europe keeps its promises. Results are consistent with previous clinical



trials NCT02987556 (SP7) and NCT04190277 (SP8) and are in compliance with the international recommendations for the TIR (>70%) and the TBR (<4%) for 3515 patients.

OP017 / #785

OP018 / #661

Topic: *AS03 Closed-loop System and Algorithm*

RAPID REVERTING SUBOPTIMAL GLUCOSE CONTROL BY IMPLEMENTING AN ADVANCED HYBRID CLOSED-LOOP SYSTEM IN NON-COMPLIANT ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: AHCL systems represent the next step of automation intended to maximize normoglycemia. Many adolescents with T1D may experience a deterioration in metabolic control due to erratic meal, poor adherence to treatment regimens and endocrine changes.

The aim of our study was to evaluate the impact of Tandem Control IQ (CIQ) AHCL in a cohort of diabetic adolescents with suboptimal glucose control.

Methods: We enrolled 20 patients with T1D using MDI and flash glucose monitoring. All patients were upgraded and educated on the use of CIQ. Carbohydrate was not included as patients had previously expressed non- compliance. Glucometrics (TIR,TAR,TBR) were downloaded at baseline, after 2-weeks and after 1 month of CIQ use.

Results: 20 adolescents with T1D were included (age: 15.7 ± 1.9 years, diabetes duration: 6.2 ± 4.0 years, HbA1c: 10.0% ± 1.7). TIR increased from 27.1% ± 13.7 at baseline to 68.6% ± 14.2 at 2-weeks and to 66.6% ± 10.7 at 1 month ($P < 0.001$). TAR >250 mg/dL decreased from 46.1% ± 23.8 to 9.9% ± 9.5 at 2-weeks and to 10.8% ± 6.1 at 1 month ($P < 0.001$). TAR 180-250 mg/dL decreased from 23.0 ± 10.9 to 19.2% ± 6.1 at 2-weeks and to 20.8% ± 6.6 at 1 month. Mean glucose improved from 251mg/dl ±68.9 to 162mg/dl ±25.0 and to 164mg/dl ±17.5 ($P < 0.001$).

No differences in TBR 54-70 mg/dl or <54 mg/dL were found.

Similar glucose profiles were found between 2-weeks and 1 month of use of AHCL.

A patient suffered from a single event of mild DKA.

Conclusions: AHCL systems allow significantly, quickly and safely improve their glucose control. This is a turning point for technology that used to favour mainly those who were already compliant.

OP019 / #329

Topic: *AS03 Closed-loop System and Algorithm*

12-MONTH RESULTS OF THE ADAPT RANDOMIZED CONTROLLED TRIAL: ADVANCED HYBRID CLOSED LOOP THERAPY VERSUS CONVENTIONAL TREATMENT IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: The ADAPT trial[1] demonstrated a significant 1.4% reduction in HbA1c with Advanced Hybrid Closed Loop (AHCL) therapy, when adults with type 1 diabetes using multiple daily injections plus intermittently scanned continuous glucose monitoring (MDI+isCGM, HbA1c>8.0%) were randomized to AHCL (MiniMed™ 780G) or continued current treatment. Time in range (TIR) improved (27.6%) as well while safety remained. We investigated (1) whether these achievements were reproduced in the MDI+isCGM arm after individuals switched to AHCL, and (2) whether the successful outcomes in the AHCL arm were maintained after 12 months.

Methods: Endpoints are within-arm changes in HbA1c and other parameters of glycemic control from 6 to 12 months.

Results: Thirty-five patients in the AHCL arm and 32 in the MDI+isCGM arm completed follow-up. The figure and table show glycemic control over time. The MDI+isCGM arm, switching to AHCL therapy, repeated the successful improvement in HbA1c (change: -1.36%. 95%CI: -1.65% to -1.08%) and other parameters. In the AHCL arm, HbA1c (7.4%) and other parameters were maintained. After 12 months, there was no more between-arm difference in HbA1c decrease (0.1; -0.30 to 0.52).

Conclusions: This analysis showed that the substantial efficacy improvement as seen in the ADAPT[1] publication was reproduced in the control arm and sustained after 12 months. These

Figure: HbA1c during study

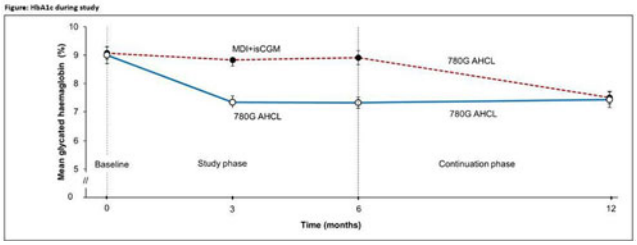

Table: Glycemic control in subjects that continued with AHCL and subjects that transitioned from MDI+isCGM to AHCL

	Subjects that continued with AHCL (N=35)			Subjects that transitioned from MDI+isCGM to AHCL (N=32)		
	End of 6M	End of 12M	Estimate of change (95%CI)	End of 6M	End of 12M	Estimate of change (95%CI; p)
HbA1C, % (SD)✣	7.3 (0.6)	7.4 (0.8)	0.1 (-0.05 to 0.25)*	8.9 (0.8)	7.5 (0.6)	-1.4 (-1.7 to -1.1; <0.001)
Time in Range, % (SD)	70.4 (9.9)	69.7 (9.0)	-0.7 (-2.1 to 0.7)*	43.6 (15.4)	70.7 (9.5)	28.1 (22.8 to 33.4; <0.001)
Time above 180mg/dL, % (SD)	27.1 (10.4)	28.0 (9.6)	0.9 (-0.5 to 2.3)*	53.8 (16.5)	27.6 (9.5)	-27.2 (-32.9 to 21.6; <0.001)
Time above 250mg/dL, % (SD)	6.7 (4.6)	7.2 (4.9)	0.5 (0.0 to 1.1)*	22.5 (13.2)	6.6 (4.3)	-16.6 (-21.7 to -11.6; <0.001)
Time below 70mg/dL, % (SD)	2.5 (1.9)	2.3 (1.9)	-0.2 (-0.7 to 0.2)*	2.6 (2.5)	1.8 (1.4)	-0.5 (-1.5 to 0.1; 0.1345)*
Time below 54mg/dL, % (SD)	0.6 (0.6)	0.5 (0.5)	-0.1 (-0.2 to 0.0)*	0.7 (1.2)	0.4 (0.4)	-0.2 (-0.4 to 0.0; 0.0598)*
Mean sensor glucose, mg/dL (SD)	152.7 (16.0)	154.4 (15.6)	1.76 (-0.4 to 3.9)*	194.7 (29.5)	155.0 (13.8)	-41.4 (-51.7 to -31.0; <0.001)
Standard deviation of SG, mg/dl (SG)	54.8 (9.8)	56.0 (10.0)	1.3 (-0.2 to 2.8)*	69.4 (12.8)	53.8 (8.7)	-14.7 (20.7 to -10.9; <0.001)
Glucose management indicator, % (SD)	7.0 (0.4)	7.0 (0.4)	0.0 (-0.0 to 0.1)*	7.9 (0.6)	7.2 (0.5)	-1.0 (-1.24 to -0.74; <0.001)

* Non-inferiority met
✣ Number of subjects with HbA1c measurements at 6 and 12 months: 33 in continuation with AHCL and 31 in transition from MDI+isCGM to AHCL

data further support expanded access of MiniMed™ 780G system to those with poorly controlled type 1 diabetes at an early stage.

1 Choudhary et al., Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT), Lancet Diabetes Endocrinol. 2022 Oct;10(10)

OP020 / #408

Topic: ***AS03 Closed-loop System and Algorithm***

PATIENT-REPORTED SEVERE HYPOGLYCEMIA AMONG HYBRID CLOSED LOOP SYSTEM (HCLS) USERS: REAL-WORLD EVIDENCE FROM A MULTI-CENTER STUDY FOR PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Background: There is growing evidence that Hybrid Closed Loop Systems (HCLS) are associated with a lower risk of severe hypoglycemia (SH) in people with type 1 diabetes. In this study, we use real-world data from the T1D Exchange (T1DX-QI) EMR database to investigate the association between HCLS use and patient-reported SH events using propensity score matching.

Methods: In this analysis, we examined SH events across propensity score-matched HCLS user and HCLS non-user groups. All available data for the pediatric (6 years and older) and adult population with T1D from March 2018-March 2022 were included in this analysis. Patient-reported SH events are defined as SH events reported by the patient at their most recent clinic visit and were classified as a binary variable (Yes/No), with those reporting one or more SH events being classified under 'Yes' Similarly, HCLS device use was defined as the use of HCLS reported by the patient at their most recent clinic encounter.

Results: Propensity scores were estimated using a logit model, including age, gender, race/ethnicity, and insurance status as covariates. Matching was done using 1:1 matching with the nearest neighbor approach and a caliper of 0.1. There were 1537 matched people with T1D in the HCLS user and non-users group. Analysis showed that HCLS users were less likely than HCLS non-users to report >1 SH event (OR [95% CI]: 0.2 [0.1, 0.4] when controlling for covariates.

Conclusions: In this population-level real-world data analysis, we found HCLS use among people with T1D associated with lower patient-reported SH events.

Table 1: Association of HCLS use and patient reported Severe Hypoglycemia using propensity score matched data

Variables	Odds Ratio	p-value
HCLS		
Non-users	-	<0.0001
Users	0.2 (0.1,0.4)	
Age	1.01 (0.9, 1.0)	0.2
Gender		
Female	-	0.42
Male	1.1 (0.8,1.7)	
Race ethnicity		
White	-	
Black	2.6 (1.0,1.7)	0.04
Hispanic	1.3 (0.8, 2.1)	0.28
Insurance		
Private	-	
Public	0.8 (0.4, 1.6)	0.62

OP021 / #576

Topic: ***AS03 Closed-loop System and Algorithm***

THE EFFECT OF ADVANCED HYBRID CLOSED LOOP USE ON D GLYCEMIA RISK INDEX (GRI) IN CHILDREN WITH DIABETES:AN EVALUATION ACROSS REAL-WORLD DATA FROM SINGLE CENTER

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Background and Aims: GRI which is based on weighted combinations of TBR (hypoglycemia component) and TAR (hyperglycemia component), is an emerging parameter assesing glycemic quality in adults. As yet, GRI has not been validated in children. This study aims to investigate the effect of AHCL on GRI in children.

Methods: A data set of 85 children with type 1 diabetes (T1D) using AHCL between January 2021- October 2022 was analysed. Baseline, 3-6-12 and 18 month-data were compared regarding GRI and continuous glucose monitoring (CGM) metrics, using linear regression model. Quality of glycemia was classified in five different risk zones, from the best to the worst, as zone A-E.

Results: Of the participants 55% were girls, the mean age and duration of diabetes were 11.2 and 4.7 years, respectively. The mean TIR increased from 69.5 ± 12.5% at baseline to 79.9 ± 8% at 3 months(p:0.009), this improvement sustained over 18 months. Meanwhile,mean GRI score decreased from 37.6% at baseline to 24% at 3 months (p:0.310). GRI did not change significantly during 18 months after transition to AHCL (table). Although the difference was statistically insignificant in the whole group, a significant decrease in GRI from 45.1% at

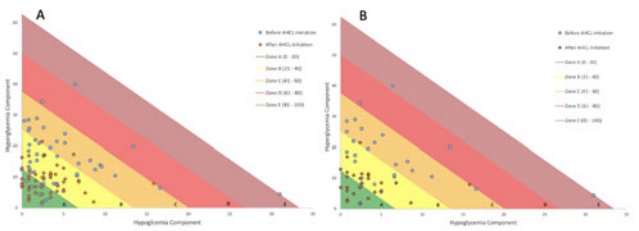

Figure:Pre- and post-AHCL GRI zones in all participants (A) and those transitioning from MDI to AHCL (B)

Table 1: CGM metrics and GRI across time intervals

	Baseline (n:52)	3-month (n:77)	6-month (n:66)	12-month (n:43)	18-month (n:24)	p
TIR 70-180mg/dl (%)	69.5±12.5	79.9±8	79.7±8.5	79.4±10.1	78.9±7.8	0.009*
TAR 180-250mg/dl (%)	19.3±8.3	13.9±6	14.3±6.2	14.6±6.1	15.2±5.3	0.159
TAR >250mg/dl (%)*	3.9 (0-24)	2 (0-14)	2 (0-14)	2 (0-25)	2 (0-10)	0.105
TBR 54-70mg/dl (%)	3.5±3.1	2.7±2	2.2±1.4	2.4±1.9	2±1.7	0.146
TBR <54mg/dl (%)*	1 (0-31)	0 (0-7)	0 (0-4)	0 (0-4)	0 (0-2)	0.295
Mean SG (mg/dl)	148.4±32.3	136.2±13.3	135.3±17.2	138.1±15.8	139.6±12.5	0.351
GMI (%)	-	6.5±0.28	6.5±0.29	6.6±0.38	6.6±0.3	0.217
CV (%)	34.7±7.5	34±4.8	33.3±4.1	32±6.6	33.8±5.1	0.194
GRI (%)	37.6±20.7	24±10.4	22.9±9	23.7±12.7	23.7±9.7	0.310

*median (minimum – maximum)
* Significant difference is between baseline and 3rd month

baseline to 22.8% at 3 months was noted in children who transitioned from MDI to AHCL ($p < 0.001$)(figure).

Conclusions: This study is the first study assessing the effect of AHCL on GRI in children with T1D. AHCL provides improvement in GRI, however further studies are needed to determine if GRI is a useful metric in monitoring glycemic control in children.

	GMI_{PLGS} <= 6.9% (N=254)	6.9% < GMI_{PLGS} <=7.4% (N=284)	7.4% < GMI_{PLGS} <= 8% (N=234)	GMI_{PLGS} > 8% (N=164)
GMI (%) *				
PLGS	6.6 ± 0.3	7.2 ± 0.1	7.7 ± 0.2	8.6 ± 0.6
AID (1m)	6.6 ± 0.3	7.0 ± 0.3	7.3 ± 0.3	7.7 ± 0.6
AID (3m)	6.6 ± 0.3	7.0 ± 0.3	7.3 ± 0.4	7.8 ± 0.6
Mean BG (mg/dL) *				
PLGS	136 ± 11	161 ± 6	183 ± 7	221 ± 23
AID (1m)	136 ± 12	153 ± 12	165 ± 13	185 ± 24
AID (3m)	139 ± 14	154 ± 13	167 ± 17	186 ± 26
TIR (%) *				
PLGS	86 ± 7	69 ± 6	52 ± 6	31 ± 11
AID (1m)	87 ± 8	76 ± 9	66 ± 10	53 ± 16
AID (3m)	85 ± 8	75 ± 10	65 ± 12	53 ± 17
TAR (%) *				
PLGS	13 ± 7	30 ± 6	47 ± 6	69 ± 11
AID (1m)	12 ± 8	24 ± 9	33 ± 10	47 ± 16
AID (3m)	14 ± 9	25 ± 10	34 ± 12	47 ± 17
TAR2 (%) *				
PLGS	1 ± 1	5 ± 3	12 ± 5	32 ± 13
AID (1m)	1 ± 2	4 ± 4	7 ± 5	15 ± 10
AID (3m)	1 ± 2	4 ± 4	8 ± 6	15 ± 12
TBR (%)				
PLGS	1.1 ± 1.5	0.7 ± 1.0	0.4 ± 0.8	0.3 ± 0.5
AID (1m)	0.7 ± 1.1	0.7 ± 1.0	0.5 ± 0.9	0.5 ± 0.8
AID (3m)	0.8 ± 1.4	0.6 ± 0.9	0.5 ± 0.9	0.5 ± 0.8
TBR2 (%)				
PLGS	0.2 ± 0.3	0.1 ± 0.3	0.1 ± 0.2	0.1 ± 0.1
AID (1m)	0.1 ± 0.3	0.1 ± 0.3	0.1 ± 0.3	0.1 ± 0.2
AID (3m)	0.1 ± 0.3	0.1 ± 0.2	0.1 ± 0.2	0.1 ± 0.2
TDI (units) *				
PLGS	65 ± 36	69 ± 38	71 ± 38	78 ± 43
AID (1m)	67 ± 33	74 ± 40	79 ± 40	93 ± 50
AID (3m)	70 ± 37	74 ± 38	78 ± 41	92 ± 50
TDB (units) *				
PLGS	36 ± 23	34 ± 21	37 ± 23	37 ± 21
AID (1m)	34 ± 20	37 ± 19	41 ± 21	49 ± 28
AID (3m)	35 ± 20	37 ± 19	42 ± 22	50 ± 28
Manual correction boluses (#/day) *				
PLGS	1.7 ± 1.8	1.9 ± 2.0	1.8 ± 1.6	2.2 ± 1.8
AID (1m)	1.4 ± 1.7	1.4 ± 1.8	1.2 ± 1.5	1.3 ± 1.6
AID (3m)	1.5 ± 1.9	1.4 ± 1.7	1.1 ± 1.6	1.1 ± 1.4

AID: automated insulin delivery; BG: blood glucose; GMI: glucose management indicator; GMI_{PLGS}: GMI during PLGS use; PLGS: predictive low-glucose suspend; TAR: time >180 mg/dL; TAR2: time >250 mg/dL; TBR: time <70 mg/dL; TBR2: time <54 mg/dL; TDB: total daily basal insulin; TDI: total daily insulin; TIR: time in 70-180 mg/dL. Data are reported as mean ± standard deviation.
* P < 0.001 for within-subjects contrasts of general linear model comparing PLGS, AID (1m), AID (2m), and AID (3m).

OP022 / #777

Topic: ***AS03 Closed-loop System and Algorithm***

REAL-WORLD EVIDENCE OF AUTOMATED INSULIN DELIVERY (AID) USE BY INDIVIDUALS WITH TYPE 2 DIABETES (T2D)

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Background and Aims: AID has been shown to improve the quality of glycemic control in both type 1 diabetes (T1D) and T2D. Here, the effect of real-life transition from a predictive low-glucose suspend (PLGS) system (Basal-IQ, Tandem Diabetes Care) to an AID system (Control-IQ Technology, Tandem Diabetes Care) by individuals with T2D has been explored.

Methods: A retrospective analysis of data from 936 individuals with T2D who used PLGS for one month followed by AID for three months in the real world and uploaded their data to Tandem's Customer Relations Management database, was performed. Participants consented to the use of their data for research, when initiating their t:connect accounts. Continuous glucose monitoring and insulin delivery records were analyzed for glycemic outcomes and bolusing behaviors, comparing PLGS to AID.

Results: The transition from PLGS to AID led to a rapid and sustained improvement in glycemic outcomes. Glucose management indicator (GMI) decreased, with larger decreases associated with higher GMI values during PLGS use. Time in 70-180 mg/dL and >180 mg/dL improved, with no change in exposure to hypoglycemia. Total daily insulin increased, mostly due to increased basal insulin by AID, particularly in those with baseline GMI >8%. The number of manual correction boluses per day decreased. Results are summarized in the attached table.

Conclusions: AID is safe and effective for use in T2D in the real world. TIR and GMI improved after transitioning to AID, without increasing the risk for hypoglycemia. The changes were comparable to those previously reported in T1D [Kovatchev et al., Diabetes Care, 2022].

OP023 / #769

Topic: ***AS03 Closed-loop System and Algorithm***

METABOLIC IMPROVEMENT WITH THE MEDTRONIC MINIMED™ 780G ADVANCED HYBRID CLOSED-LOOP SYSTEM IN PEDIATRIC PATIENTS WITH TYPE 1 DIABETES AFTER 12 MONTHS OF TREATMENT

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Background and Aims: The Medtronic MiniMed™780G is a closed-loop hybrid system, that automatically adjusts insulin delivery and corrects glucose levels to a modifiable target. The immediate benefit in metabolic control of patients using the system is known. The aim of the study is to analyze glycaemic control and glycaemic variability data in pediatric patients with T1D after change from their usual treatment to the Medtronic™780G system and confirm that the early improvement is maintained in the first year of treatment.

Table 1. Data on glucose control and glycaemic variability before starting treatment with closed-loop system MiniMed™780G and after 3, 6 and 12 months (n=32).

	Baseline	3 months MiniMed™780G	p*	6 months MiniMed™780G	p*	12 months MiniMed™780G	p*
HbA1c (%)	7,1	6,7	**<0.001**	6,7	**<0.001**	6,7	**<0.001**
TIR 70-180 mg/dl (%)	62,5	77,4	**<0.001**	77,6	**<0.001**	79,1	**<0.001**
Time <70 mg/dl (%)	2,8	1,6	**<0.05**	1,4	**<0.005**	1,4	**<0.005**
Time <54 mg/dl (%)	0,7	0,4	*0.094*	0.3	**<0.05**	0.3	**<0.05**
Time >180 mg/dl (%)	25,7	17,1	**<0.001**	17,1	**<0.001**	16,5	**<0.001**
Time >250 mg/dl (%)	7,7	3,4	**<0.001**	3,4	**<0.001**	2,5	**<0.001**
Sensor use (%)	94,4	94,3	*0.951*	93,7	*0.634*	92,4	*0.206*
Mean glucose (mg/dl)	159,8	144	**<0.001**	144,8	**<0.001**	142,8	**<0.001**
SD of glucose (mg/dl)	55,9	46,9	**<0.001**	47,5	**<0.001**	45,7	**<0.001**
CV (%)	45,1	32,4	*0.197*	32,6	*0.208*	32	*0.191*

*Compared to baseline.

Methods: This is a prospective study in pediatric patients who start treatment with the Minimed™780G system, from different previous treatments. Data on glucose control and glycemic variability were studied at the beginning and 3, 6 and 12 months after treatment.

Results: Thirty-two patients (17 women) with a mean age of 13,8 ± 3,4 years were studied. Four patients had previous treatment with MiniMed™640G system (predictive low glucose suspend). The rest of the patients were previously treated with multiple daily injections, associated continuous glucose monitoring with DEXCOMG6™ or flash glucose monitoring with FREESTYLE2. After 3 months of treatment a statistically significant reduction in HbA1c was observed, as well as an increase in the time in the target range 70-180 mg/dl and a decrease in the time in hyperglycemia. This improvement was maintained after 6 and 12 months of treatment (table 1). A significant improvement in the time in hypoglycemia appeared with continued use of the system (6 and 12 months).

Conclusions: The MiniMed™780G system improves metabolic control in pediatric patients and this improvement is maintained after 12 months of treatment.

OP024 / #337

Topic: ***AS03 Closed-loop System and Algorithm***

PROGRESSION OF DIABETIC RETINOPATHY (DR) AFTER INITIATION OF AUTOMATED INSULIN DELIVERY (AID) SYSTEM IN ADULTS WITH TYPE 1 DIABETES (T1D)

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Background and Aims: Rapid improvement in A1c may worsen diabetic retinopathy (DR). However, the progression of DR and factors affecting it after initiation of AID systems, which are known to reduce A1c in T1D are unknown.

Methods: In this retrospective, longitudinal study, demographics, A1c, and eye exams were retrieved from electronic medical records of T1D adults who initiated AID between January 2020 and January 2022. DR worsening was defined as an increase in ETDRS scores and/or qualitative eye examination from the eye exam prior to AID initiation to the first eye exam following AID use.

Results: Of 152 T1D adults, 42 (28%) had DR worsening over mean 1.6 years. Those with DR worsening had higher baseline A1c, LDL, and eGFR (**Table 1**). In mixed models, there was no significant change in ETDRS score in either eye by time interval (p = 0.3 for OS, p = 0.4 for OD) or by A1c over time (p = 0.5 for OS, p = 0.4 for OD). In a logistic regression adjusted for age, duration, and sex, higher baseline A1c was associated with 2-fold

Table 1: Differences in characteristics between adults with type 1 diabetes who had worsening of diabetic retinopathy vs no worsening after initiation of an AID system.

	Overall (n=152)**	No worsening of DR (N=107)	DR worsening (n=42)	p-value*
Mean age (years)	42 ± 14	43 ± 14	41 ± 14	0.4787
Diabetes Duration (years)	26 ± 13	26 ± 14	26 ± 14	0.7251
Sex, F(n[%])	86 (57)	64 (60)	22 (52)	0.4099
Mean A1c (%)	7.6 ± 1.3			
Baseline		7.4 ± 1.1	8.0 ± 1.5	0.0213
After Tandem start		7.0 ± 0.9	7.7 ± 1.5	0.0030
Change in A1c		-0.47 ± 0.9	-0.38 ± 1.2	0.6286
Insurance, private (n[%])	132 (87)	96(90)	33 (79)	0.0836
Race/ethnicity NHW(n[%])	129 (85)	92 (86)	35 (83)	0.6849
ACR (median, IQR)	5.8 (3, 10.1)	6 (3, 11)	5 (3, 10)	0.2999
Baseline ETDRS score				
OD	27 ± 16	26 ± 16	27 ± 15	0.9137
OS	27 ± 16	27 ± 15	27 ± 17	0.8945
LDL (mg/dL)	87 ± 26	82 ± 24	95 ± 28	0.0079
BMI (kg/m²)	28.0 ± 5.6	27.6 ± 5.5	28.9 ± 6.0	0.2009
eGFR (ml/mi/1.73m²)	97 ± 18	95 ± 19	102 ± 16	0.0481
Smoking n(%)	6 (4.0)	3 (2.8)	3 (7.1)	0.3510
Hypertension, yes (n[%])	10 (6.6)	6 (6)	4 (10)	0.4687

*p-value between DR worsening and no worsening of DR groups.
** 3 subjects couldn't be classified because of missing retinopathy data in one eye at one of the time points.
Abbreviations: F; female, OD; right eye, OS: left eye, NHW; non-Hispanic Whites, ETDRS; early treatment of diabetic retinopathy study score, LDL; low density lipoprotein, BMI; body mass index (kg/m²)

increased risk for DR worsening (OR = 2.1 [1.34-3.04], p = 0.0008). Patients with LDL >100 and A1c >8% (n = 16) had 3-fold increased risk for DR worsening (OR = 3.33 [1.12-9.91], p = 0.03).

Conclusions: Higher baseline A1c and LDL were associated with worsening of retinopathy after initiation of the AID system in adults with T1D. Further research is needed to evaluate the needed frequency of eye examination in high-risk patients.

OP025 / #165

Topic: ***AS03 Closed-loop System and Algorithm***

FIRST REPORT OF AT-HOME USE OF A PREGNANCY-SPECIFIC HYBRID CLOSED-LOOP SYSTEM FOR PREGNANCIES COMPLICATED BY TYPE 1 DIABETES: A MULTICENTER US CLINICAL STUDY

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Background and Aims: To evaluate the feasibility of outpatient extended duration use of a closed-loop glucose control system during pregnancies complicated by type 1 diabetes (T1D).

Methods: Ten pregnant people with T1D using insulin pump therapy were enrolled in the study at three US sites (NCT04492566). After a run-in week on their own therapy and supervised 48-hour training on the interoperable artificial pancreas system (iAPS) running a Zone-Model Predictive Control (zone-MPC) algorithm, participants continued using iAPS at home for the remainder of their pregnancy. The system was customized for

Table 1. Mean±SD continuous glucose monitoring (CGM) metrics for the 1-week run-in period, compared to the iAPS use during pregnancy for 10 pregnant people with type 1 diabetes.

Sensor Glucose Metrics (mg/dL)	1 Week Run-in Period (N=10)	14±4 Weeks iAPS Period (N=10)	p-value (paired t-test)
Percent time 63-140	64.5 ± 16.3	78.6 ± 9.2	**0.002***
Percent time <54	2.1 ± 2.9	0.4 ± 0.3	0.072
Percent time <63	5.8 ± 6.4	1.7 ± 0.9	0.056*
Percent time >140	29.8 ± 19.5	19.7 ± 9.5	**0.033***
Percent time >180	12.4 ± 12.4	5.6 ± 4.9	**0.030***
Percent time >250	1.4 ± 2.2	0.4 ± 0.6	0.100
Mean CGM Glucose	123.1 ± 24.1	115.1 ± 10.6	0.139
SD CGM Glucose	40.9 ± 11.8	33.5 ± 6.3	**0.011***
CV CGM Glucose (%)	33.5 ± 8.2	28.9 ± 3.1	0.088

* p<0.05

stricter glycemic targets for pregnancy using glycemic target zones of 80-110 mg/dL during the day and 80-100 mg/dL overnight, with assertive insulin delivery in the postprandial period. The primary outcome was sensor glucose time in range (TIR) for pregnancy 63-140 mg/dL as per international consensus guidelines. Meals and physical activity were unrestricted.

Results: All participants completed the trial. Mean duration of iAPS use was 13.9 ± 3.9 weeks. Participants had a mean age of 32.6 ± 4.3 years, gestational age of 22.0 ± 3.4 weeks, weight of 75.7 ± 17.2 kg, and HbA1c of 5.8 ± 0.6% at screening. Mean sensor TIR 63-140 mg/dL was 78.6 ± 9.2% on iAPS, compared to 64.5 ± 16.3% for the week prior in open loop at home ($p = 0.002$). Nine out of 10 participants had >70% time in range during their time of system use. No system related safety concerns were observed.

Conclusions: A pregnancy-specific zone-MPC system demonstrated glycemic effectiveness for home-use during pregnancies with T1D.

OP026 / #771

Topic: ***AS03 Closed-loop System and Algorithm***

PERFORMANCE OF A DUAL-HORMONE CLOSED-LOOP SYSTEM VERSUS INSULIN-ONLY CLOSED-LOOP IN ADOLESCENTS WITH TYPE 1 DIABETES. A SINGLE-BLIND, RANDOMIZED, CONTROLLED, CROS-OVER TRIAL

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Background and Aims: The most advanced commercially available technology for type 1 diabetes (T1D) is the insulin-only artificial pancreas (AP). We created a dual-hormone (insulin and glucagon) AP for individuals with T1D. We aimed to assess the efficacy of our dual-hormone (DH) AP compared to our single-hormone (SH) AP in adolescents with T1D.

Methods: In this 26-h, two-period, randomized, crossover, inpatient study involving 11 adolescents with T1D (nine males [82%], mean ± SD age 14.8 ± 1.4 years, diabetes duration 5.7 ± 2.3 years) we used two configurations of our DiaCon AP: DH and SH. Each visit included an overnight stay, meals/snacks, and a bout of exercise. We hypothesized that DH would perform superiorly to SH. The primary endpoint was percentage time spent with sensor glucose values below range (TBR <3.9 mmol/L) during AP control.

Results: Overall, DH and SH performed similarly for the following outcomes (median [IQR]): TBR 1.6 [0.0-2.4] vs. 1.28 [0.16-3.19]%, p = 0.999; time in range (TIR; 3.9-10.0 mmol/L) 68.4 [48.7-76.8] vs. 75.7 [69.8-87.1]%, p = 0.079; and time above range (TAR; >10.0 mmol/L) 28.1 [18.1-49.8] vs. 23.3 [12.3-27.2]%, p = 0.101. Insulin administration was similar between the two arms (p = 0.954). Glucagon administration varied between participants (median [IQR]; 549 [229, 1034]μg/26-h). Compared to DH, SH performed superiorly overnight (TIR 73.0 [53.9, 87.4] vs. 96.5 [84.3, 100]%, p = 0.019 and TAR 27.0 [12.6, 42.6] vs. 0 [0.0, 10.0]%, p = 0.018) and around exercise (TIR 64.5 [50.0, 91.9] vs. 83.9 [80.6, 100.0]%, p = 0.018).

Conclusions: In this study, DH did not perform superiorly to SH. Limited knowledge regarding individual glucagon sensitivity may have influenced the performance of the DiaCon DH-configuration.

OP027 / #720

Topic: ***AS03 Closed-loop System and Algorithm***

LOW-DOSE EMPAGLIFLOZIN AS ADJUNCT TO HYBRID CLOSED-LOOP INSULIN THERAPY IN SUB-OPTIMALLY CONTROLLED ADULTS WITH TYPE 1 DIABETES: A RANDOMIZED CROSSOVER CONTROLLED TRIAL

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Background and Aims: SGLT inhibitors have both benefits and risks as adjunct to type 1 diabetes therapy. The aim was **t**o assess whether low doses of empagliflozin as adjunct to hybrid closed-loop therapy improve glycemia compared to placebo in adults with type 1 diabetes who are not able to achieve targets with the system alone.

Methods: A double-blind, crossover, randomized controlled trial was performed in sub-optimally controlled (HbA1c 7.0-10.5%) adults who were not able to achieve a target time-in-range (3.9-10.0 mmol/L) ≥70% after 14 days of hybrid closed-loop therapy. Three 14-day interventions were performed with placebo, empagliflozin 2.5 mg, or empagliflozin 5 mg, as adjunct to the McGill Artificial Pancreas. The primary outcome was time-in-range. Analysis was by intention to treat and a p-value of less than 0.05 was regarded as significant. [NCT04450563].

Results: 24 participants completed the study (50% male, age 33 ± 14 yrs, HbA1c 8.1 ± 0.5%). The time-in-range was 59.0 ± 9.0% for placebo, 71.6 ± 9.7% for empagliflozin 2.5 mg, and 70.2 ± 8.0% for empagliflozin 5 mg (p < 0.0001 between empagliflozin 2.5 mg and placebo, and empagliflozin 5 mg and placebo). Mean daily capillary ketone levels were not different between arms. There were no serious adverse events, diabetic ketoacidosis, or severe hypoglycemia in any intervention.

Conclusions: Empagliflozin 2.5 and 5 mg increased time-in-range on hybrid closed-loop therapy by 11–13 percentage points compared to placebo, in those who otherwise were unable to attain glycemic targets. Future studies are required to assess long-term efficacy and safety.

OP028 / #423

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCEMIC OUTCOMES OF ADVANCED HYBRID CLOSED LOOP SYSTEM IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES, PREVIOUSLY TREATED WITH MULTIPLE DAILY INJECTIONS: ONE-YEAR EXPERIENCE

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Background and Aims: The objective of this study was to evaluate the glycemic outcomes of one-year Advanced Hybrid Closed Loop (AHCL) Minimed 780G system in children and adolescents with Type 1 Diabetes (T1D) previously treated with Multiple Daily Injections (MDI).

Methods: The prospective open label single-arm, single-center, clinical investigation was conducted at Sidra Medicine in Qatar study and enrolled 34 individuals aged 7-18 years with T1D >1 year, on MDI with self-monitoring of blood glucose or continuous glucose monitoring, with no prior pump experience, and baseline HbA1c <12.5% (<113 mmol/mol). Patients were followed for one year and HbA1c was obtained, and pump data was collected every 3-months during the study.

Results: All 34 participants (age 12.5 ± 3.7, female 53%), who initiated AHCL completed one-year of automated insulin delivery. The participants used the sensor 94.3 ± 5.6% of the time with Auto Mode usage 91.2 ± 7.1% during 12 months of AHCL system use. HbA1c decreased from 8.6 ± 1.7% (70 ± 18.6 mmol/mol) at baseline, to 6.5 ± 0.7% (48 ± 7.7 mmol/mol) at 3 months ($p = 0.001$) and remained stable to 7.0 ± 0.7 (53 ± 7.7 mmol/mol) at 12 months ($p = 0.002$). TIR (70-180mg/dL) increased from 42.1 ± 18.7% at baseline to 78.8 ± 6.1% during the first 3-months and remained above 75% during the 12 months of HCL use. Remote follow-up visits were noted in 41% of the participants between 3 and 12 months of HCL initiation.

Conclusions: The glycemic outcomes can be improved using AHCL system in individuals previously treated with MDI and maintained over the one year following automated insulin delivery. Remote follow ups should be offered to individuals on AHLC system.

OP029 / #315

Topic: ***AS03 Closed-loop System and Algorithm***

AN AUTOMATED INSULIN DELIVERY (AID) SYSTEM WITH AUTOMATIC MEAL BOLUS BASED ON A HAND-GESTURING ALGORITHM

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Background and Aims: To manage postprandial hyperglycemia, premeal bolusing via carb-counting is the current standard of care for individuals with type 1 diabetes (T1D). However, counting carbs and announcing them prior to eating introduces a significant burden. An AID system with an auto meal-bolus feature that eliminates manual mealtime bolusing was studied in a feasibility trial of adults with T1D.

Methods: The system included the MiniMed™ 780G pump and a smartphone-paired smartwatch with the KLUE application (app) that detects eating and drinking gestures. A smartphone algorithm converted gestures to carb amounts that were transmitted to the pump for automatic bolusing. For 6 days, subjects (N = 17, aged 18-75 years) used the system with the KLUE app disabled while traditional carb-counting and -entry were completed (Baseline). Thereafter, the KLUE app was enabled for 5 days and carb-counting/carb-entry were prohibited (Study).

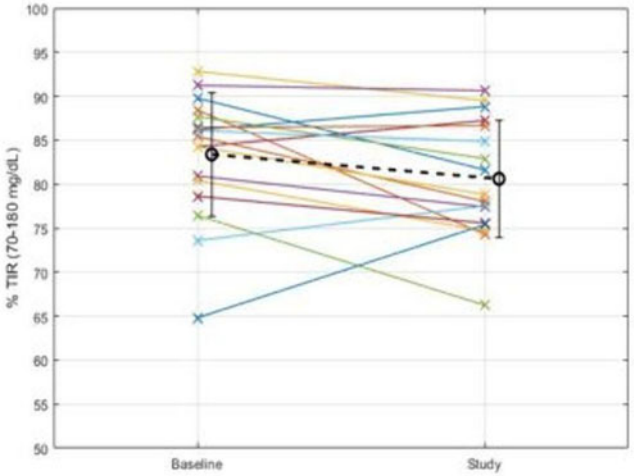

Figure 1. The %TIR for each subject (solid lines) is shown for the KLUE app-disabled baseline and KLUE app-enabled study phase. The averaged %TIR (dashed line) is also shown. %TIR 70-180 mg/dL (3.9-10 mmol/L).

	Change (Study - Baseline)	p-value
Overall glycemic outcome		
Mean SG, mg/dL	5 (-1.6 to 11.7)	0.1294
Mean SG, mmol/L	0.28 (0.09 to 0.65)	
Time at sensor glucose ranges, %		
70-180 mg/dL (3.9-10.0 mmol/L)	-2.8 (-5.8 to 0.3)	0.07
<70 mg/dL (3.9 mmol/L)	-0.1 (-1.4 to 1.2)	0.9144
<54 mg/dL (3.0 mmol/L)	0 (-0.2 to 0.2)	0.765
>180 mg/dL (10.0 mmol/L)	2.8 (-0.7 to 6.3)	0.1046
>250 mg/dL (13.9 mmol/L)	0.8 (-1.2 to 2.7)	0.4299
Postprandial (4h) glycemic outcome for the eight test meals - combined		
Mean SG, mg/dL	7.7 (0.4 to 15.1)	0.06
Mean SG, mmol/L	0.43 (0.02 to 0.84)	
Time at sensor glucose ranges, %		
70-180 mg/dL (3.9-10.0 mmol/L)	-4.5 (-9.5 to 0.6)	0.1073
<70 mg/dL (3.9 mmol/L)	-0.5 (-2.7 to 1.7)	0.7096
<54 mg/dL (3.0 mmol/L)	-0.1 (-0.4 to 0.2)	0.5854
>180 mg/dL (10.0 mmol/L)	4.9 (-0.06 to 9.9)	0.0736
>250 mg/dL (13.9 mmol/L)	1.3 (-0.5 to 3.0)	0.1806

Table 1. The change in each outcome between the study and baseline phase is shown as average (95% confidence interval).

Subjects were given the same 8 test meals (6 solid and 2 liquid) of varying caloric and carb size during both phases. Otherwise, there were no other meal restrictions.

Results: The figure shows absolute percentage of time in range (%TIR, 70-180 mg/dL) during the baseline and study phase for all 17 subjects, along with the population average. There was no significant difference in any overall or 4-hour postprandial glycemic outcome between the phases (Table 1).

Conclusions: Data suggest that the novel AID system maintains glycemic control, including %TIR, similar to that observed with manual meal bolusing. By eliminating the burden of carb-counting, the new system may improve quality of life in persons with T1D.

OP030 / #64

Topic: ***AS03 Closed-loop System and Algorithm***

MINIMISING MEALTIME MANAGEMENT - THE OPEN SOURCE AID COMMUNITY'S ATTEMPTS TO REDUCE THE ONUS TO BOLUS

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Background and Aims: This session provides an overview of the ways that the Open Source Community has adapted the oref1 codebase, created by Dana Lewis and Scott Leibrand, to try and eliminate the need to manually manage mealtime insulin and remove the onus to bolus. It will look at the various approaches taken to identify meals and manage glucose variation as a result, and the various mechanisms available to users to tune and adapt the approaches to attempt to get the best outcomes.

Methods: A review of the different codebases developed on top of oref1 to identify how developers and users have adapted the code to provide ''hands-free'' meal time management, and data gathered from users via survey to determine the effectiveness of the adaptations.

Results: Multiple different adapatations are being used by different user groups to successfully aid meal-time management. There are clear benefits and drawbacks to the different approaches taken but in general, users are finding that carbohydrate measurement and entry are not required, and in many cases, remembering to mealtime bolus may also not be required.

Conclusions: Within ''Expert systems'' such as oref1, it is possible to adapt the codebase to allow signals to be identified that negate the need to calculate mealtime carbohydrate amounts and boluses, and allow a user to manage mealtimes with far less mealtime intervention than has previously been seen with hybrid closed loop systems.

OP031 / #846

Topic: ***AS03 Closed-loop System and Algorithm***

PEDIATRIC TYPE 1 DIABETES MELLITUS: A COMPARISON BETWEEN MULTI-INJECTION THERAPY AND ADVANCED HYBRID CLOSED LOOP PUMP IN THE FIRST YEAR AFTER THE ONSET

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Background and Aims: Advanced Hybrid Closed Loop (AHCL) systems represent the most advanced technology for continuous insulin delivery. Although they have demonstrated positive effects on patients' glycemic values, their use is still considered as alternative to insulin injections (MDI) at the time of T1DM onset.

Methods: All patients with new onset type 1 diabetes in 2021 were recruited. Patients and families were advised to start with AHCL (Group B) while, in case of refusal, started with MDI and CGM (Group A). For both groups, glycemic targets (at 3, 6 and 12 months after diagnosis) and quality of life (QoL) were assessed by PedsQL questionnaire.

Results: Clinical characheristics are shown in Table.

GMI was lower in Group B from 6 months (6.8 ± 0.7 vs. 7.2 ± 0.8, $p = 0.020$) while Time in Range (TIR) was higher (73 ± 18 vs. 61 ± 19, $p = 0.004$). Same differences were found for TAR-1 and TAR-2 whereas no differences were observed for TBR-1 and TBR-2 for the whole study period. Regarding QoL, AHCL were found to improve patients' lives compared to MDI for all dimensions (mean difference +16, mean $p < 0.001$). Group B parents also scored higher in all domains except for communication (mean difference +14, mean $p < 0.001$).

Conclusions: AHCL systems used in children and adolescent from T1DM onset showed better glucose outcomes as well as quality of life in patients and parents from 6 months after utilization.

Variable at onset	Group A (MDI) n = 39	Group B (AHCL) n = 32	p-value
Age (years)	11.33±2.6	6.7±3.7	<0.01
Sex (females,%)	20(51%)	13(41%)	ns
BMI	17.8±3.0	16.6±3.4	ns
HbA1c (mmol/mol)	103±25	96±23	ns

OP032 / #605

Topic: ***AS04 New Insulins***

CONTINUOUS GLUCOSE MONITORING IN INSULIN-EXPERIENCED INDIVIDUALS WITH TYPE 2 DIABETES SWITCHED TO ONCE-WEEKLY INSULIN ICODEC VERSUS ONCE-DAILY COMPARATORS IN ONWARDS 2 AND 4: POST-HOC ANALYSIS

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Background and Aims: Insulin icodec (icodec) is a once-weekly basal insulin under clinical development. Here, we investigated time in, above, and below range (TIR, TAR, TBR) using continuous glucose monitoring (CGM) data during the switch period (weeks 0–4) and steady state (weeks 22–26) from two phase 3, randomized, treat-to-target trials in type 2 diabetes (T2D).

Table. CGM outcomes from ONWARDS 2 and ONWARDS 4 trials.

CGM outcomes	ONWARDS 2 (N=526)			ONWARDS 4 (N=582)		
	Icodec (n=263)	Degludec (n=263)	Treatment difference or ratio (95% CI), P value	Icodec (n=291)	Glargine U100 (n=291)	Treatment difference or ratio (95% CI), P value
Weeks 0–4 (During switch)						
$TIR_{70-180\ mg/dL}$, %	51.2	53.4	ETD=−2.57 (−6.24; 1.09)[a,b] P=0.168	56.6	56.1	ETD=0.22 (−3.16; 3.60)[a,b] P=0.896
$TAR_{>180\ mg/dL}$, %	48.1	45.9	ETD=2.56 (−1.19; 6.32)[a,b] P=0.181	41.6	42.2	ETD=−0.41 (−3.91; 3.10)[a,b] P=0.820
$TBR_{<70\ mg/dL}$, %	0.8	0.7	ERR=1.0 (0.68; 1.47)[b,d] P=0.988	1.8	1.7	ERR=1.09 (0.83; 1.43)[b,d] P=0.544
$TBR_{<54\ mg/dL}$, %	0.2	0.1	ERR=1.32 (0.79; 2.20)[b,d] P=0.288	0.5	0.5	ERR=1.17 (0.82; 1.67)[b,d] P=0.378
Weeks 22–26 (At steady state)						
$TIR_{70-180\ mg/dL}$, %	63.1	59.5	ETD=2.41 (−0.84; 5.65)[a,c] P=0.146	66.9	66.4	ETD=0.29 (−2.52; 3.09)[a,c] P=0.841
$TAR_{>180\ mg/dL}$, %	35.5	39.7	ETD=−2.93 (−6.25; 0.39)[a,c] P=0.083	30.4	31.3	ETD=−0.60 (−3.47; 2.28)[a,c] P=0.683
$TBR_{<70\ mg/dL}$, %	1.4	0.8	ERR=1.59 (1.21; 2.08)[b,d] P=0.001	2.7	2.1	ERR=1.17 (0.95; 1.45)[b,d] P=0.137
$TBR_{<54\ mg/dL}$, %	0.3	0.2	ERR=1.37 (0.92; 2.04)[b,d] P=0.118	0.7	0.6	ERR=1.20 (0.91; 1.58)[b,d] P=0.205
Participants achieving >70% TIR + <25% TAR + <4% $TBR_{<70\ mg/dL}$, n (%)	67 (28.2)	53 (22.2)	EOR=1.23 (0.80; 1.88)[c,d] P=0.348	71 (29.1)	75(31.7)	EOR=0.91 (0.62; 1.34)[c,d] P=0.643

[a]Value is the estimated treatment difference between the groups (icodec – degludec [ONWARDS 2]; icodec – glargine U100 [ONWARDS 4]). [b]Statistical analysis based on observed data. [c]Statistical analysis based on multiple imputed data. [d]Value is the estimated treatment ratio (icodec/degludec [ONWARDS 2]; icodec/glargine U100 [ONWARDS 4]), including EOR (estimated odds ratio) and ERR (estimated rate ratio). Statistical models: ANOVA, logistic regression and negative binomial regression are applied according to different response variables and ETD, EOR and ERR obtained accordingly. All models are adjusted for geographic region and use of personal CGM or isCGM device.
ANOVA, analysis of variance; CI, confidence interval; CGM, continuous glucose monitoring; degludec, insulin degludec; EOR, estimated odds ratio; ERR, estimated rate ratio; ETD, estimated treatment difference; glargine U100, insulin glargine U100; icodec, insulin icodec; isCGM, intermittent scanning CGM; TAR, time above range; TBR, time below range; TIR, time in range.

Methods: Insulin-experienced individuals with T2D received once-weekly icodec or once-daily degludec (ONWARDS 2), or icodec or once-daily glargine U100 with mealtime insulin aspart (ONWARDS 4). When switching, a one-time additional 50% dose of icodec was administered at first dose; basal insulins were titrated weekly (target: 80–130 mg/dL). TIR (70–180 mg/dL), TAR (>180 mg/dL), and TBR (<70 and <54 mg/dL) were calculated using double-blinded Dexcom G6® CGM data.

Results: Immediately after switch, TIR, TAR and TBR were not significantly different between once-weekly icodec and comparators (Table). At steady state, there was no significant difference between arms in TIR or TAR. Except for ONWARDS 2, where $TBR_{<70mg/dL}$ was significant longer with icodec (ERR = 1.59; 95% CI 1.21; 2.08; P = 0.001), all other TBR comparisons in both trials were not statistically different. From switch to steady state, overall observed mean TIR increased, TAR decreased and TBR remained below internationally recommended targets in all groups.

Conclusions: In insulin-experienced participants with T2D, TIR and TAR were not significantly different versus once-daily degludec or glargine U100. TBR remained within the international targets in all groups.

OP033 / #100

Topic: ***AS04 New Insulins***

TERTIARY CGM ENDPOINTS COMPARING SECOND-GENERATION BASAL INSULIN ANALOGS GLARGINE 300 U/ML AND DEGLUDEC 100 U/ML IN PEOPLE WITH T1D: INRANGE RANDOMIZED CONTROLLED TRIAL

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Background and Aims: The InRange study demonstrated non-inferiority of insulin glargine 300 U/mL (Gla-300) to insulin degludec 100 U/mL (IDeg-100) in people with T1D using continuous glucose monitoring (CGM) metrics. In this subanalysis, the results for the tertiary CGM endpoints are presented.

Methods: InRange (NCT04075513) was a multicenter, randomized, active-controlled, parallel-group, 12-week, open-label trial comparing Gla-300 vs IDeg-100 in adults with T1D using 20-day CGM profiles (≥10 days evaluable). Here we present descriptive, exploratory data for CGM metrics including mean glucose, Glucose Management Indicator (GMI), and time spent above, within and below glucose ranges, at Week 12.

Results: Overall, 343 participants (Gla-300, n = 172; IDeg, n = 171) were randomized with mean (±SD) age 42.8 ± 13.3 years. HbA_{1c} (%) at Week 12 was 7.5 ± 0.8 for Gla-300 and 7.4 ± 0.8 for IDeg-100. Mean number of days of evaluable CGM data at Week 12 was 16 for both treatment groups. Mean (±SD) percent TIR 70–180 mg/dL for Gla-300 and IDeg-100 was 51.9 ± 13.8 and 55.4 ± 13.7, respectively. Percent TAR >180 mg/dL and TBR (<70 and <54 mg/dL; anytime and nocturnal) were comparable between the two groups. At Week 12, the mean glucose and GMI were comparable between Gla-300 and IDeg-100 groups (**Table**). CGM-derived hypoglycemia rates were 3–5-fold (anytime) and 5–6-fold (nocturnal) higher than SMPG-derived rates during the CGM data collection period (Weeks 10–12).

Table. CGM Endpoints at Week 12 with Gla-300 and IDeg-100

	Anytime (24 h)		Nocturnal (00:00–05:59 h)	
Metric, mean (SD)	**Gla-300**	**IDeg-100**	**Gla-300**	**IDeg-100**
Glucose total CV (%)	40.4 (6.4)	40.8 (6.6)		
% TAR >250 mg/dL	16.8 (12.6)	14.5 (11.0)		
% TAR >180 mg/dL	42.2 (15.5)	38.4 (15.4)		
% TIR 70–180 mg/dL*	51.9 (13.8)	55.4 (13.7)	51.5 (18.1)	50.4 (17.7)
% TITR 70–140 mg/dL	32.2 (11.0)	35.2 (11.9)	31.9 (15.4)	30.7 (15.3)
% TBR <70 mg/dL	5.9 (5.4)	6.2 (5.9)	6.7 (7.7)	6.1 (7.1)
% TBR <54 mg/dL	2.0 (2.8)	2.1 (3.2)	2.6 (4.2)	2.3 (4.1)
Hypoglycemia events (events/patient-week [number of events])				
CGM-derived hypoglycemia (<70 mg/dL)†	7.34 (2674)	8.19 (2840)	1.74 (633)	1.61 (558)
CGM-derived hypoglycemia (<54 mg/dL)‡	2.63 (956)	2.86 (992)	0.77 (282)	0.60 (208)
SMPG-derived hypoglycemia (<70 mg/dL)†	2.53 (936)	2.47 (874)	0.31 (116)	0.29 (101)
SMPG-derived hypoglycemia (<54 mg/dL)‡	0.76 (280)	0.58 (205)	0.14 (51)	0.11 (40)
Mean glucose (mg/dL)	174.9 (30.6)	167.8 (28.8)		
GMI (%)	7.5 (0.7)	7.3 (0.7)		

*Primary endpoint analysis was performed on the least squares (LS) mean % TIR. LS mean [95% CI] % TIR was 52.74% [51.06, 54.42] for Gla-300 and 55.09% [53.34, 56.84] for IDeg-100; LS mean difference (non-inferiority, 10% margin) 3.16% [0.88, 5.44] (p=0.0067). †CGM: Number of periods with at least 15 minutes with sensor glucose <70 mg/dL. ‡CGM: Number of periods with at least 15 minutes with sensor glucose <54 mg/dL. Post hoc analysis of CGM- and SMPG-derived hypoglycemia rates during the on-treatment CGM data collection period (Week 10–12).
CGM, continuous glucose monitoring; CI, confidence interval; CV, coefficient of variation; Gla-300, insulin glargine 300 U/mL; GMI, glucose management indicator; IDeg-100, insulin degludec 100 U/mL; LS, least squares; SMPG, self-measured plasma glucose; SD, standard deviation; TAR, time above range; TBR, time below range; TIR; time in range; TITR, time in tight range

Conclusions: The InRange study shows that after 12 weeks of treatment with Gla-300 or IDeg-100, comparable CGM-derived outcomes are observed in people with T1D.

OP034 / #587

Topic: ***AS05 Artificial Pancreas***

MATURATION AND EVALUATION OF 3D PRINTED BIONIC PANCREAS WITH A DEDICATED BIOREACTOR

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Background and Aims: The technology of 3D printing of bionic organs gives an opportunity to solve the problems of classical transplantology. After printing, the bionic pancreas requires an optimal environment conditioning the process of its maturation, which consists in the colonization of the produced vessels with endothelial cells and the tubularization of the endothelium within the microcirculation. After the maturation process is completed, it is necessary to evaluate the functionality and safety of the organ.

Methods: 10 procedures of maturation and bionic pancreas evaluation were performed using a novel, dedicated bioreactor. 5 pancreas contained human beta cells and 5 pancreas contained porcian islets. The mean pancreatic maturation time was 23 hours (2-72 hours). The effectiveness of adhesion of endothelial cells to the vascular wall and tubularization of endothelial cells was assessed by immunohistochemistry. The GSIS test was performed by automatically. The integrity of the vascular system was assessed by maintaining a pressure of 190 mmHg for 5 minutes.

Results: The adhesion of endothelial cells to the bioink was observed after 1 hour. Tubularization of the endothelium was observed after 48 hours. Insulin secretion upon stimulation with glucose was observed without delay to the control (beta cells or islets) and the insulin concentration during the observation showed a constant ratio compared to the control, but without a clear peak at high glucose concentration.

Conclusions: The use of a dedicated bioreactor enables safety during the bionic maturation process of the organ, while allowing for an effective assessment of the organ's functionality and the tightness of the vascular system.

OP035 / #450

Topic: ***AS05 Artificial Pancreas***

RELATIONSHIP BETWEEN BOLUSING BEHAVIOR AND GLUCOSE CONTROL USING A COMMERCIAL HYBRID AUTOMATED INSULIN DELIVERY SYSTEM

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Background and Aims: Hybrid automated insulin delivery (AID) systems are not expected to respond optimally to prandial excursion without manual dosing. Thus, we can hypothesize that the achieved glycemic control will rely on user adherence to meal boluses. We aim to quantify this relationship using data collected during real-life use of a commercial hybrid AID system.

Methods: Linear regression models of daily time between 70-180 mg/dL (TIR) and coefficient of variation (CV) were used to account for patients' average number of daily manual insulin doses (aMD), daily deviations from aMD ($\Delta MD = MD\text{-}aMD$), and their interaction term ($X = aMD \cdot \Delta MD$); using 1,577,988 days of continuous glucose monitoring (CGM) and insulin data collected from 18,690 Control-IQ users with type 1 diabetes: F/M: 55%/45%, age, weight, and total daily insulin ranges were [1-92y], [24.9-140.0kg], and [6.3-269.8U], respectively.

Results: For the TIR model, the intercept term (TIR at 0 manual bolus) was 61.91%, and aMD, ΔMD, and X coefficients were 1.57%, -3.83%, and 0.21%, respectively. For the CV model, the intercept term was 31.83%, and aMD, ΔMD, and X coefficients were -0.40%, 0.64%, and -0.023%, respectively. All p-levels <0.0001.

Conclusions: aMD coefficient signs confirm that glycemic control improves with increased daily bolus *average* numbers (+1.57% of TIR and -0.40% of CV per additional bolus); but positive deviation from this average is associated with degraded control (-3.83% of TIR and +0.64% of CV), potentially related to difficulties regulating glucose on unusual days. The interaction terms show that this latest effect is primarily observed in individuals with low daily bolus averages.

OP036 / #905

Topic: ***AS05 Artificial Pancreas***

MANAGEMENT OF PROLONGED AEROBIC EXERCISE IN PATIENTS WITH TYPE 1 DIABETES ON ADVANCED TECHNOLOGIES (MARTA)

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Background and Aims: Managing physical activity in individuals with type 1 diabetes (T1DM) is very complex due to the variability of glycemic response to exercise. We aimed to identify an optimal strategy for the management of prolonged aerobic exercise in sedentary/moderately active T1DM patients using hybrid artificial pancreas (HAP).

Methods: According to a randomized, cross-over study design, individuals with T1DM on HAP, both genders, age >18 years, no contraindications to prolonged aerobic physical activity, underwent on different occasions one-month apart to three walk mountain sessions with similar characteristics (distance, approximately 10 km; duration, 4 hours; difference in altitude, 200-300 m). Three different therapeutic/nutritional approaches were compared: 1) exercise glycemic target (Target); 2) carbohydrate integration, 15 g complex carbohydrates every 30 minutes during the session (Snack); 3) exercise glycemic target and carbohydrate integration (Target+Snack). Blood glucose control during the exercise sessions was assessed by CGM.

Results: Preliminary analysis ($n = 7$) shows that the Target intervention determined a significantly higher time in range (TIR 70-180 mg/dl) ($95.3 \pm 7.5\%$) compared to Target+Snack ($70.6 \pm 19.4\%$) and Snack ($89.1 \pm 10.8\%$) ($p = 0.020$, two-way repeated measures analysis), and a significantly reduced time above range (TAR 180-250 mg/dl) ($4.4 \pm 7.6\%$) compared to Target+Snack ($19 \pm 14.5\%$) and Snack ($9.1 \pm 11.3\%$)($p = 0.007$).

Conclusions: In patients with T1DM on HAP, the modification of the glycemic target resulted in a better glycemic control during prolonged aerobic exercise than only supplementing complex carbohydrates or combining both strategies.

OP037 / #674

Topic: ***AS05 Artificial Pancreas***

A RANDOMIZED CROSSOVER TRIAL TO COMPARE AUTOMATED INSULIN DELIVERY (THE ARTIFICIAL PANCREAS) WITH CARBOHYDRATE COUNTING OR SIMPLIFIED QUALITATIVE MEAL-SIZE ESTIMATION IN TYPE 1 DIABETES

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Background and Aims: Objective: Qualitative meal-size estimation has been proposed instead of quantitative carbohydrate (CHO) counting with automated insulin delivery. We aimed to assess the non-inferiority of qualitative meal-size estimation strategy.

Methods: Research Design and Methods: We did a two-center randomized crossover non-inferiority trial to compare 3 weeks of automated insulin delivery with (i) carbohydrate counting and (ii) qualitative meal-size estimation in adults with type 1 diabetes. Qualitative meal-size estimation categories were low, medium, high, or very high CHO and were defined as <30 g, 30-60 g, 60-90 g, and >90 g of CHO, respectively. Prandial insulin boluses were calculated as the individualized insulin-to-CHO ratios x 15, 35, 65, and 95, respectively. Closed-loop algorithms were otherwise identical in the two arms. The primary outcome was time in range 3.9–10.0 mmol/L, with a pre-defined non-inferiority margin of 4%.

Results: 30 participants completed the study (20 females, age 44 (SD 17) years, A1c 7.4 (0.7%)). The time in 3.9-10.0 mmol/L was 74.1% (10.0%) with carbohydrate counting and 70.5% (11.2%) with qualitative meal-size estimation; mean difference -3.6% (8.3%; non-inferiority p = 0.78). Times <3.9 mmol/L and <3.0 mmol/L were low (< 1.6% and <0.2%) in both two arms. Automated basal insulin delivery was higher in the qualitative meal-size estimation arm (34.6 vs. 32.6 u/day, p = 0.003).

Conclusions: Conclusions: Though QMS method achieved a high time in range and low time in hypoglycemia, non-inferiority was not confirmed. The qualitative meal-size estimation method may benefit from larger prandial boluses and more responsive post-meal automatic basal delivery.

OP038 / #436

Topic: ***AS05 Artificial Pancreas***

AUTOMATED INSULIN DELIVERY IN OVER 2,000 YOUNG CHILDREN: ARE IMPROVED GLYCEMIC OUTCOMES MAINTAINED IN THE REAL WORLD?

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Background and Aims: To determine real-life glycemic outcomes in a large cohort of pediatric patients after switching from a predictive low glucose suspend (PLGS) system to automated insulin delivery (AID) as well as to explore changes in insulin delivery and bolusing behaviors with the use of AID.

Methods: CGM and pump data were analyzed from 2,340 pediatric patients with T1D (age 1-13 years) using PLGS (Basal-IQ) for one month followed by AID (Control-IQ) for three months. Glycemic outcomes and changes in insulin delivery were compared across age groups (0-5 years, 6-10 years, 11-13 years).

Results: Glycemic control improved within the first month of AID use and was sustained through month three with time in the target range increasing 13% (Table). Hypoglycemia remained low and was marginally higher in the youngest age group. Fewer manual boluses were entered per day on AID compared to PLGS, however the number of carbohydrate boluses did not change. The youngest children had the most carbohydrate bolus entries. Only a small percentage of children (2.3%) entered 1 or fewer carbohydrate boluses per day at three months. Total daily insulin (TDI) increased across all age groups due primarily to an increase in basal insulin delivery, although basal insulin remained <50% of the TDI.

Conclusions: Glycemic outcomes significantly improved in a large cohort of young children on AID in the real world, similar to published study outcomes. Patterns of insulin delivery and bolusing behaviors change slightly with AID use.

Table: Glycemic and insulin delivery outcomes across age groups (mean ± SD)

	1-5 years N=92	6-10 years N=932	11-13 years N=1,316	All N=2,340
GMI (%)[a,c]				
B-IQ	7.6 ± 0.9	7.8 ± 0.8	7.9 ± 0.9	7.8 ± 0.8
C-IQ (1m)	7.1 ± 0.6	7.2 ± 0.5	7.3 ± 0.5	7.3 ± 0.5
C-IQ (3m)	7.2 ± 0.7	7.3 ± 0.5	7.4 ± 0.6	7.4 ± 0.6
Mean BG (ng/dL)[a,c]				
B-IQ	179 ± 36	188 ± 34	191 ± 36	189 ± 35
C-IQ (1m)	160 ± 24	164 ± 21	167 ± 23	166 ± 22
C-IQ (3m)	164 ± 29	167 ± 23	172 ± 25	170 ± 24
%TIR (70-180)[a,c,f]				
B-IQ	54 ± 18	50 ± 17	49 ± 18	50 ± 18
C-IQ (1m)	66 ± 13	66 ± 11	65 ± 12	65 ± 12
C-IQ (3m)	64 ± 15	64 ± 12	62 ± 14	63 ± 13
%TAR (>180)[a,c]				
B-IQ	43 ± 19	48 ± 17	50 ± 19	49 ± 18
C-IQ (1m)	31 ± 13	32 ± 12	34 ± 13	33 ± 13
C-IQ (3m)	33 ± 15	34 ± 13	36 ± 14	35 ± 14
%TBR (<70)[a,c]				
B-IQ	2.1 ± 1.9	1.7 ± 1.9	1.3 ± 1.6	1.5 ± 1.8
C-IQ (1m)	2.5 ± 1.8	1.9 ± 1.7	1.3 ± 1.3	1.6 ± 1.5
C-IQ (3m)	2.4 ± 1.7	1.7 ± 1.6	1.2 ± 1.2	1.4 ± 1.4
%TBR (<54)[a,c,f]				
B-IQ	0.40 ± 0.5	0.33 ± 0.5	0.25 ± 0.5	0.29 ± 0.5
C-IQ (1m)	0.53 ± 0.6	0.38 ± 0.5	0.26 ± 0.4	0.32 ± 0.5
C-IQ (3m)	0.48 ± 0.5	0.37 ± 0.5	0.24 ± 0.3	0.30 ± 0.4
Total Daily Insulin (units/day)[a,c,d]				
B-IQ	15.7 ± 11.8	22.6 ± 10.1	39.1 ± 18.7	31.6 ± 17.8
C-IQ (1m)	16.9 ± 11.9	24.5 ± 11.0	42.6 ± 20.6	34.4 ± 19.5
C-IQ (3m)	16.6 ± 10.3	25.5 ± 11.5	44.5 ± 21.2	44.5 ± 20.1
Total Basal (units/day)[a,c,d]				
B-IQ	5.1 ± 3.4	8.5 ± 4.2	15.2 ± 8.1	12.1 ± 7.6
C-IQ (1m)	6.1 ± 3.8	10.8 ± 5.7	19.4 ± 10.7	15.4 ± 9.9
C-IQ (3m)	6.3 ± 3.7	11.3 ± 6.0	20.4 ± 11.0	16.2 ± 10.3
Total Bolus (units/day)[a]				
B-IQ	10.6 ± 9.3	14.1 ± 6.8	23.9 ± 12.4	19.5 ± 11.6
C-IQ (1m)	10.8 ± 9.5	13.6 ± 6.2	23.3 ± 11.6	19.0 ± 10.9
C-IQ (3m)	10.3 ± 8.1	14.2 ± 6.6	24.0 ± 12.1	19.6 ± 11.3
Carbohydrate Boluses (#/day)[a,c]				
B-IQ	5.8 ± 2.4	4.8 ± 1.7	4.7 ± 1.8	4.8 ± 1.8
C-IQ (1m)	5.9 ± 2.4	4.8 ± 1.7	4.7 ± 1.7	4.8 ± 1.8
C-IQ (3m)	5.6 ± 2.6	4.8 ± 1.7	4.6 ± 1.9	4.7 ± 1.9
Manual Correction Boluses (#/day)[a,d,f]				
B-IQ	2.5 ± 1.8	2.1 ± 1.6	2.3 ± 1.9	2.2 ± 1.8
C-IQ (1m)	1.4 ± 1.3	1.1± 1.2	1.2 ± 1.3	1.2 ± 1.3
C-IQ (3m)	1.4 ± 1.3	1.2 ± 1.3	1.3 ± 1.5	1.2 ± 1.4

GMI, glucose management indicator; BG, blood glucose; m, month; TIR, time in range; TAR, time above range; TBR, time below range
B-IQ vs. C-IQ: [a]p<0.001, [b]p<0.05
B-IQ vs. C-IQ x Age group: [c]p<0.001, [d]p<0.05
Age group effect: [e]p<0.001, [f]p<0.05

OP039 / #511

Topic: ***AS05 Artificial Pancreas***

HEALTHCARE PROFESSIONALs' VIEWS ON OPEN SOURCE ARTIFICIAL PANCREAS SYSTEMS IN TYPE 1 DIABETES CARE

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Background and Aims: This qualitative study examined views of healthcare professionals (HCPs) on open source Artificial Pancreas Systems (APS) in type 1 diabetes care.

Methods: Nineteen HCPs were recruited through professional networks to cover various regions of the Netherlands. Eight diabetes specialized nurses, eight endocrinologists, two technical physicians and one physician assistant were interviewed. Topics of the semi-structured interviews included interaction with people with diabetes (PWD), perceived healthcare needs and (ideal) image of future diabetes care. Individual and thematic content analyses were performed (open, axial, selective coding).

Results: HCPs interacted with $M = 4.7$ ($SD = 3.4$) PWD using open source APS. Overall, participants felt free to discuss open source APS, provided that the initiative came from PWD. HCP assistance to (potential) users was limited: many considered extensive assistance to be 'off-limits'. Barriers to engage with PWD about the systems laid on the personal (sense of losing control), legal (fear of liability/adverse events) and practical level (lack of manufacturer support). Perceived healthcare needs of PWD involved in open source APS included openness, understanding, cooperation and autonomy. HCPs expected open source APS to remain used by a motivated and skilled minority and hoped for the systems to become redundant by increased accessibility of commercial systems. In the meantime, education on open source APS was desired.

Conclusions: Although HCPs experienced freedom to discuss open source APS, they also felt reluctant and insufficiently knowledgeable to start the conversation and to extensively support PWD involved in these systems. A more proactive attitude requires better education on open source APS.

OP040 / #815

Topic: ***AS05 Artificial Pancreas***

HYBRID CLOSED-LOOP WITH FASTER INSULIN ASPART COMPARED WITH STANDARD INSULIN ASPART IN VERY YOUNG CHILDREN WITH TYPE 1 DIABETES: A DOUBLE-BLIND, MULTICENTRE, RANDOMISED, CROSSOVER STUDY

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Background and Aims: Type 1 diabetes (T1D) remains challenging to manage in very young children, and performance of ultra-rapid insulins with hybrid closed-loop therapy has not been assessed in this age-group. We evaluate the use of hybrid closed-loop insulin delivery with faster insulin aspart (Fiasp) in very young children with T1D.

Methods: In a double-blind, multicentre, randomised, crossover study, very young children aged 2-6 years with T1D using insulin pump therapy were recruited. Participants underwent two 8-week periods comparing hybrid closed-loop using CamAPS FX with Fiasp and hybrid closed-loop using CamAPS FX with standard insulin aspart in random order. Primary endpoint was the between-group difference in time in target glucose range 3.9 to 10.0mmol/L at 8 weeks. Analysis was by intention-to-treat.

Results: We randomised 25 participants: mean (±SD) age 5.1 ± 1.3 years, baseline HbA1c 55.5 ± 8.5mmol/mol. The proportion of time sensor glucose was in the target range was not different between interventions (64 ± 9% vs 64 ± 9% for hybrid closed-loop with Fiasp vs hybrid closed-loop with standard insulin aspart; mean adjusted difference -0.31% [95% CI -2.13, 1.51; p = 0.74]). There was no difference in time with sensor glucose <3.9mmol/L and >16.7mmol/L, and no difference in mean sensor glucose or glucose variability. Total daily insulin requirements did not differ (0.74 [IQR 0.68, 0.83] vs 0.71 [0.68, 0.83] units/kg/day; p = 0.06). No severe hypoglycaemia or DKA events occurred.

Conclusions: Use of Fiasp in the CamAPS FX hybrid closed-loop system demonstrated no difference in glycaemic outcomes compared with standard insulin aspart in very young children with T1D.

	Fiasp (n=25)	Standard insulin aspart (n=25)	Mean adjusted difference (95% CI)[b]	p value[c]
% time with sensor glucose level				
3.9 to 10.0mmol/L[a]	64.2 ± 8.8	64.5 ± 8.7	-0.31 (-2.13, 1.51)	0.74
<3.9mmol/L	3.5 (2.6, 6.2)	3.7 (2.6, 6.2)	-0.05 (-0.44, 0.33)	0.79
>16.7mmol/L	4.5 (1.9, 6.6)	4.1 (1.7, 7.8)	-0.17 (-0.77, 0.43)	0.57
Mean sensor glucose (mmol/L)	8.89 ± 0.88	8.86 ± 0.83	0.02 (-0.16, 0.21)	0.79
Glucose SD (mmol/L)	3.74 ± 0.64	3.73 ± 0.62	0.02 (-0.12, 0.16)	0.77
Glucose CV (%)	42.0 ± 4.6	41.9 ± 4.7	0.10 (-1.08, 1.29)	0.86
Total daily insulin (U/kg/day)	0.74 (0.68, 0.83)	0.71 (0.68, 0.83)	0.03 (-0.00, 0.06)	0.06
Total daily basal (U/kg/day)	0.37 (0.31, 0.47)	0.37 (0.27, 0.43)	0.03 (-0.00, 0.06)	0.06
Total daily bolus (U/kg/day	0.40 (0.30, 0.45)	0.39 (0.30, 0.44)	0.00 (-0.01, 0.02)	0.68

Table legend: Outcomes during hybrid closed-loop insulin delivery with faster insulin aspart and standard insulin aspart over 8 weeks.

Table footnote:
Data are mean±SD, median (IQR).
[a]Primary endpoint.
[b]Treatment difference is calculated as Fiasp minus standard insulin aspart.
[c]Based on linear mixed model adjusting for repeated participant measures, baseline value, period as fixed effects, site as random effect.

OP041 / #131

Topic: ***AS06 Glucose sensors***

SOCIOECONOMIC DISPARITIES IN ACCESS TO CGM FOR ADULTS WITH DIABETES. RESULTS FROM THE GERMAN DPV REGISTRY

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Background and Aims: Data on socioeconomic disparities in access to CGM in adults is still rare in Europe. We therefore investigated differences in CGM usage between differently deprived areas in Germany.

Methods: In adults with type 1 diabetes (T1D) or type 2 diabetes (T2D) from the German prospective diabetes follow-up registry (DPV), we analyzed CGM use (any use or regular use: ≥90 days per year) in 2021 by quintile of area deprivation (German index of Multiple Deprivation [GIMD] 2015, from Q1, least deprived, to Q5, most deprived districts), using multiple adjusted regression models.

Results: In 2021, 58.0% of adults with T1D (n = 9,368) and 12.3% of adults with T2D (n = 27,949) used a CGM at any extent. A regular use was documented in 32.4% of adults with T1D and 4.8% of those with T2D. Socioeconomic disparities in access to CGM were greatest in adults with T2D using CGM regularly: 14.8% in Q1 districts (men: 15.5%; women: 13.8%) compared to ≤1.8% in Q2-Q5 districts (p for trend <0.001). The difference was greater in T2D individuals without insulin therapy (12.1% in Q1 vs. ≤0.3% in Q2-Q5, $p < 0.001$), than in those with insulin therapy (21.4% in Q1 vs. ≤4.3% in Q2-Q5, $p < 0.001$). The largest proportion of adults with T2D using CGM regularly was in Hamburg (>10%).

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Conclusions: For patients with T2D in Germany in 2021, CGM use is almost limited to adults living in the least deprived districts, especially in the absence of insulin therapy.

OP042 / #722

Topic: ***AS06 Glucose sensors***

AUDIT OF TECHNOLOGIES USED FOR GLUCOSE MONITORING IN PATIENTS WITH TYPE 1. DIABETES AT DIABETES CENTER DURING 2019-2022 – REAL WORLD DATA

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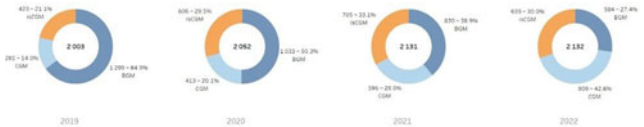
Background and Aims: The new NICE guidelines recommend that all adults with type 1 diabetes should have access to either Intermittently Scanned Continuous Glucose Monitoring (isCGM) or Continuous Glucose Monitoring (CGM). The aim of the study was to evaluate the type of used method for glucose monitoring in patients with type 1 diabetes treated at our diabetes center during 2019-2022.

Methods: 2132 patients with type 1 diabetes (1199 with pens and 933 with pumps) were enrolled in the present study between 2019 and 2022. The patients were divided into three groups according to the type of monitoring used - BGM, CGM and isCGM. In all patients basic characteristics, diabetes history, type of treatment, glucose control (HbA1c) and frequency of downloads of data were assessed.

Results: A significant increase in the proportion of patients using CGM or isCGM in comparison to BGM during the years 2019-2022 was seen (Fig 1). There was a significant improvement in diabetes control in CGM and isCGM between 2019-2022, but not in BGM (CGM: 2019 63.1 ± 12.4 mmol/mol vs. 2022 58.7 ± 11.7; $p < 0.0001$; isCGM: 64.5 ± 14.2 vs. 61.7 ± 13.1; $p < 0.001$; BGM: 60.8 ± 16.3 vs. 59.3 ± 16.4; NS). CGM-monitored patients had better glucose control than isCGM patients ($p < 0.0001$). There was a significantly higher frequency of data download in CGM and isCGM in comparison with BGM (mean 2/year and 1.8 vs. 1.1; $p < 0.001$).



Conclusions: Our study demonstrated that more than 2/3 of patients meet the NICE guidelines in 2022, and this ratio is improving year by year. Glucose monitoring by CGM and isCGM has led to better diabetes control.

OP043 / #727

Topic: ***AS06 Glucose sensors***

SAFETY AND COST-EFFECTIVENESS OF GUARDIAN CONNECT CGM SYSTEM USAGE DURING INTRAVENOUS INSULIN THERAPY IN PATIENTS AFTER TOTAL DUODENOPANCREATECTOMY

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Background and Aims: Estimating safety and cost-effectiveness of use Guardian Connect continuous glucose monitoring (CGM) system in early postoperative period in hospitalized patients after total duodenopancreatectomy (TDPE) on continuous intravenous insulin therapy (CIVIT).

Methods: Glucose measurement results of 26 patients in early postoperative period after TDPE were analyzed. In 12 of them, we used Guardian Connect CGM system. In this group 43 cycles (1 cycle – 6 days, 258 days total) of CGM and 971 glucometer measurements used for CGM calibration were analyzed; in other 14 patients in whom only glucometer was used we analyzed 2496 glycemic values. Main safety criteria for CGM were frequency of hypoglycemic episodes and time-in-range (5.7-10 mmol/L (102.6-180 mg/dL)). Cost-effectiveness was calculated over 6 days for CGM and only glucometer use (including cost of CGM, glucometers, disposable materials, clinic wage-costs to medical staff for time required for glucose control).

Results: In CGM group 10 episodes of hypoglycemia were observed over 258 days, one episode was <2.8 mmol/L (confirmed by glucometer); time-in-range was 66.74%. In glucometer-only group - 44 episodes of hypoglycemia, of which eight episodes were <2.8 mmol/l; time-in-range was 61.2%. Total cost of glucose control in CGM group during 1 cycle was 97.2 Euro compared with 154.6 Euro for using only glucometer (18 measurements per day). One cycle of CGM saved 255 minutes of nurse labor time.

Conclusions: Guardian Connect CGM have demonstrated its safety and significant cost-effectiveness during glucose control in patients in early postoperative period after TDPE on CIVIT.

OP044 / #344

Topic: ***AS06 Glucose sensors***

IMPROVING GLYCAEMIC CONTROL WITH FLASH GLUCOSE MONITORING: THE ADVANTAGE OF USING THE APP VS THE READER

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Background and Aims: The benefits of using a connected smartphone application (app) with flash glucose monitoring (fCGM) are under discussion. We aimed to assess the impact of switching from reader to app on glucose metrics of patients with type 1 diabetes (T1D).

Methods: Retrospective cohort study of T1D on fCGM, using Freestyle Libre sensor 1 (FL1) or 2 (FL2) with the app (LibreLink) and with active fCGM time ≥70%. Glucose metrics were collected from the last 90 days while using the reader (FL1) and while using the app (FL1 or FL2) and compared by paired analysis.

Results: 89 patients were analysed, age 30.6 ± 10.5 years, mean duration of T1D 17.4 ± 10.0 years; 76.4% on insulin pump. 57.3% used FL2. When using the app, patients showed significantly lower time below range [TBR] (5.7 ± 4.3 vs 8.5 ± 5.6, $p < 0.001$), due to less time <54mg/dL (0.9 ± 1.4 vs 3.3 ± 2.9, $p < 0.001$); lower coefficient of variation (41.1 ± 6.8 vs 42.2 ± 6.9, $p = 0.002$) and glycaemia risk index (54.7 ± 18.5 vs 61.8 ± 20.9, $p < 0.001$); and a trend towards greater time in range (57.2 ± 13.1 vs 55.6 ± 14.3, $p = 0.058$). Time with active fCGM increased with the app, especially when it was ≤95% with the reader (88.1 ± 6.9 vs 78.6 ± 18.6, $p < 0.001$). Diferences were similar in FL1 or FL2 users, with the exception of FL2 users with hyper- and hypoglycaemia alarms (N = 30), that also showed a reduction in time >250mg/dL (14.7 ± 7.3 vs 17.2 ± 9.6, $p = 0.049$).

Conclusions: Patients that switched from reader to app had significantly less TBR, independently of FL1/FL2 use. Alarm users had less severe hyperglycaemia. Using the app increased adherence to fCGM and improved overall glycaemic risk.

OP045 / #521

Topic: ***AS06 Glucose sensors***

CONTINUOUS GLUCOSE MONITORING METRICS AND NEONATAL OUTCOMES IN PREGNANT WOMEN WITH INSULIN-TREATED DIABETES

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Background and Aims: Poorly controlled diabetes in pregnancy may increase the rate of adverse neonatal outcomes. Analysis assessing whether Continuous Glucose Monitoring (CGM) metrics are related to neonatal outcomes is still limited.

Methods: CGM metrics (TIR 63-140 mg/dL, TAR >140 mg/dL, TBR <63 mg/dL, Mean Glucose, GMI and CV) at 24 ± 2 and 36 ± 2 gestational weeks (GW) in pregnant women with insulin-treated diabetes were prospectively collected. Adverse neonatal outcomes (Large for Gestational Age (LGA), preterm and perinatal complications) were collected at hospital discharge.

Results: We identified 22 pregnant women with insulin-treated diabetes (12 type 1, 4 type 2 and 6 gestational diabetes; age 33 ± 4; pre-pregnancy BMI 27 ± 6 kg/m^2) using CGM. Out of 22 newborns (delivery at 37(36-38) weeks, birth weight 3142 ± 551gr), 8(36%) were LGA and 7(32%) preterm. Overall, 14(64%) infants had at least one adverse outcome. Despite similar HbA1c during pregnancy (5.5 ± 0.3 vs. 5.7 ± 0.5%; p = NS), women with at least one adverse neonatal outcome had higher Mean Glucose (126 ± 24 vs. 100 ± 16 mg/dL), TAR (31 ± 22 vs. 8 ± 9%), GMI (45 ± 7 vs. 38 ± 5 mmol/mol), CV (29 ± 7 vs. 22 ± 5%) and lower TIR (65 ± 22 vs. 87 ± 7%) at 24 ± 2 GW, compared to women without adverse outcomes; likewise, TAR (24 ± 15 vs. 10 ± 12%), GMI (44 ± 4 vs. 39 ± 4 mmol/mol) and CV (32 ± 8 vs. 22 ± 3%) were higher at 36 ± 2 GW (all $p < 0.05$). On a logistic regression analysis including HbA1c, TAR at 24 ± 2 GW was associated with a 14% increased risk of adverse neonatal outcomes [OR = 1.14(1.02-1.29), $p = 0.047$].

Conclusions: Irrespective of HbA1c level, TAR at 24 ± 2 GW is associated with increased risk of adverse neonatal outcomes in pregnant women with insulin-treated diabetes.

OP046 / #590

Topic: ***AS06 Glucose sensors***

INSULIN RESISTANCE IS ASSOCIATED WITH A LOWER TIME IN RANGE IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: An increasing number of people with type 1 diabetes (T1D) have co-existent insulin resistance (IR). We investigated whether IR is associated with continuous glucose monitor-derived parameters (CGM) such as time-in-range (TIR), time-above-range (TAR), time-below-range (TBR) and glycaemic variability (GV).

Methods: This is a retrospective analysis of a clinical database (NCT04664036). IR was determined according to the estimated glucose disposal rate (eGDR) formula: 19.02 − (0.22 x BMI, kg/m2) − (3.26 x hypertension) − (0.61 x HbA1c, %). TIR (70-180 mg/dl), TAR (>180 mg/dl), TBR (<70 mg/dl) and GV were retrieved using CGM readings. CGM usage <70% was excluded.

Results: 287 individuals were included. The mean age was 47 ± 17 years, 55 % were male, diabetes duration was 26 ± 14 years, TIR was 57 ± 14 % and eGDR was 7.39 ± 2.19 mg/kg/min. The cohort was divided in tertiles based on their eGDR. The TIR of the group with the lowest eGDR was significantly lower than the TIR of the group with the highest eGDR (55 ± 14 versus 59 ± 14 %, $p < 0.001$). A correlation was found between eGDR and TIR, TAR, diabetes duration, waist circumference and HbA1c ($p < 0.05$), but not with GV and TBR. In linear regression analysis, parameters independently associated with TIR were eGDR and age ($\beta = 0.019$ and 0.003 respectively, both $p < 0.001$), but not gender, diabetes duration, smoking and alcohol status.

Conclusions: In people with T1D and IR, a lower TIR can be expected. Assessing and targeting IR could aid to acquire optimal glycaemic control.

OP047 / #594

Topic: ***AS06 Glucose sensors***

ASSOCIATION BETWEEN PERSON-REPORTED HYPOGLYCAEMIA AND TIME BELOW RANGE: THE HYPO-METRICS STUDY

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Background and Aims: Time below range from continuous glucose monitoring (CGM), is widely used to assess hypoglycaemia risk. However, its relationship with personal experience of hypoglycaemia is unclear. We investigated the association between time <3.9 mmol/l ($TBR_{3.9}$) and person-reported hypoglycaemia; symptomatic episodes that resolved on carbohydrate ingestion and/or a measured glucose ≤3.9mmol/l.

Methods: This analysis included 401 adults with insulin-treated diabetes (n = 204 with type 1 diabetes (T1D); n = 197 with type 2 diabetes (T2D)), who reported ≥1 hypoglycaemic episode in the past 3 months. For 10 weeks, they wore blinded CGM and recorded person-reported hypoglycaemia in real time using the Hypo-METRICS app. Data were analysed using generalised linear regression.

Results: Participants had a median (IQR) age 58 (47-66) years and 45% were women. HbA1c was 7.4% (6.8-8.0%), 23% had impaired awareness of hypoglycaemia, and 43% used capillary glucose monitoring only. During 658,802 hours of CGM, $TBR_{3.9}$ was 3.0% (1.1-5.9%) and 11,600 person-reported hypoglycaemia episodes were recorded. Using a generalised linear regression model, $TBR_{3.9}$ explains 25% of the variation of person-reported hypoglycaemia (21% in T1D, 12% in T2D). With every 1% change in $TBR_{3.9}$, the weekly rate of person-reported hypoglycaemia changes by 9.4% ($p < 0.0001$), with a 6.2% change in T1D ($p < 0.0001$) and 9.4% change in T2D ($p < 0.0001$).

Conclusions: While $TBR_{3.9}$ is a valuable tool to understand hypoglycaemia risk, it explains a relatively small proportion of the variation in person-reported hypoglycaemia rates and highlights the limitation of using this metric as a surrogate marker for the experience of hypoglycaemia by the person living with diabetes.

OP048 / #404

Topic: ***AS06 Glucose sensors***

IMPROVED CLINICAL CONCORDANCE OF TIR AND HBA1C BY ACCOUNTING FOR PERSONAL GLYCATION FACTORS

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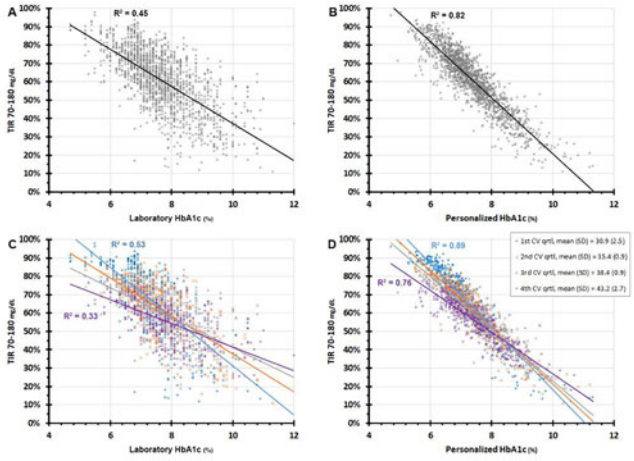
Background and Aims: HbA1c and time in range (TIR) are important glycemic markers but they can be discordant, creating clinical management difficulties. Our aims were to improve HbA1c accuracy at reflecting glucose exposure by adjusting for personal glycation factors and to investigate the effects of glycaemic variability (GV) on HbA1c accuracy.

Methods: Three months of continuous glucose monitoring (CGM) preceding HbA1c values were obtained from 758 individuals with type 1 diabetes (T1D) from 7 clinical trials. A total



of 1,636 periods had glycemic metrics of average glucose (AG), time in range (TIR) 70-180 mg/dL, and HbA1c. Apparent glycation ratio (AGR) was calculated as:

$$AGR = \frac{AG^{-1} + K_M^{-1}}{A1C^{-1} - 1},$$

where AG is average glucose and K_M is 472 mg/dL, thus allowing personalized HbA1C (pHbA1c):

$$[pHbA1c\ in\ NGSP\ \%] = \frac{100}{1 + \frac{AGR}{AGR_{ref}}\left(\frac{100}{[HbA1c\ in\ NGSP\ \%]} - 1\right)}$$

where AGR_{ref} is assumed at 65.1 ml/g. Due to the known effect of glucose variability on the TIR-HbA1c relationship, the paired metrics were grouped by quartiles of glucose CV, and agreements were evaluated by linear regression.

Results: The agreement between pHbA1c and TIR was greater than that of TIR and HbA1c ($R^2 = 0.45$ v. 0.82, Figure 1A-B). GV was divided by CV quartile groups (30.9±2.5, 35.4±0.9, 38.4±0.9 and 43.2±2.7%) with linear regression correlations demonstrating that increasing CV is associated with worsening HbA1c-TIR correlations (R^2 ranging between 0.33-0.53; Figure 1C). Accuracy for the correlations improved substantially with the use of pHbA1c (R^2 ranging between 0.76-0.89; Figure 1D).

Conclusions: Accounting for a personal glycation factor improves the accuracy of HbA1c at reflecting average glucose even in the presence of high GV.

OP049 / #701

Topic: ***AS06 Glucose sensors***

IMPACT OF RESIDUAL B CELL FUNCTION IN TYPE 1 DIABETES PATIENTS UNDER INTENSIVE INSULIN TREATMENT AND FLASH GLUCOSE MONITORING

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Background and Aims: To evaluate the impact of serum c-peptide measurement in pediatric and adult patients with type 1 diabetes (DM1)

Methods: Cross-sectional study in DM1 patients under intensive insulin treatment and flash glucose monitoring (FGM) (32.2% continuous subcutaneous insulin infusion(CSII)). Clinical and metabolic data, fasting serum c-peptide and FGM glucometric data were obtained in last follow-up visit.

Results: A total of 208 DM1 patients (51.9% women,39.9% pediatrics-<18 years old-) were included. Mean age was 31.6 ± 19.4 years, 14.1 ± 11.8 years of DM1 duration and 15.2% with any grade of diabetes retinopathy. 13.9% showed C-peptide levels ≥200pmol/L. C-peptide ≥200pmol/L was more frequent in pediatric patients than in adults (19.3% vs 10.4%,p <0.05) and in multiple doses of insulin(MDI) treatment than CSII (16.1% vs 1.5%; p < 0.01). Patients with C-peptide ≥200 pmol/L showed a significantly better control: higher time in range 70-180 mg/dl -TIR-(74.9 ± 15.6 vs 66.1 ± 16.0%,p <0.05) and lower time below range -TBR-<54mg/dl (0.2 ± 0.6 vs 0.8 ± 1.6%,p <0.01), TBR54-70mg/dl (1.9 ± 2.0 vs 4.3 ± 3.1%,p <0.01) and lower coefficient of variation (CV) (30.5 ± 6.7 vs 36.8 ± 6.6,p <0.001) than those with c-peptide <200pmol/L. There was no differences in the rest of FGM glucometric parameters, included GMI (6.9 ± 0.8 vs 7.0 ± 0.7%,ns). C-peptide levels showed a significant negative correlation with time above range -TAR-180-250mg/dl (-0.253,p <0.01); TAR >250mg/dl (-0.186,p <0.01), CV (-0.362,p <0.001) and years of DM1 evolution (-0.350,p <0.001), and a positive correlation with TIR (0.297,p <0.001). However, a correlation with HbA1c or islet autoantibody was not found.

Conclusions: Detectable c-peptide levels had a clinically meaningful beneficial effect on DM1 control on pediatric and adult patients. These improvements were more evident in TIR, TBR and CV than in classical parameters as HbA1c.

OP050 / #535

Topic: ***AS06 Glucose sensors***

INTERMITTENT USE OF FLASH GLUCOSE MONITORING IS USEFUL TOOL FOR PATIENTS WITH TYPE 1 DIABETES IN DEVELOPING COUNTRIES

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Background and Aims: Flash Glucose Monitoring (FGM) is important in management of Type 1 diabetes (T1D), but its cost is still big issue in developing country like Egypt. This study was conducted to explore the efficacy of using FGM intermittently on glycaemic control & acute diabetes complications.

Methods: We included 90 patients with T1D ≥ 2 years of diagnosis, on Degludec U100 & insulin aspart. Education for carb counting & correction doses were done to all participants. Furthermore, we divided them into 3 subgroups: **Group (1)** 30 patients on Self-Monitoring Blood Glucose (SMBG) only, **Group (2)** 30 patients on Freestyle Libre (FsL) continuously for 3 months, **Group (3)** 30 patients on FsL for 2 weeks then on SMBG for 4 weeks alternatively. Base line HbA1c & 3 months later were compared. Moreover, episodes of nocturnal & severe hypoglycemia and Diabetic Ketoacidosis (DKA) were also monitored. Time In Range (TIR) were compared between group (2) & group (3).

Results: HbA1c is significantly higher among group (1) versus group (2) & (3) [8.21 ± 72 gm % versus 7.14 ± 43 gm % versus 7.34 ± 62 gm% respectively]. Three attacks of DKA were reported in group (1) versus zero attacks in other groups. TIR is Significantly higher in group (2) (68 ±56 % versus 54 ± 48

% in group (3). 12 attacks of severe hypoglycemia versus zero versus 3 attacks among group (1), (2), (3) respectively.

Conclusions: Using FGM intermittently is useful tool for those who can't afford continuous use of FGM & improves glycaemic control significantly.

OP051 / #396

Topic: ***AS06 Glucose sensors***

CHANGES IN HOSPITALIZATIONS FOR SEVERE HYPOGLYCEMIA AND HYPERGLYCEMIA AND CONTINUOUS GLUCOSE MONITOR (CGM) USE IN TYPE 2 DIABETES AND CHRONIC KIDNEY DISEASE (CKD) PATIENTS

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Background and Aims: Glycemic control is important among patients with diabetes and CKD. Frequent blood glucose monitoring is crucial to preventing diabetes-related hospitalizations, comorbidities, and CKD progression. This study evaluated change in hospitalizations for severe hypoglycemia and hyperglycemia before and after CGM initiation in patients with type 2 diabetes (PWT2D) and moderate to severe CKD.

Methods: A retrospective analysis of US administrative claims data from Optum Clinformatics® Database was conducted. PWT2D and moderate to severe CKD who initiated CGM technology between 1/1/2017 and 3/31/2021 (index date = earliest observed claim for CGM) were identified. Continuous health plan enrollment of 12-months pre- and post-index date and insulin use 12-months pre-index date was required for inclusion. Individuals with evidence of pregnancy and dialysis were excluded. Outcomes were assessed during 12-months pre- and 12-months post index date. These included the change in number of hospitalizations for severe hypoglycemia and hyperglycemia.

Results: PWT2D and moderate to severe CKD included 10,122 CGM users (average age 67.3(SD = 10.5)). The proportion of individuals hospitalized for at least one severe hypoglycemic event was 14.9% prior to CGM use and was 13.2% after starting CGM (-11.1%, $p = 0.0002$). Hyperglycemia-related hospitalizations decreased from 27.6% to 24% (-13.2%, $p < 0.0001$). Similarly, the average number of hospitalizations for hypoglycemia (-11.6%, $p = 0.0015$) and hyperglycemia (-8.27%, $p = 0.0009$) were reduced after initiating CGM.

Conclusions: These findings provide real-world evidence that CGM initiation may help PWT2D and moderate to severe CKD maintain glycemic control and avoid serious glycemic excursions that result in hospitalization.

OP052 / #366

Topic: ***AS06 Glucose sensors***

EXTENDED OUTCOMES WITH INTERMITTENTLY SCANNED CGM(ISCGM) USED PRIOR TO FIRST APPOINTMENT WITH AN ENDOCRINOLOGIST, COMPARED TO CAPILLARY BLOOD GLUCOSE (CBG) MONITORING (SPOT-FIRST STUDY)

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Background and Aims: To investigate if having isCGM data at the first consultation with an endocrinologist leads to better outcomes than CBG data.

Methods: We enrolled 94 consecutive CBG-using(CGM-naive)patients with poorly controlled T2DM referred to endocrinology. The first 39 patients(control group) continued to use CBG as per routine. The next 55 patients(study group) were given isCGM(Abbott Freestyle Libre) for one-time use, 14 days prior to consultation appointment. Treatment changes were made at the time of appointment based on CBG/isCGM data, as per standard of care. Subsequently, both groups used CBG ongoing.

Results: A1C reduced from 8.3%(initial consultation) to 7.4%(1st follow-up visit) in the study group(p-value <0.01) and from 8.4% to 8.2% in the control group(p-value 0.082).Difference in A1C at 1st follow up visit(avg duration 133 days) was significantly lower in study group compared to control group(p-value 0.002),without increase in hypoglycemia.Lower A1c in study group compared to control group persisted at 2nd follow-up visit (avg duration 165 days),despite no longer using isCGM.

Conclusions: Canadian patients might wait many months after referral to see an endocrinologist. This study suggests that compared to CBG, one-time isCGM use before first consultation is associated with greater A1C reduction without increase in hypoglycemia. This optimizes outcome of the initial consultation visit. Improvement in A1c persists even after patients are no longer on ongoing isCGM, indicating sustained benefit.

	Study Group	Control Group
A1c at initial consultation visit(%)	8.3	8.4
A1c at first follow-up visit(%)	7.4	8.2
A1c at second follow-up visit(%)	7.6	8.2

OP053 / #440

Topic: ***AS06 Glucose sensors***

ASSESSING TIR METRICS AND A1C IN PWD AND ITS ASSOCIATION WITH TREATMENT RELATED VARIABLES

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Background and Aims: TIR obtained from CGM analytics provide more actionable information than A1C. We analyzed AGP of PwD to assess correlation of TIR with multiple treatment-related variable

Methods: Real-world retrospective raw sensor data(Libre Pro from Jan 2019- June 2022) from 1156 PwD(T1D- n = 92; 27 ± 17.2 years; A1C- 8.6 ± 1.85%; TIR- 47 ± 26.3%; T2D n = 1064; 56 ± 12.1 years; A1C- 7.5 ± 1.25%; TIR- 59 ± 22.5%) on different treatment regimens were preprocessed to exclude timeframes where actual use of CGM was <70%, harmonize data formats, and normalize timestamps with respect to starting time of monitoring. Spearman Rank correlation and Univariate regression were used to characterize relationship between A1C and CGM-related metrics. Data processing and statistical computation were performed by R(4.2.0).

Results: In T1D, TIR >70% and >50% corresponded with A1C of approximately 8.1% and 8.5% respectively. Data were classified based on disease duration (DD) >15 years and TIR >70%. A1c was 0.7% lower with DD >15 years while it was 0.98% lower with TIR >70%. In T2D, TIR >70% and >50% corresponded with A1C of approximately 7.2% and 7.5% respectively. A1c was 0.45% higher with DD >15 years while it was 0.54% lower with TIR >70%. There were significant differences in TIR among OHA + Analogue premix, OHA + analogue Basal Bolus, OHA + analogue Basal when compared to OHA+human insulin regimens. PwD with complications (CAD/CKD) spent significantly more TBR than those without complications.

Conclusions: Correlation of TIR with A1C varies with type of diabetes, therapies and co-morbidities and hence need to be regarded as independent and valuable metric for substantial clincial benefits.

OP054 / #923

Topic: ***AS06 Glucose sensors***

REDUCTION OF TIME SPENT IN HYPOGLYCEMIA THROUGH REAL-TIME CGM WITH PREDICTIVE ALARMS IN ADOLESCENTS WITH TYPE 1 DIABETES

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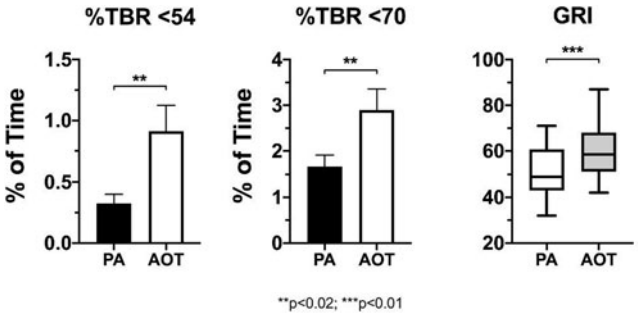
Background and Aims: Hypoglycemic events are linked to microvascular and macrovascular complications in subjects with Type 1 Diabetes (T1D). The study aimed to evaluate the efficacy of real-time continuous glucose monitoring (RT-CGM) with predictive alarm (PA) technology in reducing the time spent below the range (%TBR <70 mg/dl) in a group of adolescents with Type 1 Diabetes (T1D) treated with multiple daily insulin injections (MDI).

Methods: This is a crossover, monocentric and randomized study. Twenty patients with T1D were enrolled (M 50%, mean age 15.4 ± 1.4 years old) all using RT-CGM (Guardian Connect, Medtronic). RT-CGM could be utilized with Alarm on Threshold (AOT) or Predictive alarm (PA) for hypoglycemia. Patients were randomized to PA/AOT or AOT/PA groups spending two weeks in every single intervention arm. AOT for hypoglycemia was set at 70 mg/dl and the PA alarm for hypoglycemia was set 20 minutes before the threshold. The statistical analysis was conducted using a linear mixed-model analysis with %TBR as the dependent variable, the treatment group (PA or AOT) as a factor, and the participant as a random factor.



Results: Patients using PA for hypoglycemia, spent less time in severe hypoglycemia (%TBR <54 mg/dl; 0.32 ± 0.3 vs 0.92 ± 0.84; p < 0.02) and in hypoglycemia (%TBR <70 mg/dl; 1.67 ± 1.06 vs 2.90 ± 2.05; p < 0.02), with better Glycemia Risk Index (GRI, 51.3 ± 11.0 vs 61.6 ± 12.6; p < 0.01) (Figure 1).

Conclusions: The use of RT-CGM with PA technology reduce time spent in hypoglycemia in patients treated with MDI improving their quality of glucose control.

OP055 / #850

Topic: ***AS06 Glucose sensors***

PHYSIOLOGY BASED MODEL FOR DETECTION OF CONTINUOUS GLUCOSE MONITORING (CGM) SENSOR COMPRESSION ARTIFACTS

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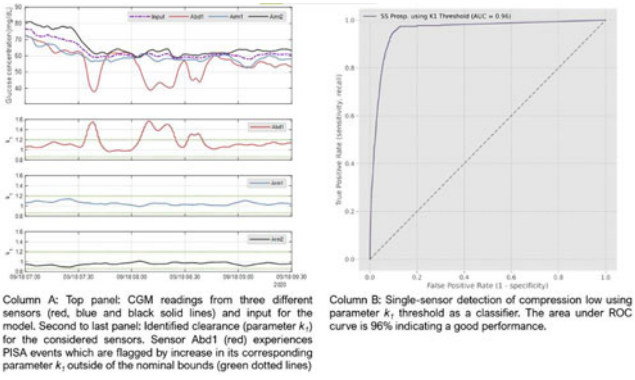
Background and Aims: Continuous glucose monitoring (CGM) sensors are vulnerable to compression artifacts, characterized by an artificial rapid drop in sensor readings, followed by eventual recovery, which may trigger false hypoglycemia alarms or insulin shutoff by insulin delivery systems. Therefore, their detection can prevent unfavorable events in diabetes management.

Methods: A physiological model of glucose concentration at the local sensor compartment (LSC) (G_{LSC}) was formulated. The change of G_{LSC} was described as the difference between the true glucose in the interstitial fluid (ISF) (G_{ISF}) entering LSC at a constant rate and glucose cleared from LSC. For the model, G_{LSC} represents the CGM under analysis and G_{ISF} was estimated from other available sensors or by extrapolation of the same sensor data. The model clearance parameter (k_1) was identified in the absence of and during compression artifacts to determine whether relevant changes in the parameter were related to the presence of compression.

Results: Under nominal conditions k_1 had a stable value that increased when compression developed (Figure) independently of the G_{ISF} trend. Parameter k_1 had median [Q1-Q3] values of 1.02 [0.98-1.06] min^{-1} under nominal conditions and 1.13 [1.03-1.27] min^{-1} during compression artifacts. After testing in a large archival data set of N = 44 individuals and 35,488 h of sensor data, the model resulted in an area under the ROC curve of 0.96.



Column A: Top panel: CGM readings from three different sensors (red, blue and black solid lines) and input for the model. Second to last panel: Identified clearance (parameter k_1) for the considered sensors. Sensor Abd1 (red) experiences PISA events which are flagged by increase in its corresponding parameter k_1 outside of the nominal bounds (green dotted lines)

Column B: Single-sensor detection of compression low using parameter k_1 threshold as a classifier. The area under ROC curve is 96% indicating a good performance.

Conclusions: A model of glucose dynamics in the local environment of the sensor needle allowed for real-time detection of compression artifacts, independent from normal physiological glucose fluctuations.

OP056 / #676

Topic: ***AS06 Glucose sensors***

SUCCESSFUL MINIATURIZATION OF AN OSMOTIC-PRESSURE BASED GLUCOSE SENSOR FOR CONTINUOUS I.P. AND S.C. GLUCOSE MONITORING BY MEANS OF NANOTECHNOLOGY

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Background and Aims: The Sencell sensor uses glucose induced changes in an osmotic pressure chamber for continuous measurement of glucose concentrations in the intraperitoneal cavity and subcutaneous tissue. The final device shall have the size of a grain of rice, which requires substantial miniaturization of the conceptional in-vitro prototypes (chamber volume 70 μL). Osmotic pressure is independent from volume, but the key limiting factor for the device size is the size of the piezo-resistive pressure transducers inside of the core sensor technology.

Methods: We decided to investigate a NanoTunneling Resistive Sensor approach. The small (20 x 50 nm) sensors are 3D-printed on the pressure membrane by means of a modified electrone microscope using the FEBID method (Fast Electron Beam Induced Deposition). For benchmark testing, we filled the chamber with bovine serum albumin (BSA, 1 mM) and closed it with a semipermeable membrane. Thereafter, the sensor chamber was exposed in a repetitive manner to distilled water followed by 1 mM BSA.

Results: Exposure of the miniaturized sensor chamber (volume $\sim$700 nL) resulted in reliable and reproducible pressure changes of 30-35 mBar, which is comparable to the pressure difference observed in the same experiment with the 70 μL chamber of the in-vitro sensor prototypes (40-50 mBar).

Conclusions: The NTR pressure sensor technology was successfully used to reduce the size of the core osmotic pressure chamber in the Sencell device by $\sim$100% without substantial loss of the osmotic pressure signal. This is a major step forward to achieve the finally anticipated size of the injectable glucose sensor.

OP057 / #915

Topic: ***AS06 Glucose sensors***

EVALUATION OF GLYCEMIA RISK INDEX AS A NOVEL METRIC OF THE QUALITY OF GLYCEMIA IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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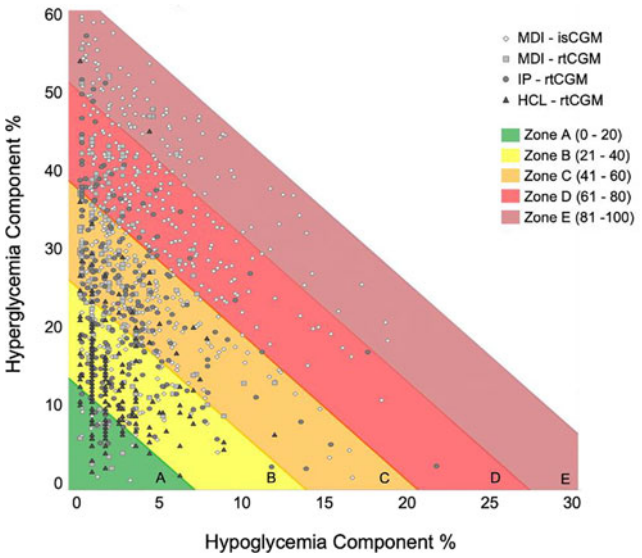
Background and Aims: Glycemia Risk Index (GRI) is a novel composite metric for the evaluation of the quality of glycemia. To date, no data about GRI has been reported in children and adolescents with type 1 Diabetes (T1D).

Methods: Clinical characteristics and real-life CGM data were collected from 1067 children/adolescents with T1D. GRI and metrics of glycemic control and variability were calculated from 28-day and 14-day CGM data. The relationships between GRI and CGM metrics were assessed by Spearman correlation coefficient. ANOVA was run to compare GRI across four groups in relation to treatment strategies (1-isCGM–multiple daily injections [MDI];2-rtCGM–MDI;3-rt-CGM–insulin pump [IP];4-Hybrid Closed-Loop [HCL] therapy).GRI grid graph was created to display hypoglycemia and hyperglicemia components according to treatment strategies.

Results: GRI was strongly negatively correlated with time in range 70-180 mg/dL. A medium-to-high positive correlation was found between GRI and time above the range >250 mg/dL, mean glycemia, its standard deviation, coefficient of variation and HbA1c, whereas a low positive correlation was found with time below range 54-69 mg/dL , time below range <54 mg/dL and time above range 181-250 mg/dL .Significant differences were found in GRI among the four treatment strategies group ($p < 0.001$). GRI grid graph displays hypoglycemia and hyperglicemia components according to



treatment strategies showing that mean GRI was lowest in HCL group (mean = 30.8) and highest in the isCGM-MDI group (mean = 68.4).

Conclusions: These findings support the use of GRI and the GRI grid for the assessment of the quality of glycemia and the glycemic effect of specific treatment in paediatric subjects with T1D.

OP058 / #395

Topic: ***AS06 Glucose sensors***

CONTINUOUS/FLASH GLUCOSE MONITORING DOES NOT PREVENT SEVERE HYPOGLYCEMIA IN REAL-WORLD SETTINGS (INPHORM, USA)

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Background and Aims: According to trial data, real-time continuous/flash glucose monitoring (rt-C/FGM) reduces severe hypoglycemia (SH). However, whether this effect translates and persists in real-world, population-based settings is unknown.

Methods: Americans (≥18 years old) with T1DM or T2DM taking insulin and/or secretagogues were recruited from a nationwide, probability-based internet panel. Data were collected online across a screener, baseline, and 12 monthly follow-ups. Among complete cases with ≥1 follow-up, we performed multivariable negative binomial regression with generalized estimating equations to assess the population-average effect of ≥1-year, <1-year, and no rt-C/FGM use on annualized SH rate. Confounding variables were identified from a directed acyclic graph.

Results: N = 845 were analyzed (T1DM: 19.12%, age: 50.57 [SD: 14.19] years, male: 48.41%). At baseline, 12.87% (T1DM: 31.41%; T2DM: 8.48%) reported using rt-C/FGM for ≥1-year, 10.66% (T1DM: 16.67%; T2DM: 9.24%) for <1-year, and 76.47% (T1DM: 51.92%; T2DM: 82.27%) not at all. The prospective crude rate of SH was 4.41 (95% CI: 3.99-4.87) events per person-year, and the incidence proportion was 15.20% (95% CI: 12.90-17.82%). Adjusting for A1C, age, comorbidity status, number of past SH events, impaired awareness of hypoglycemia, income, insurance coverage, medication regimen, and diabetes type, ≥1-year rt-C/FGM users reported 1.45-times (95% CI: 1.16-1.80) and 1.32-times (95% CI: 1.08-1.62) the annualized rate of SH as non-users and <1-year users, respectively ($P = 0.003$).

Conclusions: Our results suggest that rt-C/FGM does not independently protect against SH, especially among long-term (≥1-year) users. Complementary strategies may be required to support and potentiate sustained rt-C/FGM utilization in the real world.

OP059 / #85

Topic: ***AS06 Glucose sensors***

THE ASSOCIATION BETWEEN MEAN BLOOD GLUCOSE LEVELS AND TIME IN RANGE (TIR) WITH HBA1C: RESULTS FROM THE GOLD AND SILVER TRIALS

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Background and Aims: Previous studies have shown that different mean blood glucose concentrations (MBG) may be associated with the same HbA1c level. The aim of this study was to elucidate how the MBG level and Time in Range (TIR) are associated with HbA1c.

Methods: Analyses were performed on data from the randomized clinical GOLD trial (n = 144) and validated from the follow-up SILVER trial (n = 98). Linear mixed effects models were used to account for intra-individual correlations in repeated measures data.

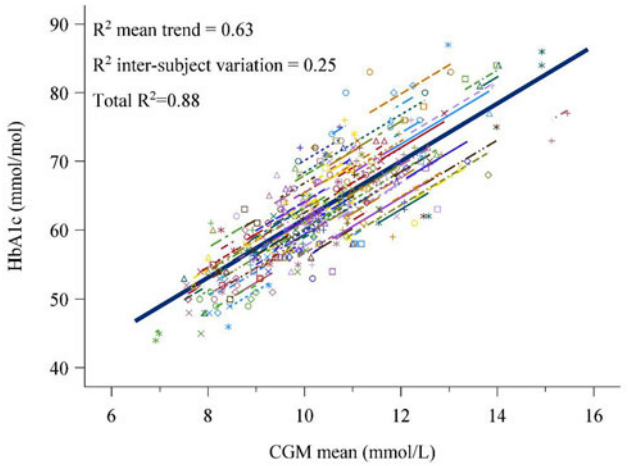

Figure 1. Relation between HbA1c and mean blood glucose level at the population level (solid blue line) and subject level (coloured symbols and coloured dashes lines) in the GOLD trial.

Results: MBG level explained only 63% of the variation in HbA1c during the GOLD trial. Subject effects unrelated to MBG level, estimated from repeated measures data by inclusion of random intercepts, explained 25% of the remaining variation in HbA1c (Figure 1). TIR explained 60% of the variation in Hba1c, which increased to 86% when accounting for subject effects. Individual variations were largely unexplained by patient characteristics, laboratory measurements or glycaemic variability measures. Time in hypo- and hyperglycaemia were significantly associated with HbA1c when controlling for TIR. For example, a TIR of 60%, with 0% compared with 15% time in hypoglycaemia, corresponded to 10 mmol/mol higher HbA1c: 60.1 vs. 50.5 mmol/mol.

Conclusions: Essential interindividual deviations exist between MBG level and HbA1c in T1D which needs to be considered in clinical practice. The relationship between HbA1c and TIR is strongly influenced by time in hypoglycaemia.

OP060 / #178

Topic: ***AS06 Glucose sensors***

TEMPORAL RESOLUTION OF CGM PROFILES FROM 6235 SUBJECTS: IDENTIFYING TIME INTERVALS WITH HIGH / LOW RISK OF HYPER- OR HYPOGLYCAEMIA IN PAEDIATRIC AND ADULT T1D

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Background and Aims: Sensor profiles yield more information concerning glucose metabolism than aggregated time in range. We analysed diurnal variation in risk for hypo- or hyperglycaemia in a multicentre registry.

Methods: We included 6,235 T1D patients of all ages from the German/Austrian/Luxembourgian DPV registry with sensor profiles 01/2010-06/2022. The 24-h-recording with most complete data was analysed. Odds ratios for time above range (>180 mg/dl)/time below range (<70 mg/dl) were adjusted for age (<12, 12-<18, ≥18 years), sex, and diabetes duration (<2, 2-<5, ≥5 years).

Results: Median age of the cohort was 12.9[9.1–16.0] years with 3.9[1.4–7.7] years diabetes duration (53.0% male, 69.4% CSII). We identified three intervals with highest hypo-/hyperglycaemia risk (Table 1). Older age, longer diabetes duration, and MDI therapy were predictors for early-morning hypoglycaemia (Table 1). Post-breakfast, hyperglycaemia was predicted by younger age, longer DM-duration, and MDI therapy. Post-dinner, young age and longer DM-duration pose a risk for hyperglycaemia. Sex was no risk factor in any time interval. Table 1: Hypo- and hyperglycaemia time intervals by risk factors.

	5–7 a.m.
Age: 12-<18 vs. <12 years	1.35 [1.01–1.80]
≥18 vs. <12 years	1.27 [0.79–2.04]
Diabetes duration: 2-<5 vs. <2 years	1.80 [1.24–2.61]
≥5 vs. <2 years	1.93 [1.34–2.78]
CSII vs. MDI	0.60 [0.46–0.77]

Conclusions: Three intervals convey highest risk for hypo-/hyperglycaemia. Sensor profiles are useful to detect these intervals, while aggregated time in range values lack this temporal resolution.

OP061 / #836

Topic: ***AS06 Glucose sensors***

EFFECT OF INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING (ISCGM) IN PEOPLE WITH DIABETES WITH A PSYCHOSOCIAL INDICATION FOR INITIATION

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Background and Aims: The objective of this study was to understand the effect of intermittently scanned continuous glucose monitoring (isCGM) in people living with diabetes with a 'psychosocial' indication for funding for access to flash glucose monitoring.

Methods: The study was performed using baseline and follow-up data from the Association of British Clinical Diabetologist (ABCD) nationwide audit of FreeStyle Libre in the United Kingdom. People living with T1D were categorized into two groups with diabetes-related distress scale (DDS2): those with moderate to high DRD, (DDS2 score ≥3) and those with low DRD (DDS2 < 3.). Mann Whitney U test was used to compare in the pre and post-isCGM variables.

Results: The study consisted of 17,036 people with diabetes, of which 1314 (7%) were initiated on isCGM (follow-up data on 327) because of a 'psychosocial' indication. With the initiation of isCGM (follow-up of 6.9 months), there was a significant reduction in DDS2 (4 (IQR = 2.8-5 vs 2.5 (IQR = 2.5-3) follow-up $P < 0.001$). The prevalence of moderate to high DRD reduced from 75% to 38% at follow-up (49% reduction in DRD, $P = 0.009$). There was also a significant reduction in HbA1c with the use of isCGM (HbA1c 75mmol/mol at baseline vs 65.0 mmol/mol at follow-up ($P < 0.001$)). This group experienced a reduction in diabetes acute events: a 97% reduction in hospital admissions due to hyperglycaemia/DKA, an 85% reduction in hypoglycaemia-related admissions and a 45% reduction in severe hypoglycaemia.

Conclusions: People with diabetes who were initiated on isCGM for a psychosocial indication had high levels of DRD and HbA1c, which improved, with the use of isCGM.

OP062 / #660

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

INCLUDING PATIENT-GENERATED HEALTH DATA IN ELECTRONIC HEALTH RECORDS – A SOLUTION FOR CGM-DATA

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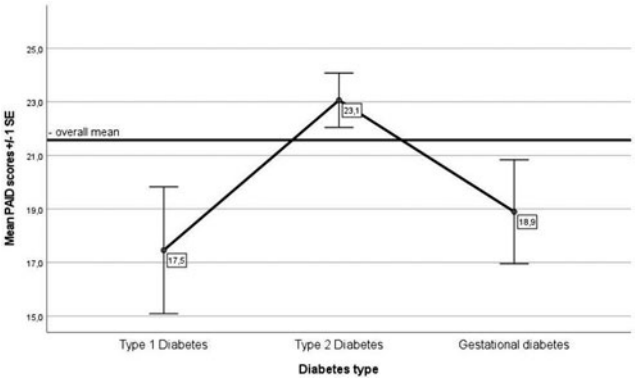
Background and Aims: Patients with diabetes and health personnel do not have an optimal way of interacting. Health personnel must use multiple ICT systems, such as third-party companies' services, to access health-related data from diverse vendors' CGM platforms and Electronic Health Record (EHR). Furthermore, other health-related data like physical activities, quality of life or well-being is often discussed but rarely stored inside the EHR system. We propose a future-proof architecture for diabetes medical consultation using the HL7 Fast Healthcare Interoperability Resources (FHIR) standard.

Methods: We designed a service, based on Tidepool, that combines generic data (e.g., sleep, physical activity, diet), disease-specific data (blood glucose, carbohydrate intake, insulin doses), PROMs (e.g., PAID, SF-36, PHQ-9) and exchange these data according to FHIR.

Results: Profiling information from CGMs or generic data like physical activities using the FHIR standard impose some new design choices. The FHIR standard permits the use of observations, making it technically possible to exchange such data. However, even with unequivocal data exchange, there are multiple ambiguities in storing patient-generated health data (PGHD) in EHRs, including ethical questions regarding responsibility, maintenance and versioning. Thus, the question: Who is responsible for the validity of such data? Remains open since multiple possible answers exist, such as the patients, healthcare systems or device producers.

Conclusions: Health-related data (e.g., CGM data, PGHD) are often obtainable exclusively via proprietary systems slowing clinical practice. A future-proof architecture based on FHIR standards may provide a comprehensive picture for patients and health personnel for diabetes medical consultation.



Background and Aims: mySugr is designed to help people with diabetes manage their diabetes and to reduce burden of diabetes management. To test the efficacy of the mySugr app, a randomized controlled trial (RCT) was designed. Baseline characteristics are presented.

Methods: The RCT was designed as a multi-center, open-label, parallel study with a 3-month follow-up in Germany. Participants were randomized to either using the mySugr app or to the treatment-as-usual control group in a 2:1 ratio. Primary outcome is change in diabetes distress using the Problem Areas in Diabetes (PAID) questionnaire. Secondary outcomes include e. g. change in HbA1c and diabetes self-management (DSMQ). Power analysis revealed that 396 participants are needed to demonstrate a significant effect ($p = 0.05$; power = 80%) for an anticipated effect size of Cohen's $d = 0.3$. A drop-out rate of 15% was assumed, leading to a recruitment goal of 466 persons.

Results: 424 people with diabetes were randomized, 282 to the intervention group and 142 to the control group (age: 51.2 ± 14.6 vs. 52.8 ± 16.3; 13.1% vs. 11.3% type 1, 66.7% vs. 71.1% type 2, 20.2% vs. 16.2% gestational diabetes; PAID: 21.62 ± 17.55 vs. 21.08 ± 17.00; DSMQ: 75.33 ± 13.84 vs. 73.69 ± 15.53; HbA1c: 7.06 ± 1.50% vs. 7.16 ± 1.47%). Baseline characteristics did not significantly differ (all $p > .05$). There was a significant difference in PAID scores across diabetes types ($p = 0.03$; Figure).

Conclusions: Randomization was successful (1.99:1 ratio), leading to comparable groups. Recruitment goal was achieved and could be stopped earlier due to lower-than-anticipated drop-outs. Participants had moderate levels of diabetes distress with people with type 2 diabetes having the highest diabetes distress.

OP063 / #871

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EVALUATING THE EFFICACY OF MYSUGR IN A RANDOMIZED CONTROLLED TRIAL: BASELINE CHARACTERISTICS

D. Ehrmann[1], B. Kulzer[1], S. Silbermann[2], J. Kober[2,3], K. Finke-Gröne[1], T. Roos[1], I. Vesper[2], V. Schäfer[4], N. Hermanns[1]

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OP064 / #373

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IMPACT OF DIGITAL COACHING ON DIABETES SELF-MANAGEMENT AND GLYCEMIC OUTCOMES FOR PEOPLE WITH TYPE 2 DIABETES

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Background and Aims: Digital coaching intervention has potential to improve self-care and outcomes for people with

diabetes. Such intervention may offer an effective, scalable, and affordable treatment solution by providing a personalized approach for managing diabetes. Dario, a digital therapeutic platform, may assist self-monitoring to achieve optimal outcomes via digital engagement and coaching.

Methods: A retrospective study was performed on Dario™ data (2019-2022). Users (n = 712) with type 2 diabetes and a starting average blood glucose (BG) >180 mg/dL, and who took ≥1BG measurement in the first and 12th months, were evaluated. A subset of 178 users made >1 coach interaction (coach-group). Propensity score matching established a control group (non-coach group) of 534 users with no-coach interaction (no difference in 1st month average BG; $p = 0.454$). Changes over a year were evaluated (nonparametric test). A Mediation effect of digital engagement in the effect of coaching interaction on reduction of BG levels was tested. Non-linear regression was applied on both groups to assess coaching impact on engagement and BG levels.

Results: Average BG level significantly reduced in coach and non-coach groups over a year (18% vs. 11%, $p < 0.001$). Digital engagement was a mediator for coaching effect on BG reduction ($p < 0.001$). Coaching interactions gradually increased measurements and improved glycemic outcomes ($p < 0.0001$) for lower engaged users ($p < 0.0001$) (non-linear regression). For high engaged users (>36 activities, 92 measurements) coaching impact was not significant.

Conclusions: Our findings underscore the need to provide personalized approaches. Digital therapeutics has a high potential to deliver person-centric care for optimizing interventions and coaching interaction.

OP065 / #813

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A HEALTH INFORMATICS LED APPROACH FOR AIDING CLINICAL PRIORITISATION AND REDUCING BACKLOG OF CARE : RESULTS FROM A STUDY IN 4013 PEOPLE WITH DIABETES

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Background and Aims: The backlog of care in resource stretched healthcare systems highlight the need for innovative data-led approaches to aid clinical prioritisation. Our aim was to identify and prioritise people who are likely to deteriorate whilst awaiting an appointment to minimise risk and optimise resource utilisation.

Methods: Using data from electronic health care records we identified modifiable risk-factors that could be addressed in 4013 people (52% male, 30% non-Caucasian) with diabetes (type 1 diabetes 20%) attending a large university hospital in London. The risk-factors were new clinical events/data occurring post their last routine diabetes clinic visit and included diabetes related emergency visit/ hospitalisation, HbA1c >86 mmol/mol or <48 mmol/mol, HbA1c rise or fall >20 mmol/mol, eGFR fall >15 ml/min, and ophthalmological treatment for retinopathy. To determine agreement between clinical and data-led prioritisation approaches, a sample of 450 patients were evaluated.

Results: Of the 4013 people, 656 (16.3%) were identified as having one or more risk factors. People with risk were more likely to be non-Caucasian with greater socio-economic deprivation. Taking clinical prioritisation as the gold standard, data-led prioritisation identified high risk patients with a sensitivity of 83% and low risk patients with a specificity of 81%. A new high-risk service has been developed to using date-led prioritisation to address backlog and enhance care.

Conclusions: A pragmatic data-driven method identifies people with diabetes at highest need for clinical prioritisation. Health informatics systems such as our can enhance care and improve clinical service efficiency/delivery for people with diabetes.

OP066 / #842

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

USING TELEHEALTH THROUGH THE MOBILE CHANNEL TO REDUCE HEALTH INEQUALITY AND DISPARITY: A REAL-WORLD STUDY EXAMINING PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: COVID-19 led to digital acceleration, raising alarms that minorities (Black/Hispanic) would be left further behind. Did patients with type 2 diabetes (PwT2D) who rely on routine care change their use of health IT resources?

Methods: Using longitudinal patient portal usage data of 55,548 PwT2D from an urban hospital in the U.S., we examined mobile-vs-desktop internet access before-and-after COVID-19. We constructed three models using the panel dataset: pooled Ordinary Least Squares (OLS), random effect (RE), and fixed effect (FE).

Results: The interaction of *COVID_PeriodxMinority* across the three models (OLS/RE/FE) was significant and showed racial disparity is *increasing* for desktop use ($\beta = -0.052/-0.053/-0.054$) and *decreasing* for mobile use ($\beta = 0.026/0.025/0.025$). COVID-19 has reduced the gap by 34% (0.025/0.073) according to the RE model. Table 1 shows that racial disparity shrinkage is largely driven by the use of mobile communication.

Conclusions: COVID-19 is a natural experiment providing the opportunity to investigate whether accelerated digitization impacted health inequality and disparity among PwT2D. The effect is mostly driven by mobile device access and cannot be explained by pre-COVID-19 trends. First, COVID-19 has been

Table 1: Digital Acceleration: Internet Access Mode by Patients with Type 2 Diabetes Mellitus

DV: ln (Usage)	Desktop (OLS)	Mobile (OLS)	Desktop (RE)	Mobile (RE)	Desktop (FE)	Mobile (FE)
COVID_Period	0.186*** (0.011)	0.220*** (0.008)	0.179*** (0.008)	0.216*** (0.005)	0.178*** (0.008)	0.215*** (0.005)
Minority	-0.120*** (0.014)	-0.079*** (0.009)	-0.110*** (0.024)	-0.073*** (0.019)		
COVID_Period × Minority	-0.052*** (0.019)	0.026* (0.014)	-0.053*** (0.014)	0.025*** (0.010)	-0.054*** (0.014)	0.025*** (0.009)
Age	0.003*** (0.0004)	-0.011*** (0.0004)	0.003*** (0.001)	-0.011*** (0.001)		
Male	-0.030*** (0.009)	0.023*** (0.007)	-0.027 (0.021)	0.025 (0.019)		
BMI	0.001* (0.001)	0.001 (0.0004)	0.001 (0.001)	0.001 (0.001)		
Abnormal BP	0.012 (0.010)	-0.012 (0.008)	0.008 (0.023)	-0.015 (0.020)		
COVID problem	0.065 (0.060)	0.082 (0.056)	0.088 (0.136)	0.096 (0.140)		
Office visits	0.215*** (0.005)	0.129*** (0.004)	0.120*** (0.004)	0.069*** (0.003)	0.101*** (0.004)	0.062*** (0.003)
Income	0.0003*** (0.0001)	-0.0001 (0.0001)	0.0003 (0.0003)	-0.0002 (0.0002)		
Constant	0.364*** (0.040)	0.584*** (0.031)	0.417*** (0.086)	0.617*** (0.081)		
Marital Status FE	Yes	Yes	Yes	Yes	--	--
Insurance FE	Yes	Yes	Yes	Yes	--	--
Month FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	55,548	55,548	55,548	55,548	55,548	55,548
R^2	0.074	0.085	0.036	0.066	0.030	0.064

Note: Robust standard errors in parentheses are clustered at the patient level. *p<0.1; **p<0.05; ***p<0.01

cited as a ''great magnifier'' of pre-existing racial inequality in health; however, telehealth can become a ''great equalizer'' for reducing inequity. Second, in the U.S., much effort in combating the digital divide has focused on the broadband connectivity gap; the transformative potential of mobile health is overlooked. Third, the lack of access to patient portals has disadvantaged PwT2D minorities; so long as they have access, they can ''catch up.'' NIH Award 5UL1TR001425-03.

OP067 / #96

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

BLUETOOTH TECHNOLOGY, SMART PHONE APPLICATION AND REMOTE DIABETES MANAGEMENT IN REDUCTION OF HBA1C IN TYPE 2 DIABETES MELLITUS PATIENTS ON INTENSIVE INSULIN REGIMEN (CLOUD-DM STUDY)

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Background and Aims: The burden of uncontrolled DM amongst insulin users in Malaysia is great. Structured Self-Monitoring of Blood Glucose (SMBG) that are stored in cloud, simplified into visual charts, graphs coupled with a diabetes management system (DMS) that allows remote insulin titration can lead to improvement of glycemic control.

Methods: 124 Type 2 DM outpatients with HbA1C $\geq$ 8% on intensive insulin therapy were recruited in this 26 weeks, multicenter, double arm, randomized controlled study. The patients were randomized to control arm which used traditional logbook and intervention arm which received remote insulin titration with a Bluetooth glucometer coupled with a DMS. The primary objective was to compare reduction of HbA1C and the secondary objective was to compare the change in Diabetes Distress Scale (DDS) between the control and intervention arm.

Results: There was significantly higher mean reduction of HbA1C in the intervention group ; -2.01 ± 1.60 versus -1.32 ± 1.51 in the control group (p = 0.027) by week 14 and was maintained till Week 26. There was no significant difference between the reduction of DDS between both groups. The mean frequency of SMBG in the intervention group was significantly higher than the control group; 339.65 ± 171.14 (intervention) versus 216.71 ± 96.40 (control) [p < 0.001].

Conclusions: Remote insulin titration has been proven effective especially during COVID-19 whereby there was imminent need for reduction of physical visits to the hospital. This has led to improvement of glycemic control but could translate to lesser waiting time and reduction of cost in the long term.

OP068 / #445

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PREDICTING THE IMMUNOLOGICAL RISK FOR TYPE 1 DIABETES (T1D) FROM OVERNIGHT CGM TRACES

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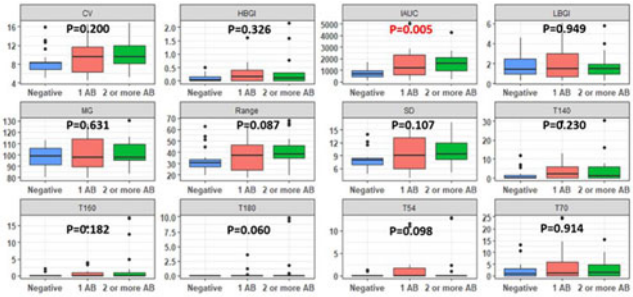

Figure: Characterization of overnight (12:00 am–6:00 am) CGM data through different glycemic features for 60 participants in the three different groups of Ab. Abbreviations: CV, coefficient of variation; HBGI, high blood glucose index; IAUC, incremental area under the curve; LBGI, low blood glucose index; MG, mean glucose; SD, standard deviation; T140, percent time >140 mg/dL; T160, percent time >160 mg/dL; T180, percent time >180 mg/dL; T54, percent time <54 mg/dL; T70, percent time <70 mg/dL.

Background and Aims: Detection of immunological risk (ImR) for type 1 diabetes (T1D) requires testing for islet autoantibodies (Ab). In this work, we characterize overnight CGM traces in healthy individuals with respect to their ImR (number of Ab) and develop a machine-learning technology for alternative ImR assessment based on these traces.

Methods: Sixty healthy relatives to individuals with T1D with mean ± SD age of 23.7 ± 10.7 (years), HbA1c of 5.3 ± 0.3%, and BMI of 23.8 ± 5.6 (kg/m^2) stratified in three ImR groups having 0 (N = 21), 1 (N = 18), and 2 or more Ab (N = 21) wear a CGM for a week as part of a NIH study using TrialNet provided subjects. Twelve glycemic features were extracted from the overnight (12:00 am–6:00 am) CGM traces (shown in the Figure). They were used for group comparison and ImR classification using 10-fold cross-validation with support vector machine (SVM) and logistic regression (LR) classification models. The receiver operating characteristic (ROC) curve AUC was used for model selection.

Results: The overnight CGM traces stratify the ImR groups with respect to their glycemia (Figure) with significant (P = 0.005) differences in the overnight CGM incremental area under the curve, with higher IAUC for those with 2 or more Ab. An ImR classifier using a SVM model with oversampling and 10-fold cross-validation outperformed the LR model (AUC-ROC of 0.81 vs. 0.76).

Conclusions: A machine-learning technology using overnight CGM data collected during a potentially self-administered, one-week home CGM test is a relevant method for assessing the immunological risk for T1D.

OP069 / #827

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EFFICACY OF INSULIN TITRATION DRIVEN BY SMS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES

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Background and Aims: The success of insulin therapy relies on the associated titration schedule, which is frequently delayed

in patients with type 2 diabetes (T2D). The lack of timely appointments for dosage adjustment is one of the most important reasons of this clinical gap. The aim is to evaluate the efficacy of self-management of insulin titration based on information received by SMS (RocheDiabetes InsulinStart service).

Methods: Case-control study with 16 weeks follow-up. A total of 59 patients were included in each arm. Inclusion criteria were T2D patients under basal insulin treatment at least 6 months but <5-years, with suboptimal glycemic control (HbA1c≥ 7.5%, and fasting capillary blood glucose (FCBG) >140mg/dL >3 times per week). Psychological aspects were evaluated in the intervention group (DDS, HADS and SF-12).

Results: The intervention group achieved a higher percentage of patients on target (FCBG between 70-130mg/dl) at 16 weeks of follow-up (59.5 ± 4.4% vs. 42.4 ± 4.4%; p = 0.04), as well as lower mean FCBG (126mg/dL ±34 vs. 149mg/dL ±46, p = 0.001) and lower HbA1c (7.5% ± 1.3 vs. 7.9% ± 0.9, p = 0.021) than control group. In addition, the intervention group showed a significantly improvement in psychological aspects related to Emotional Burden (%)(47.6 ± 0.7 vs. 30.9 ± 0.7, p = 0.031), Regimen Distress (%)(52.2 ± 7.4 vs. 17.2 ± 5.6, p < 0.001), Depression (%)(17.7 ± 0.5 vs. 6.6 ± 0.4, p = 0.049) and Mental Stress (%)(16.4 ± 0.5 vs. 14.9 ± 0.5, p = 0.016).

Conclusions: The SMS guided titration was effective in terms of improving glucometric parameters in comparison with standard of care, and improved significant psychological aspects. Therefore, it could be envisaged as a useful and easy tool to reduce the delay in insulin titration in our health-care system.

OP070 / #583

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

KARLOTTA (KIDS + ADOLESCENTS RESEARCH LEARNING ON TABLET TEACHING AACHEN) – PILOT STUDY FOR THE IMPLEMENTATION OF A DIGITAL EDUCATIONAL APP FOR PAEDIATRIC PATIENTS

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Background and Aims: Objectives: Improvement of disease-specific knowledge in pediatric patients with type 1 diabetes using a digital app and individualized teaching from physician to patient.

Methods: We developed an app called KARLOTTA (Kids + Adolescents Research Learning On Tablet Teaching Aachen) with a game of skill and diabetes questionnaire with visual feedback and high scores. In the developmental process we had first scheduled a questionnaire for inflammatory bowel disease (IBD). We conducted a randomized controlled study as a pilot project with 30 IBD patients, aged 10–18 years. The intervention group used the KARLOTTA app on a tablet before every consultation during a 12-month period. Outcome parameters were an increase in knowledge, changes in quality of life and analysis of the feedback questionnaires for patient and physician. A questionnaire based upon established educational programs used in Germany has been programmed using new illustrations and games of skill. We are starting a T1D-study for proof of feasibility, acceptability and usability.

Results: In all IBD-patients (100 %) gaps in knowledge could be discovered and specific teaching took place. In the KARLOTTA group, 11 of 14 patients (79 %) had an increase in knowledge, in the control group 7 of 15 patients (47 %), p-value of 0.08 with the X2-test. There were no differences in results for quality of life. We will report preliminary results of our feasibility-study in T1D-patients aged 8-18 years.

Conclusions: Conclusions: The KARLOTTA app can reveal individual gaps in knowledge, provides tailor-made physician-patient teaching and can be easily implemented in the outpatient clinic.

OP071 / #766

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

REAL-WORLD GLYCEMIC OUTCOMES OF PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES ACHIEVED THROUGH A FULLY VIRTUAL INTEGRATED DIABETES PROGRAM

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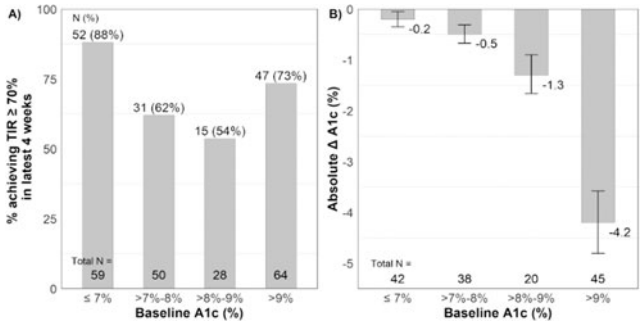
Background and Aims: Many patients with diabetes lack the resources to effectively self-manage their disease, and optimal glycemic control often remains elusive despite recent innovations. This study examines the clinical outcomes achieved through our completely remote person-centered diabetes care model, which connects patients with type 1 and type 2 diabetes with a team of diabetes specialists (endocrinologists, dietitians, educators) that personalizes recommendations based on continuous glucose monitoring (CGM) data and provides ongoing care and support between visits.

Methods: Data were collected for patients in the Carbon Health Diabetes Program who had completed onboarding by September 2022. Primary outcomes measured were the time spent in range [TIR] (70-180 mg/dL) in the latest 4 weeks of available CGM data and change in A1c. Secondary outcomes included TIR in the first 4 weeks of available CGM data while participating in the program.

Results: Baseline characteristics of 204 patients treated over a median follow-up period of 34 weeks (range 3-217) were 45.0 ± 13.1 years, 38.7% with type 1, 46.5% on insulin, and median A1c 7.9% (IQR 6.8%, 10.0%). The proportion of patients maintaining TIR ≥70% at follow-up and change in A1c, stratified by baseline A1c category, are presented in the Figure. Of 84 patients with baseline A1c >7.0% and initial CGM data available, 46 (54.8%) were able to achieve TIR ≥70% in the



program's first 4 weeks, of whom 45 (97.8%) are still doing so at follow-up.

Conclusions: Our findings suggest that patients with diabetes can achieve glycemic targets rapidly and effectively with a fully virtual model of integrated diabetes care.

OP072 / #163

Topic: ***AS08 Insulin Pumps***

NEW EX VIVO METHOD TO ASSESS SUBCUTANEOUS INSULIN ABSORPTION DURING BASAL ADMINISTRATION THROUGH PUMP : PROOF OF CONCEPT

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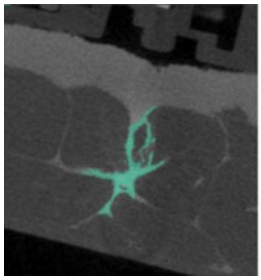
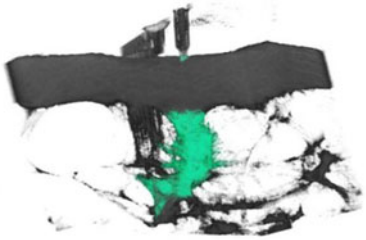
Background and Aims: Glycemic variability is still an issue among subjects with type 1 diabetes treated with pump. **Erratic subcutaneous (SC) absorption** and poor diffusion at the injection site are among the suspected causes for this phenomenon. Assessing insulin SC propagation is a challenge when it is administered by basal rate (BR) through pump and was scarcely studied. As speed of absorption increases with depot surface, we propose a **descriptive method** linking **pump delivery** and **SC propagation of insulin** through follow-up of **catheter pressure** and **high-precision time-spread imaging**.

Methods: Administration of insulin (Aspart®) and contrast agent was performed via a pump (t:slim x2, Tandem®) at **1UI/h BR in ex-vivo human skin explants** from post-bariatric surgery. Samples were placed in a **micro-CT scanner**. During 3h, one 3D-image every 5min, and continuous pressure in the tubing were recorded. Insulin depot was **numerically isolated (see figure, insulin identified in green in 2D and 3D)**. From depot area and volume we define a **unitless dispersion index (DI)** which characterizes the spread of insulin. DI is computed for each 5-minutes step of the infusion.

Results: Hypodermis was reached by cannula in 14/24 injections. One injection was extradermal, others were intradermal. Insulin spreads preferably along the interlobular septum. DI increases with time for all tissue-reaching injections, up to a mean value of 6.99(+/- 0.73) after 3h. Bubbles detected via imaging were matched with pressure events in the tubing.





Conclusions: At fixed conditions, DI standard deviation is low. This encourages DI use for **injection parameters comparison** such as **pump model** or **BR impact**.

OP073 / #482

Topic: ***AS08 Insulin Pumps***

THE IMPACT OF MINIMED™ 780G INSULIN PUMP SYSTEM - A SINGLE CENTRE PROSPECTIVE STUDY

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Background and Aims: The MiniMed™ 780G insulin pump system is one of the advanced hybrid-cloosed loop pump systems, which is available in Hungary from September 2021 for patients with type 1 diabetes mellitus. Our aim was to conduct a prospective non-interventional study in patients who start using Minimed™ 780G to compare HbA1c and metrical data before and after the 780G initiation, and determine who benefits the most.

Methods: 64 patients were enrolled in the study, among them 33 patients had minimum 6 months follow-up data. 8 patients used Multiply Daily Injections, while 25 was using Sensor Augmented Pump before.

Results: After 6 months an improvement in overall HbA1c (mean: 7.36% vs 6.78%) and TIR (mean: 62.9% vs 79.4%) was observed. Subgroup analysis based on the initial TIR (using cut-off point: 70%) showed that patients whose initial TIR was below 70% benefit more from the change. In this group we observed a significant decrease in HbA1c (mean: 7.66% vs 6.86%) and TAR (mean: 38.71% vs 19%) whereas an increase was observed in TBR (mean: 1.28% vs 1.32%). We did not make similar observation in the subgroup TIR >70%.

Conclusions: Based on our data, significant improvements in the metabolic parameters can be achieved with the AHCL system in the overall patient population. Patients who - despite all efforts -did not reach the current standardized targets with the previous treatment regimen benefit the most.

OP074 / #516

Topic: ***AS08 Insulin Pumps***

ADVANCES IN DIABETES MANAGEMENT: HAS PREGNANCY GLYCEMIC CONTROL IN WOMEN WITH TYPE 1 DIABETES CHANGED IN THE LAST DECADES?

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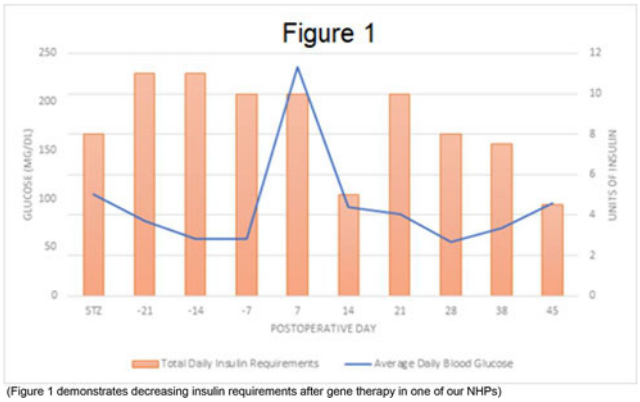
Background and Aims: Recently, multiple therapeutic and management opportunities have been made available for pregnant women with Type 1 diabetes (T1DM). However, analyses assessing whether they can improve metabolic control and outcomes is still limited.

Methods: We retrospectively analyzed metabolic data and neonatal outcomes of pregnant T1DM women, managed between 2008 and 2020, comparing different insulin administration ways (MDI or CSII) and glucose monitoring systems (SMBG or CGM/FGM).

Results: We identified 136 T1DM women (32[30-35] years; preconception HbA1c: 58.1 ± 11.6 mmol/mol), 103(76%) on MDI and 33(24%) on CSII. A CGM/FGM system was used by 33(24%) women, of these 20(19%) were on MDI and 13(39%) on CSII. As compared to women on MDI, more women on CSII had planned their pregnancy (94% vs. 60%) and had better pregestational (54 ± 5.4 vs. 60 ± 13 mmol/mol) and first trimester (48 ± 4 vs. 51 ± 7) HbA1c, lower pregnancy weight gain (10.7 ± 4.0 vs. 13.8 ± 6.2 kg), lower pre-prandial insulin dose at first (0.25 ± 0.09 vs. 0.38 ± 0.18 U/kg), second (0.30 ± 0.11 vs. 0.43 ± 0.20) and third (0.42 ± 0.20 vs. 0.54 ± 0.24) trimester. Women using CGM/FGM had significantly lower pregestational (54.1 ± 8.0 vs. 59.9 ± 13.1 mmol/mol) and first trimester (46.5 ± 5.5 vs. 51.2 ± 7.1 mmol/mol) HbA1c than those on SMBG (all p < 0,05). Neonatal outcomes were comparable in all groups. At logistic regression analysis, third trimester HbA1c was associated with Large for Gestational Age (LGA) risk [OR = 2.596 (1.408-4.787), p = 0.005].

Conclusions: In pregnant women with T1DM, CSII and CGM/FGM can optimize preconception and first trimester pregnancy glycemic control. Nonetheless, irrespective of the therapeutic management, third trimester HbA1c remains the strongest risk factor for LGA.



(Figure 1 demonstrates decreasing insulin requirements after gene therapy in one of our NHPs)

OP075 / #203

Topic: ***AS09 New Medications for Treatment of Diabetes***

PANCREATIC INTRADUCTAL INFUSION OF ADENO-ASSOCIATED VIRUS TO TREAT NON-HUMAN PRIMATES IN A TOXIN-INDUCED DIABETES MODEL

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Background and Aims: Globally, 537 million people have diabetes mellitus (DM), which in 2021 resulted in approximately one death every five seconds. T1DM, marked by a loss of beta-cells, leads to insulin deficiency and hyperglycemia. T2DM is associated with insulin resistance, reduced beta-cell mass, and impaired beta-cell function. Gene therapy may treat DM by creating new beta-like cells via forced expression of specific transcription factors: pancreas/duodenum homeobox protein-1 (Pdx1) and V-maf musculoaponeurotic fibrosarcoma oncogene homolog A (mafA). In toxin-induced and autoimmune genetic diabetic mouse models, a pancreatic intraductal infusion of AAV-CMV-Pdx1-mafA resulted in new beta-like cells and restored normoglycemia. We aimed to replicate these results in a toxin-induced diabetes model in non-human primates (NHPs).

Methods: We induced diabetes using streptozocin in NHPs. Upon stabilization, we performed a laparotomy, duodenotomy, clamped the common bile duct, and cannulated the pancreatic duct. After a five-minute infusion, we removed the catheter and clamps, and we closed the incisions.

Results: Postoperatively, NHPs (n = 8) had decreased insulin requirements (p < 0.001) (Figure 1), increased c-peptide levels (p < 0.05), and demonstrated improved glucose tolerance compared to baseline (p < 0.05), one with reestablished normoglycemia. Immunohistochemistry revealed insulin and glucagon staining, suggesting the formation of insulin-producing cells.

(Figure 1 demonstrates decreasing insulin requirements after gene therapy in one of our NHPs)

Conclusions: Newly formed beta-like cells produce insulin, may avoid the autoimmune attack, and provide long-term replacement of beta-cells. Thus, this gene therapy may be a promising treatment for diabetes, making exogenous insulin unnecessary, and may easily translate to humans via ERCP.

OP076 / #577

Topic: ***AS09 New Medications for Treatment of Diabetes***

A NOVEL ONCE-WEEKLY BASAL INSULIN FC ACHIEVED SIMILAR GLYCEMIC CONTROL WITH A COMPARABLE SAFETY PROFILE VERSUS INSULIN DEGLUDEC IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Basal Insulin Fc (BIF) combines a novel single-chain insulin variant with a human IgG2 Fc domain and is designed for once-weekly subcutaneous administration. BIF has a 17-day half-life and low peak-to-trough ratio of 1.14. This study assess the efficacy and safety of BIF versus insulin degludec (IDeg) in patients with type 1 diabetes (T1D).

Methods: This open-label, parallel trial enrolled patients with T1D who were using multiple daily insulin injections for a minimum of 3 months before screening. BIF was injected once-weekly for 26-weeks, and IDeg was injected once-daily. Both groups were titrated to fasting blood glucose levels ≤5.6mmol/L

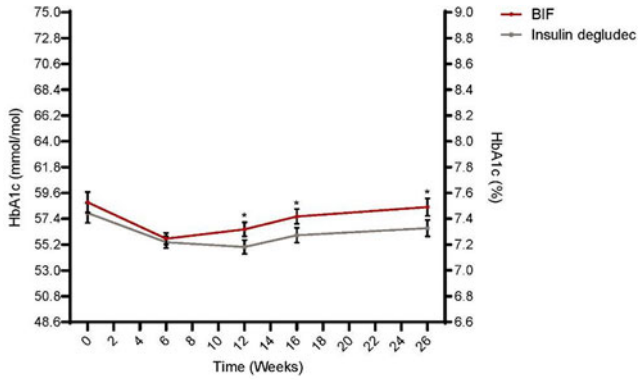

Figure 1. HbA1c over 26-week treatment period. Data presented are LSM ± SEM.
*p<0.1 for BIF versus insulin degludec HbA1c change from baseline

(100mg/dL). The primary endpoint was HbA1c change from baseline to Week 26 (non-inferiority [NI] margin = 0.4%).

Results: Patients were randomised to BIF (N = 139) or IDeg (N = 126). The baseline characteristics were well balanced among treatment groups. The HbA1c change from baseline to Week 26 treatment difference for BIF versus IDeg was 1.9mmol/mol (0.17%; [90% CI = 0.01, 0.32]; p = 0.07, Figure-1), meeting the NI margin. No significant treatment differences in patient-reported Level 1 or Level 2 hypoglycaemia were observed; 3 severe events were reported (2 on IDeg and 1 on BIF). No significant treatment differences were noted in the occurrence of serious adverse events or in body weight gain from baseline to study endpoint (BIF (0.1kg) vs IDeg (0.5kg).

Conclusions: Once-weekly BIF demonstrated similar glycaemic control versus once-daily IDeg with no difference in hypoglycaemia or other safety findings in patients with T1D. These findings support continued development of BIF in Phase-3.

OP077 / #555

Topic: ***AS10 New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

INHALED INSULIN + AID SAFELY REDUCED GLUCOSE COMPARED TO AID ADMINISTERED RAA FOLLOWING IN-CLINIC MEAL IN PROOF-OF-CONCEPT STUDY DATA SUBSET

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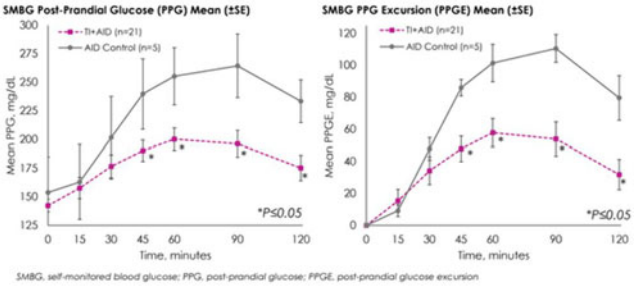
Background and Aims: Technosphere Insulin (TI) is an ultra-rapid-acting inhaled insulin. This subset analysis compares efficacy and safety for two hours after a standardized meal evaluating higher TI dose (~2x the injectable rapid-acting insulin analog, RAA, dosage) without automated insulin-delivery (AID) system meal coverage compared with an AID RAA bolus after the same standardized meal.



SMBG, self-monitored blood glucose; PPG, post-prandial glucose; PPGE, post-prandial glucose excursion

Methods: Participants with T1D on an AID system were randomized to TI+AID or AID Control and given a standardized meal (37g of a nutritional shake). The TI+AID group (n = 21) received an immediate pre-prandial dose of TI calculated by doubling their usual RAA dose and rounding down to the nearest TI dose (multiples of 4 units). The AID group (n = 5) received a typical pump bolus up to 15 minutes before the meal. Capillary glucose (SMBG) was measured by Ascensia Contour™ meters at timepoints 0, 15, 30, 45, 60, 90, and 120 minutes relative to the meal.

Results: Mean glucose and glucose excursion were significantly reduced at timepoints 45-120 minutes ($p \leq 0.05$) in the TI+AID group following the meal. Mean peak glucose occurred 30 minutes earlier and reduced by 64.1 mg/dL in the TI+AID group; mean peak glucose excursion was reduced by 52.7 mg/dL compared to AID Control. There was one instance of asymptomatic level 1 hypoglycemia at 120 minutes in the TI+AID group.

Conclusions: The results of this study indicate that TI with a higher (~2x RAA) converted dose, in combination with an AID system, significantly reduces glucose in the 2-hour postprandial period compared to an AID system alone, with no safety signals.

OP078 / #927

Topic: ***AS10 New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

PHARMACOKINETICS OF INTRAPERITONEAL FIASP DELIVERED BY ULTRASOUND-GUIDED INJECTION

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Background and Aims: The standard route of insulin administration (subcutaneous infusion) presents challenges including the slow onset and long duration of action that unfavorably pair with prandial glucose absorption. Intraperitoneal insulin (IP) has advantages for hyperglycemia prevention due to the faster onset, and shorter duration of insulin action.

Methods: 6 adult participants with type 1 diabetes age 18-60 years were injected with approximately 0.2-0.3 units/kg Fiasp insulin at each of 3 visits. Participants were randomized to receive either upper or lower intraperitoneal insulin injections

at each of the first 2 visits, followed by a subcutaneous injection at the third visit. Patients fasted overnight prior to injection, suspended subcutaneous insulin pump infusion at least an hour prior, and had intraperitoneal insulin injected under ultrasound guidance with 22 gauge 2.5-3.5 inch syringes. Samples were collected for 180 minutes following IP injection and 360 minutes following subcutaneous injection. Glucose was measured via YSI and Mercodia insulin and glucagon ELISAs performed.

Results: Tmax was roughly 30 minutes for insulin administered via the intraperitoneal route and approximately 1 hour for the subcutaneous route. For participant safety, individuals were not allowed to reach a 0-insulin state. However, intraperitoneal insulin levels dropped as low as subcutaneous levels in slightly over half the time.

Conclusions: This novel approach to intraperitoneal drug delivery in man is safe and useful for characterizing peritoneal pharmacokinetics of novel insulins. If they can be stabilized, the benefit of insulin analogs administered in the intraperitoneal space may allow for full closed-loop insulin delivery.

OP079 / #69

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

AUTOMATED INSULIN DELIVERY FOR INPATIENTS WITH DYSGLYCEMIA (AIDING) FEASIBILITY STUDY

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Background and Aims: In the hospital, management with multiple dose injection (MDI) insulin often fails to achieve glycemic goals and is limited by frequent hypoglycemia. We examined the feasibility of automated insulin delivery (AID) with remote glucose monitoring on hospital floors.

Methods: In this single-arm multicenter pilot trial (NCT04714216), the feasibility, safety, and efficacy of the Omnipod® 5 AID System with remote real-time CGM (G6) were tested. The system was initiated and used for up to 10 days in patients with insulin-requiring type 1 (T1D) or type 2 (T2D) diabetes on non-ICU medical-surgical units. Implementation involved developing protocols for nurse training, CGM telemetry monitoring/alarm response, and CGM accuracy validation. Insulin boluses were delivered by bedside nurses. Primary endpoints included proportion of time in automated mode and glycemic control as percent of time in range (TIR, 70-180mg/dL).

Results: Cumulative system use across 16 patients (2 with T1D, 14 with T2D; HbA1c mean 8.0 ± 1.3%) comprised 90 days (mean 5.6 ± 2.8 days/patient). Median percent time in automated mode was 99% [IQR 95-99%]. Participants achieved 68 ± 16% TIR overall, with 0.15 ± 0.3% <70mg/dL and 0.06 ± 0.2% <54mg/dL. Glucose mean was 168 ± 21mg/dl. There was no incidence of DKA or severe hypoglycemia. Proportion of CGM values within %15/15 and %20/20 of reference capillary glucose were 75% and 85%, respectively. MARD was 12%. Patients reported universal satisfaction with the system on survey at study end.

Conclusions: AID with remote real-time CGM is feasible, effective, and safe in the hospital. These results advocate for direct comparison to MDI in a randomized trial to determine glycemic superiority.

OP080 / #881

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

DIGITALISED IN-HOSPITAL CARE FOR PEOPLE WITH DIABETES USING CONTINUOUS GLUCOSE MONITORING: THE SMARTDIABETESCARE STUDY

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Background and Aims: The *SmartDiabetesCare* (SDC) study investigates whether digitalised in-hospital diabetes management can reduce length of stay (LOS) and risk of acute complications for inpatients with prediabetes or diabetes.

Methods: SDC was undertaken on 3 wards over 8 months at University Hospital Essen. Proactive in-hospital diabetes care (IDC) involved introduction of diabetes technology and training of staff. SDC involved diabetes screening of new in-patients, proactive diabetes management and continuous glucose monitoring (CGM). IDC and SDC outcomes were compared to usual diabetes care (UDC) on the same wards the previous year. Outcomes were LOS and relative risk (RR) of acute complications for inpatients with prediabetes or diabetes.

Results: 1,328 patients were included. Patients with prediabetes had mean LOS of 10.9 days under UDC vs. 7.6 days under IDC ($P < 0.001$) and 7.5 days under SDC ($P < 0.05$). Diabetes patients had mean LOS of 9.9 days under UDC vs. 8.1 days under IDC ($P < 0.001$) and 9.1 days under SDC ($P < 0.05$). Patients with diabetes in IDC and SDC had reduced RR for admission to intensive care unit (ICU) (RR 0.49 and 0.37 respectively; $P = 0.003$ and $P < 0.001$), compared to UDC. Compared to UDC, RR for ICU admission was reduced under IDC and SDC in patients with prediabetes (ICD: RR 0.09 and SDC 0.06; both $P < 0.001$). Compared to UDC, RR for myocardial infarction was reduced for prediabetes patients under SDC ($P = 0.036$) and for postoperative complications for diabetes patients under IDC ($P = 0.047$).

Conclusions: Digital in-hospital management can improve outcomes for patients with prediabetes or diabetes, by reducing LOS and RR of acute complications.

OP081 / #334

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

THE EFFICACY AND SAFETY OF LIRAGLUTIDE 3.0 MG FOR WEIGHT MANAGEMENT AS AN ADD-ON TREATMENT IN OBESE ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: Background: Recent data from multiple international registries showed higher rates of overweight and obesity in adolescents with type 1 diabetes (T1DM) compared with their non-diabetic peers. Aim of the study: To assess the effectiveness and safety of daily 3 mg subcutaneous (sc) Liraglutide amongst obese adolescents with T1DM.

Methods: The 26-week trial involved 32 T1DM obese adolescents and a poor response to lifestyle therapy and exercise. They received liraglutide 3 mg sc daily with their usual insulin dose. Dose was titrated up on a weekly basis . BMI, BG levels, HbA1c %, insulin dose were obtained at baseline and after the intervention.

Results: Of the 32 patients (females 84.3%), 21(65.6%) continued therapy for 26 weeks reached daily dose of Liraglutide 3.0 mg . Reduction in BMI of at least 5% was observed in 17 of 32 participants and a reduction in BMI of at least 10% was observed in 10 participants. Change from baseline in BMI SD score at week 26, with an estimated treatment difference from baseline was (−0.26, [CI] −0.34 to −0.08; P = 0.001). There was significant reduction of HbA1c from 8.5 to 7.4% (P = 0.01). Concomitant fall in basal insulin from 31.6 ± 9 to 22.4 ± 8 units (P < 0.001 for all) and total bolus insulin from 24.8 ± 7 to 16.5 ± 2 units (P = 0.02). Adverse events were mainly gastrointestinal including nausea, dyspepsia, vomiting and constipation

Conclusions: Daily Liraglutide as an add on therapy is effective in producing significant body weight reduction in obese adolescents with T1DM with tolerable minimal GIT side effects and without increase in hypoglycemic events.

OP082 / #326

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

DASIGLUCAGON CORRECTS POSTPRANDIAL HYPOGLYCAEMIA IN ROUX-EN-Y GASTRIC BYPASS-OPERATED INDIVIDUALS

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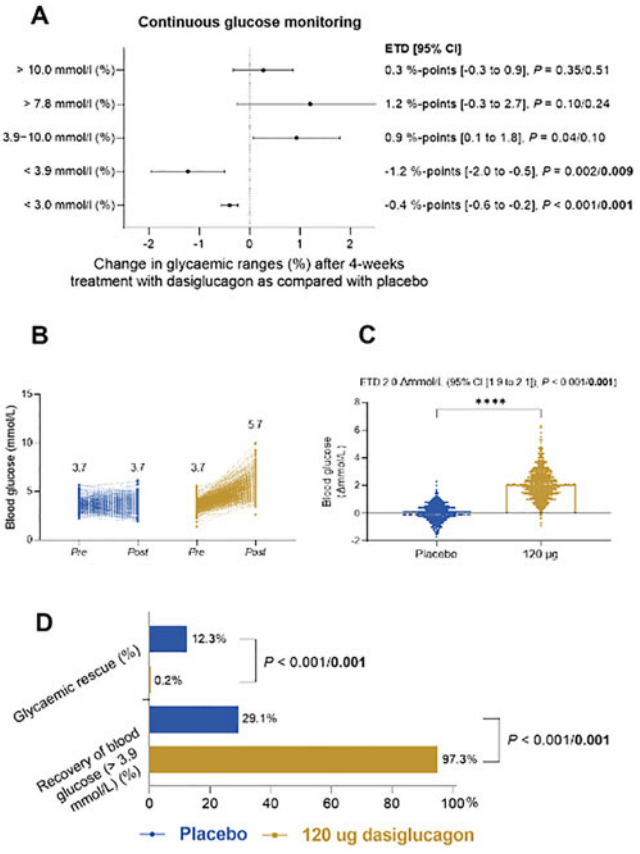
Background and Aims: Post-bariatric hypoglycaemia (PBH) is a debilitating complication following Roux-en-Y gastric bypass (RYGB) surgery affecting up to 75% of operated individuals, and is characterised by recurrent and frequent postprandial hypoglycaemic episodes; Currently, no effective medical therapy exists. Dasiglucagon is an aqueous stable glucagon analogue available in a ready-to-use pen for hypoglycaemia rescue administration. The aim of the study was to investigate the efficacy of 4 weeks of continuous glucose monitoring (CGM)-guided self-administration of dasiglucagon compared with 4 weeks placebo in reducing time in hypoglycaemia (<3.9 and <3.0 mmol/l).

Methods: Twenty-four RYGB-operated individuals with CGM-confirmed PBH (hypoglycaemia ≥3 times/week) participated in a proof-of-concept, double-blind, randomised, placebo-controlled crossover study and were instructed to self-administer 120 μg dasiglucagon when alarmed by the CGM (at plasma glucose <3.9 mmol/l) *and* after a confirmatory self-monitoring of blood glucose (SMBG) reading <3.9 mmol/l.

Results: Compared with placebo, treatment with dasiglucagon significantly reduced time in level 1 hypoglycaemia by 35% (−17.3 min/day 95% CI [−28.0 to −6.6], $p = 0.0028$) and time in level 2 hypoglycaemia by 55% (−5.7 min/day 95% CI [−8.1 to −3.4], $p < 0.0001$) (**Fig. A**). Furthermore, we observed correction of hypoglycaemia within 15 minutes in 401 of 412 dasiglucagon administrations as compared to 104 of 357 placebo



administrations (97.2% vs 29.1% recovery rate, $p < 0.0001$) (**Fig. B-D**). Dasiglucagon was well tolerated and had few adverse events, with nausea being the most frequent.

Conclusions: CGM-guided self-administration of dasiglucagon effectively corrected postprandial hypoglycaemia in RYGB-operated individuals and is a promising therapeutic avenue for the treatment of PBH.

OP083 / #623

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

HEDIA DIABETES ASSISTANT BOLUS CALCULATOR SIGNIFICANTLY DECREASES RISK OF HYPOGLYCEMIA: A REAL-WORLD NEW-USER RETROSPECTIVE COHORT STUDY

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Background and Aims: Individuals living with type 1 diabetes are at risk of long-term complications related to chronic hyperglycemia. Tight glycemic control is recommended but can increase the risk of iatrogenic hypoglycemia. Hedia Diabetes Assistant (HDA) is a bolus calculator that provides users with bolus insulin recommendations based on personalised settings. We aimed to investigate the effects of HDA on a known risk index of hypoglycemia.

Methods: In September 2022, user data was extracted from the HDA database. New users from 2019 to 2021 were included if they fulfilled the following criteria: Age ≥18 years old, ≥5 logs/1st week of use, and ≥1 log for glucose, carbohydrate, and insulin. The prespecified primary endpoint was change in Low Blood Glucose Index (LBGI) after 12 weeks of use. Secondary endpoints were changes in High Blood Glucose Index (HBGI) and eA1c. An exploratory endpoint was maintaining potential improvements of LBGI after 25 weeks. Repeated-measures mixed model with log-transformation was used.

Results: A total of 1,342 users were included. The mean age was 43.4 years (SD 14.7) with 52.3% being female. After 12 weeks, LBGI significantly improved from 0.73 to 0.61 (17% decrease, $P < 0.001$; Figure 1) with no significant changes in HBGI, and eA1c ($P = 0.547$ and $P = 0.594$, respectively). From week 12 to 25, LBGI decreased slightly from 0.61 to 0.55 (10%, $P = 0.107$).

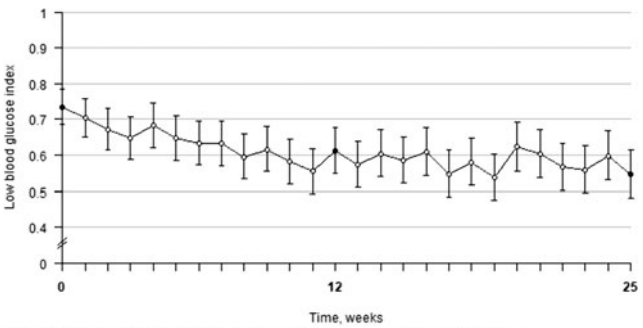

Figure 1: LBGI from baseline to week 25 for all users. Error bars indicate 95% CIs. The values are geometric means estimated from a repeated measure mixed model analysis.

Conclusions: Users of HDA experienced statistically significant improved LBGI after 12 weeks, which was successfully maintained after 25 weeks with no changes in HBGI and eA1c. These results suggest a decreased risk of hypoglycemia when using HDA.

OP084 / #336

Topic: ***AS15 Human factor in the use of diabetes technology***

VIRTUAL DIABETES SPECIALTY CARE – INDIVIDUALIZED TELEMEDICINE AND TECHNOLOGY SUPPORT

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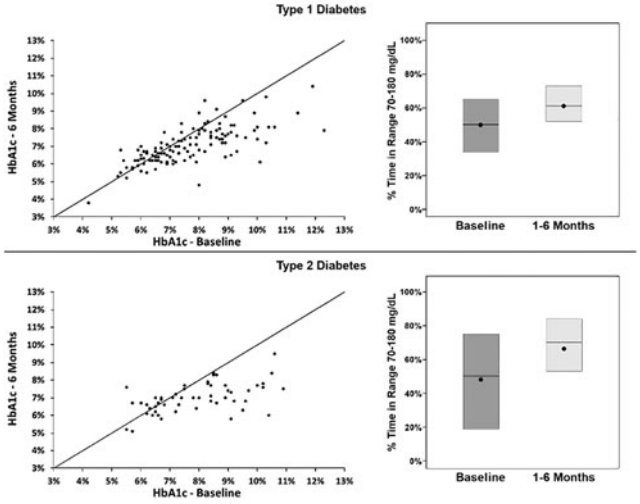
Background and Aims: The feasibility and efficacy of establishing a comprehensive care virtual diabetes clinic model including initiation and support for continuous glucose monitor (CGM) use was examined.

Figure. HbA1c at Baseline and 6 Months among Type 1 Diabetes and Type 2 Diabetes Participants. The point below the line of identity denote participants who had better HbA1c values at 6 Months when compared with Baseline. Percentages of Time in Range 70-180 mg/dL at Baseline and during 6 Months of follow-up among Type 1 Diabetes and Type 2 Diabetes Participants. Black dots denote mean values, horizontal lines in the boxes are medians, and the bottom and top of the boxes represent the 25th and 75th percentiles.



Methods: 234 adults ≥18 years old with type 1 diabetes (T1D; N = 160) or type 2 diabetes (T2D, N = 74) using basal-bolus insulin (73 pump, 161 multiple daily insulin injections) were assigned a certified diabetes care and education specialist to provide telehealth support including remote CGM training. Participants not using a Dexcom G6 CGM (N = 187) at enrollment were provided a Dexcom G6; current users (N = 47) continued use. Participants were followed for 6 months to assess CGM use, glycemic and quality of life outcomes.

Results: Mean HbA1c reduction from baseline to 6 months was 0.6% (P < 0.001)(T1D) and 1.0% (P < 0.001)(T2D). Mean glucose decreased from 183mg/dL to 165mg/dL (T1D) and 199mg/dL to 166mg/dL (T2D). Over 6 months, mean% time in range 70-180 mg/dL increased from 50% at baseline to 61% (T1D) and 48% to 66% (T2D); median use of CGM was 96% (T1D) and 94% (T2D). Glycemic outcomes improvements were observed in both current CGM users and those initiating CGM. Surveys indicated substantial benefit of CGM with reduced diabetes distress, and increased glucose monitoring satisfaction.

Conclusions: Virtual clinic support was successful in achieving sustained CGM use and improved glycemic and quality of life outcomes. This approach could substantially increase CGM adoption by people with diabetes using insulin and improve outcomes among current CGM users by eliminating barriers such as geography and access to specialty care.

OP085 / #603

Topic: ***AS15 Human factor in the use of diabetes technology***

AN INTERVENTION TO ADDRESS TREATMENT-RESISTANT HYPOGLYCAEMIA BECOMES COST-EFFECTIVE THROUGH IMPROVED QUALITY OF LIFE AND FEWER ADMISSIONS. THE HARPDOC RANDOMISED CONTROLLED TRIAL

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Background and Aims: Aim: to assess cost effectiveness of HARPdoc (Hypoglycaemia Awareness Restoration Programme for adults with type 1 diabetes (T1D) and problematic hypoglycaemia persisting despite optimised care), which addresses attitudinal barriers to hypoglycaemia avoidance, vs Blood Glucose Awareness Training (BGAT, psychoeducation not addressing cognitions) as adjunctive treatments for adults with T1D and treatment-resistant problematic hypoglycaemia in a randomised controlled trial.

Methods: Eligible adults were randomised to either intervention and followed for 24 months. Quality of life (QoL, EQ-5D-5L) was measured at baseline, 12 and 24 months; utilisation of health services (Client Services Receipt Inventory) at 12 and 24 months; time spent by educators by interview and costs from UK databases. Incremental net benefit (INB), HARPdoc over BGAT, at 12 and 24 months calculated as cost per QALY, differences adjusted for group clustering using a mixed-effects random intercepts model using Stata 17.

Results: Delivery costs for HARPdoc were higher (mean±SD £1697 ± 290 vs £541 ± 82) but EQ-5D-5L total scores were higher and service utilization lower with HARPdoc. Over 24 months, mean[95%CI] expected difference in QALYs +0.067 per participant [-0.024 to 0.155], equivalent to a gain of 24 days in full health over 24 months; expected difference in mean [95%CI] total cost (adjusted) -£194/participant [-£2498 to £1942]; adjusted difference in QALYs = -0.067/participant [-0.024 to 0.155], giving INBs £1,057 - £2,184 with 80-85% probability of cost-effectiveness at 24 months.

Conclusions: Addressing unhelpful health cognitions around hypoglycaemia in people with treatment-resistant hypoglycaemia likely achieves cost-effectiveness at 2 years, through improved QoL and reduced need for medical services

OP086 / #149

Topic: ***AS15 Human factor in the use of diabetes technology***

UNTANGLING THE BLOODY MESS OF MENSTRUAL CYCLE EFFECTS ON T1D MANAGEMENT: A SYSTEMATIC REVIEW

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Background and Aims: Almost half of all individuals living with type 1 diabetes (T1D) are pre-menopausal women. Although studies have reported that insulin sensitivity and glucose variability change throughout the cycle, the clinical evidence remains limited. This systematic review aims to gather all relevant clinical evidence on this topic, and to derive related aspects to be addressed in human factor engineering.

Methods: We searched three databases for articles on insulin sensitivity, the menstrual cycle, glycaemic variability, and T1D. We included studies which focused on in-vivo research, and excluded articles on other comorbidities, menopause, fertility, and hormonal therapy. Two researchers screened the articles and extracted the data independently.

Results: Of the 351 search results, 45 references were eligible for full-text assessment, of which ten were retained for data extraction. The sample sizes of the ten included studies ranged from 5 to 26 women with a total number of menstrual cycles ranging from 5 to 168. On average, the glucose level rose by >10% and the administered insulin up to 5% in the luteal phase compared to the follicular phase, whereas insulin sensitivity was lower in the luteal phase than in the follicular in three out of four studies reporting insulin sensitivity.

Conclusions: Our results suggest that insulin sensitivity and glucose level change throughout the menstrual cycle, increasing the burden associated with T1D management among pre-menopausal women. Development and implementation of cycle-related features should be addressed in human factor engineering and could alleviate this unmet need.

OP087 / #401

Topic: ***AS15 Human factor in the use of diabetes technology***

CONTINUOUS GLUCOSE MONITORING (CGM) THROUGHOUT GESTATION IN PREGNANT PATIENTS WITH AND WITHOUT GESTATIONAL DIABETES MELLITUS (GDM)

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Background and Aims: Comprehensive data on glucose metrics and patterns during pregnancy in pregnant patients without known diabetes is lacking. Whether or not CGM can identify GDM early in pregnancy is not known.

Methods: 760 pregnant patients ≥18 years old (mean age 33 ± 4 years, 74% White non-Hispanic) with HbA1c <6.5% (mean 5.2 ± 0.3%), no known diabetes, and gestational age <17 weeks wore a blinded CGM periodically or continuously during their pregnancy. Diagnosis of GDM was based on OGTT at 24-28 weeks.

Results: CGM differentiated participants subsequently diagnosed to have GDM (N = 55) and no GDM (N = 705) as early as 13-14 weeks of gestation. For those who did not develop GDM, mean glucose was highest in weeks 13-14 (103 ± 8 mg/dL) followed by a slight gradual decrease to 98 ± 8 mg/dL by 21-22 weeks and then stability until the time of the OGTT. Those developing GDM had a similar though higher pattern of mean glucose, 113 ± 11 mg/dL at weeks 13-14, decreasing to 106 ± 14 mg/dL in weeks 17-18 and then remaining similar until the OGTT (Figure). Median percent time >120 mg/dL was 36% versus 14% in weeks 13-14 in those with and without GDM, respectively (Figure). Predictive models for GDM showed that the area under the curve was 0.77 for 2nd trimester time >120 mg/dL exceeding 14.6%.

Conclusions: CGM can identify dysglycemia early in pregnancy, suggesting that it may be possible to diagnose GDM and initiate treatment much earlier than the current standard based on OGTT at 24-28 weeks.

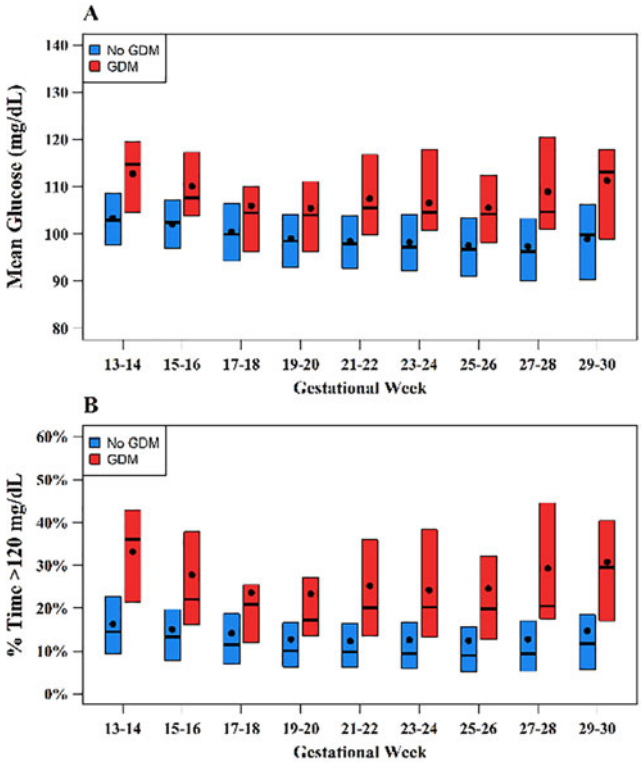

Figure 1. Boxplots of A) mean glucose and B) % time >120 mg/dL by gestational week and GDM status. Top and bottom of boxes represent the 75th and 25th percentiles, respectively. Black lines and dots in the middle of boxes represent the medians and means, respectively.

OP088 / #397

Topic: ***AS15 Human factor in the use of diabetes technology***

DIABETES-RELATED STIGMA AND DIABETES TECHNOLOGY USE AMONG US ADULTS WITH TYPE 1 AND TYPE 2 DIABETES

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Background and Aims: Four in five people with diabetes (PWD) have experienced some form of diabetes stigma including blame, shame, judgment, being treated differently, and self-stigma. The aim of this study was to explore the relationship between diabetes-related stigma and diabetes technology use.

Methods: 1,543 PWD (type 1 (T1D), n = 595; type 2 (T2D), n = 948) from the dQ&A US Adult Patient Panel completed an online survey (August 2022), receiving $10 USD for participating. Data included demographic and clinical characteristics, and study-specific items assessing diabetes stigma and technology use. Descriptive statistics compared responses by device use (pump/CGM: neither, either, both).

Results: Overall, participants reported that, in the US, diabetes comes with social stigma (T1D: 79%; T2D: 68%). Among those PWD not using a pump or CGM (n = 589), 20% reported that diabetes- and/or device-related stigma had at least a modest negative impact on their willingness to use technology. Among participants using a pump, CGM, or both (n = 954), experiences

suggestive of device-related stigma were reported by 30%, 37%, and 63% respectively. These experiences include unwanted attention or problems caused by alerts/alarms (20-53%), people staring or pointing at their device(s) (15-26%), and being asked to remove their device(s) for non-medical reasons (2-13%).

Conclusions: Our findings highlight the need to further explore the complex relationship between diabetes stigma and the use of diabetes technologies. Interventions are warranted to reduce diabetes stigma and its impacts.

OP089 / #874

Topic: ***AS15 Human factor in the use of diabetes technology***

SATISFACTION WITH MYSUGR IN THE INTERVENTION GROUP OF A RANDOMIZED CONTROLLED TRIAL

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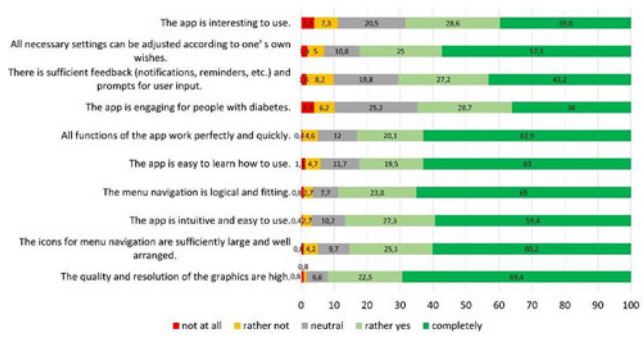
Background and Aims: The mySugr app is a digital tool for diabetes self-management. Its efficacy is being tested in a randomized controlled study (RCT). Satisfaction with the app was assessed in the intervention group receiving the app.

Methods: A total of 424 people were included in the RCT with 282 being randomized (2:1 randomization) to the intervention group using the app for 3 months (age: 51.2 ± 14.6 years; 13.1% type 1, 66.7% type 2, 20.2% gestational diabetes; diabetes duration: 9.1 ± 10.1 years; HbA1c: 7.06 ± 1.50%). Satisfaction with mySugr was assessed with an adapted version of the Mobile App Rating Scale (MARS). Mean MARS scores were calculated (range: 1-5) with higher scores indicating higher satisfaction.

Results: Overall satisfaction was very high with a mean MARS score of 4.3 ± 0.7. Responses to single items are shown in the figure. 64.7% of participants agreed that the app is appealing for people with diabetes and 82.5% agreed that the app is easy easy to use. Individualization of the app was rated very positively with 82.3% saying that all necessary settings can be adjusted to one's own needs. Satisfaction was highest in women with gestational diabetes (4.5 ± 0.5), followed by people with type 1 diabetes (4.3 ± 0.6) and people with type 2 diabetes (4.2 ± 0.7).

Conclusions: Participants in the intervention group that were randomized to using mySugr for 3 months and who have not used the app before the study were highly satisfied with the app. Satisfaction was high in all diabetes types with women with gestational diabetes having the highest satisfaction.



OP090 / #621

Topic: ***AS15 Human factor in the use of diabetes technology***

DO MODERN DIABETES TECHNOLOGIES BURDEN OR UNBURDEN PEOPLE WITH DIABETES?

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Background and Aims: To date, there is limited evidence whether modern technologies lead to a reduction in diabetes-related distress or to new burdens. We asked both people with diabetes (PwD) and diabetologists for their assessment.

Methods: 305 diabetologists (48% female, average age 53.7 years) and 2.417 PwD (47.5% female, 57.8% type 1 diabetes (T1D), 20.7% type 2 diabetes (T2D), 19.0% parents of children with diabetes; Ø 47.7 years) were asked via online surveys.

Results: Most of the diabetologists believe that for the majority of PwD (63.8%), diabetes related distress is reduced by modern technologies. However, they also believe that modern technologies cause new burdens in about one in four PwD (26,2%) due to, for example, being overwhelmed by technology, low digital literacy, disruptive alarms, skin irritation, or increased involvement with glucose levels. Also, most of the PwD has the opinion that diabetes technologies can significantly reduce the diabetes distress (64.1%). Among parents of children with type 1 diabetes this assessment is very strongly pronounced (75.8%), among PwT1D somewhat lower (64.8%), and among PwT2D significantly lower (49.6%). Overall, only 7% of PwD estimate that new diabetes-related distress will result from new diabetes technologies.

Conclusions: Most of the PwD and diabetologists perceive that diabetes technologies have the potential to reduce diabetes related distress. While PwD tend to estimate the risk of new burdens due to diabetes technologies as very low, diabetologists believe that about 1 in 4 PwD will face new burdens due to the technologies.

OP091 / #507

Topic: ***AS15 Human factor in the use of diabetes technology***

IN-DEPTH EXPERIENCE OF CGM USE: THEMATIC DOMAINS AND EMOTIONAL IMPLICATIONS

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Background and Aims: Continuous Glucose Monitoring (CGM) has been highlighted as a fundamental tool in diabetes care improving glycemic control and diabetes quality of life. In the context of a technological revolution, deepening users' subjective experiences is needed in order to promote a process of adjustment. For this reason, the present study aims at exploring the main experience domains of the use of CGM devices in the everyday life of persons with type 1 diabetes (T1D).

Methods: An online survey was conducted involving 85 persons with T1D (69% female), aged ≥18 years, and wearing a CGM sensor (usage >60% of the time). Answers to an open-ended question regarding the personal meanings of the CGM use were collected and analyzed through a computer-based text analysis which allowed the identification of thematic domains (Cluster Analysis).

Results: Five critical experience domains emerged respectively referring to: Concern about aesthetic factor (17.21%), Control of glycemic monitoring (27.24%), Relief about overcoming glucometer (25.68%), Anxiety connected to the fear of damaging the sensor (7.78%), Satisfaction regarding benefits of sensor usage (21.79%).

Conclusions: Results highlight the impact of CGM on quality of life and perceived sense of security in diabetes management for persons with type 1 diabetes. Negative aspects concerning aesthetic issues and fear of damaging the sensor emerged, enlightening potential emotional discomfort and barriers to wearing CGM.

OP092 / #399

Topic: ***AS15 Human factor in the use of diabetes technology***

EFFECT OF CHANGE IN GLUCOSE DURING EXERCISE ON POST-EXERCISE GLYCEMIA IN YOUTH IN THE TYPE 1 DIABETES EXERCISE INITIATIVE PEDIATRIC (T1DEXIP) STUDY

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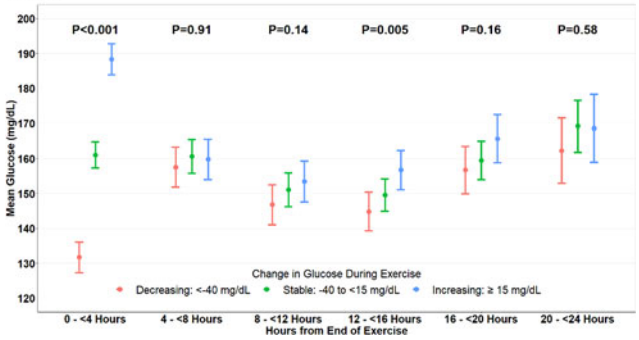
Background and Aims: Providers discuss glucose changes during exercise in youth with type 1 diabetes (T1D) during clinical care, but little is known about how these changes impact glucose in the 24-hour period following activity. To explore this question, we used data from the T1DEXIP, a U.S. observational study of adolescents.

Methods: Participants wore a continuous glucose monitor and an activity monitor for 10-days and self-reported daily exercise from their self-determined routine. We categorized change in sensor glucose during exercise into three bins based on Δglucose

Figure 1. Mean Glucose Post Exercise by Change in Glucose During Exercise
Dots indicate the least-squares means and bars are the 95% confidence interval of the mean glucose at each post exercise interval stratified by change in glucose during exercise. P-values are computed at each post exercise interval to determine if change in glucose during exercise has an effect on post exercise time in range.



(decreasing [Δ<-40mg/dL], stable [Δ-40,<15 mg/dL], increasing [Δ≥15 mg/dL]). We assessed glucose post-exercise in 4-hour bins over a 24-hour period adjusting for pre-exercise glucose level and exercise time of day.

Results: Among adolescents (N = 237) ([mean±SD] age = 14 ± 1years; T1D duration = 5.4 ± 3.9years; $HbA1_C$ = 7.1 ± 1.3%), mean glucose 0-4hours post-exercise was lowest for those with decreasing glucose during exercise as compared to those with stable or increasing glucose during exercise (see figure). There were no group differences in mean glucose levels 4-12 hours post-exercise, however, 12-16 hours post-exercise, mean glucose was lowest for youth with decreasing glucose during exercise. Percent of nights with a hypoglycemic event was 3%, 4%, and 3% for decreasing, stable, and increasing glucose during exercise groups, respectively.

Conclusions: Initial results suggest youth with decreasing glucose levels during exercise exhibit lower glycemic levels post-exercise with no greater risk of hypoglycemia. Future analyses will explore how alterations in insulin delivery and carbohydrate intake may also affect glucose patterns.

OP093 / #834

Topic: ***AS15 Human factor in the use of diabetes technology***

IMPACT OF HYBRID CLOSED LOOP USE ON DIABETES MANAGEMENT BURDEN AND QUALITY OF LIFE IN PATIENTS WITH TYPE 1 DIABETES (T1D). THE IMPLIQUE STUDY

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Background and Aims: Hybrid closed loop (HCL) systems enable improved glycemic control and reduced diabetes self-

management burdens. However, few studies have explored psychosocial aspects of HCL usage.

Methods: A French longitudinal, multicentric, prospective study was conducted to assess in T1D patients under insulin pump and continuous glucose monitoring (CGM), the impact of a closed loop system on diabetes burden and quality of life.

Results: Between September 2021 and January 2022, 257 individuals were enrolled including 202 adults. Mean age was 57 years (± 14) and 58% were female. HbA1c was 7.5 ± 0.9% and the mean percentage of time in range was 57 ± 14% with a glycemic variability coefficient at 37% ± 5%. At baseline, PAID score (burden) was 47 with 65% of patients having emotional distress. Quality of life was impaired in 41.5% of patients with an ADDQOL score of -0.6 (-3 à +3), 64% mentioning diabetes causality. Fatigue score was significant in 48%, mild to severe anxiety in 25% and poor sleep in 51.8%. Under HCL, PAID score raises by 14.4 % at 3 months and 14.8 % at 6 months ($p < 0.001$) while half patients had persistent emotional distress at both times. ADDQOL score raised by 1.2 at 3 months and 1.3 at 6 months ($p < 0.001$) while quality of life remained impaired in 30% of patients.

Conclusions: Six-months use of HCL use reduces diabetes burden and improves quality of life in adults with T1D initially under insulin pump and CGM.

OP094 / #168

Topic: ***AS15 Human factor in the use of diabetes technology***

THE EFFECTS OF COMPETITION ON GLYCEMIA DURING EXERCISE IN YOUTH IN THE TYPE 1 DIABETES EXERCISE INITIATIVE (T1DEXIP) PEDIATRIC COHORT

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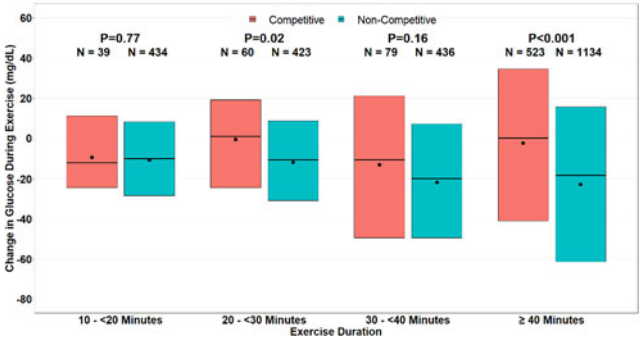
Background and Aims: Youth with type 1 diabetes (T1D) report higher glucose levels in competitive exercise events. We used data from the Type 1 Diabetes Exercise Pediatric (T1DEXIP) study to compare the acute glycemic responses to competitive and non-competitive exercise events in a real-world setting.

Methods: Adolescents with T1D (n = 237; [mean ± SD] age = 14 ± 1 years; HbA1c = 7.1 ± 1.3%; 41% female; diabetes duration = 5.4 ± 3.9 years; 16% on MDI, 31% on insulin pump, and 53% on Hybrid Closed Loop) wore a Dexcom G6 continuous glucose monitor (CGM) and an activity monitor (Garmin vivosmart 4) for 10 days and logged all personal exercise events as competitive or non-competitive. Adolescents logged 701 competitive and 2,427 non-competitive exercise events.

Results: Baseline glucose (162 ± 68 mg/dL vs. 163 ± 65 mg/dL), baseline heart rate (95 ± 16 beats/min vs. 94 ± 16 beats/min), rate of change in glucose before exercise (-0.1 ± 1.7 mg/dL/min vs. -0.0 ± 1.6 mg/dL/min) and estimated insulin on board (0.06 ± 0.06 U/kg vs. 0.06 ± 0.05 U/kg) were similar between competitive and non-competitive events. However, the change in glucose during competitive events was less than non-competitive events (-4.0 (-8.5, 0.5) vs. -18.1 (-21.0, -15.2) mg/dL; $P < 0.01$), particularly in longer exercise sessions (Figure).

Figure Change in Glucose During Exercise by Duration of Exercise and Competition Status
One box per exercise duration stratified by competition status. Black dot represents mean; line in boxplot represents median. Box limits represent the 25th and 75th percentiles.



Conclusions: Competitive exercise events have a different pattern of glycemic change than non-competitive events in youth with T1D. Future analysis of the T1DEXIP dataset will examine other factors underlying the attenuated drop in glucose during competitive exercise in youth with T1D.

OP095 / #520

Topic: ***AS16 Trials in progress***

THE ELSA STUDY - SCREENING CHILDREN FOR TYPE 1 DIABETES IN THE UK (SOONER WE SCREEN, SOONER WE CAN INTERVENE)

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Background and Aims: Multiple autoantibody testing identifies children with pre-symptomatic type 1 diabetes (T1D) and is able to stratify those at risk over a 10-15-year period. Identifying children at risk reduces the rates of DKA at presentation and allows them to participate in clinical trials for T1D prevention. T1D general population testing programmes have been trialled in the US and Germany and found a pre-symptomatic T1D rate of 0.3%, achieved a reduction in diabetic ketoacidosis rates from 20% to 5%, and were considered acceptable to families. Here we outline our plans for developing a UK based system for testing for pre-symptomatic T1D in the general population.

Methods: The ELSA-1 study has undertaken interviews with families and stakeholders to explore perspectives on screening and

address barriers to uptake. The ELSA study opened in July 2022 and will run until February 2025. ELSA aims to recruit 20,000 children aged 3-13 years and is screening for autoantibodies via dried blood spot kits. Stage of T1D will be determined using an oral glucose tolerance test. Individuals positive for one or more autoantibody will attend an education session and will be offered follow-up in INNODIA for earlier identification of overt T1D and to facilitate entry into trials for T1D prevention. Families will then be invited to qualitative interviews to explore their experiences of screening.

Results: In progress.

Conclusions: The outcomes of ELSA will determine feasibility and acceptability of paediatric general population screening for T1D in the UK. The ELSA study supports progress towards establishment of UK national screening for T1D.

OP096 / #637

Topic: ***AS16 Trials in progress***

STEM CELL-DERIVED, FULLY DIFFERENTIATED ISLET CELLS FOR TYPE 1 DIABETES

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Background and Aims: We report the first two patients administered VX-880, an investigational allogeneic stem cell-derived, fully differentiated, pancreatic islet cell replacement therapy.

Methods: Both patients had T1D complicated by impaired awareness of hypoglycemia and severe hypoglycemia (≥2 severe hypoglycemic events [SHEs] in year prior to screening) and undetectable fasting and stimulated C-peptide. At baseline, Patient 1 had HbA1c of 8.6% with 40.1% time-in-range and total daily insulin dose of 34.0 units. Patient 2 had HbA1c of 7.5% with 35.9% time-in-range and total daily insulin dose of 25.9 units.

Results: After a single VX-880 infusion at half target dose, both patients had glucose-responsive insulin production as measured by mixed-meal tolerance test; HbA1c and total daily insulin decreased in parallel. At Day 270, Patient 1 was insulin independent with HbA1c of 5.2% and 99.9% time-in-range. At Day 150, Patient 2 had improved HbA1c (7.1%) and 51.9% time-in-range taking 30% less total daily insulin. VX-880 was generally safe and well tolerated; most adverse events (AEs) were mild or moderate and there were no serious AEs considered related to VX-880. Patient 1 had 6 SHEs (not serious and not related to VX-880) during the perioperative period and none after Day 35; Patient 2 had no SHEs. The safety profile was consistent with the immunosuppressive regimen used in the study and the perioperative period.

Conclusions: These unprecedented results, at half target dose, are the first evidence stem cell-derived islets can restore insulin production and glycemic control in patients with T1D.

OP097 / #611

Topic: ***AS17 COVID-19 and Diabetes***

PRE-VACCCINATION GLUCOSE TIME IN RANGE POSITIVELY CORRELATES WITH ANTIBODY RESPONSE AFTER SARS-COV2 MRNA VACCINE BNT162B2 IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Poor glucose control has been associated with increased mortality in COVID-19 patients with type 1 diabetes (T1D). The aim of this study was to assess the effect of glucose control on antibody response to the SARS-CoV2 vaccine BNT162b2 in T1D.

Methods: We studied 26 T1D patients scheduled to receive two doses, 21 days apart, of BNT162b2, followed prospectively for six months with regular evaluation of SARS-CoV2 antibodies and glucose control. IgG to spike glycoprotein were assessed by ELISA, and serum neutralization by a live SARS-CoV2 assay (Vero E6 cells system). Continuous glucose monitoring, including time in range (TIR) and above range (TAR), and HbA1c were collected. The primary exposure and outcome measures were pre-vaccination glucose control, and antibody response after vaccination, respectively. IgG area under the curve (AUC) assessed the overall antibody response along the six-months study timeframe.

Results: Baseline TIR and TAR strongly correlated with peak-IgG, as well as with the IgG-AUC (TIR: $r=0.75$; $p=0.02$; TAR: $r=-0.81$; $p=0.008$). Furthermore, pre-vaccination TIR was associated with serum neutralization potency ($r=0.49$; $P=0.042$). Glucose control along the study timeframe was also associated with IgG response as showed by the correlation between time-dependent mean of TIR and TAR and IgG-AUC (TIR: $r=0.93$, $P<0.0001$; TAR: $r=-0.84$, $P<0.0001$). Pre-vaccination HbA1c was inversely related to peak-IgG, although the relationship did not reach statistical significance ($r=-0.33$; $P=0.14$).

Conclusions: Our findings indicate a strong relationship between glucose control and antibody response after SARS-CoV2 vaccination, highlighting the importance of achieving well-controlled blood glucose for COVID-19 prevention.

OP098 / #825

Topic: ***AS17 COVID-19 and Diabetes***

DIABCOVID A NEW TYPE OF DIABETES FOLLOWING SARS COV2 INFECTION?

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Background and Aims: During the SARS COV 2 pandemic, the number of cases of unrecognized diabetes increased in those hospitalized for pneumonia. It has been hypothesized that some forms of diabetes not classified as classic are attributable to SARS COV 2 infection.

Methods: We studied the prevalence of diabetes in those admitted to our Covid Hospital from January 2021 to September 2022. A total of 1200 subjects studied by cross-analysis of hospital discharge forms with diabetes mellitus and final therapy as research item.

Results: The prevalence of diabetes mellitus was 2.16%. Of the subjects diagnosed with diabetes, 26.9% were not classifiable as type 1 or type 2 and the condition of diabetes mellitus was not previously known. HbA1c values were not statistically (7,8 ± 0,95 vs 8,1 ± 1,1 p = NS) different among subjects with diabetes and autoimmune markers were not present. Fasting C-peptide levels (ng/ml) were significantly lower (0,8 ± 0,23 vs 2,3 ± 0,8 $p < 0.05$) in those with not previously known diabetes, 57.2% were discharged on insulin therapy. and continued it after 92 ± 18 days of follow-up.

Conclusions: The interrelationship between COVID-19 and diabetes remain uncertain and researchers hope to understand whether Covid-19 causes a new form of diabetes or more simply a stress response that triggers classic diabetes. In our experience those individuals with fasting C-peptide levels lower than usual obeserved in Type 2 diabetic subjects continued insulin theraphy for a limited time. They could be a new entity of diabetes classification but longitudinal data are further required to confirm what we can call DIabCovid.

OP099 / #565

Topic: ***AS18 Other***

LATE HYPOGLYCEMIA AFTER INSULIN INJECTION IS RELATED TO INJECTION TIME. AN INSULCLOCK® CONNECTED INSULIN CAP-BASED REAL-WORLD STUDY

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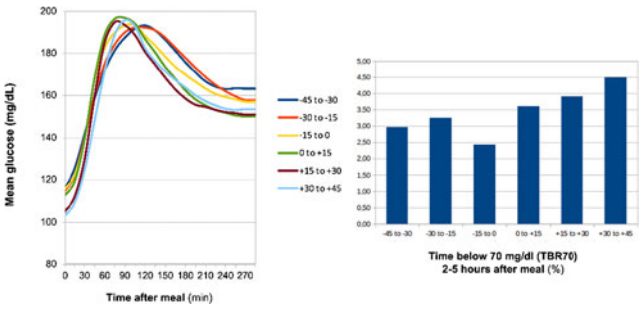
Background and Aims: Matching insulin injection time with meals to fit the optimal postprandial glucose dynamics is a daily challenge for people with type 1 diabetes (T1D) using a multiple daily injection (MDI) regimen. The study aimed to analyze the best balance between postprandial hyperglycemia excursion (PHE) and late postprandial hypoglycemia (LPH) risk according to the time of insulin injection.

Methods: Real-world (RW), retrospective study in T1D using MDI. Five hours of paired CGM and automatically tracked rapid-acting insulin injections data was collected from the connected insulin pen cap *Insulclock®* users. Meal events were identified using the ROC detection methodology. Postprandial glucometrics of PHE and LPH (2-5 hours after a meal) were evaluated using 15-minute periods around the meal, starting from -45 to +45 minutes.

Results: Meal glycemic excursions (n = 2784) were analyzed in 82 people. In 63% of meals, insulin was injected after the meal started. Higher PHE (mean glucose amplitude, mg/dl) was observed according to injection time: -45/-30: 77, -30/-15: 77; -15 / 0: 78, 0/+15: 84; +15/+30: 90, and +30/+45: 93 (p 0.017). LPH risk also increased with injections after meals TBR70 (%) : -45/-30: 2.9, -30/-15: 3.2, -15 /0: 2.4, 0/+15: 3.6, +15/+30: 3.9, and +30/+45: 4.5 ($p < 0.01$). The PHE continues five hours after meals. The best balance between PHE control and LPH risk is injecting -15 to 0 minutes before meals.

Conclusions: The timing of insulin injection is related to postprandial hyper and hypoglycemia. The use of a connected insulin pen cap is a suitable option to describe this link better.



OP100 / #688

Topic: ***AS18 Other***

RACIAL-ETHNIC DISPARITIES IN HBA1C BY BMI CATEGORY IN TYPE 2 DIABETES POPULATION AT AN ACADEMIC MEDICAL CENTER

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Background and Aims: Individuals of minoritized racial-ethnic populations, specifically those who are non-Hispanic Black (NHB) and Hispanic, often have higher HbA1c than their non-Hispanic White (NHW) counterparts. Additionally, higher

Table 1. HbA1c in Different Racial/Ethnic Groups with T2D by BMI

BMI Group	Race/ethnicity	N	Percent	Mean	SD	Range	F	Difference between groups (p value)
Underweight	NHW	270	69.2	6.85	1.68	4.3 – 13.9	-	NHW vs NHB (ns)
(<18.5 kg/m^2)	NHB	110	28.2	6.73	2.06	4.2 – 13.9	-	NHW vs H (p = 0.044)*
	H	10	2.6	8.25	2.28	5.4 – 13.2	-	NHB vs H (p = 0.031)*
	Total	390	100	6.85	2.08	4.2 – 13.9	3.23	Between all (p = 0.041)**
Normal	NHW	3710	74.5	6.89	1.59	3.5 – 16.1	-	NHW vs NHB (ns)
(18.5-25.0 kg/m^2)	NHB	1060	21.3	6.89	1.86	4.0 – 16.4	-	NHW vs H (p < 0.000)*
	H	210	4.2	8.41	2.63	4.6 – 17.8	-	NHB vs H (p < 0.000)*
	Total	4980	100	6.95	1.94	3.5 – 17.8	79.83	Between all (p < 0.000)**
Overweight	NHW	6700	73.6	7.08	1.63	3.4 – 20.3	-	NHW vs NHB (p < 0.000)*
(18.5-25.0 kg/m^2)	NHB	1830	20.1	7.26	1.99	3.4 – 17.3	-	NHW vs H (p < 0.000)*
	H	570	6.3	7.97	2.21	4.5 – 15.7	-	NHB vs H (p < 0.000)*
	Total	9100	100	7.17	2.10	3.4 – 20.3	70.93	Between all (p < 0.000)**
Obese	NHW	6120	52.5	7.46	1.76	3.4 – 16.7	-	NHW vs NHB (p = 0.016)*
(>25.0 kg/m^2)	NHB	4550	39.0	7.36	1.92	3.9 – 18.5	-	NHW vs H (p < 0.000)*
	H	990	8.5	7.82	2.11	4.1 – 15.3	-	NHB vs H (p < 0.000)*
	Total	11660	100	7.45	1.85	3.4 – 18.5	25.12	Between all (p < 0.000)**

Significance level at p = 0.05. *Significant differences as per Tukey HSD post-hoc. ** Significant differences as per ANOVA.

BMI (>25.0kg/m^2) is associated with higher HbA1c in individuals with type 2 diabetes (T2D). The goal of this analysis was to better understand relationships between HbA1c and race/ethnicity by BMI group in individuals with T2D at an academic medical center.

Methods: This retrospective study used de-identified data from electronic medical records (TriNetX, LLC) for a post hoc analysis (ANOVA and Tukey HSD tests) of HbA1c and race/ethnicity by BMI in patients (ages ≥14) with T2D.

Results: Significant differences in HbA1c between the three most representative racial-ethnic groups overall were discovered in the Underweight ($p = 0.041$) and Normal, Overweight, and Obese groups (all $p < 0.000$) (see Table 1). Across all BMI cohorts, HbA1c was significantly higher in Hispanic individuals compared to NHW (Underweight: $p = 0.044$; Normal/-Overweight/Obese: all $p < 0.000$) and NHB individuals (Underweight: $p = 0.031$; Normal/Overweight/Obese: all $p < 0.000$). Within the Underweight and Normal BMI groups, NHW and NHB individuals had comparable HbA1c. For the Overweight group, NHB individuals had higher HbA1c than NHW individuals ($p < 0.000$). In the Obese group, NHW individuals had higher HbA1c than NHB individuals ($p = 0.016$).

Conclusions: Among patients with T2D across all BMI groups at this center, the most prominent disparities in glycemic control (HbA1c) persist among Hispanic individuals when compared to NHW and NHB populations.

OP101 / #416

Topic: ***AS18 Other***

RISK OF NEW-ONSET STROKE IN PATIENTS WITH TYPE 2 DIABETES WITH CHRONIC KIDNEY DISEASE ON SGLT-2 INHIBITOR USERS: A POPULATION-BASED COHORT STUDY

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Background and Aims: Patients with chronic kidney disease (CKD) are at substantially higher risk for developing stroke than the general population. Clinical studies have investigated the effects of sodium-glucose co-transporter-2 inhibitor (SGLT-2I) use on the development of new-onset stroke (NOS) in patients with type 2 Diabetes (T2D) with CKD, but the findings are inconsistent. This study aimed to examine the association between SGLT-2I use and NOS risk in patients with T2D with CKD.

Methods: We conducted a nationwide retrospective cohort study using the Taiwan Health Insurance Review and Assessment Service database (2009–2018). The primary outcome was the risk of incident dementia by estimating hazard ratios (HRs) and 95% confidence intervals (CIs). Therefore, multiple Cox regression modeling was conducted to analyze the association between SGLT-2I use and NOS risk in patients with T2D with CKD.

Results: In a cohort of 54,099 patients with T2D with CKD using SGLT-2I and 64,900 participants not using SGLT-2Is, 3,208 and 2,890 NOS events were recorded, respectively. There was an increased risk of NOS for SGLT-2I users (adjusted HR 1.17, 95% CI 1.13–1.21) compared with non-SGLT-2I users. Results for the propensity score-matched and subgroup analysis showed similar results except that patients with hyperlipidemia.

Conclusions: SGLT-2I therapy may effectively increase NOS risk in patients with T2D with CKD. More studies are needed to credibly evaluate the effects of SGLT-2I therapy on NOS prevention in patients with T2D with CKD.

OP102 / #509

Topic: ***AS18 Other***

RESIDUAL SECRETION OF C-PEPTIDE IN TYPE 1 DIABETES MELLITUS: WHAT IS ITS METABOLIC IMPACT?

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Background and Aims: Residual C-peptide secretion, an indirect measure of endogenous insulin secretion, has been associated with better clinical outcomes. The purpose of this work was to estimate the effect, in T1DM patients, of measurable C-peptide on different CGM metrics and complications.

Methods: Retrospective descriptive study of 112 T1DM patients under intensive insulin therapy, divided into individuals with non-detectable (< 0,05 ng/ml) *vs* detectable (≥ 0,05 ng/ml) C-peptide. Data were analysed using SPSS v.27. Adjustment for covariates was assessed via linear or logistic regression for continuous or binary outcomes, respectively. Results were considered significant if $p < 0.05$.

Results: Median age at diagnosis and duration of diabetes was 22 (12-34) and 18.5 (12-29) years, respectively. Patients with detectable C-peptide had shorter disease duration (14 [9-24] *vs* 20 [14-32] years, $p = 0.004$) and older age (27.5 [16.5-38.5] *vs* 17.5 [9.8-28.8] years, $p = 0.002$). After adjustment for covariates (sex, disease duration, BMI and use of CSII), preserved C-peptide was associated with lower TAR ($a\beta = -11.03$, $p = 0.002$), GMI ($a\beta = -0.55$, $p = 0.024$), average glucose ($a\beta = -14.48$, $p = 0.045$) and HbA1c ($a\beta = -0.41$, $p = 0.035$). A statistically significant higher TIR was present in patients with measurable C-peptide, even before adjustment ($\beta = 7.13$, $p = 0.044$ *vs* $a\beta = 11.42$, $p = 0.001$). No associations were found with TBR, CV and acute and chronic complications.

Conclusions: Persistent C-peptide secretion in T1DM patients was associated with significantly better metabolic control translated into different metrics, namely TIR, TAR, GMI, and HbA1c.

OP103 / #1021

Topic: ***AS18 Other***

THE ANTIBODY DETECTION ISRAELI RESEARCH (ADIR)- A GENERAL POPULATION SCREENING PROGRAM

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Background and Aims: About 80% of the children diagnosed with T1D have multiple islet autoantibodies (IA) before age 5, with an estimated progression rate to symptomatic diabetes of about 84% by 15 years. An efficient general population screening program based on these antibodies will identify children at risk of developing diabetes during childhood, enable caregivers to prepare at-risk children and their families for future insulin treatment, prevent DKA episodes upon clinical presentation, and aid in the search for an effective therapy for T1D.

Methods: On October 2021, we began recruiting children to the Antibody detection Israeli Research (ADIR) supported by the JDRF. The ADIR study aims to screen 20,000 children aged 9-18 months all over Israel for the presence of IA. The infrastructure of ADIR includes 29 community-based screening sites, 5 diabetes centers, a central laboratory dedicated to the study, and a coordinating center. Uniquely for a general population screening program, the assay used to detect IA is the innovative Antibody Detection by Agglutination PCR (ADAP).

Results: As of September 2022, more than 2500 children were enrolled in the study. Nine children, representing 0.4% of the cohort, were found to be at risk for developing diabetes according to the study's criteria (multiple IA or a single IA and additional risk factors). Further data about the ADIR study will be presented.

Conclusions: The ADIR is an ongoing general population screening program. The percentage of children at risk of developing diabetes in the study is as previously described in the American and European populations. Nonetheless, the young age of detection of these children is encouraging regarding the screening technology and our ability to prevent DKA.

ATTD 2023 E-Poster Abstract Presentations

EP001 / #584

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

SMART INSULIN THERAPY INITIATION IMPROVES GLUCOSE CONTROL IN INSULIN-NAÏVE SUBJECTS WITH TYPE 2 DIABETES

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Background and Aims: We recently developed a machine learning model to predict basal insulin needs from anthropometric characteristics and few plasma measurements, in type 2 diabetes (T2D) subjects (Bonet et al., DTM 2022). In individuals with high insulin need (HIN), the *standard* initial insulin dose (IID), based on ADA guidelines, may lead to long time to reach the blood glucose (BG) target. To overcome this limitation, here we present a *smart* IID strategy assessing possible benefits and risks on BG control during insulin titration period.

Methods: Ninety insulin-naïve subjects of the Padova T2D simulator were classified as subjects with HIN (n = 33, of which 30 were *true positive*, and 3 *false positive*) and low insulin need (LIN, n = 57), using the machine learning model. HIN subjects underwent two 52-week trials to titrate them to basal insulin degludec towards the BG target of 70-90 mg/dL, starting from either *standard* or *smart* IID. To assess effectiveness and safety of *smart* IID, we compared time to reach BG target (T_{OBG}), time in range 70-180 mg/dL (T_{ir}), time below 70 mg/dL (T_{b70}), and cumulative number of hypoglycemic events (NH) in the two experiments.

Results: Compared to *standard* IID, *smart* IID reduced T_{OBG} of about 40 days (p-value <0.001) and significantly increased T_{ir} (p-value <0.001), without worsening T_{b70} and NH in *true positive* subjects. No statistically significant differences were observed in *false positive* subjects (Figure 1).

Conclusions: Using a *smart* IID in insulin-naïve T2D subjects with HIN allows a faster achievement of BG target, without increasing the risk for patients.

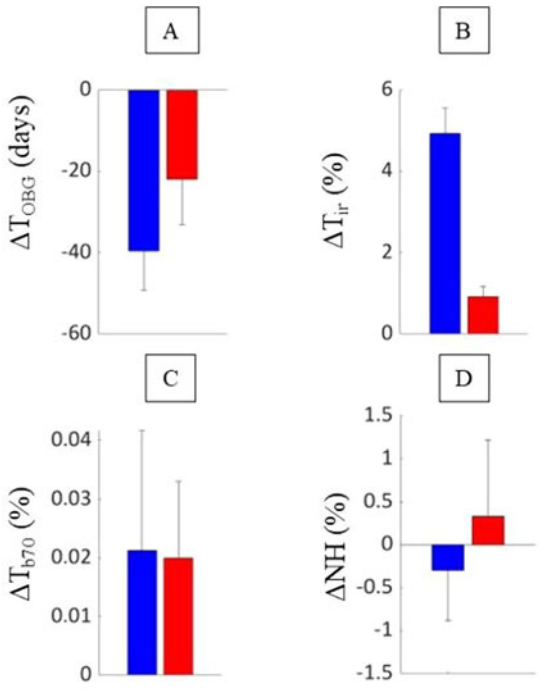

Figure 1. Absolute deviation of time to reach BG target (ΔT_{OBG}, A), percent time in range 70-180 mg/dL (ΔT_{ir}, B), time below 70 mg/dL (ΔT_{b70}, C), and cumulative number of hypoglycemic events (ΔNH, D) obtained in true positive (blue bars, n=30) and false positive (red bars, n=3). Absolute deviation was calculated as difference between the same outcome obtained when simulating smart IID and standard IID. Values are reported as mean ± standard error.

EP002 / #338

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

MACHINE LEARNING TO DETECT MEALS AND PHYSICAL ACTIVITIES FROM HISTORICAL DATA OF PEOPLE WITH TYPE 1 DIABETES IN FREE LIVING

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Background and Aims: People with Type 1 diabetes (T1D) often exhibit behavioral patterns in their meal consumption and physical activities. Detection of events that affect glucose homeostasis and estimation of their properties provide valuable information in developing glucose regulation policies. Most artificial pancreas systems use model predictive control technology and awareness of habitual disturbance pattern (meals, exercise) will increase the accuracy of predicted future glucose trajectory and enable more precise insulin dosing.

Methods: Continuous glucose monitoring (CGM) and insulin infusion pump data are used in supervised learning of recurrent

neural networks with long short-term memory (RNN with LSTM) to predict meals, exercise, and their concurrent occurrences. A framework to readily handle the missing values in the CGM data and unreported meals and physical activities is developed. Signal reconciliation and outlier removal techniques are used to improve the data fidelity, and feature variables are generated from the preprocessed signals to aid classification. Tidepool dataset donated by people with T1D in free living is used.

Results: The RNN with LSTM and 1D convolution has the highest overall prediction accuracy of 94.58%, and accuracies for each class as 98.05% for meals, 93.42% for exercise, and 55.56% for concurrent meal-exercise events. The detection of concurrent occurrences was challenging as the events affect glycemia in opposing directions, though the net effect of glycemia can be moderate.

Conclusions: Detection of meals and exercise from CGM and insulin pump data enable identification of the behavioral patterns in people with T1D and improve insulin dosing by explicitly considering the glycemic effects of future disturbances.

EP003 / #432

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

MACHINE LEARNING APPROACH TO IDENTIFY TEMPORAL PATTERNS IN INSULIN NEEDS BEYOND CARBOHYDRATES FOR PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Many factors impact insulin needs in Type 1 Diabetes (T1D). Finding the correct insulin dose and time remains a complex task. We aim to better understand factors that impact insulin needs beyond carbohydrates by learning from an automatic insulin delivery system (AID). The better we understand factors impacting insulin needs, the more we can contribute to data-driven decision-support systems for T1D management.

Methods: In the study, we utilise the OpenAPS Commons dataset collected in real-life conditions of people with T1D. Intensive pre-processing combined with time series techniques are applied to find temporal patterns when insulin on board (IOB) does not follow known factors such as carbohydrates on board (COB) and blood glucose readings (BG). This would suggest that insulin needs were different from those supplied. The various time series techniques implemented to identify such patterns include matrix profile, multi-variate clustering as well as statistical methods.

Results: Using these techniques, we found the following patterns: months where IOB is higher without COB increasing and vice versa; BG increasing hours after mealtimes IOB and COB decreasing; BG increasing at nighttime when COB is zero. We also found that these patterns vary from individual to individual.

Conclusions: These are patterns that cannot be explained by carbohydrates alone. However, if and how these patterns contribute to considering new factors for insulin dosing decision-making in T1D remains a question to be answered together with medical experts as well as the community of people with T1D. Furthermore, we are planning more research into correlations and causalities behind these patterns.

EP004 / #885

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

USE OF TECHNOLOGY FOR LOW SOCIOECONOMIC STATUS COMMUNITY SCREENING OF DIABETIC RETINOPATHY

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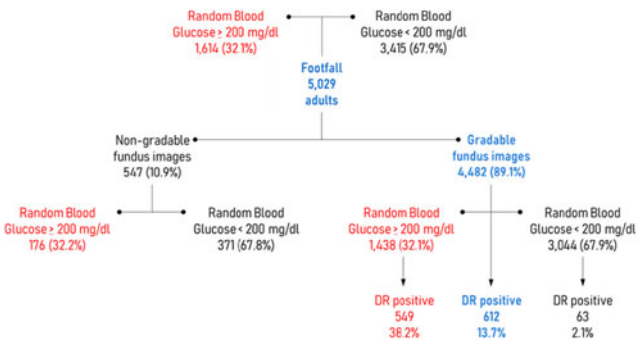
Background and Aims: Studies have reported socioeconomic status (SES) inequalities in diabetes care. The prevalence of DR in Indian diabetic population is 21.7%[1]. Early screening is the first step to avoid this disease from advancing to expensive treatment options or even permanent loss of vision. The study evaluates the effectiveness of an affordable and accesible artificial intelligence based technology for screening of diabetic retinopathy.

Methods: We conducted a month-long low-SES community screening using a survey questionnaire, Random Blood Glucose (RBG) test, Artelus automatic non-mydriatic fundus camera and Artelus Artificial Intelligence (AIDRSS). 5,029 adults were screened. Based on our survey findings, only 15.2% knew their diabetic status. 93.3% of the total screened adults were unaware of what microvascular complications are and that uncontrolled diabetes could lead to permanent blindness. 32.1% had elevated RBG, but most of them were not taking any medications and were unaware of their diabetic status.

Results: Images for 4,482 adults were gradable. The prevalence of DR in general adult population was 13.7% (DR1 = 9.16%, DR2 = 4.40%; Referable DR: DR3 and DR4 = 0.14%) and the prevalence of DR in patients with hyperglycemia was 38.2%, possibly explained by the lack of awareness and knowledge about diabetes. The Artelus AIDRSS performed well with overall 92% sensitivity and 88% specificity; and 100% sensitivity in detecting referable DR when compared with screening by a retina specialist.

Conclusions: Artelus Automatic fundus cameras and Artelus AIDRSS (DRISTi) can minimize requirement of trained human resource and improve accessibility, affordability, accuracy, ease and speed, hence can help reduce burden of blindness due to diabetic retinopathy.



EP005 / #823

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

TYPE 2 DIABETES PATIENTS SUBCLASSIFICATION ANALYSIS: PERSONALIZED T2D CARE OF DORZAGLIATIN

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Background and Aims: Our pervious study has demonstrated the potential and benefits of T2DM subgrouping where patients has been clustered into six subtypes according to their clinical characteristics. After 12 weeks treatment of dorzagliatin during a phase II trial, each cluster showed distinct responses, which suggesting a new scheme of personalized diabetes care.

Methods: We have developed a classification model to realize the of T2DM patients subtyping algorithm among different population. The classification model was based on support vector machine with radial basis function kernel. The features including demographic variables, laboratory test variables, as well as the generated clinical parameters. The algorithm was further validated through SEED study of dorzagliatin.

Results: The final classification model achieved 0.87 in prediction accuracy and relatively high specificity and sensitivity. The majority patients in SEED study were classified into subtype A and C, which were characterized as severe impaired glucose tolerance and severe impaired β-cell function, two common pathological dominators in Chinese T2DM patients. Subtype A and C show different responses to dorzagliatin treatment, where patients in subtype C are more sensitive to the treatment of drug, both HbA1c and β cell function have improved a lot, which is consistent with our previous finding in phase II data and the mechanism of action of dorzagliatin. However, for patients in subtype A, a healthy lifestyle management might enough for their glycemic control.

Conclusions: Diabetes is a complex disease, but the patients subgrouping according to their disease status might provide a new weapon in personalized diabetic care.

EP006 / #84

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

A DIABETES APP THAT USES PEER-TO-PEER SUPPORT TO MINIMIZE DIABETES ASSOCIATED EMERGENCIES

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Background and Aims: This concept of peer-to-peer support is traditionally used for multiple chronic diseases through therapy groups. Using a similar concept of peer-to-peer support, this Diabetes App, uses digital health and online platforms such as social media to advocate, educate and improve the quality of life of people with Diabetes to reduce hospitalizations.

Methods: 25 participants tried the peer-to-peer support app, my Diabetes Diary for 12 weeks. The pre-test and post-test survey showed that the app was useful in Diabetes management, Diabetes communication and Diabetes nutrition. The questions of the post tests showed that the app was useful in maintaining health of people with Diabetes.

Results: The app created accountability within people with Type 1 Diabetes through the feature of social media, encouraging the youth to educate to de-stigmatize diabetes with digital health, the peer-to-peer build-in tool helped people with Type 1 Diabetes to support others while maintaining their own health. People with Type 2 Diabetes enjoyed the nutritional feature with a simple click. 9% of participants who downloaded the app had difficulty in putting the blood sugars in the app. 86% of participants said that they like the social media and nutritional feature of the app.

Conclusions: This Diabetes App was made to reduce the challenges of people with Diabetes. There was a need for an app that incorporates the positive tasks that people look forward to throughout the day such as social media and eating tasty nutritional meals. This app also has the feature of advocacy as a form of peer support.

EP007 / #122

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

COMPUTATIONAL ANALYSIS TO MEASURE THE ACCURACY OF FOOT ULCER IN PEOPLE WITH DIABETES USING VISUAL DATA SCIENCE TO IMPROVE WOUND MEASUREMENT

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Background and Aims: People with Diabetes have enervating complications that lead to complex wound healing. Among those complications, the biggest one is the development of foot ulcers. Wound measurement is a vital part of assessment to predict treatment outcomes. Wound imaging devices assist health professionals to monitor and improve healing time. Digital imaging for wounds is currently the most reliable method for data analysis in the hospitals to assess larger, smaller or irregular shaped wounds. Statistical models are needed to improve visual data science for accuracy of wound measurement.

Methods: Multiple devices were used to collect wound images. To accelerate wound healing, computational methods were introduced. Computational models investigated the wound image with Graphic analysis, Linguistic analysis and AI platform to compute the small wounds from the large or irregular wounds. Wound Images were taken on artificially created wounds prior to animal models. Bioinformatics models measured wounds in computing large data collected from artificial models, animal models and human subjects.

Results: 10 wound models, 18 animal models, 300 human participant wound images were used to measure data. Computational methods analyzed the accuracy of images to predict wound improvement.

Conclusions: Wound Imaging Softwares have web-based tools that can store images and measure them. These tools rely on the type of wound to measure it accurately. If the size of the wound is too small or too large, the image capturing becomes difficult. Wound Imaging devices can be used with visual data science and computational analysis to vitalize therapies and management to improve wound healing.

EP008 / #910

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

CORRELATION OF CONTINUOUS GLUCOSE MONITORING METRICS WITH HBA1C REDUCTION AND BETA CELL FUNCTION AT ONE YEAR OF WHOLE-BODY DIGITAL TWIN TECHNOLOGY FOR REMISSION OF DIABETES

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Background and Aims: Twin Precision Treatment (TPT) intervention uses the Whole-Body Digital Twin Platform, with AI and Internet of Things (IoT), to predict the individual Post Prandial Glucose Response (PPGR) to specific meals to enable precise interventions.

Methods: We analysed 1 year (n = 196) data for the relationship between the HbA1c, beta cell functionality, and CGM metrics.

Results: The mean duration of diabetes was 3.6 years (±2.7, 95% CI 3.2 to 3.9). Mean age 44 years (±8.7, 95% CI 43 to 45). Based on the ADA criteria, 76.5% (n = 150/196) achieved diabetes remission. HbA1c (%) reduced from 9 (±1.9, 95% CI 8.7 to 9.2) to 5.9 (±0.56, 95% CI 5.8 to 6) $p < 0.0001$. There was a significant correlation (Pearson r, 95% CI) with a change in HbA1c and change in CGM metrics- high blood glucose index (HBGI) 0.58, 0.48 to 0.67, $p < 0.0001$; coefficient of variation (CV) -0.26, -0.38 to -0.12, $p = 0.0002$; Time in Range (TIR) -0.51, -0.61 to -0.40, $p << 0.0001$; Time Above Range (TAR) 0.60, 0.51 to 0.69, $p < 0.0001$. Significant correlation with a change in HOMA2B and CGM metrics- LBGI 0.17, 0.03 to 0.30, $p = 0.01$; HBGI -0.53, -0.62 to -0.42, $p < 0.0001$; CV 0.34, 0.21 to 0.46, $p < 0.0001$; TIR 0.39, 0.26 to 0.50, $p << 0.0001$; TAR -0.58, -0.66 to -0.48, $p < 0.0001$.

Conclusions: The correlation between the change in the HbA1c and change in beta cell function across most of the CGM-related metrics reflects the accuracy of CGM metrics to predict remission. The improvement in the beta cell function is better correlated with CGM metrics than the reduction in HbA1c.

EP009 / #772

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

USE OF ARTIFICIAL INTELLIGENCE BASED ON CONVOLUTIONAL NEURAL NETWORK TO ASSESS INTRACRANIAL CEREBRAL ATHEROSCLEROSIS IN TRANSCRANIAL DOPPLER

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Background and Aims: Diabetes mellitus is a major independent risk factor for cerebrovascular disease, especially ischemic stroke. Intracranial atherosclerotic stenosis (ICAS) is a major cause of ischemic stroke worldwide and the middle cerebral artery (MCA) is the most common site of ICAS. Ultrasound detection of ICAS helps to identify patients at risk. Transcranial doppler (TCD) can reliably rule out ICAS. The interpretation of TCD is somewhat challenging and demands expertise, thus is underused in clinical practice. Emergent Artificial Intelligence (AI) models can assist in interpretation, reducing subjectivity, and speeding up the detection of ICAS.

Methods: We conducted an automated method using neural networks to detect MCA stenosis from TCD audio signals. The Doppler audio files were obtained as short sequences of 3–5 seconds. A convolutional layer-based neural network is constructed that receives preprocessed two-dimensional data and estimates the peak, mean, and diastolic blood flow velocity. Data were classified into two categories: normal and stenosis (>50%). Data from 1078 patients were analyzed.

Results: The ground truth was the vascular neurologist's previously reported TCD diagnosis The accuracy of MCA stenosis was 0.95, the precision was 0.93 and the recall was 0.91. The Area Under the Curve of CV discrimination was 0.93 and the f1 score was 0.92.

Conclusions: The results show that the deep learning method can be used for accurate analysis and interpretation of stenosis of MCA based on audio signal analysis of TCD spectra. These novel AI-assisted interpretations may facilitate the diagnostic accuracy of TCD for the detection of intracranial atherosclerosis in diabetic patients.

EP010 / #495

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

A NOVEL ELECTRONIC-HEALTH RECORD BASED, MACHINE-LEARNING MODEL PREDICTING ONE-YEAR RISK OF SEVERE HYPOGLYCEMIA IN OLDER ADULTS WITH DIABETES

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Background and Aims: Older adults with diabetes are at highest risk of severe hypoglycemia (SH). Most machine-learning (ML) models use glucose to predict short-term hypoglycemic risk. We developed an electronic health record (EHR)-based model to predict one-year risk of SH in older adults for pre-emptive intervention.

Methods: We included 1,456,618 records of all older adults (age ≥65 years) with diabetes with at least one attendance in the Hong Kong Hospital Authority 2013-2018. We included 258 variables including demographics, in-patient/out-patient

admissions, accident & emergency attendance, complications, medications and routine laboratory tests to predict SH event in the next 12 months as defined by diagnostic codes. The cohort was randomly split into training, testing and internal validation sets in a 7:2:1 ratio. The performance of different ML algorithms were evaluated.

Results: We identified 10,395 SH events that developed within the next 12-month window. XGBoost yielded the best performance in the validation set (C statistic = 0.98; area under precision recall curve [AUCPR] = 0.67, positive predictive value = 0.48; negative predictive value = 1.0). The final XGBoost model captured 129 impactful predictors with in-patient admission, urgent emergency triage, number of emergency attendances and insulin use as top predictors.

Conclusions: Our novel ML model showed good performance in predicting one-year risk of SH in older adults with diabetes. This may be integrated within the EHR to facilitate clinical decision making and targeted interventions.

EP011 / #228

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

PREDICTING HYPOGLYCEMIA EVENTS BY CLASSIFICATION

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Background and Aims: The motivation for this research lies in the need for reliable predictive models of low blood glucose levels for people with diabetes. The prediction of a future hypoglycemic episode can lead the patient to take action to remedy it before it happens and to take better decisions in the future to avoid acute complications.

Methods: We train classification models using Structured Grammatical Evolution (SGE). We present a method to obtain White-box models composed of a set of if-then-else conditions. The conditions to evaluate include information of a set of physiological variables during the last two hours previous to the prediction time. In particular, we include glucose levels measured by a Continuous Glucose Monitoring System (CGM), heart rate information, number of steps and calories burned (these last three are obtained by wearing a smartwatch). As a result, we obtain models that predict a class which represents the future state of the person (hypoglycemia- non-hypoglycemia) in the short term (30 minutes). We investigate the performance of both static SGE and Dynamic SGE.

Results: Experimental results show a Gmean value close to 0.95. We observe no significant statistical variation between the individual and general models. The main advantage of using a general model is that it can be trained with more data, making it more robust, as some patients don't have a lot of hypoglycemic values to train with.

Conclusions: Obtained models are understandable as they are if-else statements that performs the classification and uses input data from the patient to determine the class.

EP012 / #636

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

DEVELOPING A TOOL TO VISUALISE AND ANALYSE CONTINUOUS GLUCOSE MONITORING, SLEEP, AND ACTIVITY DATA: PRELIMINARY FINDINGS FROM THE HYPO-METRICS STUDY

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Background and Aims: Technologies tracking glucose levels, sleep and exercise patterns offer potential for real-time glycaemic outcome assessment. However, we lack a tool for data linkage. Here, we report preliminary features of the 'hypometrics' package, an analytical tool for combining sensor-detected hypoglycaemia (SDH), person-reported hypoglycaemia (PRH), sleep and activity data.

Methods: In the 10-week Hypo-METRICS study, participants wore blinded continuous glucose monitors (CGM) and an actigraphy monitor (Fitbit) recording sleep, activity and heart rate data, whilst continuing their usual glucose monitoring. Using the Hypo-METRICS smartphone app, participants reported episodes of hypoglycaemia at or shortly after the episode. Using R, we developed an algorithm to produce summary metrics and data visualisations from all the datasets.

Results: Data were provided by 401 participants (45% women, 51% with type 1 diabetes, median(IQR) age 58(47-66) years, diabetes duration 21(12-29) years, 58% using Flash/CGM). Group-based metrics generated by the algorithm included total CGM hours (N = 658,802), SDH below 3.9mmol/L (N = 21,288), PRH (N = 11,600), nights with sleep data (N = 25,680), steps (N = 214,968,770) and mean(SD) heart rate (76bpm(9)). Individual-based metrics and data visualisations were also generated. Figure 1 shows combined data from a participant with impaired awareness of hypoglycaemia.

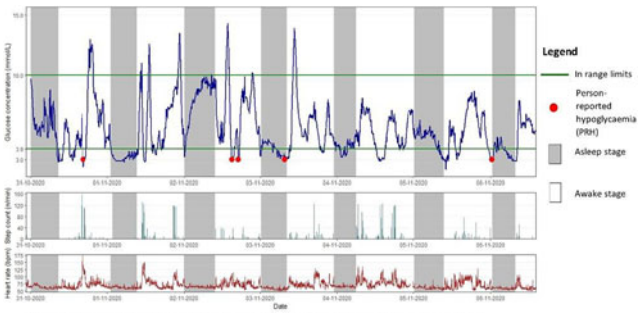

Figure 1. Example of an output of the 'hypometrics' package: 1-week CGM trace combined with PRH data, sleep and awake stages, step count and heart rate data

Conclusions: These early data suggest that the 'hypometrics' package enables automated linkage between glucose, sleep, and activity data from CGM and Fitbit devices, together with PRH data from the Hypo-METRICS app. This represents an important step in the development of a new clinical and research tool for the scrutiny of relationships between sleep, activity and hypoglycaemia in people with diabetes.

EP013 / #645

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

MULTI-SENSOR DETECTION OF NOCTURNAL HYPOGLYCAEMIA IN DIABETES PATIENTS

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Background and Aims: Hypoglycaemia is a major cause of concern in the management of insulin-dependent diabetes. If not treated appropriately, hypoglycaemia may lead to reduced motor control, arrhythmias, or even death. Due to a combination of several factors hypoglycaemic episodes occur often at night. Elderly people are especially at risk of hypoglycaemia due to the presence of comorbid conditions. Continuous glucose monitoring (CGM) has proven effective in improving glycaemic control, providing patients feedback of their glucose levels. However, CGM uptake in the general population is limited and even less popular in the elderly population. Thus, we examined whether a nocturnal hypoglycemia warning system based on a ceiling mounted radar sensor and advanced algorithms is feasible to support health care professionals in long-term care.

Methods: In a pilot study data on movement during sleep were collected using a radar sensor. Additionally, patients wore smartwatches that acquired data on sleep phases, heart rate, heart rate variability, and electrodermal activity. Algorithms based on classical and machine learning methods were developed to analyse the data. 40 patients on an insulin therapy were enrolled in the study.

Results: Preliminary results on the detection of nocturnal hypoglycemia suggest that nocturnal glucose levels in participants are correlated with symptoms that can be measured with room-based and wearable sensors, such as motion and physiological parameters.

Conclusions: Our results suggest that the combination of machine learning and both room-based and wearable sensors are a promising solution to simplify diabetes management in the elderly while contributing to cost reduction in healthcare.

EP014 / #442

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

DATA DRIVEN PATIENT COHORTS FOR AID SYSTEM USERS

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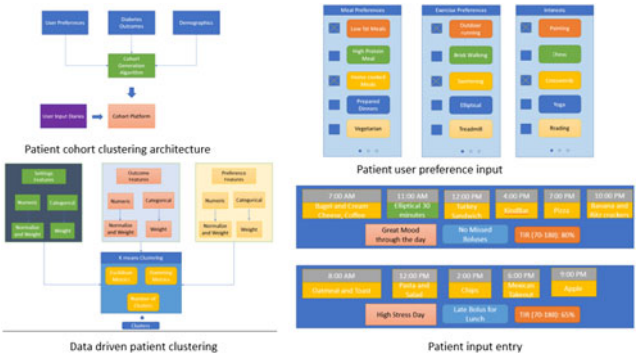
Background and Aims: An architecture for the identification of groups of diabetics who share some common patient behavior features as well as diabetic outcome measures is described. Patient cohorts can serve the purpose of a) identifying good patient behaviors and appropriate Automated Insulin Delivery (AID) control strategies, b) adapt AID insulin delivery based on patient similarity and outcomes, c) enable a platform for sharing experiences and insights, d) promote empathy, and behavioral modifications, leading to reduced burden on the users.

Methods: Patient cohorts are built based on data sources, including blood glucose traces and metrics from CGM (continuous glucose monitors), insulin delivery (from AID systems), user inputs from diaries, fitness data from wellness devices. **User Preference Interface:** The user selects dietary preferences and habits, exercise preferences and habits, hobbies, and interests. **Cohort Clustering:** Features gathered from pump settings (for example, total daily insulin, bolus to basal split ratio, insulin to carb ratio, segmented basal settings), outcome features (for example, time in range, total daily insulin, number of hypoglycemic events) and user preference features are used to generate clusters using machine learning algorithms. **User Input Diaries:** Allows users to catalog event descriptors including details on meals ingested, snacking, missed boluses, mood, sleep quality.

Results: Cohort clustering with K-means, mean shift clustering, density based spatial clustering (DBSCAN) for enhanced AID control and patient collaboration is demonstrated.

Conclusions: The cohort group can share their experiences, collaborate on experiments, share insights for improved understanding of managing their diabetes, understanding similarities while recognizing individual differences and improve diabetic outcomes.



EP015 / #642

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

ADAPTIVE BASAL-BOLUS ADVISOR FOR INSULIN TREATED PEOPLE WITH TYPE 2 DIABETES

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Table - Glucose Levels (Mean ± Standard Deviation).
Bold means statistically significant.

	BA	ABBA
TIR (%)	80.7 ± 23.3	**88.8 ± 8.5**
TBR (%)	0.6 ± 2.0	0.4 ± 0.8
TAR (%)	18.7 ± 23.5	10.7 ± 8.3

TIR [70, 180] mg/dl; TBR < 70 mg/dl; TAR > 180 mg/dl

Background and Aims: Many People with Type 2 Diabetes (PwT2D) need insulin treatment to control their glucose levels and reduce the risk of diabetes-associated long-term complications. To this end, an Adaptive Basal-Bolus (ABBA) algorithm is introduced for insulin-treated PwT2D using self-monitoring blood glucose devices and smart pens.

Methods: The ABBA for PwT2D is based on model-free actor-critic approach and minimises the risk of hyperglycaemia. The method is an extension of the already developed ABBA for type 1. The ABBA for PwT2D is in silico validated using the Diabetes Mellitus Metabolic Simulator for Research, which includes 11 virtual adults with type 2 diabetes. We tested one scenario concerning increases of 10% on the ''optimal'' (i.e., suggested by healthcare providers) basal and bolus values. We compared our approach against a baseline bolus advisor (BA). To have a competitive baseline, we used the BA, with the ''optimal'' values of CHO-to-insulin ratio and Basal Rate selected depending on the body weight of each person.

Results: Table 1 presents the results of the experimental scenario. ABBA outperforms BA in terms of Time in Range (TIR) with p-value = 0.04 under one-sided T-test. For Time Below Range (TBR) and Time Above Range (TAR), ABBA performed numerically better, but these differences were not statistically significant.

Conclusions: The results indicate the potential of ABBA for PwT2D and pave the way for future research and development concerning the application of ABBA algorithm for insulin-treated PwT2D.

EP016 / #79

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

INTERPRETABLE GLUCOSE-LEVEL PREDICTION WITH HYBRID ATTENTION-BASED DIFFUSION NEURAL NETWORK

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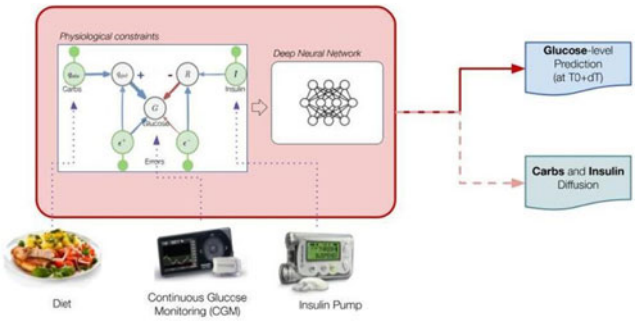
Background and Aims: AI algorithms for glucose level prediction often do not provide meaningful insights despite accurate predictions. Yet, context understanding in medicine is crucial, in particular for diabetic patient empowerment. This study aims to show the benefits of HAD-Net: a hybrid AI model that distills knowledge from physiological models into a deep neural network. HAD-Net learns from CGM data while incorporating physiological interactions between glucose insulin and carbohydrates.

Methods: We benchmark HAD-Net on a dataset from the CLOSE Study. It contains 17 patients with type-2 diabetes. Each patient has 2 weeks of data records of CGM, insulin-pump delivery and meal intakes. The total dataset contains 59k CGM data points. We compare HAD-Net against state-of-the-art models, and we analyze it depending on physiological contexts.

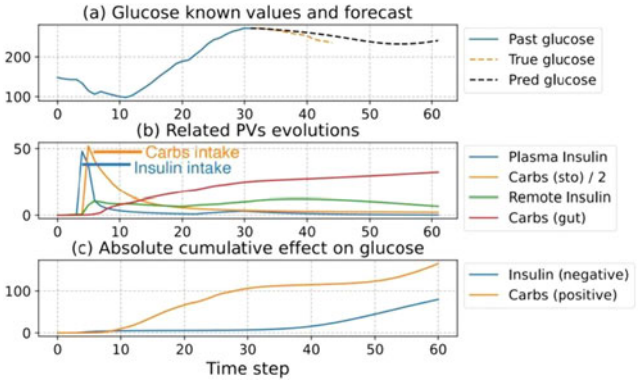


Hybrid Attentional Diffusion neural NETwork (HAD-Net) architecture. Inputs are CGM, insulin and meals at T0. The predictive algorithm incorporates physiological constraints within a deep neural network. It yields glucose-level prediction at a horizon dT and gives the diffusion curves of the carbs and insulin.

Results: show that HAD-Net outperforms linear models and is comparable to other neural networks. Also, HAD-Net provides the evolution of physiological variables. For example, a meal was taken a few minutes after insulin delivery (figure). This is explained by the fact that the carbs have a short term impact on the glucose level while the insulin impact is delayed and slower which corroborates the physiological constraints.

Conclusions: Beyond accurate glucose-level predictions, HAD-Net provides plausible measurements of insulin and carbohydrates diffusion over time. Practitioners can use HAD-Net insights to understand why a glucose level fluctuated. HAD-Net can be a pedagogic tool to raise awareness about the effect of multiple factors (glucose, insulin, carbs) regarding glycemic control.

Model	RMSE (30min)	RMSE (60min)
Baseline	24.3 ± 0.8	38.1 ± 1.3
Physiological	25.7 ± 1.1	38.1 ± 1.4
ARIMA	23.2 ± 1.1	40.0 ± 2.0
Ridge	21.4 ± 0.7	33.4 ± 1.2
Gaussian Process	23.3 ± 1.5	34.5 ± 1.2
CNN-MLP	17.9 ± 0.8	30.2 ± 1.3
LSTM	17.1 ± 0.6	**28.4 ± 1.1**
GRU	17.0 ± 0.6	28.4 ± 1.2
HAD-Net (ours)	**16.9 ± 1.2**	28.4 ± 1.7



EP017 / #741

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

PHYSIOLOGICAL SIGNALS AND THEIR EFFECTS ON PREDICTING FUTURE BLOOD GLUCOSE VALUES IN A DEEP LEARNING MODEL

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Background and Aims: Despite ongoing technological advances, managing glycemia during physical activity remains challenging for many people with type 1 diabetes (T1D). This project focuses on how physical activity, quantified using passively collected health metrics, can be combined with blood glucose measurements to impact the prediction accuracy of future blood glucose values in the artificial intelligence (AI) model.

Methods: Deep learning was applied to passively collect smartwatch physical activity data to predict 30 and 60-minute CGM-measured glucose values. Physical activity data was structured as a time series using a Long Short-Term Memory (LSTM) cell. The model was trained on all participants but tested on each participant individually by comparing experimental blood glucose predictions at 30 and 60 minutes with actual values at 30 and 60 minutes from the prediction time. Accuracy was quantified using RMSE.

Results: Data from 6 participants demonstrated that no combination of physiological features consistently outperforms models developed using just blood glucose values. However, when PCA is applied to the raw features, the results are similar to those obtained with models that only incorporate blood glucose but drastically improve training speed.

Conclusions: Findings from this study identify critical questions about what features or feature tuning, such as identifying events in activity data, should be included to improve the predictions of blood glucose data.

EP018 / #421

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

MEAL DETECTION AND ESTIMATION ON TYPE 1 DIABETIC PATIENTS

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Background and Aims: The approach of strategies aimed at the development of an artificial pancreas (AP) to control glucose levels in patients with type I diabetes mellitus are often insufficient and unsatisfactory. High glucose levels after postprandial episodes that aggressively try to be compensated with high insulin rates, not only cannot guarantee blood glucose levels within ranges characteristic of healthy subjects, but also expose the patient to possible hypoglycemic conditions. Many of these approaches including artificial intelligence, control theory - based on techniques could experiment an unexpected poor behavior since most of them do not include neither meal intake announcements nor meal size information

Methods: we cover supervised learning based techniques for meal detection and carbohydrates counting. For meal detection, decision boundaries are shown for each algorithm. Otherwise, for meal estimation, regression algorithms are trained to compare the prediction for several scheduled meals.

Results: The algorithms are validated on Food and Drug Administration (FDA)-Approved UVA/PADOVA Type 1 Diabetes Simulator. A total of 12 days recordings of data were simulated. For simulation simplicity, only one detection algorithm was chosen and we let all the regression algorithms to be shown their predictions in all over the simulation data with comparatives purposes

Conclusions: Meal detection algorithm requires glucose and its derivative recordings in order to announce when a meal was likely eaten or not. The sign of the derivative has a important role in the detection as is shown for almost all the trained algorithms excepting naive bayes. Mean time for meal detection is about 35 minutes.

EP019 / #52

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

THE ASSOCIATION BETWEEN DAILY STEP COUNT AND TIME IN RANGE IN THE TYPE 1 DIABETES AND EXERCISE INITIATIVE (T1DEXI) STUDY COHORT

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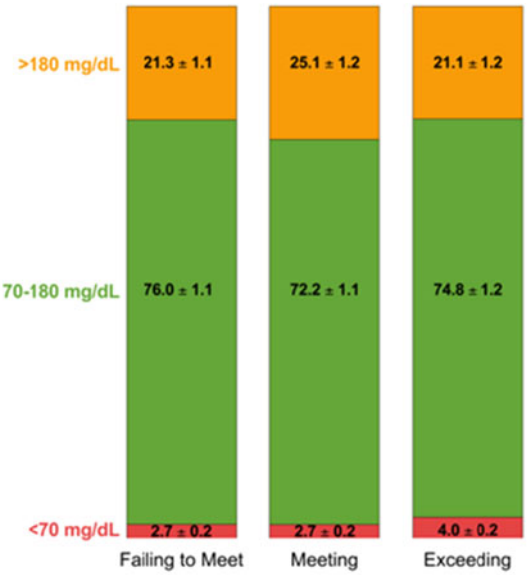
Background and Aims: Guidelines recommend 7-10K steps/day (SPD) to maintain health and fitness for adults with type 1 diabetes (T1D), but the associations between SPD and time in range (TIR) are unclear. Using the (T1Dexi) dataset, we examined if the clinical targets for glycemia are associated with meeting, exceeding, or failing to meet SPD goals.

Methods: Participants were categorized as (A) failing to meet, (B) meeting, or (C) exceeding SPD goals using a wearable (Verily Study Watch) over a 4wk observation period, while average TIR (70-180mg/dL), time below range (<70mg/dL; TBR), and time above range (>180mg/dL; TAR) were profiled using CGM (Dexcom G6). ANCOVAs were used to explore associations between group categorization and TIR metrics.



Adjusted mean±standard error percent time below range (<70mg/dL), time in range (70-180mg/dL), and time above range (>180mg/dL) after adjusting for BMI, age, and insulin modality in individuals with type 1 diabetes who are failing to meet, meeting, or exceeding 7,000-10,000 steps a day.

Results: The sample included 490 adults with T1D (37 ± 14 years, 72.4% female, 25.4 ± 4.1 kg/m^2 BMI, 6.6 ± 0.8% A1C, 45.1% using a closed loop pump). After controlling for covariates (age, BMI, insulin modality), there was a significant effect of SPD group on TIR ($p = 0.04$), TBR ($p < 0.001$), and TAR ($p = 0.02$). Individuals achieving step count goals had decreased TIR compared to those who exceeded (mean difference 2.7 ± 1.6%, $p = 0.30$) or failed to meet (mean difference 3.8 ± 1.6%, $p = 0.04$) SPD goals.

Conclusions: After adjusting for age, BMI, and insulin modality, there was no observed association with achieving daily step count goals and improved TIR in T1D. Other factors, such as food intake and/or insulin dosing may explain why TIR was lowest in those achieving step count goals.

EP020 / #556

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

PREDICTING 90-DAY CHANGE IN HBA1C WITH AN "EXPLAINABLE AI" MACHINE LEARNING MODEL DEPLOYED IN CLINIC

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Background and Aims: No pediatric diabetes clinics currently use advanced machine learning models to predict rise in HbA1c in youth. We developed a scalable model to predict 90-day change in HbA1c (ΔHbA1c).

	ΔHbA1c>0.3%	ΔHbA1c>0.4%	ΔHbA1c>0.5%	ΔHbA1c>0.6%
Sensitivity	0.26	0.14	0.10	0.05
Specificity	0.89	0.95	0.98	0.99
Precision	0.53	0.52	0.54	0.56
Negative predictive value	0.72	0.75	0.79	0.82

Methods: To enhance shareability, we engineered model features using electronic medical record data mapped to the T1D Exchange Quality Improvement Collaborative (T1DXQI) data schema and selected 15 features (demographics, laboratory values, and diabetes history/management) to yield explainable predictions. We used an ensemble of gradient-boosted, tree-based models and trained on data collected from 2017-09-01 to present day (2956 unique patients and 21,998 records) by a Midwestern, US diabetes center.

Results: The trained model has a root mean squared error (RMSE) of 0.71%. The most important model features are current HbA1c, T1D duration, and rate of HbA1c change. We calculated classification statistics for predicted ΔHbA1c>0.3% (clinically significant), 0.4%, 0.5%, and 0.6%.

Conclusions: Our ΔHbA1c model is an effective tool for predicting a youth's ΔHbA1c 90 days after a clinic visit and is readily deployable to other centers who map their diabetes data to the T1DXQI data schema. The model enables the possibility that clinic staff can direct the highest-risk youth toward interventions (like remote patient monitoring [RPM] or behavioral interventions) to prevent HbA1c rise. Future work will add features such as device data, social determinants of health, and effective self-management behaviors.

EP021 / #698

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

PREDICTING AND RANKING DKA RISK WITH A TRANSFERRABLE MACHINE LEARNING MODEL DEPLOYED IN CLINIC

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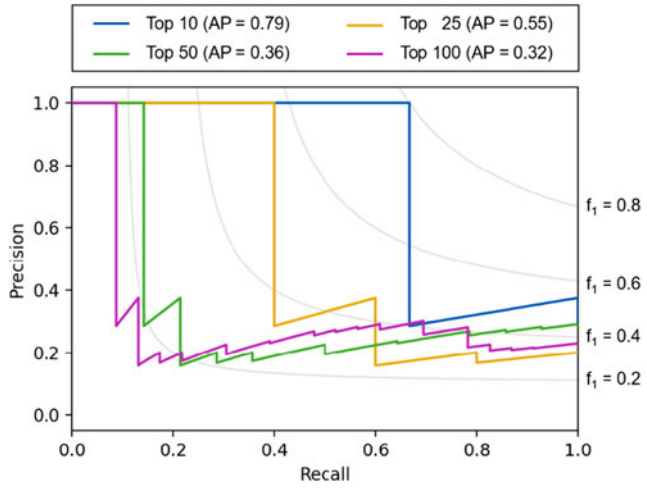
Background and Aims: No pediatric diabetes clinics have operationally deployed advanced machine learning models to predict hospitalization for DKA in youth; such models might enable development and testing of preventive interventions. We developed a scalable model to predict 6-month risk for DKA-related hospitalization.

Methods: To achieve a sharable predictive model, we engineered features using electronic medical record data mapped to the T1D Exchange Quality Improvement Collaborative (T1DXQI) data schema and chose a compact set of 15 features (demographics, laboratory values, and diabetes history/management) to yield ''explainable AI'' predictions. We used an

Top N Highest Risk	Fold-Enrichment	Average Precision
10	11.8	0.79
25	7.8	0.55
50	11.0	0.36
100	9.0	0.32



ensemble of gradient-boosted, tree-based models and trained on data collected from 2017-09-01 to present day (2956 unique patients and 21,998 records) by a Midwestern, US diabetes center.

Results: We rank-ordered the top 10, 25, 50, and 100 (≈ DKA incidence, 2.5%) highest-risk youth in an out-of-sample validation set and calculated the fold-enrichment (relative to population incidence), average precision, and precision/recall curves for the 4 top-N lists (Figure).

The model identified days since last DKA, cumulative DKAs, and most recent HbA1c value as the three most important features in predicting DKA risk.

Conclusions: Our DKA risk model is an effective tool for predicting a youth's relative risk of experiencing hospitalization for DKA and is readily deployable to other centers who map their diabetes data to the T1DXQI schema. The model makes it now possible for clinic staff to contact and intervene with the highest-risk youth. Future work will add model features such as device data, social determinants of health, and effective self-management behaviors.

EP022 / #632

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

INSULIN RESISTANCE MONITORING APPLICATION FOR HIGHLY INDIVIDUALIZED DIABETES TREATMENT

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Background and Aims: Diabetes is one of the oldest recorded diseases, and instead of having the ability to stop it, its global burden is growing. Diabetes treatment has proven to be most effective when it is highly individualized. We developed an application that automatically analyzes the glucose sensor and insulin infusion information to calculate insulin resistance to monitor the variations.

Methods: Insulin resistance is calculated with a Genetic Algorithm (GA) based on the glucose-insulin regulation minimal model. GA is a computational method inspired by natural evolution. We used a GA for model parameter estimation as an efficient method to search the parameters' values space to converge on a set of values that minimize an appropriately created fitness function. The model's parameters are tuned so its dynamics fit as closely as possible to the experimental data obtained from a glucose sensor and an infusion pump. The GA is embedded in the application that automatically calculates the insulin resistance for any given time frame that the physician wants to analyze to have a tool to individualize the diabetes treatment.

Results: The application was tested with a database of 20 patients. The Varvel Performance Measurements showed that the system has high accuracy with low bias. The insulin resistance variations in time were plotted to facilitate the interpretation.

Conclusions: Insulin resistance has several transitory changes during the day, that can easily be tracked with this application to tailor an individualized treatment scheme to minimize the time out of glucose target

EP023 / #124

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

REAL-WORLD FEASIBILITY OF THE HEMOGLOBIN A1C TARGET OF ≤7.0% IN TYPE 1 DIABETES: A RETROSPECTIVE, POPULATION-BASED COHORT STUDY

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Background and Aims: A Hemoglobin A1c (HbA1c) target of ≤7.0% is unanimously recommended by international societies to reduce the risk of long-term diabetes complications. Temporal trends for meeting the recommended Hba1c target among adults with type 1 diabetes (T1D) in Canada are unknown.

Methods: We conducted a retrospective population-based cohort study using a validated administrative data algorithm to identify Ontarians with T1D ≥18 years old and ≥1 HbA1c test between April 1, 2012 and March 31, 2018. Generalized estimating equations were used to assess the association between fiscal year and HbA1c test results categorized as ≤ or >7.0%, adjusting for predictors.

Results: Our sample included 24,315 adults with T1D (mean age 31 ± 13 yrs, 50% female, T1D duration 12 ± 7 yrs), among whom 15,343 (63%) used insulin pumps. Over the 7-year period, there were 293,206 HbA1c tests (median 2 per year (IQR 1-3)). The probability of meeting the HbA1c target of ≤7.0% was 21% in 2012 and 24% in 2018 (OR for 2018 vs. 2012: 1.16 (1.11-1.21)). Adjusting for individual-level predictors, pump users were less likely to meet target (OR 0.9 (0.86-0.94)). After additionally adjusting for provider- and system-level predictors, insulin pump use was not associated with meeting target (OR 1.05 (0.99-1.11)).

Conclusions: Three-quarters of adults with T1D in Ontario did not meet the recommended HbA1c target of ≤7.0% in 2018, with minimal change in rates between 2012 and 2018. Future studies are required to identify modifiable factors for meeting recommended HbA1c targets and to re-evaluate optimal HbA1c target thresholds.

EP024 / #734

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

AND ALL THOSE DATA…: SOLUTIONS BY POPULATION MANAGEMENT TOOL CLOUDCARE

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Background and Aims: Data usage is essential in diabetescare, but facilitating HCP's to provide patients with timely and regular (eHealth) insights is complex. We developed a brand-agnostic CE-marked, population management eHealth-application, CloudCare, providing a 'closed-data-loop' between patients and HCP's.

Methods: It uploads insulin- and glucosedevice-data from all platforms/brands both by manual uploads (patient) or automated uploading. The system is used 8 years in Diabeter and resulted in more than 10.000 'dataloops'/year mainly from manual uploads by the patient. We analysed outcomedata and visit/contactdata.

Results: The system helped to improve outcomes despite COVID-19, implementation of technologie and significant growth and helpt switching to remote care (Table) with 50% of children and 57% of adults reaching HbA1c below 7.5% (58mmol/mol) in 2021. To accommodate increasing data usage, automatic data-uploads and translate data to insights, we further developed the system to tracks data and offer decision-support. This allows triage-driven risk stratification of clinically relevant cases, allowing timely interventions. Data-use, frequencies of planned contacts as well as 'snoozing' periods are defined in a service level agreement with patients. Automated input from 2505 780G- and IS-CGM users, creates approx. 2200 daily datasets. Automated triaging reduces this to a workload to 20-65 relevant cases per day which are reviewed and forwarded to HCPs. Settings for triaging are flexible and temporary 'snoozing' is possible.

Conclusions: Further evaluation studies includes clinical impact and impact on the organization including costs. We will seek to include additional clinics in the evaluation. Solutions such as CloudCare will help to integrate modern diabetes-treatment and improve outcomes.

EP025 / #488

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

SPOTLIGHT-AQ BIOPSYCHOSOCIALLY FOCUSSED ROUTINE OUTPATIENT CONSULTATIONS: FIRST RESULTS FROM PIVOTAL MULTI-CENTRE RANDOMISED CONTROLLED TRIAL

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Background and Aims: Burnout amongst HCPs is a key challenge affecting healthcare practice, safety and quality of care. Routine outpatient visits often leave patients and HCPs feeling frustrated across primary and specialist care settings. The lack of understanding and evolving consequences of the psychosocial burden of diabetes results in a negative impact on clinical practice with sub-optimal outcomes for patients and increasing frustration for HCPs. Consistently poor outcomes highlight the urgent need for a shift to a more holistic, person-centered approach, deliverable sustainably within the constraints of existing healthcare systems.

Methods: Multi-centre RCT to determine clinical and cost-effectiveness of the Spotlight-AQ clinical care platform in routine primary and secondary care outpatient appointments. Participants: adults with T1D or T2D. Outcomes: primary outcome consultation length; secondary outcomes participant well-being, diabetes distress, usability and functional health status; and HCP burnout.

Results: Data for $1^{st} n = 72$ participants showed consultations were more focused using Spotlight-AQ, with duration reduced by 11-21% (3-6 minutes). High levels of burnout observed in half of HCPs at baseline, all reduced at 6-month follow-up. HCP satisfaction with the tool was high. Diabetes distress reduced significantly in T2D participants, specifically overall, in emotional burden and physician-related distress. Distress for T1D participants was low at baseline and remained low at follow-up. EQ5D scores improved significantly amongst T2D participants and remained consistently high for T1D participants. WHO-5 scores improved for T1D and T2D participants at follow-up. Interviews showed high levels of satisfaction amongst HCPs and patients.

Conclusions: Spotlight-AQ clinical tool facilitates improved routine outpatient appointments across primary and specialist care.

EP026 / #894

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

EARLY AND EFFECTIVE SCREENING FOR DIABETIC RETINOPATHY AMONG T2DM PATIENTS ATTENDING DIABETIC CLINICS IN INDIA

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Background and Aims: Early targeted treatment of Diabetic retinopathy (DR) can help reduce the burden of avoidable blindness in type 2 Diabetes Mellitus (T2DM). This study aims to highlight the need of quick screening for DR in T2DM vulnerable population.

Methods: A total of 753 T2DM patients visiting diabetic clinics in India were screened for the occurrence of DR. Fundus photographs were taken with a direct digital non-mydriatic camera to detect retinopathy, maculopathy, or any other changes and were interpreted remotely by Ophthalmologists. Correlation analysis was done to evaluate the association of DR diagnosis with demographic along with clinical factors.

Results: The study population (N = 753) having mean age of 52.7 ± 11.7 was screened for DR. Male-to-female ratio was 1:1. Among them, the prevalence of retinopathy was 20.5%, about one-tenth of the population had a history of cataract surgery and more than 20% had hypertension. Less than 10% of the study population showed some indications of mild to moderate retinopathy and maculopathy. There was a significant correlation (P = 0.0008) between the incidence of DR and the age of the individual.

Conclusions: DR is a preventable microvascular complication of T2DM. Though effective glycemic control is important for prevention, real-time screening for retinopathy in clinics would facilitate its early detection. Based on real-world data, healthcare authorities should institute programs to induce awareness of its early detection, and management with appropriate timely referrals to ophthalmologists, as well as invest in simple-to-use technical systems based on remote diagnosis by Eye Specialists, which would instantly predict the presence of DR in T2DM patients.

EP027 / #438

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

QUANTITATIVE ESTIMATION OF INSULIN SENSITIVITY FROM CGM AND MDI DATA IN SUBJECTS WITH TYPE 1 DIABETES

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Background and Aims: We previously proposed a method for the estimation of insulin sensitivity (SI) in subjects with type 1 diabetes (T1D) wearing both a continuous glucose monitoring (CGM) system and insulin pump (SI^{SP}), usable in everyday life. The method was validated against the insulin sensitivity index estimated with the oral minimal model (SI^{MM}) and successfully employed to optimize the insulin to carbohydrate ratio (CR) in adults with T1D during closed-loop control. Here, we aim to extend the methodology for SI^{SP} estimation to a broader population of T1D subjects wearing CGM but on multiple daily injection (MDI) therapy.

Methods: The method was tested *in silico* using the latest version of the UVa/Padova T1D Simulator incorporating MDI therapies. A single-meal scenario (80g) was performed in 100 virtual subjects, either on Glargine U300 (Gla-300) or Degludec U100 (Deg-100) as basal insulin, with pre-meal insulin bolus calculated using subject-specific CR. Simulated CGM data and MDI doses were used to calculate SI^{SP}, while simulated plasma glucose and insulin concentration data were used to estimate SI^{MM}.

Results: SI^{SP} was significantly lower than SI^{MM} (9.26 ± 0.55 vs 12.44 ± 0.89 10^{-4}dL/kg/min/(μU/mL) for Gla-300; 7.15 ± 0.61 vs 12.02 ± 1.05 10^{-4}dL/kg/min/(μU/mL) for Deg-100). However, the correlation between SI^{MM} and SI^{SP} was excellent for both insulins ($r = 0.90$ and $r = 0.93$, $p < 10^{-8}$, respectively).

Conclusions: The method can be used to assess SI in subjects with T1D on MDI therapy wearing CGM. Future work will include testing the method on a real population of children with T1D on MDI therapy and using it to optimize insulin therapy parameters.

EP028 / #426

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

USE OF EKIYOU APP FOR CARB COUNTING RESULTS IN IMPROVED GLUCOSE CONTROL IN PATIENTS WITH TYPE 1 DIABETES IN A ONE- MONTH STUDY

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Background and Aims: The accurate estimation of food carbohydrates (CHO) is essential for computing meal insulin doses and achieving optimal blood glucose (BG) control in patients with type 1 diabetes (T1D). We developed EKIYOU, a smartphone app that automatically computes CHO content of declared food intakes. We assessed the outcomes of its use in a pilot one-month study.

Methods: Seventeen adults with T1D, under basal-bolus insulin regimen, with variable skills in flexible insulin therapy received EKIYOU application for one month. The app's CHO counting (CC) function was active and patients relied on their own bolus estimation. TIR, TBR and TAR values based on 14-day CGM were compared between inclusion and after 1 month app use to evaluate the benefits of using EKIYOU for CC.

Results: Fifteen patients (age: 47 ± 10, 5 using CSII and 10 MDI, HbA1c: 7.7 ± 0.5 %) completed the study. The participants entered 2.5 meals per day in EKIYOU. TIR increased from 53.86% to 61.06%. TAR decreased by 7.91% with no increase of TBR. Those having a pump bolus calculator increased TIR by 7.7%. 80% of patients expressed their satisfaction with the application and found that it helped them with complex meals.

Conclusions: Our data suggests that CC through EKIYOU can improve BG control. Patients felt satisfied and found EKIYOU easy-to-use and relieving. All patients succeeded to use the application even without previous CC education.

EP029 / #428

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

USE OF EKIYOU APP FOR CHO COUNTING AND BOLUS COMPUTING IMPROVES GLUCOSE CONTROL IN PATIENTS WITH TYPE 1 DIABETES IN A TWO MONTH STUDY

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Background and Aims: The accurate estimation of food carbohydrates (CHO) is essential for computing meal insulin doses and achieving optimal blood glucose (BG) control in patients with type 1 diabetes (T1D). We developed EKIYOU, a smartphone app that automatically computes CHO content of declared food intakes and corresponding bolus insulin dose. We assessed the outcomes of its use in a pilot two-month study.

Methods: Seventeen adults with T1D, under basal-bolus insulin regimen, with variable skills in flexible insulin therapy participated in a two-month study. The patients received EKIYOU application for two months. During the first month only carbohydrate counting (CC) app function was active. After ICR and CF revision, the bolus calculator was activated for the second month and patients relied on its calculation. After the two month period, 14-day CGM TIR, TAR and TBR values were compared to that at inclusion.

Results: Fifteen patients (age: 47 ± 10, 5 using CSII and 10 MDI, HbA1c: 7.7 ± 0.5 %) completed the study. Patients used on average EKIYOU 2.5 times a day for CC and bolus calculation. TIR increased from 53.87% at inclusion to 62.83% at the end of study. TAR decreased by 8.27% with no change of TBR. 73% of patients had a TIR increase above 7%.

Conclusions: Our data suggests the benefits of using EKIYOU app to improve BG control through increased TIR. Patients felt satisfied and found EKIYOU easy-to-use and relieving. All patients succeeded to use the application even without previous education on CC and bolus adjustment.

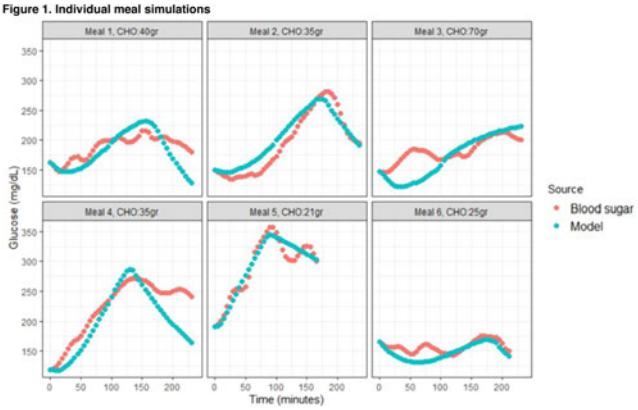

FIGURE 1. Individual meal simulations

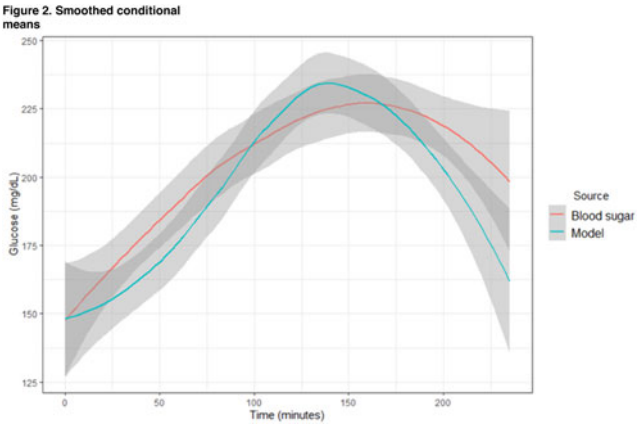

FIGURE 2. Smoothed conditional means

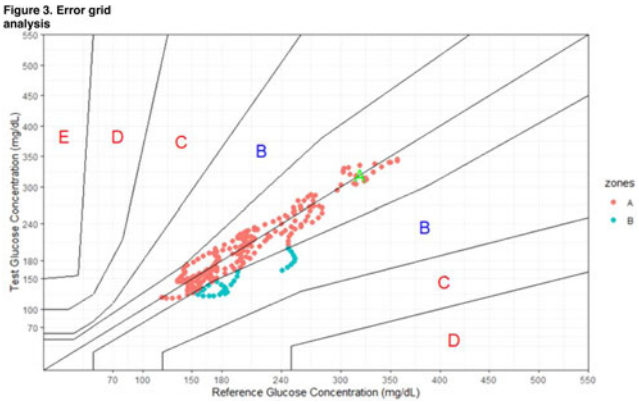

FIGURE 3. Error grid analysis

Results: Six meals with different carbohydrate content were simulated for a single subject. The model estimated blood glucose dynamics after meal ingestion and was compared with 266 readings from the CGM (Figure 1). The mean absolute error from the model was 16.89 mg/dL (±21.57) (Figure 2), and in the error grid analysis, 87.6% of the measurements fell in zone A and 12.4% in zone B (Figure 3).

EP030 / #852

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

MEAL-RELATED GLYCEMIC TREND INFORMATION TO ASSIST BOLUS DECISION-MAKING IN PEOPLE WITH TYPE 1 DIABETES – STUDIA DECISION SUPPORT SYSTEM

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Background and Aims: Gastrointestinal tract and liver are key in controlling blood glucose levels (BGL). In people with type 1 diabetes mellitus (T1D), BGL is also regulated with subcutaneous insulin injections. Therefore, predictions of BGL changes may lead to better decisions when calculating insulin bolus at a meal. Unfortunately, there are not any solutions for simulating postprandial glucose dynamics. STUDIA is a decision support system that uses mathematical modeling to simulate BGL changes after a meal.

Methods: A model was developed to represent the role of the stomach, small intestine, and liver in glucose metabolism. The model was then coupled to the minimal model to include glucose and subcutaneous insulin dynamics. Finally, with minimal parameter identification, the model response was contrasted with data from a subject using CGM and an insulin pump

Conclusions: STUDIA predicts BGL changes after a meal with a small error, and clinical decisions may be safe based on the grid analysis. STUDIA will be tested in a clinical trial to assess whether it enhances carbohydrate counting in people with T1D.

EP031 / #417

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

MINIMALLY IMPORTANT DIFFERENCE AND INFLUENCING FACTORS FOR HEALTH-RELATED QUALITY OF LIFE IN PREGNANT WOMEN WITH TYPE 1 DIABETES

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Background and Aims: Type 1 diabetes in pregnancy affects the quality of life of maternal with deteriorated physical and psychological status due to the acceleration of diabetic complications, hypoglycemia, or worry about fetus. The study aimed to evaluate the health-related quality of life(HRQoL) of pregnant women with type 1 diabetes, determine the minimally important difference(MID) and influencing factors for impaired HRQoL in this population.

Methods: 95 pregnant women with type 1 diabetes from a prospective cohort study were included in the current analysis. HRQoL was assessed with European Quality-of-life 5-Dimension 5-Level(EQ-5D-5L) on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Receiver operating characteristic curves and distribution-based methods were employed to estimate MID. Multi-adjusted logistic regression models were conducted to identify risk factors for impaired HRQoL.

Results: 50.53% of the studied women reported impaired HRQoL during pregnancy. From early to mid pregnancy, EQ-5D-5L score deteriorated from 0.97 ± 0.07 to 0.91 ± 0.14 ($P = 0.013$) and improved slightly to 0.95 ± 0.08 in late pregnancy($P = 0.03$). Of all the eligible EQ-5D-5L profiles, problems were most frequently documented in anxiety/depression, with a proportion of 43.33%(52/120). MIDs of EQ-5D-5L for impaired HRQoL were -0.043 to -0.045. Failing to achieve HbA1c target at conception [adjusted odds ratio(OR) 3.81, 95%CI 1.16-12.55] and using continuous subcutaneous insulin infusion during pregnancy (adjusted OR 3.10, 95%CI 1.14-8.43) were significant predictors of clinically important decline in HRQoL.

Conclusions: Physical and psychological quality of life deteriorated during pregnancy in women with type 1 diabetes. Preconception management to achieve HbA1c target and individualized counseling on insulin regimen might be promising in improving the quality of life in this population.

EP032 / #74

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

THE ASSOCIATION BETWEEN COGNITIVE FUNCTION, DIABETIC FOOT ULCER AND MORTALITY AMONG DIABETIC PATIENTS

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Background and Aims: Diabetic foot (DF) is a common complication of diabetes mellitus (DM). Individuals with DM and DF achieved significantly lower scores in cognitive tests than individuals without this complication. Here, we investigated whether baseline cognitive function in individuals with DF is a determinant of mortality.

Methods: A prospective study using data collected during a case-control study conducted in 2010-2012 in which 90 participants with DF took the NeuroTrax battery of cognitive tests and paper and pencil cognitive tests, depression was assessed, and DF status was evaluated. In 2020 information pertaining to participants' vital status (dead/alive) was collected and the relationship between baseline cognitive status and vital status was assessed.

Results: During a median follow-up of 6.8 years (range 0.2-9.5), 39 participants died (43.3%). The mean age of the study population at baseline was 58.28 ± 6.95 years and most participants (75.6%) were male. Individuals with a higher global cognitive score at baseline (92.16 ± 10.95 in those alive at follow-up vs. 87.18 ± 12.24 in those that died, $p = 0.045$) had a lower risk of dying: odds ratio (OR) = 0.96 (95% CI 0.93-1.00), $p = 0.0503$. A similar trend was noted for executive function, reaction time and executive Function, Reaction Time and for Digit Symbol Substitution Test.

Conclusions: Participants with lower cognitive function at study baseline and DF had a greater risk of death. Further studies are needed to elucidate if cognitive impairment should be screened routinely and if the treatment plan should be tailored accordingly to reduce adverse outcomes in this population.

EP033 / #589

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

A RANDOMIZED CONTROLLED TRIAL TO TEST THE EFFICACY OF A TITRATION APP FOR PEOPLE WITH TYPE 2 DIABETES: BASELINE CHARACTERISTICS

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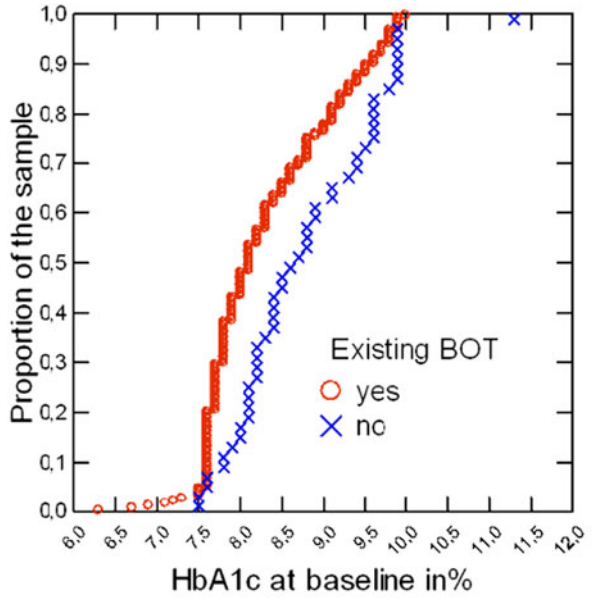
Background and Aims: The myDose Coach-study (MDC) is a multi-center, open randomized controlled study, conducted in Germany, to test the efficacy of a newly developed app (myDose Coach) for the titration of basal insulin in people with type 2 diabetes and basal-supported oral therapy (BOT). Baseline characteristics of the study sample are presented.

Methods: Eligible participants started a BOT or had an existing BOT without attaining optimal HbA1c values. They were randomized either to the intervention-group (titration by App) or to the treatment-as-usual control-group. The primary outcome is change in HbA1c 3 months after randomization. Secondary outcomes include diabetes-selfmanagement (DSMQ), diabetes-related distress (PAID) and psychological well-being (WHO-5).

Results: 123 participants (Mean age 58.7 ± 10.7 years; HbA1c 8.4 ± 0.8 %; 82.9% with existing BOT; duration of BOT 3.4 ± 4.2 years; DSMQ 7.0 ± 1.3; PAID 21.2 ± 16.3; WHO-5-index 61.2 ± 20.7) were allocated to the control-group, 128 participants to the intervention-group (Mean age 59.1 ± 11.5 years; HbA1c 8.4 ± 0.8 %; 77.3% with existing BOT; duration of BOT 3.1 ± 3.4 years; DSMQ 7.1 ± 1.4; PAID 23.7 ± 17.6; WHO-5-index 58.7 ± 21.5). There were no significant between-group-differences.



Distribution of HbA1c in participants with newly started BOT and existing BOT

However, quantile plot show that 50% of the participants with existing BOT had a HbA1c higher than 8.0% after 3.4 years with BOT.

Conclusions: Randomisation was successful to establish observational equality between both groups. Participants had suboptimal glycemic control indicating substantial clinical inertia and the need for an effective titration of the basal insulin dose in participants with new as well as exiting BOT via a digital tool. This study was funded by Sanofi, Germany.

EP034 / #822

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

EVALUATION OF THE DIABETIC NEPHROPATHY PREVENTION PROGRAM OF A JAPANESE CITY

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Background and Aims: Purpose: The aim of this study is to evaluate the original program for diabetic nephropathy prevention in a Japanese city (City A).

Methods: In 2019, After approval by the Municipal Hospital Ethics Committee of City A, seven diabetic patients were recruited to participate in an original diabetic program in City A. Subjects had had education for prevention of diabatic complication three times in three months. Their behavior was checked for prevention by a public health nurse once after three months. The behavior's evaluation consisted of a medical examination and change of their eating habit.

Results: After three months, all participants received a checkup for 1) their eyes (ophthalmologist), 2) weight variations, and 3) changes in recuperation behavior. Only three participants had HbA1c evaluated, two had decreased level after six months of health guidance, and one patient had no change. Five participants had urine protein level at 30mg / dl or more at the time of the checkup, but urine protein and eGFR test results after 6 months couldn't be obtained, thus the evaluation of nephropathy wasn't possible.

Conclusions: Conclusions: The original program in City A suggested changes in the participants' behavior. However, the study could not evaluate the preventive effects on diabetic nephropathy. In conclusion, improvements to the program are needed for checking HbA1c, urine protein, and e GFR for the evaluation index.

EP035 / #582

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

USE OF TREND ARROWS TO CALCULATE FAST-ACTING INSULIN BOLUS. COMPARISON OF 3 DIFFERENT FORMULAS

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Background and Aims: No consensus exists on the use of different formulas used for calculating insulin bolus based on the trend arrows provided by the different glucose sensors. We have designed a study with the primary aim of comparing the area under the glucose curve after a meal depending on whether the insulin bolus dose calculation was performed using or not trend arrow equations. Secondary aims were to analyze the differences in TIR, TBR, TAR, GMI, and CV.

Methods: Open crossover clinical trial. For each patient, during the first 14 days of the study, insulin bolus was calculated without taking into account the trend arrow. In the subsequent 14 days, the Pettus/Edelman equation was used and in the last 14 days the Klonoff-Kerr formula was applied. Differences in AUC corresponding to each equation respect to the reference were calculated with its confidence interval 95%. Also, student t-test was applied to check significance of these differences.

Results: 10 patients were included with a mean age of 39.9 + 12.5 years, T1D evolution of 13.7 + 10.7 years and mean HbA1c 7.6 + 0.6%. No differences were observed in the AUC with the Klonoff/Kerr equation nor with that of Pettus/Edelman. TBR was lower during the 14 days in which the Pettus/Edelman formula was used compared to not taking into account the trend arrow information. There were no further differences.

Conclusions: Use of trend arrows when calculating insulin bolus does not provide significant benefits. The best formula seems to be Pettus/Edelman, wich provides a slight reduction in TBR without affecting TIR.

	Not arrow trend	Pettus/Edelman	Klonoff/Kerr	*P* value Not arrow Vs Pettus/Edelman	*P* value Not arrow Vs Klonoff/Kerr	*P* value Pettus/Edelman Vs Klonoff/Kerr
AUC, global ((mg.min/dL) (95% CI))	0 (ref)	+ 29.62 (-221.06-280.29)	+ 84,89 (-293.39-463.18)	0.817	0.660	NA
AUC breakfast ((mg.min/dL) (95% CI))	0 (ref)	- 127.57 (-453.72-198.58)	-220.88 (-792.67-350.90)	0.443	0.449	NA
AUC lunch ((mg.min/dL) (95% CI))	0 (ref)	+ 248.89 (-79.17-576.94)	+ 532.62 (-39.36-1104.61)	0.137	0.068	NA
AUC dinner ((mg.min/dL) (95% CI))	0 (ref)	+129.45 (-206.57-465.47)	+159.89 (-430.2-743.96)	0.450	0.600	NA
GMI (% + SD)	7.26 + 0.6	7.38 + 0.5	7.32 + 0.9	0.297	0.686	0.820
TIR (% + SD)	58.8 + 14.1	59.2 + 12.5	58.1 + 19.4	0.851	0.847	0.675
TBR (% + SD)	5.5 + 5.1	2.8 + 3.0	4.89 + 3.7	**0.033**	0.676	0.282
TAR (% + SD)	35.7 + 14.6	38.0 + 12,7	37.0 + 20.4	0.364	0.667	0.937
CV (% + SD)	39.8 + 5.9	37.8 + 6.2	40.0 + 7.6	0.191	0.900	0.328

EP036 / #829

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

PREDICTING GLUCOSE DYNAMICS AS ACTIVITY INTENSITY INCREASES IN INDIVIDUALS WITH TYPE 1 DIABETES - A SUB-ANALYSIS OF THE ABC4D STUDY

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Background and Aims: Insulin dose reductions prior to exercise reduce the risk of hypoglycaemia in type 1 diabetes (T1D). The Advanced Bolus Calculator for T1D (ABC4D) study is a single-blinded randomized crossover free-living trial comparing a non-adaptive bolus calculator (control) to an adaptive bolus calculator (intervention). The aims of this sub-analysis were to identify significant predictors of glucose dynamics as activity intensity increases and analyse the effectiveness of the adaptive calculator in reducing hypoglycaemic risk during moderate-vigorous activity.

Methods: Sedentary, light and moderate-vigorous activity periods (defined by activity intensity data from participant-worn Fitbit watches) lasting twenty minutes or more throughout the study were collated. For each activity period by study phase, baseline glucose, delta glucose, mean heart rate, baseline total insulin-on-board, and baseline glucose rate of change (ROC) were calculated. Univariate and multiple regression analysis of all predictors against delta glucose were undertaken. Comparisons were made between ABC4D intervention and control.

Results: 33 participants were included (58% male, median (IQR) age 47.8 (28.2-55.2) years, diabetes duration 15.0 (9.5-29) years and baseline HbA1c 63 (58-67) mmol/mol). Baseline glucose (coefficients -0.225, -0.100, -0.126; $p < 0.001$) and glucose ROC (coefficients 10.3, 3.11, 7.11; $p < 0.001$) demonstrated the strongest associations with delta glucose across all areas of activity intensity. No differences in the associations between control and intervention were identified.

Conclusions: Our data suggest that baseline glucose and glucose ROC were the best predictors of delta glucose as activity intensity increases. These findings could be incorporated into the next generation of the adaptive bolus calculator to optimise post-exercise glycaemia.

EP037 / #593

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

A PREVENTIVE ALGORITHM FOR THE GENERATION OF POST-PRANDIAL CORRECTIVE INSULIN BOLUSES IN TYPE 1 DIABETES THERAPY

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Background and Aims: To mitigate prolonged hyperglycemic events, individuals with type 1 diabetes usually self-administer corrective insulin boluses (CIB). CIB may be delivered either according to the standard formula for bolus calculation, or resorting to more efficient heuristic strategies, as proposed by Aleppo et al., 2017, which adjusts the CIB accounting for both the current glucose level and its rate-of-change (ROC) provided by continuous glucose monitoring devices. Our work aims to develop a novel personalized strategy for triggering preventive CIB by considering the risk of upcoming hyperglycemia.

Methods: Our approach (drCIB) is based on the dynamic risk (DR) score: a nonlinear transformation of glucose levels which considers ROC in its calculation. According to drCIB, a CIB is administered when the DR of the current glycemic level crosses a tunable threshold. Moreover, drCIB implements a shut-off system that prevents delivering CIB within 2 hours from the last meal and within a personalized interval from previous CIB. drCIB is retrospectively assessed on 73 daily glucose traces, extracted from data recorded in daily-life conditions, and its efficacy is measured by: time-below-range (TBR), time-in-range (TIR), time-above-range (TAR), hyperglycemia duration (HD), and glucose risk index (GRI).

Results: Compared to the methodology of Aleppo et al., with the same number of CIB (2/day), drCIB improves TIR (57.59% vs 60.82%), significantly reduces TAR (40.08% vs 36.68%) without increasing TBR. Also, drCIB significantly reduces HD by 14.3% and lowers GRI (44.78 vs 42.03).

Conclusions: drCIB results in an effective and promising method for CIB administration, improving TIR, reducing TAR and HD, and lowering GRI.

EP038 / #402

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

BLOOD GLUCOSE LEVEL PREDICTION: AN EXPLAINABLE GRAPH-BASED METHOD

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Background and Aims: Leveraging blood glucose (BG) time series collected by continuous glucose monitoring, BG prediction enables people with type 1 diabetes (T1D) to take precautions. When considering extra factors, i.e., insulin delivery, carbohydrate intake, sleep, and exercise, the prediction accuracy can be further improved. Although long short-term memory (LSTM) has achieved satisfying performance in modelling multivariate time series (MTS), the importance of features is considerable. Comparably, a traditional approach, linear regression (LR), gives interpretability for BG time series from a temporal perspective but cannot cope with MTS.

Methods: We propose an explainable graph-based deep learning method, consisting of graph neural networks to model correlations for multiple features in MTS and gated recurrent units to model temporal dependencies. Specifically, a graph is dynamically generated at each timestep, where each node of the graph is corresponding to a variate. The weights of the edges

between adjacent nodes are also dynamically calculated to transparently extract features from MTS, which are leveraged to measure feature importance. We evaluate our proposed model in the OhioT1DM dataset, including 12 T1D participants.

Results: In terms of root mean square error (RMSE), our approach achieved 18.75 and 31.27 mg/dL for prediction horizons of 30 and 60 minutes, respectively, and outperformed LSTM (RMSE = 19.33 and 32.02 mg/dL) and LR (RMSE = 22.16 and 35.85 mg/dL).

Conclusions: Our proposed method has exhibited excellent performance, which is explainable in terms of feature importance which should translate into safer management for people with T1D.

EP039 / #671

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

PREDICTING THE EFFECTS OF LIFESTYLE ON CONTINUOUSLY MEASURED GLUCOSE LEVELS IN INDIVIDUALS WITH TYPE 2 DIABETES USING MULTILEVEL MODELING

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Background and Aims: This study aimed to quantify the acute effect of exercise, nutrition and sleep on glucose levels in people with type 2 diabetes in a real-life setting, to provide a basis for informed individual lifestyle advice.

Methods: 38 participants wore a continuous glucose monitor and activity/sleep tracker, and logged food intake for 11 periods of 4 days. The monitored lifestyle factors were used as predictors in a multilevel regression model predicting glucose values 2 hours ahead.

Results: The model included the current glucose concentration (mmol/L), carbohydrate intake (g) during the last 15 minutes, sleep (h) in the past night, and upcoming 30 minutes activity (Metabolic Equivalent of Task) as fixed effects. The average predicted glucose was allowed to differ between individuals, with a mean of 4.20 mmol/L and standard deviation of 0.86. For every unit of change in the predictor, the estimated change in 2-hour predicted glucose (mmol/L) was (estimate ± standard error): current glucose: 0.509 ± 0.002, sleep -0.022 ± 0.003, carbohydrate intake 0.018 ± 0.002, exercise -0.040 ± 0.004.

Conclusions: The multilevel model allowed to capture the effect sizes of different lifestyle behaviours across individuals. Although the effects were small, they can add up considerably, e.g. two slices of bread with 35 grams of carbohydrates would increase 2-hour glucose with 0.7 mmol/L on average. Based on the effect sizes, informed decisions on lifestyle advice for sleep, carbohydrate intake and exercise to reduce 2 -hour glucose levels can be given. The current study demonstrates the potential of glucose and lifestyle monitoring devices for supporting people with type 2 diabetes.

EP040 / #828

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

ADVANCED BOLUS CALCULATOR FOR TYPE 1 DIABETES: EVALUATION OF PARAMETER SELECTION AND ACCEPTABILITY

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Background and Aims: The Advanced Bolus Calculator for Type 1 Diabetes (ABC4D) is a decision support system on a smartphone app, employing case-based reasoning to adapt and personalise insulin bolus doses for people on multiple daily insulin injections, based on postprandial real-time continuous glucose levels. The parameters that adjusted or adapted the insulin dose recommended included exercise, delayed bolus and pre-menstrual cycle. We investigated how frequently participants selected various case parameters and ABC4D acceptability.

Methods: Participants were randomised to ABC4D or a non-adaptive bolus calculator for 12 weeks, underwent a 6 week washout then crossed-over to the other group for 12 weeks. The proportion of submissions with each case parameter selected was calculated for each participant. ABC4D acceptability questionnaires from the final visit were analysed.

Results: Thirty-three participants were included in analysis (median (IQR) age 47.8 (28.2-55.2) years, diabetes duration 15.0 (9.5-29) years, baseline HbA1c 63 (58-67) mmol/mol) (7.9 (7.5-8.3)%), male 58%). Exercise (planned and/or recent) was selected most frequently (18.6 (10.5-38.5)%) followed by delayed bolus (4.1 (1.9-8.3)%). Four female participants used the pre-cycle adjustment in 14.9 (3.3-26.5)% submissions. 75.8%/72.7% participants found planned/recent exercise respectively very or extremely useful. 93.9% considered the ABC4D application overall user friendly. 87.9% were happy overall to use the ABC4D system for bolus calculation.

Conclusions: Majority found the ABC4D application acceptable. Exercise was the most selected parameter. There is limited data on how best to manage glucose in the pre-menstrual phase and evaluating this parameter in a larger study may be of benefit for inclusion in future commercial decision support systems.

EP041 / #449

Topic: ***AS03 Closed-loop System and Algorithm***

ACHIEVEMENT OF 100% TIME IN RANGE BY USING ADVANCED CLOSED LOOP SYSTEM AFTER 12 MONTHS OF DIAGNOSIS IN TWO PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Automated insulin delivery (AID) systems have demonstrated improvements in time in range (TIR, blood glucose 70-180 mg/dl) without increasing hypoglycaemia.

Two adults (32 years and 24 years of age) with type 1 Diabetes were initiated in AID after 12 months of diagnosis with type 1 Diabetes. Both of these patients achieving 100% TIR in the most of the time without increasing hypoglycaemia. They found the AID is supporting them to achieve their blood glucose target in almost daily basis.

Methods: Carelinke data upload

Results: This is upload glucose data from carelink

Conclusions: Conclusion, the use of AID (the MiniMed 780 G system) in early stage of people with T1 DM provided robust data on achievable glycaemic control mimical normal blood glucose profile, while maintain safety from hypoglycaemia. When considering the current state of glycaemic control, it is apparent that the promise of near glycemia is achievable with AID therapies. This provides a compelling case for increasing access to these systems to people with T1DM at early stage to avoid long term complication and having normal quality of life.

EP042 / #680

Topic: ***AS03 Closed-loop System and Algorithm***

GLUCOMETRIC RESULTS OF PATIENTS TYPE 1 DIABETES WITH FREQUENT HYPOGLYCEMIA WITH THE USE OF A CLOSED LOOP SYSTEM AT THE MARQUES DE VALDECILLA UNIVERSITY HOSPITAL

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Background and Aims: A closed-loop system is one that integrates three components: an insulin pump, continuos glucose monitor, and a control algorithm that determines the infusion of insulin, based on the interstitial glucose readings, with the aim of maintaining blood glucose at stable values and close to normal. Objective: To observe whether the transition from insulin pump therapy and flash glucose monitoring to a closed-loop system in the patient entails a benefit in terms of glucometry.

Methods: Analize the results of the downloads made in libreview® in the month prior to the start of the closed-loop system and the ones made in Glooko® , Carelink® and YourLoops® , after one month of use.

Results: We coded 33 patients with recurrent hypoglycemia, severe or inadvertent, time in hypoglycemia >4%, of which 85% were women, with a mean age of 45 years, 54%(780G), 22% (Diabeloop) and 24% (Control-IQ), with no significant differences regarding the characteristics of the patients or their metabolic control. The results expressed in means are shown in the table, finding statistically significant improvements in all glucometry parameters:

	Hyper1	Hyper2	TIR	Hypo1	Hypo2	Clucemy average	GMI	CV
Prev	11,09(1-43)	21,48+/-6,6	60,91+/-14,6	5,09+/-3,3	1,45(0-8)	159+/-26	7,09+/-0,5	40,44+/-5,81
Post	3,85(0-15)	18+/-5,7	76,18+/-8,3	1,43+/-0,7	0,41(0-2)	147+/-11	6,85+/-0,2	31,02+/-3,9
p	0,00	0,02	0,00	0,00	0,00	0,02	0,03	0,00

Conclusions: The change from continuous infusion with flash monitoring glucose to a closed-loop system achieves a statistically significant improvement in glucometric control, reducing the time in hypoglycemia and achieving better metabolic control in patients with type 1 diabetes.

EP043 / #659

Topic: ***AS03 Closed-loop System and Algorithm***

ONE YEAR REAL EXPERIENCE USE OF THE CONTROL IQ ADVANCED HYBRID CLOSED LOOP TECHNOLOGY IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: Implementation of advanced hybrid closed loop systems(AHCL) has been an important advance in management of type1 diabetes mellitus (T1D) during childhood, although evidence in pediatric population is still limited. The aim of this study was to analize the evolution of international metabolic control parameters at 6 and 12 months after transition to AHCL-system, as well as to asses changes in diet and insulin requirements.

Methods: We designed a cross sectional retrospective, descriptive and analytical study. Pediatric patients with T1D with Tandem T:Slim X2 TM pump and continuos monitoring(CGM) with DexcomG6 transitioned to Control-IQ-technology for at least 6 month follow-up were included. 35 patients were studied. Mean age 11.5 ± 4years, debut at 5.4 ± 3.7years, 51% women. All variables of international CGM-consensus were recorded from online-platform Glooko®(14days)at baseline,6&12 months:sensor data(%),glucose mean and SD(mg/dl), GMI(%), glycemic variability(CV%), time in range(TIR%), hyperglycemia(levels 1&2)and hypoglycemia (levels 1&2)(%) and HbA1c(%) were analyzed. Daily insulin dose and grams of carbohydrate were registered. Statistical analysis was performed with SPSS. Data are expressed as mean ± SD. Statistical significance is considered if p-value ≤0.05.

Results: A significant improvement was observed in TIR, CV, time in hypoglycemia and HbA1c.

	0M	6M	12M	P
Coefficient of variation(%)	36,2+/-5,2	34,3+/-4,8	34,6+/-4,1	0,088
Sensor TIR(%)	75,2+/-9,7	78,6+/-7,6	78,3+/-6,3	0,025
Sensor time < 70 mg/dL(%)	5,4+/-2,9	3,8+/-2,4	3,1+/-1,9	0,020
Sensor time <54 mg/dL(%)	1,1+/-0,6	0,9+/-0,8	0,5+/-0,8	0,002
HbA1c(%)	6,6+/-0,5	6,3+/-0,5	6,2+/-0,4	0,017

Table1.Significant GlycemicOutcomes

Conclusions: -In our experience, AHCL users increased time in range and improved HbA1c from baseline to 6&12 months follow-up. -Percentage of hypoglycemia and glycemic variability decreased throughout the year.

EP044 / #62

Topic: ***AS03 Closed-loop System and Algorithm***

SODIUM-GLUCOSE COTRANSPORTER TYPE 2 INHIBITORS IN TYPE 1 DIABETES PATIENT USING CLOSED-LOOP SYSTEM IN CLINICAL PRACTICE.

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Background and Aims: The addition of gliflozins (SGLT2i) to insulin therapy in type 1 diabetes (T1D) patients allows an improvement blood glucose in levels, reduces postmeal hyperglycaemia and achieves loss weight, nevertheless there is an increased risk of diabetic ketoacidosis (DKA). The purpose was to analyse the use of SGLT2i in patients with closed-loop system (AHCL).

Methods: A retrospective, cross sectional study was performed, all AHCL users were reviewed selecting the ones that have or had had SGLT2i treatment.

Results: 195 AHCL users were analysed, 15% (n = 29) have or had had SGLT2 treatment, 72% females, age 45 ± 10 years, 50% BMI >30, 62% Medtronic 780G and 38% 670G Medtronic. Time of use 21 months. SGLT2: 76% empaglifozin, 21% dapagliflozin and 3% canaglifozin. Time of use 40 months. The average time of simultaneous use of AHCL and SGLT2i were 19 months. 14% (n = 4) presented DKA, that led to treatment suspension but it was reinitiated in 3 of them as a request of the patients to improve blood glucose and after considering the episode a infusión set failure, there were no further events. DKA happened at 33 months after SGLT2i were initiated. 3% (n = 1) suspended treatment because of pregnancy. 7%(n = 2) presented dysuria but continued the treatment. Continuos glucose monitoring data during SGLT2i treatment was analysed (Table1).

Table 1: Glucose monitoring with SGLT2	
Sensor glucosa (mg/dl)	147 ± 17
CV (%)	32 ± 4
GMI (%)	6,8 ± 0,4
Time < 54 mg/dl (%)	0,6 ± 0,9
Time 54-70 mg/dl (%)	1,8 ± 1,5
Time 70-180 mg/dl (%)	74,9 ± 11,5
Time 180-250 mg/dl (%)	18,7 ± 7,9
Time >250 mg/dl (%)	4,1 ± 4,3

Abbreviation: GMI (glucose management indicator), CV (coefficient of variation).

Conclusions: The use of SGLT2i in DT1 is a reality in clinical practice. SGLT2i can be an alternative to improve glucemic control and reduce weight in DT1 patients using AHCL. However, the increased risk of DKA has to be taken into account.

EP045 / #830

Topic: ***AS03 Closed-loop System and Algorithm***

IMPACT ON GLYCEMIC CONTROL AND QUALITY OF LIFE AFTER SWITCHING FROM A SENSOR AUGMENTED PUMP TO AN HYBRID CLOSED LOOP IN TYPE 1 DIABETIC SUBJECTS

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Background and Aims: Hypoglycemic episodes can affect the quality of life (QoL) of patients with T1DM. New technological devices such as hybrid closed loop (HCL) systems, could improve metabolic control, reducing hypoglycemic episodes, which could improve QoL of these patients. This is a real life study assessing the impact of initiating HCL on glycemic control and QoL in T1DM patients using a sensor-augmented pump (SAP).

Methods: from June 2021 to May 2022 66 patients using SAP changed to an HCL system. Data regarding hypoglycemia and QoL was assessed at the beginning and three months after initiating the HCL by means of several questionnaires.

Results: Most patients (74.2%) were women, mean age was 44 ± 11 years old and diabetes duration of 27.2 years. 44.3% had at least one chronic complication with no macrovascular complications. All patients were using a SAP and median HbA1c was 7.3 ± 0.9%. Three months after starting HCL significant improvements were observed in coefficient of variation (from 35.6% to 33.1%, p = 0.01), time in range (from 62,2 % to 73.8%, p = 0.00), time above 180 mg/dl (from 18% to 26.9%, p = 0.00), time below 70 mg/dl (from 3.3% to 2.1%, p = 0.01) and time below 55 mg/dl (0.7% to 0.3%, p = 0.01). Significant improvements were observed in fear of hypoglycemia, grade of distress and in depression and anxiety scores.

Conclusions: Switching from SAP to HCL system improves time in range, reduces time in hypoglycemia and glycemic variability at 3 months. Moreover, an improvement in the scores obtained in different QoL questionnaires has been observed.

EP046 / #735

Topic: ***AS03 Closed-loop System and Algorithm***

IMPROVED DYSPEPTIC SYMPTOMS OF TYPE 1 DIABETES ADULTS WITH GASTROPARESIS ON HYBRID CLOSED LOOP SYSTEM: CASE SERIES.

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Background and Aims: Gastroparesis is a complication of diabetes, associated with unpredictable gastric emptying (GE). It can lead to poor glycemic control and adverse gastrointestinal (GI) symptoms. It is unclear if improving glycemic control reduces GE and GI symptoms.

Methods: We followed 3 type 1 diabetic (DT1) women with long duration of diabetes (mediane (IQR): 42 (30-44) years) and gastroparesis, during 4 to 12 months after starting on HCL system. We assessed HbA1c, continuous glucose monitor based glucose metrics, and gastroparesis symptoms using validated Gastroparesis Cardinal Symptoms Index (GCSI). Gastric scintigraphy was performed in one patient, 10 months after HCL use and results were compared with the initial one (two years before starting HCL system).

Results: Overall glycemic control improved on HCL system: HbA1c reduced (difference from baseline, mediane (IQR): 0.5% (0.5%, 0.75%); Time in range (70-180mg/l) increased (median (IQR): 70% (66.5%-73%) vs 48% (43%-53%) at baseline) and time in hyperglycemia decreased (median (IQR): 30% (27%-33%) vs 52% (43%-56%) at baseline). All patients reported fewer GI symptoms on HCL system and that was confirmed by a lower GCSI score for all (median (IQR): 2.08 (1.47-2.75) vs 3.92 (2.68-4.03) at baseline. Furthermore, one patient had improved GE, yet still pathological, on gastric scintigraphy performed after HCL vs before (GE half-life: 185 vs 422 mn respectively).

Conclusions: HCL improves GI symptoms and glycemic control of T1D adults with gastroparesis. Confirmation with a larger cohort is needed.

EP047 / #893

Topic: ***AS03 Closed-loop System and Algorithm***

REAL-WORLD PERFORMANCE OF THE ADVANCED HYBRID CLOSED-LOOP SYSTEM IN ADULTS WITH TYPE 1 DIABETES PREVIOUSLY TREATED WITH DIFFERENT TREATMENT MODALITIES

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Background and Aims: The Advanced Hybrid Closed-Loop system (AHCL) MiniMed^{TM} 780G adapts basal infusion rates and delivers autocorrection boluses. The aim was to analyse the differences in glycemic outcomes according to previous treatment after 3 months of use in real-life clinical practice of the AHCL system in people with type 1 diabetes (PwT1D).

Methods: A prospective study was performed. PwT1D receiving different treatment modalities were upgraded to AHCL. Glycemic outcomes at baseline and after 3 months on AHCL were compared.

Results: 84 PwT1D were included (mean age 41.8 ± 12 years, 57.1% females, diabetes duration 27 ± 11 years). Of them, 8(9,5%) patients were on flash glucose monitoring (isCGM) and multiple daily injections (MDI), 43(51,2%) were on isCGM and continuous subcutaneous insulin infusion (CSII, MiniMed^{TM} 640G), 19(22,6%) were using sensor-augmented pumps with predictive low-glucose suspend function (SAP-PLGS) and 14(16,6%) were using hybrid closed-loop systems (HCL, Minimed^{TM} 670G). Glycemic outcomes after 3 months of use of AHCL compared to baseline with different previous therapy are shown in Table 1. In all groups, the time in range (TIR) 70-180 mg/dL increased compared to baseline associated with a reduction in time in hyperglycemia without increasing time in hypoglycemia. This increase in TIR was greater (+18.5%) in the isCGM+MDI group (p = 0.024) by a significant reduction in time in hyperglycemia >180 mg/dL from 22.2 ± 8.3 to 13.0 ± 6.1.

Conclusions: In a real-world clinical setting, the MiniMed^{TM} 780G AHCL system provides an improvement in glycemic outcomes in adults with T1D independently of the previous treatment, with the greatest improvement in patients previously treated with MDI.

EP048 / #898

Topic: ***AS03 Closed-loop System and Algorithm***

FAST-ACTING INSULIN ASPART COMPARED WITH RAPID-ACTING INSULIN ANALOGS IN THE ADVANCED HYBRID CLOSED-LOOP SYSTEM IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Faster-acting insulin aspart, Fiasp® (FA) offers a more rapid onset of insulin action when compared with current rapid-acting insulin. Our aim was to evaluate glucose control and safety using FA compared with rapid-acting insulin analogs (insulin lispro, aspart, glulisine) delivered by the AHCL system in adults with type 1 diabetes (T1D) after 3 months of use in real-life clinical practice.

Methods: A prospective study was perfomed. Glycemic outcomes were compared at baseline with sensor-augmented

Table 1. Glycemic outcomes after 3 months of use of an AHCL compared to baseline with different previous therapy

	isCGM + MDI (n=43)				isCGM + CSII (n=43)				SAP-PLGS (n=19)				HCL (n=14)			
	Baseline (isCGM)	3 months (AHCL)	Difference (95% CI)	p	Baseline (isCGM)	3 months (AHCL)	Difference (95% CI)	p	Baseline (SAP-PLGS)	3 months (AHCL)	Difference (95% CI)	p	Baseline (SAP-PLGS)	3 months (AHCL)	Difference (95% CI)	p
Time 70–180 mg/dL (%)	64.0 ± 14.3	82.0 ± 9.0	+18.5 (-16.7 to -5.9)	**0.024**	67.9 ± 15.6	74.5 ± 12.2	+7.2 (-11.8 to -2.7)	**0.003**	67.8 ± 20.2	72.6 ± 17.6	+5.2 (-14.2 to 3.8)	0.237	75.3 ± 11.9	77.6 ± 9.4	+2.5 (-6.1 to 3.0)	0.535
Time >180 mg/dL (%)	22.2 ± 8.3	13.0 ± 6.1	-9.1 (-15.9 to -17.6)	**0.024**	25.0 (3.6-29)	17 (7.82-29)	-6.5 (-23.4 to 6.4)	0.156	18.0 (10-28)	13.0 (0-30)	-3.5 (-9.0 to 6.6)	0.505	18.9 ± 11.9	16.9 ± 7.3	-2.4 (-8.4 to 5.5)	0.637
Time >250 mg/dL (%)	10.5 ± 13.1	2.8 ± 3.6	-7.6 (-15.5 to -17.6)	0.055	4.0 (0-8)	2.0 (0-4)	-2.5 (0.4 to -4.7)	**0.018**	4.0 (2-7)	2.0 (0-8)	-3.6 (-9.3 to -7.3)	**0.019**	3.8 ± 2.9	3.7 ± 2.3	-0.4 (-2.2 to -3.0)	0.705
Time <70 mg/dL (%)	8.6 ± 6.0	1.4 ± 0.9	-5.3 (-9.3 to -6.8)	0.067	4.0 (2-9)	2.0 (1-4)	-2.4 (-3.2 to -3.6)	**0.001**	2.8 ± 2.4	2.7 ± 1.5	-0.3 (-5.8 to -5.1)	0.764	2.0 (0-3)	2.0 (1-3)	-0.3 (-0.5 to -0.3)	0.564
Time <54 mg/dL (%)	0.5 (0-1)	0.0 (0-1)	-0.6 (-0.7 to -2.0)	0.157	0 (0-1)	0 (0-1)	-0.6 (-0.2 to -1.3)	0.067	0 (0-1)	0 (0-1)	0 (-0.6 to 0.4)	0.480	0.0 (0-1)	0.0 (0-1)	-0.2 (-0.7 to -0.3)	0.157
Mean glucose (mg/dL)	158.0 ± 29.2	159.5 ± 16.6	+1.5 (-44.0 to 41.0)	0.956	145 (134-171)	140 (128-163)	-4.4 (-7.1 to -15.8)	0.455	156 (140-168)	144 (126-157)	-13.2 (-23.0 to -23.5)	**0.020**	154.3 ± 30.5	148.2 ± 27.3	-13.5 (-18.6 to -28.9)	0.062
GMI (%)	7.1 ± 0.7	6.8 ± 0.37	-0.5 (-0.3 to -1.2)	0.175	6.9 (7-8)	6.8 (6-7)	-0.3 (0.1 to -0.5)	**< 0.001**	6.7 (6-7)	6.6 (6-7)	-0.2 (0.1 to -0.5)	**0.039**	6.8 ± 0.5	6.7 ± 0.3	-0.1 (+0.2 to -0.3)	0.408
CV of glucose (%)	36.5 ± 8.4	33.9 ± 3.8	-7.4 (0.4 to -14.4)	0.941	36.8 ± 7.9	32.8 ± 5.5	-4.0 (2.2 to -5.7)	**< 0.001**	35.3 ± 5.0	32.5 ± 4.1	-3.3 (-1.6 to -4.2)	0.354	33.6 ± 4.5	32.4 ± 4.4	-0.6 (-1.6 to -5.0)	0.759

Data are presented as mean ± SD or as medians (IQRs)

IQR: interquartile range, SD: standard deviation

p value <0.05 was considered statistically significant

AHCL, advanced hybrid closed-loop; CSII, continuous subcutaneous insulin infusion; CV, coefficient of variation; isCGM, intermittently scanned continuous glucose monitoring; GMI, glucose management indicator; HCL, hybrid closed-loop; MDI, multiple daily insulin injections; SAP-PLGS, sensor-augmented pump with predictive low-glucose suspend.

Table 1. Outcomes in glycemic control at baseline and after 1 and 3 months of using faster aspart *vs.* rapid-acting insulin analogs in AHCL system

	Faster aspart (n=28)				Rapid-acting insulin analogs (n=56)			
	Baseline (SAP-PLGS)	1 month (AHCL)	3 months (AHCL)	p	Baseline (SAP-PLGS)	1 month (AHCL)	3 months (AHCL)	p
Time 70–180 mg/dL (%)[1]	74.0 (66-81)[a]	84.0 (72-86)[b]	82.0 (77-87)[b]	**0.015**	69.0 (59-80)[a]	76.0 (67-82)[b]	75.0 (66-84)[b]	**0.001**
Time >180 mg/dL (%)[1]	20.0 (13-26)[a]	13.5 (9-20)	12.0 (10-17)[b]	**0.038**	25.0 (14-30)[a]	18.0 (12-28)[b]	18.0 (11-27)[b]	**0.018**
Time >250 mg/dL (%)[1]	2.0 (1-6)	1.0 (0-3)	1.5 (1-3)	0.055	4.0 (2-6)[a]	2.0 (1-5)[b]	2.5 (1-4)[b]	**<0.001**
Time <70 mg/dL (%)[1]	2.0 (1-4)	2.0 (1-4)	2.0 (1-3)	0.987	2.0 (1-3)	2.0 (1-4)	2.0 (1-4)	0.792
Time <54 mg/dL (%)[1]	0.0 (0-1)	0.0 (0-1)	0 (0-1)	0.926	0.0 (0-1)	0.0 (0-1)	0.8 (0-1)	0.123
Mean glucose (mg/dL)[2]	155.0 (143-170)[a]	157.0 (126-150)[b]	137.0 (126-158)[b]	**0.013**	161.0 (149-178)[a]	144.0 (133-163)[b]	145.5 (134-170)[b]	**0.001**
GMI (%)	6.7 ± 0.3[a]	6.5 ± 0.3[b]	6.5 ± 0.3[b]	**0.003**	6.9 ± 0.6[a]	6.7 ± 0.4[b]	6.7 ± 0.5[b]	**<0.001**
CV of glucose (%)	31.4 ± 4.9	31.2 ± 3.9	31.7 ± 4.4	0.766	33.3 ± 5.7	32.6 ± 5.2	32.3 ± 5.2	0.297

Data are presented as mean ± SD or as medians (IQRs)

IQR: Interquartile range; SD: standard deviation

p value <0.05 was considered statistically significant

[1]Friedman test; [2]Repeated measures ANOVA; [a]p-adjusted by multiple comparisons – Bonferroni Correction

Different superscripts indicate pairwise differences in monitoring times

AHCL, advanced hybrid closed-loop; CSII, continuous subcutaneous insulin infusion, CV, coefficient of variation, GMI, glucose management indicator; SAP-PLGS, sensor-augmented pump with predictive low-glucose suspend.

Table 2. Differences in glycemic outcomes and Insulin Delivery between faster aspart and rapid-acting insulin analogs at the end of follow-up

	Faster aspart (n=28)	Rapid-acting insulin analogs (n=56)	P
Time 70–180 mg/dL (%)	82.0 (77-87)	75.0 (66-84)	0.050
Time >180 mg/dL (%)	12.0 (10-17)	18.0 (11-27)	**0.044**
Time >250 mg/dL (%)	1.5 (1-3)	2.5 (1-4)	0.316
Time <70 mg/dL (%)	2.0 (1-3)	2.0 (1-4)	0.361
Time <54 mg/dL (%)	0 (0-1)	0 (0-1)	0.253
Mean glucose (mg/dL)	144.2 ± 26.5	151.5 ± 37.0	0.230
GMI (%)	6.5 (6-7)	6.6 (6-7)	0.076
CV of glucose (%)	31.7 ± 4.4	32.9 ± 5.2	0.460

Data are presented as mean ± SD or as medians (IQRs)

IQR: Interquartile range; SD: standard deviation

p value <0.05 was considered statistically significant

AHCL, advanced hybrid closed-loop; CSII, continuous subcutaneous insulin infusion; CV, coefficient of variation; GMI, glucose management indicator; SAP-PLGS, sensor-augmented pump with predictive low-glucose suspend.

pump with predictive low-glucose suspend (SAP-PLGS) function and after 1 month and 3 months of using FA vs. rapid-acting insulin in AHCL system. An active insulin time (AIT) of 3 hours were set.

Results: 84 subjects (mean age 41.8 ± 12 years, 57.1% females, diabetes duration 27 ± 11 years) were included. At 3 months, time in hyperglycemia was lower with FA compared to rapid-acting insulin (12% vs. 18%, p = 0,044). At different follow-up times, time in range (TIR) 70-180 mg/dL was significantly higher using FA. No differences in time in hypoglycemia or glycemic variability were seen. No significant differences in total daily dose or basal daily dose were found between groups, but using FA appears to require less total daily insulin dose and automatic correction boluses. At the end of follow-up, the duration of AIT was lower for FA (2.5hours vs. 3hours). No episodes of severe hypoglycemia or diabetic ketoacidosis occurred.

Conclusions: The use of FA in an AHCL system provides greater time in range and less time in hyperglycemia, in a safe manner, compared with rapid-acting insulin analogs in adults with T1D.

EP049 / #711

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCEMIC OUTCOMES AFTER 3 MONTHS OF USE IN REAL-WOLRD OF AN ADVANCED HYBRID CLOSED-LOOP SYSTEM IN TYPE 1 DIABETES

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Background and Aims: The MiniMed™ Advanced Hybrid Closed-Loop (AHCL) system includes automatic basal insulin delivery every 5 minutes, adjustable to targets of 100, 110, and 120 mg/dL and automatic correction boluses to a fixed glucose target of 120 mg/dL. The aim of the study was to evaluate the effectiveness and safety of the AHCL system in people with type 1 diabetes (T1D) after 3 months of use in real-life clinical practice.

Methods: A prospective study including people with T1D (PwT1D) previously treated with different treatment modalities who were upgraded to AHCL was perfomed. Glycemic outcomes from 2-week downloads were compared at baseline with flash or intermittently scanned continuous glucose monitoring (isCGM) and Manual Mode of AHCL and after 1 month and 3 months following the start of Auto Mode. A glucose target of 100 mg/dL and an active insulin time of 3 hours were set.

Table 1. Glycemic outcomes at 1 and 3 months of follow-up

	Baseline (isCGM)*	Baseline (AHCL Manual Mode)	1 month (AHCL Auto Mode)	3 months (AHCL Auto Mode)	p	p adjusted**
N	51	84	84	84		
Time 70–180 mg/dL (%)[1]	67 (54-80)[a]	69 (61-79)[a]	78 (67-85)[b]	78 (65-85)[b]	< 0.001	< 0.001
Time >180 mg/dL (%)[1]	23.0 (13-32)[a]	25.0 (16-29)[a]	17.0 (12-28)[a]	15.0 (10-27)[b]	0.002	0.017
Time >250 mg/dL (%)[1]	2.0 (0-8)[a]	4.0 (1-6)[a]	2.0 (1-4)[b]	2.0 (1-4)[b]	< 0.001	0.023
Time <70 mg/dL (%)[1]	4.0 (1-8)[a]	2.0 (1-3)[b]	2.0 (1-4)[b]	2.0 (1-4)[b]	< 0.001	< 0.001
Time <54 mg/dL (%)[1]	0 (0-1)[a]	0 (0-1)[a]	0 (0-1)[a]	0 (0-1)[a]	0.260	
Mean glucose (mg/dL)[1]	147 (133-171)[a]	159 (145-175)[a]	144 (128-156)[b]	141 (128-160)[b]	< 0.001	< 0.001
GMI (%)[1]	6.9 (6-7)[a]	6.8 (6-7)[b]	6.6 (6-7)[b]	6.6 (6-7)[b]	< 0.001	< 0.001
CV of glucose (%)[1]	35.6 (30-40)[a]	32.4 (29-36)[b]	32.1 (29-35)[b]	31.7 (29-36)[b]	< 0.001	< 0.001

Data are presented as medians (IQRs)
IQR: Interquartile range
p value <0.05 was considered statistically significant
*Baseline data, group previously treated with isCGM and MDI, or isCGM and CSII
[1]Friedman test; **p-adjusted by multiple comparisons – Bonferroni Correction
Different superscripts indicate pairwise differences in monitoring times
AHCL, advanced hybrid closed-loop; CV, coefficient of variation; isCGM, intermittently scanned continuous glucose monitoring; GMI, glucose management indicator.

Results: 84 PwT1D patients were included (mean age 41.8 ± 12 years, 57.1% females, diabetes duration 27 ± 11 years). Glycemic outcomes 1 month and 3 months after transitioning are shown in Table 1 and demonstrate increased time in range (TIR) 70-180 mg/dL and decreased time in hypoglycemia, time in hyperglycemia, mean glucose, GMI, and glycemic variability. Time in Auto Mode was maintained at 99% throughout the follow-up. No episodes of severe hypoglycemia or diabetes ketoacidosis occurred.

Conclusions: The AHCL MiniMed™ 780G system improves glycemic control after 3 months of use in a real-life clinical setting.

EP050 / #486

Topic: ***AS03 Closed-loop System and Algorithm***

NEXT GENERATION CLOSED LOOP ALGORITHM: QUALITY OF LIFE IMPACT

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Background and Aims: Hybrid closed loop systems (HCL) have been transformational in improving physical and mental health outcomes for people with type 1 diabetes. Their efficacy and impact have been well-reported, however challenges remain with alarm fatigue, connectivity issues and burden of system management. The impact of fully automated insulin delivery systems is unclear. The aim of this sub-study was to evaluate the impact of a fully automated CL system on quality of life.

Methods: semi-structured interviews were conducted with participants, using the Schedule for the Evaluation of Individualised Quality of Life (SeiQoL) measure. Factors important to quality of life and the impact of diabetes and its treatment were explored. Participants were interviewed twice, once at baseline and again after the intervention phase of the study.

Results: Ten participants were interviewed (nine at follow-up). Most frequently endorsed benefits included feeling better overall, feeling less stressed, greater spontaneity and ease of life generally; greater freedom associated with food, 'time off' from diabetes, ease of use, improved blood glucose control (and fewer hypos/hypers). Reported downsides were frequent alarms/vibrations (particularly at night), blue-tooth connectivity challenges, dissatisfaction with the insulin pump eg small cartridge size, and a preference by two participants for a higher 'low glucose alert' set by the doctor.

Conclusions: satisfaction with the system was high with positive impact reported by most participants. Minor technical hassles and frequent alarms remain an issue with CL systems, however this did not diminish almost all participants' enthusiasm or desire to keep it.

EP051 / #24

Topic: ***AS03 Closed-loop System and Algorithm***

TO SLEEP OR NOT TO SLEEP: AN ITALIAN CONTROL IQ-UESTION

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Background and Aims: Tandem Control-IQ is an Advanced Hybrid Closed Loop (AHCL) system with a Sleep Activity Mode to intensify glycemic control overnight. The aim of the study is to evaluate the effectiveness of using Sleep Activity Mode or not among Tandem Control-IQ users.

Methods: We performed retrospective Tandem Control-IQ data download for the patients followed at IRCCS G.Gaslini Pediatric Diabetes Centre. We divided the patients into Group 1 (Sleep Activity mode users) and Group 2 (non-users) and compared their overall glycemic data and in particular during night-time.

Results: Group 1 does not show a better nocturnal glycemic control as expected, when compared to Group 2. Group 2 shows a better night-time TIR% (69.50 versus 66.25, $p = 0.20$). Only the patients who do not use sleep activity mode and with sensor and automatic mode use ≥90% reached recommended TIR (> 70%) during night-time, as well as lower nocturnal TAR% (18.80 versus 21.78, $p = 0.05$).

Conclusions: This is the first study that evaluates the real-life effectiveness of the use of Sleep Activity Mode in young patients with T1D. Control-IQ Sleep Activity Mode may not be as effective in Italian patients as in American patients due to the different habits.

EP052 / #43

Topic: ***AS03 Closed-loop System and Algorithm***

IMPROVED TIME IN RANGE WITH A HYBRID CLOSED-LOOP SYSTEM AND LOWER CARBOHYDRATE DIET: INTERIM RESULTS FROM A 32 WEEK STUDY

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Background and Aims: Hybrid closed-loop (HCL) systems improve glycaemic control in T1D. However, many patients do not achieve glycaemic targets. A lower carbohydrate diet (LCD), <130g carbohydrates/day, may lead to improved outcomes. We present interim results from the intervention arm of a study investigating the impact on glycaemic control of a HCL system in combination with a LCD.

Methods: Adults with C-peptide negative (<200 pmol/L) T1D (>5 years) naïve to HCL and rtCGM were recruited. Participants used the Tandem t:slim X2 insulin pump with Control-IQ technology with Dexcom G6 rtCGM and consumed <40g of carbohydrate/meal. Pump data was reviewed weekly.

Results: Eleven participants (4 female) were recruited. At 12 weeks, time in range (TIR) improved in the daytime, mean ± SD 55.4% ± 15.5 to 76.8% ± 7.3 ($P = 0.001$), and night-time, 48% ± 13 to 85.5% ± 10.4 ($P < 0.0001$). Time spent >10.0mmol/L and >13.9mmol/L decreased in both the daytime, 42.4% ± 16.9 to 21.6% ± 7.2 ($P = 0.003$) and 51.9% ± 14.2 to 3.3% ± 2.8 ($P = 0.02$) respectively, and night-time, 49.6% ± 15.9 to 13.2% ± 10.4 ($P < 0.001$) and 17.6% ± 13 to 2.9% ± 4.1 ($P = 0.005$) respectively. There was no change in time <3.9mmol/L ($P = 0.55$) and <3.0mmol/L ($P = 0.54$). Total carbohydrate intake reduced from 178g±80.4 to 118g±1.83 daily but failed to reach statistical significance ($P = 0.08$). The amount of carbohydrates consumed per meal decreased ($P = 0.002$) but meal frequency increased. No adverse events were reported.

Conclusions: In this intervention, HCL combined with a LCD in adults with T1D resulted in a mean improvement in TIR of 25.4 percentage points with no adverse events. We propose this is a safe way to improve glycaemic control in this patient cohort.

EP053 / #30

Topic: ***AS03 Closed-loop System and Algorithm***

LONG-TERM GLYCAEMIC OUTCOMES OF AN ADVANCED HYBRID CLOSED-LOOP SYSTEM

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Background and Aims: The Advanced Hybrid Closed-Loop system (AHCL) MiniMed™ 780G infuses microboluses and autocorrection boluses according to sensor glucose values. The aim was to evaluate the outcomes achieved in people with type 1 diabetes (T1D) after 1 year of use of the system.

Methods: Subjects with T1D initiating the 780G system were prospectively evaluated. Time 70-180 mg/dl (TIR), >180 mg/dl, >250 mg/dl, <70 mg/dl and <54 mg/dl were compared at baseline and after 1 year of use.

Results: 135 subjects were included: 64% females, age: 35 ± 15 years, 19% <18 years-old, diabetes duration: 21 ± 12 years, baseline HbA1c: 7.30 ± 0.89%, baseline treatment: 73% (n = 99) pump therapy.

The autocorrection feature was activated in all the subjects, the glucose target was 100 mg/dl in 84% and active insulin time was 2 hours in 76% of the individuals. At the end of the follow-

Table. Outcomes after 1 year of use of the AHCL compared to baseline.

	Baseline	End of follow-up	p
GMI (%)	6.98 ± 0.49	6.67 ± 0.32	< 0.001
Time 70-180 mg/dl (%)	67.26 ± 11.80	77.41 ± 8.85	< 0.001
Time < 70 mg/dl (%)	3.48 ± 3.47	2.96 ± 2.69	0.56
Time < 54 mg/dl (%)	0.87 ± 1.36	0.71 ± 1.04	0.156
Time > 180 mg/dl (%)	29.25 ± 13.13	19.53 ± 8.98	< 0.001
Time > 250 mg/dl (%)	6.18 ± 6.21	3.27 ± 3.00	< 0.001
Sensor glucose (mg/dl)	154 ± 20	141 ± 13	< 0.001
Standard deviation of sensor glucose (mg/dl)	53 ± 9	47 ± 8	< 0.001
Coefficient of variation of glucose (%)	34.0 ± 4.5	33.5 ± 4.3	0.286
Sensor use (%)	84.7 ± 12.3	90.4 ± 9.3	< 0.001

up, time in automode was 95.6 ± 7.2% and autocorrection insulin was 31.8 ± 14.1% of bolus insulin. The percentage of people with the optimal combination of TIR >70% and time <70mg/dl <4% increased from 23% to 53% after 1 year; the percentage with TIR >70% and time <54 mg/dl <1% increased from 20% to 42% (both $p < 0.001$). No differences were seen in TIR at the end of follow-up in MDI *vs* pump users, people with high hypoglycaemia risk at baseline or children and younger adults (≤ 25 years old) compared to older adults. Similarly, no differences in improvement in TIR were seen in any of these subgroups.

Conclusions: AHCL systems provide a sustained benefit in different subpopulations of people with T1D.

EP054 / #837

Topic: ***AS03 Closed-loop System and Algorithm***

DBLG1 SYSTEM (DIABELOOP) AND HYPOGLYCEMIA UNAWARENESS: A CASE REPORT

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Background and Aims: Improving glycemic control, without increasing the risk of hypoglycemia, is a challenge in type 1 diabetes (T1D). Here, we report a case where such a goal has been attempted by using an automated insulin delivery system.

Methods: R.F. is a 49-years woman, with T1D from 39-years, with laser-treated retinopathy, nephropathy, and peripheral neuropathy. With insulin pump (Accu-Chek Spirit Combo-Roche) and isCGM (Freestyle Libre-Abbott) optimal HbA1c levels were achieved (5,9%) at the expense of an excess of hypoglycemic episodes (Time Below Range -TBR - 26%, <54 mg/dL: 14%), most of them unwarned. Therefore, she was started on a DBLG1 system (Accu-Chek Insight-Roche, DBLG1-Dexcom-G6).

Results: Two weeks after starting on TBR decreased to 1.2% (<54 mg/dL: 0.2%) and it remained low after 1, 3, 6 and 9 months (2.1%, 1.1%, 3.4%, and 1.1%, respectively). The GMI before DBLG1 was 5.9% and it increased slightly to 6.7%, 6.6%, 6.5%, 6.4%, and 6.2%, respectively. Similarly, the 14-day mean glycemia was 107 at baseline 144, 139, 132, 128 and 120 mg/dL afterwards. Conversely, the baseline coefficient of variation (CV, 44,6%) was reduced to 22%, 25%, 26%, 30% and 25% respectively. After 9-month DBLG1 the patient experienced a partial recovery of symptoms for hypoglicemia <54 mg/dl.

Conclusions: DBLG1 system in this subject lead to a rapid and persistent reduction of hypoglycemic events with partial recovery of symptoms, progressive improvement in mean blood glucose and GMI, with CV consistently <36%. These data prompt the need of confirmatory randomized controlled trials in people with T1D prone to hypoglycemia.

EP055 / #387

Topic: ***AS03 Closed-loop System and Algorithm***

SUCCESSFUL USE OF ADVANCED HYBRID CLOSED LOOP SYSTEM IN AN ADOLESCENT WITH DIABETIC GASTROPARESIS

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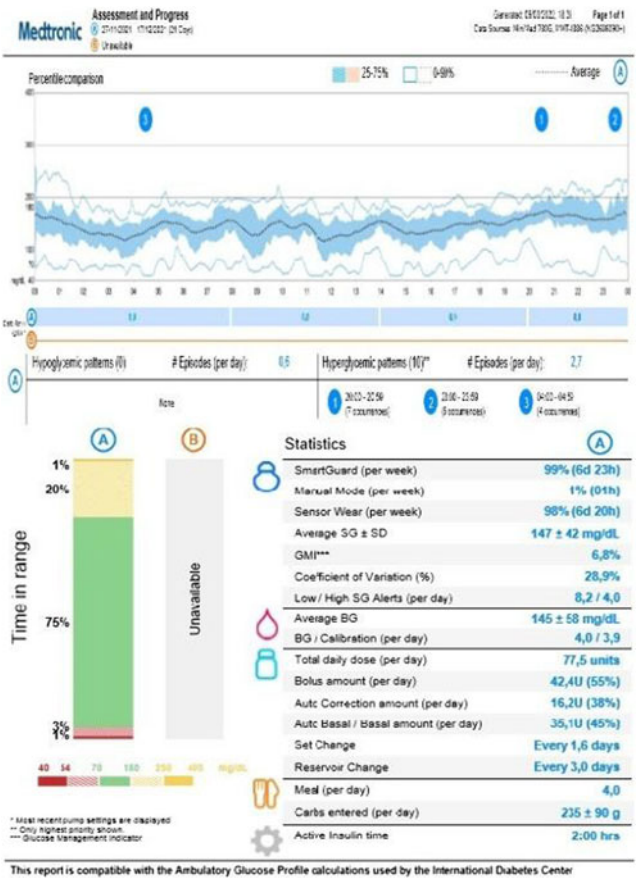
Background and Aims: Gastroparesis is a long-term complication of diabetes characterized by delayed gastric emptying, which may adversely affect glycemic variability and increase the risk of hypoglycemia. In addition to pharmacological treatment, optimization of glucose control is mandatory to normalize gastric emptying. Here, we report the case of a 16-year-old girl with diabetic gastroparesis successfully managed with an aHCL insulin pump.

Methods: A Caucasian girl with long-standing and poorly controlled T1D, previously on multiple daily injections therapy, was admitted to our Department due to a history of recurrent episodes of vomiting and abdominal pain. Diagnosis of diabetic gastroparesis was made by performing gastric emptying scintigraphy, and



treatment with metoclopramide was practiced. To reduce glycemic excursions, insulin therapy with aHCL system (Minimed™ 780G; Medtronic Diabetes, Northridge, CA, USA) was started.

Results: The patient spent only three days in manual mode before activating auto mode. Figure 1 shows the achievement of optimal glycemic control within the first 3 weeks of aHCL use. The ambulatory glucose profile revealed the following parameters: TIR 75%, TAR 21%, TBR 4%, CV 28.9%, GMI 6.8%. Thereafter, a progressive improvement of gastrointestinal symptoms was recorded and therapy with prokinetics was discontinued without any exacerbations in the following three-month follow-up.

Conclusions: To the best of our knowledge, this is the first report of real-world use of aHCL to manage gastroparesis in a pediatric patient. Our experience suggests that insulin therapy with aHCL could be considered a first-choice treatment also in children and adolescents with this rare but insidious complication.

EP056 / #343

Topic: ***AS03 Closed-loop System and Algorithm***

USE OF CONTROL-IQ SYSTEM DURING PREGNANCY IN TYPE 1 DIABETES: TWO CLINICAL CASES

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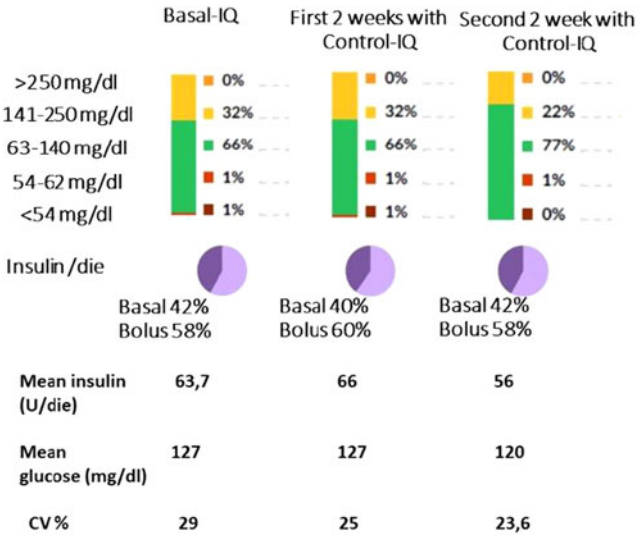
Background and Aims: The use of AHCL systems is increasing in women with type 1 diabetes (T1D), however such systems are not yet authorized during pregnancy.

Methods: We presents two clinical cases of Control-IQ system use during pregnancy in women with T1D.

Results: Case 1: A 33-year-old nulliparous with T1D used Tantem X-Slim with Basal-IQ system since 5 month with good glycemic control (TIR 86%, TBR 5%, TAR 9%, CV 32%). She was considering switching to Control-IQ when she discovered she was 8 weeks pregnant. After patient informed consent, we decided for the switch, also if pregnant, to have lower burden of glucose control on every day life and a reduction of glucose variability. To reach lower mean glucose, closer to pregnancy target, sleep-activity was sets for 24 hours/day. Pregrancy proceeded regularly with excellent glycemic values, any severe hypoglicemia and low glycemic variability (figure 1). Delivery was induced at 38 + 3 weeks, Control-IQ was used during labor and natural childbirth without complications.

Case 2: A 31-year-old with T1D used Basal-IQ system for 7 months during pregnancy without optimal glucose control, also for night-eating disorder. Switch to Control-IQ with sleep-activity for 24 hours/day improved mean glucose value and glucose variability (figure 2), without any severe hypoglicemia. Delivery was induced at 38 weeks and Control-IQ used during during labor and natural childbirth without complications.

	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER
Mean insulin (U/die)	32,5	36,9	52,7	61,9	72,5	79,8
Mean glucose (mg/dl)	111	108	112	115	116	113
CV %	27	26	27	28	25	27
Weight (kg)	68	68	70	71	74	75



	Basal-IQ	First 2 weeks with Control-IQ	Second 2 week with Control-IQ
Mean insulin (U/die)	63,7	66	56
Mean glucose (mg/dl)	127	127	120
CV %	29	25	23,6

Conclusions: Control-IQ system could be used during pregnancy in motivated women with T1D. Sleep-activity set for 24 hours/day could be usefull to reach lower mean glucose without hypoglycemic episods and with low glucose variability.

EP057 / #900

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCEMIC OUTCOMES OF REAL-WORLD MINIMED™ 780G SYSTEM USERS FROM LATIN AMERICA

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Background and Aims: Automated insulin delivery (AID) systems have shown remarkable glycemic outcomes in people with type 1 diabetes (T1D)[1-3]. The lack of racial and ethnic diversity in past analyzed cohorts has been suggested as one of the driving factors preventing universal AID adoption[4, 5]. This real-world study reports on glycemic outcomes of MiniMed™ 780G system users from Latin America.

Figure 1. Glycemic control in overall group and sub-groups

	Overall	Argentina	Brazil	Chile	Colombia	Users ≤15 years	Recommended Settings*
Users, *n*	1025	133	454	213	225	332	218
Time using sensor, %	89.6	90.9	90.6	87.8	88.4	91.4	91.7
Time using AHCL, %	91.6	92.2	92.2	91.3	90.2	93.5	95.5
Mean Sensor Glucose, mg/dL	143.7	144.0	144.4	143.4	142.2	148.9	140.7
Glucose Management Indicator (GMI), %	6.7	6.8	6.8	6.7	6.7	6.8	6.6
Time using 100mg/dL, %	57.9	55.3	55.5	60.8	61.5	44.7	>95
Time using 2h of active insulin time (2h), %	60.0	62.5	53.4	77.0	55.8	52.3	>95
Patients reaching TIR >70%, %	78.1	80.5	77.8	75.6	80.0	68.7	89.0
Patients reaching TBR <4%, %	80.1	79.7	81.8	77.5	79.6	78.0	82.6
Patients reaching GMI <7%, %	80.7	78.2	80.6	82.2	80.90	75.9	93.1

*GT=100 mg/dL and AIT=2h
AHCL: Advanced hybrid closed loop, TIR: Time in range (70-180 mg/dL), TBR: Time below range (<70 mg/dL), GT: Glucose target, AIT: Active insulin time.

Methods: MiniMed™ 780G system users from Argentina, Brazil, Chile, and Colombia with ≥10 days of sensor glucose (SG) data after Advanced Hybrid Closed Loop (AHCL) initiation were included (N = 1025). Data from August 2020 to September 2022 were used. Endpoints included metrics for glycemic control. Sub-analyses included a breakdown per country, users aged ≤15 years, and those using recommended settings (i.e., glucose target [GT] of 100 mg/dL and active insulin time [AIT] of 2 hours).

Results: Figure 1 shows glycemic outcomes. Average SG was 143.7 mg/dL, time in range (TIR) was 76.5%, time below range was 3.3%, time above range was 24.9% and glucose management indicator (GMI) was 6.7%. Sensor and AHCL use were high, as was the use of recommended settings. Data showed consistency across the countries, which was independent of age, and similar to findings observed during MiniMed™ 780G use in other geographies[2]. Individuals using recommended settings reached a TIR of 80.1% and a GMI of 6.6%.

Conclusions: On average, real-world MiniMed™ 780G users from Latin America met international consensus targets for glycemic control. These data may help further the adoption of diabetes technology in Latin America.

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EP058 / #275

Topic: ***AS03 Closed-loop System and Algorithm***

CHANGES IN HBA1C AND SENSOR GLUCOMETRICS FOLLOWING HCL COMMENCEMENT IN INDIVIDUALS WITH HBA1C>=86MMOL/MOL: SUB-ANALYSIS FROM THE ABCD CLOSED-LOOP AUDIT OF THE NHS ENGLAND PILOT

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Background and Aims: The ABCD audit captured data from the 2021 NHS England Hybrid Closed-Loop (HCL) pilot. People with T1DM were offered access to HCL therapy if they were using an insulin pump and FreeStyle Libre and had a HbA1c >=69mmol/mol. This sub-analysis focuses on those with HbA1c >=86mmol/mol at baseline.

Methods: Individuals with a baseline HbA1c>=86mmol/mol and with data available at both baseline and 3-9 months were included. Change in HbA1c and sensor glucometrics (time-in-range [TIR, 3.9-10mmol/L], time-below-range [TBR, <3.9mmol/L], time-above-range [TAR1, 10.1-13.9mmol/L], time >=13.9mmol/L [TAR2]) and coefficient of variation [CoV] were assessed using paired t-tests in Stata 16. Comparisons were made with those with HbA1c<86mmol/mol at baseline.

Results: Data were included for 77 individuals: age 33.9(±11.8) years, diabetes duration 19.3years (IQR 10.9-25.6) and pump therapy duration 6.3years (IQR 4.7-9.8). Majority were female (71.4%) and White (87.3%). Median follow-up was 4.9months (IQR 3.9-6.2). HbA1c reduced from 94.7±8.4mmol/mol to 69.3±9.7mmol/mol (-25.3mmol/mol; 95%CI -22.9, -27.8; P<0.001). TIR increased from 24.9±14.2% to 56.2±12.4% (+31.2%; 95%CI 35.2, 27.2; P<0.001). TAR2 reduced from 49.5±20.9% to 21.6±14.4% (-28.05; 95%CI -22.4, -33.5; P<0.001). No difference was observed in CoV, TBR or TAR1. Compared to those with lower baseline HbA1c levels, HbA1c (P<0.001) and TAR2 (P=0.001) reductions are larger, and TAR1 increased slightly (P=0.002).

Conclusions: In the NHS England pilot, HCL in individuals HbA1c >=86mmol/mol is associated with large reductions in HbA1c and TAR2 and improved TIR. Change in TIR and TBR are similar to those with lower HbA1c levels, but HbA1c and TAR2 reductions are significantly greater.

EP059 / #81

Topic: ***AS03 Closed-loop System and Algorithm***

FACTORS PREDICTING ACHIEVEMENT OF RECOMMEND TIME-IN-RANGE 6-MONTHS FOLLOWING CLOSED-LOOP IN USERS WITH ELEVATED HBA1C LEVELS

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Background and Aims: The ABCD audit captured data from the NHS England Hybrid Closed-Loop (HCL) pilot launched in 2021 which funded HCL therapy for individuals living with T1DM using an insulin pump and FreeStyle Libre with HbA1c >=69mmol/mol. The aim of this analysis is to identify factors that predict achievement of target time-in-range (TIR, 3.9-10mmol/L) >=70% at follow-up.

Methods: Participants who had data recorded on the secure online tool and were using HCL therapy at baseline and at 6-month (3-9 months) follow up were included. Variables assessed included: baseline TIR, time-below-range, HbA1c, age, gender, duration of pump therapy, Diabetes Distress Score, ethnicity, time in closed loop (%), index of multiple deprivation, weight, Gold Score and number of FreeStyle Libre scans per day. Relevant covariates were assessed for their predictive value in a multiple logistical regression model, performed in Stata 16.

Results: Data were included for 501 individuals: age 40.4 ± 13.7 years, baseline HbA1c 79.2 ± 9.6mmol/mol, diabetes duration 21years (IQR 14.1-30.4), pump therapy duration 7.6years (IQR 4.7-11). Majority were female (67.5%) and White British (91%). Follow-up was 5.1months (IQR 3.9-6.6). Median index of multiple deprivation decile was 6 (IQR 3-8). Higher baseline TIR (OR 1.2; 95% CI 1.1-1.3; P = 0.001), and longer pump therapy duration (OR 1.3; 95% CI 1.1-1.7; P = 0.01) were associated with the achievement of >70% TIR. No other variables demonstrated significant predictive value.

Conclusions: In the NHS England pilot, those with higher baseline TIR and longer duration of pump therapy were more likely to achieve TIR>=70% at follow-up. Notably baseline deprivation status and ethnicity showed no association.

EP060 / #802

Topic: ***AS03 Closed-loop System and Algorithm***

PSYCHOLOGICAL WELL-BEING AND QUALITY OF LIFE AFTER ONE-YEAR EXPERIENCE OF ADVANCE HYBRID CLOSED-LOOP SYSTEM IN ADULTS WITH TYPE 1 DIABETES PREVIOUSLY NAIVE TO DIABETES TECHNOLOGY

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Background and Aims: To evaluate the effect of a 1-year use of an advance hybrid closed-loop (AHCL) system on the quality of life, level of anxiety and level of self-efficacy in adults with type 1 diabetes (T1D) previously treated with multiple daily injections (MDI) and naive to advance diabetes technology

Methods: 18 participants of previously published 3-months randomized trial (10 men, age 40.9 ± 7.6 years) who were switched directly from MDI/BMG to AHCL, completed 12 months of 780G Medtronic system use. At 6 month of the study patients were switched from sensor G3 to G4. Quality of life was assessed with Polish version of the 'QoL-Q Diabetes' questionnaire, anxiety was evaluated with State-Trait Anxiety Inventory (STAI) and self-efficacy with General Self-Efficacy Scale (GSES). Results were obtained at baseline and at the end of the study.

Results: Statistically significant increase in QoL was reported in the global score ($p = 0.02$) and in as many as 11 out of 23 analyzed areas of life: Being physically active ($p = 0.02$); Feeling well ($p < 0.05$); Feeling in control of my body ($p < 0.05$); Looking good ($p < 0.05$); Working ($p < 0.05$); Sleeping ($p = 0.01$); Eating as I would like ($p = 0.00$); Looking after or being useful to others ($p = 0.02$); Being active with pets ($p = 0.00$); Being spontaneous ($p = 0.02$); Doing ''normal'' things ($p = 0.02$). Both state ($p = 0.04$) and trait ($p = 0.02$) anxiety decreased while general self-efficacy significantly increased ($p = 0.03$)

Conclusions: Adult patients with T1DM previously treated with MDI and naïve to modern technologies after transition to AHCL system for 12 months of treatment experienced significant improvement in their psychological well-being.

EP061 / #715

Topic: ***AS03 Closed-loop System and Algorithm***

GLUCOSE CONTROL USING AN ADVANCED HYBRID CLOSED LOOP SYSTEM DURING POST-PRANDIAL EXERCISE IN ADULTS WITH T1D: A PILOT STUDY

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Background and Aims: Hypoglycemia is the main factor limiting the performance of physical activity in subjects with T1D. Advanced Hybrid Closed Loop Systems (AHCL) represent a therapeutic option to mitigate the risk of hypoglycemia, however the data during exercise are still limited. Aim: To evaluate the efficacy of an AHCL on glucose control during two different postprandial exercise in adults with T1D.

Methods: 7 (M/F = 3/4) adults with T1D (HbA_{1c} 51.0 ± 1.69 mmol/mol) using the Control-IQ AHCL performed two exercise session for 30 min on an ergocycle in a randomized

order: moderate aerobic activity (AER) and high intensity interval training (HIIT). Participants consumed a standardized meal 120 min before each session. The physical activity was announced to the AHCL 60 minutes before the activity.

Results: During AER and HIIT and the following 1 h recovery period, no differences have been observed in TBR (0% vs 0%, p = 1.00 and 2.98 ± 2.98% vs 0.00 ± 0.00%; p = 0.32 respectively) and TIR (66.3 ± 16.6% vs 51.3 ± 13.6%, p = 0.35 and 88.7 ± 8.37% vs 78.6 ± 14.9%; p = 0.29 respectively). During HIIT, the glucose variability was higher than AER (CV = 19.0 ± 3.0 vs 11.0 ± 1.10 p = 0.03) and the automated insulin correction boluses released a greater amount of insulin (0.92 ± 0.13U Vs 0.42 ± 0.16U p = 0.02). Finally, during the night after AER and HIIT, no significant differences were observed in TIR (84.5 ± 8.40% vs 80.4 ± 10.7% p = 0.75) and TBR (0.81 ± 0.81% vs 1.12 ± 0.82% p = 0.59).

Conclusions: In adults with T1D, Control-IQ AHCL has been safe and efficient to mitigate time spent in hypoglycemia during both AER and HIIT. Further studies are needed to assess the performance of this advanced algorithm in different exercise trials.

EP062 / #391

Topic: *AS03 Closed-loop System and Algorithm*

RETROSPECTIVE ANALYSIS OF 24-MONTH REAL-WORLD GLUCOSE CONTROL FOR CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES USING THE MINIMED 670G INSULIN PUMP

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Background and Aims: The Medtronic MiniMed 670G™ was the first HCL system available. Data about glucose control are available up to 12 months of use. We aimed to evaluate the efficacy of this HCL up to 24 months of use.

Methods: Primary aim: HbA1c levels. Secondary aim: CGM metrics. Design: Multicentre retrospective real-world study. HbA1c, TIR, TBR and TAR were collected from the clinical charts or downloaded from the CareLink database at baseline and every 6 months up to 24 months of HCL use.

Results: We recruited 77 patients (42 males, 12.6+/-3.3 years; age at diagnosis 7.0+/-3.7 years). Median HbA1c was 7.2% at baseline and it was improved after 6 (7.0%) and 12 months (7.1%) ($p < 0.05$) (figure 1). TIR was 66.1+/-13.1% at baseline and it was increased at 6, 12, and 18 months ($p < 0.05$). Baseline TAR was 31.1+/-14.1%, without any difference with the other timepoints. The CGM was used for 87.4+/-13.4% of the time, without any difference from the other timepoints. The HCL was enabled for 84.8+/-17.8% of the time at 6 months, higher than the value at 18 months (79.2 ± 24.3%, p = 0.032). The regression analysis showed that time on auto-mode, 24-month HCL use, and 24-month TDD/kg/day predicted the 24-month HbA1c value ($R^2 = 0.632$, $p < 0.001$).

Conclusions: We show that HbA1c was improved by 0.2% versus baseline during the first year of treatment, without any significant difference in the second year. This improvement could be considered as clinically significant to a lesser extent. A larger compliance to the technology predicts a better glucose control at 24 months.

EP063 / #430

Topic: *AS03 Closed-loop System and Algorithm*

EVALUATION OF AN INSULIN/CARB RATIO ADJUSTMENT ALGORITHM PERFORMED ON A FREE LIFE DATASET

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Background and Aims: Insulin bolus adjustment depends from accurate food carb counting and using optimal insulin-carb ratios (ICR). Many people with type 1 diabetes (T1D) do not know how to readjust their ICR and need to wait for a medical visit, while benefits expected from using a bolus calculator are not met. Helping them to keep continuously adjusted ICR would be valuable for reaching an optimal glucose control.

Methods: During GLUCAL3 study, patients used the mobile application EKIYOU during two months to enter their daily meals, blood glucose values and bolus doses. For each patient, the ICR was revised twice. We evaluated the performance of an algorithm that intends to converge to the optimal patient's ICR in free life conditions while users of the application could forget some inputs or make errors on meal reports.

Results: The algorithm was evaluated in 14 T1D patients. The algorithm was initiated with patient's usual ICR or using the ''500 rule'' and succeeded in less than 10 days to converge to the ICR defined by the patient's physician at the end of the first month. In cases where the algorithm converged to a different value, our sub-analysis disclosed that the patient had been affected by an intercurrent disease.

Conclusions: Our data indicates that our algorithm allows efficient timely updating of ICR in patients with T1D between medical visits.

EP064 / #453

Topic: ***AS03 Closed-loop System and Algorithm***

REDUCED ODDS OF DIABETIC KETOACIDOSIS AMONG HYBRID CLOSED LOOP SYSTEM (HCLS) USERS: PROPENSITY SCORE MATCH OF 8,455 PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: There is growing evidence that the use of hybrid closed loop systems (HCLS) is associated with a lower risk of diabetic ketoacidosis (DKA) in people with type 1 diabetes (T1D). In this study, we use real-world data from the T1DX-QI Electronic Medical Record database to investigate the association between HCLS use and patient-reported DKA events using propensity score matching.

Methods: We used the T1DX-QI EHR database to examine DKA events across propensity score-matched HCLS users and HCLS non-user groups. All available data for the pediatric (6 years and older) and adult population with T1D from March 2018-March 2022 were included in this analysis (n = 8,455). Patient-reported DKA events were defined as DKA events reported by the patient at their most recent clinic visit. They were classified as a binary variable (Yes/No), with those reporting one or more DKA events being classified under 'Yes'. Similarly, HCLS device use was defined as the use of HCLS reported by the patient at their most recent clinic encounter. Propensity scores were estimated using a logit model, including age, gender, race/ethnicity, and insurance status as covariates. Matching was performed on propensity scores using 1:1 matching with the nearest neighbor approach and a caliper of 0.1.

Results: There were 1537 matched individuals with T1D in each HCLS user and HCLS non-users group. Propensity score-matched analysis showed that HCLS users were less likely than HCLS non-users to report one or more DKA events (OR [95% CI]: 0.7 [0.5, 0.8]) when controlling for other variables.

Conclusions: HCLS use among people with T1D was associated with fewer DKA events.

Table 1: Association of HCLS use and patient reported DKA using propensity score matched data

Variables	Odds Ratio	p-value
HCLS		
Non-users	-	<0.0001
Users	0.6 (0.5,0.8)	
Age	0.9 (0.9,0.9)	0.5
Gender		
Female	-	0.06
Male	1.1 (1.0,1.3)	
Race ethnicity		
White	-	
Black	1.0 (0.4,2.0)	0.8
Hispanic	1.2 (0.9,1.6)	0.1
Insurance		
Private	-	
Public	1.7 (1.1, 2.6)	0.01

EP065 / #474

Topic: ***AS03 Closed-loop System and Algorithm***

MEAL ESTIMATION ACCURACY IN MODEL PREDICTIVE CONTROL-MOVING HORIZON ESTIMATION CONTROL STRATEGY

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Background and Aims: Model predictive control is a tested and accepted control strategy in hybrid closed-loop AP systems. However, the performance of the control algorithm is largely influenced by the accuracy of the model parameters and CHO estimation of the patient. Our aim was to investigate the meal estimation accuracy and its effect on the prediction accuracy in a model predictive control (MPC) - moving horizon estimation (MHE) strategy in silico.

Methods: The simulation started with a 2-day-long open-loop session (MDI therapy) to provide historical data for an initial parameter estimation. After 48 hours, the closed-loop strategy took over as the controller administered micro boluses every 5 minutes. The meal estimation accuracy was evaluated based on the estimation errors (aggregated in half-hour steps) of the CHO content and the 1-step-ahead prediction accuracy of the controller.

Results: During the first 30 minutes after meals the median estimation error (33.7 g) is larger compared to the self-reporting of patients (10-20 g), with significant outliers making the estimations unreliable. After 30 minutes, the median error (15.2 g) drops below 20 g and continues to improve as at least 1 hour of CGM measurements are available (9.3 g in the third half-hour). Accordingly, the 1-step-ahead prediction error abruptly increases after meal consumption and decreases with more data to rely on.

Conclusions: Based on our simulations, the meal estimation in a MPC-MHE control strategy can reach or surpass self-reported carbohydrate counting accuracy if sufficient data is available. Moreover, safe control can be achieved with the MPC-MHE strategy.

EP066 / #331

Topic: ***AS03 Closed-loop System and Algorithm***

SETTING UP FOR SUCCESS: DATA-DRIVEN INSIGHTS FOR DETERMINING INSULIN TO CARBOHYDRATE RATIOS WITH THE OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM

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Background and Aims: Insulin to carbohydrate ratios (ICRs) are an important parameter to consider adjusting when seeking to optimize glycemic outcomes with the Omnipod 5 Automated Insulin Delivery (AID) System. ICRs carried over from a prior open-loop pump or estimated using common heuristics (e.g., the '450 rule': 450/TDD = ICR) will likely need to be adjusted after initiating AID. We analyzed data from 3 months of Omnipod 5 use in a clinical trial to assess ICRs following regular adjustments to improve postprandial hyperglycemia.

Methods: Participants (N = 315) aged 2-70 years with type 1 diabetes used the Omnipod 5 System for 3 months as part of a clinical trial. ICR settings at initiation and end of study were analyzed by age group (<10, 10 to <18, and ≥18 years) and time of day.

Results: ICR values were adjusted to deliver more insulin per gram of carbohydrate by an average of 10.7-20.1% from initiation to study end across age groups and time of day (Table). In comparison to the ICRs at study end, ICRs calculated from the 450 rule would underestimate mealtime insulin by an average of 13-22% in age groups ≥10 years and by 40-49% in the <10 years group. At study end, the mean value of ICR*TDD ranged from mean 240 for children at 07:00 (breakfast) to 418 for teens at 12:00 (lunch).

Conclusions: Healthcare providers should be prepared to adjust ICRs as needed to reduce postprandial hyperglycemia and optimize results with the Omnipod 5 AID System. Clinical data support that strengthening by 10-20% is generally to be anticipated.

Table. Insulin to Carbohydrate Ratio (ICR) Settings and Adjustments in a 3-month Clinical Trial of the Omnipod 5 Automated Insulin Delivery System

Age Group	Period	Total Daily Insulin Dose (TDD)	ICR Settings by Time of Day		
			7:00	12:00	18:00
Children <10 years n=127	Initiation	16.6 ± 7.1	18.0 ± 7.5	21.4 ± 8.8	21.9 ± 10.9
	Final	**17.2 ± 6.8**	**15.0 ± 5.2**	**17.5 ± 6.3**	**17.8 ± 6.6**
	% Change	*+6.4 ± 18.1%*	*-12.2 ± 23.4%*	*-14.3 ± 21.6%*	*-13.9 ± 21.4%*
	Final ICR*TDD	-	240 ± 80	279 ± 86	284 ± 95
Teens 10 to <18 years n=77	Initiation	46.5 ± 17.2	10.0 ± 3.6	11.3 ± 4.5	11.6 ± 5.4
	Final	**49.9 ± 18.1**	**8.3 ± 3.4**	**9.5 ± 4.4**	**9.1 ± 4.1**
	% Change	*+8.9 ± 17.4%*	*-15.8 ± 18.0%*	*-16.1 ± 18.6%*	*-20.1 ± 17.4%*
	Final ICR*TDD	-	379 ± 126	418 ± 116	404 ± 109
Adults ≥18 years n=111	Initiation	46.2 ± 21.1	9.7 ± 4.3	9.7 ± 4.3	9.7 ± 4.4
	Final	**44.4 ± 18.1**	**8.3 ± 2.8**	**8.2 ± 2.6**	**8.3 ± 2.8**
	% Change	*-1.7 ± 18.3%*	*-10.9 ± 17.8%*	*-12.5 ± 16.6%*	*-10.7 ± 18.2%*
	Final ICR*TDD	-	348 ± 144	338 ± 115	342 ± 119

Data in table are mean ± SD

EP067 / #152

Topic: ***AS03 Closed-loop System and Algorithm***

SAFETY AND GLYCEMIC OUTCOMES OF MINIMED™ 780G ADVANCED HYBRID CLOSED LOOP SYSTEM IN ADOLESCENTS AND ADULTS WITH T1DM DURING RAMADAN FASTING: A RANDOMIZED CONTROLLED TRIAL

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Background and Aims: Background: Guidelines for safe fasting strategies exist for both adolescents and adult patients living with type 1 diabetes (T1DM). Management of T1DM during fasting is complex, however, strategic approaches including insulin adjustments, education, and nutritional modifications to reduce the likelihood of hypoglycemia. Aim: This prospective study assessed the safety and effectiveness of an advanced hybrid closed-loop (AHCL) system on glycemic metrics and the level of hypoglycemia in T1DM patients who wished to fast Ramadan.

Methods: Forty-two T1DM patients (mean age 15.2 ± 3.4 years) using AHCL system were divided into two groups (each n = 21): intervention group who adjusted AHCL settings and control group who kept the same settings as before Ramadan

Results: The most aggressive system settings among control group consisting of 100 mg/dL glucose target, active insulin time of 2 hours and bolus increment, maintained exceptional glycemia with time in range reaching 82.0 ± 10.2%, time above range >180 mg/dL of 12.1 ± 3.5% without an increase in hypoglycemia (time below range 3.0 ± 0.3%). All of which were non-significant in comparison to the intervention group. Overall time spent in closed loop (SmartGuard) by users averaged 98.7 ± 2.1% in Auto Mode and involved only 1.0 ± 0.7 exits per week indicating confidence in the system's performance. No severe hypoglycemic or DKA events during study.

Conclusions: Conclusions: AHCL system assist in safe fasting with minimal user input and allows for achievement of recommended glycemic targets in people with T1DM during Ramadan fasting with reduction in hypoglycemia exposure without compromising safety.

EP068 / #685

Topic: ***AS03 Closed-loop System and Algorithm***

A COMPARISON OF DIFFERENT TREATMENT MODALITIEs' EFFECTIVITY USING GLYCEMIA RISK INDEX IN CHILDREN WITH DIABETES

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Background and Aims: The newly defined glycemia risk index (GRI) evaluates glycemic quality. In this study, it was aimed to evaluate GRI in different treatment modalities.

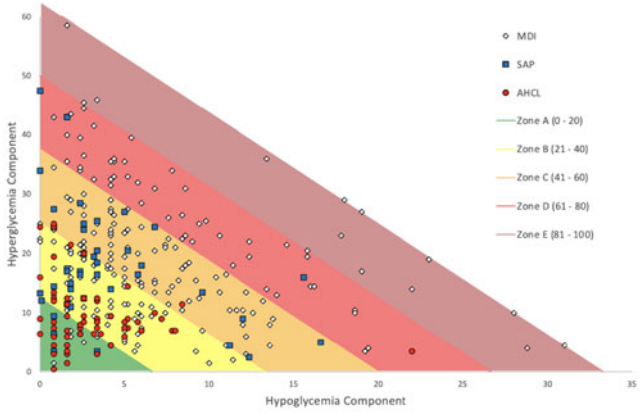

Figure 1. GRI zones in different treatment modalities

Table1: The comparison of different treatment modalities

	MDI (n: 210)	SAP (n: 44)	AHCL (n:58)	p
TDD (U/kg/day)	0.78±2.1	0.81±0.17	0.85±0.18	P1: 1 P2: 0.038 P3: 0.721
TIR (70-180mg/dl)	63.2±12.8	66.6±13	79.9±8.5	P1: 0.313 P2: 0.00 P3: 0.00
TAR >180mg/dl	20.1±7.2	20.8±8.2	13.6±6.5	P1: 1 P2: 0.00 P3: 0.00
TAR >250mg/dl	7 (0-46)	6 (0-36)	2 (0-14)	P1: 1 P2: 0.00 P3: 0.00
TBR70 <70mg/dl	5 (0-19)	2.5 (0-17)	2 (0-15)	P1:0.00 P2: 0.00 P3: 1
TBR <54mg/dl	1 (0-31)	1 (0-6)	0 (0-10)	P1:0.002 P2:0.00 P3: 0.909
Mean Sensor Glucose (mg/dl)	151.6±23.5	155±23.4	134.9±14.1	P1: 0.963 P2: 0.00 P3: 0.00
GMI (%)	6.9±0.56	7±0.55	6.5±0.34	P1: 0.805 P2: 0.00 P3: 0.00
CV (%)	40.9±6.9	37.7±5.8	33.6±5.24	P1: 0.028 P2: 0.00 P3: 0.004
HbA1c (%)	7±0.86	7.2±0.96	6.9±0.69	-*
GRI	50±19.5	41±17	24.6±11.7	P1:0.038 P2: 0.00 P3: 0.00

p_1: MDI vs SAP; p_2: MDI vs 780G; p_3 SAP vs 780G
*There is not significant difference

Methods: The CGM data of 312 children with type 1 diabetes was retrieved from electronic medical records from June 2020-June 2022. Glycemic quality was ranked from the best(A) to the worst(E) zones according to GRI values. The differences between GRI zones were examined by groups according to insulin modalities (multiple dose injection (MDI), sensor augmented pump(SAP), advanced hybrid closed loop system (AHCL)).

Results: Of 312 children, mean age was 10.5±4.1 years, duration of diabetes 3.8±3 years. 67% were using MDI, 14% SAP, 19% AHCL. The mean TIR was 66.8±13.7%, GRI was 44.2±21.2%. GRI was inversely correlated with TIR (r:-0.885, p: <0.001). TIR and GRI were, respectively, 63.2±12.8% and 50±19.5% for MDI, 66.6±13% and 41±17% for SAP, 79.9±8.5% and 24.6±11.7% for AHCL. There was a significant difference in distribution of groups by GRI zones. While 3% of MDI, 11% of SAP and 38% of AHCL were in Zone A ($p<0.001$); 7% of MDI, 2% of SAP, 0% of AHCL were in zone E ($p<0.001$).

Conclusions: In this study, GRI was evaluated in different treatment modalities in children with T1D for the first time. It was observed that the GRI was better with the use of AHCL than those who used MDI and SAP. More studies are needed on how useful the use of GRI is in addition to TIR in the evaluation of the glycemic profile.

EP069 / #50

Topic: ***AS03 Closed-loop System and Algorithm***

PANCREATIC DIABETES EFFECTIVENESS OF AN ADVANCED HYBRID CLOSED-LOOP SYSTEM

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Background and Aims: Pancreatic diabetes is a secondary diabetes form in which multiple etiologies are implicated. Exocrine pancreatic insufficiency, pathological pancreatic imaging and absence of autoimmunity associated with type 1 diabetes stand out. High glycemic variability can make diabetes control difficult. At present, there are no specific guidelines beyond maintaining HbA1c <7%, avoiding hypoglycemia and minimizing the risk of chronic complications.

Methods: We introduce a clinical case of a patient with pancreatic diabetes and her evolution from multiple daily injections, first with SMBG and second with flash glucose monitoring (FGM) to sensor-augmented pump (SAP) and finally to advanced hybrid closed-loop system (AHCL). Data were collected retrospectively from medical records.

Results: We present a 55-year-old woman with arterial hypertension; type 2 diabetes mellitus; gestational diabetes; vertical banded gastroplasty; coronal-caudal pancreatectomy, duodenojejunostomy and hepatojejunostomy for high-grade pancreatic

Table 1

	iPro 2	FGM + MDI	640G integrated system + sensor	780G hybrid closed-loop system after one month
GMI (%)	8.4*	8.7	7.8	7.1
Time 70-180 mg/dl (%)	40	26	51	72
Time 181-250 mg/dl (%)	20	40	31	21
Time >250 mg/dl (%)	40	33	17	7
Time 54-70 mg/dl (%)	0	0	0	0
Time <54 mg/dl (%)	0	1	1	0
Mean sensor glucose (mg/dl)	221	226	187	157
SD of sensor glucose (mg/dl)	94	81	69	60
CV of sensor glucose (%)	42.5	36.2	36.7	38.2
Sensor use (%)	100	89	92	97
Total daily insulin dose (units/day)	-	-	26	25

* Estimated A1c (%), instead of GMI. FGM: Flash Glucose Monitoring. MDI: Multiple Daily Injection. SD: Standard Deviation. CV: Coefficient of Variation. *iPro system for 7 days, rest 14 days.

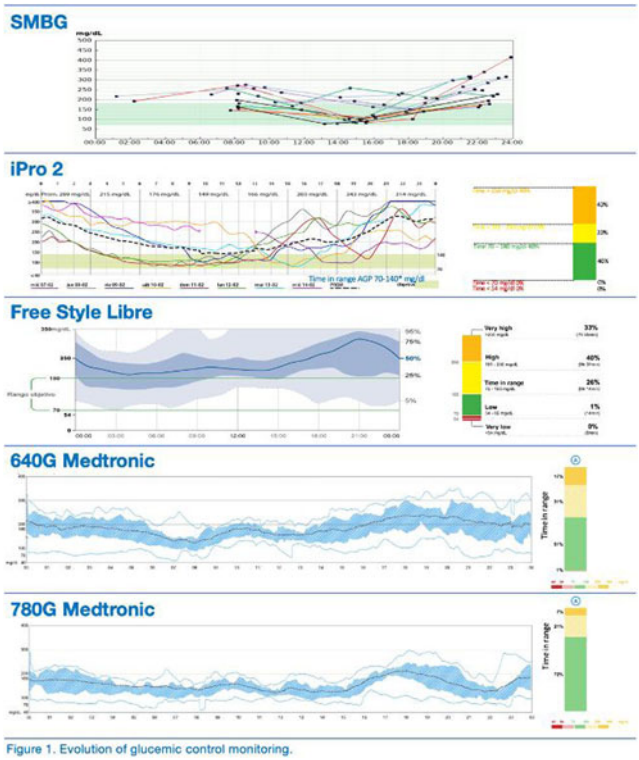

Figure 1. Evolution of glucemic control monitoring.

dysplasia; pancreatic diabetes and subsequent exocrine pancreatic insufficiency; abdominal hernias with multiorgan failure. She was on liraglutide and metformin with HbA1c <6%, until pancreatic surgery. Then, she required basal-bolus insulin regimen presenting glycemic irregularity. One year after surgery, blind continuous glucose monitoring was performed with iPro system. Two months later, she improved after FreeStyle Libre FGM. Three years later, she started SAP with 640G. She obtained better but insufficient control, switching to 780G AHCL, achieving an HbA1c of 6.8% after one month of use(Table1, Figure1).

Conclusions: A progressive improvement in glycemic control was observed with the introduction of successive technological options for diabetes. The advanced hybrid closed-loop system is an option to be considered in pancreatic diabetes with difficult glycemic control.

EP070 / #510

Topic: ***AS03 Closed-loop System and Algorithm***

BODY MASS INDEX (BMI) MODERATES THE ASSOCIATION BETWEEN AUTOMATED INSULIN DELIVERY (AID) AND GLUCOSE CONTROL IN ADULTS WITH TYPE 1 DIABETES (T1D).

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Background and Aims: Two large studies of a commercial hybrid AID system (Tandem Control-IQ, DCLP1: NCT02985866 and DCLP3: NCT03563313) showed an overall increase in percent time in target range (TIR) of 4.8% and 11% favorable to AID compared to sensor-augmented pump (SAP) therapy. However, whether this intervention has a similar effect for different BMI categories remains unclear.

Methods: We conducted a post-hoc analysis of DCLP1 and DCLP3 data (≥18 years old) to investigate whether differences in BMI categories (normal weight, overweight, and obese) mediated the association between AID and change in TIR and other relevant Continuous Glucose Monitoring (CGM) based metrics from baseline. Multivariate linear regression models were used to evaluate the described associations. Separate interaction terms were included to test for effect modification by BMI.

Results: A total of 218 participants were included in the analysis (ages 18-75 years old). Both hemoglobin A1c (HbA1c) and mean glucose increased with BMI category, with highest levels in the obese subpopulation (Table 1). A heterogeneous modification effect was also observed in terms of %TIR, %time ≥180mg/dL, and %time ≤70mg/dL (Table 2), with all metrics less favorable for people with higher BMI.

Conclusions: These findings suggest that AID has a heterogeneous effect in the T1D population in terms of different BMI categories, with a marked effect modification toward the highest BMI (≥30kg/m^2). This analysis suggests that people with T1D and BMI ≥30 kg/m^2 might need therapeutic adjustments to reach glycemic targets.

Table 1. Baseline Characteristics of the participants by BMI

Characteristics	Normal weight (N=79) BMI <25 kg/m²		Overweight (N=88) BMI 25-29 kg/m²		Obese (N=51) BMI ≥30 kg/m²	
	SAP	CLC	SAP	CLC	SAP	CLC
Female, n (%)	20 (62.5)	25 (53.2)	17 (43.6)	20 (40.8)	6 (33.3)	19 (57.6)
Age (years), median (IQR)	38.5 (29.0-52.5)	30.0 (26.0-44.0)	35.0 (23.0-44.0)	39.0 (31.5-51.0)	34.0 (28.0-48.7)	38.0 (24.5-46.5)
Duration of diabetes (years), median (IQR)	22.5 (15.2-34.2)	18.0 (9.0-27.0)	17.0 (10.0-24.0)	25.0 (20.0-36.0)	22.0 (16.0-32.5)	26.0 (16.5-33.0)
TDI (U/kg), median (IQR)	0.53 (0.44-0.62)	0.67 (0.56-0.74)	0.65 (0.50-0.76)	0.60 (0.48-0.65)	0.72 (0.50-0.83)	0.66 (0.59-0.83)
Glucose (mg/dL), median (IQR)	149.5 (139.0-177.5)	160.0 (143.0-182.0)	172.0 (154.0-192.0)	152.0 (136.0-166.5)	169.5 (164.2-193.2)	166.0 (155.0-192.5)
HbA1c (%), median (IQR)	6.7 (6.4-7.1)	7.2 (6.5-7.8)	7.5 (7.0-7.8)	7.0 (6.5-7.7)	7.4 (6.9-7.9)	7.6 (6.9-8.0)

IQR, Interquartile range; BMI, Body mass index; SAP, Sensor-augmented insulin pump; CLC, Closed-loop control; TDI, Total daily insulin; HbA1c, Glycated hemoglobin.

Table 2. Effect Modification by BMI.

	Change from baseline (95% CI) – Exposure to AID*					
Metric	BMI<25kg/m²	p-value	BMI 25-29.9kg/m²	p-value	BMI≥30kg/m²	p-value
%TIR	6.77 (3.08 to 10.46)	<0.001	10.08 (6.55 to 13.61)	<0.001	5.07 (0.33 to 9.80)	0.036
$\%TBR_{70}$	-1.61 (-2.27 to -0.96)	<0.001	-1.32 (-1.93 to -0.70)	<0.001	-1.18 (-2.02 to -0.34)	0.006
$\%TBR_{54}$	-0.36 (-0.58 to -0.13)	0.002	-0.25 (-0.46 to -0.42)	0.019	-0.22 (-0.51 to 0.06)	0.128
$\%TAR_{180}$	-5.28 (-9.09 to -1.47)	0.007	-8.60 (-12.25 to -4.96)	<0.001	-3.55 (-8.44 to 1.33)	0.153
$\%TAR_{250}$	-0.62 (-2.54 to 1.29)	0.522	-3.26 (-5.07 to -1.46)	<0.001	-1.53 (-3.98 to 0.91)	0.217
HbA1c (%)	-0.04 (-0.28 to 0.20)	0.744	-0.37 (-0.60 to -0.14)	0.002	-0.15 (-0.46 to 0.16)	0.334
Glucose (mg/dL)	-4.54 (-10.74 to 1.67)	0.151	-9.61 (-15.55 to -3.68)	0.002	-1.92 (-9.89 to 6.04)	0.635

BMI, Body mass index; TDI, Total daily insulin; HbA1c, Glycated hemoglobin; TAR, time above range; TIR, time in range; TBR, time below range. *Model Adjusted for baseline values, age, gender, and clinical center (ANCOVA, analysis of covariance). Metrics from CGM data except for HbA1c.

EP071 / #120

Topic: ***AS03 Closed-loop System and Algorithm***

ASSESSMENT OF THE PATIENT TRANSITION EXPERIENCE TO HYBRID CLOSED-LOOP INSULIN PUMP THERAPY

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Background and Aims: Hybrid closed-loop (HCL) insulin pump therapy is a promising development in the management of type 1 diabetes (T1D). However, little is known about the transition period to HCL in a real-world setting. Here, we present novel data evaluating the HCL transition experience and more specifically, its effect on diabetes distress.

Methods: 64 participants were evaluated in their transition from standard pump therapy to the MiniMed™ 670/770G HCL pump. Patients completed a baseline and 6-month post-transition diabetes distress survey using the Type 1-Diabetes Distress Survey. The patients' trust in HCL and treatment satisfaction were also assessed. A final interview was conducted for patients to elaborate on the successes and struggles of their transition.

Results: A significant reduction was seen in overall diabetes distress ($p < 0.0001$), powerlessness ($p < 0.0001$), management ($p < 0.0001$), hypoglycemia ($p < 0.001$), and eating ($p < 0.0001$) distress. A reduction of 0.5% was observed in HbA1c; 7.6% at baseline, 7.1% post-transition. Among the cohort that indicated no initial trust in HCL (25%), 67% reported their trust improving over time. Patient satisfaction was 72% and 59% reported they would recommend HCL to others. HCL met the expectations of 48% of patients and 39% reported a decrease in workload. Emerging themes from the qualitative data included unnecessary alarms, loss of sleep, and inadequate support and training.

Conclusions: Overall, although patients benefited from improved glycemic control and decreased distress levels, there are many shortcomings within the MiniMed™ 670/770G HCL system that must be addressed to ameliorate the transition experience.

EP072 / #412

Topic: ***AS03 Closed-loop System and Algorithm***

USE OF THE MEDTRONIC MINIMED 780G SYSTEM IN PREGNANCY IN TYPE 1 DIABETES

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Background and Aims: Achieving tight glucose targets in pregnancy in Type 1 diabetes (T1D) is challenging. There is little data on the use of advanced hybrid closed loop systems in pregnancy.

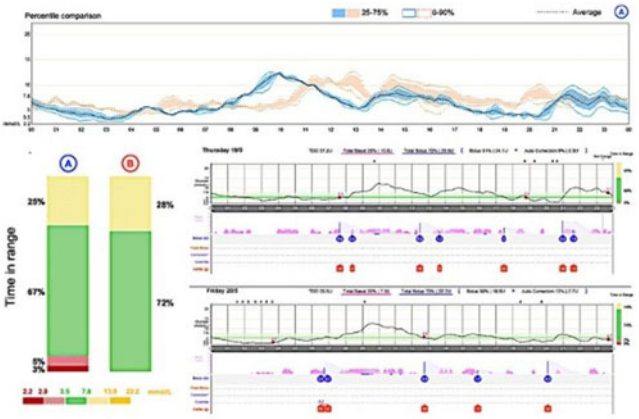
Methods: We describe the effective use of the MiniMed 780G SmartGuard system in pregnancy.

Results: A 32y-old with T1D for 27y conceived 3 months after initiating the Minimed 780G (glucose target 5.5mmol/l). Despite increasing insulin:carbohydrate ratio(ICR) and lowering active insulin time(ACT) (Table), closed loop insulin delivery failed to meet postprandial targets. From week 15, SmartGuard was used overnight for basal rate automation with daytime manual adjustments for postprandial targets. High TIR, low mean glyacemia were achieved without increased TBR throughout pregnancy.

Conclusions: Intermittent use of the MiniMed 780G SmartGuard technology can achieve pregnancy glycaemic targets.

Table demonstrating insulin use and settings and glycaemic indices through pregnancy.

Gestational age	ICR	ACT	SmartGuard Use (%)	TDD (units/day)	Basal (%)	HbA1c (%)	GMI (%)	TIR (3.5-7.8 mmol/l) %	TBR%	%CV
6w+3	7	2	82	24.4	36	5.8	6.3	68	2	28.9
10w+1	7	2:30	63	25.7	35	6.3	6.2	75	2	28
15w	7	2:30	52	32.7	34	5.9	6.0	71	8	32.9
20w	5	2:15	50	37.8	32	5.7	6.1	71	7	30.3
24w	5	2:15	85	44.7	31	5.7	5.9	82	4	29
27w+3	5	2:15	54	48.7	33	5.2	5.9	79	5	27.9
31w	5	2:15	54	56.1	34	5.7%	6	80	2	29.6
33w	5	2:15	51	67.9	29	5.7%	6.0	80	2	30.2
37w	5	2:15	45	74.2	28	5.8%	5.7%	94	1	22



At week 15, post-prandial targets not being met with closed loop insulin delivery.

Figure showing glucose profile, glycaemic indices and intermittent use of the SmartGuard at week 37 of gestation.

EP073 / #790

Topic: ***AS03 Closed-loop System and Algorithm***

COMPARATIVE ANALYSIS OF REWARD FUNCTIONS IN REINFORCEMENT LEARNING ADAPTATION OF GLUCOSE CONTROL

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Background and Aims: Previous work with Reinforcement Learning (RL) techniques applied to closed-loop glucose control have shown that reward definition can severely modify the performance of RL adaptation strategies.

Methods: In this work, we make use of the previously presented Q-learning adaptation technique for the Automatic Regulation of Glucose (ARG) algorithm [1], modifying the reward definition for training different agents. These agents were trained using the UVA simulator, for 20000 episodes of 10 steps, each step being 24hs with 4 meals. The trained agents were tested in 5 pre-classified adult patients with a common scenario, considering a 16-day, highly demanding intra-patient variability profile. 4 different schemes were compared: - Ad-hoc strategy based on medical protocols.

- Test 1: piecewise reward.
- Test 2: exponentially shaped, continuous reward.
- Test 3: same as test 2 with a factor to give pre-meal hyperglycemia more negative reward.

Table 1: Summary of compared strategies.

	Action	States	Reward
	Proportional gain that modifies the IOB limit	State space: s ∈ S, where every s is of the form s=(s_1,s_2) or s=(s_1,s_2,s_3)	
Ad-hoc	$\begin{cases} +5\%, & s_1 > hypo_{max} \\ -5\%, & s_1 < hypo_{max} \\ & s_2 > hyper_{max} \\ 0\%, & otherwise \end{cases}$	s1: % g <70 mg/dL s2: % g >180 mg/dL	-
Test 1	0%, ±1%, ±2%, ±3%, ±4%, ±5%, ±10%, ±20%, ±50%	s1: % g <70 mg/dL s2: % g >180 mg/dL	$r = \begin{cases} -5, & s_1 > hypo_{max} \\ -2, & s_1 < hypo_{max} \\ & s_2 > hyper_{max} \\ +10, & otherwise \end{cases}$
Test 2	"	s1: % g <70 mg/dL s2: % g >180 mg/dL	$r = 10 - \left(11.967 * (s_1 + 0.1 * s_2)\right)^{0.778}$
Test 3	"	s1: % g <70 mg/dL s2: % g >180 mg/dL s3: average of glucose readings at meal times	$df = \begin{cases} 1 & if\ s_3 \le 130 \\ 1 + (s_3 - 130)/20 & if\ s_3 > 130 \end{cases}$ $r = 10 - \left(11.967 * (s_1 + df * 0.1 * s_2)\right)^{0.778}$

[1] Serafini, Rosales, Garelli, (2022) ''Long-Term Adaptation of Closed-Loop Glucose Regulation Via Reinforcement Learning Tools'', IFAC-PapersOnLine 55,7, pp. 649–654.

Results:

Table 2: Mean ± standard deviation across all patients for the following metrics: overall % of time in range (TIR), number of hypoglycemic episodes, overall % of time below (TBR) and above (TAR) range, maximum values of %TBR and %TAR in the 16 days.

	% TIR (mean ± std)	Hypo episodes (mean ± std)	% TBR (mean ± std)	% TAR (mean ± std)	max % TBR (mean ± std)	max %TAR (mean ± std)
Ad-hoc	96.47 ± 1.95	6.00 ± 0.82	2.02 ± 0.71	1.52 ± 2.18	12.05 ± 3.61	2.53 ± 3.13
Test 1	85.00 ± 4.13	0.17 ± 0.37	0.09 ± 0.21	14.92 ± 4.08	1.38 ± 3.37	40.59 ± 12.37
Test 2	94.75 ± 1.12	1.00 ± 1.83	0.33 ± 0.60	4.93 ± 1.23	2.80 ± 4.39	16.07 ± 11.23
Test 3	97.59 ± 1.87	0.33 ± 0.75	0.11 ± 0.27	2.30 ± 1.67	1.16 ± 2.83	4.89 ± 2.20

The ah-hoc strategy has good average %TIR but does not avoid hypoglycemic episodes successfully. All adaptation schemes using RL agents avoid hypoglycemic episodes, but the ones trained under shaped rewards also achieve better %TIR (avoiding hyperglycemia). When adding a reward discount for premeal hyperglycemia (Test 3) this further improves.

Conclusions: Reward shaping has shown to play a key role in RL, but for glucose control, some sort of pre-classification of patients might be needed to properly train agents. Given this, agents trained under continuous rewards may greatly improve adaptation techniques.

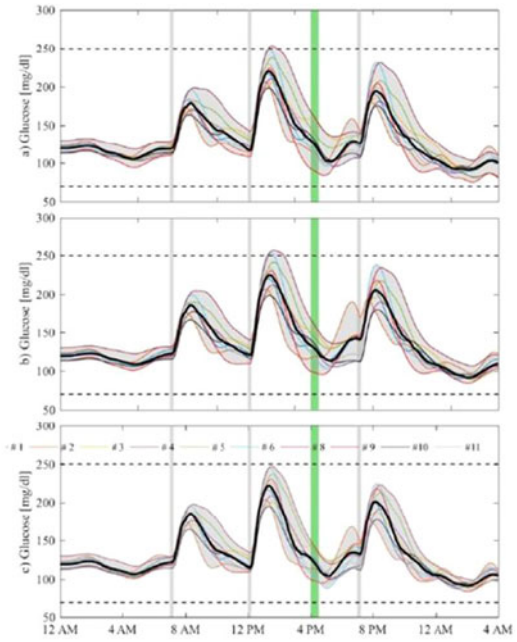

Figure: Nonlinear simulations for all patients in UVA simulator (except for subject 7) using several LPV controllers. The gray areas indicate the meal ingestion period and the green area when PA is performed. a) Using a baseline control tuning, b) controller with θ2 = 0.5, and c) controller with θ2 tuned to achieve a trade-off between maximum and minimum glucose peaks. The thick, black lines indicate the median response.

EP074 / #118

Topic: ***AS03 Closed-loop System and Algorithm***

LINEAR PARAMETER VARYING CONTROLLER FOR LONG-TERM ARTIFICIAL PANCREAS TRIALS.

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Background and Aims: Three short-term artificial pancreas (AP) trials were performed in Argentina from 2016 to 2021 [1]. The last one tested in an outpatient setting both, the Automatic Regulation of Glucose (ARG) algorithm and the InsuMate platform, locally developed. The ARG algorithm is a commuted controller based on a switched LQG algorithm combined with the SAFE layer [2].

Methods: In this work, a new algorithm based on Linear Parameter Varying (LPV) control theory is presented with time-varying capacity to account for insulin sensitivity and other parameter variations during long-term trials. Also, on-line tuning without controller re-design, unannounced meals and physical activity (PA) compensation, and simplified implementation in the InsuMate platform, were sought. Focused on clinical trials, on-line tuning can be made by simply setting two parameters (Θ_1, Θ_2), based on rules that are easy to apply by physicians.

Results: The proposed AP scheme has been tested with the distribution UVA/Padova simulator under meal and PA disturbances. The results showed that this parameterization achieves similar performance to ideally tuned controllers, and similar or better than our previous ARG algorithm, but with the new added features.

Conclusions: A new fully parameterized LPV controller has been proposed with the aim of improving online tuning and long-term performance. Simulations show the proposed controller effectiveness. [1] Garelli et al (2022). First outpatient clinical trial of a full closed-loop artificial pancreas system in South America. Journal of Diabetes Science and Technology. PubMed ID:35549733. [2] Colmegna, Garelli et al (2018). Automatic regulatory control in type 1 diabetes without carbohydrate counting. Control Eng Pract(74),22-32.

EP075 / #341

Topic: ***AS03 Closed-loop System and Algorithm***

IMPROVED GLYCEMIC OUTCOMES WITH INCREASING AUTOMATION: A REAL-WORLD ANALYSIS OF PATIENTS TRANSITIONING FROM EARLIER MINIMED™ SYSTEMS TO THE MINIMED™ 780G SYSTEM

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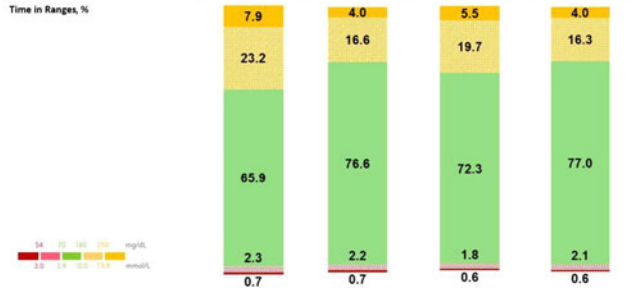
Background and Aims: The rapid pace of innovation in automated insulin delivery systems has introduced unprecedented

Figure: Glycemic control in both cohorts

	MM640G Cohort (N=381)		MM670G Cohort (N=78)	
	MM640G system Mean (SD)	MM780G system Mean (SD)	MM670G system Mean (SD)	MM780G system Mean (SD)
Mean sensor glucose, mg/dL	158.3 (20.3)	143.3 (12.4)	152.5 (16.3)	143.1 (14.1)
Standard deviation of SG, mg/dl	55.9 (11.0)	49.7 (9.1)	50.5 (11.7)	49.1 (10.9)
Glucose management indicator, %	7.1 (0.5)	6.7 (0.3)	7.0 (0.4)	6.7 (0.3)



outcomes of glycemic control in patients with type 1 diabetes. Real-world studies that encompass large and unbiased populations provide opportunities to study the contribution of increased automation with each iteration of technology. The current study utilizing such real-world data derived from Chile, Argentina, Brazil, and Colombia aimed to compare glycemic outcomes of MiniMed™ (MM) 780G system users that transitioned from a previous MM system.

Methods: CareLink™ data from August 2020 to September 2022 were extracted. The 2 cohorts analyzed consisted of individuals currently on the MM780G system (Advanced Hybrid Closed Loop), who also had data from previously used MM640G system (Predictive Low Glucose Management; MM640G cohort) or from MM670G system (Hybrid Closed Loop; MM670G cohort). Glycemic control was compared pre and post transition.

Results: The MM640G cohort included 381 users, the MM670G cohort 78. In both, the mean time in range (TIR) increased substantially after transition, whereas mean sensor glucose, standard deviation and time above range decreased (Figure). The positive changes were incremental with each system enhancement. The international composite target of TIR >70%, time below 70mg/dL of <4%, and glucose management indicator of <7% was met for 26.0%, 42.3% and 59.2% of users on MM640G, MM670G and MM780G system, respectively.

Conclusions: This real-world analysis shows substantial improvement in glycemic control with each iteration of MiniMed™ insulin delivery therapy that provided more automated dosing. As the same users were followed over time, improvements can largely be attributed to the advanced technology.

EP076 / #918

Topic: ***AS03 Closed-loop System and Algorithm***

WHAT DOES HYBRID CLOSED-LOOP SYSTEM BRING TO WELL-CONTROLLED TYPE 1 DIABETIC PATIENTS?

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Background and Aims: Hybrid Closed-Loop (HCL) represents a significant improvement in glycemic control. The aim of this study was to find out in real practice what HCL will bring to patients who have already been well controlled.

Methods: 24 adults (pts) with Type 1 Diabetes were included in the study. Glycemic control parameters were assessed before HCL treatment (SmartGuard in 16 pts, Control-IQ in 8 pts) and during the first 12 months of using. The results of patients with initial well glycemic control (HbA_{1C} <53 mmol/mol) in ''WC group'' were compared with patients with unsatisfactory control at the beginning of HCL using (''PC group'', $HbA_{1c}\geq$ 53 mmol/mol).

Results: The table: Parameters of glycemic control.

	WC (n=8)	
	baseline	follow-up
HbA1c (mmol/L)	50.7±4.0	51.1±2.0
TIR (%)	74	83
TAR (%)	20	14
TBR (%)	6	2
SD	2.8±0.6	2.4±0.5
DDI (IU/day)	37	42

The HbA_{1c} significantly decreased in PC (by 13%) but did not change in WC. TIR increased similarly in both groups. Pts in WC experienced a greater decrease in TBR compared to PC (by 61% vs. 11%) and in SD value (by 14% vs. 11%). The daily dose of insulin (DDI) during HCL rose in both groups, surprisingly more in WC one (by 15% vs. 10%).

Conclusions: Our results indicate that HCL system significantly reduces the time spent in hypoglycemia as well as glycemic variability in patients who were previously well controlled. *Supported by MH CZ-DRO (,,IKEM, IN 00023001'').*

EP077 / #586

Topic: ***AS03 Closed-loop System and Algorithm***

DETECTION OF UNANNOUNCED MEALS IN ARTIFICIAL PANCREAS SYSTEMS USING ISOLATION FOREST ALGORITHM AND SURVIVAL ANALYSIS TECHNIQUES

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Background and Aims: Current Artificial Pancreas systems usually require information about upcoming meals to compute prandial insulin. Missed meal announcements (MMAs) result in missed insulin boluses, that significantly affect the effectiveness of the device. This work proposes a new approach to detect unannounced meals capable of integrating information about patient's daily habits by means of a survival analysis technique.

Methods: Data of 100 virtual subjects were simulated for 60 days using the UVA/Padova T1D simulator. Insulin was delivered by a linear model predictive control based on a population physiological model. In the first 30 days, all meals were announced, and a survival analysis based on Kaplan-Meyer method was performed to estimate the probability of meals' occurrence, thus capturing the patient's daily eating habits. The remaining data were simulated with 12.5% of MMAs and were used to develop and test the detection pipeline. Four features, one of which is based on the survival analysis, were then provided to an

unsupervised anomaly detection algorithm, namely Isolation Forest, to obtain an anomaly score. Finally, an alert of MMA was issued when the anomaly score exceeded a threshold, tuned using the Precision-Recall Curve.

Results: On the test set (30 days of 20 subjects not previously seen), MMAs were detected with a sensitivity of 78.4%, while the method produced 0.05 false positives per day. The detection delay was 34.8 minutes on average.

Conclusions: In the simulated environment, the combined use of anomaly detection algorithms and survival analysis shows promising results for the detection of MMAs.

EP078 / #503

Topic: ***AS03 Closed-loop System and Algorithm***

DESIGN OF THE DUAL HORMONE FULLY CLOSED LOOP IN TYPE 1 DIABETES: A RANDOMIZED (DARE) TRIAL

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Background and Aims: Many people with type 1 diabetes mellitus (T1DM) do not achieve glycemic treatment goals despite advanced therapies such as continuous or flash glucose monitoring (CGM or FGM) and hybrid closed loops (HCLs). The dual hormone fully closed loop (DHFCL) approach with both insulin and glucagon infusion has shown promising results in small studies in T1DM patients. Larger studies are needed on effectiveness, tolerability, safety and cost-effectiveness.

The primary aim of the DARE-study is to evaluate long-term effects on glycaemic control, PROMs and cost-effectiveness of DHFCL compared with currently most advanced technological care (i.e. HCL) and most used care (i.e. multiple daily insulin injections (MDI) in combination with FGM/CGM).

Methods: The DARE-study is a 12 month open-label, two-arm randomized parallel-group trial study funded by the Dutch National Health Care Institute/ZonMw. In this study, 240 adult T1DM patients are to be included in 14 hospitals in the Netherlands. Patients will be randomized 1:1 to using the DHFCL or continuation of their current care as control. In one arm, the DHFCL is compared to HCL (n = 170, each n = 85; most advanced care) and in the other arm against MDI treatment (n = 70, each n = 35; at least once daily long-acting insulin and thrice daily short-acting insulin; usual care) together with FGM or CGM.

Results: are expected in the second half of 2024.

Conclusions: Results of this large pivotal trial will expand knowledge on this novel dual-hormone approach in T1DM, not only regarding glycemic outcomes but also PROMs and cost-effectiveness.

EP079 / #372

Topic: ***AS03 Closed-loop System and Algorithm***

COST-EFFECTIVENESS ANALYSIS OF THE MINIMEDTM 780G SYSTEM VERSUS MULTIPLE DAILY INJECTIONS WITH INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN INDIVIDUALS WITH TYPE1 DIABETES ACROSS EUROPE

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Background and Aims: The standard of care for people with type 1 diabetes (T1D) is continually evolving and Automated Insulin Delivery system (AID) systems and continuous glucose monitoring (CGM) are emerging as the standard of care for many individuals with T1D. This study aimed to compare the long-term cost-effectiveness of the MiniMed™ 780G system versus MDI+ intermittently scanning CGM in people with T1D across European countries.

Methods: Long-term costs and clinical outcomes were estimated using the CORE Diabetes Model. Clinical data were derived from ADAPT, prospective, multicentre, open-label, randomized control trial [1]. MiniMed™ 780G system was associated with a reduction in HbA1c of 1.54%, from 9.04% (75 mmol/mol) at baseline to 7.5% (58 mmol/mol) at the end of the study; isCGM was associated with a reduction in HbA1c of 0.2%1. Quality of life benefits associated with a reduced fear of hypoglycaemia were also applied. Analyses were conducted in Sweden and other countries across Europe.

Results: The MiniMed™ 780G system was associated with a quality-adjusted life-year (QALY) gain of 2.24 with higher overall costs versus MDI+isCGM, leading to an incremental cost-effectiveness ratio of SEK 366,919 (33,757 Euro) per QALY-gained. MiniMedTM 780G system resulted in a lower cumulative incidence of diabetes-related complications. Higher acquisition costs were partially offset by reduced complications costs. Extensive analysis of key drivers and analysis conducted across different countries confirmed the robustness of the results.

Conclusions: Over patient lifetimes, for adults with T1D, the use of the AID system is projected to be cost-effective when compared with MDI+isCGM.

1. Choudhary P, et al. Lancet Diabetes Endocrinol 2022 https://doi.org/10.1016/S2213-8587(22)00212-1.

EP080 / #375

Topic: ***AS03 Closed-loop System and Algorithm***

LARGE-SCALE LONG-TERM VIRTUAL CLINICAL TRIALS OF CLOSED-LOOP SYSTEMS FOR DIABETES TREATMENT

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Background and Aims: Clinical trials are expensive and time-consuming, and ultimately, there are limits on the total number of participants. The aim of this work is to develop a large-scale long-term virtual clinical trial for estimating key performance indicators (KPIs) of closed-loop diabetes treatment strategies. The purpose is to improve pre-trial development and reduce the risk of unsatisfactory results in the actual clinical trials.

Methods: We use mathematical pharmacokinetic and pharmacodynamic models together with high-performance parallel programming to simulate closed-loop diabetes treatment of 2 million automatically generated virtual individuals with type 1 diabetes. Furthermore, we propose a 1-year protocol with bodyweight-dependent meals as well as daily, weekly, and seasonal variations in meal sizes.

Results: We demonstrate the utility of the virtual clinical trial using an artificial pancreas for closed-loop treatment of all virtual individuals (2 million) during the entire protocol (1 year). In this example, we use two different mathematical models to each represent 1 million individuals. The simulation takes 2 h and 9 min, and it allows us to estimate the mean and standard deviation of KPIs such as average glucose, time in ranges (TIRs), glucose management indicator (GMI), and glucose variability (coefficient of variation).

Conclusions: For a given closed-loop diabetes treatment strategy, the virtual clinical trial can be used to 1) identify potential shortcomings (e.g., causing frequent hypoglycemia for some individuals), 2) compare algorithms and mathematical models, and 3) tune parameters in the closed-loop strategy (e.g., how much to adjust the basal rate close to hypoglycemia).

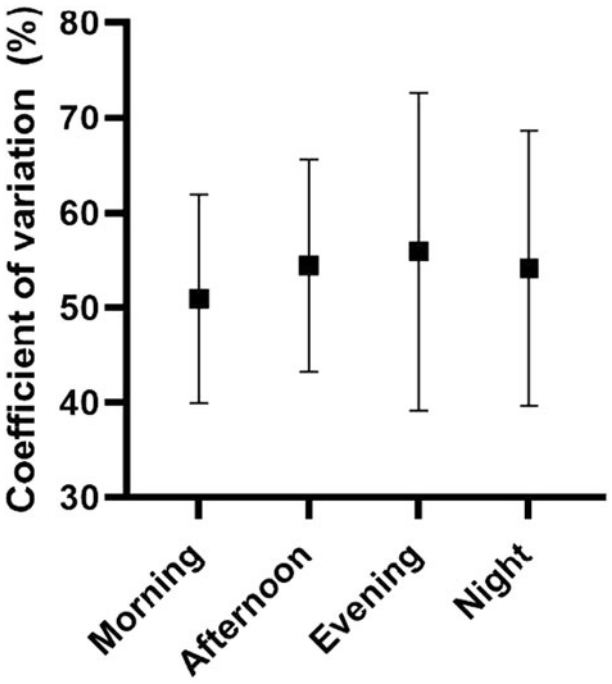

Figure 1: Variability of exogenous insulin requirement by time period (mean±SD)

EP081 / #480

Topic: ***AS03 Closed-loop System and Algorithm***

VARIABILITY OF INSULIN REQUIREMENTS OVER 8 WEEKS OF FULLY CLOSED-LOOP INSULIN DELIVERY IN ADULTS WITH TYPE 2 DIABETES

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Background and Aims: This study aimed to characterise the variability of exogenous insulin requirements during fully closed-loop insulin delivery in outpatients with type 2 diabetes (T2D), and to determine patient-related characteristics and glycaemic endpoints associated with higher day-to-day variability of insulin requirements.

Methods: We analysed data retrospectively from a fully closed-loop study involving adults with T2D requiring insulin therapy. The coefficient of variation (CV) quantified day-to-day variability of exogenous insulin requirements during up to 56 days of unrestricted living using fully closed-loop insulin delivery. Data were analysed from 1349 days in 25 participants.

Results: The coefficient of variation of day-to-day exogenous insulin requirements was 38 ± 10%, with no significant differences in variability between morning (6:01 to 12:00), afternoon (12:01 to 18:00), evening (18:01 to 00:00) or night time (00:01-06:00) periods (Figure 1). Participants with higher variability of insulin requirements (CV >40%, n = 11), had lower baseline HbA1c (68 ± 14 vs. 82 ± 14mmol/mol, P = 0.02), lower mean glucose (8.5 ± 1.0 vs. 9.4 ± 1.0mmol/L, P = 0.04) and greater time in range 3.9-10mmol/L (75 ± 13 vs. 63 ± 11%, P = 0.03) than those with lower variability of insulin requirements (n = 14). Time spent in hypoglycaemia (<3.9mmol/L) was similar between groups. There was no significant difference between the groups in terms of age, sex, BMI, diabetes duration, or total daily insulin dose per kilogram.

Conclusions: There is high day-to-day variability of exogenous insulin requirements in outpatients with T2D, which would be difficult to overcome with conventional therapeutic tools. Those with higher insulin variability showed evidence of lower glucose levels both at baseline and during the fully closed-loop period.

EP082 / #870

Topic: ***AS03 Closed-loop System and Algorithm***

GLUCOSE AND HBA1C OUTCOMES 6-MONTHS FOLLOWING HYBRID CLOSED-LOOP AT THE UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS TRUST: SINGLE-CENTRE REPORT FROM THE NHS PILOT

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Background and Aims: The University Hospitals of Derby and Burton NHS Trust was one of the largest centres included in the NHS England Hybrid Closed-Loop (HCL) pilot, launched in 2021. This pilot funded HCL therapy for individuals living with T1DM using an insulin pump and FreeStyle Libre with HbA1c >69mmol/mol. The aim of this analysis is to report real-world outcomes from a single-centre.

Methods: Participants who had data recorded on the secure online tool and were using HCL therapy at baseline and at 3-9 months follow-up were included. Characteristics reported as mean ± SD or median (interquartile range, IQR). Paired t-tests were used to assess change in HbA1c and sensor derived glucose outcomes between baseline and follow-up.

Results: Data were included for 52 individuals: age 40.7 ± 12.1 years, baseline HbA1c 78.7 ± 11.0mmol/mol, diabetes duration 18.5 years (IQR 14.0-27.8), pump duration 8.2 years (IQR 5.7-10.7). The majority were female (65.4%) and White British (94%). Over a median follow-up 5.6 months (IQR 4.2-6.4) HbA1c fell from 76.8mmol/mol to 62.5mmol/mol (-14.3mmol/mol, 95%CI -12.2, -16.5, $P < 0.0001$). Time-in-range (% 3.9-10mmol/L) increased from 35.0% to 63.0% (+28.0%, 95%CI 31.4, 24.7, $P < 0.0001$). Time >13.9mmol/L decreased by 24% (95%CI -19.9, -29.4, $P < 0.0001$). Time in level 1 hypoglycaemia (3-3.9mmol/L) fell by 0.8% (95%CI 0.03, 1.6, $P = 0.04$). No change was noted in time in level 2 hypoglycaemia (<3mmol/L) or time in 10-13.9mmol/L range.

Conclusions: HCL therapy is associated in reductions in HbA1c, improved time-in-range, time >13.9mmol/L and in level 1 hypoglycaemia in this data from a large UK centre participating the NHS England pilot.

EP083 / #851

Topic: ***AS03 Closed-loop System and Algorithm***

IMPROVED TIR AND HYPERGLYCEMIA WITH ADVANCED HYBRID CLOSED LOOP SYSTEM VS. CONTINUOUS SUBCUTANEOUS INSULIN INFUSION AND FLASH GLUCOSE MONITORING

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Background and Aims: Despite technological improvements in electronic devices in TD1, it continues to be difficult to achieve the consensus objectives in the pediatric population using Continuous Subcutaneous Insulin Infusion (CSII) and Flash Glucose Monitoring (FGM). The aim of this study is to determine the possibilities of achieving the control objectives by means of the Advanced Hybrid Closed Loop System (AHCL) in an early and sustained manner.

Methods: Single-centre prospective study including 28 paediatric patients (4-14 years-old) with T1D, previously treated with CSII/FGM and replaced with AHCL (MiniMedTM 780G), followed-up for 6 months after installation (48 hours, 7 days, 14 days, 21 days, 1 month, 3 months and 6 months). Metabolic control variables were extracted using the LibreView® and CareLink® download platforms at baseline and at the different cut-off points previously described. The data were analyzed with R 4.0.2 software

Results: Although improved hypoglycemia parameters have been described after the installation of closed-loop systems, in our population the target figures standardized in the consensus were already reached with CSII/FGM. We observed improvements in both Time In Range (TIR)/Time Above Range (TAR) from the first 48 hours after installation of AHCL

Conclusions: The novelty of our work is the early evaluation of results and their follow-up to 6 months. CSII/FGM system reached control objectives in hypoglycemia parameters but did not achieve results either in TIR or TAR according to consensus. The AHCL system solves in pediatric population the limitation to achieve these control objectives in an early and maintained manner in these two parameters

EP084 / #775

Topic: ***AS03 Closed-loop System and Algorithm***

ONE-YEAR EXPERIENCE OF ADVANCE HYBRID CLOSED-LOOP SYSTEM IN ADULTS WITH TYPE 1 DIABETES PREVIOUSLY NAIVE TO DIABETES TECHNOLOGY:THE EFFECT OF SWITCHING TO A CALIBRATION-FREE SENSOR

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Background and Aims: To observe the one year outcomes of people with type 1 diabetes who switched from MDI+BGM to an advanced hybrid closed-loop (AHCL) system during a randomized 3 month control trial (RCT). Additionally, the effect of changing to a calibration free sensor was evaluated.

Methods: The details of the 3 months RCT of adult patients with T1D to be managed with Medtronic MiniMed™ 780G system (MM 780G) was previously published. After the first 3 months of AHCL use, patients on the MM 780G were followed at months 6, 9 and 12. At 6 months the patients were switched from Guardian™ Sensor 3 (GS3) to Guardian™ 4 Sensor (G4S).

Results: 18 participants (10 men, age 40.9 ± 7.6 years) completed 12 months of MM 780G use. Sensor use was 95.9% of the time with Auto Mode usage of 97.7% and 0.5 exits from AHCL per week during 12 months of AHCL system use. HbA1c was 6.8 ± 0.4% at 3 months, 6.6 ± 0.6% at month 6 ($p = 0.322$), decreased to 6.2 ± 0.4% at month 9 ($p < 0.001$) and to 6.5 ± 0.5% at the end of the study ($p = 0.020$). TIR (70-180 mg/dL) remained stable and ranged from 83.2 ± 6.5% in month 9 to 84.8 ± 4.4% at month 3. The mean TIR for the 12 months was 84%. There was no difference between TIR at 3 months before switching vs 3 months after switching to G4S ($p = 0.614$).

Table 1: Quarterly Glycemic Control Outcome PP Population

	All Day			
Metrics	Q1	Q2	Q3	Q4
Number of Subjects	18	18	18	18
Total SG Points	22869.3±1618.4 (23395.5)	26244.9±3140.9 (25619.5)	23808.7±2829.1 (24679.0)	22450.1±5414.4 (24010.0)
Average SG (mg/dL)	132.3±7.1 (131.8)	133.0±9.8 (133.2)	137.5±11.8 (137.3)	136.3±10.2 (135.8)
SD of SG (mg/dL)	41.2±5.1 (40.1)	41.3±5.5 (42.1)	41.5±7.0 (41.6)	41.4±7.3 (42.0)
CV of SG (%)	31.1±3.0 (30.8)	31.0±2.9 (31.0)	30.1±3.9 (30.0)	30.3±3.8 (29.8)
GMI (%)	6.5±0.2 (6.5)	6.5±0.2 (6.5)	6.6±0.3 (6.6)	6.6±0.2 (6.6)
SG < 54 mg/dL (%)	0.4±0.4 (0.3)	0.4±0.5 (0.3)	0.2±0.3 (0.1)	0.3±0.3 (0.1)
54 <= SG <70 mg/dL (%)	2.1±1.4 (2.0)	2.0±1.5 (1.8)	1.4±1.3 (0.9)	1.5±1.2 (1.0)
70 <= SG <= 180 mg/dL (%)	84.8±4.4 (85.5)	84.1±5.3 (83.7)	83.2±6.5 (83.5)	84.9±4.4 (83.7)
180 < SG <= 250 mg/dL (%)	11.3±3.5 (11.5)	12.0±5.0 (12.7)	13.3±5.7 (13.5)	12.3±5.2 (13.4)
SG > 250 mg/dL (%)	1.4±1.0 (1.1)	1.5±1.1 (1.3)	1.9±1.7 (1.5)	2.0±1.7 (1.5)

Values are presented by Mean ± SD (Median)

Conclusions: AHCL system in adults significantly improves glycemic outcomes. This improved glycemic control was maintained over the 12 months. G4S is similarly effective to GS3 but requires less patient involvement.

EP085 / #872

Topic: ***AS03 Closed-loop System and Algorithm***

AUTOMATIC INSULIN DELIVERY AROUND EXERCISE IN ADULTS WITH TYPE 1 DIABETES: A RANDOMISED CONTROLLED STUDY

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Background and Aims: To assess the efficacy of an automatic insulin delivery (AID) system around exercise in adults with type 1 diabetes (T1D).

Methods: This was a three-period, randomised, cross-over trial involving ten adults with T1D (HbA_{1c}: 8.3 ± 0.6% [67.2 ± 5.9 mmol/mol]) using an AID system (MiniMed 780G, Medtronic USA). Participants cycled for 45-minutes, 90 minutes after consuming a carbohydrate-based meal using three strategies: (i) a 100% dose of bolus insulin with spontaneous exercise announcement at exercise onset (SE) or a 75% dose of bolus insulin with exercise announcement either (ii) 90-minutes (AE90) or (iii) 45-minutes (AE45) before exercise. Venous-derived plasma glucose (PG) taken in 5- and 15-minutely intervals over a 3 hour collection period was stratified into time spent below (TBR [<3.9 mmol/L]) within (TIR [3.9-10 mmol/L]) and above (TAR [>10 mmol/L]) the target range.

Results: Overall TBR was greatest during SE (SE: 22.9 ± 22.2, AE90: 1.1 ± 1.9, AE45: 7.8 ± 10.3%, p = 0.029). Hypoglycaemia during exercise occurred in 40% of participants in SE lasting triple the length of time than the single events logged per person in AE90 and AE45 (SE: 16.3 ± 2.5, AE90: 5.0 ± 0.0, AE45: 5.0 ± 0.0 minutes, p = 0.032). In the one-hour post-exercise period, AE90 was associated with higher TIR (SE: 47.8 ± 4.6, AE90: 97.9 ± 5.6, AE45: 66.7 ± 34.5%, p = 0.033) and lower TBR (SE: 56.3 ± 49.6, AE90: 2.1 ± 5.9, AE45: 29.2 ± 36.5, p = 0.041).

Conclusions: In adults with T1D using AID, an exercise management strategy involving both i) exercise declaration and ii) a 25% reduced dose of bolus insulin 90-minutes before exercise commencement is most efficacious at minimising hypoglycaemia and maximising time in range.

EP086 / #866

Topic: ***AS03 Closed-loop System and Algorithm***

TWO CASES OF HYBRID CLOSED-LOOP INSULIN DELIVERY IN T1DM PREGNANCY

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Background and Aims: Hybrid closed-loop automated insulin delivery (AID) in pregnancy is currently not TGA-approved in Australia. Few studies have reported on the safety and efficacy of AID in pregnancy, none used MiniMed 780G pump. This abstract presents the experience of using Medtronic MiniMed 780G for two Australian primigravid pregnant women with T1DM.

Methods: During preconception and the first trimester, both women used 670G Medtronic pumps, one combined with continuous glucose monitoring. Both were informed about AID not being approved during pregnancy. Weekly adjustments of the pump settings were made by an endocrinologist or diabetes educator.

Results: Patients' characteristics and glycaemic outcomes are presented below demonstrating good glycaemic management & minimal hypoglycaemia. Both babies were large for gestational age and delivered via C-section due to failure to progress in labour. AID was switched to manual mode during labour and continued postpartum using a saved basal setting (35% reduction in insulin requirements). Adjustments were made on days 1 and 2 postpartum to reduce hypoglycaemia with breastfeeding. AID was successfully restarted on day 3. Both women expressed less stress and fear of hypoglycaemia and more satisfaction with the AID.

Conclusions: AID may provide better glycaemic management in pregnancy with less diabetes-related stress and burden of self-management. AID effectiveness and safety in pregnancy need to be established by high-quality clinical trials.

	Woman A
Age(years)	33
T1DM duration(years)	8
Preconception HbA1c	6.1%
1st trimester HbA1c	5.9%
2nd trimester HbA1c	5.6%
3rdtrimester HbA1c	5.5%
TIR (3.9 to 6.9mmol/L)	59-71%
Hypoglycaemia	1%
Gestational age at delivery	38+1/40

EP087 / #382

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCEMIC CONTROL DURING PREGNANCY WITH HYBRID CLOSED LOOP SYSTEM

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Background and Aims: Hybrid closed loop (HCL) can help achieving glycemic targets. However, there are a few data in real life of diabetic women in pregnancy; moreover,almost all HCL insulin pumps are not validated for this use, because of glycemic targets not suitable for pregnant patients.

Methods: We report the 'CGM glucose metrics' throughout pregnancy of 6 women with type 1 diabetes who were on HCL pump treatment (5 with Medtronic 780G, 1 with 670G in first trimester and 780G in second and third trimester) before conception and wanted to keep on with the automatic delivery mode system until the end of gestation. 780G target was always set at

Table 1

	Age (years)	BMI	Years of diabetes	HbA1c at conception mmol/mol
Median	35.4	23	9.5	51
Min	29	20	2	43
Max	39	25	26	52

Table 2

	TIR 63-140 %	TAR >140 %	TBR <63 %	CV %	Mean CGM glycemi mg/dl
I trimester	75.5 (61-80)	21 (16-30)	2.5 (0-9)	25.4 (19.1-36)	119.5 (107-121)
II trimester	75.5 (68-81)	19.5 (12-30)	1.5 (0-11)	27.25 (21.1-31-7)	117 (101-128)

100 mg/dl in all patients, 670G target was pre-set at 120 mg/dl. Active Insulin Time was 2 hours. Patients were recruited from 3 italian centers (ASL Viterbo, Salerno, Latina).

Results: All data are reported as median (min-max). Table 1 shows patients' clinical features at conceiving. Table 2 shows glycemic control throughout pregnancy (data reported for the last two weeks of each trimester).All patients achieved all glycemic goal for pregnancy at the end of pregnancy (except TBR in one patient, who never achieved the target <5%).

Conclusions: HCL could help achieving and even improving glycemic control during pregnancy, despite the blood glucose target set of these HCL system is off label in pregnancy. Restrained weight gain probably affected glycemic control and pregnancy outcomes. However HCL is a very strict system and does not allow a lot of interferences, so that for some patients manual mode could be necessary.

EP088 / #597

Topic: ***AS03 Closed-loop System and Algorithm***

RISK OF IMPAIRED AWARENESS HYPOGLYCEMIA IN PATIENTS WITH TYPE 1 DIABETES USERS OF AN ADVANCED HYBRID CLOSED-LOOP SYSTEM

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Background and Aims: To evaluate the risk of impaired awareness hypoglycemia (IAH) in patients with type 1 diabetes (T1D) users of an advanced hybrid closed-loop (AHCL) system.

Methods: We conducted a prospective evaluation of subjects with T1D users of AHCL 780G system (*ClinicalTrial.gov ID NCT04900636*). Uploaded data were analyzed from 15 days of sensor glucose data at baseline and after 6 months on AHCL. We assessed IAH by Clarke's scores, and compared at baseline and 6 months recordings.

Results: Forty-seven subjects with a mean age of 37 ± 15 years and 20 ± 10 years of diabetes duration were included. We found a decrease in HbA_{1c} (NGSP), from 6.90 ± 0.48 % at baseline to 6.67 ± 0.57 % after 6 months on AHCL ($p < 0.003$). After 6 months of follow-up, they spent a mean of 90 ± 18% of time on AHCL and achieved a mean glucose management indicator (GMI) of 6.5 ± 0.3%, CV of 31.9 ± 3.7%, TIR of 82 ± 7%, TBR <70 mg/dL of 3.0 ± 2.1%, and TAR >180 mg/dL of 14 ± 6%. A TIR >70%, TBR <5%, and GMI <7.0% were achieved by 70% of patients. IAH improved from baseline to 6 months, showing a decrease in Clarke's scores from 1.5 ± 0.2 at baseline to 1.0 ± 0.2 after 6 months of follow-up ($p < 0.037$). At baseline, 12 patients (26% [95%IC 17-39]) showed IAH. After 6 months on AHCL, only 3 patients (7% [95%CI 3;15]) presented with a Clarke's score ≥3, resulting in an absolute risk reduction of 20% (95%CI 7;32) of having IAH.

Conclusions: Our cohort of patients with T1D, AHCL use was accompained by an improvement in metabolic control and a decrease in the risk of severe hypoglycemia.

EP089 / #840

Topic: ***AS03 Closed-loop System and Algorithm***

OPEN-SOURCE AUTOMATED INSULIN DELIVERY SYSTEMS (OS-AIDS) IN A PEDIATRIC POPULATION WITH TYPE 1 DIABETES IN A REAL-LIFE SETTING: THE AWESOME STUDY GROUP EXPERIENCE

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Background and Aims: Data regarding safety and efficacy of open-source automated insulin delivery systems (OS-AIDs) in the pediatric population with type 1 diabetes (T1D), remain limited. We aimed to examine the impact of OS-AIDs on glycemic parameters, characterize the population, and assess user experience.

Methods: In this multi-center observational real-life study from the AWeSoMe Group, we compared glycemic parameters of 52 individuals with T1D (56% males, mean diabetes duration

4.2 ± 3.9 years), from the last clinic visit prior to OS-AIDs initiation to the most recent clinic visit while using the system. Socioeconomic position (SEP) index was retrieved from the Israel Central Bureau of Statistics. Caregivers completed questionnaires assessing reasons for system initiation and treatment satisfaction.

Results: Mean age at OS-AIDs initiation was 11.2 ± 4 years, range 3.3-20.7 years with a median usage duration of 11.1 months (range 3-45.7). Mean SEP Index was 1.033 ± 0.956 (value range: -2.797 to 2.590). Time in range (TIR) of 70 to 180 mg/dl increased from 69.1 ± 12% to 75.1 ± 11.6%, ($P < 0.001$), and HbA1c decreased from 6.9 ± 0.7% to 6.4 ± 0.6%, ($P < 0.001$). Time in tight range (TITR) of 70 to 140 mg/dl increased from 49.71 ± 12.9% to 58.82 ± 10.8% ($P < 0.001$). No episodes of severe hypoglycemia or DKA were reported. Reduction in diabetes burden and sleep quality improvement were the main reasons for OS-AID initiation.

Conclusions: In our cohort of youth with above average SEP, OS-AIDs proved beneficial, regardless of age, diabetes duration or SEP. Since our study population had excellent glycemic control at baseline, improvement in TIR, with a simultaneous decrease in severe hypoglycemia, is all the more remarkable.

EP090 / #560

Topic: ***AS03 Closed-loop System and Algorithm***

ADVANCED HYBRID CLOSE LOOP SYSTEM DURING ATHLETICS HIGH-PERFORMANCE COMPETITION: A CASE REPORT

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Background and Aims: Current evidence indicates that physical activity and nutrition are a fundamental part of managing type 1 diabetes mellitus (T1D). Maintaining normal glucose levels during high-performance training and competition can be a major challenge for people living with T1D. Given advances in technology, there is little evidence on high-performance competition and Advanced Hybrid Close Loop System (AHCL) We present the case of a woman with T1DM, user of AHCL, during Bolivarian Games 2022.

Methods: Patient female 25 years old, with 17 years of evolution of DM1, in treatment with Faster Aspart and Minimed 780G for 1.5 year. During the 3 days of competition (athletics, 4x100 relay and 200 meters), exercise management strategies and Carelink data were analyzed.

Results: Metabolic control month prior to competition was: Automode 94%, Sensor use 89%. TIR 70-180 mg/dL: 72%, TAR: 27%, TBR: 1%, Mean SD 156 +-51, ICG 7.0%, DDT 36.9 U/day. Metabolic control during competition was: Automode 100%, Sensor use 96%. TIR 70-180 mg/dL: 80%, TAR: 19%, TBR: 1% Mean SG 143 +-45 ICG 7.0%, DDT 33.6 U/day, Carbs 163 +- 19 gr. Exercise strategies includes: Use of Temp Target, meal insulin reductions, non insulinized Carbs.

Conclusions: The use of MiniMed 780g in addition to diabetes exercise strategies are effective in achieving metabolic targets during high-performance competition. Further research is needed to generate recommendations.

EP091 / #724

Topic: ***AS03 Closed-loop System and Algorithm***

QUALITY-OF-LIFE QUESTIONNAIRE SCORES IN ADULTS WITH TYPE 1 DIABETES USING LOW-DOSE EMPAGLIFLOZIN VERSUS PLACEBO AS ADJUNCT TO HYBRID CLOSED-LOOP THERAPY: A RANDOMIZED CONTROLLED TRIAL

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Background and Aims: While there are both benefits and risks to SGLT inhibitor use in type 1 diabetes, data on effect on quality-of-life are limited. The aim of this sub-analysis was to assess differences in scores of quality-of-life questionnaires in those with type 1 diabetes who used low doses of empagliflozin as adjunct to hybrid closed-loop therapy.

Methods: A double-blinded, cross-over, randomized controlled trial was performed in sub-optimally controlled (HbA1c 7.0-10.5%) adults with T1D who were not able to achieve a time-in-range (3.9-10.0 mmol/L) of >70% after 14 days on hybrid closed-loop therapy. Three 14-day interventions were performed with placebo, empagliflozin 2.5 mg, or empagliflozin 5 mg, as adjunct to hybrid closed-loop therapy. Quality-of-life questionnaires were performed at the admission visits, and after each intervention. These surveys included: the Diabetes Distress Scale, Fear of Hypoglycemia Survey, the INSPIRE Questionnaire.

Results: Twenty-four participants completed the study; 19 participants completed all questionnaires. There were no differences in the scores and sub-scores between interventions in all 3 questionnaires. The percentage of participants scoring Diabetes Distress ≥2.0/6.0 (considered moderate distress) was not different between interventions. Pearson correlation demonstrated higher distress scores and regimen distress in those with reduced time-in-target ($p = 0.040$; 0.003) at the admission visit, which did not persist later on.

Conclusions: The use of low-dose empagliflozin did not affect quality-of-life as measured by questionnaires after each 14-day intervention. Larger studies are likely required to fully assess objective changes in quantitative patient-reported outcomes.

EP092 / #490

Topic: ***AS03 Closed-loop System and Algorithm***

PARTICIPANTS' EXPERIENCES USING LOW-DOSE EMPAGLIFLOZIN AS ADJUNCT TO HYBRID CLOSED-LOOP THERAPY: A QUALITATIVE ANALYSIS

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Background and Aims: Very little patient-reported outcomes, and no qualitative data, have been published concerning opinions of people with type 1 diabetes concerning adjunctive therapy. The aim of this sub-analysis was to qualitatively assess the themes of thoughts and experiences of participants' with type 1 diabetes who have used low doses of empagliflozin as adjunct to hybrid closed-loop therapy.

Methods: Semi-structured interviews were performed in adult participants who completed a double-blinded, crossover, randomized controlled trial using low-dose empagliflozin as adjunct to the hybrid closed-loop therapy. A qualitative analysis was used to code themes in an inductive-deductive approach, with quantitative measures as needed. [NCT04450563]

Results: Twenty-four participants were interviewed; 15 (63%) could feel differences between interventions despite blinding due to glycemic control or side effects. Advantages from participants included better glycemic control, in particular post-prandially, requiring less insulin, and ease of administration. Disadvantages included side effects, increased hypoglycemia, and increased pill burden in some. Thirteen (54%) participants were interested in using low-dose empagliflozin in their personal diabetes care, with 11 (46%) expressing general interest in adjunctive therapy outside of the study, for reasons such as weight loss, better health, and insulin sensitivity.

Conclusions: Many participants had positive experiences with low-dose empagliflozin as adjunct to hybrid closed-loop therapy. A dedicated study with unblinding would be beneficial to better characterize patient-reported outcomes.

EP093 / #407

Topic: ***AS03 Closed-loop System and Algorithm***

MINIMED 780™G SIX-MONTH USE ON CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: A REAL-WORLD STUDY

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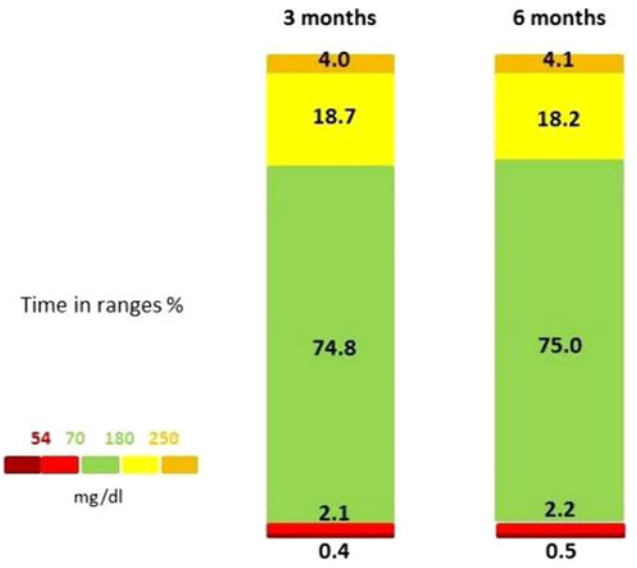
Background and Aims: The Medtronic Minimed™ 780G is one of the most innovative technological devices for diabetes management. The aim of this multicentre observational real-world study was to investigate glycemic outcomes in children and adolescents with T1D over the first six-month use of Minimed™ 780G. Secondary objective was to evaluate clinical factors that may significantly influence the achievement of therapeutic goals.

Methods: Study participants' demographic, anamnestic, and clinical data were collected at the time of enrolment. AGP data were acquired 3 and 6 months after activating Auto Mode. Aggregated glucose metrics and device settings of the whole study period were analyzed to identify predictors of optimal glycemic control, assessed by the simultaneous achievement of TIR >70%, CV <36%, GMI <7%, and TBR <4%.

Results: Our study cohort consists of 111 patients (54.1% female) aged 7-18 years. Data on Minimed™ 780G performance at 3 and 6 months are shown in Figure 1. When considering aggregated data, primary goals in terms of TIR, CV, GMI, and TBR were achieved respectively by 72.1%, 74.8%, 68.5%, and 74.8% of participants. Additionally, 44 patients (39.6%) concomitantly addressed all the above clinical targets. Regression analysis revealed that older age, briefer duration of disease, and shorter active insulin time were significant predictors of better glucose control.



	3 months	6 months
AutoMode %	92.7 ± 9.6	93.1 ± 10.3
CV %	34.1 ± 4.1	34.4 ± 3.6
Mean glucose	146.9 ± 14.1	146.4 ± 14.8
GMI (%)	6.8 ± 0.3	6.8 ± 0.4
TDD (IU/kg/day)	0.85 ± 0.30	0.84 ± 0.22
Basal %	41.9 ± 6.6	41.8 ± 6.9
Boluses%	58.1 ± 6.6	57.6 ± 8.1

Conclusions: Our study highlights the effectiveness and safety of Minimed™ 780G in the pediatric population. More extensive and personalized training on aHCL use should be considered for younger patients and those with long disease duration.

EP094 / #66

Topic: ***AS03 Closed-loop System and Algorithm***

HYBRID CLOSED LOOP (HCL) TECHNOLOGY IMPROVES GLYCEMIC CONTROL AMONG NON-HISPANIC BLACK (NHB) YOUTH WITH SUBOPTIMALLY CONTROLLED TYPE 1 DIABETES (T1D)

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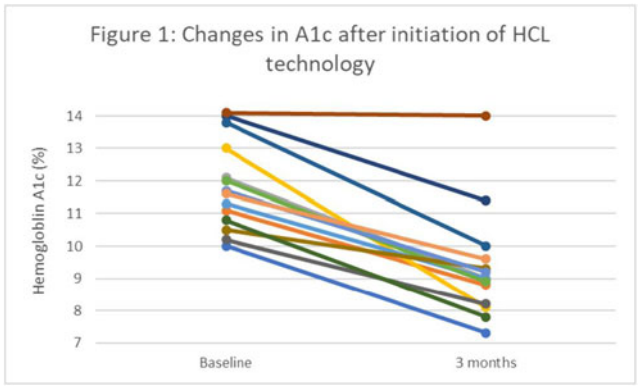
Background and Aims: NHB youth with T1D are more likely to have suboptimal glycemic control and less likely to use



continuous glucose monitors (CGM) and HCL systems. We evaluated changes in glycemic control with use of Tandem t:slim X2 insulin pump with Control IQ technology in a population traditionally underrepresented in T1D research.

Methods: This prospective non-randomized pilot study enrolled 15 publicly insured, NHB youth (6-21 years) with T1D managed with injection therapy and hemoglobin A1c (A1c) ≥10% in a 6-month trial of HCL use. CGM time-in-range (TIR) 70-180mg/dL, time above range (TAR) >250mg/dL, time below range (TBR) <70mg/dL, A1c and incidence of DKA at baseline and 3-months were assessed using paired t-tests and Wilcoxon signed rank.

Results: Fourteen participants (M_{age} 14.6 ± 3.7 years, $M_{T1Dduration}$ 6.0 ± 3.5 years) completed the 3-month study period; thirteen had CGM data at both timepoints. Time in HCL was 73.3 ± 29.5% with 2.6 ± 2.1 user-initiated and 7.1 ± 3.1 HCL-initiated boluses per day. TIR increased 22.4 ± 15.7% (5.4 hours/day) from 16.5% to 38.8% ($p < 0.001$); A1c decreased 2.5 ± 1.1% from 11.9 ± 1.4 to 9.3 ± 1.7% ($p < 0.001$) (Figure 1). TAR decreased 31.6 ± 25.6% (7.6 hours/day) from 66.0 ± 25.6% to 34.4 ± 17.8% ($p < 0.001$). TBR was not different (0.9 ± 1.1% vs 1.5 ± 3.2%, $p = 0.56$). In the 6-months pre-enrollment, there were 5 episodes of DKA among study participants (0.67 episodes/person year) versus 2 episodes of DKA during the study period (0.57 episodes/person year).

Conclusions: HCL use in NHB youth with suboptimal T1D control improved TIR and A1c without increases in DKA or TBR. These findings emphasize the importance of supporting equal access to diabetes technology among all people with T1D.

Table 1: Glycemic control in Fix versus Flex group

	Fix Group			Flex Group			Group Difference
	Baseline	Study	*P*	Baseline	Study	*P*	*P*
HbA1c, %	8.0±2.1	6.8±0.3	0.026	7.9±1.5	6.6±0.5	0.001	0.168
HbA1c, mmol/mol	64±26.2	51±3.3	0.026	63±18.6	49±5.5	0.001	0.168
Sensor glucose, mg/dL	174±26	147±23	0.002	168±29	145±18	0.005	0.804
CV, %	35.6±8.1	34.1±5.0	0.520	30.1±4.4	30.8±4.2	0.634	0.045
Percent of sensor glucose values in range*							
<54 mg/dL	0.2±0.4	0.1±0.3	1.000	0.8±1.4	0.5±0.3	0.275	0.167
54-70 mg/dL	1.4±0.5	1.5±1.5	0.605	2.0±1.5	2.7±1.7	0.718	0.283
70-180 mg/dL	47.5±18.3	73.5±6.7	0.001	49.1±16.8	80.3±7.4	0.001	0.043
180-250 mg/dL	22.6±8.1	19.0±5.2	0.122	26.8±8.2	13.5±5.9	0.001	0.114
>250 mg/dL	28.3±15.9	5.7±3.6	0.001	21.3±11.8	3.0±2.4	0.001	0.012
TDD, u/kg/d	1.0±0.6	1.1±0.4	0.517	1.0±0.6	1.1±0.5	0.601	0.984
Basal insulin, % of TDD	43.2±6.7	34.2±7.1	0.001	44.8±5.9	32.6±5.2	0.001	0.459
Weight, kg	52.2±12.7	53.5±11.2	0.753	51.3±10.7	52.4±9.6	0.754	0.765

Values are shown as mean±SD, unless otherwise specified; study, 12 weeks of MiniMed 780G use; CV, Coefficient of Variation; TDD, Total Daily Dose; CGM data at baseline were collected using Guardian 4 sensor with MiniMed 780G system for one week period of training (no insulin delivery with pump)

Methods: This randomized controlled trial included 34 participants (12-18 years) with T1D that were on multiple daily injections or insulin pump and were scheduled to start using MiniMed 780G system at Sidra Medicine, Qatar. After a 7-day run-in period, participants were 1:1 randomly assigned to the Fix group (i.e., simplified meal announcement by preset of 3 fixed carbohydrate amounts) or the Flex group (i.e., precise carbohydrate counting) and followed for 12 weeks. Between-group difference in time in range (TIR) was the primary endpoint. Secondary endpoints included HbA1c and other glycometrics.

Results: Table 1 shows the glycemic control in both groups. During the 12-week study phase, TIR was 73.5 ± 6.7% in the Fix and 80.3 ± 7.4% in the Flex group, with a between-group difference of 6.8% in favor of Flex ($p < 0.043$, 95%CI 4.1-9.2). Time above 250 mg/dl and coefficient of variation was better in the Flex group, whereas other reported metrics did not differ. 70% of participants in the Fix group reached HbA1c<7% at study end, 67% TIR >70% and 82% TBR <4%.

Conclusions: Albeit glycemic control in the Flex group was better than in the Fix group, international recommended glycemic targets were met for most patients in both groups. A preset of 3 fixed carbohydrate settings is a valuable alternative in those adolescents on MiniMed 780G that encounter difficulties in precise carbohydrate counting.

EP095 / #804

Topic: ***AS03 Closed-loop System and Algorithm***

SIMPLIFIED MEAL ANNOUNCEMENT VERSUS PRECISE CARBOHYDRATE COUNTING IN ADOLESCENTS WITH TYPE 1 DIABETES USING THE MINIMED 780G ADVANCED HYBRID CLOSED LOOP SYSTEM

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Background and Aims: We aimed to compare glucose control in adolescents with Type 1 Diabetes (T1D) on MiniMed 780G system that used simplified meal announcement to those that used precise carbohydrate counting.

EP096 / #572

Topic: ***AS03 Closed-loop System and Algorithm***

INTEGRATING RUN-TO-RUN AND PERSONAI ALGORITHM FOR INSULIN INJECTION ADAPTATION IN LONG TERM UNANNOUCED-MEAL CONTROL SCENARIO: IN SILICO RESULTS

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Background and Aims: The intra- and inter-daily variability of type 1 diabetes patients' insulin sensitivity is always the main problem that hinders the implementation of an artificial pancreas system (APS) in a real-life scenario. In this work, we ensure the

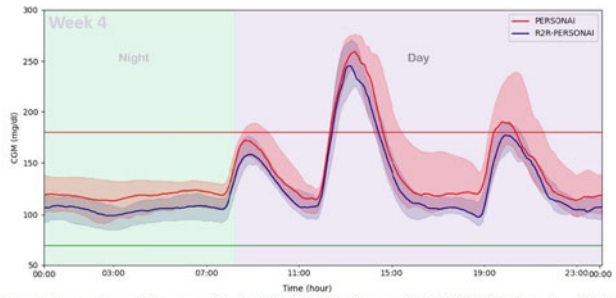

Figure 1: Comparison of glucose profiles in PERSONAI (red) versus R2R-PERSONAI (navy) on Week 4. Continuous lines are median across patients, with [25th, 75th] percentiles as shading.

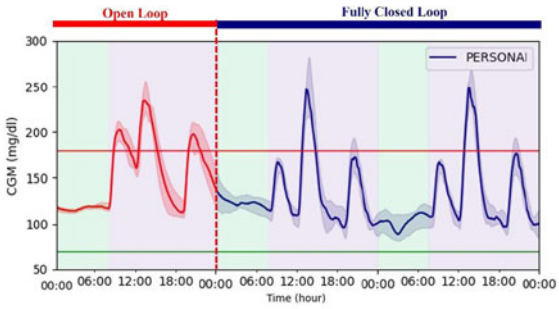

Figure 1: Glucose profiles of the representative 10 in silico patients, over the duration of three days control scenario; the first day is Open Loop Algorithm and continued with Fully Closed Loop PERSONAI algorithm.

safety and performance of our PERSONAI algorithm in long-term APS usability, by integrating a run-to-run (R2R) control approach on daily updates of our personalization parameters, so-called day-scale (s_{day}), night-scale (s_{night}), and IOB maximum (IOB_{max}).

Methods: Here, the proposed R2R strategy updates the personalization parameters of PERSONAI at the end of every successful fully closed loop control day. Daily, the CGM data histories are collected, and several performance matrices are derived as an input of our R2R-PERSONAI algorithm. The input order based on its priority in the proposed R2R-PERSONAI algorithm is mentioned as follows: percentage of time spent below range, coefficient of variation of CGM, the minimum value of CGM, and percentage of time spent in range.

Results: The in-silico test results which simulated a one-month APS control on an aggressive scenario that daily randomized ±30% variation of nominal insulin sensitivity shows the improvement of the average time in range (TIR) on day-30 compared to day-1 TIR of the treatment by ∼9 %. More importantly, with the proposed aggressive simulation of insulin sensitivity variation, the proposed R2R-PERSONAI successfully maintained the model to avoid the hypoglycemia episode.

Conclusions: The safety and long-term control capability of R2R-PERSONAI are proven in an in-silico environment, A further long-term real-life outpatient clinical trial could be performed.

EP097 / #419

Topic: ***AS03 Closed-loop System and Algorithm***

A RETRAIN-FREE DEEP LEARNING MODEL FOR PERSONALIZED PERSONAI ALGORITHM IN FULLY CLOSED LOOP ARTIFICIAL PANCREAS SYSTEM: IN SILICO RESULTS

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[1]*Pohang University of Science and Technology, Convergence It Engineering, Pohang, Korea, Republic of,* [2]*Curestream, Research, Seoul, Korea, Republic of*

Background and Aims: Previous studies have shown the power of deep-reinforcement learning (deep-RL) model in both hybrid- and fully closed-loop artificial pancreas system (APS). However, the real-world implementation of deep-RL in APS is rather hard and/or impossible due to the long personalization of the model that typically requires >1-month model *''re-training''*. In this work, we proposed an all-subject-in-one control model called PERSONAI algorithm which is re-train free, safe for intra-daily insulin sensitivity variability, and ready for multiple subjects' insulin injection control in APS.

Methods: The proposed personalized PERSONAI is realized by three novel and adjustable initial control parameters, the so-called day-scale (s_{day}), night-scale (s_{night}), and IOB maximum (IOB_{max}). Here, a realistic implementation protocol with one-day open loop initialization experiments to determine the required initial control parameters is proposed. Thus, the result of the proposed personalization strategy is evaluated in a consecutive two-day of fully closed loop in-silico clinical trial using UVA/-Padova (10 patients) and Hovorka (30 patients) virtual patient model.

Results: The in-silico test results showed that the proposed personalized PERSONAI model has shown efficacy in safely insulin treatment with the top priority of hypoglycemia prevention (time below range <1 %) while performing a relatively high performance (average time in range ∼89 %).

Conclusions: The fully closed loop APS which is powered by the proposed personalized PERSONAI algorithm provides both safety and high performance in controlling the glucose of the virtual patients, a further real-life clinical trial could be performed.

EP098 / #345

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCEMIC CONTROL IN PRESCHOOL CHILDREN WITH TYPE 1 DIABETES TREATED WITH THE ADVANCED HYBRID CLOSED LOOP SYSTEM REMAINS STABLE - 1-YEAR PROSPECTIVE, OBSERVATIONAL, TWO-CENTER STUDY

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Background and Aims: The MiniMed 780G, first Advanced Hybrid Closed Loop (AHCL) pump available in Poland. The goal was to analyse glycemic control parameters in T1D children under 7 years of age treated with the AHCL in relation to the previous pump therapy.

Methods: We compared continuous glucose monitoring (CGM) records of 10 children with T1D , aged 5.76 ± 1.36 yrs, who switched from sensor augmented pump(SAP; personal

insulin pump with real time continuous glucose monitoring) to AHCL. SAP records from the two weeks preceding the AHCL connection were compared to the records of the first two weeks in the automatic insulin dose adjustment system (SmartGuard) and two-week records from 6 and 12 months of AHCL use.

Results:

	SAP	AHCL First two weeks	AHCL two weeks after 6 months	AHCL two weeks after 12 months
AvgSG[mg/dl]	149.31±15,56	134.17±13.30	135.44±17.23	137.23±15.46
TDI[u.]	15.42±4.43	14.86±4.26	16.90±5.80	19.13±7.71
GMI[%]	6.88±037	6.52±0.32	6.54±0.41	6.59±0.37
Percent of sensor glucose values in range [%]				
>250mg/dl	6.09±4.68	4.29±2.96	4.49±4.55	4.12±4.64
180-250mg/dl	22.06±5.68	14.67±4.37	14.70±6.72	15.90±5.04
70-180mg/dl	65.63±9.68	72.34±6.68	73.70±10.07	74.26±8.67
54-70mg/dl	4.12±2.60	6.22±3.65	5.09±3.02	4.37±2.40
<54mg/dl	2.09±2.63	2.47±2.40	2.01±2.30	1.48±1.02

AvgSG and GMI decreased significantly between SAP and AHCL ($p < 0.05$). The sensor glucose profile shifted significantly towards the target TIR (70–180 mg/dl) ($p < 0.05$).

Conclusions: There was an effective and safe improvement of glycemic control - expressed as an increase in the TIR (70-180mg/dl) and decrease of the average glucose concentration - after switching to AHCL from a SAP in children under 7 years of age. This improvement was maintained after one year of AHCL use.

EP099 / #602

Topic: ***AS03 Closed-loop System and Algorithm***

REAL WORLD GLYCAEMIC OUTCOMES IN WESTERN AUSTRALIAN YOUTH WITH TYPE ONE DIABETES ON CONTROL IQ TECHNOLOGY

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Background and Aims: There is a need to evaluate if improvements reported in clinical trials of advanced hybrid closed loop systems are reflected in real-world outcomes. The aim of this study was to determine glycaemic outcomes in youth commencing Control IQ (CIQ).

Methods: Youth with T1D commencing CIQ from April 2022 were included. CGM metrics were collected prospectively at baseline (BL), 2 weeks and 3 months post-CIQ start. Outcomes evaluated included time in range (TIR 3.9-10 mmol/l), time below range (TBR <3.9 and <3 mmol/L), and time above range (TAR >10 mmol/L).

Results: 115 youth, mean (SD) 12.6 (2.9) years, 47% female, diabetes duration 5.0 (3.3) years, HbA1c 7.3 (0.9)% were included. CGM metrics were available for 114 and 99 youth at 2 weeks and 3 months respectively. TIR increased from 60.0 (16.1)% at BL to 67.3 (11.4)% at 2 weeks ($p < 0.001$) and 66.0 (13.1)% at 3 months ($p < 0.001$). TBR <3.9 decreased from 2.3% at BL to 1.9% at 2 weeks and 1.8% at 3 months (both $p < 0.02$ vs BL). TBR <3.0 decreased from 0.5% at BL to 0.4% at 2 weeks ($p = 0.03$) but at 3 months was not different to BL. TAR >10 decreased from 37.1 (16.5)% at BL to 30.9 (11.7)% at 2 weeks ($p < 0.001$) and 32.1 (6.5)% at 3 months ($p < 0.001$).

Conclusions: Glycaemic outcomes in real-world use of CIQ therapy approach those seen in clinical trials during early use but require ongoing evaluation to see if improved control can be sustained over time.

EP100 / #782

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCEMIC CONTROL WITH ADVANCED HYBRID CLOSED-LOOP (AHCL) TECHNOLOGY IN A DEVELOPING COUNTRY: RESULTS FROM 219 PATIENTS WITH DIABETES IN INDIA

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Background and Aims: Developing countries, like India, face a multitude of challenges in diabetes management. Evaluating the use and impact of new diabetes technologies in underdeveloped regions is important. Therefore, we assessed AHCL technology on glycemic outcomes of persons with diabetes in India, who received diabetes education and training on the MiniMed™ 780G system.

Methods: CareLink™ Personal data of consenting individuals (N = 219, N = 64 aged <15 years), who used the MiniMed™ 780G system from January 2022 to June 2022, were aggregated and retrospectively analyzed. Glycemic metrics including the mean Glucose Management Indicator (GMI) and percentage of time spent within (TIR), below (TBR), and above (TAR) target sensor glucose (SG) ranges were summarized for patients with ≥10 days of SG data, after initiating AHCL.

Table 1. Overall outcomes of MiniMed™ 780G system patients in India

	Patients (N=219)
Time in AHCL, %	87 ± 18.3
Mean SG, mg/dL	146.2 ± 16.0
SD of SG	48.9 ± 10.3
GMI, %	6.8 ± 0.4
Patients with GMI <7.0%, %	69.9
Patients with TIR >70%, %	72.1
Time at SG ranges, %	
>250 mg/dL	4.3
180 - 250 mg/dL	18.1
70 - <180 mg/dL	75.4
54 - <70 mg/dL	1.7
<54 mg/dL	0.5

Data are shown as mean or mean ±SD.

Table 2. Longitudinal outcomes of MiniMed™ 780G system patients (N=29) in India

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Time in AHCL, %	92.5	93.4	96.1	95.1	94.6	94.1
Mean SG, mg/dL	146.7	146.4	144.8	144.4	146.3	143.6
GMI, %	6.8	6.8	6.8	6.8	6.8	6.7
Time at SG ranges, %						
>250 mg/dL	4.4	4.4	3.7	3.6	4.2	3.7
180 - 250 mg/dL	22.8	23	21.2	21.9	23	21.5
70 - <180 mg/dL	75.1	75.1	76.7	75.8	74.8	75.7
54 - <70 mg/dL	2.1	2.0	2.1	2.3	2.3	2.8
<54 mg/dL	0.4	0.4	0.5	0.5	0.5	0.8

Data are shown as mean.
[1]Arrieta A et al. *Diabetes Obes Metab.* 2022;24:1370–1379.

Results: Data included 18,994 days of system use and 16,116 days of sensor use (85.2% of time). An overall mean ± SD of 87 ± 18.3% of time was spent in AHCL. Overall mean TIR was 75.4%, TBR <70 was 2.2%, and TAR >180 was 22.4% (Table 1), and similar to outcomes observed during MiniMed™ 780G system use in Europe (TIR: 75.8%, TBR <70: 2.5%, TAR >180: 21.7%).[1] Additional outcomes including the proportion who achieved GMI of <7% (69.9%) and TIR >70% (72.1%) are also shown (Table 1). Sub-analysis of those (N = 29) who used the system across six months showed sustainability of outcomes (Table 2).

Conclusions: Real-world data of individuals using AHCL in India demonstrate good glycemic control similar to that achieved in more developed countries. These results suggest that advanced diabetes technologies have the potential to be beneficial in developing countries.

EP101 / #914

Topic: ***AS03 Closed-loop System and Algorithm***

HYBRID CLOSED LOOP SYSTEMS IN PAEDIATRIC PATIENTS: 18 MONTH FOLLOW UP SHOWS ONGOING BENEFITS.

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Background and Aims: To assess if hybrid closed loop (HCL) systems improve time in range (TIR) and HbA1c in paediatric patients with type 1 diabetes in real world conditions and if they are sustained over 18 months.

Methods: Retrospective analysis of TIR values for 44 patients pre starting closed loop systems and 3 monthly following commencement of HCL. Percentage of time hypoglycaemic and HbA1c levels were compared pre HCL and at 18 months of treatment.

Results: 68% of patients in this cohort were already on a pump prior to commencing HCL, 47% had a basal suspend system. TIR improved markedly on commencement of HCL and was still evident at 18 months.

Month	Mean TIR	Mean Change in TIR	95% confidence Interval		P Value
			Lower	Upper	
Pre	53.4				
3	65.2	+11.8	7.62	16.01	< 0.001
6	64.5	+11.1	6.71	15.51	< 0.001
9	64.6	+11.2	7.11	15.29	< 0.001
12	60.9	+7.5	2.88	12.03	0.02
15	62.8	+9.4	4.59	14.14	<0.001
18	60.8	+7.4	2.10	12.67	0.007

Hypoglycaemia was 3.13% at baseline and 2.31% at 18 months, mean difference -0.82 (CI -1.74 to 0.46, p = 0.082). HbA1c data was available for 38 patients. Mean HbA1c before commencing HCL was 58.7, at 18 months HbA1c mean was 55.7 – mean difference -3 (95% CI -7.8 to 1.8, p = 0.214).

Conclusions: HCL resulted in an improvement in TIR, ongoing improvement in TIR was still evident at 18 months of treatment compared to baseline. Improvements were also seen in HbA1c and percentage time hypoglycaemia but did not reach statistical significance, potentially due to high amount of pump use at baseline in this cohort.

EP102 / #916

Topic: ***AS03 Closed-loop System and Algorithm***

FULLY CLOSED LOOP INSULIN DELIVERY IN A PAEDIATRIC PATIENT WITH DIABETES SECONDARY TO ACUTE PANCREATITIS

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Background and Aims: Background: Variable rate intravenous insulin infusion (VRIII) is used in unwell patients with diabetes and complex nutritional needs. Frequent blood glucose monitoring with infusion rate adjustment gives rise to significant safety concerns and is extremely resource intensive. Fully closed-loop (FCL) systems which automatically deliver insulin in a glucose-responsive manner improve glycaemic control in adult inpatients requiring nutritional support. CamAPS HX algorithm, one such system, is an Android 'app' initialised by input of body weight and total daily insulin dose that has an adjustable nominal glucose target of 5.8mmol/l and options for bolusing for carbohydrate intake. **Aim:** We present a case of a hospitalised adolescent with diabetes secondary to acute pancreatitis managed with a FCL system.

Methods: A 14 years-old boy (weight = 63kg) was admitted to the paediatric intensive care unit with acute necrotizing pancreatitis and oesophageal perforation. Persistent hyperglycaemia with low c-peptide levels (12pmol/L with glucose level of 14.4mmol/L), suggested diabetes secondary to pancreatitis. VRIII was commenced on Day-2 of admission to support total parental nutrition (TPN). Frequent titration of TPN and variable tolerance to nasogastric feeds posed significant challenges to conventional insulin pump therapy. CamAPS HX FCL was started off-licence on Day-20.

Results: CamAPS HX FCL provided excellent glycaemic control (mean±sd sensor glucose- 8.2 ± 1.9mmol/l, time in range 89% and time below range 1%) with no adverse effects during time on and off TPN and while reintroducing enteral feeds.

Conclusions: This case supports the safe and effective use of FCL systems for inpatient management of paediatric patients with complex nutritional needs.

EP103 / #147

Topic: *AS04 New Insulins*

TREATMENT SATISFACTION IN PEOPLE WITH T2D SWITCHED FROM BASAL INSULIN (BI) TO INSULIN GLARGINE 300 U/ML (GLA-300): PATIENT REPORTED OUTCOMES FROM ARTEMIS-DM STUDY

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Background and Aims: Treatment satisfaction is key for treatment adherence, to improve long-term outcomes and avoid diabetes complications. However, there is limited data on treatment satisfaction in people with T2D who switch to Gla-300 from other BI in regions outside US and Europe.

Methods: The current analysis of the 26-week ARTEMIS-DM study presents patient perspective on treatment satisfaction using the Insulin Treatment Satisfaction Questionnaire (ITSQ), in people with T2D, from Asia, Middle East Africa (MEA) and Latin America (LaTAm), uncontrolled on BI and who switched to Gla-300.

Results: A total of 362/372 (97.3%) participants completed the study. Mean ± SD ITSQ total score increased from 76.30 ± 15.63 at baseline to 83.51 ± 13.29 and 84.42 ± 13.15 at Weeks 12 and 26, respectively. Improvements were noted for all ITSQ domain scores, especially glycemic control (baseline: 65.83; mean change from baseline to Week 12: 15.12 and Week 26: 16.06) (**Table**). Despite similar mean baseline scores (73.08 to 79.31), LS mean change in ITSQ total score was numerically greater in LaTAm (10.86) and MEA (10.40) compared with Asia (1.56) at Week 26.

Conclusions: In ARTEMIS-DM study, people with T2D uncontrolled on BI, switching to Gla-300 demonstrated improvement in treatment satisfaction and specifically in glyce–mic control in a diverse population from multiple geographic regions.

Table. Change from baseline in ITSQ total and domain scores at Weeks 12 and 26

ITSQ Scores	Evaluable participants, N	Baseline* Mean (SD)	Week 12 Mean (SD)	Week 12 Mean (SD) change from baseline	Week 26 Mean (SD)	Week 26 Mean (SD) change from baseline
Total Satisfaction Scores	345	76.30 (15.63)	83.51 (13.29)	7.37 (13.46)	84.42 (13.15)	7.49 (14.12)
Regimen inconvenience score	353	82.66 (18.00)	87.64 (15.16)	5.33 (15.77)	88.33 (14.35)	5.14 (16.53)
Lifestyle flexibility score	355	74.85 (21.83)	78.47 (21.78)	3.54 (21.12)	79.54 (19.60)	3.60 (21.36)
Hypoglycemic control score	358	76.10 (19.68)	82.30 (16.30)	6.24 (19.66)	83.04 (16.16)	6.38 (20.02)
Glycemic control score	352	65.83 (23.94)	80.92 (18.18)	15.12 (24.30)	82.75 (17.09)	16.06 (24.61)
Delivery device satisfaction score	355	77.37 (18.68)	84.51 (14.61)	7.27 (16.54)	85.75 (14.03)	8.14 (16.72)

ITSQ total satisfaction scores and domain scores range from 0 to 100, with higher scores indicating better treatment satisfaction. All post-baseline values were included in the appropriate visit according to the following time windows (in analysis days): Week 12 (55-115), Week 26 (153-213).
ITSQ, Insulin Treatment Satisfaction Questionnaire; SD, standard deviation.

EP104 / #390

Topic: *AS04 New Insulins*

EVALUATION OF SENSOR-MEASURED OUTCOMES IN ADULTS WITH TYPE 1 DIABETES SWITCHING TO INSULIN GLARGINE 300 U/ML: A RETROSPECTIVE, PROPENSITY-SCORE MATCHED STUDY

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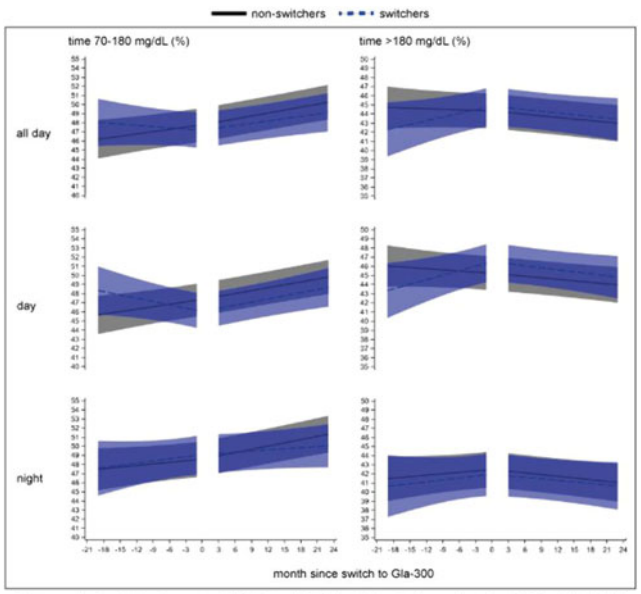
Background and Aims: Real-world evidence shows possible risks/benefits outside controlled settings, which is lacking for sensor-measured glucose in people with type 1 diabetes (T1D) switching to second-generation long-acting insulins.

Methods: This retrospective secondary-use study (NCT05109520) included 151 adults with T1D who switched to Insulin Glargine 300 U/mL (Gla-300) from first-generation long-acting insulins between July 2016-2020 (switchers) and 281 non-switchers who continued first-generation long-acting insulins. Groups were propensity-score matched for center, gender, T1D duration, BMI, HbA1c, time in range (TIR), and time <54 mg/dL. A fictive ''switching'' date was assigned to non-switchers to facilitate between-group comparisons. Primary endpoint was difference in TIR evolution before versus after Gla-300-initiation compared between groups using linear mixed models.

Results: In the period before switching, TIR decreased numerically for people in whom Gla-300 was eventually initiated (-0.05%/month [-0.16;0.07]), while it increased for matched people in whom switch did not happen (0.08%/month



Linear evolution in time in range (70-180 mg/dL, left) and time in hyperglycemia (>180 mg/dL, right) before and after switch to Gla-300 for switchers (blue) and non-switchers (black), divided by time of day: all day (24h), day (6 am – 10 pm), night (10 pm – 6 am). Shaded areas refer to the 95% CI for the linear slopes from the linear mixed model The first three months after prescribing Gla-300 have been omitted from the analysis.

[0.02;0.015]; between-group difference p = 0.047). After Gla-300-initiation, switchers showed a similar TIR increase compared to non-switchers (p = 0.531). For switchers, differences in slopes before versus after Gla-300-initiation were more pronounced during daytime (Δ0.24%/month [0.08;0.39]) while absent during nighttime (figure). The observation that Gla-300-initiation reversed a negative evolution was also seen for time >180 mg/dL (figure), but not for time <54 mg/dL. However, the observed effect was mainly driven by 2% outliers. Switchers had higher basal Gla-300-dose (24.9 U/day [23.2;26.5]) than before Gla-300-initiation (23.6 U/day [22.0;25.3]; Δ1.23 U/day [1.02;1.43], p < 0.001).

Conclusions: Gla-300 was typically initiated in people where TIR was decreasing, which might be reversed after switch using higher basal insulin dose.

EP105 / #132

Topic: ***AS04 New Insulins***

COMPARISON OF SECOND-GENERATION BASAL INSULIN ANALOGS GLARGINE 300 U/ML AND DEGLUDEC 100 U/ML IN INSULIN-NAÏVE PEOPLE WITH T2DM AND RENAL IMPAIRMENT: TRENT CLINICAL TRIAL DESIGN

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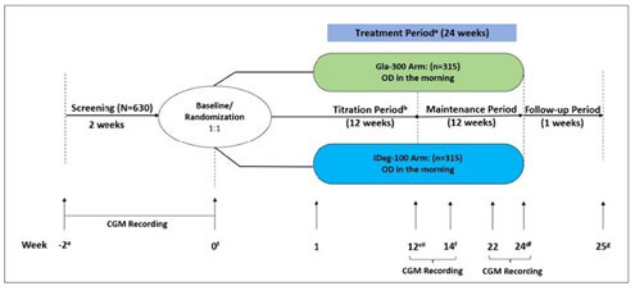
Background and Aims: People with type 2 diabetes mellitus (T2DM) and chronic kidney disease are at increased risk of hypoglycemia and other diabetes-related complications. Second generation basal insulin (BI) analogs, glargine 300 U/mL (Gla-300) and degludec 100 U/mL (IDeg-100), have more stable and prolonged pharmacokinetic/pharmacodynamic profiles with lower risk of hypoglycemia compared to first-generation BI analogs. To date there is no dedicated randomized clinical trial comparing the two second-generation BI analogs in insulin-naïve people with T2DM and renal impairment (RI). Hence, the TRENT trial is designed to confirm the efficacy and safety of Gla-300 versus IDeg-100 in this high-risk population.

Methods: TRENT is a multicenter, randomized, parallel-group, 24-week, open-label, phase 4 comparative study in insulin-naïve adults with T2DM and RI who have glycemic levels above target with oral antihyperglycemic drugs with/without GLP-1 receptor agonists. Participants will be randomized to receive once-daily Gla-300 or IDeg-100. A CGM substudy will be conducted. (**Figure**) (ClinicalTrials.gov Identifier: NCT05552859).

Results: Planned outcomes The primary objective is to demonstrate non-inferiority (margin 0.3%) and, if achieved, superiority of Gla-300 vs IDeg-100 in terms of change in HbA_{1c} from baseline to Week 24 in insulin-naïve people with T2DM and RI. Secondary endpoints include changes from baseline to Week 24 in FPG, SMPG, and HbA_{1c} target achievement. Hypoglycemia and AEs will be reported. A CGM substudy with exploratory endpoints that include TIR, TAR, TBR will be conducted.



Abbreviations: AE, adverse event; CGM, Continuous glucose monitoring; Gla-300, insulin glargine 300 U/mL; GLP-1, glucagon-like peptide-1; IDeg-100, insulin degludec 100 U/mL; SMPG, self-measured plasma glucose; TIR, time in range; TAR, time above range; TBR, time below range. **Note:** Hypoglycemia during the 24-week treatment period, during the titration period, and during the maintenance period by diurnal distribution by ADA/EASD classification will be reported.
*CGM substudy will include 100 participants (n = 50 participants in each group) from the total study population.
a - An unscheduled visit can be planned anytime during the treatment period if study drug resupply is required. **b** - During the titration period, the doses of Gla-300 and IDeg-100 will be adjusted using a recommended dose-adjustment algorithm. **c** - A blinded CGM device will be applied onto the patients who are enrolled in the CGM substudy. The blinded CGM recording will be done for 14 continuous days. The baseline CGM measurements will be captured before initiation of study drug treatment. **d** - At the end of the trial, patients should discuss with the investigator, in collaboration with their HCP, whether to continue the Gla-300 or IDeg-100 treatment regimen or transition to an alternate antihyperglycemic therapy. **e** - A blinded CGM device will be applied onto the patients who are enrolled in the CGM substudy. The blinded CGM recording will be done for 14 continuous days. The baseline CGM measurements will be captured before initiation of study drug treatment. **f** - At baseline, the CGM device will be removed, and the data will be downloaded and reviewed by the investigator to determine patients' eligibility for the CGM substudy. The blinded CGM recording will be done for 14 continuous days for the baseline CGM assessment and again for two 14 day intervals during the treatment period (ie, from Week 12 to Week 14 and from Week 22 to Week 24). **g** - This will be a phone contact but could be a site visit if ongoing or new AEs emerge during the post-treatment period, if necessary.

Conclusions: TRENT study results will help to confirm the efficacy and safety of 2nd generation BIs in clinical practice in insulin-naïve people with T2DM and RI.

EP106 / #427

Topic: ***AS04 New Insulins***

ONE YEAR RESULTS AFTER INITIATION DEGLUDEC INSULIN THERAPY IN ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: An intensive insulin regimen improves glycaemic outcomes measured by hemoglobin A1c (HbA1c) and reduces the rates of long-term complications. Our goal is to determine whether insulin degludec is noninferior or superior to other long-acting insulins in reducing HbA1c in adolescents with type 1 diabetes (T1D).

Methods: Study included 43 adolescents (19 females, 24 males) with T1D on intensive insulin regimen therapy receiving long-acting insulins before bedtime. The mean age was 13.06 ± 2.19 years, with a mean disease duration of 3.9 ± 3.52 years. Patients started degludec insulin given once daily with insulin aspart as bolus insulin for remaining meals. Data on HbA1c, frequency of diabetic ketoacidosis (DKA), change in body mass index (BMI), and a total daily dose of insulin doses were recorded at baseline and after one year of degludec treatment. Alteration in HbA1c was observed after 3, 6, and 12 months of a new therapy.

Results: showed a significant decrease in HbA1c from 7.88 ± 1.31% to 7.55 ± 0.85% (p = 0,033) after 3 months of therapy. After 6 months HbA1c decreased to 7.63 ± 0,82% (p = 0,166), after 12 months mean HbA1c was 7,71 ± 0,86 (p = 0,68). In the year before switching to degludec, one patient had 1 episode of DKA, whereas this increased to 3 DKA attacks in 2 patients after one year of degludec therapy (p = 0.045). A total daily dose of insulin significantly increased (p = 0,045). BMI didn't change significantly after 12 months.

Conclusions: One year of degludec therapy didn't show significantly superior in minimizing HbA1c that other long-acting insulins in our small group of patients.

EP107 / #598

Topic: ***AS04 New Insulins***

TREATMENT SATISFACTION AND HEALTH STATUS IN PEOPLE WITH T2D TREATED WITH INSULIN GLARGINE 300 U/ML (GLA-300): PATIENT-REPORTED OUTCOMES (PRO) FROM ATOS STUDY

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Background and Aims: Patients' satisfaction is a key determinant of treatment adherence and persistence, for optimal management of type 2 diabetes (T2D). ATOS study showed improved glycemic control with low rates of hypoglycemia in insulin-naïve people with T2D who initiated Gla-300 therapy across wide geographic regions. This analysis evaluated changes in treatment satisfaction and health status among participants.

Methods: ATOS (NCT03703869) was a 12-month prospective, observational study conducted in insulin-naïve people with T2D who initiated Gla-300 therapy in Asia, Middle East, North Africa, Latin America, and Eastern Europe. In the present analysis, data were collected using PRO questionnaires – Diabetes Treatment Satisfaction Questionnaire status (DTSQs) and change versions (DTSQc), EuroQoL 5-dimension scale version 3L (EQ-5D-3L) at baseline, Month 3, 6 and 12.

Results: Overall, 3931 participants completed the questionnaires. Mean ± SD age was 57.5 ± 10.6 years, duration of diabetes was 10.1 ± 6.2 years and baseline HbA_{1c} was 9.3 ± 1.0%. Treatment satisfaction improved over time (DTSQs score of 21.7 at baseline to 29.8 and 31.3 at Month 6 and 12, respectively) and perceived frequency of hyperglycemia decreased over 12 months. DTSQc results were aligned with DTSQs. EQ-5D-3L results showed that proportion of people with better health status increased over time (**Table**).

Table: Changes in patient-reported outcomes between baseline and months 3, 6 and 12

	Baseline	Month 3	Month 6	Month 12
DTSQs				
Treatment satisfaction score, n	3818	3730	3779	3653
Mean (SD)	21.7 (7.4)	28.0 (5.5)	29.9 (5.0)	31.3 (4.7)
LS mean change from baseline, 95% CI		6.4 (6.3; 6.6)	8.2 (8.1; 8.4)	9.7 (9.6; 9.9)
Perceived frequency of hyperglycemia score, n	3831	3723	3781	3652
Mean (SD)	4.1 (1.5)	2.5 (1.6)	1.9 (1.7)	1.5 (1.7)
LS mean change from baseline, 95% CI		-1.7 (-1.7; -1.6)	-2.3 (-2.3; -2.2)	-2.7 (-2.7; -2.6)
Perceived frequency of hypoglycemia score, n	3820	3727	3775	3646
Mean (SD)	1.6 (1.6)	1.4 (1.5)	1.2 (1.5)	1.0 (1.4)
LS Mean change from baseline, 95% CI		-0.3 (-0.3; -0.2)	-0.5 (-0.5; -0.4)	-0.7 (-0.7; -0.6)
DTSQc, n			3743	3641
Mean (SD) Treatment satisfaction score			13.2 (4.6)	14.3 (4.3)
Mean (SD) Perceived frequency of hyperglycemia score			-0.9 (1.8)	-1.2 (1.9)
Mean (SD) Perceived frequency of hypoglycemia score			-1.2 (1.7)	-1.3 (1.7)
EQ-5D-3L*				
Mobility, n	3828	3722	3765	3635
I have no problems walking around, n (%)	2505 (65.4%)	2663 (71.5%)	2940 (78.1%)	2969 (81.7%)
Selfcare, n	3822	3727	3753	3634
I have no problems with self-care, n (%)	3260 (85.3%)	3306 (88.7%)	3417 (91.0%)	3363 (92.5%)
Usual Activities, n	3819	3714	3753	3621
I have no problems with performing my usual activities, n (%)	2533 (66.3%)	2902 (78.1%)	3146 (83.8%)	3121 (86.2%)
Pain/Discomfort, n	3821	3717	3753	3633
I have no pain or discomfort, n (%)	1929 (50.5%)	2447 (65.8%)	2720 (72.5%)	2803 (77.2%)
Anxiety/Depression, n	3824	3721	3763	3636
I am not anxious or depressed, n (%)	2482 (64.9%)	2928 (78.7%)	3236 (86.0%)	3219 (88.5%)
VAS, n	3568	3513	3574	3449
Mean (SD) total score, n (%)	60.8 (18.5)	71.2 (15.1)	76.6 (13.5)	81.4 (13.0)

- The DTSQs consisted of 8-item questionnaire conducted at baseline, and Months 3, 6 and 12, each item scored on a scale from 0 [very dissatisfied] to 6 (very satisfied). Treatment satisfaction total score was determined from summing the scores on items 1, 4, 5, 6, 7, and 8 (minimum score 0, maximum score 36). Perceived frequency of hyperglycemia was determined from item 2, and hypoglycemia from item 3; each could have a minimum score of 0 (none of the time), maximum score of 6 (most of the time).
- The DTSQc was conducted after the DTSQs at Months 6 and 12, was the same as DTSQs but with a small alteration to the wording of item 7, which assessed the relative change in treatment satisfaction with respect to a prior treatment, the items scored on a scale from 3 (much more) to -3 (much less). Therefore, treatment satisfaction total score (items 1, 4, 5, 6, 7 and 8) could have a minimum score of -18 and a maximum of 18. DTSQc noted at Month 6 and 12 only.
- Health status was measured by EQ-5D-3L and VAS. The EQ-5D-3L consisted of 5 descriptive dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression; with the patients' self-rated responses coded as 1 [no problem], 2 or 3 [extreme problems]), and VAS recorded the respondent's health on a vertical scale from 0 (worst imaginable health state) to 100 (best imaginable health state). *Code 1 [no problem] is presented in the table.

DTSQc Diabetes Treatment Satisfaction Questionnaire change version; DTSQs Diabetes Treatment Satisfaction Questionnaire status version; EQ-5D-3L, EuroQol 5-dimension scale version 3L; LS, Least-squares; SD, standard deviation; SE, standard error; VAS, Visual Analogue Scale

Conclusions: Results showed that initiating Gla-300 in insulin-naïve people with T2D across multiple geographic regions improved treatment satisfaction and health status.

EP108 / #105

Topic: ***AS04 New Insulins***

TITRATION PATTERNS OF INSULIN GLARGINE 300 U/ML IN INSULIN-NAÏVE PEOPLE WITH TYPE 2 DIABETES AND CLINICAL OUTCOMES: A SUBGROUP ANALYSIS OF ATOS STUDY

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Table: Baseline characteristics and results at Month 5 and 12 by magnitude of Gla-300 U/mL dose change from baseline to Month 3

Baseline characteristics	Group A (0-2 U) (N=1210)	Group B (2-6 U) (N=1076)	Group C (6-10 U) (N=585)	Group D (>10 U) (N=780)
% of participants in each subgroup	33.1% (1210 /3651)	29.5% (1076/3651)	16.0% (585/3651)	21.4% (780/3651)
Age, years	56.6±10.9	57.5±10.7	58.6±10.3	58.8±9.4
Female, n (%)	598 (49.4)	602 (55.9)	345 (59.0)	412 (52.8)
BMI, kg/m^2	28.3±5.2	29.7±5.1	30.9±5.3	30.7±5.2
SU/DPP4i, n (%)	814 (67.3)/599 (49.5)	813 (75.6)/395 (36.7)	463 (79.1)/204 (34.9)	615 (78.8)/308 (39.5)
HbA_{1c}, %	9.31±1.05	9.23±0.99	9.26±0.92	9.27±0.95
Daily Gla-300 dose, U/kg (U)	0.21±0.10 (16.1±7.5)	0.17±0.1 (13.8±5.6)	0.16±0.1 (13.9±5.5)	0.15±0.1 (13.1±4.8)
Month 6/12				
HbA_{1c}, %	7.81±1.09/7.43±0.96	7.80±1.02/7.43±1.02	7.71±0.95/7.26±0.82	7.67±1.09/7.29±0.98
At HbA_{1c} target, %*	24.0/36.6	21.5/44.3	23.4/49.7	34.4/54.6
Gla-300 dose, U/kg/day	0.23±0.10/0.23±0.1	0.24±0.1/0.26±0.1	0.29±0.1/0.32±0.1	0.38±0.1/0.40±0.1
Gla-300 dose, U/day	17.1±7.9/17.6±8.1	19.2±6.5/20.9±7.3	24.6±6.8/27.2±7.7	32.1±8.4/34.0±9.4
Hypoglycemia*, %	0.1/0.1	0.1/0.2	0/0.3	0.1/0.1

Data shown are mean±SD unless otherwise specified. *Data presented as the percentage of participants who achieved their individualized HbA_{1c} target at Month 6 and 12. *Hypoglycemia presented is BG<3.0 mmol/L.
BG, blood glucose; BMI, body mass index; DPP4i, dipeptidyl-peptidase 4 inhibitors; Gla-300, insulin glargine 300 U/mL; HbA_{1c}, glycated hemoglobin; SU, sulfonylureas.

Background and Aims: ATOS, a 12-month prospective observational study conducted in Asia, Middle East, North Africa, Latin America, and Eastern Europe, showed that initiating insulin glargine 300 U/mL (Gla-300) in insulin-naïve people with type 2 diabetes (T2D) resulted in improved glycemic control with low rates of hypoglycemia and minimal weight change. This post hoc analysis aimed to explore the baseline factors and outcomes associated with different magnitudes of Gla-300 titration.

Methods: Participants were categorized based on the magnitude of Gla-300 dose change from baseline to Month 3: 0-2 U (Group A); 2-6 U (Group B); 6-10 U (Group C) and >10 U (Group D).

Results: This analysis included 3651 participants, age and body mass index increased from groups A to D. Starting dose was highest in Group A. At Month 6, the individualized HbA_{1c} target achievement was 24.0%, 21.5%, 23.4% and 34.4% in Groups A, B, C and D respectively (**Table**). Clinically meaningful improvements were seen in HbA_{1c}, fasting plasma glucose and self-monitored blood glucose at 6 and 12 months across the groups. Insulin dose increased over time in all the groups with minimal changes in Group A. Overall, hypoglycemia incidence was low in each group.

Conclusions: This post hoc analysis showed baseline factors appear to impact the titration patterns. Over the course of time more participants reached HbA_{1c} target with increasing magnitude of titration with low incidence of hypoglycemia across the groups and no increase in clinically meaningful hypoglycemia. Basal insulin titration could be further optimized.

EP109 / #78

Topic: ***AS05 Artificial Pancreas***

CLOSED-LOOP HIGH-FAT MEAL MANAGEMENT

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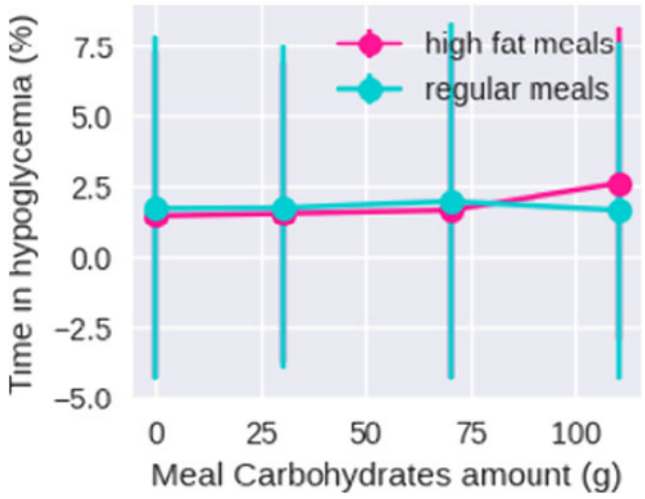
Background and Aims: High-fat meals are a challenge for closed-loop systems for diabetes as they generally have longer carbohydrates absorption time than regular meals. Thus standard meal management may lead to hypoglycemia. DBLG1 System is able to handle regular and high-fat meals. We evaluate the performances of the high-fat meal option.

Methods: We use data from 145 adult T1D patients from DBLG1 clinical trial NCT04190277. We compute the mean of peak glycemia, time in range 70-180 mg/dL (TIR) and time below range 70 mg/dL (TBR) during the 3 hours following each meal. To correct for the impact of the amount of carbohydrates and for the patient-specific effects, we fit mixed-effect linear models where we consider the patient as a random effect, the high-fat meal label and the meal amounts as fixed effects and the peak glycemia or TIR or TBR as target.

Meal type	Carbohydrates amount (g)	Peak glycemia (mg/dL)	TIR	TBR
Regular (N=10759)	49	227	54%	1.8%
High-fat (N=380)	71	235	58%	1.6%



Results: Once corrected for meal amounts and patients effects, the high-fat meal option leads to no statistical difference (p-values = 0.54, 0.088 and 0.68 for peak glycemia, TIR and TBR). Additionally, we look at the TIR/peak glycemia/TBR with respect to the meal sizes, displayed below. This shows that for very large meals (above 100g), the high-fat meal option increases TIR, reduces peak glycemia but increases TBR.

Conclusions: The DBLG1 high-fat meal strategy allows to maintain similar TIR, TBR and peak glycemia to regular meals.

EP110 / #863

Topic: ***AS05 Artificial Pancreas***

TIME SPENT IN HYPOGLYCAEMIA ACCORDING TO AGE AND TIME OF DAY: OBSERVATIONS DURING CLOSED-LOOP INSULIN DELIVERY

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Background and Aims: To assess whether percentage of time spent in hypoglycaemia during closed-loop insulin delivery differed by age-group and time of day

Methods: We retrospectively analysed data from hybrid closed-loop studies involving young children (2-7 years, n = 22), children and adolescents (8-18 years, n = 22), adults (19-59 years, n = 22), and older adults (≥60 years, n = 22) with type 1 diabetes. The main outcome was time spent in hypoglycaemia <3.9 mmol/l by time of day. The groups were compared using one-way ANOVA.

Results: Eight weeks of data for 88 participants were analysed. The median time spent in hypoglycaemia during daytime (6:00 a.m. to 11:59 p.m.) was highest in children and adolescents at 5.1% (interquartile range [IQR] 2.8-5.8) and very young children at 4.6% (IQR 3.8-5.9), followed by adults (3.1%, IQR 1.7-4.4), with the least time in hypoglycaemia among the older adults (2.1%, IQR 1.4-2.5); $p < 0.001$ for the difference between age-groups. The median time spent in hypoglycaemia during nighttime (midnight to 5:59 a.m.) was lower than in the daytime across all age-groups, but remained significantly higher in very young children (2.6%, IQR 1.3-3.7) and children and adolescents (2.0%, IQR 1.4 to 3.0), compared to adults (1.7%, IQR 1.2 to 2.1) and older adults (1.0%, IQR 0.6 to 1.3); $p < 0.001$ for the difference between age-groups.

Conclusions: Hypoglycaemia burden was lowest overnight across all age-groups when using closed-loop . Percentage of time spent in hypoglycaemia was higher among very young children and children and adolescents during both daytime and nighttime as compared to adults and older adults.

EP111 / #886

Topic: ***AS05 Artificial Pancreas***

IN SILICO RESULTS OF THE INCONTROL AUTO FULLY CLOSED-LOOP ALGORITHM REQUIRING A SINGLE CONFIGURATION INPUT

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Background and Aims: For people with type-1 diabetes mellitus (T1DM), automated insulin delivery (AID) promises to be the easiest, safest, and most efficient technological answer to glucose management. Although first-generation AID systems alleviate some of the round-the-clock patient interaction required by the disease, most systems require numerous user inputs such as detailed therapy parameters (for configuration) and estimated meal sizes (at run-time), increasing burden and potentially compromising reliability. The inControl Auto algorithm is part of a next-generation AID system that only requires a single basal rate value as a configuration input. With only a single patient-specific parameter, the algorithm is biased toward conservative treatment of hyperglycemia. To manage inter-subject insulin needs and achieve personalization, a CGM-based two-week run-to-run aggressiveness parameter adaptation method is proposed.

Methods: The adaptation method was evaluated on 144 subjects with >90 days of data from the TypeZero/Dexcom T1DM simulator, which captures real-world glucose variability. Ability to personalize was assessed through the median version of Levene's test with the null hypothesis of equality of variance for population percentage of times <70 mg/dL and >180 mg/dL, with and without adaptation.

Results: Across-subject coefficient of variation with versus without adaptation decreased from 99% to 73% for time <70 mg/dL ($p < 0.01$) and decreased from 36% to 32% for time >180 mg/dL ($p = 0.019$).

Conclusions: Based on these in silico experiments, the proposed AID adaptation technique successfully tightened population distributions for both hypoglycemia and hyperglycemia using only total daily basal insulin for initial configuration.

EP112 / #890

Topic: *AS05 Artificial Pancreas*

INCONTROL AUTO FULLY CLOSED-LOOP: AUTOMATED RESPONSE TO MEAL, EXERCISE, AND SLEEP EVENTS TO IMPROVE EASE-OF-USE

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Background and Aims: InControl Auto is part of a new fully closed-loop Automated Insulin Delivery (AID) system designed with the goal of improving patients' quality of life. The system eases patient burden by streamlining configuration and eliminating requirements for meal, sleep, and exercise announcements and carbohydrate counting. The aim of this work is to evaluate inControl Auto's performance when responding to these challenges in free-living conditions.

Methods: Fifteen AID-naïve subjects participated in an ongoing 84-day study. Initialization of inControl Auto requires a single daily basal insulin rate parameter, and its operation does not present the opportunity to announce meals, sleep, or exercise. To understand the response of inControl Auto to these unannounced events, we analyzed the study data for meal detection, hypoglycemia avoidance, and response to meal-induced hyperglycemia.

Results: Postprandial hypoglycemia, measured by percent time <70 mg/dL within 5 hours of detected meals, exceeded the overall time <70 mg/dL by 0.3%. Unannounced sleep was safely handled with inControl Auto leading to a 12% increase in TIR in the 02:00-06:00 interval, with a very small increase of 0.2% in time <70 mg/dL. The meal detection features of inControl Auto effectively identified a mean ± SD of 2.8 ± 1.3 meals per day. Insulin administered in direct response to meals was 7.8 U/day, about 14.2% of the total daily dose.

Conclusions: InControl Auto demonstrated improved glycemia with no adverse events, requiring minimal configuration and patient engagement when used in free-living conditions.

EP113 / #913

Topic: *AS05 Artificial Pancreas*

EFFECTS OF LOW-DOSE GLUCAGON ON SUBCUTANEOUS INSULIN ABSORPTION IN PIGS

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Background and Aims: Slow absorption of insulin after subcutaneous administration is the main factor preventing the development of a fully automated artificial pancreas with subcutaneous insulin delivery. Insulin absorption correlate to local blood flow and additives that increase local blood flow are used in some insulin formulations. We recent showed that glucagon increases subcutaneous blood flow in healthy adults. Accordingly, we investigated if small doses of glucagon can be used to accelerate the absorption of meal-boluses of insulin in an artificial pancreas.

Methods: Anesthetized pigs were included and randomized to receive 10 IU of insulin aspart subcutaneously together with either 100 μg glucagon or the equivalent volume of placebo (0.9 per cent saline). Endogenous insulin and glucagon secretion were suppressed by infusion of octreotide. Arterial samples were collected for 180 minutes to determine plasma insulin, glucagon, and glucose concentrations.

Results: The initial absorption of insulin was rapid, and maximum insulin plasma concentration was reached after median 30 minutes in both groups. Preliminary analyses indicate that glucagon increase the area under insulin curve for the first 60 minutes 30-40 percent and for the first 120 minutes >50 percent. Final results will be presented.

Conclusions: Area under the insulin curve is significantly increased by injection of glucagon at the same site. This effect of glucagon could be utilized in a bihormonal artificial pancreas. Clinical studies are needed to investigate if micro-doses of glucagon can be used to improve postprandial insulin absorption and make a fully automated artificial pancreas possible in subjects with DM1.

EP114 / #614

Topic: *AS05 Artificial Pancreas*

INTRAPERITONEAL INSULIN DELIVERY CLOSED-LOOP SYSTEM: DESIGN OF A SAFETY MODULE

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Background and Aims: At ATTD 2022 we have presented a novel time-varying proportional derivative integral controller for intraperitoneal (IP) insulin delivery which will be implemented in the FORGETDIABETES IP closed-loop system (H2020 FET 951933). The controller has been validated in silico on the IP-modified FDA type 1 diabetes (T1D) simulator. A safety system is fundamental for a closed-loop system to alert a subject with T1D if the glucose concentration is expected to reach critical values, in order to allow him/her to prevent both hypo and hyperglycemia by acting in advance. While some systems exist for subcutaneous (SC) closed-loop systems, no safety technology has yet been proposed for an IP insulin delivery closed-loop system.

Methods: Recent studies have shown that Long Short-Term Memory (LSTM) neural networks are effective in the glucose prediction for T1D patients with SC systems. In this work we propose a customized alarm system based on a LSTM model able to effectively predict glycemic concentration and to prevent hypoglycemia events in systems exploiting the IP site for insulin infusion.

Results: Promising results have been obtained: system-generated alarms effectively predict hypoglycemic events allowing the patient to avoid potentially dangerous situations.

Conclusions: LSTM networks are suitable for ensuring patient safety in the glycemic control even with the most innovative technologies of intraperitoneal infusion.

EP115 / #499

Topic: ***AS05 Artificial Pancreas***

GLYCEMIC OUTCOMES IMPROVE REGARDLESS OF DEMOGRAPHICS AND BASELINE CONTROL FOR YOUNG CHILDREN WITH TYPE 1 DIABETES USING CONTROL-IQ – RESULTS FROM THE PEDAP TRIAL

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Background and Aims: Recently published studies demonstrate that hybrid closed-loop systems improve glucose control in young children with Type 1 Diabetes (T1D). How sensitive these promising results are to patients' baseline characteristics remains to be shown.

Methods: In a 13-week, multi-center, randomized controlled trial, 102 children with T1D age 2 to <6 years were assigned to use the Tandem t:slim X2 insulin pump with Control-IQ technology, an advanced hybrid closed-loop system, or standard care following two weeks of baseline Continuous Glucose Monitoring (CGM) data. We compared CGM Time In Range 70-180 mg/dL (TIR) from baseline to end of study among subgroups classified by race/ethnicity, family income, parent education, type of health insurance, baseline HbA1c and experience with pumps.

Table 1. TIR and change in TIR from baseline according to subgroups

	Control-IQ (N=67)			Standard Care (N=34)			
	N	Baseline (*mean ± SD*)	Change from Baseline (*mean ± SD*)	N	Baseline (*mean ± SD*)	Change from Baseline (*mean ± SD*)	P-value for interaction[a]
Overall	67	57% ± 18%	12.5% ± 11.8%	34	55% ± 15%	1.0% ± 6.6%	
Race/Ethnicity[b]							-
White non-Hispanic	50	57% ± 17%	12.1% ± 11.9%	25	55% ± 15%	1.6% ± 7.0%	
Other	17	55% ± 20%	13.4% ± 11.9%	9	54% ± 14%	-0.6% ± 5.2%	
Family Income		N=63[c]			N=32[c]		0.30
<$100,000	27	49% ± 18%	15.9% ± 13.1%	18	51% ± 14%	1.4% ± 6.8%	
≥$100,000	36	62% ± 17%	10.1% ± 10.6%	14	60% ± 15%	0.1% ± 6.8%	
Parent Education							0.99
≤Bachelor's Degree	36	51% ± 18%	14.4% ± 12.8%	22	52% ± 15%	2.1% ± 6.4%	
>Bachelor's Degree	31	63% ± 16%	10.2% ± 10.3%	12	60% ± 13%	-1.0% ± 6.6%	
Health Insurance[b]					N=33[c]		-
Private	51	59% ± 18%	12.3% ± 11.3%	26	58% ± 14%	-0.2% ± 5.8%	
Not Private	16	51% ± 18%	13.0% ± 13.7%	7	47% ± 16%	5.3% ± 8.4%	
Baseline HbA1c		N=64[c]			N=33[c]		0.003
<7.0%	22	73% ± 13%	6.4% ± 9.8%	8	73% ± 6%	-0.4% ± 5.6%	
7.0%-<8.0%	21	56% ± 10%	11.4% ± 9.3%	9	58% ± 7%	-1.5% ± 6.2%	
≥8.0%	21	41% ± 12%	19.4% ± 12.4%	16	45% ± 12%	2.6% ± 6.9%	
Insulin Modality before Enrollment[d]							0.66
Pump	41	62% ± 16%	9.4% ± 10.4%	24	55% ± 14%	0.4% ± 6.0%	
Multiple Daily Injections	26	48% ± 18%	17.2% ± 12.4%	10	55% ± 17%	2.6% ± 7.9%	

Data are mean ± SD. Baseline CGM data were not available for one of the 68 participants in the CLC group.

a- FDR-adjusted p-value for interactions between treatment group.

b- Per study analysis plan, p-values not calculated for categorical variables by subgroups for subgroups with fewer than 10 participants

c- Baseline values missing for one or more participants as noted above

d- All but 2 participants were actively using CGM at the time of enrollment

Results: Participants were age 3.9 ± 1.2 years old at baseline with 26% of minority race/ethnicity, 47% with annual household income less than $100,000; 57% had one parent with a bachelor's degree or less (11% with an Associate degree only, 11% with no college degree), 24% had public insurance, 68% had baseline HbA1C higher than 7%, and 35% used multiple daily injections. TIR improved in all subgroups regardless of their race/ethnicity, family income, education, health insurance type, baseline HbA1c, and experience with pumps (Table 1). Benefits were especially pronounced in participants with higher HbA1c.

Conclusions: The glycemic benefits of Control-IQ technology are independent of a broad selection of baseline characteristics, encouraging universal access to this technology for young children with T1D.

EP116 / #554

Topic: ***AS05 Artificial Pancreas***

A NEW PHARMACOKINETICS AND PHARMACODYNAMICS MODEL OF SUBCUTANEOUS PRAMLINTIDE INFUSION

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Background and Aims: Several clinical trials have shown the benefit of pramlintide in postprandial glucose management by delaying gastric emptying, which have led to consider pramlintide in artificial pancreas systems. However, there is a gap in pramlintide models for pre-clinical *in silico* evaluations. This work develops a new populational model for the pharmacokinetics (PK) and pharmacodynamics (PD) of the subcutaneous pramlintide infusion.

Methods: The model was built in three stages: (1) PK of intravenous injection, (2) PK of subcutaneous injection, and (3) PD of the effect on gastric emptying. Different model structures were proposed for each stage. Aggregated clinical datasets from literature were used to identify the models, minimizing the Root Mean Square Error (RMSE) between the data points and the simulation.

Results: A final 7th-order compartmental model is proposed assembling results of the three evaluated stages. Compared to a state-of-art model, the RMSE results showed an improvement in the data fit of 53.94 % in the first stage and 86.10 % in the second. Although a direct comparison for the third stage was not possible, the model accurately fitted gastric emptying data with an RMSE of 0.79 μmol/kg/min.

Conclusions: The results of this work will help develop simulators for evaluating insulin-pramlintide artificial pancreas systems. **Acknowledgements**: This work was supported by grants PID2019-107722RB-C21 funded by MCIN/AEI/10.13039/501100011033, FPU17/03404 funded by MCIN/AEI/10.13039/501100011033 and by ''ESF Investing in your future'', CIPROM/2021/012 funded by Conselleria de Innovación, Universidades, Ciencia y Sociedad Digital, Generalitat Valenciana.

EP117 / #492

Topic: ***AS05 Artificial Pancreas***

DIABETES TECHNOLOGY USE AND THE RELATIONSHIP TO FAMILY ROUTINES AND QUALITY OF LIFE

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Background and Aims: Use of diabetes technologies are associated with better glycemic control, reduced rates of hyper and hypoglycemia, and improved patient satisfaction for children with T1D. However, it is critical to examine how technologies impact a family's competence and satisfaction with their daily health management routines and diabetes distress if adoption of the newest technologies will occur. The study aim was to examine the relationships among different diabetes technologies and family routines and quality of life.

Methods: Caregivers of children (n = 89) with T1D completed the Zarit Burden Interview Scale (ZBIS), WHOQOL-BREF, and the Diabetes Health Management and Distress–Caregivers of Children. Exploratory analyses were completed to examine relationships between diabetes technology use (MDI, CSII, CSII+CGM open loop, CSII+CGM closed loop) and the family's perceived competence and satisfaction with their health management routines, caregiver diabetes distress, family QOL, and caregiver burden.

Results: Analyses are ongoing, but preliminary findings indicated significant differences in ZBIS and physical health, psychological health, and environment among participants who used different diabetes technologies. Use of MDI and CSII only had severe burden scores. Closed loop systems had the highest levels of caregiver physical health. No significant relationships were noted between diabetes technology use and family health management routines.

Conclusions: Future research must include largers samples. Families who do not use technology reported the highest levels of burden and lowest levels of QOL ratings for psychological health, physical health, and environment. Providers are encouraged to provide equitable diabetes technology access and tailored training to families regarding routines to promote overall family quality of life.

EP118 / #908

Topic: ***AS05 Artificial Pancreas***

BIONIC PANCREAS - THE FIRST RESULTS OF FUNCTIONALITY OF 3D-BIOPRINTED BIONIC TISSUE MODEL TRANSPLANTATION WITH PANCREATIC ISLETS.

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Background and Aims: Tissue engineering is currently on advanced stage of development which gives a possibilities for novel strategy of personal treatment of T1D. In the following study, a bioink based on ECM derived from decellularization of porcine pancreas was applied for 3D-bioprinting.

Methods: The SCID (n = 60) and BALB (n = 20) mice were used as a model for *in vivo* study. Porcine islets mixed with bioink were printed on extrusion printer and transplanted on studied animals. Effectiveness of transplanted petals with regard of their insulin secretion was evaluated based on glucose and c-peptide concentration in blood samples of studied animals. Thus, animals were divided into three groups: mice with transplanted islet-laden petals, mice with transplanted islets into kidney capsule and untreated mice. Examination of studied parameters took place at four time points during the experiment, at the beginning and on day 7^{th},14^{th} and 28^{th} day of experiment.

Results: Group with transplanted petals from day 7^{th} expressed lower mean fasting glucose concentration while compared with untreated group (129mg/dl, 119mg/dl, 118mg/dl vs.140mg/dl, 139mg/dl, 140mg/dl respectively in 7^{th},14^{th} and 28^{th} day post-transplantation; $p < 0.001$). Post-surgery transverse section of petals revealed that connective tissue of studied animals surrounded and stabilized transplanted petals. Fibroblasts infiltration over time resulted in the process of new blood vessels formation within the petals. Hence, presented in the study bioink provides a favorable conditions for islets functionality. The bioprinted construct was stable over time. Furthermore, no pathological conditions of studied animals were observed which indicates that bioprinted petals were biocompatible.

Conclusions: Bionic flake transplantation lowered glucose levels significantly.

EP119 / #864

Topic: ***AS05 Artificial Pancreas***

ELECTROCARDIOGRAM AS A PREDICTOR FOR EARLY AND ROBUST MEAL ONSET DETECTION IN ARTIFICIAL PANCREAS

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Background and Aims: The hybrid artificial pancreas relies on continuous glucose monitoring (CGM) sensors as the only measured variable used for insulin dosing and additional glucose control functions in people with diabetes mellitus. To adequately treat postprandial hyperglycemia, the users must make manual meal announcements that are often forgotten or subject to errors. A meal can affect the electrocardiogram (ECG) parameters. We

propose a non-invasive ECG-based system for early detection of meal onset that can be included in the basis for automated insulin dosing in an artificial pancreas.

Methods: ECG signals during 46 meals in 28 healthy volunteers were collected and preprocessed, relevant features were calculated, and a Leave-One-Out Cross-validated support vector machine was constructed. We aimed to determine the delay between meal onset and detection and to evaluate the system under daily life situations. Two experiments were conducted: Experiment I without any activity (35 meals: 22 for training and 13 for testing), and Experiment II with activities of daily life (11 meals: 7 for training and 4 for testing).

Results: The algorithm in Experiment I detected 11 of 13 meals within 2 minutes, with a positive predictive value of 95%, while in Experiment II, all 4 meals were detected in 2.75 minutes and with a positive predictive value of 100%.

Conclusions: The results indicated that ECG carries information for the detection of meal onset. Our ECG-based approach can detect meals with an average delay of below 3 minutes after ingestion in both experiments, including activities of daily life.

EP120 / #472

Topic: ***AS05 Artificial Pancreas***

DETECTION OF INSULIN PUMP FAULTS IN ARTIFICIAL PANCREAS SYSTEMS LEVERAGING ON THE MEAN VALUES OF KALMAN FILTER RESIDUALS

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Background and Aims: Pumps for Continuous Subcutaneous Insulin Infusion (CSII) are crucial parts of an artificial pancreas. If the pump fails, the effectiveness of glucose management offered by such a system may seriously deteriorate, endangering patients' safety. Here, we concentrate on nighttime CSII pump malfunctions, one of the most frequent and concerning forms of faults in artificial pancreas, since they can cause persistent hyperglycemia and even diabetic ketoacidosis. Therefore, their reliable and timely detection is of critical importance.

Methods: We propose a model-based pump fault detection strategy that monitors the sample mean of the prediction residuals, i.e., the difference between the glucose levels measured by the sensor and those obtained by a Kalman predictor. The sample mean is expected to be small in fault-free situations while large values suggest a malfunction. Results are compared to those of a previously proposed approach, that only considered the magnitude of the prediction residuals.

The effectiveness of the two strategies is assessed in-silico on the UVa/Padova T1D simulator. The test lasts 90 days and is performed on 50 subjects each dealing with 3 random nighttime faulty episodes.

Results: With the new approach the recall is enhanced from 82.7% to 88%, while the number of false positives was lowered from 0.13 to 0.11 per day. Finally, the detection time was reduced from 231min to 225min.

Conclusions: The use of the mean values properties of the prediction residuals, instead of just their punctual value, proved to have a positive impact on CSII pump failures detection.

EP121 / #504

Topic: ***AS05 Artificial Pancreas***

SAFETY AND PERFORMANCE OF A HYBRID CLOSED-LOOP INSULIN DELIVERY SYSTEM WITH CARBOHYDRATE SUGGESTION IN ADULTS WITH TYPE 1 DIABETES PRONE TO HYPOGLYCEMIA

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Background and Aims: To evaluate the safety and performance of a hybrid closed-loop (HCL) insulin delivery system with carbohydrate suggestion, tailored for adults with type 1 diabetes (T1D) prone to hypoglycemia.

Methods: A 32-hour in-hospital pilot study including a night period, 4 meals and 2 vigorous 45-minute aerobic sessions was conducted in 11 adults with T1D, users of an insulin pump and prone to hypoglycemia (history of severe and/or impaired hypoglycemia awareness). The primary outcome was the percentage of time in range 70-180 mg/dL (TIR) and secondary outcomes were other glucometrics [time below range <54 mg/dL (TBR <54), time below range <70 mg/dL (TBR <70), coefficient of variation (CV)], the percentage of patients achieving glycemic targets and the number of acute complications.

Results: The participants, 54.5% men, were 31.7 ± 10.9 years old, had 20.3 ± 8.9 years of T1D duration and a 5-year HbA1c mean of 7.5 ± 1%. The mean TIR was 78.7% (75.6-91.2): 92.7% (68.2-100.0) during exercise and recovery period (ERP), 79.3% (34.9-100.0) during postprandial period (PPP) and 95.4% (66.4-100.0) during overnight period (ONP). Global CV was 26.7% (22.6-34.1) and global TBR <70 and TBR <54 were 0.0% (0.0-6.6) and 0.0% (0.0-1.2), respectively. 90.9% (n = 10) of the participants achieved a TIR >70% and 81.8% (n = 9) a TBR <54 < 1%. 8 (4-10) suggestions of 15g of carbohydrates were administered per patient and there were no severe acute complications during the study.

Conclusions: The HCL system with carbohydrate suggestion performed well and was safe in adults with T1D prone to hypoglycemia during challenging conditions in a hospital setting.

EP122 / #897

Topic: ***AS05 Artificial Pancreas***

INCONTROL AUTO FULLY CLOSED-LOOP IMPROVES GLYCEMIC CONTROL WHILE MITIGATING THE NEED FOR MANUAL BOLUSING

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Background and Aims: inControl Auto is part of a new fully closed-loop automated insulin delivery (AID) system specifically designed with the goal of improving quality of life for patients. inControl Auto only recognizes the following aspects of patient engagement: configuring a single basal insulin rate (required), changing the insulin pump battery and insulin cartridge (required), changing the CGM (required), turning the system on and off (discouraged), and manual bolusing (discouraged). Results from a purely free-living clinical trial indicate that – compared with a run-in on usual therapy – 53% of subjects experienced simultaneous improvement in all three glycemic ranges (<70 mg/dL, 70-180 mg/dL, >180 mg/dL), and 87% of subjects experienced improved time in 70-180 mg/dL. The present inquiry aims to determine whether the observed glycemic benefits are due to behavioral engagement, particularly manual bolusing.

Methods: Fifteen AID-naive subjects participated in an ongoing 84-day study. We calculated changes in glycemic outcomes versus run-in (dependent variables) and checked for correlations with engagement behaviors (independent variables).

Results: We found no statistical evidence that changes in glycemic outcomes versus run-in are significantly correlated with any engagement behaviors. In particular, the number of manual boluses per day is not significantly correlated with changes in percent time <70 mg/dL ($p = 0.570$), percent time in 70-180 mg/dL ($p = 0.573$), percent time >180 mg/dL ($p = 0.504$), or average estimated glucose value ($p = 0.360$).

Conclusions: Study subjects were sufficiently engaged to maintain proper operation of the insulin pump. Glycemic outcome improvements (versus run-in) were due to inControl Auto and not to additional patient interventions such as manual bolusing.

EP123 / #585

Topic: ***AS05 Artificial Pancreas***

POSTPRANDIAL GLUCOSE VALUES AFTER RISOTTO MEAL: IS IT BETTER A SIMPLE OR AN EXTENDED BOLUS?

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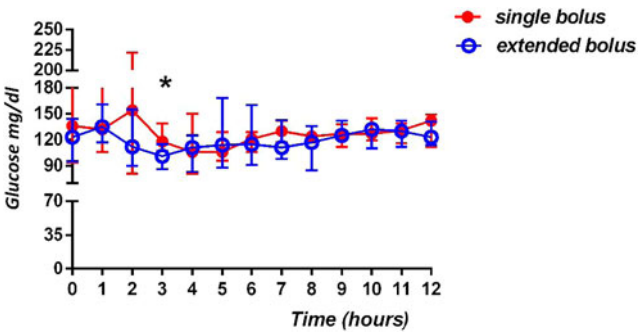
Background and Aims: Technology has an important role in postprandial glycemic control due to advanced hybrid closed loop (AHCL) systems. Indeed, there are some types of food difficult to manage in terms of glycemic response, such as pizza or risotto. The aim was to evaluate the impact of different boluses (single or extended) on postprandial glucose values in children and adolescents with type 1 diabetes using an AHCL system (Tandem Control-IQ™) after eating zucchini risotto.

Methods: Eighteen type 1 diabetes subjects (M 11/F 7, aged 11.8 ± 2.6 yrs, HbA1c 6,4 ± 0.8%) using an AHCL system for at least 3 months were enrolled. White Risotto (Gigante Vercelli) was prepared by the same cook for all patients. Among subjects, 50% used extended bolus (70%/30% in 2 hours), and 50% a single bolus. Glucose values were downloaded on Diasend platform and CGM metrics were evaluated for 12 hours after dinner. Total automated basal and bolus insulin (IU/kg) was assessed.



Results: We found an optimal postprandial glycemic control for both types of bolus with mean glucose values in target (<180 mg/dl) within 2 hours after eating risotto. At 3 hours after dinner, subjects using extended bolus had lower median glucose values than the ones using single bolus ($p < 0.05$) ***(Figure)***. No differences in the automatic basal and bolus insulin delivered were observed.

Conclusions: Our findings suggest optimal glycemic control when using AHCL systems in the management of complex meals like risotto. The extended bolus might determine better postprandial glycemic excursions in the case of a meal with a high glycemic index.

EP124 / #638

Topic: ***AS05 Artificial Pancreas***

USE OF CONTROL-IQ IN VERY YOUNG CHILDREN

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Background and Aims: Automated insulin delivery (AID) improves glycemic outcomes in people with type 1 diabetes (T1D) across all ages. Control-IQ is currently FDA-approved for children aged 6 years and older who use at least 10 units of insulin daily, although has been used in younger patients and those with lower insulin requirements. We sought to determine glycemic outcomes in very young children with T1D using C-IQ in the real-world setting prior to age 6 years.

Methods: CGM and pump data were analyzed from a large database of patients using a predictive low glucose suspend system (Basal-IQ) for 1 month followed by AID (Control-IQ) for 3 months. Outcomes were compared across two age groups (1-3 years and 4-5 years).

Results: 92 children under the age of 6 years met criteria with 14 being under the age of 4 years. The lowest total daily insulin (TDI) on Basal-IQ prior to upgrading to AID was 2.91 units in a 3-year-old. Time in target range increased on average 10% and GMI was reduced by 0.5% after 3 months of AID use (Table).

Table: Glycemic outcomes (mean ± SD)

	1-3 years N=14	4-5 years N=78	All N=92
GMI (%)[a]			
B-IQ	7.8 ± 1.2	7.6 ± 0.8	7.6 ± 0.9
C-IQ (1m)	7.2 ± 0.8	7.1 ± 0.5	7.1 ± 0.6
C-IQ (3m)	7.2 ± 0.7	7.2 ± 0.7	7.1 ± 0.6
Mean BG (ng/dL)[a]			
B-IQ	186 ± 48	178 ± 34	179 ± 36
C-IQ (1m)	164 ± 33	159 ± 22	159 ± 24
C-IQ (3m)	166 ± 33	164 ± 28	164 ± 29
%TIR (70-180)[a]			
B-IQ	52 ± 23	55 ± 17	54 ± 18
C-IQ (1m)	66 ± 18	67 ± 12	66 ± 13
C-IQ (3m)	64 ± 18	65 ± 14	64 ± 15
%TAR (>180)[a]			
B-IQ	47 ± 23	43 ± 18	43 ± 19
C-IQ (1m)	33 ± 18	31 ± 13	33 ± 18
C-IQ (3m)	34 ± 18	33 ± 15	33 ± 15
%TAR (>250)[a]			
B-IQ	17 ± 21	17 ± 13	17 ± 15
C-IQ (1m)	10 ± 14	10 ± 8	10 ± 8
C-IQ (4m)	11 ± 14	12 ± 11	12 ± 11
%TBR (<70)[a]			
B-IQ	1.2 ± 1.1	2.3 ± 2.0	2.1 ± 1.9
C-IQ (1m)	1.9 ± 1.4	2.7 ± 1.9	2.5 ± 1.8
C-IQ (3m)	1.8 ± 1.4	2.5 ± 1.7	2.4 ± 1.7
%TBR (<54)[b]			
B-IQ	0.2 ± 0.3	0.4 ± 0.5	0.4 ± 0.5
C-IQ (1m)	0.4 ± 0.4	0.5 ± 0.6	0.5 ± 0.5
C-IQ (3m)	0.3 ± 0.4	0.5 ± 0.5	0.5 ± 0.5
Total Daily Insulin (units/day)[a]			
B-IQ	16.3 ± 15.4	15.5 ± 11.0	15.7 ± 11.8
C-IQ (1m)	18.1 ± 15.2	16.8 ± 11.3	16.9 ± 11.9
C-IQ (3m)	15.2 ± 11.1	16.8 ± 10.1	16.6 ± 10.3

Abbreviations: BG, blood glucose; m, month; B-IQ, Basal-IQ; C-IQ, Control-IQ; TIR, time in range; TAR, time above range; TBR, time below range
B-IQ vs. C-IQ: [a]p<0.001,[b]p<0.05

Glycemic outcomes were similar between age groups. Rates of hypoglycemia, both <70 ng/dL and <54 ng/dL, were slightly higher with AID.

Conclusions: Toddlers and preschoolers with T1D demonstrated improved glycemic control with use of Control-IQ, even without the increased supervision and monitoring that occurs during a research trial. Rates of hypoglycemia did not improve in this challenging age range, although remained below CGM consensus targets on AID while achieving tighter glycemic control.

EP125 / #452

Topic: ***AS05 Artificial Pancreas***

PERSONALIZED BLOOD GLUCOSE FORECASTING FROM CGM DATA USING AN INCREMENTALLY RETRAINED LSTM

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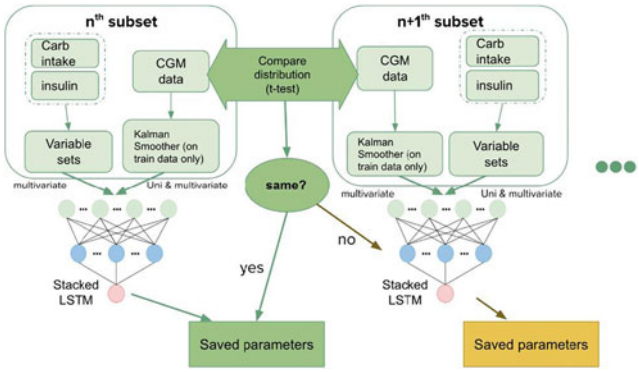
Background and Aims: Artificial pancreas (AP) systems rely on blood glucose (BG) forecasts to deliver insulin, and better forecasts could improve their efficacy. However, while deep learning frameworks like Long Short-Term Memory (LSTM) perform well for BG forecasting, they are slow to train and do not take advantage of long-term individual data. To address this we propose to efficiently personalize BG forecasting using incremental retraining of an LSTM.



Methods: We use data from 126 Open Artificial Pancreas (OpenAPS) project participants with Type 1 diabetes. Individuals had >50 days of continuous glucose monitor (CGM) data recorded at 5 min intervals (mean = 463.48 days, sd = 376.98). We train a 2-layer stacked LSTM to forecast BG at a future time (called prediction horizon, PH) using a subset of the data (e.g. first 7 days). At regular intervals (e.g. weekly) the distribution of current and past data subsets are compared. When they differ significantly the model parameters are updated. We evaluate with PH = 30 and 60min.

Results: The RMSE(in mg/dL) for our personalized incremental LSTM, averaged across all participants, was 10.23 for PH = 30min, and 15.08 for PH = 60min. In contrast, RMSE trained on the same dataset using a stacked LSTM without incremental updating was 14.55 for PH = 30min and 19.30 for PH = 60min.

Conclusions: We show that incremental learning significantly reduces RMSE for BG forecasting compared to baselines, while also enabling efficient learning.

EP126 / #883

Topic: ***AS05 Artificial Pancreas***

REAL-WORLD EVIDENCE OF AUTOMATED INSULIN DELIVERY (AID) USE IN A LARGE SAMPLE OF OLDER ADULTS WITH TYPE 1 DIABETES

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Background and Aims: As patients with type 1 diabetes (T1D) age into older adulthood, unique challenges arise. AID has been widely utilized in T1D to improve glycemic control; however, barriers such as decreased cognition and dexterity may impede AID use in older adults.

Methods: We explore the effect of real-life transition from a PLGS system with Basal-IQ to AID with Control-IQ, Tandem Diabetes Care, by individuals with T1D, ages >65 years. Analysis of data from 3309 people who used PLGS for a month followed by AID for 3 months and uploaded data to Tandem's Customer Relations Management database was used to compare CGM-based metrics and bolusing patterns on PLGS vs AID. Participants consented to the use of their data for research, when initiating their t:connect accounts.

Results: In this population, transition from PLGS to AID resulted in immediate improvement in glucose control, most pronounced in those with baseline GMI >8.0%. Importantly, there was also reduction of time <70 mg/dL in the tightly controlled subgroup with GMI <6.9%, and reduction in manual correction boluses per

	GMI_{9-10} <= 6.9% (N=1004)	6.9% < GMI_{9-10} <=7.4% (N=1183)	7.4% < GMI_{9-10} <= 8% (N=799)	GMI_{9-10} > 8% (N=323)
GMI (%) †				
PLGS	6.6 ± 0.2	7.1 ± 0.1	7.7 ± 0.2	8.5 ± 0.4
AID (1m)	6.6 ± 0.2	6.9 ± 0.2	7.1 ± 0.3	7.5 ± 0.4
AID (3m)	6.6 ± 0.3	6.9 ± 0.3	7.2 ± 0.3	7.6 ± 0.5
Mean BG (mg/dL)*				
PLGS	137 ± 10	160 ± 6	182 ± 7	216 ± 18
AID (1m)	136 ± 10	149 ± 9	160 ± 11	177 ± 18
AID (3m)	136 ± 11	150 ± 11	161 ± 13	179 ± 19
TIR (%) †				
PLGS	82 ± 6	67 ± 5	53 ± 5	35 ± 8
AID (1m)	86 ± 6	77 ± 7	69 ± 8	59 ± 11
AID (3m)	85 ± 7	76 ± 8	68 ± 9	58 ± 12
TAR (%)*				
PLGS	16 ± 6	32 ± 5	46 ± 5	65 ± 8
AID (1m)	13 ± 6	22 ± 7	29 ± 8	40 ± 11
AID (3m)	13 ± 7	23 ± 8	31 ± 9	42 ± 12
TAR2 (%)*				
PLGS	2 ± 2	6 ± 3	14 ± 4	30 ± 9
AID (1m)	2 ± 2	4 ± 3	7 ± 4	13 ± 8
AID (3m)	2 ± 2	4 ± 3	7 ± 5	14 ± 8
TBR (%)‡,*				
PLGS	2.4 ± 2.7	1.3 ± 1.3	0.8 ± 0.9	0.5 ± 0.8
AID (1m)	1.7 ± 1.8	1.2 ± 1.2	1.0 ± 1.0	0.7 ± 0.9
AID (3m)	1.8 ± 1.9	1.2 ± 1.2	1.0 ± 1.0	0.8 ± 0.9
TBR2 (%)				
PLGS	0.4 ± 0.9	0.2 ± 0.4	0.2 ± 0.3	0.1 ± 0.2
AID (1m)	0.3 ± 0.6	0.2 ± 0.4	0.2 ± 0.3	0.1 ± 0.3
AID (3m)	0.3 ± 0.6	0.2 ± 0.3	0.2 ± 0.3	0.2 ± 0.3
TDI (units)*				
PLGS	39 ± 22	43 ± 24	46 ± 23	50 ± 29
AID (1m)	40 ± 21	45 ± 24	49 ± 25	55 ± 33
AID (3m)	40 ± 22	45 ± 24	49 ± 25	54 ± 33
TDB (units)*				
PLGS	19 ± 12	21 ± 13	23 ± 13	25 ± 15
AID (1m)	18 ± 11	22 ± 12	25 ± 14	30 ± 18
AID (3m)	18 ± 11	22 ± 13	25 ± 15	29 ± 14
Manual correction boluses (#/day) †				
PLGS	2.7 ± 2.4	2.5 ± 2.1	2.4 ± 2.0	2.6 ± 2.2
AID (1m)	2.2 ± 2.2	1.8 ± 1.8	1.6 ± 1.6	1.7 ± 1.8
AID (3m)	2.2 ± 2.2	1.8 ± 1.8	1.6 ± 1.8	1.7 ± 1.8

Table 1: BG: blood glucose; GMI: glucose management indicator; TAR: percent time above 180 mg/dL; TAR2: percent time above 250 mg/dL; TBR: percent time below 70 mg/dL; TBR2: percent time below 54 mg/dL; TIR: percent time in 70-180 mg/dL; TDB: total daily basal insulin; TDI: total daily insulin.
* P < 0.001 or **P<0.05 for within-subjects contrasts of general linear model comparing PLGS, AID (1m), AID (2m), and AID (3m).

day across all subgroups. Further stratification into age quartiles, 65-67, 68-70, 71-74 and >75 years old, demonstrated uniform improvement across all. There were no significant gender differences.

Conclusions: In selected patients with type 1 DM and age >65 years old, this AID system improved time in range, reduced frequency of hypoglycemia in those at risk, and reduced the need for user-directed correction boluses, all of which could improve safety the risk of hypoglycemia-related complications.

EP127 / #844

Topic: ***AS05 Artificial Pancreas***

USE OF AID SYSTEMS VERSUS STANDARD SENSOR-AUGMENTED THERAPY DURING A 14-DAY DIABETES SUMMER CAMP: AN OBSERVATIONAL STUDY

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Background and Aims: Keeping glucose levels in target during a summer camp for children with type 1 diabetes (T1D) including prolonged periods of physical exercise is challenging. Hence, in camp settings, insulin dose adjustments are carried out very frequently by health care professionals (HCPs). In this respect, the use of automated insulin delivery systems (AID) could bring great relief to both camp participants and HCPs.

Methods: 27 out of 35 camp participants (mean age 11.0 ± 1.3 years, 74% female, mean HbA1c 7.0 ± 0.5%), for whom CGM data was available at least 70% of the time during a 14-day diabetes summer camp were included in this analysis. In a retrospective, observational study, we compared CGM profiles from children using AID (n = 12, Medtronic 670G/770G/780G) with data from children on sensor-augmented therapy (ST; n = 15, 13 pump users and 2 on multiple daily injections). Due to the small sample size, outcomes were summarized descriptively only.

Results: The proportion of time when the sensor glucose level was in the target range (3.9-10.0 mmol/L) was 74.2 ± 9.1% (mean±SD) on AID and 70.2 ± 10.3% on ST. Time in hypoglycemia (<3.9 mmol/L) was 5.5% (3.9;7.8) (median;IQR) for AID and 5.1% (4.1;7.8) for ST, time in hyperglycemia (>10.0mmol/L) was 20.3 ± 9.6 vs. 24.0 ± 10.2 (AID vs. ST). Mean glucose was 7.8 ± 0.8mmol/L for AID and 7.9 ± 1.0mmol/L for ST. Glucose CV was 0.3 (0.3;0.4) vs. 0.4 (0.3;0.4).

Conclusions: At a diabetes camp, the use of AID systems is a safe alternative to standard therapy and frequent adjustments of settings by HCPs with similar overall performance.

EP128 / #687

Topic: ***AS06 Glucose sensors***

HIGHER UTILIZATION OF DEXCOM G6 SYSTEM FEATURES IS ASSOCIATED WITH HIGHER TIME IN RANGE IN EIGHT EUROPEAN COUNTRIES

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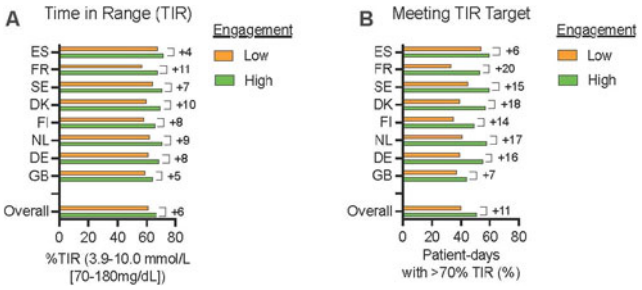
Background and Aims: Percentage of time with glucose values of 3.9-10.0 mmol/L, also known as time in range (TIR), is emerging as a key metric for assessing glycemic outcomes. The Dexcom G6 real-time continuous glucose monitor (RT-CGM) measures glucose values and provides multiple features for visualizing, sharing, and interacting with the data. In this analysis, we assessed whether RT-CGM feature utilization was associated with TIR outcomes in eight European countries.

Methods: We analyzed real-world data in the United Kingdom (GB), Germany (DE), Netherlands (NL), Finland (FI), Denmark (DK), Sweden (SE), France (FR), Spain (ES), and in all countries combined, from G6 launch in each country through July 19, 2022. Data were from customers who uploaded at least one glucose value during the observation window and who agreed to Dexcom's GDPR-compliant analytics policy. For each patient-day, engagement was quantified based on the number of features used on that day, ranging from 0-5. The five features included high alert enablement, low alert enablement, urgent low soon (ULS) alert enablement, remote data sharing (Share/-Follow) use, and interaction with retrospective data analysis



platform (Clarity). Patient-days where 0-2 features were utilized were labelled as ''low engagement''; patient-days where 4-5 features were utilized were labelled as ''high engagement.''

Results: In all countries, patient-days with high feature engagement were characterized by higher TIR (**Figure 1A**) and a higher proportion of days with >70% TIR (**Figure 1B**).

Conclusions: Higher levels of RT-CGM feature set engagement may facilitate appropriate diabetes treatment decisions that contribute to improved glycemic outcomes.

EP129 / #35

Topic: ***AS06 Glucose sensors***

FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM FACILITATES SUSTAINABLE IMPROVEMENTS IN GLYCEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES: A 12-MONTH FOLLOW-UP STUDY IN REAL LIFE

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Background and Aims: To investigate the glycemic control as assessed by Ambulatory Glucose Profile (AGP) metrics while patients with type 1 diabetes (T1D) worn Flash Glucose Monitoring (FGM) system for one-year.

Methods: This prospective study was performed among 187 patients with T1D (13-40 yrs) who switched from conventional finger pricking to FGM system. Mean glucose level, low glucose events hemoglobin A1c (HbA1c), sensor scans frequency were collected at baseline, 3, 6, 9 and 12 months. CGM metrics i.e., glucose variability (GV) (%), glucose management indicator (GMI), mean time in range (TIR), time above range (TAR) time below range (TBR), average duration of hypoglycemic events, and time sensor in active were collected at 3 months, 6 months and 12 months.

Results: Compared to 3 months values, no significant changes ($p > 0.05$) were noticeable in terms of the GV, GMI, % in target (70-180 mg/dL), TAR (181-250 mg/dL) and %>250 mg/dL at 6 and 12 months. However, a significant differences were observed on mean glucose level at 3 ($p = 0.027$), 9 ($p = 0.041$) and 12 months ($p = 0.32$) compared to baseline. Similarly, HbA1c showed a significant decline at 3 ($p = 0.044$), 6 ($p = 0.039$), 9 ($p = 0.031$) and 12 months ($p = 0.047$) compared to the baseline values.

Conclusions: Switching from conventional finger pricking to FGM system improved markers of glycemic control to a substantial degree, and the effect was sustained for up to 1 year.

EP130 / #410

Topic: ***AS06 Glucose sensors***

THE RELATIONSHIP OF HEMOGLOBIN A1C TO TIME IN RANGE AND GYLCEMIC MANAGEMENT INDICATOR IN PATIENTS WITH DIABETES IN A TERTIARY CARE HOSPITAL IN SAUDI ARABIA

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Background and Aims: The correlation between TIR and HbA1c has not been studied in Saudi patients with diabetes. The aim of this study was to assess the correlation between HbA1c and TIR in patients with Diabetes who are using flash glucose monitoring (FGM) device (FreeStyle Libre Device) in the Saudi population.

Methods: This is a retrospective study that looked at the data of patients with diabetes using freestyle libre in the period between January 2020 to June 2022. The study was approved by IRB at KFMC. SPSS was used for statistical analysis.

Results: Data were available for 327 patients, mean age was 33 ± 17.1 years old, 55.7% were females, 77% had type 1 diabetes (T1DM), 22% had type 2 diabetes (T2DM), 1% had Latent Autoimmune Diabetes in Adults (LADA) and mean HbA1c was $7.8\% \pm 1.3$ while average blood glucose was 9.9 mmol/L (178.2 mg/dL). Active sensor usage time was $86.5\% \pm 10.3$, glucose variability was $39.7\% \pm 18.1$, and study subjects had TIR of $52.7\% \pm 17.7$, TAR $38.86\% \pm 7.9$, and TBR $5.0\% \pm 5.3$. Patients with T2DM had a significantly higher TIR ($62.69\% \pm 20.6$) than patients with T1DM ($49.94\% \pm 15.8$) ($p < 0.0001$). Similarly, males had significantly higher TIR ($54.86\% \pm 18.1$) than females ($51.03\% \pm 17.3$) ($p = 0.044$). There was a significant correlation between lab HbA1c and both TIR and glucose management Indicator (GMI) with R^2 values of 0.78 and 0.83 respectively, p value <0.001 for both.

Conclusions: The obtained regression model suggests that TIR and GMI are reliable predictors of laboratory Hb1Ac in our patient population. Thus, they could be used to follow patients and modify treatment.

EP131 / #896

Topic: ***AS06 Glucose sensors***

COST-EFFECTIVENESS OF REAL-TIME CONTINUOUS GLUCOSE MONITORING SYSTEM (RTCGM) VERSUS SELF-MONITORING OF BLOOD GLUCOSE (SMBG) IN PEOPLE WITH TYPE 2 DIABETES ON INSULIN THERAPY IN FRANCE

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Background and Aims: In France, two-thirds of insulin-treated patients with type 2 diabetes (PwT2D) do not achieve

their glycemic targets. RtCGM has been shown to improve glycemic control in insulin-treated PwT2D. The aim of this study is to examine the cost-effectiveness of rtCGM for insulin-treated PwT2D in France.

Methods: The IQVIA CORE Diabetes Model was used to project the long-term direct costs and clinical outcomes. Clinical effectiveness data was sourced from a large retrospective cohort study. Patients were assumed to be 64 years old with an average baseline HbA1c of 8.3%. Patients using rtCGM were assumed to have a 0.56% absolute reduction in HbA1c based on the adjusted mean difference vs SMBG after 12 months of follow-up (Karter et al. 2021). An additional utility of 0.03 was applied to the rtCGM group for the avoidance of fingersticks. The analysis was performed over a 30-year time horizon from a French healthcare system perspective with 4% discount rate for future costs and outcomes.

Results: Simulations showed rtCGM was associated with an incremental quality-adjusted life year (QALY) of 0.473, incremental mean total lifetime costs of €10,505, and an incremental cost-effectiveness ratio of €20,214 per QALY compared with SMBG, which is below a common willingness to pay threshold (WTP) of €50,000 for France. RtCGM was estimated to be cost-saving when rtCGM costs were reduced by 45% (ICER: -€556/QALY).

Conclusions: The findings suggest rtCGM is cost-effective in insulin-treated PwT2D in France compared to SMBG. This analysis can inform policy decisions for rtCGM access for PwT2D.

EP132 / #901

Topic: ***AS06 Glucose sensors***

QUALITY OF LIFE IN PATIENTS WITH DIABETES USERS OF INTERMITTENT GLUCOSE MONITORING

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Background and Aims: Interstitial glucose monitoring has shown an improvement in the metabolic control of patients with diabetes mellitus, but its impact on the quality of life of patients has been less studied. **Objective**: to evaluate the impact of glucose monitoring using the DTSQ-c questionnaire.

Methods: DTSQ-c questionnaire was sent to patients with type 1 diabetes and ''no 1 no 2'' in treatment with MDI or BICI, users of the FreeStyle Libre intermittent monitoring system financed by the hospital. 247 responses were received, of which 35 could not be assessed for various reasons, mainly incorrect identification. The total score of the test as well as the individual answers to each question were evaluated, together with clinical, analytical and glucometric data at the beginning of the use of the sensor and at the time of the answer.

Results: Of the 212 evaluable questionnaires, 116 corresponded to men and 96 to women, with a mean age of 48 years and a time of evolution until the start of the use of monitoring of 21.8 years. Most of the answers showed a global score >15 (69.8%), while the answers to questions 2 and 3 (hyper- and hypoglycemia) were more variable. An improvement in control measured by HbA1c is observed, but a slight deterioration measured by GMI, probably due to the fact that the gap between both methods is much greater at the initial moment.

Conclusions: DTSQ-c questionnaire does not seem to be an adequate method to measure QOL improvement since it presents a marked ''ceiling effect''

EP133 / #882

Topic: ***AS06 Glucose sensors***

REAL-LIFE IMPACT ON GLUCOSE METRICS OF USING OR NOT USING THE FREESTYLE LIBRE 2 ALARM SYSTEM

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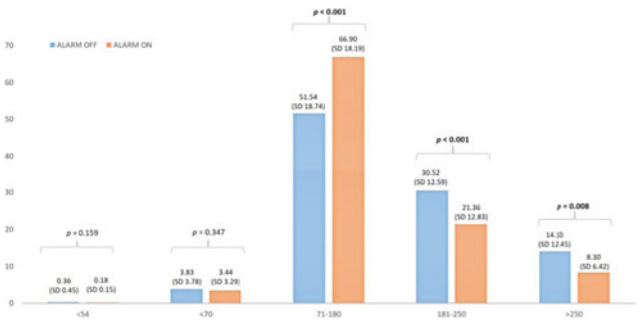
Background and Aims: The objective of this study was to determine the impact on blood glucose metrics of alarm users versus non-alarm users for Freestyle Libre 2 system.

Methods: Single center, independent, observational, retrospective study; patients were consecutively enrolled at the first reimbursement of FSL2 .At that time, all patients who agreed to participate in the study were given a self-completed questionnaire with different tests related to knowledge of diabetes (DKQ2), perception of hypoglycemia (Clarkés test) or digital skills (Cambadoś test). Likewise, the downloading of data from the previous 14-day period was carried out telematically 90 days after inclusion in the study.

Results: 92 patients were divided into two groups: the first group of 37 subjects who did not use any auxiliary alarm during the previous 14 days due to complete deactivation of the alarms, and the second group of 55 subjects who used both the hypoglycemia and hyperglycemia alarms, within the acceptable limits and 24 hours a day. 2 of 37 (5.40%) patients in the group without alarms reached all therapeutic objectives according to the recommendations of the international consensus by 13 of 55 (23.64%) in the group with alarms (p = 0.020).

Conclusions: Our findings show a clear impact of the use of alarms on time-in-range targets at the expense of a reduction in time in hyperglycemia, with no apparent effect on time in hypoglycemia, nor on the number of hypoglycemia events.



EP134 / #98

Topic: ***AS06 Glucose sensors***

IMPROVEMENT IN HYPOGLYCEMIA AWARENESS AFTER INITIATION A FLASH GLUCOSE MONITORING

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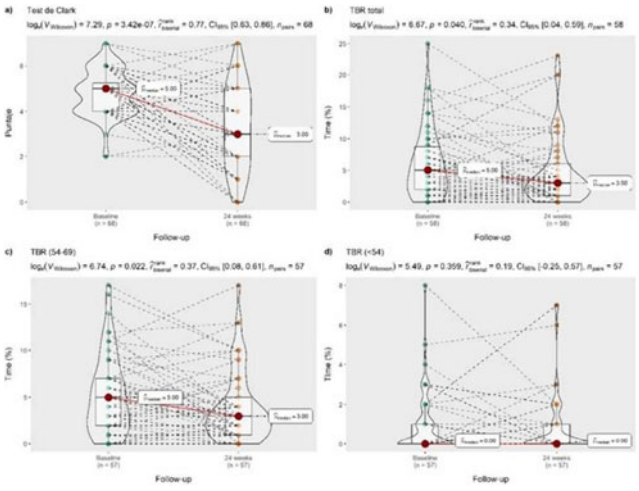
Hospital Universitario Virgen del Rocío, Endocrinology, Sevilla, Spain

Background and Aims: Impaired awareness of hypoglycemia (IAH)is associated with high morbidity and mortality in people with type 1 diabetes (T1D). We aimed to assess the impact of initiating flash glucose monitoring (FGM) on the awareness of hypoglycemia in people with T1D and IAH.

Methods: A 24-week before-after study was performed in a tertiary hospital. The primary endpoint was the difference in the Clarke score between baseline and 24 weeks after initiation of FGM (FreeStyle Libre 2®, Abbott). A score of ^{3}4 indicated IAH. Logistic regression analyses were performed to explore factors associated with IAH.

Results: Participants (29 men, 39 women) had a median (IQR) age of 49 (41-56) years, duration of diabetes of 23 (14-31) years, HbA_{1c} of 7.4 %(6.6–8). The Clarke score decreased from 5 (4-5) at baseline to 3 (2-5) at 24 weeks after FGM initiation, $p < 0.001$. Time in hypoglycemia (TBR) decreased from 5% (2-10) to 3% (1-7), $p = 0.040$. TBR level 1(54-69 mg/dL) decreased from5 %(2-9) to 3% (1-6), $p = 0.022$) (figure 1). The coefficient of variation decreased from 39% (34-42) to 35% (32-39), $p = 0.003$. A diabetes evolution time of more than 23 years was associated with a higher probability of having IAH after FGM initiation (OR 2.83 (95% CI1.01-7.90).

Conclusions: FGM use was associated with an improvement in hypoglycemia awareness in people with T1D and IAH, based on the results of the Clarke questionnaire. A longer duration of diabetes was associated with an increased likelihood of having hypoglycemia unawareness after FGM initiation.



EP135 / #635

Topic: ***AS06 Glucose sensors***

BLOOD CONDUCTIVITY AS A FUNCTION OF GLUCOSE CONCENTRATION: TOWARDS A NEW GLUCOSE SENSOR

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Background and Aims: A non-invasive glucose measurement device that matches or exceeds the gold standard colorimetric tests is compared to a bioimpedance glucometer. It uses the predicting Bruna' model, which expresses the bioimpedance as a function of glucose. The objective is to investigate the relationship between the electrical conductivity and the volumetric fraction of glucose.

Methods: The specimen was fresh bovine blood and measurements were recorded from 50 to 100 kHz.

Results: showed a very significant relationship with a maximum error of 1.3% between theoretical and experimental data.

Conclusions: The experimental methodologies used to obtain data proved to be consistent with the other results published in the literature. However, the lack of establishment of a universal method for comparing results using the electrical impedance spectroscopy (EIS) technique is significant and needed, as it can only give a good data repeatability but not reproducibility. However, the characterization of blood conductivity shows admissible results into comparison to the one presented in our previous work. This work used fresh bovine blood for avoiding human ethical issues and blood transport to the place where bioimpedance measurements were collected. Future works will investigate the comparison between glucose in the plasma matrix and the one of whole blood. Therefore, small ex-vivo samples of human blood will be analyzed in order to take another step towards the development of a non-invasive device.

EP136 / #282

Topic: ***AS06 Glucose sensors***

REAL-WORLD 24-MONTH IMPACT OF INTERMITTENTLY-SCANNED CONTINUOUS GLUCOSE MONITORING IN ADULTS WITH TYPE 1 DIABETES LIVING WITH NORMAL OR IMPAIRED AWARENESS OF HYPOGLYCEMIA

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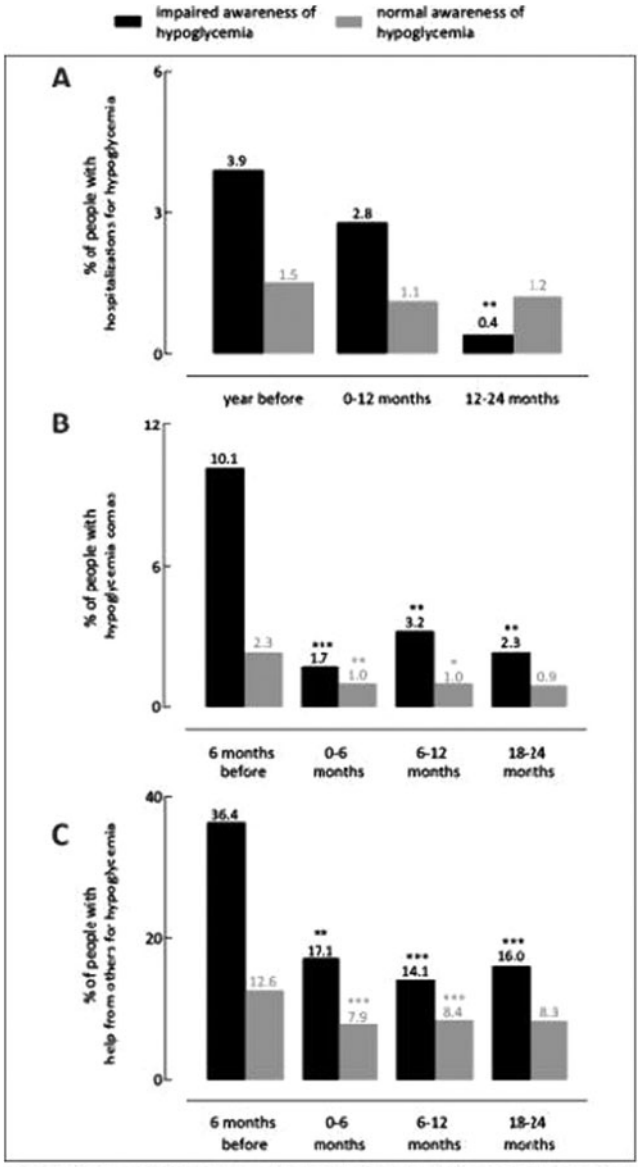
Background and Aims: Nationwide reimbursement of intermittently-scanned continuous glucose monitoring (isCGM) was introduced in Belgium (2016). This real-world observational study investigates the impact of isCGM over 24 months on adults with type 1 diabetes with impaired or normal awareness of hypoglycemia (IAH or NAH).

Methods: We included 1905 people who started first-generation 14-day FreeStyle Libre (without alerts). Sixteen percent had IAH. Primary endpoint was evolution of quality of life (QOL);

secondary endpoints were evolution of severe hypoglycemia, work absenteeism, HbA1c, and sensor-measured outcomes.

Results: At baseline, people with IAH had significantly worse QOL than people with NAH. Only people with IAH improved on the hypoglycemia fear survey-worry subscale after 24 months (22.8 [95% CI 21.4-24.2] baseline; 20.6 [19.0-22.1] 24 months, $p = 0.002$). For both groups, Diabetes Treatment Satisfaction Scale improved over 24 months (IAH: +3.1 [2.1-4.1], $p < 0.001$; NAH: +2.3 [1.9-2.7], $p < 0.001$), while general QOL, diabetes distress, and HbA1c remained stable. People with IAH showed the strongest decline in work absenteeism and severe hypoglycemia (36.4% having an event six months prior to isCGM-initiation; 16.0% having an event in the last six months of follow-up, $p < 0.001$), with similar observations for hypoglycemia hospitalization, and hypoglycemia coma (figure). Over 24 months, people with IAH spent more time in hypoglycemia, but less time in hyperglycemia than people with NAH.

Conclusions: This data show sustained improvement of severe hypoglycemia, work absenteeism and hypoglycemia fear after isCGM-reimbursement, mostly driven by people with IAH. Together with improved treatment satisfaction, irrespective of hypoglycemia awareness level, isCGM without alerts is a valuable tool under long-term real-world conditions.



Hypoglycemia-related acute complications for people with impaired and people with normal awareness of hypoglycemia

Data points represent percentage of people with (A) hypoglycemia-related hospitalizations per year of follow-up, (B) hypoglycemic comas per 6 months of follow-up, and (C) help from third parties due to hypoglycemia per 6 months of follow-up, as a function of hypoglycemia awareness.

***p<0.001, **p<0.01, and *p<0.05 for the within-group comparisons versus the before period.

EP137 / #648

Topic: ***AS06 Glucose sensors***

IMPROVEMENTS IN ACCURACY OF A NOVEL WEARABLE NON-INVASIVE GLUCOSE MONITOR USING AI TECHNIQUES

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Background and Aims: Afon Technology is developing a wearable, non-invasive BGM based using resonance shifts in the microwave spectrum. An ongoing clinical trial currently investigates the accuracy, safety, and specificity of the device in patients with T1D and T2D. We aim here to report on the results from cohort 1.

Methods: Testing involves applying the Afon device to the wrists of T1D and T2D subjects to correlate the resonance shifts with changes in their venous BG. The device automatically collects data every 60 seconds for four hours. Five subjects were tested on four separate days. A global AI model was built and trained on a subset (80%) of the total data and tested on the remaining subset of the cohort data. In this manner, the training model achieved a MARD of 5.3% (Figure 1).

Results: Tests of the model on unseen data resulted in predictive MARDs of 14%, 15% and 22% as shown in Figure 2.

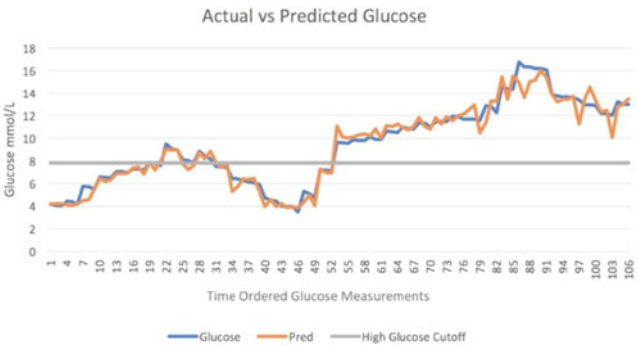
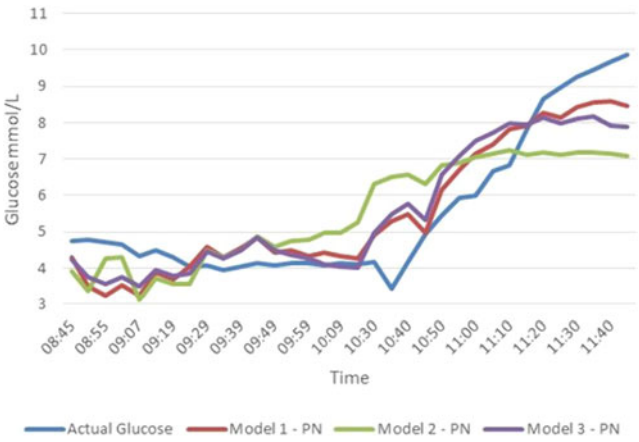


Figure 1. Plot of global model applied to 20% of the data



Blind test	Model 1	Model 2	Model 3
MARD	14%	22%	15%

Figure 2. Global models (x3) tested on blind data

This model resulted in a 95% accuracy in predicting glucose levels above 8 mmol/L.

Conclusions: AI can dynamically adapt the signal analysis over time to match with the changing BG. The results here demonstrate that a global model based on a limited data set can achieve modest MARD values. With additional data, normalisation techniques, and parameter optimisation, it should be possible to further reduce the MARD to commercially available minimally invasive CGMs'.

EP138 / #470

Topic: ***AS06 Glucose sensors***

ACCURACY OF A FOURTH-GENERATION SUBCUTANEOUS CONTINUOUS GLUCOSE MONITOR (CGM) IN INDIVIDUALS WITH DIABETES ON PERITONEAL DIALYSIS

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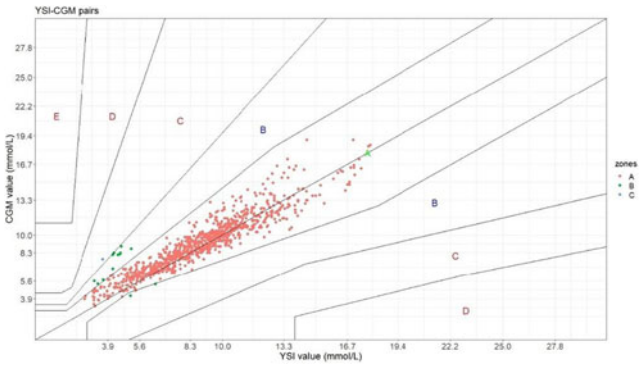
Background and Aims: To evaluate the accuracy of a fourth-generation subcutaneous real-time CGM (Medtronic Guardian™ Sensor 3) in individuals with diabetes on peritoneal dialysis (PD).

Methods: We included 30 participants with type 2 diabetes (mean±SD age 65 ± 6 years, diabetes duration 17 ± 8 years, HbA1c 7.1 ± 0.9%, 66% on insulin) on continuous ambulatory peritoneal dialysis (CAPD). Each participant wore a Guardian Sensor™ 3 on the upper arm paired with Guardian Connect™ mobile app for 14 days and sensor calibrations 12-hourly. Participants attended an 8 hour in-clinic session on day 3 or 5 with comparison of CGM readings against Yellow Springs Instrument (YSI) venous glucose every 15 minutes. We additionally assessed laboratory and PD parameters including pH, uremia and hydration status by bioimpedance.



Results: Based on 941 paired CGM-YSI values, the overall mean absolute relative difference (MARD) was 10.4% (95% Confidence interval: 9.6, 11.7%). 81.3% of readings were within 15/15% and 88.6% within 20/20% of YSI values across the full glycemic range. Consensus error grid analysis showed 98.5% and 1.4% of sensor values in clinically-acceptable error zones A and B respectively. We observed no correlations between pH, uremia, hydration status and MARD. No device-related severe adverse events occurred with overall good user satisfaction.

Conclusions: We showed good performance of a real-time CGM sensor in individuals with diabetes on PD, similar to non-PD populations. Future studies are needed to evaluate whether use of CGM in PD can improve clinical outcomes.

EP139 / #744

Topic: ***AS06 Glucose sensors***

EFFECTIVENESS OF FLASH MONITORING TECHNOLOGY IN THE GLYCEMIC CONTROL OF PATIENTS WITH TYPE 1 DIABETES MELLITUS

E. Cytrynbaum Young[1], M. De Almeida Pinto Borges[1], S. Figueiredo[2], M.L. Pires[2], N. Figueiredo[2], R. Lyra Da Silva[2]

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Background and Aims: Type 1 Diabetes Mellitus (DM1) is associated with chronic complications when not properly controlled. A barrier to achieving satisfactory blood glucose levels is a need for frequent self-monitoring of blood glucose (SMBG). This study aims to evaluete the effectiveness of Flash Glucose Monitoring (FGM) in patients with type 1 diabetes compared to SMBG

Methods: Twenty four patients with DM1 for at least one year and aged over 18 years, treated at Gaffrée e Guinle University Hospital, were recruited. They were instructed to use the Accu Check glucometer for two weeks and to perform SMBG four times a day. Subsequently, they made use of two FGM sensors lasting two weeks each. To check the effectiveness of the FGM, the average proportion of glycemia in the target (range 70 to 180 mg/dl), hyperglycemia at level 2 (> 250mg/dL) and hypoglycemia at level 2 (< 54mg/dL) were evaluated separately, and later the proportion of glycemia was compared in these ranges between the two devices

Results: The use of FMG, when compared to the Accu-Chek system, made it possible to increase the proportion of blood glucose levels in Time in Range (70 to 180 mg/dl) by 51% (Libre 65% & Accu-Chek 43%), as well as reduction in level 2 hyperglycemia of 90.48% (Libre 2% versus Accu-Check 21%). However, the Libre system was not able to reduce the occurrence of level 2 hypoglycemia.

Conclusions: Flash monitoring technology appears to be an effective tool for glycemic control in T1DM patients.

EP140 / #502

Topic: *AS06 Glucose sensors*

FIRST-IN-MAN EARLY FEASIBILITY STUDY WITH AN IMPLANTABLE SENSOR FOR CONTINUOUS MONITORING OF GLUCOSE, KETONES, LACTATE AND ETHANOL VIA NEAR-INFRARED SPECTROSCOPY: THE GLOW STUDY

F. De Ridder[1,2], R. Braspenning[3], J. Ordonez[4], G. Klarenbeek[4], P. Lauwers[3], K. Ledeganck[5], D. Delbeke[4], C. De Block[3,5]

[1]Antwerp University Hospital, Endocrinology, Diabetes And Metabolism, Edegem, Belgium, [2]University of Antwerp, Laboratory Of Experimental Medicine And Pediatrics, Wilrijk, Belgium, [3]University Hospital Antwerp, Endocrinology-diabetology-metabolism, Edegem, Belgium, [4]Indigo Diabetes N.V., Medical Devices, Ghent, Belgium, [5]University of Antwerp, Laboratory Of Experimental Medicine And Pediatrics And Member Of The Infla-med Centre Of Excellence, Antwerp, Belgium

Background and Aims: Continuous glucose monitoring has improved diabetes care. Monitoring of additionali biomarkers (ketones for early detection of ketoacidosis, lactate during physical activity) may offer further advantages. This study evaluated the safety and performance of a new implantable near-infrared (NIR) spectroscopy sensor for multi-metabolite monitoring of glucose, ketones, lactate, and ethanol.

Methods: We performed an early feasibility study (NCT04782934), including 4 participants with type 1 diabetes (T1D) and 3 healthy volunteers. The YANG NIR spectroscopy sensor (Indigo) was implanted for 28 days. Different protocols were performed to induce a broad range of glucose levels (glucose drink, from 40-400 mg/dL, 2.2-22.2 mmol/L), ketones (ketone drink, up to 3.5 mM), lactate (exercise, up to 13 mM) and ethanol (40-80g ethanol intake). NIR spectra for glucose, ketones, lactate, and ethanol levels analyzed with partial least squares regression, were compared with blood values for glucose (Biosen EKF), ketones and lactate (GlucoMen LX Plus), and breath ethanol levels (ACE II Breathalyzer).

Results: The implanted YANG sensor was safe, well tolerated, and did not cause any infectious or wound healing complications. Six out seven sensors remained fully operational over the entire study period. Glucose measurements were sufficiently accurate (overall mean absolute (relative) difference MARD of 7.4%, MAD 8.8 mg/dL) without a significant impact of 8 potential confounders. MAD values were 0.12 mM for ketones, 0.16 mM for lactate, and 0.002% BAC (Blood Alcohol Concentration) for ethanol.

Conclusions: The first implantable multi-biomarker sensor proved to be well tolerated and produced accurate measurements of glucose, ketones, lactate, and ethanol.

EP141 / #903

Topic: *AS06 Glucose sensors*

GLUCOSE VARIABILITY AND MOMENTARY MOOD IN PEOPLE WITH TYPE 1 DIABETES: AN EXPLORATIVE STUDY

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Background and Aims: Mood fluctuations resulting from glucose excursions are commonly reported sources of diabetes distress. Research to date found small if any association between covariance (CV) measures of glucose variability and mood states but lack precision measurements. We aimed to assess the relationship between real-time glucose variability and momentary mood in adults with type 1 diabetes (T1D).

Methods: Participants with T1D wore a blinded diagnostic CGM and answered questions 6 times a day about their current mood, measured with the Profile Of Mood States (POMS)-SF (Anxiety, Depressive symptoms, Anger, Fatigue, Vigor) for 2 weeks. Mixed model analyses examined daily associations over time between %CV of glucose and mean and variability (CV) of POMS mood-scores. Between-person differences were examined by moderation analyses for sex, age and baseline well-being. Further, the role of within-person differences of sleep and nocturnal hypoglycemia were explored.

Results: N = 18 (10 female) with T1D, mean age 44.3 ± 13.2, mean TIR 57.8 ± 14.5% and mean HbA1c 60.0 ± 10.5 mmol/mol participated. Overall, no significant associations were found between %CV of glucose and mean and CV of POMS scores. Within-person analyses showed nocturnal hypoglycemia moderated these associations: after a night with any norcturnal hypoglycemic episode, higher %CV of glucose was associated with more Fatigue (Estimate = 1.998, $p < .006$) and less Vigor (Estimate = -3.308, $p < .001$) as well as variability of Anger (Estimate = 0.731, $p = .02$) and Vigor (Estimate = -.525, $p = .006$).

Conclusions: We found little evidence for a relationship between glycemic variability and changes in mood. However, on an individual level nocturnal hypoglycemia impacts the relationship between glycemic variability and daily mood, especially fatigue and vigor.

EP142 / #548

Topic: *AS06 Glucose sensors*

HEAD-TO-HEAD COMPARISON OF TWO ALGORITHMS ADJUSTING MEAL-TIME INSULIN DOSES BASED ON CGM TREND ARROWS IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: In clinical practice, CGM users are advised to consider the direction and the rate of change of glucose, as indicated by trend arrows, before administering a meal bolus. To date, there is no consensus on how to adjust meal-time insulin doses, and different strategies have been proposed. We aimed to evaluate the effectiveness and safety of two different algorithms for adjusting meal-time boluses based on the trend arrows in patients with type 1 diabetes.

Methods: This was a single-arm, cross-over study conducted at University ''Magna Graecia'' of Catanzaro, Italy. Major inclusion criteria were: age ≥18 years, diagnosis of type 1 diabetes since at least one year, intensive insulin therapy (MDI or CSII), use of Dexcom G6 CGM for at least 3 months. Patients treated with LGS, PLGS, or HCL systems were excluded. Participants were randomized to the DirectNet/JDRF algorithm or the Ziegler et al. algorithm for two weeks. After a 7-day washout period, they crossed over to the alternative algorithm for another additional 2 weeks.

Results: Twenty patients with 36 ± 10 years of age and HbA1c 7.3 ± 0.4% completed the study. The Ziegler et al. algorithm was associated with a significantly higher TIR compared to the DirectNet/JDRF algorithm (69.0 ± 10.4% vs 65.8 ± 12.7%, p = 0.02), lower mean glucose (148 ± 10 vs 156 ± 16 mg/dl, p = 0.05) and lower glycemic variability. No severe hypoglycemic or hyperglycemic episodes occurred during the study.

Conclusions: Despite being more complex than the DirectNet/JDRF, the Ziegler et al. algorithm was safe and provided better glucose control and variability over two weeks.

EP143 / #439

Topic: ***AS06 Glucose sensors***

EFFECT OF TRANSITION TO DAYLIGHT SAVING TIME ON FLASH GLUCOSE MONITORING METRICS IN PATIENTS WITH AUTOIMMUNE DIABETES

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Background and Aims: Circadian rhythm variations, including transition from solar time to daylight saving time (DST), are associated with measurable effects on health. It is not known whether the transition to DST could impact on glucose control in patients with autoimmune diabetes on intensive insulin treatment.

Methods: This was a single-center 4-week observational study. All FGM users sharing spontaneously their glucose readings on the LibreView platform were evaluated for eligibility. Pittsburgh Sleep Quality Index (PSQI) and Epworth sleepiness scale (ESS) questionnaires were administered to all patients on the day before and one week after the transition to DST to evaluate their sleep quality. In addition, FGM metrics from two weeks before and two weeks after DST transition were acquired.

Results: Thirty-six patients with autoimmune diabetes (age 43.3 ± 14.7 years, diabetes duration 10.7 ± 8.7 years, and HbA_{1c} 7.5 ± 1.2%) were included. Sixteen patients reported worsening of PSQI, along with significant increase of GMI, mean glucose and TAR level 1, and reduction of TIR and CV. Conversely, FGM metrics were unchanged in the 20 patients who reported no variation or amelioration of PSQI. In the whole cohort, significant correlations emerged between worsening of PSQI and increase in GMI (r = 0.349) and mean glucose (r = 0.372), and reduction of TIR (r = 0.336). Consistently, in a logistic regression model, PSQI variation predicted worsening of GMI (OR 1.83), mean glucose (OR 1.88), TIR (OR 1.44) and CV (OR 0.66).

Conclusions: Even small circadian rhythm variations, such as transition to DST, may be associated with glucose control derangement and could require a more intensive diabetes management.

EP144 / #501

Topic: ***AS06 Glucose sensors***

IMPACT OF THE GLYCEMIA RISK INDEX IN ADULT AND PEDIATRIC POPULATION WITH TYPE 1 DIABETES IN CLINICAL PRACTICE

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Background and Aims: To evaluate the usefulness of the Glycemia Risk Index (GRI) in pediatric and adult population with type 1 diabetes (DM1) in clinical practice.

Methods: Cross-sectional study of 202 DM1 patients under intensive treatment with insulin and flash glucose monitoring (FGM) (25.2% continuous subcutaneous insulin infusion (CSII))). Clinical, metabolic and glycometric parameters were obtained in last follow-up visit. hypoglycemia(Chypo) and hyperglycemia(Chyper) components of the GRI were calculated.

Results: A total of 202 patients(53% males,67.8% adults) with mean age of 28.6 ± 15.7 and 12.5 ± 10.9 years since DM1 diagnosis were evaluated. Adult patients(>18 years) showed a significantly higher HbA1c(7.4 ± 1.1 vs 6.7 ± 0.6%;p<0.01), and lower TIR(55.4 ± 17.4 vs 66.4 ± 13.1%;p<0.01) and coefficient of variation(38.5 ± 7.2 vs 42.4 ± 8.8%,p <0.05) than the pediatric population. The GRI was significantly lower in pediatric patients(48.0 ± 22.2 vs 56.7 ± 23.4; p<0.05) with higher Chypo (7.0 ± 5.0 vs 4.9 ± 4.5;p<0.01) and lower Chyper(16.7 ± 9.7 vs 26.5 ± 15.0;p<0.01) than in adults. CSII compared to multiple doses of insulin(MDI) treatment showed a non-significant trend towards a lower GRI(50.9 ± 15.3 vs 54.9 ± 25.4;p = 0.16) with higher levels of Chypo(6.5 ± 4.0 vs 5.3 ± 5.0;p<0.01), and lower of Chyper(19.6 ± 10.6 vs 24.6 ± 15.1;p = 0.05). Finally, GRI showed a strong negative correlation with TIR(r = -0.917, p <0.001) and a positive correlation with HbA1c(r = 0.617,p <0.001).

Conclusions: Despite a better control by classical and GRI parameters, pediatric patients and those under CSII treatment showed a higher overall Chypo than in adults and MDI, respectively. A strong correlation was observed between GRI and classical glycometric parameters. Our study supports the GRI as a new glycometric parameter to assess the risk of hypoglycemia-hyperglycemia in both pediatric and adult patients with DM1 in clinical practice.

EP145 / #622

Topic: ***AS06 Glucose sensors***

EVALUATING THE IMPACT OF DAILY STEP COUNT ON GLUCOSE INDICES ACROSS 10 WEEKS OF MONITORING: THE HYPO-METRICS STUDY

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Background and Aims: Physical activity is important for cardiovascular health in both type 1 (T1D) and type 2 (T2D) diabetes. However, impact of exercise on overall glucose control is unclear and fear of hypoglycaemia can be a barrier to increased activity. We investigated the association between daily step count and glucose metrics for up to 10 weeks.

Methods: We included 190 participants with T1D and 181 with T2D from the HypoMETRICS study who wore blinded FreeStyle Libre 2 and Fitbit Charge 4 devices. We used generalised estimating equations to evaluate relationships between daily step count and CGM derived glucometrics including daily mean glucose, time in ranges, and sensor detected hypoglycaemic (SDH) events, adjusting for baseline HbA1c, wear time and mean step count.

Results: Participants provided a mean of 55 (SD = 15.0) valid days of data, had a mean daily step count of 7061 (SD = 3,542) and a mean daily glucose of 9.0mmol/l (SD = 1.8). Every 1000 increase in steps per day was associated with a change in mean glucose of -0.03mmol/l in T1D and -0.02mmol/l in T2D (both $p < 0.001$), a change in time >10mmol/l of -0.33% in T1D and -0.28% in T2D (both $p < 0.001$), a change in time in range (3.9-10 mmol/l) of 0.31% in T1D and 0.30% in T2D (both $p < 0.001$), and a 0.01 change in the number of SDH events per day (<3.9mmol/l) for T1D participants only ($p = 0.02$).

Conclusions: Greater daily step count had a weak association with improved glucose metrics within individuals over 10 weeks of monitoring.

EP146 / #471

Topic: ***AS06 Glucose sensors***

THE EFFECTS OF HIGH INTENSITY INTERVAL EXERCISE ON HYPOGLYCAEMIA INCIDENCE IN PEOPLE WITH TYPE 1 DIABETES AND IMPAIRED AWARENESS OF HYPOGLYCAEMIA

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Background and Aims: Real-time continuous glucose monitoring (RT-CGM) with low glucose alarms reduces the risk of severe hypoglycaemia. People with type 1 diabetes (T1D) and impaired awareness of hypoglycaemia (IAH) are at high risk of hypoglycaemia during exercise. We compared RT-CGM data from people with T1D and IAH undergoing 4 weeks High Intensity Interval Exercise (HIIE) or control (no exercise) as part of a clinical trial.

Methods: Participants were randomised to 4 weeks of unsupervised at home HIIE (4 x 30 s cycle sprints [2 min recovery]) or rest (control). Each participant wore a RT-CGM (Dexcom G6) and heart rate monitor to ensure participants achieved ≥90% peak heart rate during home HIIE. Standardised advice (based upon JDRF consensus guidelines) was given to those in the HIIE group regarding insulin dose adjustment and carbohydrate management.

Results: All participants (9 male and 9 female, age 19-54 years, median (IQR) duration of type 1 diabetes 27 years (13.25), HbA1c 55.5 (11.5) mmol/mol) completed the study. Frequency of level 1 (3.0-3.9 mmol/l); 38.2 [8.22] vs 27.2 [5.29], p = 0.28 and level 2 hypoglycaemia (<3.0 mmol/l); 5.6 [1.74] vs 3.4 [0.96], p = 0.30 (control vs HIIE respectively) and mean duration of level 1 hypoglycaemia was similar between groups; 30.0 vs 30.1 min. Duration of level 2 hypoglycaemia was longer controls; 26.5 vs 20.8 mins.

Conclusions: HIIE does not increase hypoglycaemia incidence or duration in T1D and IAH. This is clinically relevant as fear of hypoglycaemia remains a significant barrier to exercise.

EP147 / #693

Topic: ***AS06 Glucose sensors***

BEYOND GLUCOSE: ADAPTATION OF FREESTYLE LIBRE TO MEASURE VARIOUS NEW ANALYTES

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Background and Aims: FreeStyle Libre's sensing platform is based on a redox polymer ''wired'' enzyme technology that is sensitive, specific, and compatible with a wide variety of

analytes, many of which are important in Diabetes management. We discuss here the adaptation of Libre to non-glucose analytes, including ethanol, lactate, b-hydroxybutyrate, and creatinine, in order of decreasing *in-vivo* concentration. The ca. 2 order of magnitude concentration decrease from glucose to creatinine requires creative strategies for increasing sensitivity and rejecting background noise.

Methods: Libre-based sensors for ethanol, lactate, b-hydroxybutyrate, and creatinine were fabricated and tested, both *in-vivo* and *in-vitro*. These sensors required a wide variety of enzyme types, (including those specifically engineered for a particular sensor) as well as membranes of various charge and polarity.

Results: Sensors exhibited good *in vitro* sensitivity and linearity over the desired measurement range, from low millimolar for ethanol to mid-micromolar for creatinine. In vitro stability was consistent with a 15 day wear time. Sample *in-vivo* results for these sensors have also been obtained, showing in all cases an excellent signal/noise ratio in the *in-vivo* environment.

Conclusions: The FrreeStyle Libre platform has been adapted for accurate *in vivo* measurement of a number of analytes important to Diabetes management. In addition, Libre's electrode geometry is well suited to multi-analyte detection with a single implanted sensor: thus these new analytes can be paired with glucose or each other in various configurations.

EP148 / #93

Topic: ***AS06 Glucose sensors***

CORRELATION BETWEEN PERCENTAGE OF TIME IN RANGE MEASURED BY CONTINUOUS GLUCOSE MONITORING AND GLYCATED HEMOGLOBIN IN PREGNANT WOMEN DIAGNOSED WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Percentage of time in range (%TIR) could help overcome the limitations of glycated hemoglobin (HbA1c) as an estimator of metabolic control during pregnancy. The aim of this study was to determine the correlation between %TIR and HbA1c in pregnant women diagnosed with type 1 diabetes mellitus (DM1).

Methods: Diagnostic testing of a retrospective cohort of Latin American pregnant patients diagnosed with DM1, receiving sensor-augmented pump therapy (SAPT), in Colombia and Chile.

Results: In total, 52 patients were included in the study (31.8 ± 6.2 years old, 7.2% [interquartile range (IQR), 6.5–8.2] pregestational HbA1c). Metabolic control improved during the second (HbA1c, 6.40% [IQR, 5.9–7.1]; %TIR, 59.0% [IQR, 551.8–73.0]) and third (HbA1c, 6.25% [IQR, 5.9–6.8]; %TIR, 66.6% [IQR, 57.3–72.0]) trimesters. A weak and negative correlation was found between %TIR and HbA1c in the second (Spearman's rank correlation coefficient = -0.13, p = 0.38) and third (Spearman's rank correlation coefficient = -0.26, p = 0.08) trimesters. %TIR had poor discriminating capacity for predicting HbA1c 66.1% (65% sensitivity, 62% specificity) for predicting HbA1c 61.1% (59% sensitivity, 54% specificity) for predicting HbA1c <6.5%.

Conclusions: The correlation between HbA1c and %TIR in patients diagnosed with DM1 during pregnancy was weak. The optimal cutoff points for identifying patients with HbA1c 66.1% and 61.1%, respectively, with moderate sensitivity and specificity.

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Topic: ***AS06 Glucose sensors***

RAPID HBA1C REDUCTIONS IN PATIENTS WITH TYPE 2 DIABETES IN A COMMUNITY SETTING FOLLOWING INITIATION OF REAL-TIME CONTINUOUS GLUCOSE MONITORING

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Background and Aims: Continuous glucose monitoring (CGM) offers actionable insights for people with type 2 diabetes (T2D) and their physicians; however, many patients have limited access to this technology because of disparities in insurance coverage. We examined the effects of providing no-cost real-time (RT) CGM to underinsured patients with T2D in a community setting.

Methods: Patients with T2D whose insurance coverage did not include CGM were eligible for inclusion. RT-CGM systems (Dexcom G6) were provided at no cost. Patients were referred to the program by their primary care providers to the local health department for RT-CGM initiation and training. All patients were new to CGM, had HbA1c ≥7.4%, and there were no restrictions based on comorbidities or diabetes treatment regimens. Follow-up visits at 3-month intervals were for supplies, HbA1c measurements, and weight determinations.

Results: Interim data from 31 patients (out of a forecasted 200) with ≥2 HbA1c values were analyzed. Mean BMI was 37.8 kg/m^2. HbA1c values obtained before RT-CGM initiation ranged from 7.4% to >15%. HbA1c changes versus the first value obtained after RT-CGM initiation ranged from 0 to 7.9 percentage points (mean±SD, 2.76 ± 1.99; median (IQR) 1.95 (1.38-3.93)). No device-related adverse events were reported.

Conclusions: RT-CGM helps underinsured people with T2D successfully improve their diabetes control. It is likely that people used the data to modify dietary and behavioral choices. The large and clinically significant HbA1c reductions will likely reduce the risk of long-term complications. Expanded coverage for RT-CGM devices may have beneficial cost implications for insurance providers.

EP150 / #148

Topic: ***AS06 Glucose sensors***

FROM A LIFE-THREATENING SITUATION TO OPTIMAL GLYCEMIC CONTROL, WITH THE HELP OF DIABETES TECHNOLOGY

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Background and Aims: New technologies are improving diabetes control, but there are still subjects who may put their lives at risk due to insufficient self-care. Diabetic ketoacidosis (DKA) is one of the most serious diabetes complications and may require advanced life support

Methods: We analyzed a case of a subject with type 1 diabetes mellitus (TIDM) and suboptimal glycemic control, who required admission for DKA and suffered from multiple subsequent complications.

Results: We present a case of a 36-year-old male with TIDM since the age of 7. From diagnosis, he frequently omitted insulin injections, glucose control was suboptimal and he required multiple admissions for DKA. The last and most serious admission was at the age of 35, presenting severe DKA (blood glucose: 2400 mg/dL, pH 6.6, acute renal failure and Glasgow 8 points), and HbA1c 12.4%. During his prolonged ICU hospitalization, he suffered from multiple complications, such as status epilepticus and polyneuropathy of critical patient, he required prolonged orotracheal intubation, which led to bilateral vocal cord paralysis and initiation of enteral nutrition by nasogastric tube. During the stay in the hospital ward, flash monitoring of glucose was initiated and an injection port was placed, due to the need for multiple insulin injections with the administration of enteral nutrition. After good oral tolerance was recovered, the Medtronic 780G system was started, achieving optimal glucose control.

Conclusions: Diabetes technology can facilitate adherence to diabetes treatment, showing in this case how a subject, who ended up in a critical situation, progressed to optimal control with the help of technology.

Table 1. Glucometric variables during the evolution

	FREESTYLE LIBRE 2	MEDTRONIC 780 G
Sensor Glucose (mg/dl)	177	144
Glucose Management Indicator (GMI) (%)	7.5	6.8
Coefficient of Variation (%)	36.1	30.3
Time < 54 mg/dl (%)	1	0
Time 54-70 mg/dl (%)	4	1
Time 70-180 mg/dl (%)	47	82
Time 180-250 mg/dl (%)	34	15
Time >250 mg/dl (%)	14	2

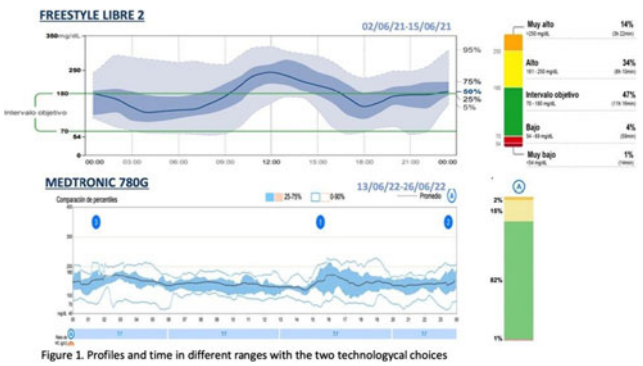

Figure 1. Profiles and time in different ranges with the two technologycal choices

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Topic: *AS06 Glucose sensors*

REBOUND HYPO-AND HYPERGLYCEMIA IN TYPE 1 DIABETES

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Background and Aims: Rebound hypo- and hyperglycemia are rarely discussed phenomena in the context of continuous glucose monitoring (CGM). The aim was to quantify these events and describe their relation to other glycemic metrics.

Methods: Data from intermittently scanned CGM was downloaded for 90 days for 159 persons with type 1 diabetes and active CGM time >70 %. Rebound hypoglycemia (Rhypo) and rebound hyperglycemia (Rhyper) were defined as a hypoglycemic event <3.9 mmol/l for at least two periods of 15 min, preceded or followed by glucose >10.0 mmol/l within 120 min.

Results: A total of 10,977 hypoglycemic events were identified of which 3,193 (29%) were Rhypo and 3,653 (33%) were Rhyper, corresponding to a median frequency of 10.1, 2.5 and 3.0 events per 14 days. For 1,267 (12 %) of the cases Rhypo and Rhyper coexisted. The mean peak glucose was 12.8 ± 1.6 mmol/l before Rhypo and 12.8 ± 1.1 mmol/l in Rhyper. Glucose nadir was 3.0 ± 0.3 mmol/l. The frequency of Rhyper was significantly ($p < 0.001$) correlated with both Rhypo (Spearmańs rho 0.84), glucose CV (0.78), and time below range (0.69) but not with time above range (0.12, $p = 0.13$).

Conclusions: Of all hypoglycemic events Rhypo was present in approx. 1/3, Rhyper in 1/3 and the combination in 1/9 of the cases. The strong correlation between Rhyper and Rhypo suggest an individual behavioral characteristic towards rapid and intensive treatment of both high and low glucose excursions, which may be corrected by reinstruction.

EP152 / #200

Topic: *AS06 Glucose sensors*

ASSOCIATION OF FREESTYLE LIBRE USAGE AND TREATMENT SATISFACTION AMONG PEOPLE WITH DIABETES

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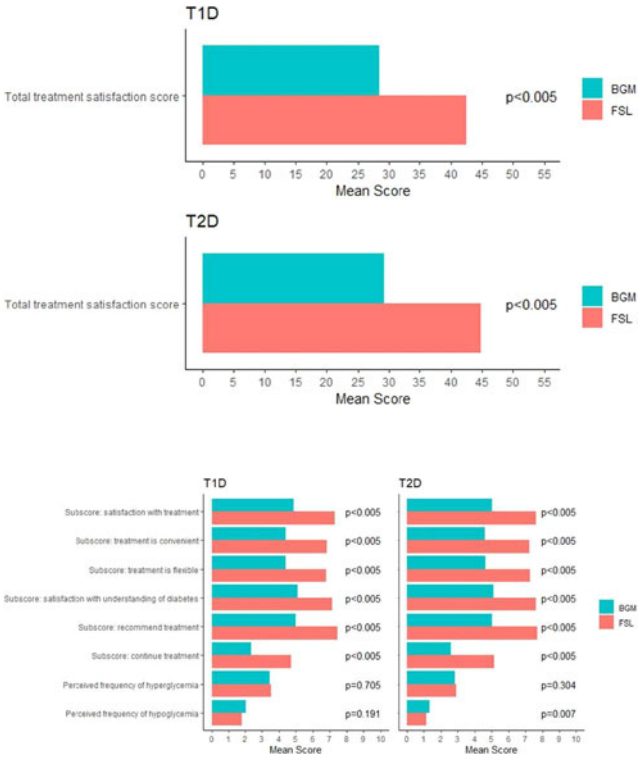
Background and Aims: Satisfaction with continuous glucose monitors is receiving growing attention as more people with diabetes (PWD) adopt this novel technology to manage their condition. This study assessed diabetes treatment satisfaction (DTS) using FreeStyle Libre 14-day (FSL) glucose monitoring system among people with Type 1 (T1D) and Type 2 diabetes (T2D).

Methods: This is a post-approval, prospective, multi-center, non-randomized, adult (≥18 years) study based in United States. It consisted of a 6-month baseline period where participants used blood glucose monitoring (BGM) device, and a 6-month follow-up period where participants used FSL to manage their diabetes. Diabetes Treatment Satisfaction Questionnaires (DTSQ) and HbA1c values were collected and the differences between the baseline and follow-up periods were assessed.



Results: This study enrolled 935 participants; 744 completed both the baseline and follow-up periods and were included in the analysis: 10.8% have T1D and 89.2% have T2D. FSL usage was associated with a significant increase in diabetes treatment satisfaction in persons with T1D (mean total DTS change score: +13.95; $p<0.005$) or T2D (mean total DTS change score: +15.57, $p<0.005$). In addition, the perceived frequency of hypoglycemia among T2D was significantly less after using FSL (mean score: -0.18, $p=0.007$). Finally, daily scan frequency was correlated with a decrease in HbA1c, where each additional scan was associated with a reduction of 0.04% in HbA1c (adjusted 95% CI: (-0.06, -0.01); adjusted $p=0.001$).

Conclusions: Using FSL was associated with significant improvement in diabetes treatment satisfaction among people with T1D or T2D. Frequent daily scan was also associated with a reduction in HbA1c.

EP153 / #202

Topic: ***AS06 Glucose sensors***

ASSOCIATION OF FREESTYLE LIBRE USAGE AND TREATMENT SATISFACTION AMONG THE ELDERLY PARTICIPANTS WITH TYPE 2 DIABETES

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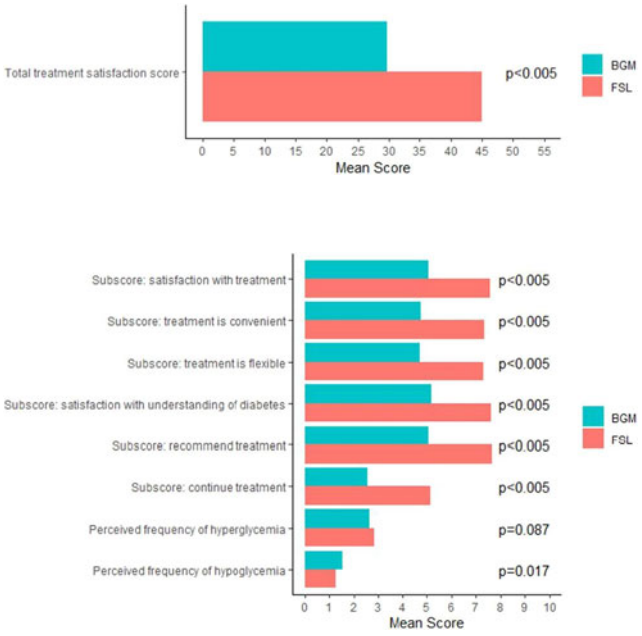
Background and Aims: Usage of continuous glucose monitors (CGMs) among the elderly population is receiving growing attention as adults 65 years and older adopt this novel technology to manage type 2 diabetes. However, knowledge of CGM satisfaction among this group is scarce and difficult to collect. This study assessed diabetes treatment satisfaction (DTS) of using FreeStyle Libre 14-day (FSL) glucose monitoring system among ≥65 years old adults with T2D.



Methods: This is a post-approval, prospective, multi-center, non-randomized study based in the United States. It consisted of a 6-month baseline period where participants used blood glucose monitoring (BGM) device, and a 6-month follow-up period where participants used FSL to their manage diabetes. Diabetes Treatment Satisfaction Questionnaires (DTSQ) and HbA1c values were collected and the differences between the baseline and follow-up periods were assessed.

Results: This study included 267 elderly T2D adults (≥65 years) who completed both baseline and follow-up periods. FSL usage was associated with a significant increase in diabetes treatment satisfaction (mean total DTS change score: +15.3, $p<0.005$), and the perceived frequency of hypoglycemia was significantly less after using FSL (mean score: -0.2, $p=0.017$) compared to using BGM. Furthermore, daily scan frequency was correlated with a decrease in HbA1c, where each additional scan was associated with a reduction of 0.036% in HbA1c (adjusted 95% CI: (-0.070, -0.003); adjusted $p=0.032$).

Conclusions: Using FSL was associated with significant improvement in diabetes treatment satisfaction among the elderly population with T2D. Frequent daily scan was also associated with a reduction of HbA1c in this population.

EP154 / #833

Topic: ***AS06 Glucose sensors***

GLYCEMIC VARIABILITY IN IMPAIRED GLUCOSE TOLERANCE WITH DIET WITH LOW GLYCEMIC INDEX AND GLYCEMIC LOAD

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Background and Aims: It is very important to prevent type 2 diabetes mellitus. Our aim was to assess the change in glycemic variability in impaired glucose tolerance when replacing products in Uzbek dishes based on the glycemic index and glycemic load

Methods: For a female patient, a personalized menu was developed, taking into account the interchangeability of products based on national dishes. We used data from the database of the University of Sydney https://glycemicindex.com. DEXCOM G6 24-hour glucose monitoring was used to assess glycemic variability.

Results: Continuous glucose monitoring system report showed that the average indicators of 2-hour postprandial glycemia of 7 main national dishes after replacing ingredients with high glycemic index and glycemic load with lower ones significantly) decreased from 152.0 to 128.92 mg/dl.

Conclusions: A decrease in glycemia by an average of 1.23 times was achieved by replacing the ingredients of the usual national dishes, which will increase the adherence of patients with impaired glucose tolerance to dietary recommendations and delay the development of type 2 diabetes mellitus. Reducing the rate of digestion, absorption, and metabolism of carbohydrates through foods with a low glycemic index and glycemic load may improve glycemic control in individuals with impaired glucose tolerance

EP155 / #650

Topic: ***AS06 Glucose sensors***

EFFECT OF DIFFERENT METHODS OF GLUCOSE MONITORING AND INSULIN DELIVERY ON GLYCEMIC REGULATION IN PATIENTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Backgrounds and Aims: This study aimed to evaluate the impact of diverse glucose monitoring/insulin delivery methods on glycemic control and the incidence of diabetic complications in patients with type 1 diabetes mellitus (DM1).

Methods: Methods: A total of 143 patients with DM1 were retrospectively evaluated for 2 years. 60 patients were treated with multiple daily insulin regimen (MIDR) with self-monitoring of blood glucose (SMBG), 40 with MIDR and continuous glucose monitoring systems (CGMS) and 43 patients with CGMS and continuous subcutaneous insulin infusion (CSII). This study aimed at comparing the evolution of HbA1c values and the incidence of hypoglycemic episodes among the 3 groups.

Results: Results: Mean age at diagnosis of DM1, bone mass index (BMI), mean HbA1c values and age at the beginning of the study were similar for all patients. On the contrary, MIDR-SMBG patients used notably lower TDDI and experienced significantly less hypoglycemic episodes. Two-years after the baseline, mean HbA1c values were significantly decreased among patients with MIDR-CGMS and CSII-CGMS. On the contrary, there was no reduction of HbA1c in the MIDR-SMBG group. Hypoglycemic episodes were almost halved after 2 years in the MIDR-CGMS and CSII-CGMS groups. The decrease of hypoglycemias in the MIDR-SMBG group was far more limited.

Conclusions: Conclusions: Both CGMS and CGMS-CSII separately or combined proved to be superior as monitoring/treatment modalities for patients with DM1 in comparison to the MIDR-SMBG. Therefore, diabetes technology is extremely beneficial and safe for DM1 patients and further research towards the improvement and wider use of this technology is needed.

EP156 / #522

Topic: ***AS06 Glucose sensors***

THE USEFULNESS OF CONTINUOUS GLUCOSE MONITORING SYSTEM IN CHILDREN WITH TYPE 1 DIABETES – A DESCRIPTIVE STUDY WITH PARENTS IN THE REPUBLIC OF GEORGIA

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Background and Aims: Diabetes is a complicated metabolic disorder and a continuous subcutaneous glucose monitoring sensor as FreeStyle Libre Continuous Glucose Self-Monitoring System (CGM) is an essential tool in its management, but in the Republic of Georgia the cost of CGM is a part that the family must bear. The aim was to understand parents' experiences during their daily lives and support needs when a child uses the CGM.

Methods: Parents (n = 17 mothers - n = 3 fathers), to children (age ranged between 22 months and 16 years), with Diabetes Mellitus type 1, using CGM sensors (used for an average of 7 months (range 1-72) at home, where included in this study. A qualitative questionnaire survey with open questions, including follow-up dialogues was distributed to the parents. The collected data was analysed using qualitative content analysis. An Overall satisfaction with the concept is described with a median (Md, Likert scale 1-10) and interquartile range (IQR) value.

Results: One main theme Advances in technology significantly improved everyday life, emerged from two categories: Improvements in quality of life and Elements of challenges. The parents experience a great improvement in quality of daily life, as the children's blood glucose levels were perceived to be better adapted to their illness and the parents experienced better opportunities for the children within the school and other social activities. The Overall satisfaction with the CGM was Md 10 (IQR 9.25-10).

Conclusions: Implementing CGM device in diabetic care for Georgia children will be a major step toward the European medical quality standards

EP157 / #824

Topic: ***AS06 Glucose sensors***

CONTINUOUS GLUCOSE MONITORING FOR DETECTING OVERBASALIZATION; A CASE-SERIES

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Background and Aims: The role of CGM in diagnosis and management of overbasalization is unknown. We present data from CGM use in 4 adults.

Methods: We defined overbasalization as difference between bedtime and morning blood glucose (BeAM) ≥50mg/dl or basal insulin ≥0.5units/Kg/d with elevated HbA1c. Ambulatory Glucose Profile was evaluated using intermittently scanning CGM (Abbott, FreeStyle Libre). Case 1: 66M, type 2 diabetes, HbA1c:7.8% on metformin, empagliflozin, pioglitazone, degludec 0.6U/Kg/d. Case 2: 60F, type 2 diabetes, HbA1c: 7.5% on metformin, liraglutide, glargine U300 0.7U/Kg/d. Case 3: 62M, type 2 diabetes, HbA1c:10.5% on metformin, sitagliptin, glargine U100 0.2U/Kg/d. Case 4: 42F, type 1 diabetes, HbA1c:6.7% on aspart and degludec 0.35U/Kg/d.

Results:

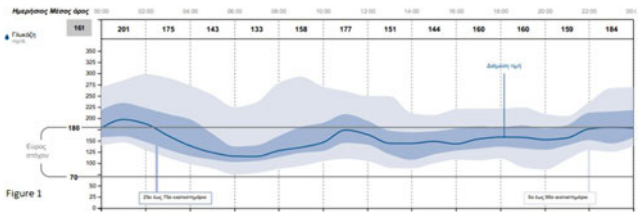
Figure 1

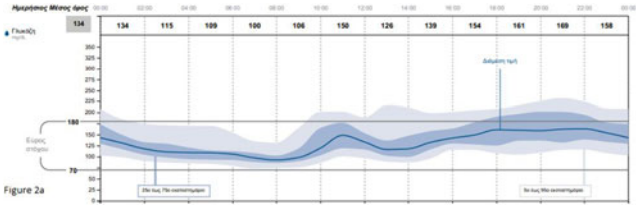
Figure 2a

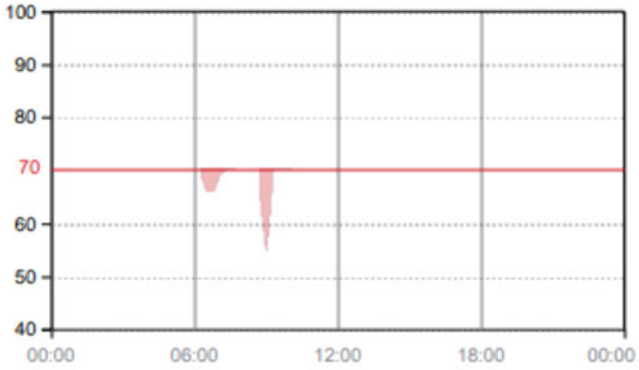

Figure 2b

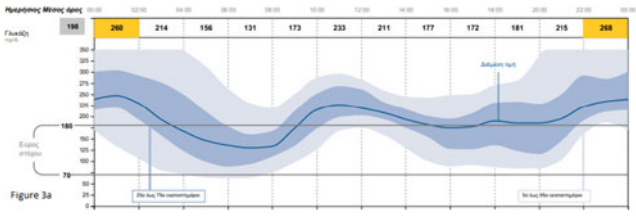
Figure 3a

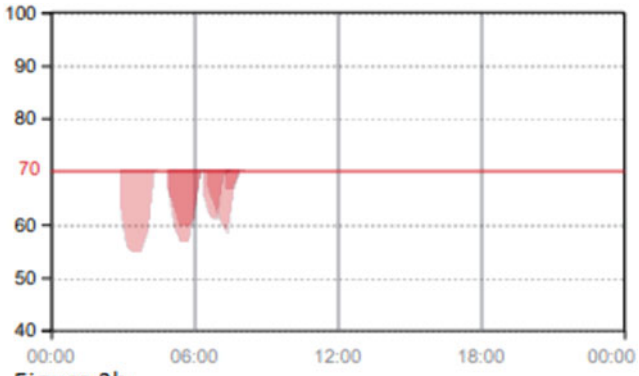

Figure 3b

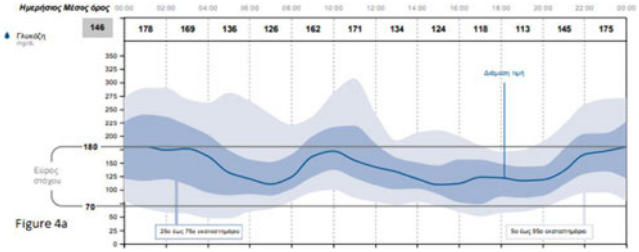
Figure 4a

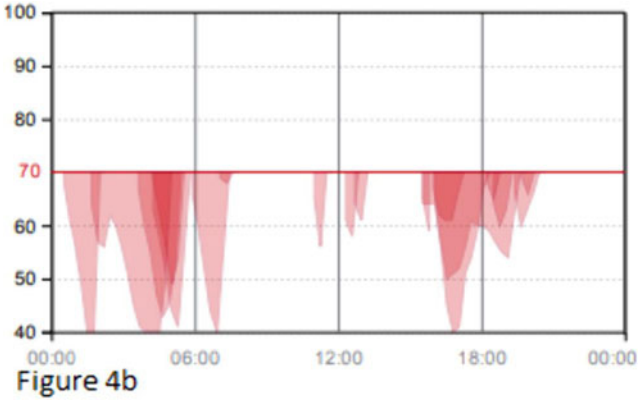

Figure 4b

In Case 1, BeAM: 68mg/dl and Fasting Plasma Glucose (FPG): 133mg/dl without hypoglycemia were detected (Figure 1). Prandial insulin before dinner was initiated. In Case 2, within target FPG and low BeAM (Figure 2a) were accompanied by hypoglycemia (Figure 2b). A 10% reduction in basal insulin and prandial insulin before lunch were proposed. In Case 3, BeAM :129mg/dl, FPG 131mg/dl (Figure 3a) and multiple episodes of nocturnal hypoglycemia (Figure 3b) were detected. Test for anti-GAD antibodies was positive. Basal bolus was initiated as LADA. In Case 4, BeAM :52mg/dl, FPG :126mg/dl (Figure 4a) and hypoglycemia during nighttime and in the afternoon were detected (Figure 4b). A 10-20% decrease in basal insulin with equal increase in prandial insulin were proposed.

Conclusions: CGM may be a useful tool to early detect and address overbasalization both in Type 1 and Type 2 Diabetes.

EP158 / #814

Topic: *AS06 Glucose sensors*

EVALUATION OF THE FOREIGN BODY REACTION OF THREE COMMERCIAL GLUCOSE SENSORS IN A PORCINE AND A MURINE MODEL

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Background and Aims: Continuous glucose monitoring platforms can function for >7 days before a sensor change is necessary. Current challenges to extending the lifespan of glucose sensors involves surmounting the tissue reactions at device sites. Furthermore, episodes of unreliable sensor performance are known to occur in the early days following sensor insertion. Study aims are to characterize *in vitro* cell toxicity and *in vivo* tissue toxicity and pro-inflammatory activity of three commercial glucose sensors, Libre 2, Medtronic Guardian 4 and Dexcom G6.

Methods: *In vitro* sensor toxicity studies included cell viability and netosis imaging assays using leukocytes from healthy and diabetic individuals. *In vivo* studies employed FLOW cytometry to quantify sensor induced leukocyte influx in a murine air-pouch model. Histopathologic evaluations at sensor insertion and implantation sites were conducted in mice and swine for the three commercial sensors.

Results: *In vitro* studies demonstrated sensor induced cell death and neutrophil extracellular TRAPs (NET) formation. Mouse air pouch studies showed that influx of inflammatory cells is augmented in the presence of the devices. NET formation was confirmed in both animal models and particular visible following sensor insertion in swine tissue. Chronic inflammation, fibrosis, and blood vessel regression is seen post 7-day insertion.

Conclusions: Cumulative sensor insertion and sensor composition (material) are contributors to cell toxicity (e. g. cell death, NET formation), and tissue reactions (inflammation, fibrosis and blood vessel regression) at implantation sites. Future strategies designed to optimize sensor performance and sensor longevity must mitigate sensor induced cell and tissue toxicity.

EP159 / #713

Topic: *AS06 Glucose sensors*

CONCORDANCE OF 7-POINT SELF-MONITORING BLOOD GLUCOSE WITH CONTINUOUS GLUCOSE MONITORING (CGM) DURING CLINICAL TRIAL OF AUTOMATED INSULIN DELIVERY DURING PREGNANCY IN PRE-EXISTING TYPE 1 DIABETES

R. Jeet Kaur[1], I. Zaniletti[2], B. Ozaslan[3], C. Levy[4], K. Castorino[5], G. O'Malley[6], C. Levister[4], S. Rizvi[1], M.M. Church[5], D. Desjardins[1], S. Mccrady-Spitzer[1], M.C. Trinidad[7], S. Ogyaadu[4], C. Reid[1], W. Kremers[8], F. Doyle[9], J. Pinsker[5], E. Dassau[3], Y. Kudva[1]

[1]Mayo Clinic, Division Of Endocrinology, Diabetes, Metabolism & Nutrition, Rochester, United States of America, [2]Mayo Clinic, Department Of Biomedical Statistics And Informatics, Scottdale, United States of America, [3]Harvard University, John A. Paulson School Of Engineering, Boston, United States of America, [4]Icahn School of Medicine, Endocrinology, NY, United States of America, [5]Sansum Diabetes Research Institute, -, Santa Barbara, United States of America, [6]Icahn School of Medicine at Mount Sinai, Endocrinology, New York, United States of America, [7]Mayo Clinic, Obstetrics And Gynecology, Rochester, United States of America, [8]Mayo Clinic, Department Of Biomedical Statistics And Informatics, Mayo Clinic, Rochester, United States of America, [9]Harvard University, John A. Paulson School Of Engineering And Applied Sciences, Boston, United States of America

Background and Aims: Automated insulin delivery (AID) systems for pregnancy with type 1 diabetes (T1D) are being developed and tested to achieve pregnancy-appropriate glucose control safely in the USA and UK. CGM is an essential part of these systems. In the first US clinical study testing a pregnancy-specific AID system (NCT04492566) at-home, study safety protocol included the use of 7-point self-monitoring of blood glucose (SMBG) to be performed during the use of the investigational AID system until CGM (Dexcom G6) and SMBG fulfilled the %20/20 criteria for two weeks.

Methods: Ten pregnant women with T1D from three US sites participated in a supervised 48-hour AID session followed by at-home use for the rest of the pregnancy. SMBG and CGM data were analyzed biweekly to compare SMBG and closest CGM values before CGM was used exclusively. A paired t-test was used to compare the mean SMBG and mean closest CGM.

Results: All participants completed the trial with extension phase. Participants were 32.6±4.3 years, gestational age of 22.0±3.4 weeks, BMI of 27.2±4.9 kg/m^2, and HbA1c of 5.8±0.6% at enrollment. Seven out of ten participants ''graduated'' from 7-day SMBG after ≥90%CGM values fulfilled the %20/20 rule (Table 1). Three participants did not fulfill %20/20 criteria for any 2-week analysis mainly because frequency of SMBG did not meet daily 7-point testing requirements. No adverse events were reported.

Conclusions: Dexcom G6 CGM is safe and effective as part of a pregnancy-based AID system in pregnant patients with T1D.

Table 1. Individual self-monitoring of blood glucose data (SMBG) and percentage of CGM glucose that fall within %20/20 of SMBG

Subject ID	Number of weeks before graduation	Graduated from SMBG testing (Yes/No)	Mean ± SD SMBG	Mean ± SD CGM glucose	P-value	Mean Number of SMBG readings per day	MARD	% Of CGM glucose within 20%20 mg/dL of SMBG*
1	NA	No	115.38 ± 43.88	114.22 ± 42.04	**0.036**	7	9.43	94.59%
2	2 weeks	Yes	98.57 ± 22.76	97.24 ± 11.95	0.201	5.6	6.53	98.65%
3	4 weeks	Yes	110.43 ± 40.66	110.08 ± 35.31	0.815	5.6	13.5	86.71%
4	NA	No	104.33 ± 39.22	101.29 ± 34.40	**0.012**	5.8	13.41	85.71%
5	2 weeks	Yes	115.55 ± 36.30	112.33 ± 32.83	**0.005**	6.4	7.64	94.38%
6	2 weeks	Yes	127.39 ± 50.73	122.38 ± 40.40	**0.010**	6.4	11.52	90.00%
7	NA	No	135.93 ± 47.59	132.54 ± 46.87	**0.015**	3.2	10.58	90.00%
8	2 weeks	Yes	112.37 ± 33.15	110.31 ± 33.39	0.135	6.6	9.59	95.70%
9	4 weeks	Yes	138.65 ± 54.53	133.27 ± 47.93	**<0.001**	6.1	11.26	87.79%
10	6 weeks	Yes	122.21 ± 36.46	125.75 ± 30.58	**0.002**	6	12.58	85.32%
Total Mean	-	-	118.10 ± 40.53	115.90 ± 35.57	-	5.9 ± 1.0	10.6 ± 2.3	90.9 ± 4.7%

MARD-mean absolute relative difference
*%20/20: percentage of values within 20mg/dL or within 20% of corresponding SMBG values ≤ or >100mg/dL, respectively
NA-Not applicable, as SMBG was performed until delivery

EP160 / #888

Topic: *AS06 Glucose sensors*

ACUTE AND DELAYED EFFECTS OF MEAN DAILY AIR TEMPERATURE ON TIME BELOW RANGE AND TIME ABOVE RANGE IN 2,582 CHILDREN AND ADOLESCENTS WITH T1D

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Background and Aims: Health effects of ambient air temperature have been shown to be acute and delayed for a few days. We aimed at assessing acute (day 0) and up to 6 days delayed effects of mean daily air temperature on time below range (TBR <54 mg/dl) and time above range (TAR >250 mg/dl) in type 1 diabetes (T1D).

Methods: Children and adolescents with T1D < 21 years with information on daily glucose profiles from the diabetes prospective follow-up registry (DPV) were included. Further inclusion criteria were age at diabetes onset at least six months, diabetes duration for at least one year and the treatment years 2020 and 2021. Mean daily air temperature and other meteorological parameters from 78 measurement stations in Germany were linked to the individuals via the five-digit postcode areas of residency. We used multivariable repeated measures fractional logistic regression models to study acute and delayed effects of an 1°C increase in daily mean temperature on TBR and TAR.

Results: 2,582 children and adolescents with T1D were included. A 1°C increase in daily mean temperature was associated with an acute (0.9% (95%-CI: 0.7-1.1% (Odds Ratio (OR) 1.009 (1.007-1.011)) and up to 6 days delayed (0.3% (0.1-0.5%) increase in TBR. TAR decreased by 0.3% (0.3-0.4%, OR 0.997 (0.996-0.997)) on day 0 and by 0.1% (0.1-0.2) with a delay of 3 days.

Conclusions: Temperature effects on TBR and TAR were strongest on the same day and might indicate a higher blood flow and faster insulin absorption.

EP161 / #38

Topic: ***AS06 Glucose sensors***

LONG-TERM SAFETY EVALUATION OF THE 90-DAY EVERSENSE CGM SYSTEM IN THE U.S.POST APPROVAL SETTING

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Background and Aims: The implantable 90-day and 180-day (XL) Eversense CGM Systems were shown to be safe over multiple sensor cycles in 3023 patients (534 centers) in a post-market clinical follow-up study conducted in Europe (2016 to 2020). Consistent accuracy metrics across multiple sensor cycles were reported in a European real-world analysis in 945 users (2016 to 2019). After 2018 approval of the 90-day Eversense CGM System in the US, a post-approval study was begun to assess safety after repeated insertions in a US-based population.

Methods: Eversense CGM System safety is being evaluated over 2 years in adult patients with either type 1 or type 2 diabetes in US centers. After baseline assessment and placement of the Eversense sensor, visits were made every 90 days to place a new sensor, remove the prior sensor and document adverse events (AEs) since the previous visit. The study is enrolled and follow-up visits are ongoing.

Results: Across 18 centers, 273 users were enrolled in the study (55% male, 80% reported having type 1 diabetes). As of May 2022, 1,343 sensors had been inserted. There were 3 device-related SAEs due to hypoglycemia in 2 users and 1 procedure-related SAE due to infection at the sensor site. There were 270 AEs in total, of which 81 were adjudicated as related to the study device or insertion/removal procedure (Table).

Adverse Event (AE)	Number of Events	Number of Subjects	Percentage of Sensors inserted
Total	**81**	**54**	**6.0**
Unable to remove Sensor on first attempt	18	16	1.34
Skin irritation, adhesive patch (erythema, pruritis, contact dermatitis, blister)	13	11	0.97
Sensor insertion site (erythema, swelling, pruritis, redness, rash)	9	7	0.67
Sensor insertions site - Pain	8	8	0.60
Skin discoloration	5	4	0.37
Skin atrophy	4	4	0.30
Scarring	4	3	0.30
Hypoglycemia	4	3	0.30
Bleeding	3	3	0.22
Sensor insertions site - Infection	3	3	0.22
Bruising	2	2	0.14
Cellulitis	2	2	0.14
Prolonged wound healing	2	2	0.14
Sensor fragmented upon removal	2	2	0.14
Vasovagal episode/Cold sweat	2	2	0.14

Conclusions: Repeated insertions/removals of the Eversense 90-day CGM System in the US were shown to have a safety profile consistent with the prior European PMCF study.

EP162 / #547

Topic: ***AS06 Glucose sensors***

SHORT-TERM EFFECTS OF FLASH GLUCOSE SELF-MONITORING ON GLYCAEMIC CONTROL IN ELDERLY PEOPLE WITH DIABETES

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Italian National Research Centres on Aging (INRCA), Ancona, Metabolic Disease And Diabetology Unit, Ancona, Italy

Background and Aims: Flash glucose monitoring (FGM) technology is effective in improving glycaemic control and quality of life in people with type 1 and type 2 diabetes treated with multiple insulin injections (MDI). Data regarding older

people using FGM are limited. This study evaluate the FGM short-term effects on glycaemic control in elderly people with T1DM and T2DM in MDI.

Methods: Metabolic data and ambulatory glucose profile (AGP) reports of 37 older adults (75,6 ± 6,0 ys; 22/15 males/females; 10/27 T1DM/T2DM) using FGM for at least 3 months were retrospectively analized. Diabetes duration was variable (29,1 ± 12,3 ys); 10/37 subjects wore the sensor for at least 3 months, 27/37 for ≥6 months. Glucose statistics were collected at time +1/+3/+6 months (T1/T2/T3) from starting use of FGM technology (T0). HbA1c variation and daily insulin dose (TDI) were evaluate from T0 to T3.

Results: The use of FGM for ≥6 months resulted in significant HbA1c reduction (T1 65,1 ± 8,6 vs T3 60,0 ± 5,5 mmol/mol; p = 0,002). However TAR level 1 augmented significantly from T1 to T2 (27,1 ± 12,2 vs 32,3 ± 13,5; p = 0,005) and TIR decreased (T1 63,8 ± 18,5 vs T3 63,4 ± 12,2; p = 0,093). No significant changes in TDI (0,64 ± 0,25 vs 0,60 ± 0,20; p = 0,054), TAR level 2, TBR, mean glucose value and CV were observed. A significant reduction of TIR (65,2 ± 18,1 vs 61,0 ± 16,7; p = 0,031) and an increase of TAR level 1 (25,8 ± 12,0 vs 30,5 ± 13,3; p = 0,001) were also observed in the whole group (T1-T2).

Conclusions: FGM technology is a viable option to help older people with T1DM and T2DM in management hyperglycaemia, control variability, prevent hypoglycaemic episodes and augment quality of life.

EP163 / #709

Topic: ***AS06 Glucose sensors***

ASSOCIATION OF SENSOR-DETECTED HYPOGLYCAEMIC EPISODES (SDHE) WITH HYPOGLYCAEMIA FROM SMBG IN 15 CLINICAL TRIALS WITH SHORT-DURATION CGM. PRELIMINARY RESULTS FROM THE HYPO-RESOLVE DATABASE

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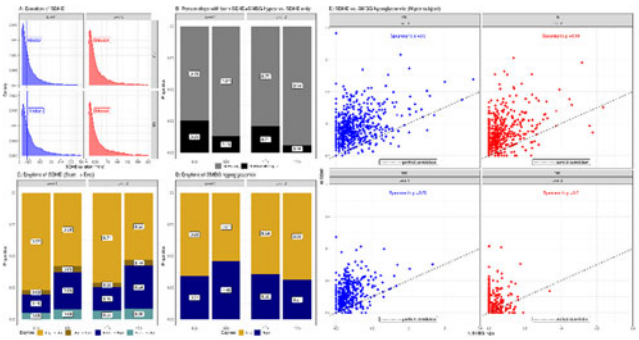
Background and Aims: CGM is important for the study of hypoglycaemia because it can detect hypos outside of patients' SMBG testing regimes and records hypo duration. However, CGM may overestimate hypoglycaemia as the CGM algorithms are conservative. To assess how well short-duration CGM (≤14 days) reflects SMBG hypoglycaemia rates, we conducted pooled analysis of 15 clinical trials in T1D and T2D.



Methods: We used harmonized data from the Hypo-RESOLVE (Hypoglycaemia - REdefining SOLutions for better liVEs) database. We identified 1704 persons who have both CGM- and SMBG-recorded hypos. These amounted to >22.000 SDHE and >4000 SMBG hypos on either level 1 (L1: <70 mg/dl) or level 2 (L2: <54 mg/dl). We matched SDHE and SMBG hypos per person-day to calculate the daily number of hypos. We then conducted graphical and descriptive analyses by diabetes type.

Results: SDHE mainly last <1 hour with a few very long episodes (Fig.A). Only a small proportion of person-days had records for both SDHE and SMBG hypos, the number was even smaller for T2D (Fig.B). The majority of hypoglycaemia happen during daytime (6-0h), even more so for T1D, with SDHE also crossing over from/into the night (0-6h, Fig. C+D). For person-days with both SDHE and SMBG hypos, per-day hypo rates are correlated, more so for T1D (Fig.E).

Conclusions: We identified a much larger number of SDHE than SMBG hypos, but there is a positive correlation between the two, which is stronger for T1D. Future more complex modelling will evaluate if and with what precision CGM can predict hypoglycaemia when considering covariates.

EP164 / #340

Topic: ***AS06 Glucose sensors***

FLASH GLUCOSE MONITORING IN GESTATIONAL DIABETES MELLITUS (FLAMINGO): A RANDOMISED CONTROLLED TRIAL

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Background and Aims: Gestational diabetes mellitus (GDM) is the most common type of hyperglycaemia in pregnancy. GDM is a risk factor of adverse perinatal outcomes, with the incidence rate increasing proportionally to level of maternal dysglycaemia. Therefore, glycaemic control plays an important role in management of GDM. The aim of this study was to assess the efficacy of flash glucose monitoring in gestational diabetes.

Methods: This was a cross-over, non-blinded, randomised controlled trial, that recruited 100 pregnant women diagnosed with GDM between 24 and 28 weeks of gestation at the 1st Department of Obstetrics and Gynaecology, Medical University

of Warsaw. After meeting the inclusion criteria patients were randomly allocated either to the study group (on flash glucose monitoring – FGM, n = 50) or control group (on self-monitoring of blood glucose – SMBG, n = 50). Clinical and laboratory results were assessed at four follow-up visits. The primary outcome of the study was mean fasting and postprandial glycaemia. The secondary outcomes were maternal and neonatal outcomes.

Results: Compared to the control group, the study group significantly reduced their fasting glycaemia (p = 0.02) and improved dietary habits (p < 0.001); there was no significant difference in qualification to insulin therapy between the groups (SMBG 68.6%, FGM 70.0%; p = 0.89). FGM was more sensitive to reveal hypoglycaemic events. There was higher incidence of macrosomia in SMBG group compared to FGM group, with OR 3.34 (95% CI 0.6-34.1).

Conclusions: FGM improved detection of hyper- and hypoglycaemic events, and had an impact on lifestyle habits in GDM patients. However, further studies are needed to support our findings.

EP165 / #606

Topic: ***AS06 Glucose sensors***

A COMPARISON OF ALGEBRAIC AND DYNAMIC MODELS TO ESTIMATE BLOOD GLUCOSE AND A1C FROM CGM TIME SERIES

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Background and Aims: CGM manufacturers such Abbott Freestyle typically report raw ISF data collected by the device. However, obtaining good blood glucose (BG) estimates from CGM data which correlate well with traditional measures of diabetes (such as A1C) continues to be an active area of research. A number of strategies have been pursued, for instance: (i) shifting the baseline (upwards by about 25 mg/dl) or (ii) a multiplicative relation (BG = 1.05 ISF; Nathan et al., 2008). Another alternative to these additive or multiplicative relations is the two-compartment dynamics introduced by Cobelli et al., 2016. Here we attempt to evaluate these models on a dataset collected in Pune, India (50 subjects: 19 non-diabetic, 15 pre-diabetic and 16 diabetic).

Methods: We use linear regression analyses and trajectory optimization techniques (trapezoidal collocation method) for estimating BG and A1C.

Results: The Nathan et al. estimate of BG, together with the eAG/A1C Conversion Calculator, yielded A1C that were significantly different from the HPLC measurements (paired t-test; p < 0.001). Linear regression indicates a better model is BG = 1.25 ISF, ($R^2 = 0.768$, p-value <0.001); this is also similar to the results from a baseline shift. Trajectory optimization for the (modified) Cobelli model confirms this estimate.

Conclusions: We suggest computational strategies for re-parametrizing both the Nathan and Cobelli models for better calibration to the Pune dataset.

EP166 / #629

Topic: ***AS06 Glucose sensors***

WHICH FACTORS ARE IMPLICATED IN THE DISCREPANCY BETWEEN PLASMA A1C AND THE GLUCOSE MANAGEMENT INDICATOR (GMI) IN DIABETIC PATIENTS UNDER CONTINUOUS GLUCOSE MONITORING SYSTEMS?

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Background and Aims: Factors implicated in the discrepancy between plasma A1c and GMI are still largely unknown. In order to identify them, we evaluated the absolute difference between laboratory plasma/point-of-care A1c (LA1c) and GMI [defined from now on as AD(LA1c-GMI)] in diabetic patients under insulin and CGM-FreeStyleLibre® (time active ≥70%).

Methods: For each patient, GMI was obtained from AGP-reports of either 14 or 28 days and compared with LA1c obtained with a maximum difference of 1 month. Linear and logistic regression were used to assess the effect of demographic and clinical data on AD(LA1c-DMI).

Results: 174 patients were analyzed (89,7% had T1DM): median age = 34,5 years(IQR 27,0); median disease duration = 15.0 years(IQR 19.0). 78,9% were under insulin injections; 21,1% used insulin pump. 16,9% were also taking others anti-diabetic drugs. Agreement between laboratory A1c and GMI occurred in only 8.1% of patients. Median AD(LA1c-GMI) was 0.4%(IQR 0.7). There were no demographic, treatment features or laboratory data associated with AD(LA1c-GMI). The %time CGM-active (OR = -0.007; 95%CI(-0.013;0.000); $p = 0.040$), the AGP-report days considered (OR = 0.006; 95%CI(0.002;0.011); $p = 0.009$), the number of readings/day (OR = -0.023; 95%CI (-0.037;-0.009); $p = 0.002$), and time-in-range (OR = -0.009; 95%CI(-0.013;-0.004); $p < 0.001$) had a negative effect on AD (LA1c-GMI). Time-above-range (OR = 0.007; 95%CI (0.003; 0.011); $p = 0.001$), very-high range (OR = 0.011; 95%CI (0.006; 0.017); $p < 0.001$), and mean glucose (OR = 0.004; 95%CI (0.002; 0.006); $p = 0.001$) had an incremental effect on AD(-LA1c-GMI). Coronary disease (present in 5,2%) was associated with an increased AD(LA1c-GMI) (OR = 8.935; 95%CI (1.093; 73.073); $p = 0.041$).

Conclusions: Identifying subgroups of patients in whom GMI should not be used at risk of extrapolating their glycemic control data is of major importance.

EP167 / #398

Topic: ***AS06 Glucose sensors***

CHARACTERISTICS OF CONTINUOUS GLUCOSE MONITORING (CGM) USERS AND NON-USERS IN WOMEN WITH GESTATIONAL DIABETES MELLITUS (GDM)

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Background and Aims: GDM is dysglycemia first diagnosed during pregnancy. Patients develop hyperglycemia and insulin resistance, which increase the risk of adverse maternal and neonatal outcomes. CGM (either real-time or intermittently scanned) is uncommonly used during GDM, and little is known about the characteristics of CGM users in this population. This study describes the demographics, comorbidities, and medication use among CGM users and non-users with GDM.

Methods: Retrospective analysis of de-identified GDM patients was conducted from 01/01/2016 through 06/30/2020 using US administrative claims from the MarketScan® Research Database. Pregnancy start date was estimated from gestational age corresponding to end of pregnancy outcomes. Women with no prior Type 1 or Type 2 diabetes diagnosis and who were continuously enrolled in a health plan 12-months from start of their pregnancy were included.

Results: Data from 81,188 GDM patients were assessed (0.17% CGM users, n = 139). CGM users were slightly older (mean age±SD 32.9 ± 4.8 vs 31.5 ± 5.1, p = 0.001) and had a higher Charlson comorbidity score (mean±SD 0.22 ± 0.49 vs 0.13 ± 0.46, p = 0.049). Insulin use during pregnancy was significantly higher in CGM users (30.9% vs 11.7%, p < 0.0001). GDM was detected earlier in the CGM group (mean gestational weeks±SD 27.9 ± 7.5 vs 31.0 ± 6.3, p < 0.001). Diagnosis of T2D within 1 year of pregnancy was more prevalent among CGM users (9.4% vs 2.7%, p = 0.001).

Conclusions: Findings suggest CGMs are currently used to monitor pregnancies complicated by GDM, particularly for insulin management. Increased adoption of CGM in GDM patients may contribute to improved glycemic benefits and appropriate management.

EP168 / #157

Topic: ***AS06 Glucose sensors***

DO OVERWEIGHT OR OBESITY IMPLY A WORSE GLYCEMIC CONTROL AMONG PATIENTS WITH TYPE 1 DIABETES?

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Background and Aims: The global increase in the prevalence rates of overweight or obesity has also affected patients with type 1 diabetes (T1D), where this disease had traditionally been associated with a lean phenotype. On the other hand, the effect of obesity on new glycemic control metrics obtained from continuous glucose monitoring (CGM) in T1D is poorly understood. We wanted to know the prevalence of overweight/obesity in a sample of patients with T1D with flash-type CGM. To assess whether there is any relationship between BMI and the different CGM glycemic control metrics or HbA1c.

Methods: 225 patients with T1D (47.1% ♀, mean age 42.9 ± 14.7 years) with a CGM for a minimum of 6 months were analyzed by downloading their CGM and collecting clinical and anthropometric variables.

Results: 35.1% (79/225) of the T1D patients had overweight and 17.3% (39/225) lived with obesity, while the remaining 47.6% had a normal weight. A negative correlation was found between GMI and BMI (-0.2; p = 0.008) and HbA1c (-0.2; p = 0.01). In contrast, a positive correlation was observed between the total dose of insulin and the BMI (0.3; p < 0.0001). No significant correlations were found between BMI and TIR, TAR, TBR, CV, average glucose, or average daily readings.

Conclusions: Overweight or obesity do not imply worse glycemic control in patients with T1D or less use of CGM. Possibly, and in order to achieve a good glycemic control, more units of insulin are necessary in these patients which, in turn, makes weight control more difficult.

EP169 / #539

Topic: ***AS06 Glucose sensors***

CONTINUOUS GLUCOSE MONITOR (CGM) DERIVED GLYCEMIC OUTCOMES AMONG REAL-TIME CGM VS. FLASH CGM USERS IN A MULTI-CENTER EMR DATABASE FOR PEOPLE WITH T1D

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Background and Aims: Evidence from clinical trials suggest that use of CGM devices decreases hypoglycemia, but no real-world studies have demonstrated efficacy of real-time CGM vs. flash CGM device use in improving CGM derived glycemic outcomes. A flash or intermittently scanning CGM (isCGM) provides glucose levels immediately upon scanning sensor; whereas real-time CGM (rtCGM) device automatically transmits a continuous stream of glucose data to the user. We examined efficacy of isCGM vs. rtCGM device use using real-world EMR data from 19 endocrinology clinics participating in the T1DX-QI Collaborative.

Methods: Main outcomes were a) mean time in range (TIR: 70-180 mg/dL), b) time above range (TAR: ≥250 mg/dL) and c) time below range (TBR: <70 mg/dL). Patients ≥6 years with T1D from 2018 to 2022 were included. Discriptive differences between isCGM and rtCGM groups were assessed using chi-square and Mann-Whitney U tests. Bootstrapped point estimates and 95% CIs were reported. Linear mixed models examined association between type of CGM and TIR adjusting for covariates.

Results: This analysis included 6234 people in the rtCGM group and 412 people in the isCGM group. In the overall study population, mean TIR was higher for rtCGM users relative to isCGM users (Mean(95% CI): 50 (49-51) vs. 40 (38-43)) [p = 0.0001], mean TBR was lower for rtCGM users relative to isCGM users (Mean (95% CI): 1.9 (1.8-2.0) vs. 2.6 (2.2-3.0)) [p = 0.001] and mean TAR was also lower for rtCGM users (Mean(95% CI): 19 (18-20) vs. 26 (23-30)) [p < 0.001].

Conclusions: We found improved CGM derived glycemic outcomes for rtCGM relative to the isCGM grroup.

EP170 / #549

Topic: ***AS06 Glucose sensors***

HEMOGLOBIN A1C LEVELS AMONG PEOPLE WITH TYPE 1 DIABETES SWITCHING FROM SELF-MONITORING OF BLOOD GLUCOSE TO REAL-TIME CGM USE: A RETROSPECTIVE LONGITUDINAL STUDY

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Background and Aims: T1D Exchange Quality Improvement Collaborative (T1DX-QI) is a network of 50 Diabetes clinics across the U.S. sharing data and contributing to QI efforts. In this retrospective, longitudinal analysis, we aimed to examine A1c levels for blood glucometer (BGM) users having switched to continuous glucose monitor (CGM) within a 5-year follow-up period.

Methods: We used T1DX-QI EMR data to identify BGM users within a year of T1D diagnosis and follow them for a 5-year period to identify switch to CGM. BGM users at baseline are described as T1D patients with first available evidence of BGM use after 1-year post T1D diagnosis, with an additional record of BGM use from a preceding clinic visit. BGM users who switch to CGM are described as BGM users at baseline who switched to CGM use at any of their subsequent clinic visits within the 5-year period. Change in A1c was examined across both groups before and after device switch. Change in A1c was also examined for people using CGM at baseline and having switched to BGM use.

Results: Of 18,169 BGM users, 7,709 switched to CGM use. Mean(SD) duration between switch from BGM to CGM was 0.9yrs (1.2). Those who switched from BGM to CGM mean(SD) A1c at baseline was 8.6 (2.1) and after switch to CGM was 8.0 (1.7) [$p < 0.001$]. For those who switched from CGM to BGM, A1c at baseline and after switch to BGM was 8.2 (2.1) and 8.4(1.9), respectively [$p < 0.001$].

Conclusions: In this population-level analysis of real-world data, CGM initiation was associated with lower A1c, whereas CGM discontinuation was associated with increased A1c.

EP171 / #534

Topic: ***AS06 Glucose sensors***

ACCURACY OF THREE FACTORY-CALIBRATED CONTINUOUS GLUCOSE MONITORS DURING INPATIENT AEROBIC EXERCISE AND AT HOME IN INDIVIDUALS WITH TYPE 1 DIABETES

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Background and Aims: Continuous glucose monitors (CGMs) are valuable tools for improving glycemic control, but their accuracy may be impacted by exercise. We aimed to compare the accuracy of the three latest factory-calibrated CGM systems available in Europe during aerobic exercise and in general.

Methods: Thirteen adults with type 1 diabetes (3 females, age 59 ± 9 years, HbA1c $7.2 \pm 0.6\%$) simultaneously wore a Dexcom G6, a Guardian 4 and a FreeStyle Libre 2 sensor during an inpatient 1-hour moderate-intensity (50% VO_2-max) exercise session followed by a 2-hour post-exercise rest phase and a 3-day home period. During the inpatient session, venous plasma glucose (PG, Yellow Spring Instrument 2300 STAT+) and capillary blood glucose (BG, Contour Next One) were measured every 5-15 minutes. At home, BG was measured five times daily. Sensor accuracy was assessed by median absolute relative difference (MARD) and Clarke-Error-Grid analysis (CEGA).

Results: During exercise, no statistically significant differences were seen between the CGM systems in BG-derived MARD (Dexcom 12.6%, Guardian 10.7%, and Libre2 17.2%; $p = 0.31$) and CEGA Zone AB (100%, 96.8%, and 100%; $p = 0.37$). Similar results were observed for the entire inpatient period and using PG as reference. At home, MARD for FreeStyle Libre 2 (16.3%) was significantly higher than for Dexcom G6 (10.2%) and Guardian 4 (11.9%), $p = 0.02$. CEGA Zone AB was comparable between sensors (97.7%, 99.0% and 98.0%; $p = 0.42$).

Conclusions: Accuracy of FreeStyle Libre 2 was numerically, but non-significantly, lower during aerobic exercise, and significantly lower during the home period compared to Dexcom G6 and Guardian 4.

EP172 / #679

Topic: ***AS06 Glucose sensors***

PRACTICAL STRATEGIES TO INCREASE CONTINUOUS GLUCOSE MONITOR (CGM) USE FOR UNDERSERVED PATIENTS WITH T1D IN THE US: RESULTS FROM THE T1D EXCHANGE MULTICENTER EQUITY STUDY

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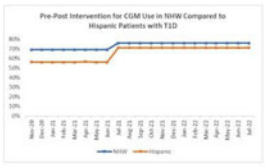
Background and Aims: Studies have demonstrated lower use of CGM in Non-Hispanic Black (NHB) and Hispanic patients compared to Non-Hispanic White (NHW) patients with type 1 diabetes (T1D) in the United States. This study describes practical solutions from the T1D Exchange Quality Improvement Collaborative (T1DX-QI) to increase CGM use and reduce disparities.



Methods: T1DX-QI recruited 2 adult and 3 pediatric endocrinology centers serving 13,000+ patients with a mean (SD) age of 25.9 (15.6). Aggregate baseline data were stratified by race and ethnicity between November 2020 and June 2021. Centers met monthly to identify contributors and brainstorm and prioritize interventions from June to July 2021. Centers used rapid Plan-Do-Study-Act improvement cycles to test interventions from July 2021 to September 2022. Successful interventions such as provider bias training, translation of CGM materials, CGM education in other languages, SDOH screening, and shared decision-making were expanded and sustained. Data was reported monthly to the coordinating center and plotted on a trend chart. Statistical analysis testing for significance between pre and post-interventions was conducted using McNemar's test.

Results: Pre-intervention median CGM use was 69% among NHW patients, 51% among NHB patients, and 56% among Hispanic patients. The median increased by 7% in NHW, 12% in NHB, and 15% in Hispanic patients. The gap between NHW and NHB was reduced by 5% and the gap between NHW and Hispanic patients were

reduced by 6%. The trend was significant with a P value <0.05 for both groups.

Conclusions: QI methodology is feasible in reducing disparity gaps and increasing CGM use.

EP173 / #161

Topic: ***AS06 Glucose sensors***

IMPUTATION MODEL FOR GLUCOSE VALUES OUT OF MEASURING RANGE FOR CONTINUOUS GLUCOSE MONITORING

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Background and Aims: Continuous glucose monitors (CGMs) have an upper detection limit of typically 22.2 mmol/L (400 mg/dL). This might bias CGM metrics. We aimed to develop and validate a statistical model for imputing CGM values above the upper detection limit.

Methods: We analysed in-hospital CGM data from 105 patients with diabetes. A Bayesian non-parametric latent Gaussian process regression model was applied to the CGM data intentionally censored at the 70% and 80% percentile (i.e., 30% and 20% censoring during a day) and compared to the uncensored CGM data. Three different covariance functions for the latent Gaussian process were examined. The performance of the imputation model was assessed by the bias and the mean squared error (MSE) of standard CGM metrics, i.e., mean glucose level, standard deviation (SD) and coefficient of variation (CV).

Results: For 20% censoring, the performance of the imputation model was very high across the three covariance models with MSE (range) 0.0008 to 0.2 and bias (range) -0.02 to 0.07 of standard CGM metrics. For 30% censoring, the performance of the imputation model was lower with MSE (range) 0.002 to 1.7 and bias (range) -0.03 to 0.3 of standard CGM metrics. Generally, one covariance model was superior with MSE <0.09 and <0.2 and absolute values of bias <0.03 and <0.03 of all CGM metrics for 20% and 30% censoring, respectively.

Conclusions: An imputation model for glucose values above the upper detection limit of CGMs was developed and validated. This enables more unbiased quantification of CGM metrics for patients with moderate to severe hyperglycemia.

EP174 / #405

Topic: ***AS06 Glucose sensors***

THE IMPACT OF REAL WORLD CGM DATA COVERAGE PATTERNS ON THE ACCURACY OF THE GLUCOSE MANAGEMENT INDEX

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Background and Aims: The estimation of the Glucose Management Index (GMI) from intermittently scanned CGM devices is often hampered by data loss. Given that real data loss patterns are not random, we sought to understand the impact on accuracy of GMI estimates.

Methods: We used de-identified real world data from the Bigfoot commercial database to analyze CGM data from the Bigfoot Unity System. We identified 655 2-week periods where CGM data availability, defined as the percent of 15-minute intervals with a valid reading, was greater than 90%. We then calculated GMI, which we considered the ''true'' GMI. To realistically simulate data loss from intermittent scanning, we utilized 338 real use data capture patterns over a 2-week period to delete data from the periods with high data availability. As a comparison, we also simulated random data loss by randomly sampling from the periods with high data availability.

Results: The random data loss simulation produced estimates of GMI which remained stable. Even with large amounts of data missing (~95%), fewer than 1% of absolute errors were greater than 0.5%. When real loss patterns are considered, the risk of poor GMI estimation increases. To maintain an approximately 1% chance of large errors (> 0.5%) for a 14-day period, at least 50% data availability is required, as shown in Figure 1.

Conclusions: Real data loss patterns using scanned CGM devices introduce substantially more error into GMI estimations than random loss. Nonetheless, 50% data availability is adequate to limit the rate of clinically meaningful errors.

EP175 / #475

Topic: ***AS06 Glucose sensors***

NON-INVASIVE GLUCOSE METER TECHNOLOGY: AN EXPLORATORY STUDY OF BRAZILIAN POPULATION COSTS

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Background and Aims: The health care(HC) costs are progressing exponentially. Diabetes affects more than 450 million people. Uncontrolled Diabetes increase complications and further increase the HC costs. Daily finger pricks contribute to poor Diabetes compliance and control. Non-invasive glucose meter devices(NIGMD) have a potential to improve the Diabetes outcomes including the long-term costs though compliance. However, the implantation cost is important to a fast implementation. Our goal is esteeming the NIGMD costs to makes his implantation easy and faster in Brazilian public HC system.

Methods: Was searched in the last twelve mounts the cost of bids in all Brazilian states to purchase standard devices and supplies to invasive point of care glucose measure. Was used an online tool in https://www.cotacaozenite.com.br to search bids between April 2021 and April 2022. The prices founded was converted from Brazilian reais to Euros in the October 6th, 2022.

Results: The median price for a standard invasive glucose meter was 14,48 Euros, covering nineteen bids. The lancing median price was 1,06 Euros covering three bids. The lancet median price was 0,03 Euros covering thirty-seven bids. The strips median price was 0,19 Euros covering 53 Bids. So that the cost for one glucose measurement was 15,79 Euros while the cost of three times a day measurement for one year was 264,53 Euros.

Conclusions: The technology evolution must be less expensive. Taking it account the ideal price of a NIGMD was about 15 Euros. However, in a public economic perspective targeting a one-year savings, a cost of 260 Euros still a big deal.

EP176 / #279

Topic: ***AS06 Glucose sensors***

INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING SYSTEMS IN A PEDIATRIC INTENSIVE CARE UNIT, USEFULNESS AND RELIABILITY

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Background and Aims: In recent years, continuous glucose monitoring (CGM) systems have been a revolution in the treatment of diabetes. Although their clinical use is mostly restricted to Diabetes units, the information provided could be very useful in other hospital settings such as pediatric intensive care units (PICU). Our aim was to study the use of intermittently scanned CGM systems in the PICU.

Methods: We analyzed the use of CGM in patients with Type 1 diabetes (T1D) admitted to the PICU of our center in the period of September 2021 to September 2022. In addition, we compared the CGM-reported glucose data versus data from capillary blood glucose (CBG) measurement.

Results: 12 patients (58% female) were admitted to the PICU during the study period due to T1D debut (75%), ketoacidosis (16.7%) and severe hypoglycemia (8.3%). 5 were excluded due to lack of CGM data. 8 patients were included in the analysis admitted for T1D debut (n = 6), ketoacidosis (n = 1) and severe hypoglycemia. Trend arrows were recorded in the follow-up of 1 patient. Mean absolute relative difference between GCM and CBG was 11,5%, decreasing after 8 hours. Clinical and CGM data are shown in the following table:

PICU stay (days)	CGM wearing time (%)	CGM scans (Number per day)
2.5±3.1	92.4±16.8	17.7±5.3

Conclusions: CGM systems are a tool that provides very useful information in the management of patients with T1D in the PICU. Future works should examine the clinical utility of trend arrows and sensor warm-up period.

EP177 / #710

Topic: ***AS06 Glucose sensors***

DYNAMIC INTERFERENCE TEST METHOD FOR CONTINUOUS GLUCOSE MONITORING SENSORS

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Background and Aims: Only few is known about the impact of potential interfering substances on the performance of needle

sensors for continuous glucose monitoring (CGM). Static in-vitro testing similar to blood glucose test strip interference protocols is not optimal, as CGM needle sensors need an almost stable fluidic environment for proper function.

Methods: We designed a test bench where the needle sensors are placed in a 15x2x500 mm channel, which is constantly fueled with buffer solution at a low fuel rate by means of several HPLC pumps. The system allows for testing of different glucose gradients and also for dynamic interference tests at stable glucose levels with increasing and decreasing interferent concentrations. We validated the set-up using Dexcom G6 (G6) and Freestyle Libre 2 (L2) sensors using YSI 2300 Stat plus as the reference glucose device at room temperature.

Results: Glucose changes were closely tracked by G6 after calibration and YSI. Factory calibrated L2 displayed ~50% lower readings than G6. We dynamically exposed the sensors to increasing and decreasing concentrations of maltose without signal changes. G6 but not L2 readings were substantially elevated by acetaminophen, while L2 but not G6 was substantially affected by xylose.

Conclusions: Dynamic interference testing for CGM sensors provides a useful in-vitro tool for fast and economic identification and/or exclusion of potentially interfering substances. Subsequent clinical studies can focus on substances that show in-vitro interference. This test may support efforts to improve the accuracy of future CGM sensor generations.

EP178 / #917

Topic: ***AS06 Glucose sensors***

GLYCEMIC VARIABILITY AND TIME IN RANGE AFFECT THE RISK OF OVERWEIGHT AND HIGH LDL CHOLESTEROL IN CHILDREN AND YOUTHS WITH TYPE 1 DIABETES

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Background and Aims: Poor long-term glycaemic control, measured by HbA1c, hasd been (is) recognized as the main factor affecting CVRFs profile and CVD risk. To date, the possible association between short-term glycaemic control and variability measured by continuous glucose monitoring (CGM) metrics and CVRFs has not been explored. The aim of this study is to test the hypothesis that CGM metrics of contribute to CVRFs exposure in children and youths with T1D.

Table 1. Logistic regression analyses.

	Dependent variable: BMI percentile ≥85th								
	Total			Males			Females		
Variables	OR	95%CI	p value	OR	95%CI	p value	OR	95%CI	p value
Age	0.918	0.875 – 0.964	0.001	0.91	0.85 – 0.974	0.007	0.947	0.884 – 1.013	0.115
Diabetes duration	1.028	0.975 – 1.084	0.313	1.049	0.974 – 1.13	0.21	0.99	0.917 – 1.068	0.79
Gender (1=Female)	0.712	0.512 – 0.991	0.044	NA	NA	NA	NA	NA	NA
HbA1c (%)	1.011	0.824 – 1.23	0.919	0.80	0.591 – 1.081	0.146	1.307	0.996 – 1.716	0.064
CGM device (isCGM vs rtCGM)	1.483	0.874 – 2.516	0.144	1.914	0.885 – 4.138	0.099	1.121	0.543 – 2.313	0.757
Insulin therapy (MDI vs CSII)	0.791	0.461 – 1.302	0.356	0.782	0.384 – 1.595	0.5	0.684	0.342 – 1.369	0.283
TBR (1=>5%)	0.815	0.558 – 1.192	0.291	0.966	0.533 – 1.943	0.904	0.729	0.434 – 1.223	0.231
%CV (1=>36%)	1.424	1.004 – 2.206	0.044	1.026	0.541 – 1.943	0.908	2.152	1.195 – 3.874	0.011
	R^2 Nagelkerke= 0.05			R^2 Nagelkerke= 0.051			R^2 Nagelkerke= 0.072		
	Dependent variable: LDL-C > 100 mg/dL (>2.6 mmol/L)								
	Total			Males			Females		
Variables	OR	95%CI	p value	OR	95%CI	p value	OR	95%CI	p value
Age	0.931	0.861 – 1.003	0.051	0.939	0.864 – 1.019	0.132	0.931	0.863 - 1.005	0.069
Diabetes duration	1.053	0.998 – 1.111	0.058	1.06	0.981 – 1.144	0.142	1.044	0.968 – 1.127	0.264
Gender (1=Female)	1.959	1.393 – 2.755	< 0.001	NA	NA	NA	NA	NA	NA
BMI	1.034	0.980 – 1.091	0.219	1.069	0.983 – 1.162	0.12	1.006	0.937 – 1.079	0.871
HbA1c (%)	1.08	0.87 – 1.342	0.485	0.824	0.59 – 1.153	0.259	1.346	0.999 – 1. 815	0.061
CGM device (isCGM vs rtCGM)	0.78	0.46 – 1.325	0.358	0.877	0.387 – 1.985	0.753	0.703	0.348 - 1.418	0.324
Insulin therapy (MDI vs CSII)	1.693	0.989 – 2.845	0.057	1.572	0.712 – 3.469	0.263	1.652	0.822 – 3.319	0.159
TIR (1=<70%)*	2.643	1.099 – 6.355	0.030	3.171	1.021 - 12.248	0.044	2.295	1.112 - 7.361	0.034
%CV (1=>36%)	0.87	0.579 – 1.307	0.503	0.951	0.493 – 1.835	0. 881	0.87	0.509 – 1.488	0.612
	R^2 Nagelkerke= 0.79			R^2 Nagelkerke= 0.056			R^2 Nagelkerke= 0.066		

Methods: BMI, blood pressure, lipid profile and CGM data of 805 children and youths with T1D were analysed. Binary logistic multivariable regression analyses were performed to test independent associations between cardiovascular risk factors (BMI percentile >85th, LDL-c>100 mg/dL, Blood Pressure >90th percentile) and CGM metrics according to gender and adjusting for confounding factors.

Results: In both males and females, correlation analysis showed that TBR <70 mg/dL, TBR <54 mg/dL, %CV and LBGI were positively correlated with BMI percentile. Mean glucose, its SD, TAR >180 mg/dL, TAR >250 mg/dL, HBGI positively correlated with LDL-c, whereas TIR inversely correlated with LDL-c in both malesmale and females. No significant correlations were found between CGM metrics and BP percentiles. Binary logistic multivariable regression analyses showed that TIR <70% significantly predicted LDL-c >100 mg/dL in both malesmale and females. Being overweightOverweight was significantly predicted by CV >36% in females.

Conclusions: This study provides novel insight regarding the contributioncontribute of CGM metrics to CVRFs exposure in children and youth with T1D demonstrating that the non-achievement of the recommended target for CV and TIR increase the risk of overweight in females and unfavourable lipid profile in both genders, respectively.

EP179 / #169

Topic: ***AS06 Glucose sensors***

SKIN REACTIONS TO FREESTYLE LIBRE PRO SENSOR USE AMONG PEOPLE WITH TYPE 1 DIABETES IN TROPICAL SINGAPORE

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Background and Aims: Skin reactions to diabetes wearables is one of the factors impeding the use of diabetes technology among people with type 1 diabetes. People living in the tropics may be at a higher risk of such reactions due to the higher humidity and sweating rate. Data about incidence of skin reactions

to diabetes wearables is lacking from the tropics. We aimed to study the incidence and severity of skin reactions to Freestyle Libre Pro sensor wear in tropical Singapore.

Methods: Twenty-seven adults with type 1 diabetes wore up to 3 Freestyle Libre Pro sensors over a period of 3 months. A single investigator (MZ) graded the skin reaction on removal of each sensor. (Grades: 1 No reaction, 2 Pruritus but no erythema, 3 Pruritus and Erythema without ulceration, 4: Skin ulceration)

Results: Sixty-five sensor sites were graded. None of the participants had ulceration at the insertion sites. Majority of the insertion sites, 42 (64.6%), had no reaction. Three (4.6%) had pruritus only while 20 (30.8%) sites had pruritus and erythema. No significant correlation between first and second sensor site reaction grade existed among 26 participants who wore two sensors one after the other.

Conclusions: Skin reactions to Freestyle Libre Pro sensors with pruritus and/or erythema occurred in 35.4% of the sensor wears which is much higher than 4-8% reported from American and European studies (T Bailey et al. Diabetes Technol Ther 2015, J Bolinder et al. Lancet 2016). Presence and severity of skin reaction on initial wear may not predict future reactions to sensor wear.

EP180 / #418

Topic: ***AS06 Glucose sensors***

INTERIM 365 DAY PERFORMANCE OF A LONG TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING SYSTEM WITH REDUCED CALIBRATION

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Background and Aims: A next-generation long-term, implantable sensor with redundant optical measurement electronics (ROME) and the ability to measure sensor degradation caused by foreign body response (FBR) has enabled development of an algorithm with reduced calibrations. Performance to 365 days with a reduced calibration scheme on day 7 and 14 is reported.

Methods: A feasibility study was conducted with 14 subjects with ROME sensors. Ten users were evaluated through day 365; 4 through day 300. A new CGM model incorporating changes related to sensor FBR and redundant sensor capabilities was utilized to calculate glucose with SMBG as reference. The data were post processed separately with two reduced calibration schemes, one with one calibration every 7th day and another with two calibrations occurring every 14th day (semi-monthly), following an initial 2-week period where calibrations were done twice a day. Accuracy was assessed against SMBG.

Results: Over 365 days, the 7-day calibration algorithm provided MARD vs. SMBG of 10.4% and 40/40% concurrence of 98.5% and the 14-day calibration algorithm provided MARD vs. SMBG of 10.3% and 40/40% concurrence of 98.8% compared to a 1 calibration per day MARD of 9.2% and 40/40% of 98.9%. MARD with SMBG when compared to that with YSI was previously demonstrated to be 1.4% higher.

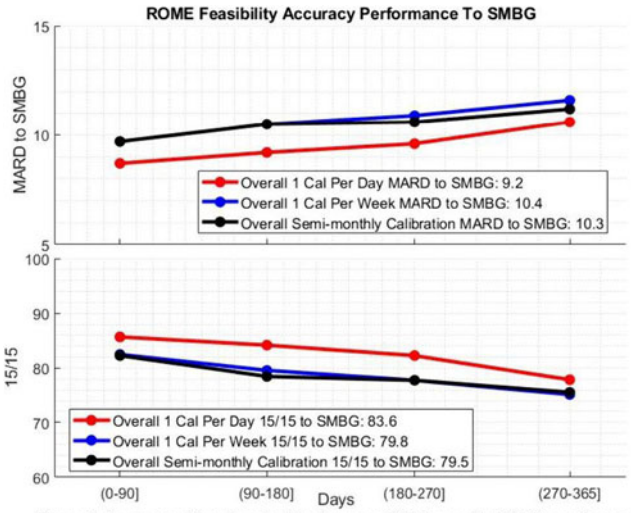

Figure 1: Accuracy with reduced calibration over 365 days, with SMBG as reference

Conclusions: Improvement in sensor chemistry and electronics allowed for a significant reduction in calibration frequency while maintaining clinical accuracy over one-year of use as measured with SMBG as reference.

EP181 / #204

Topic: ***AS06 Glucose sensors***

PROOF-OF-CONCEPT APPLICATION OF GLUCOSE DATA ANALYTICS TO IDENTIFY DIABETES GLUCOTYPES AND PHENOTYPES: A PRECISION MEDICINE STRATEGY TO DIFFERENTIATE BETWEEN HNF1A-MODY AND TYPE 1 DIABETES

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Background and Aims: Monogenic diabetes due to mutations of the *HNF-1α* gene (HFN1A-MODY) is the most common monogenic diabetes phenotype and is often mis-diagnosed as type 1 diabetes (T1D), leading to unnecessary life-long insulin treatment. Continuous glucose monitoring (CGM) offers the opportunity to identify various ''glucotypes,'' supporting a precision medicine approach to diabetes phenotype-genotype correlation. We sought to evaluate if HNF1A-MODY has a distinctive CGM glucotype, in comparison to individuals with T1D

Methods: Dexcom CGM data from genetically confirmed HNF1A-MODY (n = 5) and T1D (n = 115) subjects were analyzed, calculating multiple glucose metrics comparing the two cohorts, including measures of within- and between-day variability, including Mean Amplitude of Glycemic Excursion (MAGE), % coefficient of variation for the entire time period (%CV) and coefficient of variation for each hour ($\%CV_{b\_1\ hour}$).

Results: The two cohorts showed no statistically significant differences in Mean Glucose, Glucose Management Indicator, %

Time-In-Range, %CV, or MAGE. The HNF1A-MODY and T1D cohorts had minimum $\%CV_{b\_1\ hour}$ of 11.3 ± 4.4 and 18.±4.9, respectively (p = 0.02), and maximum $\%CV_{b\_1\ hour}$ of 33.9 ± 5.0 and 50.3 ± 10, respectively (p < 0.001). All HNF1A-MODY patients had minimum $\%CV_{b\_1hour} \leq 17.3\%$ and maximum $\%CV_{b\_1\ hour} \leq 37.1\%$. In contrast, only 12 of 115 T1D patients had both a minimum and maximum $\%CV_{b\_1\ hour}$ below these thresholds. (p = 0.0002)

Conclusions: To our knowledge, this is the first application of CGM for identification of diabetes genotypes. HNF1A-MODY is characterized by a very low between-day glucose variability within 1 hour segments. CGM-derived glucose metrics have potential applicability for the screening for monogenic diabetes in the T1D population.

EP182 / #462

Topic: ***AS06 Glucose sensors***

VARIATION IN THE REPORTING OF GLUCOSE VALUES DURING SIMULTANEOUS GLUCOSE SENSOR WEAR

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Background and Aims: We evaluated variations in glucose values recorded by simultaneously worn glucose sensors.

Methods: Children and adolescents (n = 44) recruited to the hybrid-closed loop arm of the CLOuD study (Closed-Loop from Onset of Diabetes; NCT02871089) had multiple two-week periods of simultaneous sensor wear e.g. sensors A and B or sensors C and D were worn together. Glucose metrics were calculated from the different sensors and paired sample t-tests used to evaluate differences between the sensors.

Results: There were 36 pairwise comparisons between sensor A and sensor B and significant differences were observed across all 10 measured glucose outcomes (P < 0.05). Sensor A recorded a lower mean glucose by -0.4mmol/L (95%CI: -0.8, -0.1) than sensor B. Sensor A recorded 2.1 percentage points (95%CI: -3.4, -0.9) less time with glucose <3.9mmol/L than sensor B. The difference in time spent with glucose in target range 3.9 to 10mmol/L was 7.9 percentage points (95%CI: 5.0, 10.7) greater with sensor A than sensor B. There were 32 pairwise comparisons between sensor C and sensor D and 9 out of 10 glucose metrics were significantly different (P < 0.05). Sensor C recorded higher mean glucose by 1.2mmol/L (95%CI: 1.0, 1.5) than sensor D. Sensor C recorded 9.9 percentage points (95%CI: -11.8, -8.0) less time with glucose <3.9mmol/L than sensor D. The difference in time spent with glucose in target range 3.9 to 10mmol/L was 3.9 percentage points (95%CI: 2.2, 5.7) greater with sensor C than sensor D.

a

Sensor Glucose Endpoints	Sensor A (N=36)	Sensor B (N=36)	Mean difference (95% CI)	P value
Mean Glucose (mmol/L)	7.6 ± 0.5	8.0 ± 0.9	-0.4 (-0.8, -0.1)	0.009
Time with glucose: (%)				
3.9-10mmol/L	78.7 ± 5.1	70.8 ± 8.0	7.9 (5.0, 10.7)	<0.001
<3.9mmol/L*	3.2 (2.3, 4.4)	4.3 (2.5, 7.4)	-2.1 (-3.4, -0.9)	0.001
<3.0mmol/L*	0.5 (0.2, 0.9)	0.8 (0.3, 2.1)	-0.7 (-1.2, -0.1)	0.019
>10.0mmol/L	17.7 ± 5.4	23.7 ± 8.3	-6.0 (-9.2, -2.7)	0.001
>16.7mmol/L*	0.3 (0.0, 1.8)	1.1 (0.0, 3.6)	-1.1 (-1.6, -0.5)	<0.001
SD of glucose (mmol/L)	2.6 ± 0.4	3.0 ± 0.5	-0.4 (-0.5, -0.3)	<0.001
CV of glucose (%)	34.6 ± 4.1	37.7 ± 4.6	-3.1 (-4.3, -2.1)	<0.001

b

Sensor Glucose Endpoints	Sensor C (N=32)	Sensor D (N=32)	Mean difference (95% CI)	P value
Mean Glucose (mmol/L)	8.3 ± 0.7	7.1 ± 2.7	1.2 (1.0, 1.5)	<0.001
Time with glucose: (%)				
3.9-10mmol/L	73.1 ± 6.9	69.2 ± 8.3	3.9 (2.2, 5.7)	<0.001
<3.9mmol/L*	2.2 (1.6, 3.4)	12.8 (8.0, 17.2)	-9.9 (-11.8, -8.0)	<0.001
<3.0mmol/L*	0.4 (0.2, 0.8)	3.0 (1.8, 5.1)	-2.7 (-3.6, -1.8)	<0.001
>10.0mmol/L	24.2 ± 7.3	17.3 ± 7.0	6.9 (5.0, 8.7)	<0.001
>16.7mmol/L*	1.7 (0.7, 4.6)	1.0 (0.0, 3.2)	1.1 (0.6, 1.6)	<0.001
SD of glucose (mmol/L)	3.2 ± 0.5	3.1 ± 0.6	0.1 (-0.1, 0.1)	0.35
CV of glucose (%)	37.8 ± 3.3	43.8 ± 4.4	-6.0 (-7.0, -4.9)	<0.001

* Variable winsorized at the 10th and 90th centiles. Data reported as mean ± SD, or median (IQR). Standard Deviation (SD), Coefficient of Variation (CV)

Conclusions: There is variability in the reporting of glucose values by different sensors across different glucose ranges.

EP183 / #489

Topic: ***AS06 Glucose sensors***

THE EFFECT OF RECENT EXPOSURE TO HYPOGLYCAEMIA ASSESSED BY CONTINUOUS GLUCOSE MONITORING ON COUNTERREGULATORY RESPONSES TO CONTROLLED HYPOGLYCAEMIA IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Recent treatment initiatives, including continuous glucose monitoring (CGM), have reduced the exposure to hypoglycaemia in people with type 1 Diabetes (T1D), especially in people with impaired hypoglycaemia awareness. In these new settings, we aimed to assess the impact of recent exposure to CGM-recorded hypoglycaemia and awareness status on the counterregulatory responses to hypoglycaemia in people with T1D.

Methods: In a two-centre study within the Hypo-RESOLVE project, 42 patients with T1D (HbA1c (mean ± SD) 61.9 ± 10.3mmol/mol, diabetes duration 23.5 ± 13.0 years, 20 women, 29 CGM users, and 19 participants with impaired awareness) wore an intermittently scanned CGM (isCGM) (Freestyle Libre 1®) for one week to detect hypoglycaemic metrics before a standardised hyperinsulinaemic hypoglycaemic (2.8 ± 0.1mmol/L) glucose clamp. Symptomatic responses (Edinburgh Scale) and counterregulatory hormones were measured during the clamp.

Results: Frequency of hypoglycaemia (<3.9mmol/L, ≥15min) in the week prior to clamp was (median (IQR) 5.8 (3.1-8.8) events, and time below range (TBR) (<3.9mmol/L) was 5.7 (3.0-9.9) %. CGM-recorded hypoglycaemia in the week before clamp was negatively associated with the adrenaline response (β: -0.09 95%CI (-0.16 to -0.02) nmol/L, p = 0.011), particularly driven by recurrent level 2 hypoglycaemia (<3.0mmol/l, ≥15min) (β: -0.22 95%CI (-0.43 to -0.02) nmol/L, p = 0.034). Hypoglycaemia awareness status was neither associated with hormonal nor symptom responses to hypoglycaemia.

Conclusions: Recurrent CGM-recorded hypoglycaemia predicts an attenuated counterregulatory sympathoadrenal response to hypoglycaemia in people with T1D and seems more important than awareness status.

EP184 / #543

Topic: ***AS06 Glucose sensors***

WHEN IT JUST BECOMES A BLIP – A QAULITATIVE STUDY OF PATIENT EXPERIENCES OF USING FLASH GLUKOSE MONITORING.

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Background and Aims: In 2016, a new generation of technological measuring equipment, Flash Glucose Monitor (FGM), came to Denmark. An observational real-life study from our regional diabetes database shows that changing the measurement method from self-monitoring of blood glucose to FGM significantly reduced the patient's HbA1c over 12 months. There is limited empirical evidence on the patient's experience of using FGM. The aim was to investigate adult type 1 diabetes patients experiences during the transition and use of flash glucose monitoring.

Methods: This project employed a qualitative methodology. Data was collected through individual semi-structured telephone interviews. Seven patients from an outpatient diabetes clinic were interviewed using a flexible topic guide.

Results: Four themes and appertaining subthemes were identified. The themes were: When it just becomes a blip, from a passive to active co-operation, a liberation in life, and a sense of security living with the disease.

Conclusions: What was prevalent in the interviews was that FGM provided liberation and relief in life. It was emphasized that it was easy and fast, and the procedure was reduced to just a blip. The study pointed out that the patients experienced certain disadvantages with usage, but the they agreed that the disadvantages were by far outweighed by the advantages. Several patients experienced that FGM could promote involvement in the consultation due to the curves that FGM generates. A finding that was not described previously, showed the time aspect of the use of FGM in everyday life, in the form of liberation, and the opportunity to stay in the present.

EP185 / #859

Topic: ***AS06 Glucose sensors***

POSTPRANDIAL SYMPTOM PATTERNS IN PATIENTS WITH POST-BARIATRIC HYPOGLYCAEMIA

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Background and Aims: Post-bariatric hypoglycaemia (PBH) is a metabolic complication of Roux-en-Y gastric bypass (RYGB), particularly manifesting after meals. Diagnosis usually relies on the Whipple's triad (hypoglycaemic symptoms at low glucose concentrations, relieved after correction). However, the high variability and subjectivity of symptom perception challenges clinical decisions. Here, we evaluated patient-reported postprandial symptoms with respect to continuous glucose monitoring patterns.

Methods: Twenty-five patients (age: 48.5 ± 13.2 years, BMI: 27.3 ± 5.4 kg/m^2, female: 76%) with diagnosed PBH after RYGB wore a blinded Dexcom G6 sensor and logged their meals and symptoms (categorised as autonomic, neuroglycopenic and gastrointestinal) using an eDiary over 50 days. Postprandial periods (PPPs) (defined as 3h after meals) were assessed for the presence of Level 1 or Level 2 hypoglycaemia (nadir sensor glucose [SG] <3.9mmol/L or <3.0mmol/L) and symptoms. The timing of symptoms was classified as early-postprandial (meal intake-halved time distance between peak and nadir SG) and near nadir SG (end of first period-end of the 3h-PPP).

Results: Among 4234 analysed PPPs, the highest symptom frequency (41.1%) occurred during PPPs with Level 2 hypoglycaemia; however, symptoms also occurred in PPPs without hypoglycaemia (15.9%). In PPPs with hypoglycaemia (PPP+H), 37.1% of symptoms were classified as early-postprandial (before reaching low glucose concentrations). Of the reported symptoms during PPPs+H, 41.9% of gastrointestinal symptoms, 25.0% of autonomic symptoms, and 33.3% of neuroglycopenic symptoms were classified as early-postprandial.

Conclusions: The relationship between the occurrence of hypoglycaemia-suggesting symptoms and biochemical PBH is complex and challenges the diagnostic utility of the Whipple's triad for clinical decision-making. Investigator Initiated Study supported by Dexcom Inc.

EP186 / #262

Topic: ***AS06 Glucose sensors***

LONG-TERM COST-UTILITY ANALYSIS OF REAL-TIME VERSUS INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN ADULTS WITH TYPE 1 DIABETES IN BELGIUM

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Background and Aims: To assess long-term cost-effectiveness of Dexcom G6® real-time continuous glucose monitoring (rtCGM) with alerts compared to FreeStyle Libre 1® intermittently scanned CGM (isCGM) without alerts in adults with type 1 diabetes (T1D) in Belgium.

Methods: The IQVIA CORE Diabetes Model was used to estimate cost-effectiveness. The baseline cohort was sourced from the randomised ALERTT1 trial (NCT03772600). Mean age was 42.9 years (SD 14.1), mean baseline HbA1c was 7.4% (SD 0.9). People using rtCGM reduced their HbA1c by 0.36% points based on the 6-month mean between-group difference. Both rtCGM and isCGM were priced at €3.92/day (excluding VAT) according to the Belgian reimbursement system. The analysis was performed from a Belgian healthcare payer perspective, considering only direct medical costs. A lifetime time horizon was applied. Probabilistic and one-way sensitivity analyses were used to account for parameter uncertainty.

Results: In the base case, rtCGM dominated isCGM, resulting in lower costs associated with diabetes-related complications and better health outcomes. Main drivers associated with these health improvements favouring rtCGM were less fear of hypoglycaemia, lower HbA1c and less severe hypoglycaemic events. Results were robust under a wide range of one-way sensitivity analyses. Increasing the rtCGM price to €5.11/day or €12.34/day, resulted in rtCGM becoming cost-neutral or reaching an incremental cost-effectiveness ratio of €40,000/quality-adjusted life year, respectively.

Conclusions: Dexcom G6® rtCGM with alerts has both economic and clinical benefits compared to FreeStyle Libre 1® isCGM without alerts in adults with T1D in Belgium, as rtCGM appears to be dominant or cost-effective over isCGM, depending on the price of rtCGM.

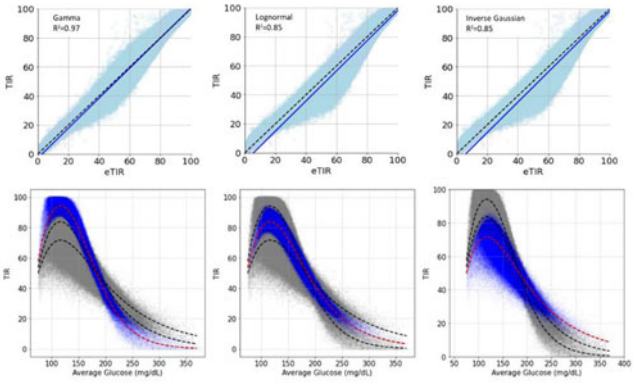

Figure 1. Top: Linear regression (blue line) of measured TIR compared to estimate (eTIR) values from average glucose and glucose standard deviation for Gamma, Lognormal, and Inverse Gaussian distributions (n= 739,037 14-day sensors from 29,164 people self-identified with type 1 and type 2 diabetes). Dashed unity lines are presented as references. Bottom: distribution of average glucose and TIR in CV tertile. Blue dots are subjects in first (bottom left, CV mean 24.7%, range 8.2-29.5%), second (bottom middle, CV mean 33.2%, range 29.5-37%), and third (bottom right, CV mean 43%, range 37-84.6%) tertile groups, grey dots otherwise. Red curves are modeled TIR and AG curve under group average CV using Gamma distribution, black curves otherwise.

EP187 / #320

Topic: ***AS06 Glucose sensors***

GLUCOSE VARIABILITY ALTERS THE RELATIONSHIP BETWEEN AVERAGE GLUCOSE AND TIME IN RANGE: IMPLICATIONS FOR CLINICAL PRACTICE

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Background and Aims: Investigate the effects of glucose variability, measured as coefficient of variation (CV) on the relationship between average glucose (AG) and time in range (TIR), and determine the distribution that best fits these two glucose metrics.

Methods: Real-world glycemic metrics were evaluated among users of flash glucose monitoring (FLASH, FreeStyle Libre, Abbott Diabetes Care) and the effects of CV on AG-TIR relationship were investigated. In order to determine the best fit model, we examined nine different scenarios and the initial goodness of fit was carried out using the fitDist function (R GAMLSS), Akaike information criterion (AIC).

Results: In total, glucose data from 739,037 qualified sensors of 29,164 from self-identified type 1 and type 2 diabetes users were retrieved. AG-TIR relationship is affected by CV with TIR varying up to 24% for the same AG. For AG of 120mg/dl (6.7 mmol/l), median (IQR) TIRs were 95 (92-97), 82 (82-87), and 71 (64-75)% for CV tertile groups (mean CV = 24.7, 33.2 and 43%, respectively). Of the nine scenarios examined, the three top-ranked distributions were Lognormal, Inverse Gaussian, and Gamma, with the latter demonstrating the best fit (Figure 1, $p < 0.0001$).

Conclusions: In clinical practice, TIR can be improved by reducing CV without altering AG, which has important clinical implications and offers one mechanism for the disconnect between TIR and glycated haemoglobin observed in some patients. The Gamma distribution is the best fit to analyse AG and TIR relationship, regardless of CV.

EP188 / #42

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ON THE ROLE OF "DIABETES TECHNOLOGY" FOR SELF-MANAGEMENT EDUCATION IN TYPE 1 DIABETES: EXPANDING AN IRANIAN SOFTWARE USING THE NATIONAL DIETARY PATTERN FOR CARBOHYDRATE COUNTING

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Background and Aims: Hopefully seeking for new insight for the absolute treatment, patients with type 1 diabetes (T1DM) have normally restricted opportunity to use a continuous subcutaneous insulin infusion for disease management, particularly in developing countries. A multiple insulin injection regimen is thus, commonly recommended. In an effort to involve the so-called ''diabetes technology'' to daily life of patients with the purpose of improving their self-management capabilities, an Iranian software (mobile application), named ''*Carbulin*'' (''*Carbu*'' (from carbohydrate)+ ''lin'' (from insulin)), was developed, the randomized, controlled trial of efficacy of which is currently ongoing.

Methods: To *expand* the ''*Carbulin*'', information on carbohydrate content of a near of 130 local foods were further added to the database including: 1) up to 5 most popular recipes of each of the Iranian ethnicities (Fars, Azari, Kurd, Gilak, Lur, Turkman, Qashqaei, Arab, and Balouch); and 2) up to 5 most common recipes of each of the 31 provinces of the country. Besides, calculation of the calorie consumed in selected activity and comparison with the energy content of specific amount of the selected food were also considered in the updated version.

Results: The expanded version of the ''*Carbulin*'' becomes specifically more individualized for type one diabetic patients with any ethnicity living in Iran. It also encourages the user to consume the healthier traditional foods and enables him/her to have a better control on energy intake and energy consumption.

Conclusions: Intended to involve patient with T1DM as an active member of the management team, expanded version of the ''*Carbulin*'' may help in Iran.

EP189 / #339

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EFFICACY OF MOBILE APP BASED DIABETES CARE PROGRAM IN REMOTE MANAGEMENT OF DIABETES

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Background and Aims: Background: The development of digital health technology, mainly health applications (''apps''), has changed the approach to management of metabolic disorders including diabetes. **Aims:** To study the efficacy of BeatO's mobile app based diabetes care program in remote management of diabetes

Methods: A retrospective analysis of 202 participants enrolled in BeatO's App based diabetes care program for 3 months, between 20 March to 30 June 2022. Participants received diabetes education, guidance on nutrition and doctor consultation through the BeatO app. They were connected through the app with the dedicated healthcoach during the period. The medication prescribed by the doctor were sent as part of program. The participants checked their blood glucose using BeatO's smartphone connected glucometer that works in unison with BeatO app. FBG, PPBG, HbA1c and weight at baseline and at 3 months were recorded.

Results: Of the 202 subjects, 96.5 % had Type 2 diabetes. The majority were in the age between 41-60 years (57.4%) and had diabetes from 2-5 years (32.2%). The mean FBG was reduced by 63mg/dL, PPBG by 87.28 mg/dL and HbA1c was reduced by 1.88 % (9.28 to 7.4%) at the end of 3 months from baseline. An average 2.5 kg weight reduction was observed. Average 25 mins/day walking was done by 61% of the users in the program.

Conclusions: BeatO's mobile app based diabetes-care program, which provides complete care including blood glucose monitoring, diabetes education, personalized nutrition therapy, physician consultation and the medicines provided at the doorstep, is an effective digital solution for management of diabetes

EP190 / #619

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

SAFETY OF A CGM-INFORMED INSULIN BOLUS CALCULATOR MOBILE APPLICATION FOR PEOPLE WITH TYPE 1 AND TYPE 2 DIABETES

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Background and Aims: People with diabetes on basal-bolus insulin regimens face challenges adjusting bolus doses. CGM systems can assist users with bolus doses optimization through trend arrows. The purpose of this study was to demonstrate the safety of a novel, CGM-informed insulin bolus calculator (IBC, Welldoc, Inc., Columbia, Maryland, U.S.A.) that applies trend arrow adjustments to the bolus insulin dose recommendation. This investigational software also provides real-time coaching on CGM data to assist users in improving their time in range.

Methods: Twenty-seven participants (T1 and T2 diabetes) using CGM (Dexcom, San Diego, California, U.S.A.) were enrolled in a 30-day prospective study where they were asked to use the mobile application to monitor their CGM data and calculate their insulin doses using the IBC. CGM metrics during the prospective 30-day period were compared to 30 days of baseline data.

Results: Nineteen participants who each used the IBC over 30 times during the study were pre-defined to be in the per-protocol group. The primary endpoint of non-inferiority was met, with an increase in TIR from 67.7% to 70.6% ($p = 0.0006$) without increase in hypoglycemia. In a sub-group analysis, individuals with T2 diabetes (59%) had a significant increase in TIR from 73.9% to 79.6%.

Conclusions: The data of this study showed that the use of a novel CGM-informed insulin bolus calculator with trend arrow dose adjustment within a mobile application was safe and provided individuals with real-time coaching on their CGM data.

EP191 / #592

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

MOBILE NUTRITIONAL DELIVERY SYSTEM FOR PEOPLE WITH INSULIN-TREATED DIABETES

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Background and Aims: People with insulin-treated diabetes often have challenges related to physical activity and hypoglycemia. Increasingly more people are using CGMs, which can provide users with blood glucose status every few minutes. Utilization of data from CGMs, as well as from physical activity sensors, and data from insulin pumps, are still yet to be optimized. We have previously demonstrated how these data could be used to automatically provide users with carbohydrates in liquid form, when users experience hypoglycemia, or approaches low glucose, as a stationary device. In the current project we aim to make a mobile device, which the user can carry along when hiking, or in other physically challenging situations.

Methods: We are utilizing data from CGM devices, physical activity trackers/smartwatches, as well as historical data of insulin doses and carbohydrate intakes, carbohydrates- and insulin on board from insulin pump systems, to make a mobile carbohydrate dispenser. To demonstrate the possibilities, we are using open-source solutions for accessing and using these data, and collaborating with do-it-yourself environments, to secure a substantial degree of user-involvement.

Results: The concept has been successfully demonstrated as a stationary system, see Randine et al. 2020, ''The House of Carbs: Personalized Carbohydrate Dispenser for People with Diabetes.'' PMID:32570472. Ongoing work is demonstrating how this could be made into a mobile system, and will be presented at ATTD2023.

Conclusions: Better systems for avoiding hypoglycemia during physical activities are needed for people with diabetes. Designing for a mobile nutritional delivery system is technically possible, but the feasibility is yet to be tested.

EP192 / #573

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EXPLORING THE IMPACT OF MOBILE APPS ON SELF-MANAGEMENT AND CLINICAL CARE FOR PEOPLE WITH DIABETES IN THE UNITED STATES

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Background and Aims: With countless diabetes-related decisions made daily, mobile apps offer an avenue to track diabetes data, make informed treatment decisions, and communicate with healthcare providers (HCPs) outside of scheduled medical appointments. This study aimed to further understand how apps affect diabetes management.

Methods: Through an online survey, 677 adults living with diabetes (69% T1D; 66% female) in the U.S. evaluated the role of diabetes-specific apps in their lives and their perceived impact on diabetes management. Key outcomes including helpfulness toward various aspects of diabetes outcomes and clinical care were measured on a 10-point scale.

Results: Half of participants (51%) reported daily usage of diabetes-specific apps. Apps were perceived to be reasonably helpful toward lowering HbA1c (M = 7.11; SD = 2.62), keeping blood glucose in an ideal range (M = 7.16; SD = 2.64), and making management feel less burdensome (M = 7.10; SD = 2.68). Additionally, apps were rated moderately helpful in reducing fear of hypoglycemia (M = 6.30; SD = 2.96) and easing concerns about long-term complications (M = 5.87; SD = 2.89). Apps' greatest perceived value was their ability to provide users with helpful information (M = 8.34; SD = 2.07) such as trended blood glucose readings. Furthermore, participants felt apps worked well alongside clinical care (M = 7.73; SD = 2.45); however, adoption among HCPs was low with 32% recommending and 7% requiring app usage.

Conclusions: This study highlights how mobile app usage can benefit diabetes outcomes, but direct utilization into clinical care may fall short. With usage and digital innovation likely to increase, future research should explore unique ways that apps can support diabetes management as well as how HCPs can incorporate apps' abilities into practice.

EP193 / #631

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DESIRED IMPROVEMENTS TO HEALTH APPS AMONG PEOPLE WITH DIABETES IN EUROPE

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Background and Aims: With smart device use on the rise, health apps are becoming a valuable tool to monitor health metrics and achieve health goals. Despite a broad range of features, advancements to health apps are still needed to maximize their impact on people with diabetes (PWD). The present study aims to investigate the top desired improvements to health apps among PWDs in Europe.

Methods: From October-November 2021, 3,356 PWDs in France, Germany, Italy, Netherlands, Sweden, and UK took an online survey on their experience with general and diabetes-specific health apps. App users (n = 1,804) reported their top 3 and most desired app improvements. The subsequent responses (76% T1, 53% female) were analyzed.

Results: Among all app users, improved integration with other devices, more pattern-analysis information, and fewer errors were considered the most desired improvement to health apps (11%, 10%, and 10%, respectively). Integration with other

health-related apps also ranked highly among the top 3 desired improvements (30%). App users age 65+ were significantly more likely to desire improvements to the app interface (30%, 3%, $p = .01$), while those under 65 were most likely to desire more pattern-analysis information (28%, 18%, $p < .05$). One third of T2 users want apps to track more types of health data (33%), while T1s want improved integration with health-related apps and devices (31%).

Conclusions: These findings reveal the top desired improvements to health apps among PWD, which differ by diabetes type and age. Further research is needed to inform future app developments of the needs of key demographic groups within the diabetes population.

EP194 / #433

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A MODEL-BASED EDUCATIONAL DIGITAL SYSTEM TO IMPROVE STANDARD GUIDELINES LEARNING IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Education is fundamental to effectively manage type 1 diabetes (T1D) therapy and achieve treatment objectives. It is well-known that good education of patients/caregivers correlates with good metabolic control. Digital systems such as web interfaces and mobile apps can foster education in T1D by delivering functionalities able to engage user more effectively than standard approaches. We explored the feasibility of adopting a new model-based digital system for T1D education for the scope.

Methods: The system includes a mobile app that implements a quiz-based game where users are challenged to find the therapeutic actions able to achieve optimal glucose control in five common scenarios of daily T1D management, and a web server which incorporates a simplified model of glucose-insulin dynamics (Cappon et al., IEEE Trans Biomed Eng, 2022) to simulate and obtain the glucose time-course resulting from user's answers for visual feedback. System usability has been evaluated in a benchmark test involving seven bioengineers experienced in diabetes technology and T1D management. Users were asked to use the app and quantify the overall usability according to the standard system usability scale (SUS).

Results: show that the developed system is easy-to-use achieving an average SUS of 90%. Users' feedbacks were positive and indicate the willingness of using the system frequently in the future.

Conclusions: The system can potentially promote the learning process of standard guidelines of T1D management. Future work will focus on including more scenarios reflecting the current clinical practice and exploring the efficacy of the tool via dedicated clinical trials involving people with T1D.

EP195 / #838

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EFFECT OF A TELEMEDICINE-BASED TYPE 1 DIABETES INTEGRATIVE ACCOMPANIMENT PILOT PROGRAM ("CADENA DE FAVORES")

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Background and Aims: *Cadena de favores* (i.e., chain of favors) pilot multi-sponsored project through Diabetes Mexican Association of Mexico. The aim of the study was to evaluate the effect of an interdisciplinary telemedicine-based program on blood biomarkers, life satisfaction and self-perceived quality of life in DT1 patients.

Methods: Four women (23.4 years ±7.8) participated in the study for a year. Health team: endocrinology, nutrition, diabetes education, psychology, ophthalmology and a technology specialist. Participants received 12-hour training course on using a MiniMed® 640G insulin pump system, followed by 12 monthly psychoeducational accompaniment group sessions and health team follow-up. Psychology and diabetes knowledge questionnaires were applied. Normality was analyzed using the Shapiro-Wilk test, and the Wilcoxon test was estimated to analyze differences between baseline and final assessments.

Results: Hb1ac and body fat decreased, while time in range, fat-free mass, and knowledge in diabetes, lipid profile, creatinine, weight, body-mass index, increased. Marginally significant differences ($p < 0.069$) were observed in time in range, fat-free mass, diabetes knowledge, total cholesterol, HDL, LDL and creatinine. Emotional accompaniment favored motivation and attachment, increasing self-efficacy, and the degree of empowerment.

Conclusions: An interdisciplinary telemedicine-based program plus a psychoeducational component could contribute to the increase of time in range, fat-free mass, diabetes knowledge and self-reported life satisfaction in type-1 diabetes patients. Hb1ac decreased, but statistical significance was not observed, possibly due to sample size. Study replication with a representative sample size is recommended as secondary prevention strategy.

Table I. Results of metabolic, anthropometric and knowledge level variables in diabetes

VARIABLES	BASAL	FINAL	p
METABOLIC			
HbA1c (%)	8.6 (± 1.5)	7.3 (± 0.1)	0.109
C-TOTAL (mg/dl)	129 (± 21.6)	149.9 (± 30)	0.068
HDL-C (mg/dl)	47.3 (± 4.2)	49.7 (± 5.3)	0.068
LDL-C (mg/dl)	60 (± 13.1)	83 (± 22.3)	0.068
Triglycerides (mg/dl)	71.8 (± 22.7)	86.8 (± 45.7)	0.273
Creatinine (mg/dl)	0.6 (± 0.1)	0.7 (± 0.2)	0.066
Time in range (%)	59.5 (± 7)	74.3 (± 3.6)	0.068
ANTHROPOMETRIC			
Weight (kg)	56.7 (± 11.6)	57.3 (± 8.1)	0.715
BMI (kg/m2)	21.8 (± 2.2)	21.9 (± 0.9)	0.713
Body fat (%)	30.7 (±6.3)	29.9 (±4.3)	0.715
Fat-free mass (kg)	21.0 (±3.9)	21.7 (±3.6)	0.068
LEVEL OF KNOWLEDGE IN DIABETES (%)	77%	84%	0.068

EP196 / #810

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

INCREASED AVAILABILITY OF ISCGM SHOWS STABLE GLYCEMIC CONTROL DESPITE COVID-19 PANDEMIC – A GLYCULATOR 3.0-BASED BENCHMARK ANALYSIS

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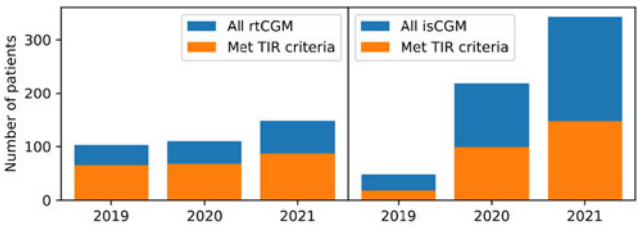
Background and Aims: Despite advances in CGM technology, most studies rely on industry support, making multi-manufacturer analyses difficult. Here, using a new open-access CGM benchmarking platform – GlyCulator 3.0, we analyzed the impact of reimbursement of isCGM (November 2019) and rtCGM (March 2018) in Poland on management of diabetes throughout COVID-19 pandemic.

Methods: The study was performed in a single diabetes center that manages patients aged 0-26 years. Percentage of CGM users who satisfied Time in Range (TIR) criterion (>70% of time glucose levels within 70-180 mg/dl) was calculated for 2019-2021. To create a uniform benchmark, we selected two weeks from March each year- a period not confounded by country-specific holidays. CGM files were manually downloaded and included into analysis if provided at least 70% CGM active time in the predefined periods. Glycemic variability metrics were computed using GlyCulator 3.0 (https://glyculator.btm.umed.pl/).

Results: After download and filtering, 971 periods from 604 patients were included for analysis. The number of isCGM users increased over years 2019-2021 (Chi2 for users over total clinic population, $p < 0.0001$), for rtCGM users this trend was not significant ($p = 0.6066$). Percentages of users who met TIR >70% target remained at ~60% for rtCGM and ~40% for isCGM. There was no significant difference in the fraction of patients meeting TIR criteria during the analyzed years (Chi2 for rtCGM $p = 0.5279$, isCGM $p = 0.6038$).

Conclusions: Widespread CGM use allowed us to confirm that the patients' diabetes management was not significantly affected by the COVID-19 pandemic. The GlyCulator 3.0 software allows for fast and reliable CGM benchmarking in similar epidemiological scenarios.



	2019	2020	2021
rtCGM	63.1% (103)	61.8% (110)	58.8% (148)
isCGM	37.5% (48)	45.2% (219)	42.9% (343)

% (N total) of patients satisfying 2019 Time-in-Range criteria

EP197 / #909

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ASSESSMENT OF THE CLINICAL USER EXPERIENCE OF THE IMPACT PLATFORM DURING A CLINICAL TRIAL IN INDIVIDUALS WITH POST-BARIATRIC HYPOGLYCAEMIA

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Background and Aims: Recently, we created IMPACT (Cappon et al., JDST, 2021), a modular platform that aims at easing and improving data collection and management in clinical trials. IMPACT is composed of a mobile app to gather patient-generated data and a web interface for clinicians to enable real-time patient monitoring for diagnostic purposes. IMPACT has been recently deployed during a study involving patients with post-bariatric hypoglycaemia (NCT05212207) where its components have been adapted to fit the need of both patients and the clinical trial team. In this work, we evaluated the clinical research team experience of the IMPACT web interface.

Methods: Nine members of the clinical team (29 ± 5 y.o.), who self-reported a medium to high level of experience with digital health tools, have been asked to quantify their user experience with IMPACT during the trial. This has been achieved via a state-of-the-art questionnaire, the System Usability Scale (SUS), that scores the user experience on a 0-100 scale via ten questions.

Results: show an average±SD SUS score of 86.2 ± 8, which corresponds to ''Acceptable'' on the system acceptability scale of Bangor et al. Achieved conclusiveness rate is 77%, which marks the obtained SUS score given the number of respondents as reliable. Particularly, the web interface has been indicated as very easy-to-use by all users.

Conclusions: The interface is found to be of practical value with good usability across the clinical team. Future work will investigate experience of the IMPACT mobile app for therapeutic purposes from the perspective of patients and will push forward the usability of the web interface.

EP198 / #558

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IN-PERSON VERSUS VIRTUAL INSULIN PUMP TRAINING EXPERIENCES AMONG PEOPLE WITH DIABETES IN 6 EUROPEAN COUNTRIES

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Background and Aims: While insulin pump training has historically been conducted in person, the COVID-19 pandemic has necessitated a rise in virtual alternatives. The present study aims to examine the perceived effectiveness of in-person versus online pump training among people with diabetes in Europe.

Methods: From April-May 2022, 2,457 people with type 1 diabetes in France, Germany, Italy, Netherlands, Sweden, and UK took an online survey in which they indicated their use of pump therapy. Respondents who started using a new pump model in the last year indicated their pump training method (n = 366) and those who received training reported their confidence in pump use after training (n = 356). Confidence scores were calculated as the proportion of users selecting 9 or 10 on a 10-point scale.

Results: The majority of pump users trained in person with an HCP or pump company representative (76%). One quarter of pump users trained virtually with a professional (24%), and 12% completed a self-guided training tutorial online. Those who completed a self-guided tutorial were significantly less confident using their pump than those who trained with a professional in person (34% vs. 51%, p = 0.021) or virtually (34% vs. 55%, p = 0.006). No differences in confidence were observed between those who trained with a professional in person or virtually (51% vs. 55%).

Conclusions: These findings suggest that virtual training may be an effective alternative to in-person methods, though professional guidance is critical to building confidence in pump use. Further research is needed to identify improvements to online, self-led trainings to increase proficiency among new pump users.

EP199 / #835

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ECONOMY-GRADE FITNESS SMARTWATCH 24HR DATA TO LEND PREDICTIVE INSIGHT INTO BLOOD GLUCOSE TRENDS AMONG TEENS WITH TYPE 1 DIABETES

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Background and Aims: Adolescents with type 1 diabetes not using continuous glucose monitors (CGM) require fingersticks, which are cumbersome and performed too infrequently in this age group. Therefore, we sought to determine if an economy-grade fitness smartwatch (Fitbit Inspire 2) – which may be more accessible than CGM - could be combined with a single glucose value to lend predictive insight into upcoming glucose trends.

Methods: Fourteen participants (age 15.7 ± 1.6yr, 43% F, 50% non-Hispanic white, A1c 8.7 ± 2.2%) wore the Fitbit and Dexcom G6 (n = 12) or Abbott Libre 2 (n = 2) for 6wk. We sought to predict glucose values based upon the single glucose value 60min beforehand (simulating a fingerstick test), using Fitbit metrics over either 5min or 180min beforehand (steps, heart rate), prior night sleep duration, and demographics (age, gender, race/ethnicity, A1c, BMI %ile) using both ordinary least squares regression and random forest machine-learning (80% training/20% testing). Each method was run on 3 models: Fitbit not included (BASIC), Fitbit over previous 5min (FITBIT-5) or 180min (FITBIT-180).

Results: Analysis included 83,070 complete timepoints (non-wear CGM 16%, Fitbit 36%). For both methods, FITBIT-180 (root-mean-square error 30-32mg/dL, $R^2 = .87$) outperformed the other models (41-43mg/dL, $R^2 = .72$-$.75$) ($p < .05$).

Conclusions: The Fitbit data improved glucose prediction compared to fingerstick testing alone by 10%-20% when aggregated over previous 180min, achieving a final error margin (15%), which is superior to other biometrics the Fitbit predicts, such as physical activity. Along with insulin and diet, Fitbit data may assist in alerting teens not using CGM to times of increased probability of dysglycemia and encourage additional fingerstick testing.

EP200 / #478

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

REAL-WORLD EFFECTIVENESS OF INTEGRATED CARE PROGRAM "NORMA" IMPLEMENTATION IN THE MANAGEMENT OF PEOPLE WITH DIABETES MELLITUS TYPE 1 AND 2

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Background and Aims: Many people with diabetes mellitus (DM) do not achieve their individual glycemic targets despite the use of effective treatment. The new approaches to DM management are needed to enhance self-management skills and improve clinical outcomes. The aim was to assess the real-world effectiveness of the integrated approach to DM management used in program "NORMA" for people with DM who did not reach glycemic targets.

Methods: "NORMA" is a pilot program designed to implement an integrated approach to DM management. The Program combines structured online education, blood glucose monitoring, supervision by endocrinologist, and administrative support. The program consisted of two phases (phase with and without support) for 3 months each. A retrospective analysis of clinical data was performed.

Results: Data from 207 subjects were analyzed: 132 with T1DM and 75 with T2DM, 68,6% women, age 42.2 ± 14.8 years; the DM duration was 13.0 [7.0;18.5] years, 177 people (85.5%) had diabetes complications. Mean HbA1c in people with T1DM decreased from baseline 8.5 ± 1.4% to 7.2 ± 1.2% and 7.5 ± 1.5% ($p < 0.001$) and with T2DM from 9.4 ± 1.4% to 7.7 ± 1.1% and 7.8 ± 1.2%, at months 3 and 6 respectively ($p < 0.001$). The individualized HbA1c targets were achieved in 36.2% of participants at month 3 and in 34.0% at month 6. The mean total daily insulin dose did not changed within the Program. The knowledge level and the mean scores of diabetes perceptions increased significantly ($p < 0.05$).

Conclusions: The implementation of an integrated approach to DM management was associated with improvement of glycemic control in people with T1DM and T2DM.

EP201 / #707

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ASSESSING THE PATIENT EXPERIENCE WITH A NOVEL REPORT COMBINING FOOD DATA AND CGM DATA AMONGST CHILDREN LIVING WITH DIABETES

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Background and Aims: Understanding how food impacts blood glucose remains an important component of diabetes care, however it is challenging for patients to easily get this information. RxFood is an AI-based mobile application developed with the diabetes community to reduce the burden of food logging. RxFood previously demonstrated reduced carbohydrate counting errors and lower HbA1C. This project aims to assess the patient experience with a novel CGM-Food-overlay report, which automatically combines food data from RxFood with glucose data from Continuous Glucose Monitoring (CGM) sensors.

Methods: Voluntary participants recruited from two diabetes clinics completed a three-five-day food log using RxFood while wearing their CGM. A CGM-Food-overlay report was provided to participants along with a cross-sectional survey related to usability and satisfaction. Descriptive statistics and satisfaction scores were calculated. Open-ended questions were analyzed for themes.

Results: 20 participants completed logs and received reports, and 12 completed surveys (mean age 9.3, 92% Dexcom sensors). The mean satisfaction score was 4.2/5. After reviewing the report, 75% of participants reported dietary changes (e.g., eating less sugar/lower glycemic foods, higher fiber foods, pairing protein with carbohydrate sources). Participants reported ease of use, photo-recognition/AI technology and knowledge gained from the report as benefits, while challenges included inability to enter insulin in RxFood with food logs, remembering to log and technical challenges. 83% would recommend the report to others.

Conclusions: Patients found the CGM-Food-overlay report easy to understand, highly satisfactory, and led to dietary changes intended to improve glycemic control. Further research is needed to assess longer term outcomes on patient self-management, glucose variation and A1c.

EP202 / #155

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EFFECTIVENESS OF MY DOSE COACH (MDC) USE DURING BASAL INSULIN (BI) TITRATION IN TYPE 2 DIABETES (T2D): REAL-WORLD DATA FROM COLOMBIA

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Background and Aims: My Dose Coach (MDC) is a US FDA-approved digital app that assists users with type 2 diabetes (T2D) to adjust their basal insulin (BI) dose based on individualized titration plans provided by their healthcare providers (HCPs). This retrospective cohort study evaluated the impact of the frequency of MDC usage on fasting blood glucose (FBG) target achievement, change in FBG, and hypoglycemic events during BI titration.

Methods: A total of 594 active users (registered 08/01/2018 – 03/31/2022) from Colombia were stratified based on frequency of MDC usage into high (>3 days/week; 80.9%) and moderate-to-low usage (≤3 days/week; 19.0%). FBG target achievement (≥3 consecutive measurements within the target range), change in FBG, and hypoglycemia events were assessed.

Results: Overall, 477 (80.3%) users achieved individualized FBG target and the mean (± standard deviation [SD]) time to reach target was 9.9 (±15.5) days. Among individuals with high MDC usage, a significantly greater proportion of users achieved FBG target (91.0%), displayed a shorter time to target achievement (9.4 ± 14.8 days) and a greater reduction in FBG (–26.5 ± 49.6 mg/dL) as compared to moderate-to-low users ($p < 0.01$; **Table**). The mean ± SD number of days to first hypoglycemia event was longer in high MDC users (7.3 ± 9.0) compared to moderate-to-low users (3.2 ± 5.2; $p < 0.01$).

Table: Clinical outcomes analysis by MDC usage subgroup

Clinical outcomes	Total participants	MDC App Usage* (Colombia)		
		High (>3 days/week)	Moderate-to-low (≤3 days/week)	p-value
Total participant, *n* (%)	594 (100)	481 (80.9)	113 (19.0)	–
Average days recording FBG per week (7 days)	4.9 ± 2.1	5.7 ± 1.4	1.5 ± 0.8	–
Proportion reaching target†, *n* (%)	477 (80.3)	438 (91.0)	39 (34.5)	<0.01
Time to FBG Target, days	9.9 ± 15.5	9.4 ± 14.8	15.6 ± 21.5	<0.01
FBG outcome, mg/dL				
First FBG reading	140.4 ± 54.5	138.1 ± 51.7	150.1 ± 64.5	
Last FBG reading	117.6 ± 32.0	111.6 ± 22.6	143.3 ± 49.0	
FBG change	−22.8 ± 51.8	−26.5 ± 49.6	−6.8 ± 57.8	<0.01
Insulin dose outcome, U				
Users reporting ≥1 dose, *n* (%)	551 (92.8)	450 (94)	101 (89.3)	
Starting dose	22.2 ± 11.2	22.1 ± 11.2	22.6 ± 11.1	
Last dose	24.0 ± 14.1	23.8 ± 12.2	25.2 ± 20.4	
Dose change	1.8 ± 9.9	1.7 ± 7.4	2.2 ± 17.2	0.7
Hypoglycemia events‡				
Users with ≥1 hypoglycemia event, *n* (%)	83 (14)	63 (13.1)	20 (17.7)	0.2
Time to first hypoglycemia event, days	6.3 ± 8.4	7.3 ± 9.0	3.2 ± 5.2	<0.01

Data is presented as mean ± SD unless otherwise specified.
*APP usage level is defined based on number of days in a week (7 days) the patient recorded FBG during titration: High (>3 days/week); Moderate-to-low (≤3 days/week)
†For users who achieved target, last FBG and last dose data are captured at date of target achievement
‡Readings below HCP-defined cut-off per dose plan
A p-value <0.01 was considered statistically significant for High versus moderate-to-low usage
FBG, fasting blood glucose; HCP, healthcare professional; MDC, My Dose Coach; SD, standard deviation; U, unit.

Conclusions: In a real-world setting, patients with high MDC app usage displayed improved glycemic outcomes and a low risk of hypoglycemia among those with T2D from Colombia being treated with BI therapy.

EP203 / #367

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

MODEL-BASED INSULIN SENSITIVITY AND BETA CELL FUNCTION ESTIMATION FROM CGM

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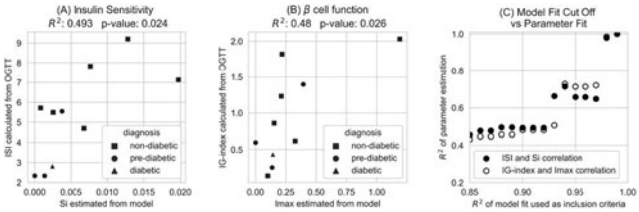

Figure 1: (A) Correlation between insulin sensitivity parameter, Si, estimated from model and ISI from OGTT. (B) Correlation between β cell function parameter, Imax, estimated from model and IG index from OGTT. (C) Relationship between goodness-of-fit of model and correlation of parameters. (A) and (B) use only patients with model fit R^2 greater than .9 (n=10).

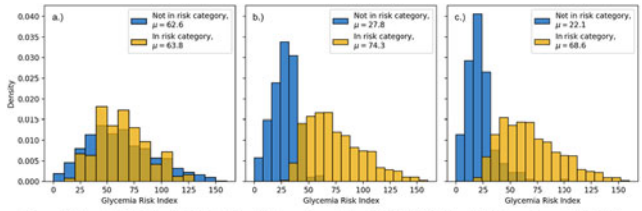

Figure 1: Glycemia Risk Index distribution for a) % time extremely low >1%, b) TIR <65% and c) % time extremely high >4%

Background and Aims: Estimating insulin sensitivity and beta-cell function is useful for choosing therapy for T2D, but it typically requires measurements obtained from a clinic. Our work shows the feasibility of using CGM to estimate those parameters using a model-based approach.

Methods: We use a public dataset that contains CGM data from patients without diabetes, with T2D diabetes, and with prediabetes who were instructed to eat standardized meals at home [1]. We use pre-processed CGM data to estimate model parameters in a minimal insulin-glucose model proposed by Goel et al [2]. Laboratory fasting insulin levels are predefined in the model. We fit the model using a least squares method. We validate the parameters by obtaining clinical estimates for the Matsuda Insulin Sensitivity Index (ISI) and the Insulinogenic [IG] index, for beta cell function, using data from an OGTT.

Results: Figure 1 shows the correlation plots between the estimated and OGTT parameters. As the goodness-of-fit of the model increases, parameter correlation to OGTT measurements increases.

Conclusions: We demonstrate that through a model-based approach, physiological parameters obtained from CGM correlate with indices derived from in-clinic OGTT, suggesting the potential utility of CGM for an at-home OGTT. **Acknowledgements:** This material is based upon work supported by the National Science Foundation Graduate Research Fellowship Program under grant 1745302. **References:** [1] Hall et al.. Glucotypes reveal new patterns of glucose dysregulation. PLoS Biol. 2018. [2] Goel et al. A minimal model approach for analyzing continuous glucose monitoring in type 2 diabetes. Front. Physiol. 2018.

Background and Aims: Previous work has prioritized patient outreach by analyzing weekly CGM data and assigning threshold-based risk categories [Ferstad et al., Ped Diab, 2021; 22(7): 982-991]. To further explore the use of Glycemia Risk Index (GRI) as a biomarker, this study examined the relationship between GRI and three CGM risk categories: time in range (TIR) <65%, %time extremely hypoglycemic (<54 mg/dL) >1%, and %time extremely hyperglycemic (>250 mg/dL) >4%.

Methods: We used retrospective weekly CGM data from 2016-2022 collected by a Midwest USA pediatric diabetes center. GRI was calculated as (3 × %measures <54 mg/dL) + (2.4 × %measures 54-70 mg/dL) + (1.6 × %measures >250 mg/dL) + (0.8 × %measures 170-250 mg/dL). We ran two-sample t-tests to compare differences in mean GRI between youth who were/were not in each risk category.

Results: We calculated the mean GRI for the population within and outside each risk category. There were GRI score differences between qualifiers and non-qualifiers in the TIR <65% and severe hyperglycemia categories ($p < .001$); however, no difference was found for the clinically significant hypoglycemia risk category ($p = .59$).

Conclusions: Preliminary findings suggest that GRI may be useful as a risk assessment tool for diabetes management. Future testing should compare individual components (high and low) of the GRI in relation to these risk categories and explore changes to the category thresholds, such as applying a threshold of extreme lows over two percent or relating the GRI low component to the risk category for >4% time low.

EP204 / #728

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EXAMINING THE GLYCEMIA RISK INDEX AND ITS ASSOCIATION WITH CONTINUOUS GLUCOSE MONITOR (CGM)-DERIVED GLYCEMIC RISK CATEGORIES IN PATIENTS WITH TYPE 1 DIABETES

J. Litwin[1], B. Lockee[1], C. Vandervelden[1], M. Barnes[1], R. Mcdonough[2], S. Patton[3], D. Williams[4], K. Noland[1], M. Clements[5]

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EP205 / #732

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EXAMINING THE GLYCEMIA RISK INDEX (GRI) AS A RISK BIOMARKER FOR ELEVATED HEMOGLOBIN A1C (HBA1C) IN INDIVIDUALS WITH TYPE 1 DIABETES (T1D)

B. Lockee[1], J. Litwin[1], C. Vandervelden[1], D. Williams[2], M. Barnes[1], R. Mcdonough[3], S. Patton[4], K. Noland[1], M. Clements[5]

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Background and Aims: The Glycemia Risk Index (GRI) is a new metric for interpreting the quality of glycemic control using CGM data. The GRI has two main components: risk from high blood sugars and risk from lows. We examined the relationship between GRI and future HbA1c levels to evaluate the validity of GRI as a prognostic tool to provide a more complete picture than time in range (TIR).

Methods: We retrospectively analyzed 12-week CGM data aggregates preceding an HbA1c assessment date using data collected at a Midwest pediatric diabetes center between 2016-2022. We performed bivariate correlations and multivariable linear regressions to evaluate associations between GRI (and its components) and most recent HbA1c value for patients who had a wear time >50% (N = 994).

Results: Both the GRI and GRI high component positively correlated with HbA1c levels (r = 0 .819 and r = 0.832 respectively, $p < 0.001$), which had a correlation of similar magnitude with TIR (r = -0.817, $p < 0.001$). The GRI low component negatively correlated with HbA1c (r = -0.269, $p < .001$). We ran two regression models (N = 993) with HbA1c levels as the dependent variable: one including age, gender, race, ethnicity, insurance type, diabetes duration, and GRI high component as explanatory variables ($r^2 = .700$) and one with only the GRI high component ($r^2 = .694$).

Conclusions: Reporting the GRI with CGM data may provide a more complete picture of the quality of a youth's glycemic control than TIR. Further testing is needed to determine if GRI improves clinician risk assessment for glycemic outcomes beyond those provided by TIR.

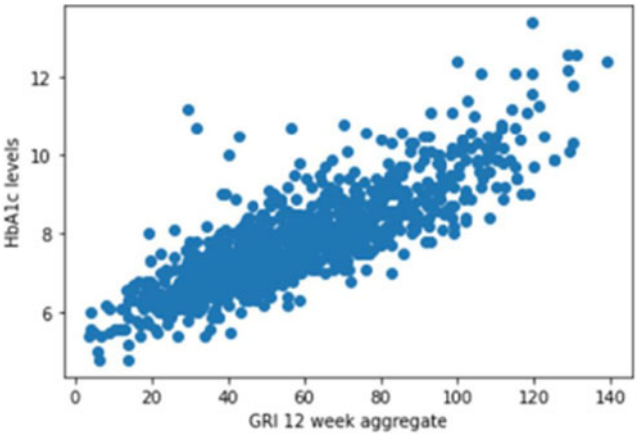

Figure 1: Relationship between 12-week GRI and contemporaneous HbA1c levels.

EP206 / #616

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

RWD ANALYSIS SHOWS A SIGNIFICANT IMPROVEMENT ON GLYCEMIC MANAGEMENT WHEN USING A BLOOD GLUCOSE MONITOR CONNECTED WITH A MOBILE HEALTH APPLICATION IN PEOPLE WITH T2D

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Background and Aims: The use and recommendation of mHealth applications in diabetes management has increased over the last decade. Previous RWD studies have shown an improvement of blood glucose (BG) with the use of these tools, but mainly in people with T1D. Our aim was to investigate the impact of using BG monitoring connected to the mySugr® mHealth app on the diabetes management of T2 users, since this population tends to show poorer glycemic outcomes and more diabetes-related complications.

Methods: We performed a retrospective analysis of 3,274 users of Accu-Chek meters connected to mySugr® app with T1D & T2D from 9 countries in North Western Europe & Canada, who enrolled between March 2016 and May 2022, and were highly engaged, defined as ≥2 logs on at least 14 out of 30 days. Impact on estimated HbA1c (eHbA1c) and percentage of Tests in Range (TiR) were calculated after 4 months of connecting the BG meters to the mobile app.

Results: After 4 months of use of mySugr® app connected to the BG meters, a statistically significant improvement in eHbA1c and percentage of TiR was observed, being specially remarkable in users with T2D (-0.35%; $p < 0.001$ & 6.13%; $p < 0.001$, respectively). Even though the greatest improvement in eHbA1c was seen in people with T2D starting with eHbA1c>9% , we also observed a significant improvement in those with an initial HbA1c>7.5%.

Conclusions: Among a population with T2D across Europe and Canada, use of a BG meter connected with mySugr® app was shown to significantly improve diabetes management over a 120-day period

EP207 / #738

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ESTIMATING THE RISK OF DEVELOPING TYPE 1 DIABETES (T1D) THROUGH URINARY C-PEPTIDE AND ONE-WEEK HOME CGM TEST

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Background and Aims: The risk of developing type 1 diabetes (T1D) can be assessed by the number of islet autoantibodies (Ab), genetic, and metabolic markers to predict the progression to the diagnosis of the disease. Our aim is to develop a technology to estimate the T1D risk from a simple continuous glucose monitoring (CGM) home test using a machine-learning approach.

Methods: Data from a NIH study with 51 TrialNet healthy relatives to T1D with (Ab+, N = 34) or without Ab (AB-, N = 17), mean ± SD age of 24.9 ± 10.1, HbA1c of 5.4 ± 0.2%, and BMI of 23.1 ± 5.1 (kg/m^2) were used. Subjects wear CGM for a week, and consumed 3 caloric drinks (Boost); urine C-peptide (CP) was measured 2h after one Boost in the hospital. Nine glycemia features were extracted from the 75 minutes post-Boost CGM traces and used for risk classification. A decision tree model with 10-fold cross-validation (CV) was used to develop a risk classifier. The receiver operating characteristic (ROC) curve was used to identify the optimal CP cut-off and estimate model

accuracy. A CP cutoff was determined to identify people at T1D risk based on Ab status.

Results: A CP cut-off of ≥6.7 nmol/l distinguished between Ab+/Ab- subjects (AUC-ROC, 0.70) with 60% sensitivity and 88% specificity. A decision tree model with a 10-fold CV achieved an AUC-ROC of 0.82 for classifying those participants based on a CP class (low risk vs. high risk).

Conclusions: A machine-learning technology combining a potentially self-administered one-week CGM home test can reliably assess the individual T1D risk.

EP208 / #457

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A SELF-MANAGEMENT ADVOCATE APP TO ENHANCE THE EFFECTIVENESS AND EFFICIENCY OF CONSULTS FOR PATIENTS WITH DIABETES

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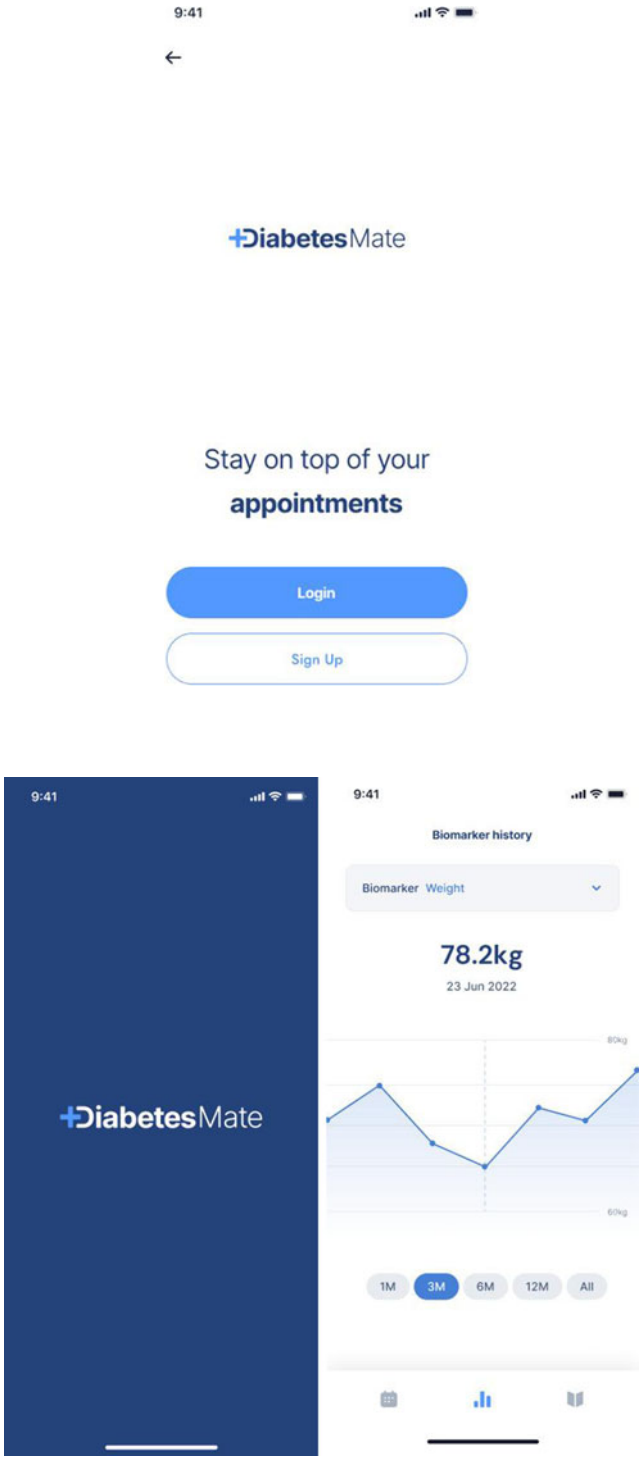
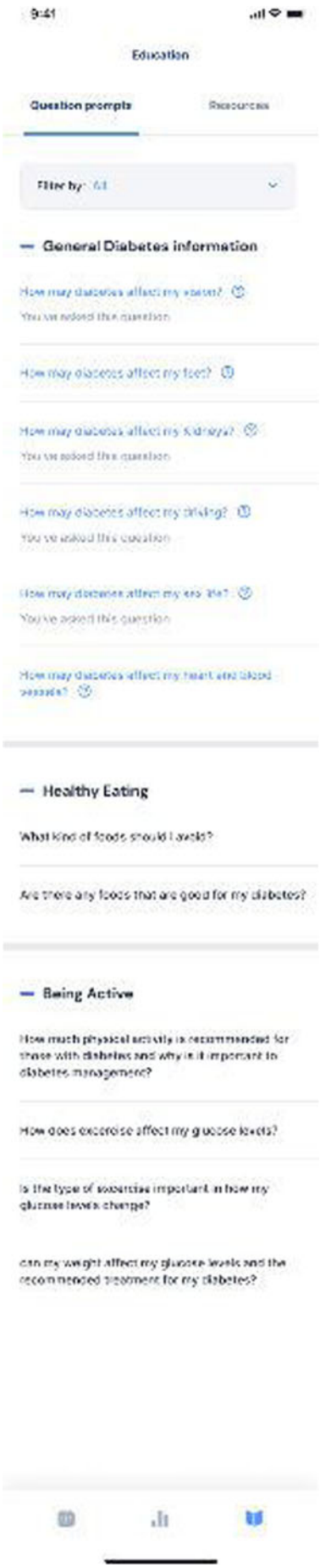
Background and Aims: Self-management & multidisciplinary teams are critical in diabetes treatment. Mobile applications potentially improve outcomes by automating and enhancing data collection and accessibility. No previous app has been designed to improve the effectiveness of diabetes consults. We aimed to develop an app to advance diabetes self-management and optimise the effectiveness of consultations with healthcare professionals(HCPs).

Methods: The DiabetesMate app was developed using co-design, engaging patients, clinicians, administrative staff, IT professionals, and software developers. This approach includes four stages:1)Literature review, 2)Interviews with endocrinologists and a patient survey further identifying barriers to effective consults, 3)Concept design & development of DiabetesMate, 4)Implementation and efficiency evaluation.

Results: Four main barriers were identified. High failure to attend (FTA) rates resulted in management delays and increased administrative workload. Among patients, 50% found coordinating appointments difficult, 40% forgot to bring relevant items to consults, 24% couldn't remember part of the discussed plan, and 43% needed help with self-management. HCPs were frequently unable to formulate a plan due to inadequate information requiring appointment rescheduling. Forgetting or misunderstanding medical advice further slowed treatment progress. Accordingly, four app features were prioritised:1)appointment reminders & notifications for relevant items to bring, 2)diabetes question prompt list to facilitate communication, 3)biomarker tracker for HbA1C, weight, blood pressure, cholesterol, and urine albumin/creatinine, 4)recording a summary of the agreed management plan.

Conclusions: DiabetesMate is co-designed to assist self-management and optimise the effectiveness of consults in resource-limited healthcare. DiabetesMate is predicted to reduce FTA rates, improve patient engagement, and increase patient & clinician satisfaction, ultimately improving clinical and economic outcomes.





EP209 / #912

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

UTILIZATION OF A CGM-BASED DASHBOARD TO PRIORITIZE DISTINCT COHORTS OF YOUTH WITH TYPE 1 DIABETES

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Background and Aims: A CGM-based population health dashboard, created by researchers at Stanford University, was adapted/adopted by Children's Mercy (CM). The dashboard flags youth with T1D into risk categories: extreme lows >2%, no alerts, lows >4%, >15% drop-in time-in-range (TIR), TIR <65%, extreme highs >10%, >15% drop in wear time, insufficient data, extreme highs >3%. These categories help clinicians prioritize at-risk patients for proactive outreach to families for intensive support between standard-of-care clinic visits.

Methods: Utilizing Power BI for data visualization, the dashboard was implemented targeting biomarker-based risk groups. Modifications to filters within the dashboard allows a focus on specific cohorts of youth such as new-onset, new-to-technology, teens transitioning to adulthood, and lost-to-follow-up (LTF). Diabetes educators used the filters to identify patients that fell in risk categories within each cohort and provide a one-time outreach to provide problem-solving support.

Results: After an adjustment to dashboard filters, the percentage of appropriate patients populating in the dashboard increased from 56% to 100%. Although all patients populated accurately, not all were eligible for outreach due to TIR >80%, recent adjustments with the diabetes clinic, or no longer attending CM. Reachability varied with LTF, teens transitioning, new to CGM, and newly diagnosed respectively at 25%, 57%, 60%, and 66%.

Conclusions: The specificity of the dashboard helps clinicians identify cohorts of youth at risk for poor outcomes by providing an at-a-glance view of the T1D population using CGM. Future work will include additions to the dashboard to improve provider engagement and decrease clinic time spent reviewing data.

EP210 / #643

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

OPTIMIZING DIABETES MANAGEMENT WITH PERSONALIZED TELEMEDICINE

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Background and Aims: Diabetes remains the leading cause of serious chronic complications in many countries of the world, with anaccelerated growth, affecting productive age groups. At the same time, diabetes care is more demanding,requiring a

structured evaluation of multiple clinical aspects, including education, individualization and theachievement of personalized goals of good control to prevent complications, improving the quality of life ofpatients. For their part, most of those diagnosed with diabetes are seen by primary care physicians who areexpected to manage these patients by meeting all the criteria of international guidelines, in a limited time of care.In addition, the gap in diabetes care is widening globally.

Methods: To address this, the first telemedicine platform specialized in diabetes, MEDDI Diabetes®, has been developed tocombine face-to-face and virtual care through telemedicine, together with the possibility for the healthcareprofessional to structure personalized care according to updated guidelines, as well as diabetes education,ambulatory monitoring of clinical parameters, and more for a whole year, two-way doctor-patient communicationin real time, and the possibility for the patient to have his or her medical history at hand anywhere just by a click.

Results: It is the first opportunity to close the care gap and bring the doctor and the patient closer together without losinggood control or collapsing care systems.

Conclusions: Now, Telemedicine platform specialized in diabetes, MEDDI Diabetes®, combine the best of both worlds, just by aclick, optimize control, with quality of care and adherence to diabetes care, improving quality of life.

EP211 / #634

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

AN OPEN-SOURCE COMPARATIVE STUDY ON AVAILABLE MODELS TO DESCRIBE THE INFLUENCE OF PHYSICAL ACTIVITY ON PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Physical exercise is one of the dominant sources of disturbance on blood glucose levels. To predict it and account for its impact during automated blood glucose control in people with diabetes, it is imperative to have reliable mathematical models at hand. The goal of this contribution was to identify relevant models for describing the effect of physical exercise on glucose metabolism from the literature and compare their resulting glucose trajectories in an in silico study.

Methods: Exercise models were implemented within the framework of the recently introduced open-source diabetes simulator LoopInsighT1. It allows for open-loop and closed-loop simulation and has been developed to make state-of-the-art simulation technology available to all stakeholders concerned with diabetes, most importantly patients and their relatives, medical staff, researchers, and developers.

Results: More than a dozen exercise models have been found in the literature. They mostly describe mild or moderate exercise, but are based on different assumptions and use different input variables to parametrize exercise intensity. While some of the models sporadically lacked parameters or misused units, most of them were suitable for implementation in the context of this study. The simulated blood glucose trajectories were found to be considerably different, even for mild exercise.

Conclusions: The heterogeneity in model output found in this investigation is an obstacle towards the inclusion of exercise in diabetes simulators and closed-loop control algorithms. However, the open-source implementation provided in this study is a starting point for further investigation and analysis.

EP212 / #907

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A NUMERICAL COMPARISON OF THE UVA/ PADOVA TYPE 1 DIABETES SIMULATOR AND THE OPEN-SOURCE SIMULATOR LT1

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Background and Aims: The UVA/Padova Type 1 Diabetes Simulator, commercially available as T1DMS S2013, is a simulation tool approved by the FDA as an alternative to pre-clinical assessments of treatment strategies – both open-loop and closed-loop – for type 1 diabetes mellitus. Since the underlying UVA/Padova model has been published in scientific articles, a number of open-source implementations have been introduced, including the browser-based LoopInsighT1 (LT1) simulator. The aim of this work is to validate the results of LT1 in comparison to T1DMS in a single-patient scenario.

Methods: We have extended the UVA/Padova model as described in available publications with respect to the gastrointestinal tract so that it became possible to consider consecutive meals of nonzero duration. We validated the implementation by comparing the output of T1DMS and a corresponding virtual patient in LT1, in response to identical scenarios. These included the consumption of consecutive meals of varying carbohydrate content in conjunction with a constant basal rate and meal boluses (CSII).

Results: LT1 produced almost exactly the same results as T1DMS in all scenarios. This implies that the implementation of the UVA/Padova model is equivalent in both simulators. Remaining deviations mainly trace back to the use of different numerical solvers.

Conclusions: This contribution closes the gap between the UVA/Padova model in its published form and the FDA-approved software tool. This helps to increase transparency and facilitates the realization of open-source in silico studies.

EP213 / #895

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

FOOD FRIEND: AN INFORMATION SYSTEM TO MANAGE TYPE 2 DIABETES MELLITUS

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Background and Aims: Type 2 diabetes mellitus (T2DM) is a chronic disease with an increasing prevalence worldwide, with significant healthcare needs and serious complications with high economic costs. The healthcare systems are required to solve this problem with strategies of capacitation and empowerment of the patients. So, we aim to create a mobile application that helps T2DM patients manage their disease.

Methods: For this, we are developing a mobile app that allows patients to record their meals, blood glucose levels, and physical activity.

Results: To maximize user usability and acceptability, we introduced an image recognition system through machine learning algorithms and a barcode system for an easier introduction of a food diary. Additionally, a coaching system based on behavioural theory is under development to provide personalized feedback based on the user choices as well as a gamification system through a system of badges and points and also with an introduction of challenges adapted to the user's profile. We believe these strategies will induce behavioural change.

Conclusions: The Food Friend application provides an innovative tool for T2DM management. The next phases will include usability tests with the patients and studies to measure T2DM outcomes improvement.

EP214 / #500

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

MEAL IDENTIFICATION FROM CGM TIME SERIES WITH HYBRID AI ALGORITHMS

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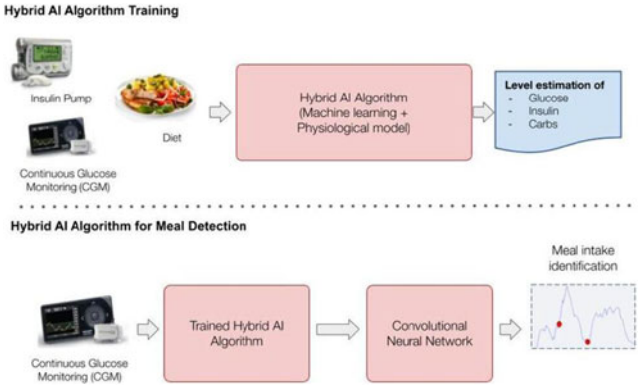
Background and Aims: Retrospective patient CGM time series analysis brings valuable insights on diabetes management. Besides classical analytics (e.g. time in range), there is a growing interest in more advanced analytics on the glucose-level fluctuations like the nutrition.

Recent AI algorithms can automatically detect meal intake phases from CGM time series only.

We propose a hybrid AI algorithm for meal detection, it relies on a combination of CGM data and glucose kinetics. This study shows the benefits of such an algorithm with respect to common machine learning algorithms.



Model	AUC	F1-Score
Logistic Regression	0.671	0.395
XGBoost	0.772	0.602
LSTM	0.853	0.662
Hybrid AI Algorithm	0.864	0.689

Methods: The hybrid AI algorithm was trained on the CLOSE Study. It contains 17 patients with type-2 diabetes. Each patient has 2 weeks of data records of CGM, insulin-pump delivery and meal intakes. The total dataset contains 59k CGM data points and over 700 meals events.

We benchmark the hybrid AI against common machine learning algorithms in a leave-one patient-out-scheme.

Results: The results show overall good accuracy of the hybrid AI algorithm. Deep neural networks outperform logistic regression and XGboost algorithms. However, errors in the reporting of the meals may lead to false positives.

Conclusions: The experiments suggest that incorporating physiological models in machine learning algorithms can improve meal detection on CGM time series only. This is particularly useful in retrospective analysis of the patient glycemic control, without requiring logs on meal intakes. Future work calls for validation over a larger and more diverse dataset.

EP215 / #103

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

SMARTPHONE-BASED ACTIVITY TRACKING IS NOT ASSOCIATED WITH NOCTURNAL HYPOGLYCAEMIA IN PEOPLE WITH TYPE 1 DIABETES ENGAGING IN UNSTRUCTURED PHYSICAL ACTIVITY

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Background and Aims: Nocturnal hypoglycaemia (NH) remains a major burden for people with type 1 diabetes (T1D). Daytime physical activity (PA) increases the risk of NH. This pilot study tested whether cumulative daytime PA measured using a smartphone-based step counter was associated with NH.

Methods: Adults with T1D for ≥5years(y) on MDI or CSII, not using continuous glucose monitoring and HbA1c 6-10% wore blinded Freestyle® Libre Pro sensors sequentially for 28 days and recorded total daily carbohydrate (TDC), total daily insulin (TDI) and capillary glucose measurements. They self-adjusted insulin as usual and performed unrestricted physical activity. Daily step count (DSC) was tracked using the Fitbit® Mobile application. Mixed effects logistic regression was used to estimate the effect of DSC on NH (sensor glucose <3.9 mmol/L for ≥15 minutes), while adjusting for TDC and TDI, and treating participant as a random effect.

Results: Twenty-six adults, with 65.4% females, median age 27y (IQR 26,32), mean BMI 23.9 kg/m^2 (SD 3.3), median HbA1c 7.6% (IQR 7.1, 8.1) and mean Gold Score 2.1 (SD 1.0) formed the study population. NH occurred on 12.5% of the nights. Median DSC for the group was low at 2867 (IQR 1820, 4807). Interestingly, median DSC was higher in those without NH vs. those with NH [6314 (IQR 3282, 11648) vs 2855 (IQR 1596,4778), $p < 0.001$]. There was no significant effect of DSC on the occurrence of NH. [Adjusted OR (95% CI): DSC OR 1.0 (0.9, 1.0), $p = 0.20$].

Conclusions: Daily step count measured using a smartphone application was not associated with NH in people with T1D.

EP216 / #791

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PATIENTS WITH UNCONTROLLED TYPE 2 DIABETES: SHOULD CONTINUOUS GLUCOSE MONITORING BE PART OF THE TREATMENT ALGORITHM?

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Background and Aims: Current guidelines suggest that patients with A1c > 10% be started on two medications including insulin. Continuous glucose monitoring (CGM) modifies behavior facilitating lifestyle changes. Our care model incorporating CGM facilitates rapid medication adjustment. We had several patients with type 2 diabetes achieve marked glycemic improvement using metformin and CGM. We report on outcomes in these six patients with an A1c >10%.

Methods: Patients were seen in our technology enabled, person-centered care model incorporating personalized recommendations based on CGM data along with ongoing care and support. Primary outcomes were time in range 70-180 mg/dL (TIR), time to achieve first week of TIR ≥70% and medication use. Secondary outcome was follow up TIR.

Results: Weekly TIR ≥ 70% was achieved by 67% at week one and 100% by week two. At the end of 2 weeks, 5 patients were controlled with metformin and lifestyle changes and one patient with lifestyle intervention alone. Mean TIR for the last 4 weeks of follow up was 97% (+3.9) with a median follow up of 18.5 weeks.

Patient	Baseline A1c %	TIR% week 1	TIR% week 2
1	10.6	90.1	94.5
2	10.8	74.1	99.1
3	12.8	64.6	95
4	10.4	99.6	100
5	12.9	63.2	99.4
6	14	97.8	98.4

Conclusions: Consideration should be given to incorporating CGM as part of the algorithm for management of patients with uncontrolled type 2 diabetes.

EP217 / #749

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IS THE COMBINED TARGET TIME IN RANGE/TIME BELOW RANGE ACHIEVABLE? EVALUATION OF GLYCEMIC PARAMETERS IN TYPE I DIABETES USERS OF FLASH CONTINUOUS GLUCOSE MONITORING SYSTEM

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Background and Aims: MCG allows knowing glycemic parameters and defining follow-up targets that are associated with less risk.Aim:To determine the TIR,TBR,TAR and CV in type1 diabetes users of MCG Flash system.To evaluate the percentage of patients achieving TIR+TBR as defined by international recommendations

Methods: Data from a cohort of type I diabetes users of MCG Flash system and Libreview platform were analyzed. The variables analyzed were %:TIR, TBR,TAR,CV,GMI and %TIR+TBR. The population was divided into two groups according to age, Group I:18 to 64 and Group II: over 65 years old.The number of daily scans was correlated with the TIR.The Pearlson correlation test was used

Results: 84 patients were included, age:45 years(18-79), 69% female, the averageTIR: 51.89%,TBR:4.70%,TAR:44.27%, CV37.21% and the GMI:7.52%.Only the 9.8% of patient achieved TIR >70%, 66%TBR <4% and TIR+TBR: 8.4%.Group I presented an average TIR of 50.46%, TBR 5.12%,CV 37.85% and GMI 7.61%.The TIR of group II was 57.86%,TBR 2.93%,TAR 39.21%,CV 32.9 and GMI 7.23%.TIR +TBR in this group was 21.4% and 50% achieved TIR >50% and TBR <1%. The correlation between the number of daily scans and TIR in both groups were moderate p 064(r 0.003) and p 045 (r 0.048) respectively

Conclusions: The evaluation of glycemic parameters defined by MCG Flash system in this study, showed that the combined target TIR+TBR was achieved in 8.4% of cases.The older adults group achieved it in 21.4% of patients.These data reflect the urgent need to optimize treatment strategies in people with diabetes, , in order to improve the achievement glycemic targets and reduce complications.

EP218 / #651

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IMPACT OF MOBILE MESSAGING ON FOLLOW UP AND GLYCEMIC CONTROL IN THE INDIAN POPULATION

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Background and Aims: Diabetes treatment requires the involvement of people with diabetes as regular clinical follow-up. which is necessary for good Glycaemic control and Metabolic health. Newer Communication techniques, such as mobile messaging are now finding their way into diabetes care and treatment. It can assist diabetes patients to maintain a regular follow-up routine.

Methods: 326 patients were selected by random sampling. Age 15–65 years with T1DM and T2DM. Inclusion Criteria: 1. Known case of Diabetes mellitus 2. Ability to use messaging Exclusion criteria: 1. Inability to use messaging Randomly allocated to two groups of 163 persons each. In the first group, the participants were sent regular messages to remind them of their follow-up dates. The other group was treated as usual. The participants were monitored for follow-up frequency, meeting testing deadlines and resultant glycemic control measured by Hba1c at 3 and 6 months. The results were analysed using SPSS.

Results: 17 patients each dropped out from the messaging group and 16 patients dropped out from routine care groups, out of the remaining 297 patients the analysis of data shows: in the messaging group, 63 % maintained their follow-up dates as compared to 42 % in the other group, patients achieving the target goal of 7% HBA1C and Blood sugar testing frequency was better in the messaging group (54%) as compared to the routine group (31%).

Conclusions: Newer messaging platforms if used correctly can not only improve follow-ups but result in better patient outcomes and will lead to reduced complications and financial implications.

EP219 / #335

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PERSONALIZING SELF-MANAGEMENT VIA BEHAVIORAL PREDICTIVE ANALYTICS WITH HEALTH EDUCATION FOR IMPROVED SELF-EFFICACY

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Background and Aims: There are over 537 million type-2 (pre)diabetics worldwide. Less than 25% of patients are actively engaged. We investigate the feasibility of behavioral predictive analytics to optimize diabetes self-management. The goal is to affect individuals on behavior change toward actionable health activities for improved patient engagement, which is known to link to better health outcomes.

Methods: Behavioral predictive analytics relies on manifold clustering to identify subpopulations by patients' behavior readiness, which exhibits non-linear properties. We conducted a pilot study approved by CUNY Institutional Review Board (#2018-1043). Patient subpopulations were derived by applying manifold clustering to the behavior readiness data of 148 subjects. Personalized actionable health activities were then devised.

Results: The preliminary result shows (1) improved engagement among 22 subjects involved in personalized self-management under different scenarios including students as a proxy for the elderly, and (2) improved diabetes self-efficacy among 34 subjects. Compared to the engagement rate of the subjects prior to the intervention, it was improved by 20% on average when behavioral predictive analytics was applied to devise personalized actionable health activities. In the asynchronous setting of delivering health education through the SIPPA Health mobile app, we found the improvement in diabetes self-efficacy statistically significant based on Repeated Measure-ANOVA.

Conclusions: This study shows evidence of improving diabetes self-efficacy. We are in discussion with the NYS Health Department regarding the priority of incorporating self-management into the public health agenda and seek partnerships to examine the effect of languages and the social-economic context on delivering health education, which are two limitations of the reported pilot.

EP220 / #641

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DIGITAL BIOMARKERS TO SUPPORT PERSONALIZED LIFESTYLE AND DISEASE MANAGEMENT IN DIABETES TYPE 2

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Background and Aims: Digital health technologies may support the management and prevention of disease through personalized lifestyle interventions. Wearables and smartphones are increasingly used to derive digital biomarkers for continuous, non-invasive monitoring of lifestyle and diabetes in everyday life. The challenge is to come to meaningful, reliable digital biomarkers that can be combined to actually support diabetes management and prevention. Here we present two examples of digital biomarkers based on multimodal wearable tracking.

Methods: Twenty-four healthy volunteers continuously monitored glucose, food, activity, and sleep over a period of 14 days. Gradient boosting machine was applied to derive two digital biomarkers from this study. The first digital biomarker was developed for eating moment detection from continuous glucose monitor and activity data. A second digital biomarker was developed to predict continuous glucose data from macronutrient intake, activity, sleep, and cardiometabolic features collected from a wearable. Explainable AI was applied to derive insights into factors driving glucose peaks.

Results: Eating moments were classified with an accuracy of 92.3% (87.2% – 96%) and 76.8% (74.3% - 81.2%) in the train and test datasets, respectively. Glucose levels were predicted with an overall mean absolute error of 0.32 (+/- 0.04) mmol/L and 0.62 (+/- 0.15) mmol/L for the training and test data, respectively. The contextual factors that were responsible for predicting glucose peaks varied among individuals, indicating a basis for personalized advice.

Conclusions: Pending further validation and integration of these digital biomarkers in e-health solutions, they show promise in supporting the prevention and management of type 2 diabetes through personalized lifestyle recommendations.

EP221 / #580

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

AN EASY-TO-USE INNOVATIVE NUTRITION APP FOR DIETARY ASSESSMENT

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Background and Aims: We created an innovative nutrition application to track dietary intake, which uses a smartphone for food intake data capture via text or images. The fit-for-purpose app also includes a novel portion size estimation image slider bar, provides feedback to users on their macro- and micro-nutrient intakes, and is customizable to geography with country-specific nutrient databases in various languages.

Methods: Its usability and acceptability were assessed in the context of a proof-of-concept randomized controlled cross-over trial.

Results: Using the app, participants (n = 26) tracked their food and beverage intake for 12 days, adding up to ~4000 entries which includes 189 images. The average number of photos per day per user for users that took photos (15/26) was 2.3 and their preferred meal occasion on image capturing was dinner, followed by lunch, breakfast and snack. Participant feedback was collected by a dedicated questionnaire (response rate: 53.8%). Ease of use was rated high, and the portion size estimation feature was perceived as an attractive alternative to conventional methods.

Conclusions: Validation trials are needed to assess the app's usability in different settings. The accuracy of different portion size estimation methods to support healthy balanced diets and potentially specific disease management needs to be investigated in controlled feeding studies.

EP222 / #51

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

THE EFFECTIVENESS OF MOBILE APPLICATIONS AMONG PEOPLE WITH TYPE 2 DIABETES INCLUDING DIETARY RECOMMENDATIONS

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Background and Aims: Worldwide, diabetes is a common metabolic disorder that creates many complications. In nowadays mobile-based application could be included in the therapeutic approaches of self-management. This study is about to present the impact of the intervention based-on mobile apps on diet among people with type 2 diabetes mellitus (T2DM) in randomized control trials.

Methods: PubMed database was examined to identify the impact of interventions based-on mobile apps on diet recommendations among people with T2DM comparing with usual diabetes care. The keywords were ''Type 2 diabetes'', ''smartphone'', ''app'', ''diet'', nutrition'' in randomized control trials. Search was limited to the last 5 years. The inclusion criteria of this research were interventions based-on mobile apps including mostly dietary recommendations and other capabilities into the control group.

Results: For the purpose of this study 21 trials were reviewed by applying the inclusion criteria. 16 trials were found non-relevant and were excluded. 5 trials met the inclusion criteria. 608 individuals participated in these studies. To summarize, in the control groups were observed a decrease levels of hemoglobin A1c (HbA_{1c}), weight loss, reduction of diabetes medication and differences in the fasting blood glucose, diastolic blood pressure, dietary habits, total cholesterol, triglycerides.

Conclusions: These findings underling that the diet recommendations including in a smartphone app can affect levels of HbA_{1c}. Furthermore, these could help healthcare professionals to encourage patients use mobile applications to manage their diabetes and inspire app developers to improving those app designs and capabilities.

EP223 / #487

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

REAL-WORLD EFFECTIVENESS OF TOUJEO+ PROGRAM IN ADULT PATIENTS WITH TYPE 2 DIABETES MELLITUS IN TAIWAN

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Background and Aims: Digital health technology platforms such as Health2Sync (H2S) can help improve glycaemic control by providing coaching and titration support to patients with diabetes. Mallya cap is a smart device which converts conventional insulin pens into connected devices which automatically record dose and associated timestamp. This study evaluated effectiveness of insulin glargine 300 U/mL (Gla-300) with Mallya cap and H2S (Toujeo + Cap + App program) on clinical outcomes among patients with type 2 diabetes (T2D) in Taiwan.

Methods: This retrospective cohort study included patients with T2D aged ≥20 years, registered on H2S and initiated Mallya cap use (index date) for a new/existing Gla-300 regimen (identification period: May 1, 2021–May 31, 2022). Follow-up was 90 days after index date. Data were collected from H2S. Primary outcomes were HbA_{1c} change (baseline to follow-up) and HbA_{1c} goal attainment. Secondary outcomes included change in fasting blood glucose (FBG) and Gla-300 dose.

Results: Overall, 83 patients were included; 55% were male and mean (SD) age was 49.2 (13.1) years. At baseline, H2S

Table: Clinical outcomes with Toujeo + Cap + App program for total T2D population and stratified by baseline Gla-300 use

	Total T2D Population N=83 (100%)	New Gla-300 User N=32 (38.6%)	Previous Gla-300 User N=51 (61.4%)
HbA_{1c} Change, Mean (SD)			
Baseline HbA_{1c} (%)	8.4 (2.2)	9.6 (2.3)	7.7 (1.8)
Follow-up HbA_{1c} (%)	7.2 (1.1)	7.2 (1.0)	7.2 (1.1)
Change in HbA_{1c} (%)	−1.2 (2.3) *	−2.4 (2.7) *	−0.5 (1.6) *
HbA_{1c} Goal Achievement, N (%)			
HbA_{1c} <7 % at baseline	27 (32.5)	4 (12.5)	23 (45.1)
HbA_{1c} <7 % at follow-up	37 (44.6)	13 (40.6)	24 (47.1)
HbA_{1c} reduction >0.5 %	36 (43.4)	21 (65.6)	15 (29.4)
FBG Change, Mean (SD) †			
Baseline FBG (mg/dL)	131.1 (49.0)	155.4 (72.5)	119.9 (29.5)
Follow-up FBG (mg/dL)	122.2 (28.9)	118.5 (19.4)	123.9 (32.4)
Change in FBG (mg/dL)	−8.9 (51.9)	−36.8 (71.7) *	+3.9 (33.8)
Gla-300 Dose Change, Mean (SD)			
Baseline dose (U)	19.5 (12.8)	18.8 (12.1)	19.9 (13.2)
Follow-up dose (U)	22.9 (13.8)	22.1 (14.7)	23.4 (13.4)
Change in dose (U)	+3.3 (12.3) *	+3.3 (16.5)	+3.4 (9.2) *

*Indicates statistically significant difference ($p<0.05$)

†Among individuals with baseline and follow-up FBG value (Total N=67, New user N=21, Previous User N=46)

FBG, fasting blood glucose; Gla-300, insulin glargine 300 U/mL; T2D, type 2 diabetes; U, Unit

tenure was 185.9 (230.6) days; 38.6% of patients were new Gla-300 users. HbA1c (%) fell significantly between baseline and follow-up (mean [SD] change: −1.2 [2.3], $p<0.01$), with new Gla-300 users showing most improvement (**Table**). HbA1c <7 % was achieved by 44.6% of patients at follow-up, and 43.4% had a reduction of >0.5 %. Mean FBG change was −8.9 mg/dL and mean Gla-300 dose increased by 3.3 units.

Conclusions: The Toujeo + Cap + App program may help to improve glycaemic control in patients with T2D.

EP224 / #39

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PEDIATRICS DIABETES CARE: FROM COMMUNITY CARE TO SPECIAL CENTERS

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Background and Aims: Providing pediatrics type 1 and type 2 diabetes care has been always focused in major centers rather than primary care providers' offices. Analyzing the available resources is the first step in understanding the actual needs to provide the best pediatric diabetes outcomes. Providing pediatric diabetes care depends on multidisciplinary approach and availability of modern technology equipment, staff, and on- site medications

Methods: A survey was sent to three pediatric fellows in training exploring the difference between their delivery of pediatric diabetes care prior and after their formal training

Results: Two fellows have entered the pediatric endocrinology training immediately after formal pediatric residency while the third, has been practicing general community pediatrics for several years The survey listed different resources such as diabetes technology tools (HbA1c machine, access to Continuous Glucose Sensor Monitoring System: CGMS, demo training kits of insulin pens and pumps), human resources (on site specialized pediatric endocrinologists, Certified Diabetes Educator, dietitian) and availability of rescue medications (Glucagon, insulin). The community- based system lacked the availability of modern technology devices, some human resources, and availability of on- site rescue medications.

Conclusions: Disparities in diabetes health care access and services are well known globally. Medical treatment and quality of resources in pediatrics diabetes differed significantly between primary and specialty care systems. Disparities in individual socioeconomic status, regional deprivation, and differences in medical reimbursement decisions may contribute to access of specialty care. Understanding available resources for pediatric diabetes care is an important factor during formal post-doctoral training and when evaluating future job opportunities

EP225 / #906

Topic: ***AS08 Insulin Pumps***

THE CONTINUOUS SUBCUTANEOUS INSULIN INFUSION TREATMENT WITH CONTINOUS GLUCOSE MONITORING SYSTEM AFFECTS TO POOR DIABETES CONTROL: A CASE REPORT

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Background and Aims: Diabetes can pose a risk to both mother and child and therefore requires careful management.

Methods: In this case, we present the benefits of advanced medical technologies for better diabetes control.

Results: A 35-year-old female patient, who was diagnosed at age 5 with insulin-dependent diabetes mellitus, is referred to an endocrinologist for poor glycemic control while attempting to conceive. She was treated with multiple insulin injections, but despite the diabetes education diabetes control was poor with frequent severe unnoticeable hypoglycemia followed by hyperglycemia (HbA1c 8.0%). Diabetic nephropathy (albumin excretion rate 49.5 mg per 24 h), proliferative retinopathy and polyneuropathy were observed. In 2014-2016 (when she was pregnant for the first time), CSII treatment was used and diabetes control improved (HbA1c 6.4%). However, due to skin reactions (rash at the site of the patches and pain at the site of the needle stick), the patient stopped using the insulin pump and continued treatment with multiple insulin injections. In 2022, a panel of physicians decided that in the presence of very poor disease control (TIR 31%, readings below target 10%, HbA1c 12.4%), treatment with an insulin pump with CGM and stopping insulin in the presence of hypoglycemia was appropriate. As a result, the patient became pregnant at 2 months and disease control improved: HbA1c at baseline was 7,8%, TIR 56%. When she was 5 months pregnant, her subtarget values dropped to 0%, HbA1c to 5.6% and TIR 70%.

Conclusions: It is important to start the use of advanced technologies in order to avoid at serious health complications during pregnancy and childbirth.

EP226 / #288

Topic: ***AS08 Insulin Pumps***

OMNIPOD® DASH ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS (ABCD) AUDIT: AN INTERIM REPORT OF USERs' BASELINE CHARACTERISTICS

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Background and Aims: The ABCD Omnipod® Dash is the first international audit launched in early 2022 with the aim of collecting data on the use of Omnipod® Dash System and provide real-world insights.

Methods: Cross-sectional report of baseline data in the ABCD Omnipod® Dash tool using descriptive statistics in Stata 16. Data are reported as mean ± SD or median (interquartile range).

Results: Presently 144 users have data entered into the secure online tool. The baseline (pre-Omnipod Dash) characteristics are as follows: HbA1c 66.8 ± 15.3mmol/mol, weight 74.3 ± 20.2kg, BMI 25.5 ± 7.8kg/m^2, diabetes duration 19.0 years (7.0-28.1). Age at Omnipod® Dash commencement 36 years (23-48), 11.8% (17/144) <18 years. Majority (69.4%,100/144) female; 95.8% (138/144) White British. Median index of multiple deprivation was 8 (6-9) with more individuals from non-deprived backgrounds (Chi-squared P = 0.003), although this may be due to the characteristics of the registered centres. One third (32.6%,47/144) were new to pump therapy. If established on pump, median duration was 7.2 years (4-10.5). The most frequent indications for pump therapy were problematic hypoglycaemia (46/134, 34.3%) and HbA1c above target (37/134, 27.6%). Most (77.8%) use flash/continuous glucose monitoring; 5 individuals were using closed-loop. Mean baseline total daily dose (TDD) was 46.8 ± 23.5units; 25% of individuals have a TDD >60units.

Conclusions: The ABCD Omnipod® Dash audit includes data from a wide range of individuals. These data provide the first clinical data related to Omnipod® Dash use in the UK allowing determination of valuable insights into who is using this technology and why. Of note, there may be implications from the data on socioeconomic status, ethnicity and TDD.

EP227 / #523

Topic: ***AS08 Insulin Pumps***

PRIOR THERAPY AND GLYCEMIC CONTROL IN PATIENTS INITIATING AUTOMATED INSULIN ADMINISTRATION IN MEXICO

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Background and Aims: Background: Traditionally, the indication of advanced technologies was limited to a small group of patients. Automated insulin delivery devices (AID) have shown excellent results in the treatment of T1D, allowing more patients to reach their glycemic goals. Aims: To describe the effect of previous therapy on the glycemic targets achieved by patients initiating AIDs.

Methods: Prospective observational registry, including all patients who initiated AID with the MiniMed™ 670G System in Mexico. Glycemic control (Time in Range [TIR] and Glucose Control Indicator [GMI]) was compared according to previous therapy at 180 days with respect to baseline.

Fig. 1. Time in range at different visits from baseline up to 180 days according to previous therapy

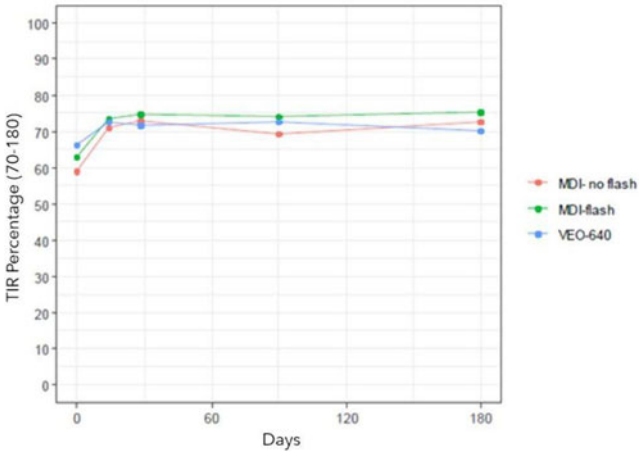
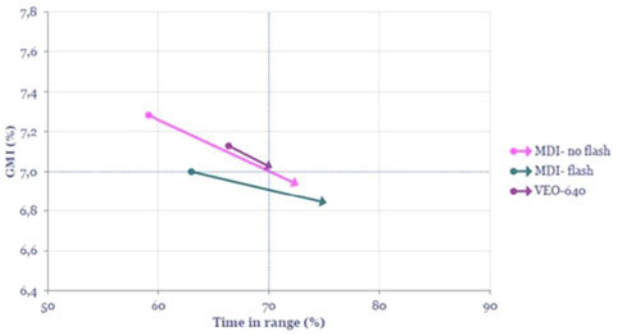


Fig.2. Patients' evolution (baseline vs. 6 months) according to previous therapy



	MDI- no flash (n=12)		MDI- flash (n=10)		VEO-640 (n=18)	
	TIR	GMI	TIR	GMI	TIR	GMI
Basal	59,08	7,28	63,00	7,00	66,35	7,13
6 meses	72,67	6,93	75,20	6,84	70,29	7,02

Results: 39 patients were included (age: 27.2 ± 18.4 years, range 6 to 76), 53.8% female, previous treatment with MDI 30.8% (n = 12), MDI-Flash 25.6% (n = 10) and PLGM-LTS 43.6% (n = 17). The Time In Range (TIR) between 70-180 mg/dl was significantly increased at day 180 from baseline in patients from MDI, MDI-Flash and PLGM-LTS from 59.1% to 72.7%; 63% to 75.2% and 66.4% to 70.3, respectively (Figure 1). The GMI showed a significant reduction (p = 0.03) in all groups at the end of follow-up (Figure 2). Of the patients, 64.1% and 61.5% achieved the recommended international consensus targets of both TIR and GMI, respectively.

Conclusions: The MiniMed™ 670G System enabled the most patients who started treatment to achieve the recommended international consensus glycemic targets of both TIR and GMI, regardless of the previously used therapy.

EP228 / #889

Topic: ***AS08 Insulin Pumps***

COMPARISON OF SENSOR-AUGMENTED PUMP THERAPY WITH PREDICTIVE INSULIN SUSPENSION AND MULTIPLE DAILY INJECTIONS THERAPY WITH INTERMITTENT GLUCOSE MONITORING IN PATIENTS WITH DM1

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Background and Aims: To investigate which regimen, between sensor-augmented pump (SAP) therapy with predictive insulin suspension and multiple daily injections (MDI) therapy with intermittent glucose sensor (IGS) in DM1, is better to manage HbA1c less than 7%, time in range (TIR) 70-180 mg/dl more than 70%, time below range (TBR) <70mg/dl less than 5% and coefficient variance ≤36%, in real-world conditions.

Methods: 62 patients with DM1 were recruited during the last trimester. 33 patients were on MDI-IGS therapy (female = 18, mean age = 53.21 ± 15.98 years, BMI = 26.74 ± 3.72 Kg/m^2, mean DM duration = 25.42 ± 12.65 years) and 29 patients were on SAP therapy (female = 9, mean age = 42.17 ± 12.04 years, BMI = 24.57 ± 3.47 Kg/m^2, mean DM duration = 24.71 ± 12.33). Anthropometric measurements were recorded, HbA1c was measured, and the continuous and intermittent glucose sensors' reports for the last two weeks were generated.

Results: The glucose variability (mean CV = 33.81 ± 4.82% vs 37.15 ± 6.43, p = 0.032), time below range 69-54 mg/dl (3.03 ± 2.03 vs 5.03 ± 5.01, p = 0.044) and time below range <54 mg/dl (0.59 ± 0.68 vs 1.5 ± 2.21, p = 0.032) were significantly better in the SAP therapy group. There was no significant difference between the two groups in HbA1c (6.86 ± 0.86 vs 7.12 ± 0.86), glucose management indicator, time in range 70-180 mg/dl (73.28 ± 12.63 vs 68.34 ± 12.54), time above range 181-250 mg/dl, time above range >250 mg/dl, total daily dose, and diabetes duration.

Conclusions: The challenging optimal glycemic control in DM1 seems more achievable by the SAP therapy, regardless of the total daily dose and diabetes duration.

EP229 / #485

Topic: ***AS08 Insulin Pumps***

HUMAN FACTORS VALIDATION OF THE TEMPO SMART BUTTON

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Background and Aims: A simulated-use Human Factors (HF) study was conducted to validate that the Tempo Smart Button (TSB) and compatible mobile application (MA) are safe and effective for the intended users and uses, in the intended use environments. When attached to a Lilly pre-filled Tempo Pen, the TSB can detect, store, and transfer insulin dose-related data to a compatible MA.

Methods: A HF validation study was conducted including adult caregivers and adult people with diabetes, both experienced and naïve to pen-injector use (n = 30). In each two-hour study sessions, a participant completed 4 simulated use scenarios and 8 knowledge tasks to assess the usability and use-safety of the Tempo Smart Button in conjunction with a compatible MA.

Results: All participants were successfully able to pair the module with the compatible MA. There were no dosing errors (i.e., over/under doses or the inability to deliver a dose) resulting from the use of the TSB. Additionally, none of the participants reported or exhibited interference when using the pen-injector with the TSB attached to the pen (e.g., difficulties related to the reachability of the TSB, force required to dial doses, or viewability of dose window when dialing doses). All dose amounts administered by participants were accurately shown in the compatible MA.

Conclusions: Based on using regulated HF testing methodology, the TSB and compatible MA are safe and effective for use for its intended use, by the intended users, in the intended use environment.

EP230 / #613

Topic: ***AS08 Insulin Pumps***

CARE EFFICIENCIES WITH TUBELESS VS. TUBED PUMPS: A TIME-AND-MOTION STUDY OF NEW INSULIN PUMP USERS

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Background and Aims: There is currently limited understanding of the process of initiating standard Insulin Pump Therapy (IPT) and how this differs with pump type. A time-and-motion study was conducted in Germany and the UK to evaluate the time required for initiation with a tubeless insulin pump (a Pod) versus other tubed pumps.

Methods: The time taken to initiate people onto tubeless IPT and tubed IPT (excluding automated insulin delivery systems) was self-recorded by diabetes specialist nurses using a web-based tool. Pump users were adults with and without prior experience of IPT, and initiations were conducted face-to-face and remote.

Results: In total, 75 nurses (48 UK, 27 Germany, mean 14 years' experience) recorded 269 initiations (105 tubeless, 164 tubed, 90% type 1 diabetes) . The mean time for initiating IPT was 116 mins (range 8–305 min). The mean time for initiating tubeless IPT was 15 mins shorter compared to tubed IPT (mean±SD 107 ± 77min vs. 122 ± 95min, $p < 0.05$). Tubeless IPT initiations were significantly shorter than tubed IPT initiations for MDI users (mean time difference 19min, $p < 0.05$) and for those with prior experience of IPT (mean time difference 10 min, $p < 0.05$). Tubeless pump initiations were shorter than tubed pump initiations in the face-to-face setting (19 min less on average $p < 0.05$), but not significantly shorter in the remote setting (plus 3 min on average, $p > 0.05$).

Conclusions: This novel time-and-motion study identified significant time reductions for initiating tubeless IPT versus tubed IPT. Applying this time saving across pump services could help increase efficiencies and reduce workloads for pump services.

EP231 / #630

Topic: ***AS08 Insulin Pumps***

TRAINING NEW USERS WITH TUBELESS AND TUBED INSULIN PUMPS: A SURVEY OF NURSE EXPERIENCES

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Background and Aims: Despite increasing use of insulin pump therapy (IPT) little research exists on practices for initiating IPT. We aimed to gather insights into the experience of initiating a tubeless insulin pump (a Pod) compared to other types of tubed IPT and the challenges for doing so remotely.

Methods: An online survey was developed with 18 questions, containing Likert Scale, choice based and free text responses, about diabetes nurses experience of, and estimated time for, initiating new users on different IPT across the UK (n = 75) and Germany (n = 75).

Results: The most common setting for initiations was in hospital in the UK (79%) and outside hospital, in community settings, in Germany (72%). Respondents estimated average time savings of 15 min ($p < 0.05$) for tubeless pump initiations compared to tubed pumps, with 45% (CI 95%: 38%-53%) answering that it takes less time to initiate tubeless pumps, 9% (CI 95%: 5%-14%) saying that it takes longer and 46% (CI 95%: 38%-54%) saying that it takes about the same time. Tubed pumps were found to be more complex than tubeless pumps by 46% (CI 95%: 38%-54%) and less complex by 12% (CI 95%: 7%-17%). Most respondents agreed that users find it more difficult to understand the features when IPT are initiated remotely compared to face-to-face, 79% (CI 95%: 71%-85%).

Conclusions: Nurses in the UK and Germany judged tubeless IPT to require less time and be less complex for initiation than tubeless IPT. Use of this system could help address constraints health services face in starting new users on insulin pumps.

EP232 / #878

Topic: ***AS08 Insulin Pumps***

OCCLUSION DETECTION IN A NOVEL, AFFORDABLE INSULIN PUMP

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Background and Aims: Occlusions in an insulin pump can impair blood glucose control and lead to adverse events (AEs). Most insulin pumps incorporate a predictive algorithm to detect occlusion and deliver an occlusion alarm. The time until the alarm is triggered is a critical parameter. The present work undertakes experiments to determine this time for a novel, affordable insulin pump.

Methods: A reservoir connected with an infusion set, containing distilled water was mounted into the equipment under testing (EUT). Priming was undertaken as per requisite instructions. The Teflon cannula of the infusion set was then clamped to simulate an acute/complete occlusion. The EUT was subsequently programmed to deliver a bolus dose (1.5U/min.), followed by a basal dose (1U/hour). Time until an alarm is triggered was noted for each of the five runs.

Results: Mean time until an occlusion is detected for the EUT was found to be significantly lower than a commercially available device (Medtronic 722G, M722G), for both bolus and basal modes of delivery: 28.8s vs. 116s (bolus), 0.46 hours vs. 3.09 hours (basal). This was also reflected in the difference between maximum and minimum values: 32s vs. 70s (bolus), 0.1 hours vs. 2.27 hours (basal). Reported data translates to an 75.2% (bolus), 85.1% (basal) reduction in time for occlusion detection by the EUT.

Conclusions: Shorter times for occlusion detection in the EUT can allow for quicker patient intervention and diminished risk of AEs. This can be further improved by incorporating delivery rates within the detection algorithm.

EP233 / #649

Topic: ***AS08 Insulin Pumps***

EFFECTS OF RESERVOIR, PLUNGER MATERIAL COMBINATION ON INSULIN DELIVERY FORCES AND ACCURACY

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Background and Aims: Most insulin delivery devices make use of a reservoir and plunger, actuated by a piston to deliver the drug. Reservoirs are typically made of plastic/glass, with the plunger composed of rubber/glass or a hybrid plastic-rubber construction. A combination of these two materials (reservoir-plunger) governs delivery forces and can affect the accuracy of delivery.

Methods: Two combinations of reservoir-plunger materials (A: plastic-hybrid plastic rubber, B: glass-glass) were setup in a motorized force stand with delivery output fluidly connected to a weighing scale setup to evaluate the quantity of liquid discharged. The plunger was actuated at fixed velocities (1μm/s - 25μm/s), with corresponding force readings captured. In a second set of experiments within the same setup, ten bolus doses of 10U unit each were given with a varying inter-dose interval (parking time) (10 minutes – 24 hours), and the delivered volume was captured.

Results: The peak force and relaxation time constant for combination A were found to be higher than for combination B (1.5N, 4.8s vs. 0.4N, 0.8s). Phenomenon characteristic of viscoelastic elements, such as inter-actuation force relaxation, was also observed. Change in parking time did not have any significant effect on the delivery accuracy of combination A, except for 24-hours (-7.5%).

Conclusions: The reservoir-plunger material combination affects delivery forces, which is critical for the design of insulin delivery systems. This also governs the nature of force relaxation post completion of delivery, which can potentially explain why a significant fraction of delivery happens after the planned bolus duration in insulin pumps.

EP234 / #933

Topic: ***AS08 Insulin Pumps***

REMOVING PHENOL PRESERVATIVES AND INSULIN FIBRILS EXTENDS THE LIFESPAN OF INSULIN INFUSION PUMPS – THE SALIENT ROLE OF CYCLODEXTRIN

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Background and Aims: Extended shelf life and sterility of commercial insulin formulation is achieved through the addition of insulin phenolic preservatives (IPP). Insulin-derived fibrils (IDF) can develop as a result of thermal, mechanical or chemical stressors. Our published data indicate that both IPP and IDF are pro-inflammatory. This response leads to cumulative cell/tissue toxicity, inflammation, and maladaptive wound healing. Study aims are to evaluate a novel filtration platform targeting IPP and IDF.

Methods: Cyclodextrin (CyD) beads and microfiltration platform are used to remove IPP and IDF. *In vitro* IPP and IDF toxicity studies included cell viability and netosis imaging assays using leukocytes from healthy and diabetic individuals. *In vivo* studies employed FLOW cytometry to quantify IPP and IDF induced leukocyte recruitment in murine air-pouch model. Histopathologic evaluations at IPP and filtered IPP infusion sites were conducted in mice and swine.

Results: CyD platform is able to remove IPP and IDF from commercial insulin formulations. *In vitro* studies demonstrated IPP and IDF induced cell death and neutrophil extracellular TRAPs (NET) formation. Mouse air pouch studies demonstrated that influx of inflammatory cells is augmented in the presence of IPP and IDF. NET formation was confirmed in mice and swine. Chronic inflammation, fibrosis, and granulation tissue is seen post 3-day insertion.

Conclusions: Causes of insulin infusion sets limited lifespan are likely multi-factorial and dynamic. Thus, any strategy designed to optimize exogenous insulin administration and efficacy must mitigate pro-inflammatory factors arising from IPP, IDF, catheter materials and/or insertion site reactions to ensure tissue integrity.

EP235 / #26

Topic: ***AS08 Insulin Pumps***

RAMADAN FASTING IN PATIENTS WITH TYPE 1 DIABETES MELLITUS ON INSULIN PUMP FOLLOWED UP IN A VIRTUAL DIABETES CLINIC

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Background and Aims: Ramadan is a lunar-based holy month in which Muslims are obligated to fast from before the dawn until sunset. The objective of this study is to assess the efficacy and safety of fasting Ramadan in patients with type 1 diabetes mellitus (T1DM) on sensor augmented pump therapy followed up in a virtual insulin pump clinic.

Methods: A prospective cohort study was conducted in the months of Shaban, Ramadan, and Shawwal on all subjects who were eligible and willing to fast Ramadan. Patients received five virtual visits. Clinical data were collected using a unified data collection sheet. Patients were encouraged to share continuous glucose monitoring (CGM) data with the research team. Simple descriptive statistics and inferential analysis were employed as necessary.

Results: 48 patients were included in the study. Of whom, 60.4% participants were on Medtronic MiniMed Paradigm Real Time 722, while 39.6% were on Minimed® 640G with SmartGuard®. On average, the number of days of breaking the fast due to diabetes-related complications was 1.92 ± 3.0. CGM data were available for 12 participants on Minimed® 640G with SmartGuard®. On average, participants showed serum glucose (SG) of 70-180 mg/dl in $68.67 \pm 13.1\%$, SG >180 mg/dl in $11.35 \pm 5.2\%$, and SG <70 mg/dl in $3.56 \pm 3.1\%$ with glycemic variability of $31.62 \pm 11.5\%$.

Conclusions: Findings of this study demonstrated that Ramadan fasting is possible for patients with T1DM on insulin pump therapy with minimal risks of hypoglycemia and hyperglycemia while maintaining acceptable glycemic control.

EP236 / #921

Topic: ***AS08 Insulin Pumps***

A NEW PROPOSAL FOR A SECOND INSULIN BOLUS TO OPTIMIZE POST-PRANDIAL GLUCOSE PROFILE IN ADOLESCENTS WITH TYPE 1 DIABETES

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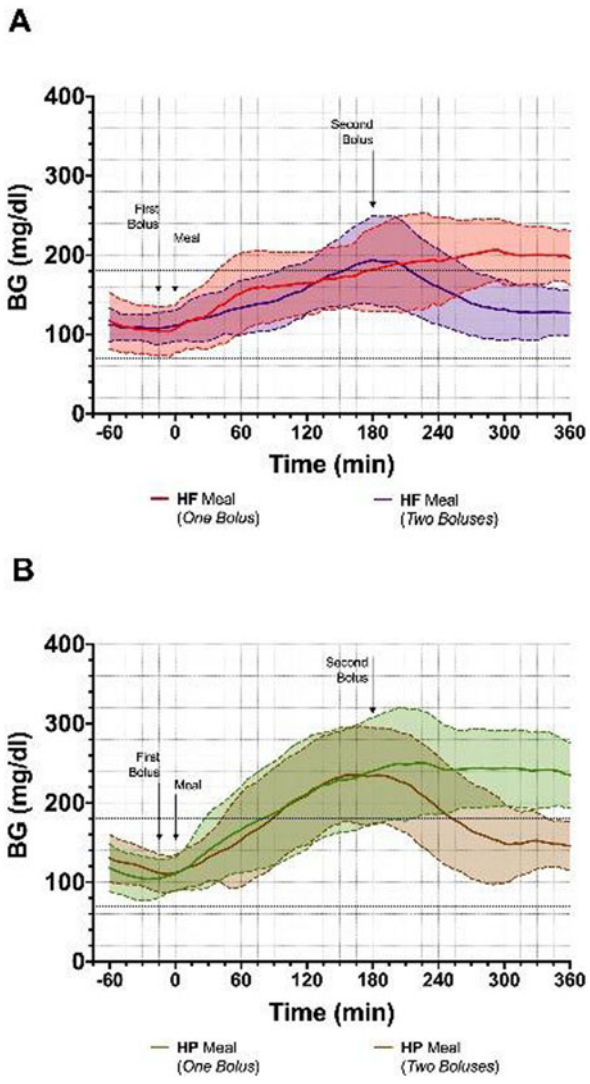
Background and Aims: Post-prandial hyperglycemia is still a clinical challenge for patients with T1D. The aim of this study was to evaluate if a second insulin bolus, calculated with a new approach, could improve post-prandial glucose (PPG) after the intake of real-life moderately high-fat (HF, fast-food) and high-protein (HP, pizza) meals.

Methods: Fifteen adolescents with T1D treated with non-automated insulin pumps and CGM were enrolled. In the first part of the study, patients received three meals (standard, HF, and HP mixed meals) treated with one pre-meal insulin bolus; based on differences in PPG between standard, HF, and HP meals, correction boluses were calculated (30% and 65% of pre-meal bolus for HF and HP meals, respectively). Then patients received the same HF or HP meal treated with pre-meal bolus plus the calculated correction bolus after 3hrs. Differences between post-prandial variables after HF and HP meals treated with one or two insulin boluses were assessed by paired Student's t-test.

Results: Treating HF and HP meals with two insulin boluses significantly reduced the post-prandial BG-AUC (21% and 26% respectively, $p < 0.05$), increased %TIR (from 52.5% to 78.3% for HF meal; from 32.7% to 57.1% for HP meal; $p < 0.01$), reduced mean BG and %TAR ($p < 0.01$), with no differences in %TBR (see Figure 1).

Conclusions: The new way to calculate and administer correction boluses 3hrs after HF and HP meals is effective and safe in reducing post-prandial hyperglycemia avoiding hypoglycemic episodes.

Figure 1



EP237 / #689

Topic: ***AS08 Insulin Pumps***

A COMPARISON OF GLYCEMIC VARIABILITY IN CSII VS MDI IN PEOPLE WITH TYPE 1 DIABETES: A REAL-WORLD DATA ANALYSIS

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Background and Aims: People with Type 1 diabetes mellitus (TIDM) either choose multiple daily insulin injections (MDI) or continuous subcutaneous insulin infusion (CSII) for metabolic control. However, comparing glycemic metrics of TIDM using MDI and CSII technology is limited in real life.

Methods: A total of one hundred sixteen (116) people with Type1DM were included in this study. Of them, 52 were on CSII, and 64 were on MDI with CGM systems. Both CSII and MDI groups had received structure education for Dose Adjustment for Normal Eating (DAFNE) and had matched HbA1c (median 7.50 vs. 7.45%), BMI (27.9 vs. 25.6 kg/m2), age (32.2 vs. 31.3 years), and diabetes duration (17 vs. 19 years). The device data was obtained, downloaded, and compared by Mann-Whitney U test.

Results: There was no significantly difference between CSII and MDI groups for mean interstitial glucose (9.6 ± 1.8 vs. 8.9 ± 1.4 mmol/L), time in the range 3.9 to 10 mmol/L ($62.8 \pm 15.4\%$ vs. $60.5 \pm 13.7\%$), coefficient of variability ($39.0 \pm 5.1\%$ vs. $38.6 \pm 7.2\%$) and total daily insulin dose (46.7 ± 20.4 vs. 51.7 ± 21.6 unit) (all $p < 0.21$). The CSII user showed significantly less time spent in the hypoglycemia range <3.9 mmol/l (3.8 ± 5.3 %) than the MDI ($5.7 \pm 5.4\%$, $p = 0.01$). No severe hypoglycemia and diabetes ketoacidosis were reported in the last 12 months.

Conclusions: CSII technology showed no difference in glycemic control compared to MDI therapy in DAFNE graduates. Investing in education is the key.

EP238 / #884

Topic: ***AS08 Insulin Pumps***

AUDIT OF PATIENTS WITH TYPE 1 DIABETES TREATED BY INSULIN PUMPS AND HYBRID CLOSED LOOP SYSTEMS IN A SINGLE DIABETES CENTRE

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Background and Aims: The latest treatment modality for type 1 diabetes is represented by the hybrid closed-loop systems (HCL), which consists of an insulin pump (IP), continuous glucose monitor and smart algorithm regulating the glycemia in response to the real time blood glucose levels and trends. The aim of this study was to assess the glycemic control in patients with type 1 diabetes using IP and HCL in our center between 2020 and 2022.

Methods: There are 2132 patients with type 1 diabetes (48.9% males, mean age 43,6 years) registered in our Diabetes Centre, whereof 967 (45.4 %) using IP and 354 (36.6%) of them using HCL in 2022. We assessed the glycemic control (by glycated hemoglobin - HbA1c) in all patients and compare data between patients using IP and HCL; and also changes in glycemic control after the start using HCL systems.

Results: A significant decrease of HbA1c through the past 2 years in all patients using IP (2020: 63.7 vs. 2022 60.3 mmol/mol, $p < 0.001$). In 2022, patients using HCL reached better glycemic control than only IP users (HCL 59.8 vs. IP 61.9 mmol/mol; $p<0.05$). Patients using HCL had a significant decrease of glycated hemoglobin in 2022 in compare to 2020 when using only IP (2022: 59.8 vs. 2020: 64.3 mmol/mol; $p < 0.0001$).

Conclusions: This study demonstrates the improvement of the glycemic control among the patients treated by insulin pumps in our centre between 2020 and 2022. It is very likely caused by implementation of HCL systems into the treatment of patients with type 1 diabetes.

EP239 / #692

Topic: ***AS08 Insulin Pumps***

MULTI-CENTER DIABETES PROVIDER PERSPECTIVE ON BARRIERS TO SMART INSULIN PEN USE IN THE UNITED STATES

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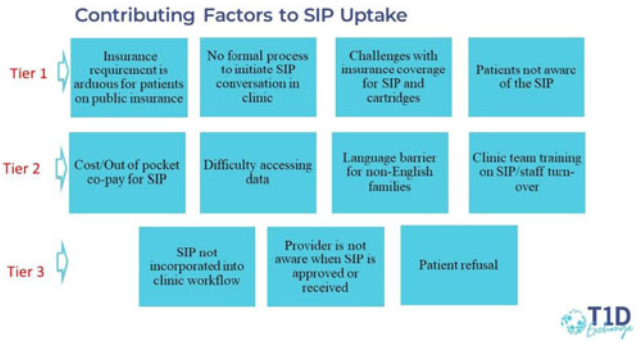

Background and Aims: Smart Insulin Pen (SIP) use has been shown to improve glycemic control and insulin management for patients with type 1 and type 2 diabetes on multiple daily injections (MDI). Despite these benefits, the uptake of SIP is low. The purpose of this study is to describe barriers to the adoption of SIP from the provider's perspective.

Methods: The T1D Exchange Quality Improvement Collaborative (T1DX-QI) identified nine endocrinology centers (5 adult and 4 pediatric centers to participate in a collaborative quality improvement (QI) study. Participating centers used QI tools, like the Ishikawa diagram, Affinity diagram, and process maps, to identify barriers to equitable use of SIP in clinical processes. Barriers were identified and categorized into three tiers based on the number of times barriers were reported by participating centers (Tier 1 > 80% of centers reporting, tier 2 50-80%, tier 3 < 50%).

Results: Identified barriers are highlighted in the figure attached.

Conclusions: Understanding the contributing factors to SIP uptake is a major step in designing quality improvement processes and research frameworks to increase uptake and address disparities in outcomes for patients with diabetes on MDI.

EP240 / #150

Topic: ***AS08 Insulin Pumps***

CLOSED-LOOP INSULIN DELIVERY IN A FEMALE PATIENT AGED 80 YEARS OLD: A CASE REPORT

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Background and Aims: Glucose management for old people with diabetes can be very challenging. We present a case of a woman aged 80-years-old with type 1 diabetes who switch to the advanced hybrid closed loop system.

Methods: A female patient, 80-years-old, with type 1 diabetes, with clinical history of HbA1c 9% to 11% in the last 4 years, on Medtronic Minimed 640G for 8 years was switched to Medtronic Minimed 780G integrated with Guardian 3 sensor. Patient had a history of hypertension, dyslipidemia and diabetic retinopathy with bilateral papillopathy, without reduction of visual acuity bilaterally.

Results: At baseline patient had the following metrics; time in range (TIR): 61%, time below range (TBR): 1% and time above range (TAR): 38%. Glucose management indicator (GMI) was 7.5% and mean blood glucose levels were 175 mg/dl. The optimization of the Medtronic Minimed 780G led to the following changes in the next 3 months; TIR: 87%, TBR: 0% and TAR: 13%, GMI was 6.4%, sensor wear of 93% and an auto mode period of 94% per week. After 9 months of follow-up the above metrics were; TIR: 78%, TBR: 0% and TAR: 22%, GMI was 6.9%, sensor wear of 91% and an auto mode period of 96% per week. No severe hypoglycemia nor ketoacidosis episodes were recorded during the follow-up period.

Conclusions: Advanced hybrid closed loop systems in an old woman allowed a rapid improvement of the overall glucose control. Advanced hybrid closed loop systems might provide a safer and less burdensome approach to glucose management in older patients.

EP241 / #612

Topic: ***AS08 Insulin Pumps***

CARBOHYDRATE INTAKE AND CLOSED LOOP INSULIN DELIVERY SYSTEM DURING TWO SUBSEQUENT PREGNANCIES IN TYPE 1 DIABETES

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Background and Aims: New hybrid closed loop systems (HCLs) changed clinical landscape by providing new therapeutic targets. In pregnancy, achievement of tight glycemic control is of utmost importance. However, data on HCLs in pregnancy is scarce. We aimed to assess glucose control achieved through the use of HCL and compared it to the one achieved by the sensor-augmented pump therapy (SAP) during two subsequent pregnancies.

Methods: We identified 6 women (age 30.2 ± 3.6 vs. 33.0 ± 3.6 years, diabetes duration 23.5 ± 5 vs. 26 ± 5 years, baseline HbA1c 6.7 ± 0.7% [50.1 ± 7.7 mmol/l] vs. 6.3 ± 0.6% [45.2 ± 6.5 mmol/l] in the first and second pregnancy, respectively) with SAP therapy during the first pregnancy and HCL (Minimed 780G) use during the subsequent pregnancy. Student's paired t-test was used to compare glycemic data between both pregnancies.

Results: Although there was no significant difference in the mean sensor glucose concentration or HbA_{1c} found between the HCL and SAP system across pregnancy trimesters, time in range was 69.1 ± 6.7 vs. 78.6 ± 7.4%, p = 0.045 in the second trimester with the HCL compared to SAP system, respectively, and has increased further to 84% with HCL in the third trimester. With HCL, less time was spent with glucose above 7.8 mmol/l (16.6 vs. 26.6% in the second trimester). Moreover, coefficient of glucose variation was lower.

Conclusions: Use of the commercially available HCL system was associated with better glycemic control compared to the SAP system in a small series of pregnant women with type 1 diabetes. If this translates also to better perinatal outcomes, remains to be seen.

EP242 / #415

Topic: ***AS08 Insulin Pumps***

ADVANCED HYBRID CLOSED LOOP SYSTEM IN TYPE 1 DIABETES, EXPERIENCE FROM SINGAPORE

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Background and Aims: Despite advances in diabetes therapies and technologies, achieving target glycaemia remains elusive and burdensome for people with type 1 diabetes (T1D). We report the early experience of the first commercially available advanced hybrid closed loop (AHCL) system (MiniMed 780G) among people with T1D in Singapore.

Methods: Real-time Continuous glucose monitoring (RT-CGM) data was analysed to determine time-in-range (TIR, 3.9-10 mmol/l), time-below-range (TBR, <3.9 mmol/l), time-above-range (TAR, >10mmol/L) and coefficient of variation (%CV). HbA1c, Glucose Monitoring System Satisfaction Survey (GMSS) and Insulin Device Satisfaction Survey (IDSS) were done before and 3-6 months after. Comparison of variables were done using the paired samples T test. Data are presented as mean ± standard deviation or n(%).

Results: n = 15 with T1D, 11 women (73.3%), 9 Chinese (60.0%) and 6 non-Chinese (40.0%), age 35.9 ± 9.3y, weight 67.4 ± 15.1kg, BMI 24.6 ± 3.3kg/m^2 and T1D duration 21.9 ± 14.0 years. All achieved TIR >/= 70% (81.4 ± 6.8%) at 3-6 months post initiation. 14/15 had RT-CGM prior to AHCL automode initiation. In these, TIR increased from 71.0 ± 6.5% to 81.7 ± 7.0%, p < 0.05 without increase in TBR (5.5 ± 5.3% to 3.7 ± 2.6%, p = 0.20). HbA1c improved from 7.2 ± 0.8% to 6.5 ± 0.6% (p < 0.05). %CV was low (33.2 ± 3.6%) at 3-6 months. No adverse events occurred. A higher satisfaction for insulin delivery was seen (IDSS: 3.23 ± 0.64 to 3.69 ± 0.55, p < 0.05) while GMSS score was unchanged (GMSS: 3.40 ± 0.56 to 3.69 ± 0.54, p = 0.31).

Conclusions: Use of the advanced hybrid closed loop system improved time-in-range and mean glycaemia (HbA1c) without increased time-below-range. These improvements occurred alongside improved device satisfaction for insulin delivery in a real-world Asian setting.

EP243 / #493

Topic: ***AS08 Insulin Pumps***

COMPARISON OF INSULINPUMP TREATMENT, CONTINUOUS BLOOD SUGAR MONITORING WITH TRADITIONAL SELF-BLOOD GLUCOSE MEASUREMENT AMONG MOTHERS WITH TYPE 1 DIABETES AND THEIR NEONATES

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Background and Aims: In type 1 diabetes, pregnancy planning and preconceptional care is exeptionally important. Neglected carbohydrate metabolism is hazardous for both the fetus and the mother.

Methods: We summarized data from 55 pregnancies. In 25 cases, in addition to fractional human insulin (ICT) therapy, self-blood glucose monitoring (SMBG) was used, and in 30 cases sensor-glucose monitoring (CGM) accompanied pregnancy, of which 13 were accompanied by insulinpump treatment (SAP). Average age of mothers was 31.27 ± 6.06 years, with an average diabetes duration of 14.49 ± 7.55 years at birth.

Results: HbA1c in the first trimester, was significantly higher in the SMBG group than in the ICT group using CGM (7.35 ± 0.19 vs. 6.51 ± 0.16, $p = 0.027$). Newborns had a difference in birth weight between the ICT+SMBG vs. pump+CGM group (3485.42 ± 22.42 vs. 4065.38 ± 138.23 grams). There was no significant difference in preterm birth rates between groups, but the ICT group had a numerically more premature births, and in the SAP group there was no preterm birth before 35th weeks of pregnancy compared to 5 cases in the ICT group. Maternal weight, insulin demand, maternal hypertension and the frequency of caesarean sections did not differ between groups, however, maternal quality of life in the sensor group was shown to be better, according to patient reports. In newborns, we found no difference in the frequency of macrosomy, hypoglycaemia, and other complications between the groups.

Conclusions: However result were not significant in its tendency, it seems that the CGM system has a more uniform blood sugar balance and fewer complications.

EP244 / #448

Topic: ***AS08 Insulin Pumps***

INSULIN PUMP IN TYPE 2 DIABETES MELLITUS; HYPERBOLE OR NEW HOPE

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Background and Aims: Insulin pump is proven effective in Type 1 Diabetes Mellitus (T1DM) as compared to multiple injections in lowering HbA1c, hypoglycemia and improving quality of life. In the present study, we have performed a meta-analysis of previews studies in order to evaluate the use of insulin pump in T2DM.

Methods: A systematic literature search was conducted in Pubmed, Clinicaltrials.gov and Cochrane Central Register for Controlled Trials (RCT) databases for relevant studies until March 2022. Search keywords were ''type 2 diabetes'', ''continuous insulin infusion'', ''insulin pump'', ''multiple insulin injection'', ''daily injections''. Our search was limited to clinical trials and RCTs in humans in English.

Results: Included stydies were ten RCTs with parallel study design, four with crossover design and one with subgroup analysis from a large trial. Insulin pump, was proven more effective in reducing HbA1c from baseline. The same effect persisted when RCTs with parallel design were analyzed separately. Analysis of RCTs with crossover design did not demonstrate a significant pooled effect in HbA1c reduction. No significant differences were evident between fasting plasma glucose and weight change. The daily insulin dose required to achieve target glucose levels was significantly lower in the intervention group There does not appear to be significant publication bias as depicted in the present analysis.

Conclusions: The use of insulin pump may has a role in T2DM especially in patients difficult to control. However, many randomized double blind controlled trials are needed in order to generalize the use of insulin pump in these patients

EP245 / #625

Topic: ***AS08 Insulin Pumps***

TUBELESS INSULIN PUMP THERAPY COMPARED TO MULTIPLE DAILY INJECTIONS AND CONVENTIONAL INSULIN PUMPS: A SYSTEMATIC REVIEW

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Background and Aims: Several studies have demonstrated significant clinical benefits and improved quality-of-life of continuous subcutaneous insulin injection (CSII) compared to multiple daily injection (MDI) insulin therapy in type 1 diabetes. During the past few years, the newly developed tubeless pumps are starting to capture a significant portion of the insulin delivery market as they pose an attractive alternative to conventional insulin pumps in people with type 1 diabetes. The aim of this review was to systematically evaluate all the available literature on the effect of the tubeless pumps on type 1 diabetes management and quality of life compared to MDI and conventional insulin pumps.

Methods: An extensive literature search was conducted through electronic databases (PubMed, Scopus and CINAHL) with the terms 'continuous subcutaneous insulin injection', 'tubeless pump', 'multiple daily injections', 'insulin pumps' and 'quality of life'. Articles published in English, until September 2022, were included; no other criteria on publication dates were set.

Results: A total of 7 studies were included. Most of the studies showed that tubeless pumps were associated with statistically significant improvement in glycemic control, reduction in frequency and severity of hypoglycemic episodes compared to MDI. Regarding the quality of life, positive changes were reported in overall well-being, perceived control over diabetes, hypoglycemic safety, and diabetes distress considering the tubeless pumps.

Conclusions: Despite the limited number of studies included, the benefits of tubeless pumps are significant in people with diabetes type 1.

EP246 / #699

Topic: ***AS08 Insulin Pumps***

THE EFFECT OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION ON TYPE 2 DIABETES MELLITUS MANAGEMENT COMPARED TO MULTIPLE DAILY INJECTIONS

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Background and Aims: Insulin pump therapy (continuous subcutaneous insulin infusion (CSII)) is now an established form of intensive insulin therapy. Patients with type 2 diabetes (T2DM) can be treated with a variety of insulin regimen strategies such as basal insulin only, basic bolus therapy via multiple daily injections [MDI] or CSII. CSII is widely used for the treatment of type 1 diabetes (T1DM), however, the clinical evidence is not definite, and the international guidelines do not primarily recommend the use of CSII for T2DM group. The aim of this review was to systematically evaluate all the available literature on the effect of CSII on T2DM management compared to MDI.

Methods: An extensive literature search was conducted through electronic databases (PubMed, Scopus and CINAHL) with the terms 'continuous subcutaneous insulin infusion', 'type 2 diabetes', 'multiple daily injections' and 'insulin pumps'. Articles published in English, until September 2022, were included; no other criteria on publication dates were set.

Results: A total of 9 studies were included. Most of the studies showed a significant mean reduction in HbA1c (hemoglobin A1C) and in total daily dose of insulin with the CSII compared to MDI group. Moreover, the CSII group demonstrated a limited incidence of hypoglycemic events and weight gain compared to MDI regimen.

Conclusions: Insulin pump therapy is a potentially useful method for intensification of insulin regimen in type 2 diabetes. In patients with poorly controlled T2DM, pump therapy is considered a safe and valuable treatment option especially to those for whom MDI therapy has failed.

EP247 / #677

Topic: ***AS08 Insulin Pumps***

REASONS FOR PUMP ADOPTION HESITANCY AMONG PEOPLE WITH DIABETES IN THE U.S. TAKING MULTIPLE DAILY INJECTIONS

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Background and Aims: Compared to multiple daily injections (MDI), insulin pump therapy has been shown to improve glycemic control for people with diabetes (PWD), including reducing hypoglycemia and lowering HbA1c. Despite these benefits, pump uptake rates show room for improvement among PWD on MDI. The present study aims to examine intensive insulin users' reasons for not adopting a pump, and how they differ by diabetes type.

Methods: In September 2022, 779 PWD on MDI in the U.S. completed an online survey on why they do not currently use an insulin pump. Of this sample, 22% had never considered a pump, 47% did not think a pump was right for them, and 31% were open to trying. Additional demographic information was collected (45% T1, 60% female).

Results: Overall, the top reasons for not adopting a pump were reluctance to have a device attached to their body (47%), preference for injecting insulin (39%), and reluctance to change infusion sets often (38%). Reasons for non-use varied according to diabetes type. Compared to people with T2D, people with T1D were more likely to be concerned about pump experience (e.g., having a device attached to their body (56% vs. 39%, $p < .001$)), while people with T2D were more likely to cite a lack of recommendation from their healthcare provider (47% vs. 12%, $p < .001$).

Conclusions: Reasons for pump adoption hesitancy vary by type of diabetes. Recognition of these reasons may allow clinicians to tailor their approaches when treating people who may benefit from acquiring a pump.

EP248 / #751

Topic: ***AS09 New Medications for Treatment of Diabetes***

LUMINAL COATING OF THE INTESTINE FOR TREATMENT OF OBESITY-ASSOCIATED TYPE 2 DIABETES

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Background and Aims: Roux-en-Y gastric bypass surgery (RYGB) is the golden standard treatment for obesity-related T2D, but many patients are reluctant to proceed due to its invasive and non-reversible nature. We have developed a novel oral formulation (LuCI) that provides a transient coating of the proximal bowel and mimics the effects of RYGB. Herein, we aim to investigate the chronic outcomes of LuCI and evaluate the larger-scale LuCI manufacturing method using an acute oral glucose tolerance test.

Methods: DIO rats on a high-fat diet received five weeks of daily LuCI or normal saline as control ($n = 8$/*group*). Up to 5 weeks, systemic blood was sampled to investigate changes in key hormones involved in glucose metabolism. To evaluate the larger-scale manufacturing, animals received oral LuCI

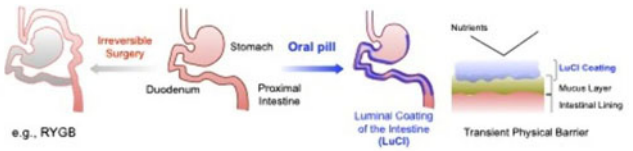

Figure 1. Representative cartoon demonstrating the oral administration luminal coating of intestine as an alternative of highly invasive and irreversible bariatric surgeries. The coating is designed to form a transient physical barrier on mucosa against substances such as nutrients, acids, and enzymes, and a drug delivery platform that can deliver therapeutics (e.g. protein) protected from stomach acid and digestive enzymes.

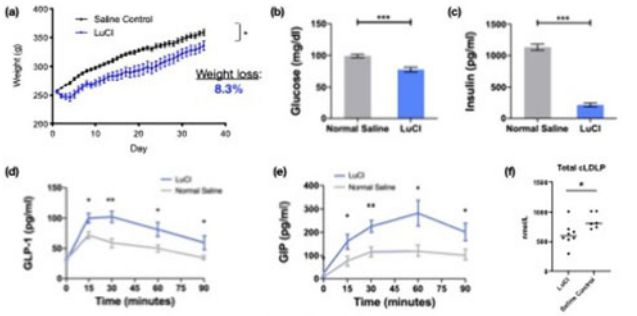

Figure 2. Metabolic benefits of daily administration of LuCI in a rat model. (a) Weight over 35 days of LuCI and vehicle oral gavage. (b) Mean fasting glucose levels 5 weeks after beginning of treatment. (c) Systemic fasting insulin level 5 weeks after beginning of treatment. (d-e) Circulating plasma hormone levels measured 5 weeks using standard oral glucose tolerance test following daily gavage of LuCI or normal saline. (d) GLP-1 levels at time points indicated, (e) GIP levels at time points indicated. (f) Total cLDL particle counts after 5 weeks after beginning of treatment.

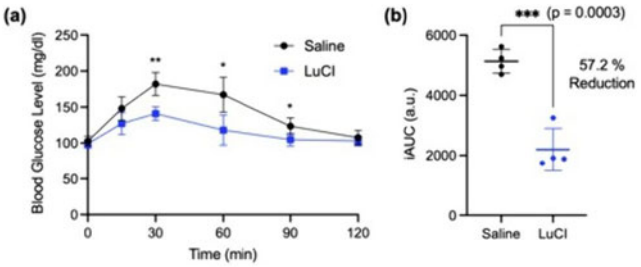

Figure 3. Acute OGTT results using LuCI fabricated using the larger-scale manufacturing method. (a) OGTT curves, (b) iAUC of (a)

fabricated using the larger-scale method or saline, followed by oral gavage with glucose solution for standard OGTT.

Results: At 5 weeks, LuCI animals weighed 8.3% less and had lower fasting glucose levels than Controls. LuCI-treated animals had lower baseline insulin and HOMA-IR and increased GLP-1 and GIP secretion following a glucose challenge. Serum lipid analysis revealed lowered LDL levels suggesting the potential for reducing cardiovascular risk. In addition, the larger-scale LuCI showed 57.2 ± 7.9% reduction in blood glucose responses ($P < 0.001$).

Conclusions: LuCI can ameliorate weight gain and improve insulin sensitivity in a long-term diet-induced obese rat model. We have developed and validated a scale-up manufacturing method for phase 1 clinical studies. Specifically, batches of products produced with this method demonstrated substantial glucose reduction, which was on par with published lab-scale results.

EP249 / #620

Topic: ***AS09 New Medications for Treatment of Diabetes***

ONCE-WEEKLY BASAL INSULIN FC (BIF) DEMONSTRATED SIMILAR GLYCEMIC CONTROL TO ONCE-DAILY INSULIN DEGLUDEC (DEG) IN INSULIN-NAÏVE PATIENTS WITH TYPE 2 DIABETES (T2D)

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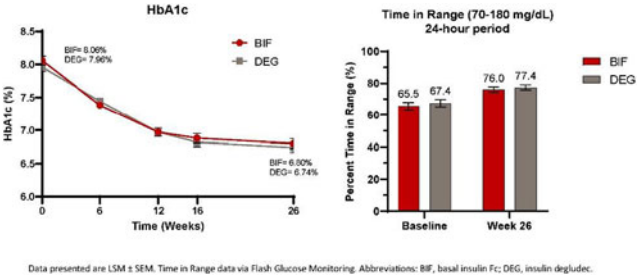

Data presented are LSM ± SEM. Time in Range data via Flash Glucose Monitoring. Abbreviations: BIF, basal insulin Fc; DEG, insulin degludec.

Background and Aims: Basal Insulin Fc (BIF), a fusion protein combining a novel single-chain insulin variant with a human IgG Fc domain, is designed for once-weekly administration. This randomized, parallel, open-label Phase-2 study assessed safety and efficacy of BIF vs DEG in insulin-naïve patients with T2D previously treated with oral antihyperglycemic medication.

Methods: BIF was injected once-weekly, and DEG was injected once-daily. Both groups were titrated to achieve a fasting blood glucose (FBG) ≤5.6mmol/L (≤100 mg/dL). The primary endpoint was HbA1c change from baseline (CFBL) to Week 26 (non-inferiority margin = 0.4%).

Results: Patients were randomized to BIF (N = 129) or DEG (N = 135) with a mean age of 58.4 years and baseline HbA1c of 8.0%. After 26 weeks, BIF showed non-inferiority vs DEG for HbA1c CFBL with a treatment difference of 0.7 mmol/mol (0.06% [90% CI = -0.11, 0.24]; p = .56), and both groups had >75% time in range (70-180 mg/dL) on average at Week 24-26 CGM assessment (**Figure**). BIF and DEG significantly reduced FBG from baseline (treatment difference BIF vs DEG = 4.7 mg/dL [90% CI = 0.1, 9.3]; p = .09). Rate of Level 2 hypoglycaemia was low and not significantly different (BIF = 0.22; DEG = 0.15 events/pt/yr; p = 0.64). No severe hypoglycaemia was reported. Occurrence of treatment-emergent adverse events was similar between BIF and DEG.

Conclusions: Once-weekly BIF achieved excellent glycaemic control similar to DEG with no concerning hypoglycemia or other safety findings, supporting continued development of BIF in Phase-3.

EP250 / #571

Topic: ***AS09 New Medications for Treatment of Diabetes***

INCREASED TIME IN RANGE WITH ULTRA RAPID LISPRO (URLI) TREATMENT IN PARTICIPANTS WITH TYPE 2 DIABETES: PRONTO-TIME IN RANGE

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Background and Aims: To evaluate time in range metrics and HbA1c in people with type 2 diabetes (T2D) treated with ultra rapid lispro (URLi) using continuous glucose monitoring (CGM).

Methods: In this Phase 3b, single-treatment study, 176 adults with type 2 diabetes (T2D) on basal-bolus multiple daily injection (MDI) insulin therapy including glargine U-100 were newly treated with prandial URLi and used unblinded continuous glucose monitoring (CGM) (FreeStyle Libre).

Results: Improved glycemic control was observed at Week 12 vs baseline including primary objective of daytime time in range

(70-180 mg/dL) (TIR) (p = 0.007) and gated secondary objectives of HbA1c (p < 0.001) and 24-hour TIR (p = 0.016) without evidence of increased hypoglycemia/time below range. Postprandial glucose was significantly reduced at Week 12 vs baseline.

Conclusions: URLi in an MDI regimen was efficacious with improved glycemic control and an acceptable safety profile in people with T2D.

EP251 / #378

Topic: ***AS09 New Medications for Treatment of Diabetes***

ZYGOAID-50 - A NOVEL METTALO-COMPLEX ACTING VIA EXCHANGE OF INTRACELLUAR IRON BY ZINC YIELDING A ROBUST REDUCTION IN INSULIN RESISTANCE IN EXPERIMENTAL MODELS OF DIABETES

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Background and Aims: New drugs with notable specialized protective efficacy in Type II Diabetes (T2D) became clinically available. Elevated insulin resistance (IR) seems to underlie many of the T2D complications. No available drug yields robust reduction in the high IR levels in Diabetes. We aimed to identify and dissect modes of action of new drug candidates that would markedly cancel elevated IR and correct deleterious effects in Diabetes.

Methods: Two broadly accepted T2D male models were employed: Sand Rat (*Psammomys obesus*) and db/db mouse. Sand Rats fed high energy diet (HED), 24–27 days, became diabetic. Subsequently, on the same diet were also treated (i.p.) injection containing 2-6mg/kg, of Zygosid, 3x/week, for additional 26-28 days. Blood glucose levels (BGL) were monitored 3x/week. The db/db (10-week old) mice, were treated analogously starting on Day 1 (after. BGL was monitored 3x/w.

Results: Control Sand rats maintained adequate BGL while fed on native low-energy-diet BGL = 70-80mg/dl (Days 1-65). On HED Sand Rats reached a stable high levels (BGL = 190–240 mg/dl), After 7–12 days of treatment with Zygosid BGL <100mg/dl). GTT curves returned to normal. The db/db mice showed initial BGL >500mg/dl, and were treated with Zygosid-50 for 52 days demonstrating monotonic and near-linear decrease in BGL, during the first 25 days. BGL stabilized and remained at 253-329mg/dl (Days 25-52). The non-treated animals maintained BGL >590mg/dl. Treatment caused a marked improvement of GTT curves, as compared to non-treated mice.

Conclusions: The members of the Zygosids family showed a remarkable therapeutic efficacy in the treatment of diabetes, in two models; and icomplete correction of T2D-associated parameters.

EP252 / #446

Topic: ***AS09 New Medications for Treatment of Diabetes***

IMPACT OF PREVIOUS USE OF SULFONYLUREAS ON THE EFFECTIVENESS AND SAFETY OF IGLARLIXI IN PEOPLE WITH TYPE 2 DIABETES: SOLO STUDY POST HOC ANALYSIS

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Background and Aims: SOLO observational study showed effectiveness and safety of iGlarLixi in type 2 diabetes (T2DM) adults. Previous treatment regimen could influence outcomes such as the use of sulfonylurea (SU) before iGlarLixi initiation (Index Event-IE). **Aim:** to estimate the potential effect of previous use of SU on the effectiveness and safety of iGlarLixi in the SOLO study population.

Materials and Methods: Post hoc analysis was performed in subgroups of people who received SU (n = 258/69.5%, **SU+**) or did not receive SU (n = 119/30.5%, **SU-**) before IE (6 people continued SU after IE and were not included in this analysis).

Results: In people receiving or not SU, mean ± SD HbA1c at IE was 9.2 ± 1.1% and 9.0 ± 0.9% respectively. Significant HbA1c decrease was observed (p < 0.001 vs baseline) in SU+ after 6 and 12 months (mean±SD: -1.4 ± 0.9% and -1.8 ± 0.9% respectively) and in SU- (mean±SD: -1.2 ± 0.9% and -1.6 ± 0.8% respectively). No significant intergroup differences (p > 0.05). Significant body weight decrease was observed (p < 0.001 vs baseline) in SU+ after 6 and 12 months (mean±SD: -1.7 ± 3.7 and -2.9 ± 4.3 kg) and in SU- group by (mean±SD: -2.6 ± 4.8 and -3.6 ± 5.5 kg). There were no significant intergroup differences (p > 0.05). In SU+ group 32 (12.4%) reported symptomatic hypoglycemia (SH) before, and 3 (1.16%) after IE. In SU- group 12 (10.08%) reported SH before, and 1 (0.84%) after IE, without significant intergroup differences (p > 0.05).

Conclusions: In the SOLO real world observational study the effectiveness and safety of iGlarLixi was not affected by previous use of SU

EP253 / #70

Topic: ***AS09 New Medications for Treatment of Diabetes***

INSULIN ADJUSTMENTS AND TIME IN RANGE AFTER INITIATION OF EMPAGLIFLOZIN 2,5 MG IN PATIENTS WITH TYPE 1 DIABETES: REAL LIFE DATA

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Background and Aims: Scarce literature reports insulin adjustments when initiating coadjuvant antihyperglicemic drugs in T1D. We examined insulin adjustments in a cohort of patients with T1D who initiated Empagliflozin 2,5mg.

Methods: Medical records were reviewed. TIR and detailed doses of basal insulin, carbohydrate ratio (CR) and sensitivity factor (SF), separated for breakfast and other meals, were extracted and analyzed using non-parametric tests.

Results: Data from 30 adults was obtained, average age 36 years, 17 years of T1D, and BMI of 28,4 kg/m2. 17 were on PLGS-SAP and 13 on MDI. Average follow up was 26 months. TIR increased from 58,7 to 65,4% (p = 0,0002) during the first 3 months, in which basal insulin was reduced 28,1 to 24,5 units (14,7%, p = 0,0001), breakfast and other meals' CR increased from 7,8 to 8,6 g/U (10.3%, p = 0012) and from 8,7 to 9,7 g/U (11.5%, p = 0,005), respectively, and breakfast and other meals' SF increased from 37 to 44 mg/dL/U (18.9%%, p = 0,00004) and 40 to 47 mg/dL/U (17.5%, p = 0,00008), respectively. TIR, basal insulin and CR were stable over follow-up. SF increased significantly 9,7 and 7,8% for breakfast and other meals, respectively. 2 patients experienced non-attributable DKA events, and 1 discontinued therapy for urogenital infections.

Conclusions: Use of Empagliflozin 2,5mg in patients with T1D results in a 6,7% increase in TIR, while it warrants an approximate reduction of 15% in basal insulin, 10% in nutritional insulin and over 20% in correctional insulin doses,

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Topic: *AS09 New Medications for Treatment of Diabetes*

EFFECT OF LOW DOSE SEMAGLUTIDE IN WEIGHT, CARBOHYDRATE INTAKE, INSULIN DOSES AND GLYCEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES AND EXCESS WEIGHT.

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Background and Aims: Excess weight is a common problem in people with T1D. Use of Liraglutide in this population has shown promising results, but there is scarce data on other GLP1-ra. We aimed to explore the effect of low dose Semaglutide in a cohort of persons with T1D and excess weight.

Methods: Prospective analysis of Insulin pump users with excess weight who initiated Semaglutide titrated to 0.5 mg weekly. Weight, time in ranges, carbohydrate intake (C-I) and total daily insulin dose (TDD) were recorded on every control. Data was analyzed using non-parametric tests.

Results: 10 adults were followed with average age 33 years, 20 years of T1D, and baseline GMI 6.9%, TIR 72.6%, TBR 2.6%, TAR 24,8%, weight 82.7 kg, BMI 30.9 kg/m2, C-I 139 g and TDD 46.4 U/day. After 3 months, weight, BMI, C-I and TDD were reduced to 76.8 kg (p = 0,005), 28.7 kg/m2 (p = 0,005), 96.9 g (p = 0.005) and 39.5 U/day (p = 0,009), respectively. At month 6, further reductions were observed, reaching weight 71.4 kg (p = 0,028), BMI 27.4 kg/m2 (p = 0,012), with a slight increase in C-I up to 104 g (p = 0,028) and non significant changes in TDD. When adjusting insulin doses per weight, no significant differences were observed. During the follow-up, no significant changes occurred in GMI, TIR, TBR or TAR.

Conclusions: Use of Semaglutide 0,5mg in patients with T1D results in a significant weight loss of approximately 14% of initial weight, associated with a reduction of carbohydrate intake and total insulin daily doses.

EP255 / #469

Topic: *AS09 New Medications for Treatment of Diabetes*

GREATER DERIVED TIME-IN-RANGE IN PEOPLE WITH TYPE 2 DIABETES ADVANCING TO IGLARLIXI: A POOLED ANALYSIS OF THE LIXILAN CLINICAL TRIAL PROGRAMME

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Background and Aims: Derived time-in-range (dTIR), an alternative to time-in-range, is the proportion of self-measured blood glucose (SMBG) measurements within a person's target glucose range. The dTIR, derived time above range (dTAR), and derived time below range (dTBR) help capture blood glucose fluctuations that are inadequately identified using HbA_{1c}. The present descriptive, post-hoc analysis assessed dTIR with iGlarLixi in the LixiLan clinical trial programme.

Methods: The global LixiLan programme included three open-label, randomized, parallel-group, multicenter Phase 3

Table. Participant baseline characteristics and change in dTIR, dTAR, and dTBR with iGlarLixi and iGlar from the pooled LixiLan clinical trial programme data

Baseline characteristics (Randomized population)	iGlarLixi (n=1093)	iGlar (n=836)
Age, years	58.9 ± 9.5	59.2 ± 9.1
BMI, kg/m²	31.8 ± 4.4	31.4 ± 4.4
Duration of diabetes, years	10.5 ± 6.5	10.2 ± 6.4
HbA_{1c}, %	8.0 ± 0.7	8.1 ± 0.7
HbA_{1c}, mmol/mol	64 ± 8	65 ± 8
Proportion of SMBG readings in-range, above-range, and below-range (mITT population)	**iGlarLixi (n=1086)**	**iGlar (n=831)**
dTIR (70–180 mg/dL [3.9–10 mmol/L]), %		
BL	57.5 ± 31.6	57.9 ± 31.1
W12	83.9 ± 21.0	76.0 ± 24.4
EOT	86.6 ± 20.2	77.5 ± 24.7
Change from baseline to EOT	28.7 ± 34.2	18.1 ± 34.7
dTAR (>180 mg/dL [>10 mmol/L]), %		
BL	42.4 ± 31.6	42.0 ± 31.1
W12	15.7 ± 20.9	23.8 ± 24.3
EOT	12.7 ± 20.1	21.9 ± 24.6
Change from baseline to EOT	−29.3 ± 34.1	−18.7 ± 34.6
dTBR (<70 mg/dL [<3.9 mmol/L]), %		
BL	0.1 ± 1.4	0.1 ± 0.9
W12	0.4 ± 2.5	0.2 ± 1.8
EOT	0.7 ± 3.4	0.6 ± 3.2
Change from baseline to EOT	0.6 ± 3.4	0.6 ± 3.3
Participants with dTIR >70%, dTAR <25%, and dTBR <4% at EOT, n (%)	653 (60.1)	397 (47.8)

Data are mean ± SD unless stated otherwise.

For clarity, only data for the iGlarLixi and iGlar groups are presented in the table. Changes from baseline with LixiLan were similar to those with iGlar, except for a negligible change in dTBR; changes with GLP-1 RA were lower than those with iGlar, but with a negligible change in dTBR.

The LixiLan clinical trial programme exposed different participant populations, screening iGlarLixi in people advancing from basal insulin (LixiLan-L) and antihyperglycemic drugs (LixiLan-O), and a GLP-1 RA (LixiLan-G).

iGlarLixi data pooled from LixiLan4 (FOT: 52 weeks) LixiLan-G (FOT: 26 weeks), and LixiLan-O (FOT: 30 weeks). iGlar data pooled from LixiLan4 and LixiLan-O.

BL, baseline; dTAR, derived time-above-range; dTBR, derived time-below-range; dTIR, derived time-in-range; EOT, end of treatment; GLP-1 RA, glucagon-like peptide-1 receptor agonist; iGlarLixi, basal insulin glargine 100 U/mL + the GLP-1 RA lixisenatide; mITT, modified intention to treat; SD, standard deviation; SMBG, self-measured blood glucose; W, week.

trials comparing iGlarLixi with basal insulin glargine 100 U/mL (iGlar; LixiLan-L, NCT02058160), iGlar or lixisenatide alone (Lixi; LixiLan-O, NCT02058147), or a glucagon-like peptide-1 receptor agonist (GLP-1 RA; LixiLan-G, NCT02787551) in people with T2D. These data were pooled and dTIR (70–180 mg/dL), dTAR (>180 mg/dL), and dTBR (<70 mg/dL) calculated from participant 7-point SMBG profiles.

Results: Participant baseline characteristics were comparable across treatment arms (**Table** [only iGlarLixi vs iGlar presented]). Pooled data indicate a greater dTIR increase from baseline to end of treatment with iGlarLixi versus iGlar. These results reflect the individual LixiLan studies, where greater dTIR increases occurred with iGlarLixi versus iGlar (mean ± standard deviation, 18.1% ± 29.3 vs 2.4% ± 29.3 of participants; LixiLan-L), versus a GLP-1 RA (18.7% ± 31.7 vs 11.3% ± 31.4 of participants; LixiLan-G), and versus iGlar or Lixi (42.0% ± 34.4 vs 30.9% ± 33.4 or 28.4% ± 34.6 of participants; LixiLan-O). dTAR decreased further with iGlarLixi versus iGlar, alongside an equally small dTBR increase.

Conclusions: iGlarLixi is associated with greater dTIR increase and dTAR decrease without increasing dTBR in people with T2D versus iGlar, Lixi, or a GLP-1 RA.

EP256 / #384

Topic: ***AS09 New Medications for Treatment of Diabetes***

GREATER DERIVED TIME-IN-RANGE SWITCHING TO IGLARLIXI VERSUS UP-TITRATING IGLAR IN BASAL INSULIN-TREATED PEOPLE WITH TYPE 2 DIABETES: A SUBANALYSIS OF THE LIXILAN-L CLINICAL TRIAL

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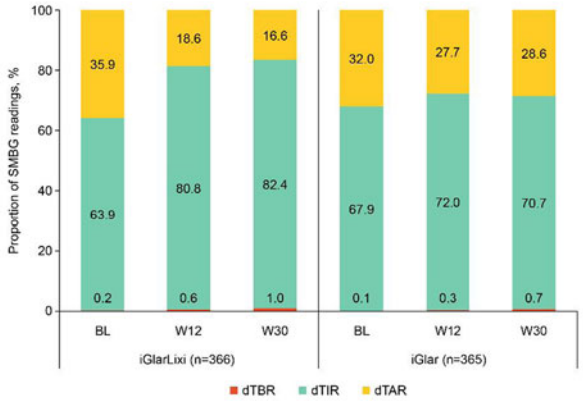
Background and Aims: Use of continuous glucose monitoring to assess time-in-range (TIR) can identify daily glucose fluctuations better than HbA_{1c}, helping guide insulin management in people with type 2 diabetes (T2D). Alternatively, derived TIR (dTIR) is the proportion of self-measured blood glucose (SMBG) measurements within target glucose range. The current descriptive, post-hoc analysis compares dTIR with iGlarLixi and iGlar in the LixiLan-L trial.

Methods: LixiLan-L (NCT02058160) was an open-label, randomized, parallel-group, multicenter Phase 3 trial comparing iGlarLixi with basal insulin glargine 100 U/mL (iGlar) in people with T2D advancing from basal insulin ± ≤2 oral antihyperglycaemic drugs (OADs). dTIR (70 – 180 mg/dL), derived time-above-range (dTAR, >180 mg/dL), and derived time-below-range (dTBR, <70 mg/dL) were calculated using participant 7-point SMBG profiles.

Figure. Proportion of participant SMBG readings in-range (dTIR), above-range (dTAR), and below-range (dTBR) with iGlarLixi versus iGlar during the LixiLan-L study period (mITT population)



dTIR: 70–180 mg/dL (3.9–10 mmol/L); dTAR: >180 mg/dL (>10 mmol/L); dTBR: <70 mg/dL (<3.9 mmol/L).
BL, baseline; dTAR, derivec time-above-range; dTBR, derived time-below-range; dTIR, derived time-in-range; iGlarLixi, basal insulin glargine 100 U/mL + the glucagon-like peptide-1 receptor agonist, lixisenatide; mITT, modified intention-to-treat; SMBG, self-measured blood glucose; W, week.

Results: Participants receiving iGlarLixi (n = 366) demonstrated a greater increase in dTIR from baseline to Week 30 (mean ± standard deviation, 18.1% ± 29.3) versus iGlar (n = 365, 2.4% ± 29.3; **Figure**). Overall, more participants receiving iGlarLixi had ≥70% of their SMBG readings in-range versus iGlar (65.6% vs 51.5% of participants, respectively), alongside clinically significant improvements of ≥5% dTIR at Week 30 (50.0% vs 31.8% of participants, respectively). dTAR decreased further with iGlarLixi (–18.7% ± 29.1) versus iGlar (–3.1% ± 29.2), while the dTBR increase was similarly small (0.6% ± 4.2 vs 0.6% ± 3.4, respectively). The dTIR >70%, dTBR <4%, and dTAR <25% triple target was achieved by 53.6% of participants receiving iGlarLixi versus 39.7% of those receiving iGlar.

Conclusions: iGlarLixi is associated with greater improvements in dTIR and dTAR versus iGlar in people with T2D advancing from basal insulin ± OADs.

EP257 / #673

Topic: ***AS09 New Medications for Treatment of Diabetes***

CORRELATION OF SERUM TRACE ELEMENTAL CONTENT WITH GLUCOSE LEVELS IN DIABETES MELLITUS PATIENTS USING SRXRF

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Background and Aims: Diabetes mellitus (DM) is a chronic metabolic abnormality associated with elevated blood glucose levels. Hence, marked variations in trace elemental concentrations in the human body are speculated to be associated with the occurrence and progression of DM. The objective of this study was to examine the variation in the concentration of trace elements in the blood serum of type 2 DM patients based on their blood glucose levels by using the Synchrotron Radiation X-Ray Fluorescence (SRXRF) technique.

Methods: The SRXRF experiments were performed using microprobe XRF beam line-16 of the Indus-2 synchrotron radiation facility at Raja Ramanna Centre for Advanced Technology (RRCAT), Indore, India.

Results: Trace elements K, Ca, Ti, V, Cr, Mn, Fe, Co, Ni, Cu, Zn, As, Se, Br, Rb, Sr, and Pb were determined in the irradiated samples. The obtained results were validated by analyzing IAEA and NIST standards.

Conclusions: Statistically significant alterations were observed in the serum levels of the analyzed elements among the studied groups. The possible mechanisms by which these elements affect glucose homeostasis are discussed in this work.

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EP258 / #615

Topic: ***AS09 New Medications for Treatment of Diabetes***

EFFECT OF BASHAN DRINK, A VEGETABLE PLANT-BASED COMPOUND DRINK, ON BLOOD GLUCOSE IN TYPE 2 DIABETIC PATIENTS

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Background and Aims: The etiology and pathogenesis of diabetes are complex. Previous studies showed that effective dietary intervention can reduce the risk of diabetes. The Bashan drink is a vegetable plant-based compound drink which is a combination of several pure plant ingredients (non-extracts).This study is aim to observe the effects of Bashan on the blood glucose in type 2 diabetes(T2DM) patients by a standardized mashed potato meal.

Methods: 29 patients (26 males, age 49.1 ± 1.6 years; HbA1c 8.8 ± 0.4 %) with T2DM who were newly diagnosed or using antidiabetic monotherapy were included in this study. After enrollment, patients were randomized to receive 2 interventions :1) Water as control, taking 180ml water immediately after three meals; 2)Bashan, taking 180ml Bashan immediately after three meals. Each intervention last for 2 weeks, and switched after the 7-day wash-out period. Before and after the intervention, subjects underwent measurements of blood glucose for 240 min after a mashed potato meal (368.5 kcal). Data are mean ± SEM.

Results: Compared with control, drinking Bashan for 2 weeks significantly improved the fasting glucose (Bashan day 14:6.80 ± 0.28 vs. day 1:7.57 ± 0.35 mmol/L; P = 0.0042;control day 14:7.41 ± 0.41 vs. day 1:7.45 ± 0.32 mmol/L; P>0.05) and the peak glucose after the mashed potato meal (Bashan day 14:14.23 ± 0.55 vs. day 1:15.46 ± 0.61 mmol/L ; P = 0.0022; control day 14:15.03 ± 0.62 vs. day 1:15.68 ± 0.57 mmol/L; P>0.05). In addition, Bashan decreased the area under the curves (AUC) for plasma glucose(Bashan day 14:42.31 ± 1.94 vs.day 1:46.05 ± 2.55 mmol/L*min; P = 0.002; control day 14:44.67 ± 2.44 vs. day 1:46.87 ± 2.11 mmol/L*min; P>0.05).

Conclusions: Drink Bashan continuously for 2 weeks could improve both the fasting blood glucose and the peak glucose after a standardized mashed potato meal.

EP259 / #618

Topic: ***AS10 New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

FACTORS AFFECTING BASAL INSULIN INJECTION ADHERENCE INVESTIGATED USING SMART INSULIN PEN DATA

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Background and Aims: The challenge of managing multiple daily insulin injections can reduce treatment adherence, potentially leading to inadequate glycaemic control in type 1 diabetes (T1D). In a real-world setting, we investigated the probability and influencing factors for missing basal insulin injections.

Methods: Data from 11 countries were collected from individuals with T1D using a smart insulin pen (NovoPen 6) to deliver their basal insulin (degludec) injections. The daily probability of missing a degludec dose (≥40 hours between injections) was estimated using a generalized linear mixed model with logistic link function. Data upload frequency over the previous 14 days was used as a measure of smart insulin pen engagement.

Results: Overall, 915 individuals were included. The daily mean probability of missing a basal dose was 4.0% (95% confidence interval: 3.3–4.7%). There was a significant age effect ($p < 0.0001$), with individuals aged 20–25 years having the highest probability of missing a basal dose. Individuals with frequent NovoPen 6 data uploads had significantly fewer missed basal doses ($p < 0.0001$); a significant effect of weekday was demonstrated ($p < 0.0001$), with most missed basal doses at the weekend. Individuals with a mean daily basal dose ≤30 units were more adherent than those with higher daily basal doses.

Conclusions: NovoPen 6 injection data represent a valuable resource and provided insight into factors (e.g. age, weekday, and smart pen engagement) affecting basal insulin adherence in T1D. A similar analysis in type 2 diabetes is underway.

EP260 / #413

Topic: ***AS11 Devices Focused on Diabetic Preventions***

NON-INVASIVE MULTISENSOR DEVICE USING ARTIFICIAL INTELLIGENCE FOR GLUCOSE LEVEL ESTIMATION

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Background and Aims: Self-monitoring of blood glucose is essential for effective treatment of diabetes. Many non-invasive approaches have been investigated over the last decade in order to minimize the pain due to finger pricking and cost of the commercial invasive devices. The objective here is to investigate a homemade multisensor wearable device, based on Bioimpedance Analysis (BIA) and Near Infrared (NIR), to estimate blood glucose using ten different Artificial Intelligence (AI) network.

Methods: Temperature, oxygen saturation, heart rate, capillary blood glucose, venous blood glucose and bioimpedance using 2 and 4 electrodes were measured from a male volunteer every 15 minutes for 2 hours. Among the implemented AI networks, four of them showed better performance: decision tree regressor (DTR), bagging DTR, random forest regressor, and adaboost regressor.

Results: It was found that between 38 to 58% of input attributes are required for a good glucose estimation. It was also found a maximum error of 5% between DTR and Fast Plasma Glucose (FPG) techniques.

Conclusions: AI is a powerful tool to improve the efficiency of non-invasive self-monitoring glucose devices. More investigations and larger database are needed to better determine the best AI attributes and models.

EP261 / #36

Topic: ***AS11 Devices Focused on Diabetic Preventions***

DIFFERENCE ON GLUCOSE PROFILE FROM CONTINUOUS GLUCOSE MONITORING (CGM) IN PREDIABETIC VS NORMOGLYCAEMIC INDIVIDUALS: A MATCHED-PAIR ANALYSIS

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Background and Aims: As the glycemic profile of prediabetes is currently unknown, we evaluate any differences of CGM profiles between prediabetic and matched normoglycemic individuals including their response to OGTT.

Methods: Prediabetics matched for age, sex and BMI with normoglycemics were selected from EHS Greek cohort. Individuals with FPG levels 100-124 mg/dL or HbA1c 5.7-6.4% were classified as prediabetic, whereas participants with FPG <100 mg/dL and HbA1c <5.7% as normoglycemic. Professional CGM (Envision™Pro, Medtronic) was used. On the 2nd day a 75g OGTT was performed.

Results: 36 participants (median age 51 years; median BMI 26.4 kg/m2) formed 18 matched pairs. Statistically significant differences were observed for 24-hour TIR (median 98.5% vs. 99.9%,$p = 0.013$), TAR >180 mg/dl (0.4%vs.0%,$p = 0.0062$), and 24-hour mean interstitial glucose (113.8vs.108.8 mg/dL, $p = 0.0038$) between prediabetics compared to normoglycemics. Similarly, statistically significant differences were observed for daytime and nocturnal TIR between prediabetics and normoglycemics ($p = 0.0273$; $p = 0.0087$, respectively). Statistically significant differences favoring the normoglycemic group were found for glycemic variability indexes (median CV 15.2% vs. 11.9%, $p = 0.0156$; median MAGE 44.3 vs. 33.3 mg/dL, $p = 0.0043$). 10 participants (6 prediabetics, 4 normoglycemics) had glucose readings <70 mg/dL, while 2 prediabetics and 1 normoglycemic had <54 mg/dL. In contrast, 60% of prediabetics had glucose readings >180 mg/dL. Following OGTT, the AUC was significantly lower in normoglycemics compared to prediabetics (median 18615.3vs.16370.0,$p = 0.0347$ for total; 4666.5 vs. 2792.7,$p = 0.0429$ for incremental 2-hour post OGTT).

Conclusions: Our study highlights the different glucose profiles of prediabetic compared to normoglycemic individuals. CGM might be helpful in individuals with borderline glucose values for a more accurate classification of their glycemic status.

EP262 / #515

Topic: ***AS11 Devices Focused on Diabetic Preventions***

DIETARY SODIUM REDUCTION WITH APP-BASED EDUCATION PROGRAM FOR PEOPLE WITH HYPERTENSION AND PRE-DIABETES: RESULTS OF A PILOT STUDY

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Background and Aims: Excessive sodium intake is a well-known risk factor for hypertension. Therefore, to effectively control diabetes and hypertension and to prevent other related complications, changes to patients' lifestyles, such as reducing dietary sodium intake, are needed. The mobile application is becoming popular in the self-care of chronic diseases such as hypertension. This study is an open-label intervention study to assess the mobile application specifically designed to aid in lowering dietary salt for a 16-week run-in period.

Methods: The primary outcome is dietary sodium intake changes. Secondary outcomes include changes in blood pressure (BP), glucose and lipid profiles, and hypertension-related behaviors. Dietary sodium intake was estimated with the spot urine using the Tanaka equation. The application provides sodium content and calories for the dietary intake records made by the participants.

Results: There were 63 participants randomized, and 60 completed the follow-up assessment.24-hour sodium intake estimate decreased from 4063.22 ± 1369.02mg to 3704.32 ± 1032.05 mg($p = 0.026$). The systolic BP decreased from 134.09 ± 11.34 mmHg to 127.27 ± 10.87 mmHg ($p < 0.001$), and diastolic decreased from 80.81 ± 8.19 mmHg to 77.97 ± 8.96($p < 0.05$). Hypertension management behaviors (Confidence, Knowledge, Action, and Diet) changed significantly in all categories. Serum glucose and Hb A1C were not changed significantly.

Conclusions: This pilot study presents the possibility of dietary intervention through a mobile app. Given the direction of dietary sodium reduction, future studies are warranted.

EP263 / #109

EP264 / #721

Topic: *AS11 Devices Focused on Diabetic Preventions*

THE IMPACT OF CGM USE ON GLUCOSE RESPONSE IN PREDIABETIC INDIVIDUALS: A CROWDSOURCED RETROSPECTIVE STUDY

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Background and Aims: The benefit of continuous glucose monitor (CGM) use for at-risk, non-diabetic individuals has not yet been fully demonstrated. In this retrospective study, we introduce a novel crowdsourced dataset of over 1000 research participants with self-reported prediabetes, who took part in a wellness program that provides CGMs, a smartphone application, and on-demand access to a dietetics professional. We tested whether using the program led to improvement in CGM-derived post-prandial glucose metrics during the first month of participation.

Methods: Four CGM-derived metrics (glucose peak, mean, standard deviation, and time in range (70-140mg/dL)) were used as response variables in a longitudinal multi-level linear regression. Explanatory variables included time, participant age, sex, and BMI, and degree of participation in the program.

Results: Our preliminary results show statistically significant improvement in all glucose response variables over time. The analysis also showed that changes in the post-prandial CGM-derived variables were associated with sex and degree of participation in the program. We also present results of analyses testing the association of CGM-derived variables with passively-collected lifestyle measurements, including physical activity and sleep.

Conclusions: To our knowledge, this is the largest longitudinal study evaluating the use of CGMs in a prediabetic population. We show that crowdsourced CGM data can be leveraged to track post-prandial glucose response. Our results suggest that a wellness program combining the use of CGMs with dietitian support can improve glucose response in participants with prediabetes. We lay the groundwork for future studies to explore how CGM-based wellness programs may prevent disease onset.

EP265 / #392

Topic: *AS11 Devices Focused on Diabetic Preventions*

DYNAMIC VALIDATION OF AN INNOVATIVE SINGLE-SENSOR, IN-SHOE PRESSURE AND TEMPERATURE MEASURING DEVICE

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Background and Aims: The prevention strategy for diabetic foot ulcer includes monitoring of skin temperature and identification of peak plantar pressure areas. The aim of this study was to determine dynamic validation, of an innovative, single-sensor in-shoe pressure and temperature mapping device, on healthy participants in view of diabetic foot ulcer prevention

Methods: Five healthy adult participants were recruited. The prototype was validated against the FScan™ in-shoe system for pressures and the Flir® T630sc thermographic camera for temperatures. Participants were asked to walk at a comfortable pace on an electric treadmill for 10 minutes. The prototype and the FScan in-shoe sensors™ were superimposed inside the shoe of the participant, with the prototype on top, to ensure direct contact with the area of interest. Two thermographic images were captured using the Flir® T630sc thermographic camera, before and after the walk.

Results: The raw readings of pressure were passed to the regressor, which returned the estimated kPa value. Several evaluations metrics were used to evaluate the performance of the modal. The prototype gave equal results to that of the gold standard, the FScan™ in-shoe system. With regards to temperature measurements, both devices gave similar readings.

Conclusions: This single-sensor, in-shoe pressure and temperature device showed similar measurements to the FScan™. Temperature measurements were equivalent to the Flir® T630sc thermographic camera. The authors are confident that the innovative, single-sensor, in-shoe pressure and temperature

monitoring device may be an alternative option to the costly devices that measure pressure and temperature separately to detect early signs of complications in the high-risk foot.

EP266 / #354

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

LIPID PEROXIDATION PRODUCTS AND ENDOGENOUS INTOXICATION LEVELS IN PATIENTS WITH TYPE 1 DIABETES MELLITUS AND DIFFERENT STAGES OF ALBUMINURIA

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Background and Aims: Studies of the pathogenetic mechanisms of the development of disorders at the preclinical stages of diabetic nephropathy are relevant. Therefore, the **aim** was to study the lipid peroxidation products and endogenous intoxication parameters level in T1DM patients with different stages of albuminuria. This may allow early biomarkers of primary kidney lesions to be set.

Methods: A survey of 69 men with T1DM with unsatisfactory glycemic control was carried out. The patients were divided into two groups - with albuminuria A1 stage (A1) - 35 people and albuminuria A2 stage (A2) - 34 people. Spectrophotometric and statistical research methods were used.

Results: The level of conjugated dienes (CDs) ($p = 0{,}003$), ketodienes and conjugated trienes (KD and CT) ($p = 0{,}019$), middle molecular substances (MMS) 238 (by 3.76 times; $p < 0{,}0001$), MMS 254 (by 1.7 times; $p = 0{,}020$) in patients with T1DM and A1 stage were significantly higher, than in the control. In patients with T1DM and A2 stage, an increase in CDs ($p < 0{,}0001$), KD and CT ($p < 0{,}0001$), MMS 238 ($p = 0{,}003$) relative to the control values also was noted. The CDs level in the A2 stage was 1.32 times higher ($p = 0.011$) relative to the A1 group data.

Conclusions: In patients with type 1 diabetes, regardless of the stage of albuminuria (A1, A2 stages), oxidative damage to lipids and intensification of endogenous intoxication processes are recorded.

EP267 / #358

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

DIAGNOSTIC SIGNIFICANCE OF EARLY RENAL MARKERS PODOCALYXIN AND B-2-MICROGLOBULIN IN PATIENTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Early detection of potentially reversible kidney damage in patients with type 1 diabetes mellitus (T1DM) is extremely important. At the moment, the main groups of early potential renal markers have been identified: tubular markers, markers of podocyte damage, growth factors, etc. The aim of this study was to evaluate the area under the characteristic curve (AUC ROC), sensitivity, and specificity of early renal markers (podocalyxin and β-2-microglobulin) by ROC analysis in men with T1DM and different levels of albuminuria.

Methods: In men with T1DM and early stages of nephropathy ($n = 69$), a comparative analysis of the areas under the characteristic curves (ROC AUC) of early renal markers (podocalyxin and β-2-microglobulin in urine) in comparison with classical parameters (urine albumin and urine albumin/creatinine ratio) using ROC analysis was performed.

Results: It was found that the values of the area under the curve and the specificity index for podocalyxin were significantly higher ($p < 0.05$) compared with classical renal markers and β-2 - microglobulin. For this parameter, the ''cut-off'' (associated criterion, split point) was 1.76, which may indicate the likelihood of diabetic nephropathy in the initial stage.

Conclusions: It can be concluded that podocalyxin can be recommended for a differentiated approach to identify risk groups for the development of glomerular kidney disorders in men with type 1 diabetes.

EP268 / #666

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

MONITORING AND RECOVERY OF HYPERGLICAEMIA-INDUCED ENDOTHELIAL DYSFUNCTION WITH RHEOPHERESIS IN DIABETIC LOWER EXTREMITY ULCERATION WITH HYPERVISCOSITY

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Background and Aims: Rheopheresis is an extracorporeal haematotherapy that improves haemorheological status by filtering proteins that enhance blood viscosity. It also has anti-inflammatory effects by removing inflammatory cytokines. Our study aims to examine the effects of rheopheresis on endothelial status in diabetic lower extremity ulceration.

Methods: In in vivo studies, two rheopheresis procedures were performed on seven patients with diabetic lower extremity ulceration with hyperviscosity, and we measured the changes in plasma concentrations of IL-6, Il-8, TNF-alpha, ET-1, TXB2, SOD enzyme activity, and extracellular components of the glutathione pool depending on treatments. We also confirmed the beneficial effects of the rheopheresis on the haemorheological status.

Results: As a result of rheopheresis, we observed decreased Il-6, Il-8, TNF-alpha, ET-1, and TXB2 concentrations in the plasma, beneficial changes in the parameters of the glutathione pool, and normalization of the haemorheological status

Conclusions: Rheopheresis can effectively improve endothelial and haemorheological status by normalizing the glutathione pool, reducing inflammatory cytokines, and blood viscosity enhancing proteins.

EP269 / #750

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

DIGITAL DIABETES CLINIC

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Background and Aims: The use of digital diabetes technologies and telemedicine protocols has the potential to offer this in a specialized digital/virtual diabetes clinic (DDC). In a survey of German diabetologists, we aimed to capture attitudes toward DDC:.

Methods: 305 diabetologists (48% female; average age 53.7 years) were asked via online survey to their attitude towards DDC (100-point scale from ''very negative'' to ''very positive'').

Results: - Almost two-thirds (62.7%) of respondents have a negative attitude toward DDC, only 12.8% have a positive attitude. - Approximately two-thirds (68.6%) think that they are exposed to risks due to the lack of necessary physical examinations.

- However, a large number of diabetologists (40.3%) can imagine that DDC for the care of special groups such as athletes or people from a different cultural background or with a lack of German language skills could certainly be advantageous as an additional service.
- Most of the diabetologists disagreed that DDCs could be a competition for their own facilities.
- However, only a few of the diabetologists (18.3%) believed that such virtual services substantially improve the care of PwD.

Conclusions: The greatest benefit of DDC is seen by respondents in the care provided to specific groups of PwD. Concerns exist about the possible lack of physical examinations and a non-significant improvement in care for PwD.

EP270 / #831

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

DKA IN T1D PREGNANCY; MISSED OPPORTUNITIES TO KEEP MOTHERS AND BABIES SAFE?

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Background and Aims: Diabetes technologies are increasingly used to help pregnant women achieve glycaemic targets and reduce the risk of maternal-fetal complications. Diabetic ketoacidosis during pregnancy is a medical emergency with significant maternal-fetal morbidity and mortality.

Methods: A case of a 17-year-old woman with T1D (pre-pregnancy HbA1c 73mmol/mol) and previous self-harm. She was switched from insulin pump to multiple daily injections, 6months before pregnancy. At 12 weeks' gestation, she started hybrid-closed-loop. During pregnancy, she saw the diabetes-antenatal team every 1-2 weeks with intensive mental health support and suffered ongoing hyperemesis. Mean TIR during 12-24 weeks' was 38% (60%> 7.8mmol/l, MBG 9.7mmol/l).

Results: At 24 weeks', she collapsed (BG 4.9mmol/l) and was admitted to ED for 6hours, without any glucose checks. Meanwhile her pump had stopped delivering insulin (?battery problems) and her CGM sensor expired after repeated alarms but she was too unwell to respond. Last sensor glucose was 20mmol/l (unchecked). 12 hours later, she re-presented hypotensive, hyperglycaemic (24.1mmol/l), and ketotic (3.5mmol/l, pH 7.25) and unaware that her pump was not delivering insulin. She reported no fetal movements and intrauterine fetal death was confirmed. She was started on FRIII and delivered a stillborn baby boy. DKA resolved quickly and was discharged the next day on closed-loop with bereavement, diabetes and obstetric support.

Conclusions: Most pregnant women are expert in managing diabetes technologies when well, but non-specialist healthcare professionals need to know when step in and/or access specialist advice when technology users are unwell. This tragic case highlights missed opportunities to intervene and potentially prevent a baby's death.

EP271 / #640

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

13C GLUCOSE BREATH TEST ANALYSIS AS A SURROGATE INDEX OF INSULIN RESISTANCE IN PEOPLE WITH TYPE 1 DIABETES: A COMPARISON WITH THE EUGLYCEMIC HYPERINSULINEMIC CLAMP

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Background and Aims: The euglycemic hyperinsulinemic clamp (HEC) is the gold standard to assess insulin resistance (IR). The HEC is unsuited for epidemiological studies, so non-invasive alternatives are needed.

Methods: We performed a 240-minute HEC (120mU/min/m^2) with blood glucose clamped at 90 mg/dl (5mmol/l). The final 30 minutes of glucose infusion rate were used to determine the M-value (mg/kg/min). A 13C glucose breath test was performed, using 25 mg of universally labeled glucose, obtaining samples up to 150 minutes after ingestion. Samples were analyzed using an isotope ratio mass spectrometer. The expired $13CO_2$ after test drink ingestion was compared with the baseline value. Results are expressed as an absolute increase (Δ %) in 13C after 90 minutes.

Results: We included 29 subjects (69 % male, mean age 47 ± 15 years, BMI 28.2 ± 5.90 kg/m^2). Mean M-value was 4.86 ± 2.93 mg/kg/min, Δ13C was 6.05 ± 2.55 %. We found a

significant correlation between Δ13C and M-value ($r = 0.65$, $p < 0.001$). Both M-value ($r = -0.71$, $p < 0.001$) and Δ13C ($r = -0.58$, $p = 0.001$) were correlated with waist circumference. Linear regression showed a significant association between Δ13C and M-value, adjusted for age and gender ($B = 0.88$, adjusted $R^2 = 0.46$, $p < 0.001$). We found an AUROC of 0.86 for Δ13C to identify subjects with IR (M-value <4.9mg/kg/min). Optimal cut-off point based on Youden's J statistic was <6.79 Δ % (sensitivity 0.88, specificity 0.70).

Conclusions: The 13C breath test shows important potential as indicator for IR in T1D.

EP272 / #60

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

FIRST IN-HUMAN TESTING OF AN ARTIFICIAL INTELLIGENCE BASED FULLY CLOSED-LOOP GLUCOSE CONTROL SYSTEM IN HOSPITALIZED PATIENTS WITH DIABETES

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Background and Aims: Achieving tight blood glucose control safely is challenging in the Intensive Care Unit (ICU). We conducted the first-in-human testing of an artificial intelligence (AI)-based fully closed-loop system in a simulated ICU setting to obtain preliminary safety and efficacy estimates.

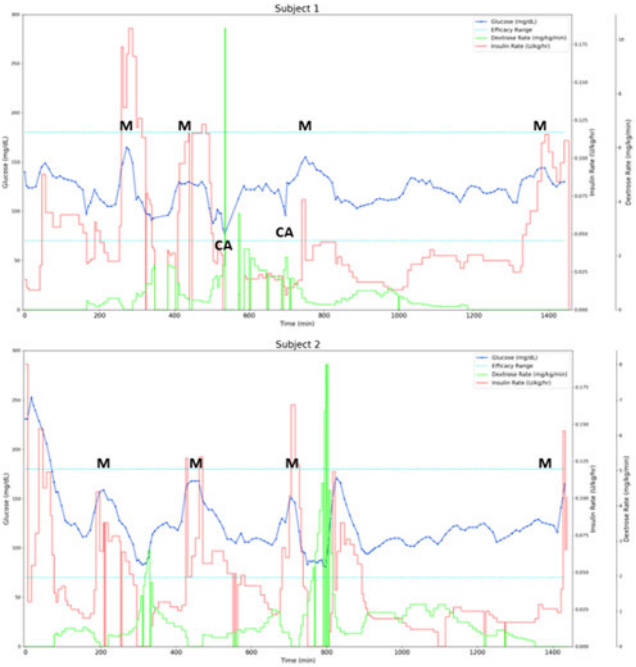

Figure. Glucose vs time plots with overlayed weight-based insulin and dextrose infusion rates. M=meal; CA=compression artifact (detected with alarms).

Methods: Two patients with type 2 diabetes were admitted for 24-hour closed-loop therapy. The system uses glucose control software that controls insulin and glucose infusion based on real-time continuous glucose monitoring (CGM) derived data. The primary safety endpoint was the percentage of glucose values <70 mg/dL. The primary efficacy endpoint was the percentage of glucose values within the range of 70-180 mg/dL. The study was registered in clinicaltrials.gov, NCT05386849.

Results: Both participants were on basal bolus therapy before admission and had a BMI >35 kg/m^2 and A1c >8%. No hypoglycemia events <70mg/dl were observed duing closed-loop therapy, meeting the primary safety endpoint. Subjects 1 and 2 maintained excellent glycemic control, including postprandial periods after ununounced meals, spending most of the time during closed-loop within the target range of 70-180 mg/dL (100% and 94.5%, respectively). The figure shows glucose vs time plots with overlayed weight-based insulin and dextrose infusion rates. No adverse events were observed.

Conclusions: This proof-of-concept data shows this novel fully closed-loop system designed for the ICU setting has the potential to achieve unparalleled glycemic control with minimal risk of hypoglycemia.

EP273 / #435

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

A DIGITAL LIFESTYLE INTERVENTION TO HELP PEOPLE WITH TYPE 2 DIABETES IMPROVE THEIR SELF-MANAGEMENT

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Background and Aims: The prevalence of Type 2 Diabetes continues to increase and new solutions to improve self-management is warranted. LIVA Health is a digital program intended to help people to improve diabetes management by supporting behavior change digitally. The study aims to evaluate the effect of LIVA Health on HbA1c (primary outcome), and quality of life, diabetes distress, and change in body weight (secondary outcome).

Methods: The study design is based on a prospective, open controlled observational study with a control group. Adult German patients (>18 years) with type 2 diabetes, BMI 25-40 kg/m2 and with HbA1c between 6.5% and 11.0% were recruited from social media campaigns. Participants received a 6-month intensive digital program focused on behavior changes and lifestyle modification. Data were collected at baseline and 3- and 6 months follow up. Repeated measures ANOVA was used to assess the overall significance of difference in outcome values.

Results: Between April-October 2022, 63 participants were recruited (51% females) with an average BMI of 33.4 kg/m2 and average diabetes duration of 5.7 years. The intervention group and the control group were comparable in social and medical conditions. During the first 3 months of the intervention period, the intervention group had a HbA1c reduction from 7.41% to 7.02%. 94% of the intervention participants were retained after 3 months.

Conclusions: This pilot trial shows preliminary results of being feasible in a German setting with high retention and efficacy. Future policies for the prevention and treatment of chronic conditions such as diabetes and obesity must include digitally delivered programs.

EP274 / #702

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

GENOTYPING CHILDHOOD OBESITY - LESSONS LEARNT

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Background and Aims: Monogenic obesity is a severe, genetically driven disorder affecting more than 1/1000 new-borns. Development of novel therapeutics and innovative clinical approaches have highlighted the need for early genotyping of children with rare genetic variants that affect the leptin-melanocortin pathway, to improve clinical intervention and reduce the risk of chronic complications later in life.

Methods: NGS of central genes in the leptin-melanocortin pathway was performed in 1508 children and adolescents with and without obesity, aged 2-19 years. The recruited cohort comprised approximately 5% of the national paediatric population with obesity. The estimated effect size of rare variants in the leptin-melanocortin pathway on weight gain was derived and approximate body mass growth curves were generated to simulate potential weight gain associated with rare gene-function-altering variants. Multiple iterations of effect size calculations were run to reduce the sampling effect and analysis bias.

Results: Causative genetic variant was identified in 1.4% (N = 21) individuals. Additionally, 4.1% (N = 62) were carriers of VOUS. Estimated incidence of obesity associated genetic variants was between 1/150 and 1/850. Excess weight gain effect of identified variants, at the age of 18 years, was estimated at ~7.5 kg on average. The significant weight gain effect was identified in autosomal recessive genes with a single heterozygous genetic variant as well.

Conclusions: Approximately 6% of all obese children have strong genetic predisposition for obesity encoded in genes of LEP-MCH signalling pathway. Early identification of population at risk could reduce the societal burden and improve the clinical management of early severe childhood obesity and should be further investigated.

EP275 / #491

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

SUSTAINABLE WEIGHT LOSS AND METABOLIC IMPROVEMENT OF A SMARTPHONE-BASED WEIGHT MANAGEMENT PROGRAMME FOR ADULTS WITH DIABETES AND PREDIABETES: RANDOMIZED CONTROLLED TRIAL

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Background and Aims: Mobile health (mHealth) can facilitate long-term weight loss through behavior change, retarding diabetes progression. However, research is scarce regarding the long-term effectiveness of mHealth over usual care. This study aimed to examine the long-term effect of mHealth intervention on weight loss maintenance, glycemic control and metabolic outcomes among obese participants with diabetes or prediabetes.

Methods: Results were analysed from previously published *Diabetes Lifestyle Intervention using Technology Empowerment (D'LITE)* randomized controlled trial. Both groups (n = 352) received diet and lifestyle advice at baseline. The intervention group received 6 months of coaching from dietitian and self-monitoring via the Nutritionist Buddy (nBuddy) Diabetes App. Student *t*-test for between-group differences and mixed effect logistic regression for modelling binary outcomes were used.

Results: Mean weight change among the mHealth vs control group was maintained at -3.0 ± 4.3kg (95% CI -3.7– -2.3) vs -1.2 ± 3.3kg (95% CI -1.7– -0.7) at 1-year, and -3.1 ± 4.3kg (95% CI -3.9– -2.3) vs -1.3 ± 3.3kg, 95% CI -1.8– -0.7) at 2-year. The odds of mHealth group achieving at least 5% weight loss were 2.9 (SE 1.34; 95% CI 1.20 – 7.19) and 2.5 (SE 1.12; 95% CI 1.01–5.99) at 1-year and 2-year respectively, as compared to the control group. Among the mHealth group with diabetes, the mean HbA_{1c} change was -0.5 ± 1.15% (95% CI -0.8– -0.3), and -0.4 ± 1.25% (95% CI -0.7– -0.3) at 1-year and 2-year, respectively. Systolic blood pressure improved significantly at $p < 0.05$.

Conclusions: mHealth intervention was able to facilitate significant long-term weight loss and glycemic control, potentially preventing diabetes conversion.

EP276 / #935

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

DJB SURGERY ENHANCES INTESTINAL AEROBIC OXIDATION IN T2DM RATS BY ACTIVATING GLP-1/GLP-1R SIGNAL

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Background and Aims: Although gastric surgery can significantly improve blood glucose homeostasis in type 2 diabetes mellitus (T2DM), its mechanism remains unclear. This study

focused on the role and mechanism of duodenal-jejunal bypass (DJB) in regulating glucose metabolism in the proximal jejunum of type 2 diabetic (T2DM) rats.

Methods: A T2DM rat model was induced via a high-glucose high-fat diet and low-dose streptozotocin injection. The diabetic rats were divided into two groups: the DJB surgery (T2DM-DJB) group, and the sham surgery (T2DM-sham) group. Wistar rats were used as wild-type control (Control). Small animal PET was used to assess the change in glucose metabolic status in the intestine. Transcriptomics is used to assess differences in gene expression, including signal transduction and catabolic pathways. Metabolomics is used to measure the aerobic oxidative capacity (including glycolysis and the tricarboxylic acid cycle). Western Blot and qRT-PCR were used to detect the expression of GLP-1/GLP-1R in proximal jejunum.

Results: Small animal PET analysis showed the proximal jejunum energy metabolism increased significantly after DJB surgery. Transcriptomic assays showed significant differences in gene expression, including signal transduction and catabolic pathways, between the T2DM-DJB and T2DM-Sham groups. Metabolomics assays showed that the proximal jejunum glucose metabolic pathways, including glycolysis and tricarboxylic acid cycle, were significantly enhanced in the T2DM-DJB group. Western Blot and qRT-PCR results showed that the expression of GLP-1/GLP-1R in the proximal jejunum was up-regulated significantly after DJB surgery.

Conclusions: DJB surgery exerts an anti-diabetic effect by up-regulating GLP-1/GLP-1R signal in the proximal jejunum and enhancing intestinal aerobic oxidation.

EP277 / #608

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

AUTOMATIC FINE-GRAINED FOOD RECOGNITION USING ARTIFICIAL INTELLIGENCE

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Background and Aims: Dietary assessment methods rely on participants recall capabilities or on weighing and describing foods consumed, which is important for diabetes management. Artificial Intelligence (AI)-based systems that allow the assessment of a meal's nutritional information based on photos are becoming more popular since they are automatic, accurate, and easy-to-use. Our aim is to create a dataset with meal images captured under real-life conditions and develop an AI-based model that recognizes multiple food items from a single image.

Methods: The food/drink items are first detected and segmented. Each segmented item provides input to a newly developed hierarchical Convolutional Neural Network (CNN) that recognizes the food category appearing in an image, in three layers, i.e., coarse, middle, and fine category (e.g., meat, red meat, meatball). The CNN focuses on recognizing the coarse category first and gradually gives more weight to the middle and fine category.

Results: We created a training database that containing 18 coarse, 34 middle, and 298 fine categories based on in-house datasets and images obtained from the internet. For the testing set, we used a tool to annotate the meal images that were captured by 50 participants in a preliminary study and images captured in a laboratory environment. The model achieved a top-1/top-3 accuracy of 43.8/60.1%, 57.1/78%, and 65.2/82.6% for the coarse, middle, and fine categories respectively.

Conclusions: We have created a database that contains images captured under various conditions and developed an AI-based model that can recognize the various plated/non-plated food and drink items that appears in an image.

EP278 / #853

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

IMPACT OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION AND FLASH GLUCOSE MONITORING ON HBA1C IN REAL LIFE: PORTUGUESE EXPERIENCE

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Background and Aims: Adequate control of blood glucose reduces the risk of complications. The Continuous Subcutaneous Insulin Infusion (CSII) and Flash Glucose Monitoring (FGM) were introduced to achieve better glucose control in type 1 diabetes (T1D) patients. In this study, we investigated the effectiveness of CSII and FGM implementation in real life, with an emphasis on the effect on glycated hemoglobin (HbA1c).

Methods: This retrospective observational study included 4082 TD1 subjects, in follow-up in APDP Diabetes, Portugal. HbA1c was evaluated in each of the four groups: FGM users/CSII users; FGM users/CSII non-users; FGM non-users/CSII users; FGM non-users/CSII non-users. ANOVA test was used to evaluate the statistical significance between the groups. Age-stratified analysis of HbA1c was performed in each group.

Results: Of the 4082 patients, 70.5% (n = 2879) were FGM users, 14% (n = 564) had CSII system and 10% (n = 410) had both. The average HbA1c in FGM users/CSII users was 7.58% ± 1.11% vs. 7.85% ± 1.31% in FGM non-users/CSII users (95% CI, 0.01 to 0.54; $p = 0.045$) vs. 8.09% ± 1.43% in FGM users/CSII non-users (95% CI, 0.37 to 0.64; $p < 0.001$) vs. 8,59% ± 1.76% in FGM non-users/CSII non-users (95% CI, 0.86 to 1.16; $p < 0.001$). In all age groups (0-14; 15-65; ≥65 years old) the average HbA1C in FGM users/CSII users was lower compared to other groups.

Conclusions: T1D patients using CSII and FGM had a significantly lower HbA1c, compared to CSII and/or FGM non-users, which translates into better metabolic control and, consequently, indicates the usefulness of the insulin infusion and glucose monitoring systems.

EP279 / #400

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

TIME ABOVE RANGE IS ASSOCIATED WITH NON-ALCOHOLIC FATTY LIVER DISEASE IN ADULT PEOPLE WITH TYPE 1 DIABETES

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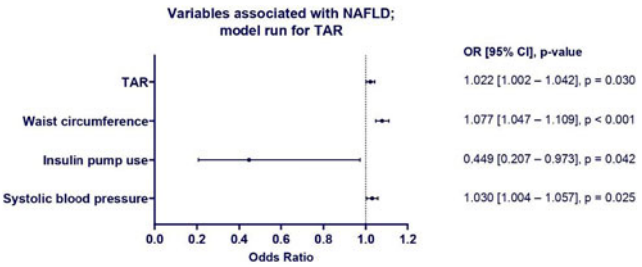
Background and Aims: People with type 1 diabetes (T1D) are increasingly becoming overweight and are showing features of the metabolic syndrome (MetS). MetS can be accompanied by non-alcoholic fatty liver disease (NAFLD), which might interfere with glucose homeostasis. However, the link between continuous glucose monitoring (CGM) derived glucometrics and NAFLD remains to be elucidated.

Methods: In this cross-sectional study, data on biometrics, glucometrics and NAFLD were collected from adults with T1D using a CGM device during a screening visit for NAFLD. NAFLD was defined by standardized ultrasound. Backward multivariate logistic regression models were applied to define variables independently associated with NAFLD.

Results: A total of 302 consecutive participants were included (median age 49 [34–61] years, male sex 58 %, median diabetes duration 29 [17–38] years, mean time-in-range (TIR) 53 ± 17 %). NAFLD prevalence was 17 %, and 32 % had MetS. TIR and HbA1c were respectively lower and higher in the NAFLD group, although not significant, while time-above-range (TAR) and MetS prevalence were significantly higher in the NAFLD group ($p = 0.010$; $p < 0.001$). TAR ($p = 0.030$), waist circumference ($p < 0.001$), insulin pump use ($p = 0.042$), and systolic blood pressure ($p = 0.025$) were independently associated with NAFLD, while sex, age, AST/ALT ratio, γ-GT, HDL, and triglycerides were not. TIR was not associated with NAFLD.

Conclusions: In people with T1D, TAR was higher in individuals with NAFLD. TAR, waist circumference, insulin pump use, and systolic blood pressure were independently associated with NAFLD.



Variables entered in model: sex, age, AST/ALT ratio, GGT, insulin pump use, waist circumference, systolic blood pressure, HDL cholesterol, triglycerides, TAR. Significant variables in multivariate analysis are shown.

EP280 / #656

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

GLUCOSE CONTROL IN TYPE 1 DIABETES: EXPERIENCE OF CAMPUS BIO-MEDICO OF ROME

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Background and Aims: flash and continuous glucose monitoring (FGM and CGM) and continuous subcutaneous insulin infusion therapy (CSII) have improved diabetes management. The aim of our study was to evaluate if a regular follow-up at the same center could influence glucose control.

Methods: 91 subjects (54 males and 37 females, aged 41.7 ± 14.5), afferent from January 2005 to May 2022 to Endocrinology and Diabetology department of Campus Bio-Medico, were retrospectively enrolled. HbA1c and time in range (TIR) were recorded as glucose control parameters.

Results: mean HbA1c (arithmetic and weighted) and TIR did not change significantly. Approximately 60% of patients had HbA1c <7%. Study population was divided in three groups: the first included patients on multi-injection insulin (MDI) therapy without FGM or CGM (20 males and 13 females, aged 40.5 ± 15.6); the second included patients on MDI using FGM (12 males and 12 females, aged 45.7 ± 13.6); the third included patients on CSII therapy + CGM (22 males and 20 females, aged 41.5 ± 13.9). Baseline and last visit HbA1c and TIR was compared in each group and between the three groups. No significant difference was observed. Concerning HbA1c, the analysis was corrected for age, disease duration, BMI, follow-up time, number of visits, HbA1c at diagnosis and C-peptide resulting significantly related only with HbA1c at diagnosis and C-peptide.

Conclusions: glucose control is influenced by patient's compliance to nutritional and therapeutic advices, however genetics plays a key role. Chronic complications should be assed to confirm these results.

EP281 / #437

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

ACCURACY OF THE DEXCOM G6 CONTINUOUS GLUCOSE MONITOR IN HOSPITALIZED PEDIATRIC PATIENTS WITH TYPE 1 DIABETES

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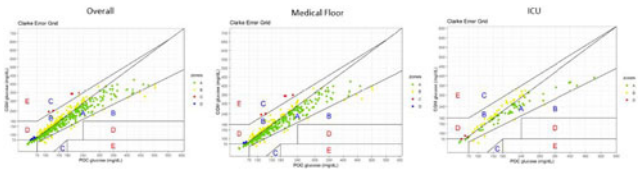
Background and Aims: Continuous glucose monitors (CGMs) are part of routine care in people with type 1 diabetes (T1D), with several systems receiving FDA approval for factory calibration and non-adjunctive use. However, this approval does not include the inpatient setting, where frequent glucose monitoring and medication adjustments are especially important. While there is some adult data, pediatric inpatient data is lacking.

Methods: This retrospective chart review evaluated accuracy of the Dexcom G6 CGM versus Nova Biomedical's StatStrip (MARD 6%) point of care (POC) blood glucose (BG) values from pediatric inpatient encounters. Blood glucose data, diagnosis codes, and medication administration were collected from hospital records. CGM values were obtained from Dexcom Clarity CSV files. The closest CGM value within 15 minutes of the BG value was used.

Results: 497 paired glucose values from 32 pediatric T1D patients (median age 14.5 years, 59.4% female, 68.8% Non-



Hispanic White) with inpatient encounters were analyzed using the MARD and Clarke Error Grid. Overall MARD was 12.5% while the medical floor MARD was 11.6% (N = 373) and the ICU MARD was 15.5% (N = 124). In each, 97.6% were within A&B zones. Clarke Error Grids are shown in the Figure.

Conclusions: CGM accuracy was comparable to previously published T1D adult inpatient data, with higher accuracy in non-critical hospital settings. Data collection is ongoing to obtain a larger sample size, differentiate POC versus lab glucose, and identify a variety of admission diagnoses and medications. Future prospective studies and inpatient protocols are necessary to ensure safe and feasible sensor use in the pediatric hospital setting.

EP282 / #425

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

CHANGES IN EA1C IN A TYPE 1 DIABETES POPULATION AFTER 41 WEEKS USE OF HEDIA DIABETES ASSISTANT: A REAL-WORLD OBSERVATIONAL STUDY

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Background and Aims: Smartphone-based bolus calculators have been shown to support glycaemic control in people with type 1 diabetes (T1D). However, little is known about the long-term effect of these in a real-world setting. We investigated the change in glycaemic control among users of Hedia Diabetes Assistant after 41 weeks use of the CE-marked bolus calculator.

Methods: In May 2021, data was extracted from the HDA database for users with ≥10 blood glucose logs per week for the first two weeks of use. The pre-defined outcomes were change in estimated A1c (eA1c) and estimated time in range (eTiR, proportion of logged blood glucose values in range 3.9-10.0 mmol/l) from week 0 to week 40.

Data was analysed with GLMM for all users and for a subgroup of poorly regulated users (mean baseline BGL ≥10mmol/l, eA1c≥7.9% in week 0).

Results: The sample contained anonymized data from 808 engaged HDA users with a mean age of 43.7 years (SD 15.9), including 407 (50.4%) females. From week 0-40, mean eA1c increased with 0.13%-points (p = 0.04) and eTiR decreased with 2.40%-points (p < 0.01) from week 0 to week 40. For poorly regulated users (n = 299) mean eA1c decreased by 0.51%-points (p < 0.01) and eTiR increased by 6.95%-points (p < 0.01).

Figure 1a. Change in eA1c from week 0 to 40 in a T1D population using Hedia Diabetes Assistant

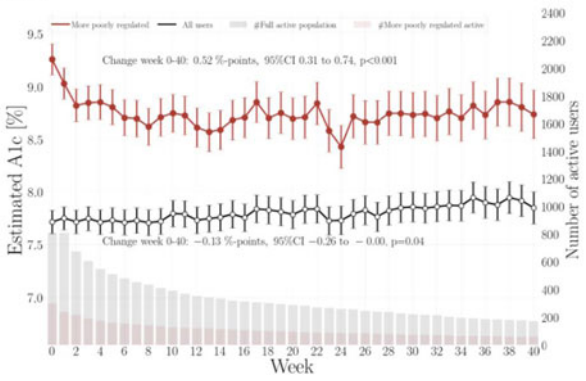
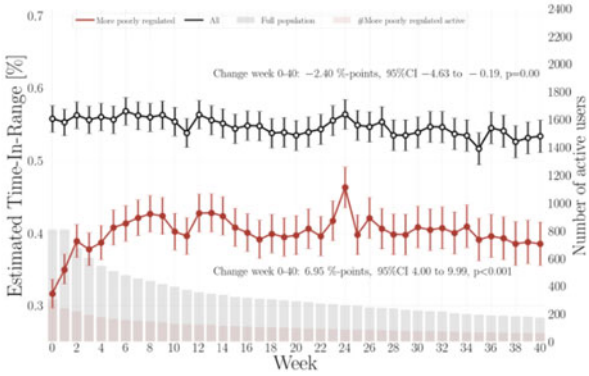


Figure 1b. Change in eTiR from week 0 to 40 in a T1D population using Hedia Diabetes Assistant



Conclusions: The results showed significant improvements in eA1c and eTiR for poorly regulated users with T1D. Prospective, interventional studies are needed to further investigate the effect of smartphone-based bolus calculators in real-world settings.

EP283 / #551

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

EFFECTS OF CUSTOMISED STRUCTURED SMBG ON GLYCEMIC CONTROL IN PEOPLE WITH DIABETES OVER 10 YEARS

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Background and Aims: Structured self monitoring of blood glucose (sSMBG) is a systematic, customised approach in which

Years	Group	Counts	Basline/ Final	Age	HbA1c (%)	p value (Wilcoxon Signed test)	Systolic BP (mm Hg)	p value (Wilcoxon Signed test)	Diastolic BP (mm Hg)	p value (Wilcoxon Signed test)	Total Cholesterol (mg/dL)	p value (Wilcoxon Signed test)
2	Control	251	B	51±13.3	8.1±2.3	0.0000*	128±16.1	0.2502	74±10.4	0.2651	182±37.3	0.0005*
			F		7.5±1.8		129±19.4		74±10.4		170±38.9	
	Treatment		B	53±12.4	8.9±2.2	0.0000*	129±17.5	0.3282	76±10.3	0.1254	182±46.1	0.0000*
			F		8.0±1.6		129±16.3		73±9.4		151±34.8	
3	Control	197	B	51±13.6	8.1±2.3	0.0048*	128±14.5	0.4581	74±8.8	0.3254	180±39.8	0.0000*
			F		7.7±1.8		126±15.7		74±9.4		164±41.7	
	Treatment		B	52±13.0	8.9±2.3	0.0000*	129±18.8	0.0612	77±10.1	0.6548	185±41.9	0.0000*
			F		8.2±1.9		130±18.5		74±9.6		153±37.6	
4	Control	116	B	54±12.6	8.2±2.6	0.0040*	129±17.5	0.4321	71±8.0	0.2645	188±42.2	0.0001*
			F		7.6±1.9		130±17.3		75±11.9		165±39.3	
	Treatment		B	54±12.8	8.9±2.1	0.0002*	130±17.1	0.2102	76±11.2	0.3521	185±42.6	0.0000*
			F		8.2±1.7		133±18.7		73±11.6		150±31.8	
5	Control	77	B	55±15.0	7.5±2.3	0.2339	132±20.1	0.2340	74±12.3	0.2653	187±39.0	0.0023*
			F		7.3±2.1		132±16.7		76±11.7		171±35.7	
	Treatment		B	54±14.3	9.2±2.5	0.0002*	133±20.9	0.3010	78±10.8	0.2458	186±37.7	0.0000*
			F		8.3±1.3		129±14.0		72±9.4		151±36.1	
6	Control	73	B	55±12.9	8.2±2.5	0.0013*	132±18.8	0.1561	74±9.3	0.2658	193±40.2	0.0005*
			F		7.5±1.5		135±19.6		79±9.7		167±38.9	
	Treatment		B	55±13.7	8.5±2.1	0.2597	129±19.4	0.2966	77±11.8	0.2145	188±48.0	0.0000*
			F		8.3±2.0		133±19.8		73±10.5		155±42.0	
7	Control	39	B	53±14.7	7.4±2.2	0.2388	132±16.7	0.4513	74±9.3	0.3214	171±30.0	0.1904
			F		7.1±2.1		133±15.6		78±9.7		163±34.5	
	Treatment		B	54±12.1	8.9±2.7	0.0004*	124±17.9	0.5321	75±9.8	0.3325	188±38.8	0.0000*
			F		7.7±1.3		127±16.0		72±7.8		147±35.6	
8	Control	36	B	55±11.5	6.8±2.0	0.9180	128±14.3	0.2341	74±9.1	0.4122	174±42.5	0.2282
			F		7.0±1.7		131±16.8		79±9.3		166±41.6	
	Treatment		B	54±13.0	8.1±1.6	0.5719	129±25.0	0.2654	77±13.1	0.1256	177±42.5	0.0000*
			F		8.2±1.7		125±15.0		72±11.4		143±37.4	
9	Control	30	B	60±14.8	6.8±2.2	0.4229	128±17.0	0.3254	72±10.2	0.2254	163±37.6	0.4419
			F		6.7±1.9		129±14.5		76±7.9		164±39.0	
	Treatment		B	61±11.6	8.7±1.7	0.0192*	137±19.2	0.5641	79±8.5	0.3365	176±48.5	0.0031*
			F		7.9±1.4		133±21.6		71±10.0		143±23.6	

* Significant

BG data are gathered so as to suit the convenience and comfort of PwD. We assessed benefits of sSMBG, in PwD who were followed up in a comprehensive chronic diabetes care program.

Methods: We extracted data of 11,516 T2D who were following up via a telemedicine program (DTMS® - Diabetes Tele-Management System) for over 10 years. 6980 belonged to treatment group(TG) [having sSMBG data either on a specified day or staggered over a week along with laboratory data] and 4536 belonged to control group(CG) [no sSMBG data but having laboratory data]. DTMS®, developed in 1997, involves unique software & trained multidisciplinary diabetes team, communicating with PwD for slow, steady titration of drugs combined with frequent tele-counselling. Data extracted was further divided into subgroups based on period of follow-up (2-9 years). Statistical analyses were performed using paired T-test, Wilcoxon Signed rank tests and Mann-Whitney tests.

Results: There were overall improvements in clinical parameters irrespective of the group (TG- n = 819; Age = 54 ± 13 yrs; CG- n = 819; Age = 53 ± 13.6yrs). For PwD with 2,3 and 4 years of follow-up, there was a significant reduction in HbA1c in both groups. For PwD with 5, 7, and 9 years of follow-up, there was a greater significant reduction in HbA1c in TG (Fig 1).

Conclusions: PwD following customized sSMBG over 10 years have documented sustained improvements in HbA1c, which may translate to a significant reduction in the burden of long-term complications with no increase in the cost of therapy.

EP284 / #45

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

CLINICAL USE OF CONTINUOUS GLUCOSE MONITORING IN PEDIATRIC DIABETIC KETOACIDOSIS IN PEDIATRIC ICU SETTING

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Background and Aims: Continuous glucose monitoring (CGM), commonly used in the outpatient setting, is yet to be implemented in the pediatric intensive care (PICU) setting. The purpose of this study was to evaluate the feasibility and accuracy of the system in pediatric patients with diabetic ketoacidosis (DKA) in a PICU setting.

Methods: This study included pediatric patients with DKA aged <18 years who were prescribed CGM cords during the PICU stay in Jeonbuk National University Children's Hospital from July 2019 to June 2022. we divided patients into those who had removed their CGM sensor for any reason during their ICU stay and those who did not.

Results: 18 patients were finally enrolled in the study. In the non-removal and removal groups, 15 patients and 3 patients were identified. The mean age was 11 ± 4.2 years (range 2 to 18). There was no statistical significance in the two groups' clinical and initial laboratory findings. Surveillance Error Grid (SEG) and Bland-Altman plot, and Pearson's correlation coefficient demonstrated an excellent clinical accuracy of CGM (SEG zone A and B = 98.5%; the mean difference of 15.5mg/dL, r = 0.87 ($p < 0.0001$)). We also calculated the mean absolute relative difference (MARD) to assess numerical accuracy. All MARD was 13.02 ± 12.52%. MARD in the non-removal group was statistically significantly lower (11.74% vs. 17.3%, $p < 0.048$).

Conclusions: CGM use in patients with DKA seems both feasible and accurate. Serum bicarbonate level does appear to impact the accuracy of CGM in the DKA setting. CGM can also see reasonable potency in ICU setting.

EP285 / #388

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

EFFECT OF CARBOHYDRATE INTAKE AND CORTICOSTEROID EXPOSURE ON POSTPRANDIAL DYSGLYCAEMIA IN HOSPITALIZED PATIENTS WITH TYPE 2 DIABETES RECEIVING FULLY AUTOMATED CLOSED-LOOP INSULIN THERAPY

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Background and Aims: Inpatient use of fully closed-loop (FCL) insulin therapy, not requiring user input at meal times, allows for automated glucose control whilst reducing workload burden of hospital staff. However, the lack of meal boluses may come at the cost of higher postprandial glucose (PPGL) values. Here, we explored the key determinants influencing postprandial dysglycaemia (PPdys) in FCL-treated inpatients with type 2 diabetes.

Methods: Insufficiently controlled PPGL values were defined as an excursion of postprandial glucose (PPGLexc) >4.0mmol/l within 2 hours after meal intake. Associations with carbohydrate (CHO) intake were estimated using a generalized additive logistic regression model based on glucose and meal data from 40 FCL-treated inpatients (N = 758 observations). Effects were adjusted for mealtime, intake of fat and protein, insulin on board, and subjects characteristics (e.g. use of corticosteroids).

Results: Meal CHO content, corticosteroid exposure interaction with lunch and timing of meal were significantly associated with PPdys. Meal CHO content had a non-linear effect on PPdys ($p < 0.01$, Figure 1). Probability for PPGLexc >4.0mmol/l remained below 50% for intake of less than 100g CHO during lunch and dinner, but increased sharply for intake of more than 100g. With regard to diurnal variation, CHO tolerance was lowest at breakfast. When exposed to corticosteroids, CHO tolerance was worse following lunch, but not following breakfast or dinner.

Conclusions: Meal CHO content, corticosteroid exposure during lunch and mealtime are key determinants of PPdys during FCL therapy in hospitalized patients with type 2 diabetes. The probability of PPdys increased steeply when meal CHO content exceeded a critical threshold of 100g.

EP286 / #525

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

EUGLYCEMIC DIABETIC KETOACIDOSIS (EDKA) IN THE TYPE 1 DIABETES YOUNG PREGNANT WOMAN IN THE THIRD TRIMESTER- WOULD YOU RECOGNIZE IT?

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Background and Aims: BACKGROUND Euglycemic diabetic ketoacidosis (EDKA) is a subtype of DKA where patients have normal glucose levels, thus making the diagnosis difficult to diagnose. A timely diagnosis is imperative as EDKA is a potentially life-threatening complication, especially during pregnancy for both the fetus and mother. AIMS To report a case of a young pregnant woman with Type 1 diabetes mellitus in her third trimester, admitted to the hospital with EDKA and to review the literature

Methods: CASE REPORT AND LITERATURE REVIEW A 21-year-old at 31-week gestation presented to the hospital with constant nausea and vomiting with associated food avoidance as well as right flank pain due to pyelonephritis. She was found to be in DKA with normal glucose levels of 4.9mmol/L. She was treated with antibiotics and fixed-rate insulin infusion. Her past medical history includes poorly controlled Type 1 DM, renal stones, hyperthyroidism, asthma, and recurrent UTIs

Results: She was found to be in severe DKA with normal glucose levels of 4.9mmol/L. She was treated with IV fluids and a fixed insulin infusion rate. She was given antibiotics. The patient had a successful forceps delivery of a healthy baby boy at 36.

Conclusions: EDKA episodes during pregnancy is an obstetric emergency.Common triggers for EDKA include pregnancy and infections. Some of the the mechanisms for EDKA include increased insulin resistance due to several hormones including placental lactogen, progesterone, and placental insulinase which peak during the second and third trimester. Also there is a shift to lipid utilization as a result of the placenta consuming glucose.

EP287 / #465

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

THE ROLE OF TECHNOLOGY (CGM/FREESTYLE LIBRE) IN IMPROVING THE QUALITY OF LIFE AMONG CANCER PATIENTS WITH STEROID-INDUCED HYPERGLYCAEMIA

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Background and Aims: BACKGROUND Steroids are the most common cause of drug-induced hyperglyacaemia and are commonly used in the treatment of patients with cancer and haematological problems The incidence of steroid-induced hyperglycaemia is variable based on different centres, and it has been linked to an increased risk of infection and longer hospital admissions. **AIMS** 1)Establish BM monitoring protocols in non-diabetic individuals receiving any sort of glucocorticoid medication. 2) Determine whether management adheres to national guidelines. 3) To create a consensus approach in haematology and oncology for patients receiving long-term steroid therapy

Methods: Retrospective study/audit over the period of 4 months of patients who are on cancer treatment. **Standards:** Local and national guidelines [Joint British Diabetes Societies for Inpatients (JBDS) guidelines] Exclusion Criteria : Pre-existing Diabetes

Results: From case notes and electronic records, 87 patients were identified for the study. Out of these,8 patients developed diabetes after commencing steroids.2 patients had prostate cancer, 2 patient with breast cancer, 1 patient had cancer of the ovary, 1 patient with Diffuse Large B cell Lymphoma (DLBCL), 1 patient with non-Small cell lung cancer(NSCLC),1 patient with glioblastoma 4 patients(50%) had baseline HbA1C and 5 patients(60%) had baseline fasting blood sugar

Conclusions: Cancer Patients on steroids may develop hyperglycemia at a lower steroid dose, so glucose monitoring is recommended with steroid therapy at any dose at baseline and during follow-up. This study suggests the use of technology such as CGM and Freestyle Libre/Flash glucose monitoring will transform and improve the care and quality of life in cancer patients

EP288 / #579

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

EFFECTIVENESS OF INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN A PREGNANT WOMAN WITH POORLY CONTROLLED TYPE 1 DIABETES AND END-STAGE RENAL DISEASE: A CASE REPORT

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Background and Aims: In people with type 1 diabetes (T1DM) and advanced chronic kidney disease (CKD), the alteration of endogenous substances in the interstitial liquid may affect the sensor performance of continuous glucose monitoring (CGM) systems. We report a case of a 34 years-old pregnant woman with T1DM and stage A3/G4 CKD, according to KDIGO classification, carrying an intermittently scanning CGM (isCGM) for management of insulin therapy while admitted to hospital for managing high-risk pregnancy.

Methods: We compared 363 glycemic values simultaneously measured by a capillary blood glucometer and the isCGM during 2 months of hospitalization for a complicated pregnancy.

Results: At 27-week gestation serum creatinine was 3.5 mg/dl with an estimated glomerular filtration rate (eGFR) of 16,4 ml/min/1,73 m^2. During the hospital stay, despite careful blood glucose monitoring, several hypoglycemic and hyperglycemic events were recorded while on multiple-dose insulin therapy (0.4 U/kg/day). isCGM and capillary blood glucose readings were highly correlated (r = 0.97; 95% CI 0.96-0.98). The mean absolute relative difference (MARD) for glucose values between 63 and 140 mg/dl was 23% and 11% for glucose values >140 mg/dl. For glucose values <63 mg/dl mean absolute difference (MAD) was 22 mg/dl.

Conclusions: In this pregnant woman with T1DM complicated by advanced CKD, isCGM appeared not sufficiently accurate to inform properly on the management of insulin, particularly at glucose values below 140 mg/dl. This observation may support the need for ad hoc studies in complicated pregnancy when glycaemic control is of particularly great importance.

EP289 / #112

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

"BLOOD GLUCOSE-SLEEP MONITORING" IN A CHILD WITH TYPE 1 DIABETES (CASE STUDY)

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Background and Aims: Nocturnal hypoglycemia is an urgent consequence of type 1 diabetes that should be avoided in children. The goal of this study was to reveal the results of simultaneous monitoring of blood glucose levels and EEG during sleep in children with type 1 diabetes.

Methods: The subject was a 7-year-old girl, and three nights of simultaneous monitoring were done with FreeStyle Libre (Abbott Japan G.K., Japan), and sleep monitoring was done with SleepScope (Sleepwell Co., Ltd., Japan)g. Blood glucose changes were graphed nightly for blood glucose monitoring, and sleep cycles and phases were extracted for sleep monitoring. The two monitoring results were superimposed. The goal blood glucose level was set at 70–180 mg/dL, and a decrease in blood glucose level was defined as a decrease of 1 mg/dL or more per minute.

Results: On day 1, there was no hypoglycemia or fast decline in blood sugar on day 1. On day 2, severe hypoglycemia below 50 mg/dL occurred in the first sleep cycle, with a rapid decline (−3.7 mg/dL/min). In the second and third sleep cycles, when hypoglycemia occurred, arousal responses lasted 1.5 minutes. On day 3, there was no hypoglycemia, but a rapid drop (−1.9 mg/dL/min) was seen in the first sleep cycle. Blood glucose levels gradually increased when non-REM sleep stage 3 was eliminated.

Conclusions: Accumulating data, it was proposed that simultaneous blood glucose-sleep monitoring could disclose the temporal relationship between blood glucose changes and sleep.

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Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

SATISFACTION ASSESSMENT OF CONTINUOUS GLUCOSE MONITORING IN TYPE 2 DIABETES PATIENTS RECEIVING INPATIENT CARE.

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Background and Aims: The use of continuous glucose monitoring (CGM) in the outpatient setting is associated with numerous clinical benefits with patients reporting high levels of satisfaction (LoS) with this technology. There is limited information on patient reported outcomes (PROs) related to CGM use in the inpatient setting. The aim of this study was to evaluate the LoS of inpatients using CGM.

Methods: This was a pilot cross-sectional descriptive study including adult patients with type 2 diabetes(T2D) admitted to medical and surgical wards at Gregorio Marañon Hospital (Madrid, Spain). Nineteen patients treated with basal-bolus insulin therapy were enrolled and monitored using CGM (Abbott FreeStyle 2- FSL2) and concomitant capillary glucose (CG) testing. A 15-item Glucose Monitoring System Satisfaction Survey (GMSS Version T2D) was administered before discharge evaluating four domains: openness and worthwhileness (higher scores = higher satisfaction), as well as, emotional and behavioral burden (lower scores = higher satisfaction).

Results: The median age was 68 (IQR 57-73) and 31.6% of patients were women. Median HbA1c was 7.6%(IQR 6.3-10.5) and T2D duration was 10 years(IQR 5-15). Median use of FSL2 was 8 days(IQR 6-14), TIR 75%(66-87), average glucose 135mg/dl(SD 26,21) and CV 29.80%(24.6-36.6). The GMSS scale output was: openness 4.2/5 points, worthwhileness 4.5/5 points, emotional burden 1.8/5 points, and behavioral burden 1.25/5 points.

Conclusions: When FSL2 is employed for T2D hospitalized patients, a high LoS regarding openness and worthwhileness is achieved with no emotional or behavioral burden increase. The use of CGM may allow patient participation in their glycemic control management, but further research is needed.

EP291 / #545

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

USING MACHINE LEARNING (XGBOOST) TO PREDICT INPATIENT HYPOGLYCEMIA FROM SPARSE / IRREGULAR CAPILLARY BLOOD GLUCOSE MEASUREMENT TIME SERIES

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Background and Aims: Inpatient bood glucose measurement time series are often short, sparse, and irregular, and are therefore difficult to manage with traditional time series methods. XGBoost (eXtreme Gradient Boosting) is a powerful decision-tree based method that has been shown to perform well across many applications and data types. We aimed to investigate the performance of an XGBoost based classifier to predict significant hypoglycaemia over a 24h period, across a range of admission durations, and (ii) to compare this approach with more simple glucometric methods.

Methods: Inpatient glucose data from a large UK Health Board from 2012-2022 was analysed. An XGBoost model was trained for each of the first n days of admission (training), predicting hypoglycemia during day n + 1 (test). Comparative models were constructed using the (i) coefficient of variation (CV) of glucose and (ii) the presence/absence of any measurement below 3mmol/l during training. XGBoost models were assessed using k-fold internal validation, with bootstrapping used for comparators. Balanced accuracy, sensitivity, specificity AUROC and f1 score were calculated.

Results: Performance of XGBoost and comparator models for sample 2 and 7 day admission durations:

train/test duration (days)	balanced_acc	sensitivity
	CBG <3mmol/l	
1/1	0.67	0.41
6/1	0.71	0.54
	CV	
1/1	0.65	0.57
6/1	0.73	0.78
	XGBoost	
1/1	0.75	0.78
6/1	0.79	0.80

Conclusions: XGBoost substantially outperforms simple glucometric based predictive approaches, particularly in the important domains of precision and recall (as evidenced by the f1 score), and when taking very short input sequences.

EP292 / #658

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

RELATIONSHIP BETWEEN TIME IN RANGE, HBA1C AND FRUCTOSAMINE IN PEOPLE WITH DIABETES UNDERGOING HAEMODIALYSIS

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Background and Aims: Diabetic nephropathy is the leading cause of end-stage renal disease (ESRD). The diagnostic accuracy of classical glycaemic markers (HbA1C and fructosamine) decline with advanced diabetic nephropathy. In this sub-analysis of the ALPHA (Accuracy of Continuous Glucose Sensors in People with Diabetes Undergoing Haemodialysis) study, we evaluate the relationship between HbA1c and fructosamine with percentage time-in-range (TIR).

Methods: Forty participants with diabetes undergoing haemodialysis wore real-time and intermittently scanned CGM (Dexcom G6 and Freestyle Libre 1, respectively) for 12 consecutive dialysis sessions (28-42 days). Blood samples for HbA1c and fructosamine were collected at the start and end of the study period. CGM data during the entire study duration were analysed for TIR. The relationship between glycaemic markers were assessed by Spearman's rank correlation coefficient.

Results: Participants were aged median (IQR) 64.7 (60.2 – 74.4) years, 30 (75%) were male with diabetes duration for 23.0 (19.0 – 31.5) years. All participants were on insulin; 37 (92.5%) had type 2 diabetes. There was a negative correlation between HbA1c and TIR with both Dexcom G6 and Libre 1 sensors (r^2 = -0.516 and r^2 = -0.486 respectively; both $p < 0.001$). With fructosamine and TIR, the correlation was less pronounced (r^2 = -0.211 with Dexcom G6; r^2 = -0.213 with Freestyle Libre 1; both $p < 0.001$).

Conclusions: A stronger correlation of time-in-range, assessed by Dexcom G6 and Libre 1, was observed with HbA1c than fructosamine. Fructosamine is unlikely to be a suitable modality for assessing glycaemia in people on haemodialysis, and alternate glycaemic markers should be considered.

EP293 / #322

Topic: ***AS15 Human factor in the use of diabetes technology***

RELATIONSHIP OF TREATMENT REGIMENS AND BEHAVIORS TO REAL-TIME CGM-BASED OUTCOMES FOR ADULTS WITH TYPE 2 DIABETES (T2D) IN EUROPE

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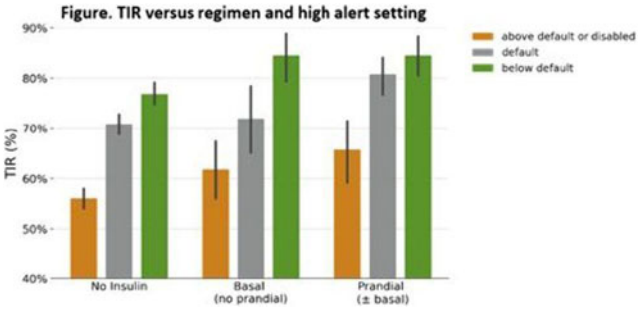
Background and Aims: The heterogeneity of T2D suggests that patients may use and benefit from real-time continuous glucose monitoring (rtCGM) to different extents. Real-world evidence was used to characterize glycemic status and rtCGM-related behaviors in a convenience sample of rtCGM users.

Methods: Data were from a convenience sample of 2,000 individuals in Europe (DACH region; Nordics; UK/Ireland; Italy/Spain; France) who self-identified as having T2D and began uploading data from an rtCGM system (Dexcom G6) between 09/2021 and 09/2022. Self-declared treatment regimens included non-insulin therapy (No Insulin), basal-only insulin (Basal), and prandial insulin with or without basal (Prandial). rtCGM use, alert-related behaviors, and interactions with retrospective data were also evaluated.

Results: The NIT, Basal, and Prandial regimens were used by 17.6%, 8.2%, and 74.3% of individuals, respectively. Metrics for mean glucose and proportion of users with TIR >70% favored the

Table. CGM data versus treatment regimen

	No Insulin	Basal	Prandial
N (%)	351 (17.6%)	163 (8.2%)	1486 (74.3%)
Mean glucose (mg/dL)	154	163	168
High alert enabled	83.8%	79.1%	76.0%
Proportion with >70% TIR	70.1%	63.2%	50.5%
Days with CGM use (%)	87.8%	87.3%	86.4%
Clarity engagement(s)	72.9%	74.8%	72.3%



NIT group, and metrics related to CGM use and engagement with retrospective data (Clarity reports) were comparable (Table). Regardless of insulin regimen, TIR was highest for individuals who lowered the hyperglycemia alert threshold value and was lowest for individuals who increased or disabled it (Figure).

Conclusions: Regardless of pharmacological regimen, adults with T2D used CGM and consistently accessed their retrospective data. Together, this suggests that rtCGM and selected Dexcom features are perceived as beneficial. Lowering the default high alert threshold value is associated with better TIR and may be appropriate for patients not reaching targets.

EP294 / #47

Topic: ***AS15 Human factor in the use of diabetes technology***

ALTERNATIVES TO IN-PERSON DIABETES DEVICE TRAINING: A SCOPING REVIEW

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Background and Aims: Diabetes devices (insulin pumps, CGMs, etc) can be difficult for providers to implement, partly due to lengthy in-person training. This requirement results in suboptimal prescribing behaviors for certain populations. The COVID-19 pandemic highlighted the need for alternatives to traditional in-person device trainings. We searched the literature for alternative methods of training, evaluated user satisfaction, and compared short-term clinical outcomes to guideline-based glucometric targets and historical traditional training results.

Methods: A scoping review of Embase articles from 2019-2021 was conducted following PRISMA-SCR guidelines using keywords relevant to diabetes technologies. Original, full-text articles investigating training of new users on devices were included. Titles and abstracts were screened for eligibility by 2 independent reviewers and results were summarized.

Results: From 25 articles retrieved from the database, 11 met the criteria and were full text. Alternative strategies included structured virtual curricula, phone calls, electronic messaging, mobile apps, videoconferencing, handouts, and hybrids with traditional trainings. Overall, there was a high degree of user satisfaction with virtual visits, with a preference for hybrid approaches (n = 6 articles). Although glucometrics varied between articles, short-term glucometrics were satisfactory overall (n = 8 articles), including improved HbA1c measurements and time in range (TIR). Two articles compared TIR over various timepoints after traditional and remote training. One found equivalency and the other identified 5% improvement with remote training.

Conclusions: Alternative training approaches are a viable option to improve the inequity in device prescribing and to alleviate training burden. Intentional implementation of alternatives should be considered as a solution to address current barriers.

EP295 / #362

Topic: ***AS15 Human factor in the use of diabetes technology***

DATA-DRIVEN PERSONALISED NUTRITIONAL ADVICE FOR HEALTHIER EATING HABITS: MOTIVATION BY VISUALISATION AND HEALTH IMPACT

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Background and Aims: With increasing prevalence of type 2 diabetes (T2DM), it becomes more important to adopt and stick to a healthy diet. Existing dietary methods have limited effect: 1) research has shown large interindividual differences in physiological response to the same meal, and 2) individuals find it difficult to adopt long-term lifestyle changes. By data-driven personalised nutritional advice we aim to give individuals insights in how their body responds to food and trigger the onset of sustainable healthy behaviour.

Methods: We performed a study with 217 people with type 2 (pre)diabetes. During two weeks, participants collected real-time glucose data with a flash glucose monitor, while logging all their food (on macronutrient level) in our digital food diary app. Both data sets were analysed by a proprietary algorithm, and response to each meal was represented in-app with a food score from 1 (poor) to 100 (good). In addition, nudging, automated tips and in-app coaching by dieticians empowered participants to adjust their meals. Perceived well-being and disease control were assessed in surveys at 2 and 12 weeks; health impact (improved glucose and food scores) was calculated.

Results: 88.2/90.0% of participants report more awareness, and 79.6/88.9% report better disease control at 2 and 12 weeks, respectively. Almost 60% of participants with T2DM showed a significantly lowered daily mean glucose after 12 weeks, and of participants using medication 25.4% reported to have lowered it.

Conclusions: These data indicate that 'motivation by visualisation' combined with personalised, actionable nutritional advice provides a powerful mechanism to support self-directed care and revert T2DM.

EP296 / #639

Topic: ***AS15 Human factor in the use of diabetes technology***

IMPACT OF EXTERNALLY WORN DIABETES TECHNOLOGY ON SEXUAL ACTIVITY FOR PATIENTS WITH TYPE 1 DIABETES AND THEIR PARTNERS

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Background and Aims: Externally worn diabetes technologies are wide used, but very little is known about impact of these

devices on sexual activity for both patients with type 1 diabetes (T1D) and their partners.

Methods: In a monocentric study, people with T1D and their possible partners were invited to complete an online anonymous survey.

Results: Of 101 patients, responded 71 in group with T1D and 46 partners. In patient group, mean age 43 years-old, 55% male, mean age at diabetes diagnosis 18 years-old, 84.5% had a stable sexual partner while 11.3% had occasional partners; 55% used both insulin-pump and CGM o FGM, 44% only glucose monitoring devices and 1% any device. Only 60% were confortable wearing devices, 40% reported issues about showing them in public, judgment of other and fair of detachment. 76% of patients reported no interferences of devices during sexual activity, 10% sometimes and 14% significant interferences. 90% of pump users disconnected them during sexual activity. 25% reported some concern about sexual activity before starting to use diabetes devices, but 93% reported a reduction of these feelings time after time. 12% believed devices were a problem for partner, however only 8.7% of partners reported this feeling. 40% of partner had fear of device's detachment and 26% fear of hypoglycemia during sexual activity, but use of GCM reduced fear of hypos in these moment for 37% of partners.

Conclusions: Externally worn diabetes devices have different impacts on sexual activity in T1D patients and their partners. Deeper education on this theme is needed

EP297 / #784

Topic: ***AS15 Human factor in the use of diabetes technology***

SEX DIFFERENCES IN SELF-REGULATION CONTRIBUTE TO TREATMENT COMPLIANCE IN ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: Adolescents with strong self-regulation (the ability to manage thoughts, emotions, and behaviors), manage their type 1 diabetes (T1D) more effectively than those with weak self-regulation. We explored whether there are sex differences in association to compliance to treatment among adolescents with T1D.

Methods: 110 adolescents (48 boys) aged 12-19 years were recruited at a tertiary diabetes center (4/2021-5/2022). Sociodemographic and clinical data were extracted from medical files. Psychosocial outcome measures were retrieved from self-reported validated translated questionnaires: Self-Care Inventory (SCI), Attachment Styles Assessment, Illness Perceptions Questionnaire Revised, Multidimensional Coping Inventory and Scale of Perceived Social Support.

Results: The participants' mean age at assessment was 16.5 ± 2.4 years, with a mean diabetes duration of 7.6 ± 4.2 years. Sociodemographic and diabetes-related characteristics were similar among the boys and girls. The mean glycated hemoglobin level was $7.6 \pm 1.6\%$, 62.8% used insulin pumps and 89% used sensors. The SCI-determined mean self-reported compliance level was relatively high (3.5 ± 0.6; maximum score 5) and significantly superior among boys ($p < 0.05$), while girls had significantly higher negative illness perception levels ($p < 0.01$). A stepwise linear regression model revealed psychosocial variables which contributed to better compliance to treatment [$F(8,85) = 4.46$, $p < 0.001$, $R^2 = 0.30$]: male sex, older age, lower negative illness perception, greater use of problem-focused coping strategies, fewer emotion-focused coping strategies and perception of better social support.

Conclusions: Sex differences exist in illness perceptions and coping strategies among adolescents with T1D. Interventions based upon a self-regulation model may promote optimal compliance in adolescents experiencing challenges with managing T1D, especially girls.

EP298 / #557

Topic: ***AS15 Human factor in the use of diabetes technology***

AWARENESS OF CGM AND BARRIERS TO USE AMONG PEOPLE WITH DIABETES IN 6 EUROPEAN COUNTRIES

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Background and Aims: Continuous glucose monitors (CGM) are increasingly becoming the standard of care for people with diabetes (PWD) and are associated with reductions in glycemic variability and HbA1c. Despite these benefits, CGMs remain underutilized. Thus, the present study aims to assess current awareness of CGM and barriers to use among non-users in Europe.

Methods: From April-May 2022, 3,536 PWD in France, Germany, Italy, Netherlands, Sweden, and UK took an online survey in which they indicated their CGM use. Non-users were asked about their awareness of CGM (n = 892). Those aware were asked about their reasons for non-use (n = 508). The subsequent responses (86% T2, 59% male) were analyzed.

Results: While one third of all non-users ''don't know much'' about CGMs (33%), T2 non-users have significantly lower awareness of CGMs than T1s (65% vs. 80%, p = 0.001). When asked about reasons for non-use, the majority of T1 non-users (52%) ''do not want something attached to their body,'' while the greatest proportion of T2s (31%) report that their doctor does not recommend a CGM. Variation was also observed across geographies. Non-users in France had the lowest awareness of CGM (55%), while Netherlands had the highest (80%). 45% of non-users in the UK report that CGMs are ''too expensive,'' whereas only 13% of non-users in France share that sentiment.

Conclusions: This research highlights discrepancies in CGM awareness and barriers to use across diabetes type and country. To boost CGM awareness and uptake, patient and provider education on the benefits of CGM for T2s and initiatives targeting country-specific barriers are needed.

EP299 / #566

Topic: ***AS15 Human factor in the use of diabetes technology***

AWARENESS OF INSULIN PUMP THERAPY AND BARRIERS TO USE VARY BY DEMOGRAPHIC GROUP AMONG PEOPLE WITH DIABETES IN EUROPE

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Background and Aims: Insulin pump therapy is associated with improved glycemic management compared to multiple daily injections (MDI). Despite these benefits, pump use varies across geographies. The present study aims to investigate awareness of pump therapy among non-users and reasons for non-use among MDIs in Europe.

Methods: From April-May 2022, 3,536 people with diabetes in France, Germany, Italy, Netherlands, Sweden, and UK took an online survey indicating their use of rapid-acting insulin and method of delivery. Respondents on MDI were asked about their awareness of pump therapy (n = 904). Those aware of pumps were asked about their reasons for non-use (n = 497). The subsequent responses (82% T1, 53% male) were analyzed.

Results: Type 2 MDIs had lower awareness of insulin pumps compared to T1s (69% vs. 88%, $p < 0.001$). Awareness also varied by educational status; non-college-educated MDIs were more likely than those with a bachelor's degree or higher to be unaware of insulin pumps (19% vs. 8%, $p < 0.001$). Among those aware of pump therapy, top reasons for non-use included not wanting anything attached to their body (63%), familiarity with injections (36%), and feeling more in control with injections (30%). Reasons for non-use varied across demographic groups; respondents ages 18-44 were more likely to be open to trying a pump than respondents 65+ (21% vs. 11%, $p = 0.034$).

Conclusions: Certain demographic groups have lower awareness of and greater barriers to pump therapy than others. To boost awareness and overcome barriers to use, patient education initiatives directed at key demographic groups, including T2s, non-college-educated PWDs, and PWD 65+, are needed.

EP300 / #364

Topic: ***AS15 Human factor in the use of diabetes technology***

PARTICIPANT EXPERIENCES OF OPEN SOURCE AUTOMATED INSULIN DELIVERY DURING THE CREATE STUDY: A 24-WEEK RANDOMISED CONTROLLED TRIAL

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Background and Aims: Psycho-social data on open-source automated insulin delivery (AID) has limited generalisability due to reporting in self-selected populations. This sub-study investigated participants' experiences in the CREATE study, a multi-site randomised controlled trial of an open-source AID algorithm

Methods: The CREATE study compared an open-source AID system (Android phone app, CGM and a Bluetooth enabled insulin pump) to sensor-augmented pump therapy. Study participants completed age appropriate psycho-social surveys (HFS-II, DTSQs, EQ-5D) at the beginning and end of the 24-week trial. Survey data were summarised by treatment group, and differences estimated using analysis of covariance. Furthermore, a representative sample of adults, children, and parents of children from the intervention group were selected for in-depth, semi-structured interviews. Interviews were recorded and transcribed. Thematic analysis was undertaken using NVivo.

Results: Ninety seven participants completed surveys. Survey data are presented in table 1. Treatment satisfaction improved for children. Most other scales favoured AID but differences were not statistically significant. Eight adults (4f, mean age 41.6), 6 children (2f, mean age 10.1y) and 8 parents (5f) participated in interviews. All interview participants reported improved quality of life and glycaemic control, reduced diabetes burden and, for parents, improved family dynamics. Most participants found the phone-based system convenient; technical problems were manageable with support; and, the system fitted with their lifestyle needs.

Table 1. Psycho-social survey data.

		Baseline		Study end			
Outcome	Age	Control	AID	Control	AID	AID- Control	P value
DTSQ - Total	7 to 17 yrs	28, 79.5 (12.0)	22, 81.4 (10.0)	27, 78.0 (10.2)	21, 85.9 (9.5)	6.1 (0.4, 11.7)	0.036
	18+ yrs	25, 76.7 (15.5)	22, 80.2 (10.9)	25, 80.0 (15.5)	21, 87.3 (13.6)	6.2 (-1.9, 14.2)	0.131
EQ5D - Health	8 to 15 yrs	24, 86.5 (11.3)	21, 85.3 (12.5)	23, 79.1 (17.4)	20, 85.2 (8.1)	6.1 (-3.0, 15.1)	0.184
	16+ yrs	26, 74.4 (17.5)	23, 70.4 (18.5)	26, 78.3 (12.8)	22, 77.9 (15.2)	1.0 (-6.8, 8.8)	0.797
HFS- Behaviour	7 to 17 yrs	28, 51.9 (14.7)	22, 53.9 (13.3)	27, 49.1 (16.4)	21, 53.9 (13.6)	3.4 (-4.3, 11.0)	0.376
	18+ yrs	25, 32.6 (16.7)	22, 32.0 (17.2)	25, 30.4 (13.5)	21, 30.5 (17.7)	-0.4 (-8.8, 8.0)	0.921
HFS - Worry	7 to 17 yrs	28, 25.2 (15.3)	22, 26.7 (15.1)	27, 29.0 (17.0)	21, 24.9 (15.1)	-5.2 (-13.6, 3.2)	0.219
	18+ yrs	25, 21.6 (21.4)	22, 31.4 (23.4)	25, 23.4 (19.7)	21, 20.0 (18.9)	-8.3 (-18.1, 1.5)	0.096

Note: Results presented as number of respondents, raw mean (SD) and mean difference (95% CI). Mean differences were estimated using linear regression with adjustment for baseline values of the dependent variable and stratification factors (site, HbA1c). Participants with missing data have been excluded from this analysis. The PSQI was only collected on adults and children aged 13+.

Conclusions: Survey data may be impacted by low numbers and reflect that the control group had access to technology that is not funded in NZ. Qualitative results suggest use of open-source AID improves quality of life and reduces treatment burden.

EP301 / #479

Topic: ***AS15 Human factor in the use of diabetes technology***

ASSESSING BARRIERS AND ADHERENCE TO INSULIN INJECTION TECHNIQUE IN PEOPLE WITH DIABETES: DEVELOPMENT AND VALIDATION OF NEW ASSESSMENT TOOLS

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Background and Aims: Barriers to insulin injections can lead to an incorrect technique and problems with injections, potentially leading to lipohyperthrophy and unexpected insulin actions. Thus, we developed two scales to assess barriers and adherence regarding the correct injection technique.

Methods: 39 items were created to assess barriers to insulin injections (Insulin Injection Technique Barriers – IIT-B). 9 items were created regarding the correct injection technique (Insulin Injection Technique Adherence – IIT-A). To evaluate the validity, participants completed the two newly created scales as well as other questionnaires. Exploratory factor analysis, correlational analysis and receiver operating characteristics curves were used to evaluate validity.

Results: Data from 313 people with type 1 and type 2 diabetes using an insulin pen for insulin injections were analyzed. For the barriers scale, nine items were selected achieving a reliability of 0.74. Factor analysis revealed three factors named emotional, cognitive and behavioral barriers, respectively. The 9 items assessing adherence achieved a reliability of 0.78. Both scales showed significant associations with diabetes self-management, diabetes distress, diabetes acceptance, and diabetes empowerment (all $p < .05$). Both scales differentiated between people with vs. without current skin irritations at an injection site and ROC analysis showed significant area under the curves for both scales regarding classification of people with skin irritations.

Conclusions: Reliability and validity of the two scales assessing barriers and adherence to insulin injection technique was demonstrated. They can be used to identify persons in need of education in insulin injection technique, allowing a personalized addressing of their barriers by health-care providers.

EP302 / #528

Topic: ***AS15 Human factor in the use of diabetes technology***

IMPLEMENTING THE TRANSITION FROM SMBG TO RTCGM IN ADULT PATIENTS WITH T1DM

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Background and Aims: The use of technology has demonstrated benefits for patients with Type 1 Diabetes Mellitus. However, there is a great variability in the response of adult patients to the initiation of a new therapeutic method. The present study aimed to quantify the evolution of the glycemic control and the transition to CGM based management in adult patients with T1DM.

Methods: The study included 71 patients from a tertiary center, newly initiated on rtCGM, mean age 39.5 ± 10.5 years, 70% women, mean diabetes duration 18 ± 10 years. Patients were specifically trained for using the device and then followed up for 6 months. Data on treatment performance and adherence were gathered and statistically analyzed.

Results: Looking into glycemic control there was a 0.3% decrease in HbA1c at 6 months. Patients using CSII reached a lower HbA1c than those on MDI (6.58% vs 7.5%). Data on HbA1c statistically correlated with TIR. TIR increased up to 75% in patients with CSII and 61% in those with MDI. TBR (70mg/dl) reached a similar 4% at 6 months in both groups showing significant benefit. We found no statistically significant correlation between age or diabetes duration and parameters of glycemic control. Patients that followed all the initiation algorithm steps had significantly better results.

Conclusions: The use of rtCGM and CSII can be helpful in reaching the targeted glycemic control in adult patients with T1DM. Patients well trained and aware of technology-based treatment obtain better results when initiated on CGM.

EP303 / #672

Topic: ***AS15 Human factor in the use of diabetes technology***

EXTREME SPORT WITH HYBRID CLOSED LOOP - SAFE COMPLETION OF 72KM AND 3900M ASCENT (111KM-EFFORT) ULTRA-TRAIL, WITH 89% TIME IN RANGE AND NO HYPOGLYCEMIA

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Background and Aims: Physical activity management remains one of the major challenges for Hybrid Closed Loop systems (HCL). HCL use during very high intensity prolonged physical activity or competition has not been described. The aim was to present the performance of an athlete with type 1 diabetes(T1DM) during participation in a 111km-effort ultra-trail with HCL.

Methods: A 58-year-old male athlete living with T1DM, participated on October 22, 2021, in a 100K semi-supported ultra-trail race of 72km and 3,900m ascent on Réunion Island. HCL system (Medtronic, Minimed 780G and Guardian Sensor 3) had been introduced in January 2021. Blood glucose (BG) target was set at 100mg/dl, the active insulin time (AIT) was of 2 hours. Temporary target (150 mg/dl) was set 30min before and stopped 30min after race. BG levels in the capillary blood were controlled at 10, 38 and 72km. Time in (TIR), below and above range; insulin delivery, the intake of carbohydrates and fluids were monitored. Medical support was similar to other participants of the race, however a referent diabetologist was on call during the race.

Results: TIR was 89% the day of the competition and 100% the day after (100% automatic mode, 100% time with sensor). There was no hypoglycemia and two episodes of moderate hyperglycemia during the race. The athlete consumed 350g CHO (17g/h) which were not declared to the algorithm and 7liters of drinks. HCL administrated 7.4U/day of insulin vs 15.1U/day the day before.

Conclusions: Safe completion of an ultra-trail is possible with HCL and requires an appropriate physical and educational preparation.

EP304 / #146

Topic: ***AS15 Human factor in the use of diabetes technology***

THE USE OF DIABETES TECHNOLOGY IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES IN GERMANY IN REGARD TO IMMIGRANT GENERATIONAL STATUS AND COUNTRY OF ORIGIN

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Background and Aims: Aim was to investigate whether the use of diabetes technology in youth with type 1 diabetes differed depending on migration background and immigrant generational status.

Methods: We analyzed the use of insulin pumps and continuous glucose monitoring (CGM) of 40,635 individuals (age <21 years) with type 1 diabetes between 2018 and 2021 from the German-Prospective-Diabetes-Registry (DPV). Using multiple logistic regressions, we evaluated the impact of immigrant generational status on technology use, and whether it differed by country of origin or by regional deprivation (measured by German-Index-of-Multiple-Deprivation).

Results: The use of insulin pumps was higher in individuals without migration background compared to those with one parent, both parents or both parents and child born abroad (61% vs 56%, 54% and 44%, respectively, $p<0.001$). Differences in CGM use were smaller, with the lowest use of CGM in first-generation immigrants compared to all other youths (64% vs 72-74%, $p<0.001$). The economic development of the country of origin had the greatest impact on the use of insulin pump for first-generation immigrants (countries with gross-domestic-product per capita ≥40,000 USD vs <10,000 USD: 55% vs 36%, $p<0.001$). The effect of deprivation was weaker and only significant in individuals without migration background.

Conclusions: The immigrant generational status has a major impact on CGM use and most notably on insulin pump use in youth with type 1 diabetes in Germany. Acknowledgments: Supported by the program for female researchers from the Office for Gender Equality, University of Ulm, Germany (student research assistant: Katharina Strehle, Grant-Number: 027/162/P/Med).

EP305 / #360

Topic: ***AS15 Human factor in the use of diabetes technology***

IMPROVEMENTS IN DIABETES-RELATED QUALITY OF LIFE (DRQL) AND EMOTIONAL DISTRESS WITH HYBRID CLOSED LOOP (HCL) TECHNOLOGY IN MARGINALIZED FAMAILIES WITH SUBOPTIMALLY CONTROLLED TYPE 1 DIABETES

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Background and Aims: Prior HCL studies enrolling participants with well-controlled type 1 diabetes (T1D) and limited financial, racial-ethnic, and socioeconomic diversity have shown limited success in improving patient-reported outcomes (PROs). We evaluated changes in DRQL and emotional distress among marginalized youth with T1D and their parents after three months of Tandem t:slim X2 insulin pump with Control-IQ technology use.

Methods: This ongoing, non-randomized 6-month pilot study enrolled publicly-insured, non-Hispanic Black (NHB) youth with T1D who had sustained hemoglobin A1c (A1c) ≥10%. Youth and parent DRQL and emotional distress, as assessed using T1D and Life (T1DAL) and Problem Areas in Diabetes (PAID) surveys, were compared at baseline and 3-months using paired t-tests or Wilcoxon signed-rank tests. Correlations assessed relationships between changes in glycemia and PROs.

Results: Fourteen subjects (M_{age} 14.6 ± 3.7 years, $M_{T1Ddurationtion}$ 6.0 ± 3.5 years, M_{A1c} 11.8±1.9%) completed the 3-month study period. M_{A1c} decreased by 2.5 ± 1.1% ($p<0.001$). TIDAL-defined DRQL increased among parents and youth (Table 1) (parent-T1DAL +9.3, $p=0.01$, child-T1DAL +6.3, $p=0.03$). PAID scores decreased among parents and youth, reflecting decreased diabetes-related distress (parent-PAID -15.0, $p=0.02$, child-PAID -7.2, $p=0.03$). No correlations were found among changes in A1c, parent-PROs, and child-PAID. However, improvements in A1c were strongly correlated with improvements in child-T1DAL ($r=0.7$, $p=0.01$).

Table 1: Youth and Parent Questionnaires

Survey Measure	Baseline score (n)	3-month score (n)	Change	p-value
Parent PAID	70 (64,77.5)* (13)	55 (40,72)* (11)	-15.0	**0.02**
Parent T1DAL	61.6 ± 8.8 (12)	70.9 ± 11.6 (12)	+9.3	**0.01**
Child PAID	41.8 ± 11.5 (13)	34.5 ± 11.7 (13)	-7.2	**0.03**
Child T1DAL	58.7 (57.2,67.7)* (13)	65.0 (58.2,71.3)* (13)	+6.3	**0.03**

Normally distributed data are reported as mean±SD. Non-normally distributed data are reported as median and IQR*.

Conclusions: Three-months of Tandem t:slim X2 insulin pump with Control-IQ technology therapy improved A1c, DRQL, and diabetes-related distress among marginalized youth with T1D and their parents. Including diverse populations in T1D research and supporting equal access to HCL technology for all people with T1D may help to demonstrate additional, previously unrecognized benefits to diabetes technology use.

EP306 / #876

Topic: ***AS15 Human factor in the use of diabetes technology***

DISPARITIES IN BENEFITS OF CONTINUOUS GLUCOSE MONITOR USE BETWEEN RACIAL-ETHNIC GROUPS WITH TYPE 1 DIABETES AT AN ACADEMIC MEDICAL CENTER

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Background and Aims: Continuous glucose monitors (CGMs) have demonstrated the ability to improve glycemic control, but different racial-ethnic groups with type 1 diabetes (T1D) do not access and use CGMs at equal rates. Specifically, non-Hispanic Black (NHB) individuals often do not initiate nor continue CGM use at the same rates as non-Hispanic White (NHW) individuals. The goal of this analysis was to retrospectively examine whether CGM use/initiation is associated with an equal difference in glycemic control (approximated for via HbA1c value) between users and non-users across racial-ethnic groups.

Methods: Using de-identified clinical data (TriNetX, LLC) from an academic medical center, we determined the difference in glycemic control (HbA1c) between CGM users vs non-users within each of three racial-ethnic groups (NHW, NHB, and Hispanic). These differences were compared using an unpaired, two-sided T-test within each group, then group improvements were compared between the three racial-ethnic groups.

Results: Compared to CGM non-users, CGM users had lower mean HbA1c values across comparisons within each racial-ethnic group, but the mean differences were only significant for the comparison within the NHW group ($p < 0.0001$) (see Table 1).

Conclusions: The insignificant difference in HbA1c values among CGM users vs non-users within the NHB and Hispanic groups likely speak to a variety of factors, including potential discontinuation rates, shorter length of time using CGMs, and the minimal statistical power of this analysis. However, it is clear that, at this medical center, NHB and Hispanic individuals with T1D are not accessing, using, and benefiting from CGMs at the same rates as NHW individuals.

EP307 / #690

Topic: ***AS15 Human factor in the use of diabetes technology***

RACIAL-ETHNIC INEQUITIES IN USE OF CONTINUOUS GLUCOSE MONITORS (CGMS) AMONG PATIENTS WITH TYPE 1 DIABETES (T1D) AT AN ACADEMIC MEDICAL CENTER

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Background and Aims: Numerous studies have evaluated the cost-effectiveness of CGMs and demonstrated the advantages of CGM use, but recent studies demonstrate that pediatric minoritized racial-ethnic groups, specifically non-Hispanic Black (NHB) and Hispanic patients, with type 1 diabetes (T1D) do not use CGMs at comparable rates to non-Hispanic White (NHW) individuals with T1D. The goal of this analysis was to determine the extent of racial-ethnic disparities in CGM use initiation in both adults and children at an academic medical center.

Methods: A retrospective analysis using de-identified clinical data from electronic medical records (TriNetX, LLC) for individuals with T1D without limits of age. Usage percentage rates were then compared to identify potential racial-ethnic disparities.

Results: Of the total 1,930 patients with T1D seen at this center, 24.9% were current or previous CGM users. CGM usage initiation rates among each racial-ethnic group were as follows: 25.6% among non-Hispanic White, 17.6% among NHB, 28.6% among Hispanic, and 23.1% among other racial-ethnic groups (see Table 1).

Table 1. Previous and Current CGM Use Among Different Racial-Ethnic Groups with T1D

Race/ethnicity	Frequency (n)	Population Percent (%)	Age (mean ± SD)	CGM-Use Percent (%)
Non-Hispanic White	1,560	80.8	38 ± 20	25.6
Non-Hispanic Black	170	8.8	39 ± 22	17.6
Hispanic	70	3.6	30 ± 17	28.6
Other	130	6.7	36 ± 17	23.1
Total	1,930	100	38 ± 20	24.9

Conclusions: NHB individuals with T1D initiated CGM use at a lower rate when compared to all other racial-ethnic groups. Hispanic individuals in this analysis had a lower mean age, which may have contributed to their higher CGM usage rate. These findings parallel the results of studies on CGM use in pediatric populations with T1D, but highlight the prominent disparity in technology use among the NHB population. Systemic racism, medical mistrust, and health care provider bias are likely to be contributing to this racial-ethnic CGM usage gap across both adult and pediatric patients.

EP308 / #745

Topic: ***AS15 Human factor in the use of diabetes technology***

CURRENT AND FUTURE IMPORTANCE AND USE OF SMART INSULIN PENS

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Background and Aims: More and more smart insulin pens (SIPs) are coming to market with real-time wireless connectivity, digital dose capture, and integration of personalized dosing decision support. We asked physicians in Germany about their views on the current and future importance and use of SIPs.

Methods: 305 diabetologists (48% female, average age 53.7 years) were asked via online survey how important they think smart pens are currently and in 5 year (5-point response scale from ''not at all significant'' to ''very significant'') and how many of their patients use them.

Results: Diabetologists consider smart pens not yet very significant (15.5%) and expect only a medium importance in the future (37.9%).They currently report a very low use of smart pens of their patients (5,3%) and estimate that growth in the next 5 years will be as rather moderate (23.9% in 5 years).

Conclusions: So far, diabetologists in Germany have rated the importance of smart pens as rather moderate, both now and in the future. This is surprising in view of the digital possibilities such as the review of insulin dose data, particularly when paired with glucose data. Nevertheless, they estimate that in 5 years about one in four people with diabetes will use a smart pen.

EP309 / #669

Topic: ***AS15 Human factor in the use of diabetes technology***

CHANGES IN QUALITY OF LIFE, MEASURED WITH A SPECIFIC QUESTIONNAIRE FOR PATIENTS WITH TYPE 1 DIABETES, AFTER CHANGING TO A HYBRID CLOSED-LOOP SYSTEM

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Background and Aims: Hybrid closed loop systems (HCL) are known to ameliorate glycemic control. Less is known about their impact on quality of life (QoL). We wanted to know changes in QoL in our patients who switched to HCL.

Methods: All patients starting a HCL system were included. Glucose-control data were collected from the specific web platforms. QoL was measured using a specific questionnaire validated for type 1 diabetes in the Spanish population: ViDa1. All data were collected basal and at 6 months of follow-up.

Results: We included 85 adult patients, 60 women. Thirty-eight patients were previously using an insulin pump. Mean diabetes duration was 15.3 ± 8.4 years. Thirty-eight patients have reached 6 months with HCL, 7 have dropped out of the study. In december 2022 all the patients will have reached 6 months of follow-up. A significant improvement in glucose control was observed in every parameter of the ambulatory glucose profile, except for time under 54 mg/dl (data not shown). We observed a positive change in three of the four dimensions of the ViDa1 questionnaire, although they did not reach statistical significance (table 1). Table 1.

ViDa 1 dimensions	Baseline	6 months	p
Interference of diabetes in everyday life	25.5	24	0.532
Self-care	42	44	0.170
Well-being	21	21	0.293
Worry about the disease	17	15.5	0.579

Conclusions: Despite an improvement in glucose control we have not detected an satitistical improvement in QoL, albeit a positive change was observed.

EP310 / #117

Topic: ***AS15 Human factor in the use of diabetes technology***

ROLE OF A "TECHNOLOGY NAVIGATOR" IN AN ACADEMIC DIABETES CLINIC

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Background and Aims: Data generated by diabetes devices play an increasingly important role in the contemporary medical management of diabetes. However, acquiring patient-generated device data can be a challenge for clinics already overburdened by administrative work. This project aimed to understand whether implementing a dedicated ''Technology Navigator'' (TN) personnel might facilitate access to device data without increasing the burden of care for clinic staff.

Methods: The University of Washington Diabetes Institute (UWMDI) implemented a TN to support patients with pre-visit data uploads. The impact of this position was evaluated using mixed methods including a time analysis of medical assistant (MA) labor extrapolated from a sample of 170 face-to-face visits in 2021 and 2022, and an analysis of clinic continuous glucose monitoring (CGM) billing claims.

Results: Pre-visit uploads can save up to 700 hours in MA time annually (n = 13,000 visits). One year following the implementation of the TN in 2021, the percentage of pre-visit home uploads at UWMDI increased from 19% to 41%. Though the financial analysis in labor costs remained neutral, UWMDI increased the billing claim for CGM interpretation by 75% (2020 vs 2022).

Conclusions: Incorporating a TN into the clinical workflow may increase billable time and decrease the time spent on non-billable and often disruptive activities such as in-clinic uploads while providing additional technology support to patients. In an environment where visits frequently switch between telemedicine and face-to-face, supporting pre-visit uploads also facilitates seamless care across modalities.

EP311 / #65

Topic: ***AS15 Human factor in the use of diabetes technology***

AGE AS AN INFLUENCE FACTOR ON CGM SYSTEM USE IN A TYPE 1 DIABETIC PATIENT

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Background and Aims: With regard to continuous glucose monitoring (CGM) system use in Germany, the aim was to investigate whether the age of a type 1 diabetic can be regarded as a significant acceptance factor of a CGM system. Therefore, we investigated whether age has an influence on CGM system use and the choice of a particular system.

Methods: A quantitative survey was conducted in which a total of 2,102 patients were interviewed via an online questionnaire, of which 1,642 patients (type 1 diabetics) responded completely. A cross table was first generated to represent the usage and the choice of a particular system (absolute and relative frequencies) under study. A chi-square test was used to prove statistical significance. Additionally, a layered bar chart was created to compare different age groups with different CGM systems (relative frequencies).

Results: Age has non influence on whether to use a CGM system, but which system to use if one is used.

Conclusions: Age counts as an acceptance factor regarding the choice of a particular CGM system. Other acceptance factors were investigated in our study.

EP312 / #748

Topic: ***AS15 Human factor in the use of diabetes technology***

100 YEARS OF INSULIN: WHAT DO PEOPLE WITH DIABETES THINK ABOUT INSULIN, WHAT ARE THE WISHES AND HOPES FOR THE FUTURE?

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Background and Aims: To honor 100 years of insulin, we asked people with diabetes (PwD) who are on insulin therapy about their attitudes, experiences, wishes, and hopes about insulin.

Methods: N = 1338 PwD (662 MDI, 408 CSII, 161 AID, 107 basal insulin therapy; 53,1% female; average age 48,2 years; 76,1% type 1 diabetes; diabetes duration 20,4 years; HbA1c 7,2%). Insulin Treatment Satisfaction Questionnaire (ITSQ), Well-being questionnaire (WHO-5), Diabetes Distress Questionnaire (PAID-5), questions to assess current available and future insulins, insulin pens.

Results: - Significantly worse quality of life compared with German norm-sample, high level of diabetes-related distress. - High satisfaction with insulin therapy, especially with application, and implementation in everyday life. Lower satisfaction with avoidance of hypoglycemia and flexibility in everyday life. - Significant higher satisfaction with insulin for PwD who use an AID system. - Insulin therapy is viewed mostly positively by PwD who use an AID system. Users of non-intensified insulin therapy perceive the therapy to be most burdensome. - PwD would particularly like to see global availability of insulin and further development of insulin with regard to glucose-dependent control without the risk of hypoglycemia. - The most important wishes with regard to further development of insulin pens are greater accuracy of insulin delivery, easier handling and accessibility.

Conclusions: Overall, PwD are quite satisfied with the insulin available. Desires for further development of insulin differ according to the form of therapy: PwD who use AID therapy want insulin to be faster acting, while PwD using non-intensified insulin therapy want it to be longer acting.

EP313 / #108

Topic: ***AS15 Human factor in the use of diabetes technology***

FACILITATORS AND BARRIERS TO HYPOGLYCEMIA SELF-MANAGEMENT IN ADULTS LIVING WITH TYPE 1 DIABETES AND USING ADVANCED DIABETES TECHNOLOGIES

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Background and Aims: Growing evidence demonstrates that level 2 hypoglycemia (with glucose levels <54 mg/dL) and severe hypoglycemia continue to develop in people living with type 1 diabetes (T1D) despite using advanced diabetes technologies such as continuous glucose monitors (CGMs). However, sparse knowledge about barriers to hypoglycemia self-management in this population exists. This study aimed to identify facilitators and barriers to hypoglycemia self-management in adults living with T1D and using advanced diabetes technologies.

Methods: Semi-structured qualitative interviews were conducted with adults with T1D who have used advanced diabetes technologies for ≥6 months. Maximum variation sampling based on the amount of time in level 2 hypoglycemia in the past 30 days was conducted. Consensus coding and thematic analysis were conducted to inductively determine themes and subthemes related to facilitators and barriers to hypoglycemia self-management.

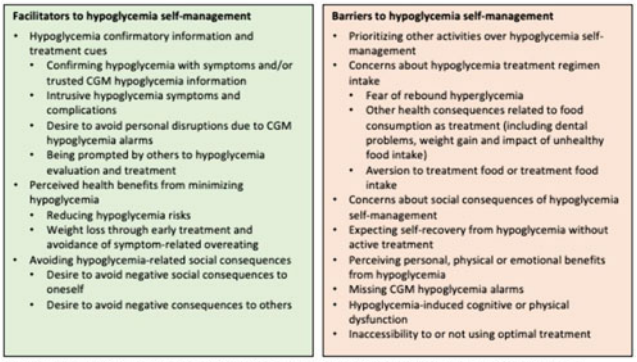

Fig. Facilitators and Barriers to Hypoglycemia Self-management in Adults with Type 1 Diabetes and Using Advanced Diabetes Technologies. CGM, continuous glucose monitor.

Results: Thirty-four respondents completed the interviews (time in level 2 hypoglycemia ranging 0-4.9%). Identified facilitators to hypoglycemia self-management (Figure) were: (1) Hypoglycemia confirmatory information and treatment cues; (2) Perceived health benefits from minimizing hypoglycemia; (3) Avoiding hypoglycemia-related social consequences. Barriers to hypoglycemia self-management included: (1) Prioritizing other activities over hypoglycemia self-management; (2) Concerns about hypoglycemia treatment regimen intake; (3) Concerns about social consequences of hypoglycemia self-management; (4) Expecting self-recovery from hypoglycemia without active treatment, and; (5) Perceiving personal, physical or emotional benefits from hypoglycemia.

Conclusions: We identified facilitators and barriers to hypoglycemia self-management in adults living with T1D and using advanced diabetes technologies. This knowledge can inform intervention development for improving hypoglycemia self-management and reducing hypoglycemia in T1D advanced diabetes technology users.

EP314 / #856

Topic: ***AS15 Human factor in the use of diabetes technology***

ASSOCIATION BETWEEN SOCIOECONOMIC STATUS, TECHNOLOGY UPTAKE AND GLYCAEMIC CONTROL IN AUSTRALIAN YOUTH WITH TYPE 1 DIABETES

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Background and Aims: Technology use, including continuous glucose monitoring (CGM) and insulin pump therapy, is associated with improved outcomes in youth with type 1 diabetes (T1D). In 2017 CGM was universally funded in Australia for youth, in contrast pump access requires private health insurance. The aim of this study was to investigate the equity of uptake of

CGM and pumps in youth with T1D in Australia. We hypothesised that technology uptake would be impacted by socioeconomic status.

Methods: A cross-sectional evaluation of 5833 youth (age <18yrs) with T1D in the national registry was performed; data included postcode, HbA1c, pump and CGM use. An Index of Relative Socio-Economic Disadvantage (IRSD) quintile was assigned; lower quintiles are associated with greater disadvantage.

Results: Greater pump use was associated with higher ISRD quintile with a near linear relationship between ISRD quintile and pump use (pump use 40.5%, 44.3%, 43.5%, 48.6%, 53.5% vs quintiles 1,2,3,4,5; $p < 0.001$). In contrast, CGM use was lower only in ISRD quintile 1 but at other quintiles was similar (CGM use 64%, 80%, 74%, 77%, 76% vs quintiles 1,2,3,4,5; $p < 0.001$). HbA1c was lower at each quintile increment (8.6 ± 0.05%, 8.3 ± 0.05%, 8.3 ± 0.05%, 8.2 ± 0.05%, 8.0 ± 0.05%, quintiles 1,2,3,4,5; $p < 0.001$).

Conclusions: A strong association between socioeconomic status and pump use was demonstrated suggesting inequitable access to pump therapy in youth with T1D in Australia. In contrast, universal CGM funding was associated with more even uptake of this technology. Universal pump funding will be required to allow the full benefits of diabetes technology to be available to all.

(*on behalf of the ADDN study group).

EP315 / #627

Topic: ***AS15 Human factor in the use of diabetes technology***

USING HEAT MAPS TO VISUALISE DIFFERENCES IN THE PREVALENCE OF HYPOGLYCAEMIA SYMPTOMS IN INSULIN-TREATED TYPE 2 DIABETES: PRELIMINARY RESULTS FROM THE HYPO-METRICS STUDY

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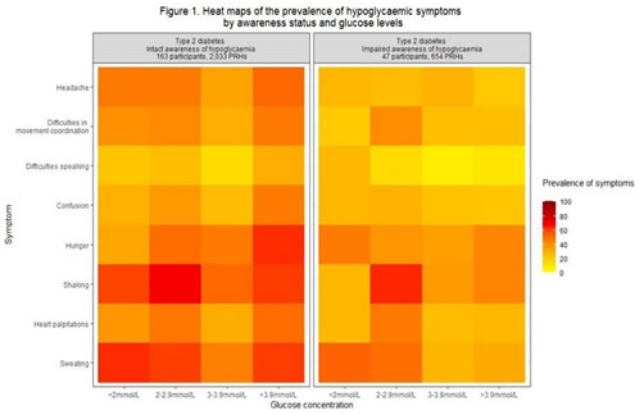
Background and Aims: Hypoglycaemia symptoms vary in intensity and frequency between and within people with diabetes, but we lack a tool to capture real-time symptoms in daily life. The Hypo-METRICS app enables reporting of hypoglycaemia symptoms, at, or shortly after, each episode. We aimed to visually examine prevalence of eight hypoglycaemia symptoms among adults with type 2 diabetes (T2D).

Methods: Over 10 weeks, at or near the time of a hypoglycaemia episode, participants could indicate in the app self-monitored glucose range (<2 mmol/L, 2-2.9mmol/L, 3-3.9mmol/L or >3.9mmol/L) and eight symptoms (e.g. sweating, heart palpitations, shaking, hunger, confusion and headache). We calculated the average symptom prevalence for each glucose range and used heat maps to generate graphical representations by hypoglycaemia awareness (Gold score: <4 vs ≥4).



Results: This preliminary analysis includes data from 210 participants with T2D (91% White, 35% women, median(IQR) age 63(56-70) years, diabetes duration 19(14-24) years, 44% using flash/continuous glucose monitoring; 22% with impaired awareness of hypoglycaemia (IAH)). 2,687 episodes of hypoglycaemia were recorded, 57% within the 3-3.9mmol/L range; for 26%, the glucose range was >3.9mmol/L. Participants reported higher prevalence of autonomic symptoms than neuroglycopenic symptoms, even above 3.9 mmol/L, with lower prevalence of symptoms at all glucose ranges in IAH (Figure 1).

Conclusions: Heat maps generated from Hypo-METRICS app data offer a clear visual representation of the prevalence of hypoglycaemia symptoms experienced during daily life. With the potential to differentiate between those with intact and IAH, heat maps provide a tool that could be implemented within clinical, research and educational settings.

EP316 / #327

Topic: ***AS15 Human factor in the use of diabetes technology***

CO-DESIGNED AND THEORY-BASED MYMANIS MOBILE APPLICATION TO PREVENT FUTURE TYPE 2 DIABETES IN WOMEN WITH GESTATIONAL DIABETES MELLITUS

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Background and Aims: Women with GDM are at risk of T2D. Mobile health interventions offer a flexible low-cost solution to providing diabetes prevention support for these women.

Methods: A cross-platform mobile application was developed according to the DoTTI (**D**esign and devel**O**pment, **T**esting early iterations, **T**esting for effectiveness, and **I**ntegration and implementation) framework, and guided by the Capability, Opportunity, Motivation and Behaviour and Behaviour Change Wheel theories. Content on needs were identified from interviews with GDM women and health care providers (HCPs), and latest evidence-based guidelines. The application underwent alpha and beta testing using the Mobile App Rating Scale and System Usability Scale.

Results: Experience, barriers and facilitators in diabetes prevention interventions were thematically analysed (16 GDM women, 30 HCPs) and incorporated into the app development. In the alpha and beta testing, most participants (14 GDM women and 12 HCPs) reported it as interesting and interactive. Six participants highlighted the need for guidance to navigate the application. Suggested improvements include: the need for more localised recipes, baby-friendly exercises, and the pre- and postnatal interfaces should be better discriminated. The application finally has GDM-related information, recipe choices with their nutritional content and preparation methods that is transcultured to local perspectives, carbohydrate exchanges that are tailored to energy requirement, information and videos on exercises, mental wellbeing, medication and health monitoring (weight, glucose and blood pressure measurements), interaction with HCPs, news page, frequently-asked-questions chatbot, and embedded motivational interviewing messages.

Conclusions: MyManis application was successfully deployed (https://rb.gy/emxrmu). It is in a feasibility RCT of its effectiveness on important health outcomes.

EP317 / #792

Topic: ***AS15 Human factor in the use of diabetes technology***

DIFFERENCES IN DIABETES TECHNOLOGY USE ONLY PARTIALLY EXPLAIN DISPARITIES IN TYPE 1 DIABETES OUTCOMES AMONG MINORITY YOUTH

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Background and Aims: Diabetes technology (DT) use is associated with lower HbA1c in type 1 diabetes (T1D). Non-Hispanic Black and Hispanic populations are more likely to have lower DT use and higher HbA1c compared to non-Hispanic White populations. We examined the extent to which differential DT use explains outcome disparities at an outpatient pediatric diabetes center in NYC.

Methods: Patients identifying as non-White, Hispanic, or non-English language preference were grouped (minority race/language; MRL) and compared to non-Hispanic White, English-preferred patients. HbA1c >9% was categorized as high. T-test and chi-square statistics compared patient characteristics by HbA1c category. Binomial regression with generalized estimating equations estimated associations (risk ratios, RR; 95% confidence intervals, CI) between MRL and high HbA1c. First, models were adjusted for insurance type and Child Opportunity Index (COI), then additionally for CGM and pump use.

Results: Patients (n = 331) aged 2-25 years with T1D ≥ 3 months attended 709 visits (mean 2.2, SD 1.2) from 2020-2021; 32% identified as MRL. At the most recent visit, 16% had HbA1c>9% (MRL 29%, non-MRL 10%), 87% used CGMs (MRL 77%, non-MRL 92%), and 78% used pumps (MRL 72%, non-MRL 81%). MRL youth were 2.5 (95% CI 1.6-4.0) times more likely to have HbA1c>9% as compared to non-MRL youth, adjusted for insurance and COI. After adjusting for DT use, MRL youth remained twice as likely to have HbA1c>9% (RR 2.0, 95% CI 1.2-3.3).

Conclusions: While the disparity in HbA1c between MRL and non-MRL youth can be partially attributed to DT use, disparity persists even after accounting for DT use.

EP318 / #843

Topic: ***AS15 Human factor in the use of diabetes technology***

DIABETES DEVICES-RELATED SKIN REACTIONS IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: A WORLDWIDE ASSESSMENT OF KNOWLEDGE AND AWARENESS OF DIABETES-CARE PROVIDERS

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Background and Aims: The aim of this study was to evaluate diabetes-care providers' knowledge on dermatological complications related to the use of diabetes technological devices.

Methods: We used an open-link web-based survey to evaluate the frequency, management practices, and knowledge related to technology use-related skin reactions.

Results: The presented preliminary results report the first 92 responses shown in Table 1. Most of the physicians (67.4%) routinely examine patients' skin at each visit. Physicians and other health-care providers are familiar with screening and diagnosis of skin reactions but seem to be less confident with

Table 1. Summary table of main findings.

Item	Responses	Frequencies (%)
Estimate prevalence of contact dermatitis in patients on insulin pump therapy (IPT) and /or continuous glucose monitoring (CGM)	<5%	13 (14.1%)
	5-20%	35 (38.0%)
	20-40%	26 (28.2%)
	40-60%	10 (9.2%)
	>60%	8 (8.7%)
Preferred prophylactic measures to prevent occurrence of contact dermatitis exacerbations	Hydrocolloid plasters	6 (6.5%)
	Protective physical skin barriers	13 (14.1%)
	Protective liquid sprays or wipes	6 (6.5%)
	Nasal steroid applied topically	4 (4.3%)
	Combination of products above	56 (60.9%)
	None of these	7 (7.6%)
Preferred therapeutic strategies to treat acute lesions of contact dermatitis	Topical corticosteroids	18 (19.6%)
	Topical steroids+ antibiotics	8 (8.7%)
	Topical antihistamines	1 (1.1%)
	Soothing/emollient creams	9 (9.8%)
	Combination of products above	51 (55.4%)
	None of these	18 (19.6%)
Awareness of any potentially harmful allergens contained in diabetes device adhesives related to the occurrence of allergic contact dermatitis	Yes	46 (50.0%)
	No	46 (50.0%)
Have you ever discussed with device manufacturers the need to receive detailed information on adhesive compounds and to reduce the amount of known harmful allergens?	Yes	38 (41.3%)
	No	54 (58.7%)
Do you observe a trend towards worsening of glycemic control in patients with contact dermatitis?	Yes	36 (39.1%)
	No	13 (14.1%)
	Not sure	43 (46.7%)
Estimate percentage of patients forced to discontinue/change brands of CGMs due to contact dermatitis	<5%	60 (65.2%)
	5-20%	26 (28.3%)
	20-40%	5 (5.4%)
	>40%	1 (1.1%)
Estimate percentage of patients forced to discontinue/change brands of pumps due to contact dermatitis	<5%	72 (78.3%)
	5-20%	16 (17.4%)
	20-40%	4 (4.3%)
	>40%	0
Do you believe that acquisition of specific knowledge and practical skills related to skin adverse reactions should be part of the mandatory training of professionals dealing with diabetes?	Yes	90 (97.8%)
	No	2 (2.2%)

preventive and therapeutic measures to protect the skin against repeated device applications. Lipohypertrophy and contact dermatitis are the most frequently reported dermatological issues. Prevalence of contact dermatitis is estimated mainly between 5 and 20%, but the most common provocative causes are not fully understood. Most physicians (58.7%) had never discussed the presence of harmful allergens contained in adhesives with device manufacturers. More than one-third of responders (39.1%) observed a worsening in glycemic measures in patients with contact dermatitis. There is general agreement on the need to strengthen knowledge on dermatological complications.

Conclusions: Although diabetes-care providers are aware of the likelihood to develop skin reactions in people with diabetes using technological devices, there is still a lack of knowledge on some aspects related to harmful allergens causing skin issues. Further dissemination tools are awaited to fill in these gaps, especially in terms of prevention and therapy.

EP319 / #847

Topic: ***AS15 Human factor in the use of diabetes technology***

UTILISING TECHNOLOGY TO SUPPORT NHS STAFF IN THE ORGANISATION AND MANAGEMENT OF SCHOOL DIABETES TRAINING DELIVERY

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Background and Aims: The University Hospitals of Leicester's Children's Diabetes Team required a more efficient and effective method for training the 536 schools in Leicestershire. The Diabetes Team identified that the management of delivering training was time-consuming and the user experience for school staff could be improved to create a more effective training method

Methods: The Children's Diabetes team consulted with HEAL. Med CIC, a not-for-profit organisation that specialises in diabetes education, to develop a new booking portal and e-learning delivery system. This allowed school staff to sign up for a convenient training date and download documents and materials provided by the Leicester Schools Authority from the HEAL.med website. E-learning training was delivered by healthcare professionals from the Children's Diabetes Team. A pilot ran from April 2022 to November 2022 to assess the impact of the method.

Results: Prior to the pilot, members of the Children's Diabetes team had to manage the administration and management of the school training, occupying 22.5 hours per week of staff members time, excluding the delivery of training. The new portal and booking system reduced this down to 0.5 hours. A reduction of 22 hours or 97.78% decrease. Over this period 678 school staff members signed up for training sessions.

Conclusions: The training platform drastically reduced the administrative time for NHS staff. Most administration for the project was redirected to HEAL.med and the Children's Research Team, accounting for 3 hours per week. Factoring in the external administration the total time taken is reduced by -84.44%.

EP320 / #63

Topic: ***AS15 Human factor in the use of diabetes technology***

GAME-SET-MATCH: SIMPLIFYING THE MOST EFFECTIVE DYNAMIC GLUCOSE MANAGEMENT STRATEGIES FOR IMPROVING TIME IN RANGE INTO A PATIENT-CREATED INFOGRAPHIC

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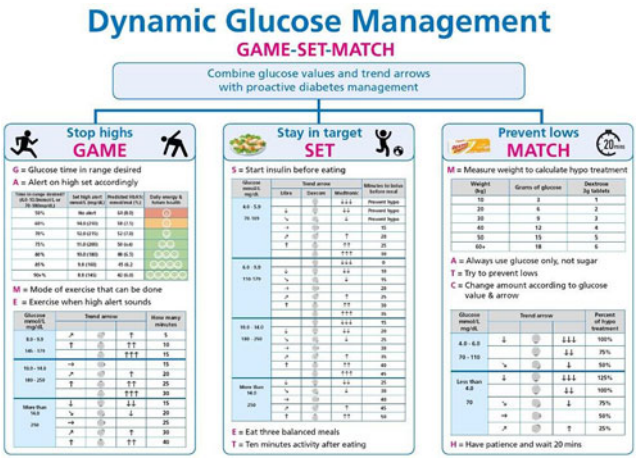
Background and Aims: Published results from the first 100 children and young people with diabetes (CYPD) graduating from the face-to-face (n = 50) and virtual teaching (n = 50) 'CGM Academy' demonstrate equivalent improvements in time in range (TIR, 3.9-10.0mmol/L) by ~9.0% ($p < .001$) and HbA1c by ~4.0mmol/mol ($p < .001$) at six months. Increasing use of dynamic glucose management (dynamic GM), proactive decisions based on glucose value and trend arrow (G&T), was the strongest predictor of TIR ($p < .001$). However, CYPD reported information overload. Aim: to determine the most effective dynamic GM strategies and co-create an infographic to streamline their teaching.

Methods: Step 1) The first 100 graduates completed a questionnaire at six months documenting their use of the seven dynamic GM strategies:(1) Prevent hypos using G&T (2) Trend Arrow Adjustment Tool (TATT), (3) Bolus timing pre-meal dependent on G&T (4) Exercise checks and carbs using G&T (5) Regular CGM report review (6) Short bursts of exercise based on G&T to lower hyperglycaemia and (7) Insulin corrections. Step 2) Factors predicting TIR were identified after



adjusting for variables, using multiple linear regression. Step 3) an infographic was co-created with CYPD using the strongest predictors of TIR.

Results: The strongest predictors for TIR: Short bursts of exercise ($\beta = 3.261$, $p < 0.001$), Bolus timing ($\beta = 2.651$, $p = 0.006$), and Prevent hypos ($\beta = 2.52$, $p = 0.015$), and these were condensed into a GAME (Stop highs)-SET (stay in target)-MATCH (Prevent lows).

Conclusions: GAME-SET-MATCH streamlines the most effective dynamic GM strategies into a teaching infographic to prevent CYPD overwhelm. Evaluation is required to assess if the GAME-SET-MATCH strategies are effective for CYPD using automated insulin delivery systems.

EP321 / #617

Topic: ***AS15 Human factor in the use of diabetes technology***

PSYCHOLOGICAL FACTORS AND TELEMEDICINE IN WOMEN WITH GESTATIONAL DIABETES

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Background and Aims: Telemedicine can improve glycemic and perinatal outcomes in women with gestational diabetes mellitus (GDM), however, it is not known for which individuals telemedicine tools are the most suitable. We aimed to assess the association of some psychological factors with glycemic parameters in women with GDM followed by telemedicine tools.

Methods: Personality traits and diabetes empowerment in association with glycemic control were assessed. Participating women completed The Big Five Inventory BFI and The Diabetes Empowerment Scale DES. Self-Monitoring Blood Glucose data were obtained from glucose meters for the third trimester of pregnancy. Associations were calculated using Spearman ρ correlation coefficient.

Results: The study included 50 women (age 32.0 ± 4.3) with GDM followed by telemedicine. From personality traits, agreeableness (Spearman $\rho = 0.422$, $p = 0.003$) and conscientiousness (Spearman $\rho = 0.346$, $p = 0.016$) were positively associated with glucose measurement realization. Surprisingly, positive association was found between postprandial glucose concentration and total score of Diabetes Empowerment Scale (Spearman $\rho = 0.324$, $p = 0.030$) and two subscales: Managing the psychological aspects of diabetes (Spearman $\rho = 0.326$, $p = 0.029$) and Assessing dissatisfaction and readiness to change (Spearman $\rho = 0.363$, $p = 0.014$).

Conclusions: Our results represent a step toward identifying psychological characteristics of women with GDM that may be important in predicting who will benefit more from the telemedicine treatment. Results indicate significant associations of agreeableness and conscientiousness with glucose measurement realization; however, associations between diabetes empowerment and average postprandial glucose concentration are surprisingly positive. More research, also on others psychological constructs, is needed.

EP322 / #145

Topic: ***AS15 Human factor in the use of diabetes technology***

INCREASED TREATMENT SATISFACTION WITH CGM IN PEOPLE WITH T1D IN THE GOLD TRIAL IS MAINLY DUE TO PERCEIVED IMPROVEMENTS IN CONVENIENCE AND FLEXIBILITY

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Background and Aims: The GOLD trial demonstrated that CGM in people with T1D on multiple daily injections (MDI) not only improved glucose control but overall well-being and treatment satisfaction. This analysis investigated which factors contributed to the improved well-being and treatment satisfaction with CGM.

Methods: The GOLD trial was a randomized cross-over trial comparing CGM versus self-measured blood glucose (SMBG) over 16 months. Endpoints included well-being measured by the WHO-5 and treatment satisfaction by the DTSQ questionnaires as well as glucose metrics.

Results: 139 participants were included in the evaluations. Multivariate analyses revealed that increased convenience and flexibility contributed with 60% (95% confidence interval (CI) 50-89%) to the improvements in treatment satisfaction (DTSQc) observed with CGM, whereas the perceived effects of hypoglycaemia and hyperglycaemia only had a minor contribution of 6%

(95% CI 2-11%).Significant improvements in well-being (WHO-5) by CGM were observed for the following items: feeling cheerful ($p = 0.025$), calm and relaxed ($p = 0.024$) being active ($p = 0.046$) and waking up fresh and rested ($p = 0.044$). HbA1c-reductions through CGM were associated with improvements in both treatment satisfaction ($p = 0.014$) and well-being ($p = 0.028$), whereas changes in glycaemic variability showed no association with treatment satisfaction.

Conclusions: While CGM improves glucose control in people with T1D on MDI, increased convenience and flexibility through CGM are of even greater importance for treatment satisfaction and patients' well-being. These CGM-mediated effects should be taken into account when considering CGM-initiation.

EP323 / #104

Topic: ***AS15 Human factor in the use of diabetes technology***

CONTINUOUS GLUCOSE MONITORING DETECTED NOCTURNAL HYPOGLYCAEMIA IS ASSOCIATED WITH A LOWER SELF-REPORTED SLEEP QUALITY IN TYPE 1 DIABETES

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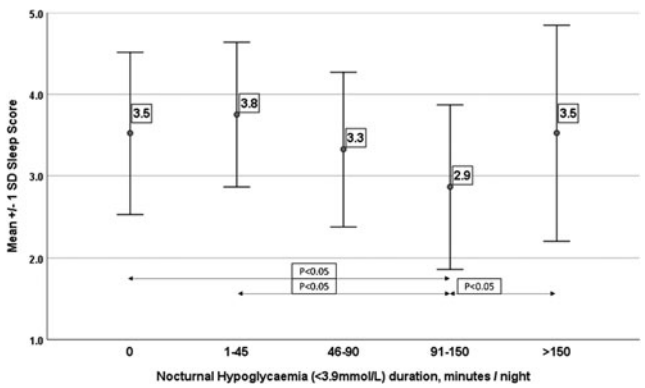
Background and Aims: Nocturnal hypoglycaemia (NH) is a significant burden for people living with type 1 diabetes (T1D). Continuous glucose monitoring (CGM) has enabled detection of asymptomatic NH. However, the impact of asymptomatic CGM detected NH on sleep quality is not clear. We aimed to study the association between CGM detected NH and sleep quality in people with T1D.

Methods: Twenty-six adults with T1D wore 2-3 blinded Freestyle LIbre Pro sensors sequentially over a period of 3 months. They self-graded their sleep quality each morning on a 5 point Likert Scale. How well did you sleep last night? (1-Very poorly, 5- Very well). Nocturnal (0000:0600) hypoglycaemia (<3.9 and <3 mmol/L) duration, Nocturnal mean glucose, Nocturnal Time-in-Range (3.9-10mmol/L) and Nocturnal glucose variability (%CV) were measured. Sleep quality scores were compared across quartiles of glycaemic indices treating each night as an independent observation.



Results: Mean (SD) sleep score was higher after nights without a NH episode [3.5(1.0) vs 3.3(1.1), $p < 0.05$]. Quartiles of NH (<3.9mmol/L) duration and corresponding mean(SD) sleep scores were **1:** 1-45 min, 3.8(0.9); **2:** 46-90 min,3.3(0.9); **3:** 91-150min, 2.9 (1.0); **4:** >150 min,3.5(1.3)]. Mean Sleep score in quartile 3 was significantly lower than those in quartile 1 & 4 as well as nights without hypoglycaemia (all $p < 0.05$, with Bonferroni correction). No significant differences existed across quartiles of other glycaemic indices.

Conclusions: Longer duration of CGM detected NH (<3.9mmol/L) is associated with a lower self-reported sleep quality. However, self reported sleep quality scores are interestingly higher in those with very long durations (>2.5 hour/-night) of hypoglycaemia.

EP324 / #550

Topic: ***AS15 Human factor in the use of diabetes technology***

24 DAYS TO OLYMPIC GAMES: A PROFESSIONAL ATHLETE NEWLY DIAGNOSED WITH TYPE 1 DIABETES

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Background and Aims: We present a case-report of diabetes management using telemedicine in a skeleton racer who successfuly competed at the 2022 Winter Olympic Games less than a month after diagnosis of type 1 diabetes.

Methods: The athlete departed to Beijing 9 days after diagnosis. The majority of diabetes education and management was performed through digital platforms and telemedicine. The athlete was started on MDI flexible insulin dosing and a CGM with remote monitoring. Insulin doses were calculated using a bolus calculator. Communication between the athlete, coaches and diabetes specialists was performed via a sport cloud platform, messaging platform or videocalls. All insulin doses were individually adjusted by a diabetologist according to the athlete's training and nutrition schedule. During the 24 days from diagnosis to competition, >5000 messages were exchanged between the athlete and the diabetologist. Challenges that had to be overcome for the athlete to safely participate in the games included traveling, 7-hour time shift, high altitude, cold temperature or rapid changes of insulin needs.

Results: During the two-week training period, the athlete achieved 91,4% TIR 3,9-10 mmol/l, 1,3% <3,9 mmol/l and 7,3%> 10 mmol/l. Average glucose was 7,0 mmol/l, CV 26,3%. During the two competition days, 97,4% values were within 3,9-10 mmol/l, 1,0% <3,9 mmol/l and 1,5%> 10 mmol/l. Average glucose was 6,6 mmol/l, CV 21,7%. There were no episodes of nocturnal hypoglycemia, severe hypoglycemia or DKA. No training sessions were ommitted due to uncontrolled diabetes.

Conclusions: We demonstrate an effective distant T1D management in a newly diagnosed professional athlete competing at the Olympic Games.

EP325 / #865

Topic: ***AS15 Human factor in the use of diabetes technology***

THE IMPACT OF TECHNOLOGY AND QUALITY IMPROVEMENT ON HBA1C AT A NATIONAL LEVEL

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Background and Aims: Denmark started a national improvement project focusing on childhood diabetes in spring 2020 at the very beginning of the Covid-19 pandemic. This study reports the development in glycemic control and BMI for the years 2020 – 2022 a period where also new automated insulin delivery systems were introduced in Denmark.

Methods: Data are retrieved from the quality improvement data from each visit 2019-2022. Children age 0-17.9 years were included. Serial diagrams were used to follow quality indicators month by month. Definition of overweight was BMI above 2 standard deviation (SD) according to age and sex.

Results: All 16 clinics in Denmark participated and during the period 3 seminars were held and 8 webinars of 1-2 hours. During the webinars different clinics presented their projects and material and ideas were shared. During the study period between 377 – 938 single HbA1c values per month were reported and contributed to the serial diagrams. There was a significant decline in mean HbA1c from 2019 (mean of 58.3 mmol/mol) to september 2021 (54 mmol/mol) and an increase in all age groups obtaining treatment goal below 53 mmol/l. There was an increase in the percentage of children with BMI above 2SD.

Conclusions: There was signs of decrease in HbA1c from the beginning of 2021 after 9 months with quality improvement and just as automatic insulin delivery was introduced with a simultaneous increase in BMI

EP326 / #860

Topic: ***AS15 Human factor in the use of diabetes technology***

AUC BASED COMPARISON OF GLYSEMIC RESPONSE AFTER THE CONSUMPTION OF DRY VS FRESH FRUITS IN DIABETIC AND NON DIABETIC VOLUNTEERS

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Background and Aims: To compare the postprandial glycemic response for the same amount of carbohydrates based from the same fruit portions in dry and fresh states in well and poor controlled diabetic patients versus healty volunteers.

Methods: The preliminary results from an unpublished research designed to study of the glycemic response for fixed combinations of macronutrients were examined. To analyse diabetic control on glycemic variability after the consumption of the same fruit in dry and fresh states, data from three groups of individuals (n = 27) who had a portion of previously weighed and standardised fresh and dry apricots were chosen. Each portion was indicating an exact amount of 15 gr carbonhydrates. Of the study group, 8 were well controlled diabetic (HbA1c<6.5%) 8 were poor controlled (HbA1c >7%) and 11 were nondiabetic individuals. All individuals were followed on continuous glucose monitorising systems (Dexcom G6). The glysemic response after consumption was monitorised and data for glycemia every five mintes was taken digitally. The postprandial glycemic response was evaluated by iAUC method.

Results: The iAUC difference for every individual for dry and fresh apricot consumpton were analysed. Poor controlled diabetics had a better glycemic response for fresh fruits ($p = 0.043$, Mann-Whitney U-test) while well controlled diabetics had better results for dry chice. Healty individuals had no variation on glycemic response for dry or fresh choices.

Conclusions: Diabetes control has impact not only on diabetic complications but also on the response of food choices on an individual's glycemic control. Even for the same food choice, counting carbohydrates is not just a numeric value.

EP327 / #102

Topic: ***AS15 Human factor in the use of diabetes technology***

THE INFLUENCE OF DIABETES TECHNOLOGY ON EVERYDAY LIFE WITH DIABETES AND THE INTERACTION BETWEEN A PERSON WITH DIABETES TYPE 1 AND THE DIABETIC NURSE

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Background and Aims: Today, people with type 1 diabetes (T1D) have a high degree of self-responsibility for monitoring and managing own treatment. Modern treatment of T1D includes the use of a large variety of technological aids involving many daily decisions for the individual. For the Diabetes Outpatient Clinic to support these daily decisions, it also places demand on the diabetes nurse's knowledge and technological skills. In the interaction between the nurse and the person with diabetes, it is a risk that the technological aspects of diabetes treatment take focus away from the conversation about other issues in the daily life with T1D. The aim of this project is to investigate how people with T1D experience diabetes technology affects their daily life, and the interaction with the diabetes nurse.

Methods: A qualitative design with data collected from two focus group interviews with nine people with T1D associated with the Diabetes Outpatient Clinic at North Denmark Regional Hospital. Participants must have at least two years of diabetes experience, using insulin pump and glucose monitor. A themed interview guide and photo-interviews will be used. The material will be analyzed from a hermeneutic approach.

Results: expected to be available by the end of 2022.

Conclusions: It is expected that the study will provide new knowledge about the influence of technology on daily life with diabetes and the importance of the interaction with the diabetes nurse and thus inspire possible nursing efforts in the Diabetes Outpatient Clinic

EP328 / #714

Topic: ***AS15 Human factor in the use of diabetes technology***

PUMP SETTING ADJUSTMENTS WHEN USING HYBRID-CLOSED LOOP (HCL) SYSTEMS IN THE HOSPITAL

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Background and Aims: Continuation of insulin pump therapy with an active hybrid-closed loops system (HCLS) is now standard of care in our hospitals for non-critically ill patients. Our hospital has a policy requiring a diabetes consultation as soon as an insulin pump is identified on a patient to assess if a patient is able to self-manage it. We had previously required patients to turn off the automated system but with the increasing use of these systems and patients not wanting to convert to manual settings, we have worked to develop best practices for managing the HCLs in the hospital.

Methods: Case report of hospitalized patients using an insulin pump in HCL upon admission and during hospitalization.

Results: We describe here our experience using the Control IQ algorithm in the hospital. Data is uploaded and reviewed daily by the Diabetes team who then develops a plan to adjust the pump settings based on glucose trends, PO intake and activity. We have found that use of the activity setting is usually not sufficient to prevent hypoglycemia so a secondary profile is typically needed. This profile will be used to either intensify or, more commonly, de-escalate insulin delivery.

Conclusions: We have found that Insulin pump settings tend to be very basal heavy such that upon hospitalization the use of the usual home program will result in hypoglycemia, even in the presence of an active HCL. In contrast, in the setting of high dose steroids the settings are changed to intensify basal deliver, insulin to carb ratio and the corrective dosing.

EP329 / #664

Topic: ***AS15 Human factor in the use of diabetes technology***

CHALLENGES TO EXERCISING AMONG PEOPLE WITH DIABETES USING DIABETES TECHNOLOGIES IN THE U.S., CANADA, AND EUROPE

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Background and Aims: Physical exercise is known to have important health benefits for people with diabetes (PWD). Diabetes technologies such as glucose sensors and insulin pumps aim to increase the ease and convenience of blood glucose management, but it is unclear how they affect PWD's exercise experience. This study aimed to explore challenges to exercising that technology-using PWD face and how they differ compared to non-users.

Methods: From May-September 2022, adult PWD on intensive insulin (N = 5,958; 87% T1) in the United States, Canada, France, Germany, Italy, Netherlands, Sweden, and United Kingdom took an online survey in which they reported challenges experienced while exercising. The subsequent responses were analyzed.

Results: Compared to non-users (n = 2,133), pump users (n = 3,825) were more likely to report frequent hypoglycemia (42% vs. 28%, $p < .001$) and concern about managing blood glucose (54% vs. 40%, $p < .001$). Among those on multiple daily injections of insulin, CGM users (n = 1,579) were more likely than non-users (n = 554) to report frequent hypoglycemia (30% vs. 20%, $p < .001$), frequent hyperglycemia (14% vs. 9% $p < .001$), and concern about managing blood glucose (43% vs. 32%, $p < .001$). Pump-specific challenges included not knowing where to put their pump (21%), adhesion issues (18%), and tubing interfering with exercise (15%).

Conclusions: Despite numerous benefits for self-management, diabetes technologies present unique challenges to PWD while exercising. Not only can the device itself be an obstacle, but increased awareness of fluctuating blood glucose levels may create management concerns that non-users do not often experience. Results from this study suggest further research on the burden of device usage is warranted.

EP330 / #678

Topic: ***AS15 Human factor in the use of diabetes technology***

UNDERSTANDING THE IMPACT OF NEUROPATHY ON TREATMENT ADMINISTRATION FOR PEOPLE WITH DIABETES

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Background and Aims: Neuropathy, or damage to the nerves, is a common complication in people with diabetes (PWD) resulting from persistent high blood glucose. Diabetic neuropathy can lead to a wide range of symptoms, including weakness and pain, that make it difficult for PWD to carry out daily activities. This study aimed to understand the impact of neuropathy symptoms on PWD's ability to use diabetes management tools and technologies.

Methods: In September 2022, 1,206 adult PWD in the United States living with symptoms of nerve damage took an online survey in which they were asked about the impact of neuropathy on their diabetes. While 83% reported no difficulties managing their diabetes due to their neuropathy, 199 further elaborated on the challenges they faced. Among those with challenges, 63 said they experienced difficulties with administering treatment (39% T1, 70% female). These 63 subsequent qualitative responses were coded and reiteratively refined to a set of final themes.

Results: Thematic analysis identified notable challenges due to issues with manual dexterity, lack of sensation, and pain. Key themes that emerged from participants highlighted numerous concerns with diabetes technology, including difficulty handling blood glucose meters (29%), injecting insulin (24%), using insulin pumps (15%), and using continuous glucose meters (5%).

Conclusions: Although not highly prevalent in our sample, the adverse effect of neuropathy on diabetes management is still a significant area of concern. Future work is needed to provide additional insight on how to make diabetes technology more accessible and easier to use for people with neuropathy.

EP331 / #40

Topic: ***AS15 Human factor in the use of diabetes technology***

THE TRAINEES OWN PERCEPTION OF DIABETES DELIVERY OF CARE

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Background and Aims: The prevalence of pediatric type 1 and type 2 diabetes mellitus has increased globally. In contrast to adult diabetes care, most of the children with diabetes receive their medical care through pediatric endocrinologists rather than primary care providers. The aim of this study is to evaluate the fellows' own perception of diabetes care at different levels of training.

Methods: A survey was emailed to three fellows in training at the beginning of the academic year asking about their previous experience with pediatric diabetes and their current comfort level in delivering pediatric diabetes care.

Results: Two fellows were in the beginning of their first year of training while one fellow has completed two years of training. The first -year fellows expressed moderate levels of confidence while the third -year fellow has expressed complete confidence in assuming diabetes care. All fellows have received exposure to pediatric diabetes management during medical school and pediatric residency training.

Conclusions: There are many international studies in adult diabetes filed showing lack of confidence among trainee physicians in the management of diabetes care. In pediatric diabetes, there is a trend towards moving long-term management of diabetes care to specialist centers. While formal pediatric training almost always offer exposure to diabetes management, this training may remain insufficient due to short duration, elective rather than mandatory exposure, and perception that other pediatric fields are more important than diabetes care. Evaluating available resources for trainee and monitoring their self confidence level in assuming pediatric diabetes care should be part of medical education goals.

EP332 / #653

Topic: ***AS15 Human factor in the use of diabetes technology***

PERSON-REPORTED OUTCOME MEASURES AND HBA1C IN THE HYPO-METRICS STUDY: HYPOGLYCAEMIA MEASUREMENTS THRESHOLDS AND IMPACTS

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Background and Aims: Hypo-METRICS is a 10-week prospective, observational study to determine the psychological, physical, and economic impact of hypoglycaemia in adults with type 1 (T1D) and type 2 diabetes (T2D). Participation involves using ecological momentary assessment (EMA, via Smartphone app), actigraphy (Fitbit) and blinded continuous glucose monitoring (CGM). Participation may have an intervention effect due to real-time reflection on experiences and use of new technologies. Our aim was to examine whether participation affected person-reported outcome measures (PROMs) or HbA1c.

Methods: 464 participants (T1D = 218, T2D = 246, 55% men, age 55 ± 16 years, diabetes duration 22 ± 13 years, using insulin with ≥1 episode of hypoglycaemia in the last month) completed PROMs at baseline and study end. Participants completed three daily EMAs, including recording of hypoglycaemia episodes, for 10 weeks. We compared 10 PROMs and HbA1c at baseline and study end, applying Bonferroni-correction ($p < .0029$) for multiple comparisons.

Results: Mean scores on the Hypoglycaemia Fear Survey reduced on both the Behaviour subscale (15.03 to 14.07; MeanDiff = -.968, SD = 6.731; $p = .001$; $d = -.144$), and Worry subscale (14.11 to 12.42; MeanDiff = -1.694, SD = 10.252; $p < .001$; $d = -.165$). Depressive symptoms increased (Mean PHQ-9 scores: 5.28 to 5.78; MeanDiff = .625, SD = 3.785; $p = .002$; $d = .135$), but remained within the 'mild' category. There was no significant change in HbA1c (MeanDiff = 1.27, SD = 37.2; $p = .265$; $d = .034$) or other PROMs.

Conclusions: After 10 weeks in the Hypo-METRICS observational study, small, albeit statistically significant, effects were apparent for fear of hypoglycaemia and depressive symptoms. While further work continues on participant experiences, these findings suggest that participation is unlikely to have had a meaningful intervention effect overall.

EP333 / #868

Topic: ***AS16 Trials in progress***

DIETARY CHOICE, UPTAKE, RETENTION AND INITIAL OUTCOMES OF A REMOTE WEIGHT MANAGEMENT PROGRAMME DELIVERED TO AN ETHNICALLY DIVERSE POPULATION LIVING WITH TYPE 2 DIABETES (T2D)

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Background and Aims: Total Diet Replacement (TDR), Low carbohydrate diets (LC) and 5:2 dietary approach, delivered through face-to-face appointments, can achieve weight loss and may achieve remission. This is possible in people with mixed ethnic backgrounds too. Diabetes prevalence in this population is high. Ensuring interventions are acceptable, scalable and accessible is key. We evaluated the uptake, retention and initial weight outcomes of 3 different dietary approaches delivered remotely either in groups or individually in ethnically diverse adults with T2D. Participants were allocated to either groups or 1:1 care but could choose their dietary intervention.

Methods: Preliminary data from 122 adults with T2D (74.2% non-caucasian), following a digitally-enabled, remote weight management programme (12w intense; 4w transition; 8 months behaviour change) determining uptake, retention and 12 week weight loss. All had self-monitoring app access and coach support either via 1:1 or groups.

Results: 124 = initial Consultation with Dietitian. 38.7% TDR, 39.5% LC, 20% 5:2. 50% 1:1 care, 48% groups.

	Diet	1:1	Group
12w retention	TDR	20(69%)	13(68.4%)
	LC	11(57.9%)	18(60%)
	5:2	9(64%)	7(63.6%)
Average weight loss	TDR	8.9kg(9.1%)	10.3kg(9.7%)
	LC	2.7kg(2.6%)	3.4kg(3.2%)
	5:2	4kg(4.6%)	1kg(1.2%)

Conclusions: Preliminary data demonstrates that a diverse population with T2D favours TDR or LC dietary intervention. Greatest weight loss and retention at 12 weeks is seen with TDR. In 2/3 interventions, group support resulted in greatest weight loss at week 12. Digitally-enabled remote weight management programmes can result in significant weight loss in an ethnically diverse adult population with T2D, with initial weight loss improving retention and peer support improving weight outcomes.

EP334 / #151

Topic: ***AS16 Trials in progress***

PARENTAL DIABETES DISTRESS IS A STRONGER PREDICTOR OF HBA1C THAN DIABETES DEVICE USE IN SCHOOL-AGE CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: Background: Diabetes distress (DD) is a term that encompasses the daily treatment demands of type 1 diabetes (T1D) and co-occurring emotional response. We are designing a digital screen-to-treat program for DD for families of school-age children with T1D. Here, we examined associations between parent-reported DD levels and HbA1c levels in school-age children while adjusting for T1D device use.

Methods: Parents completed the Parent Problem Areas in Diabetes-Child (PPAID-C) a valid DD measure and reported on children's device use. We measured children's HbA1c using a valid fingerstick home kit and central laboratory. We grouped children based on current pump and continuous glucose monitor (CGM) use (i.e., user/non-user). We used correlations and linear regression for our analyses.

Results: Participants included n = 160 parent-child dyads. Children were 50% boys and 76% Non-Hispanic White (child age [mean±SD] = 10.2 ± 1.5 years, T1D duration = 3.8 ± 2.4 years, HbA1c = 7.96 ± 1.62%). Parents were 82% mothers, 81% Non-Hispanic White, and 73% married. Mean PPAID-C score was 51.83 ± 16.79 [range: 16-96] suggesting moderate DD levels. Higher child HbA1c correlated with non-pump users (r = -0.159, p = 0.023) and higher PPAID-C scores (r = .355, p = 0.001) but there was no association between child HbA1c and CGM use. In stepwise regression, PPAID-C scores better explained variations in child HbA1c than pump use.

Conclusions: Conclusions: Our analyses suggest parent DD may be a better predictor of child HbA1c than T1D device use and an important treatment target. Our digital screen-to-treat program for DD in families of school-age children with T1D will offer a platform for widespread dissemination of an evidence-based intervention.

EP335 / #379

Topic: ***AS16 Trials in progress***

INVOLVING END USERS IN THE DESIGN AND DEVELOPMENT OF AN E-HEALTH PROGRAM FOR LIFESTYLE CHANGES IN TYPE 2 DIABETES

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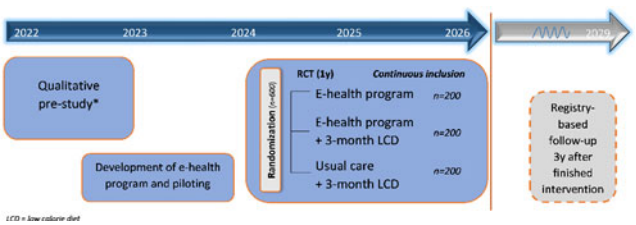
Background and Aims: Lifestyle interventions can delay progression of prediabetes to type 2 diabetes (T2D) and lead to remission. However, implementation of programs to obtain sufficient effects in the management of T2D, are both complex and costly. Self-management is crucial and can benefit from the use of modern technology. Direct involvement of users in designing and developing technology-based tools provides important information on requirements and wishes regarding design, functionalities, and usability. Based on findings from the literature and the clear need for improved options for preventing, treating, and reversing T2D, it is assumed that technology-based tools may deliver more effective lifestyle interventions than available alternatives. The long-term aim is to use this e-health program in further research (see figure).

Methods: In this qualitative pre-study, 35 healthy adults with prediabetes or T2D will participate in physical and digital focus group meetings. Participants will explore user preferences including wishes, demands, and feedback on design, functionalities, and usability. Group discussions, paper-prototyping, and questionnaires will be used. Audio recordings will be transcribed, and results from thematic analysis will inform development of the e-health program. Recruitment is done through a patient organization, hospitals, and social media. Currently 15 participants have been recruited, with mean age 59y (SD = 10.6), females 40% (n = 6), T2D 93.3% (n = 14), and prediabetes 6.7% (n = 1).

Results: from the upcoming focus group meetings, and how this will inform the design of the e-health program, will be presented at the conference.

Conclusions: This pre-study is currently in progress, and no conclusion can be drawn at this point.



EP336 / #431

Topic: ***AS16 Trials in progress***

REGULATORY T CELLS: METABOLISM AS A POTENTIAL REGULATOR OF CELL FUNCTION

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Background and Aims: The activity of T regulatory cells (Treg) is essential in establishing tolerance, preventing autoimmunity, and excessive inflammation through maintenance of the suppressive function. The study aims to assess whether T cell metabolism is connected with cell function in the immune system.

Methods: In the current study flow-sorted Treg and Teff cells from type 1 diabetic patients (n = 11) and healthy blood donors (n = 10) were cultured for 11 days under GMP conditions. On day 11 cells were harvested, washed, and suspended in PBS. 5-30mln cells were analyzed using spectrophotometry to determine enzymatic activities (hexokinase, glucose-6-phosphate dehydrogenase, isocitrate dehydrogenase, lactate dehydrogenase, fatty acid synthase). On day 11 the cell phenotype (CD27, CD28, CD57, Foxp3, CTLA-4, PD-1, TIGIT, FAS-L) was also assessed using flow cytometry. The second research stage involved the modification of culture conditions to imitate hypo- hiper- and normoglycemic conditions (0, 100, 1000mg/dl glucose). In this experiment, we cultured cells only from healthy blood donors (n = 6) and performed measurements as in the first research stage.

Results: Tregs present higher activity of mitochondria than Teff cells. Additionally, T regulatory cells cultured in conditions with a limited concentration of glucose are characterized by higher expression of CD27 and TIGIT on the cell surface.

Conclusions: T regulatory cells deprived of glucose are characterized by a higher activation (higher CD27 expression) and higher suppressive capacity (higher TIGIT expression). Differences in mitochondrial activity may indicate that Tregs use different energy sources than Teffs to fuel their activity and support function.

EP337 / #858

Topic: ***AS16 Trials in progress***

THE ENDORSE FEASIBILITY PILOT TRIAL- ADHERENCE TO STUDY PROTOCOL

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Background and Aims: The ENDORSE integrated platform capitalizes upon the latest technologies in m-health, gamification mechanisms and Artificial Intelligence towards creating an innovative software ecosystem able to deliver personalized services for the management of children with type 1 diabetes mellitus (T1DM).

Methods: ENDORSE platform utilizes various data sources, including glucose sensors, smart insulin pens, insulin pumps, activity trackers, Electronic Health Records, prototype mobile apps for parents and healthcare professionals and serious mobile games for T1DM children. A two-phase pilot trial is being conducted to evaluate the ENDORSE's feasibility. 48 patients are being monitored for 3 months at the ''Aghia Sophia'' Children's Hospital. Table 1 illustrates the baseline characteristics of the patients of each pilot phase. An adherence score has been created based on days of utilizing the ENDORSE modules. The adherence level was defined as low (level 1-module used for ≤24 days), medium (level 2- module used for 25 to 50 days) and high (level 3- module used for >50 days), respectively.

Results: Despite the increased variability among participants, 47% of them had high total adherence level (>2). A statistically significant positive correlation between the adherence level and the age was revealed, while the adherence level was not correlated with diabetes duration, BMI, baseline HbA1c and sex. The level of adherence is presented in Table 2.

Conclusions: The ENDORSE software ecosystem can improve diabetes management through facilitating training, monitoring and feedback to the patients and their caregivers,

Table 1: Patients' Characteristics

	Prepilot group (prepilot ENDORSE mobile app and serious game, activity tracker, SmartPen cap/insulin pump and app, FGM/CGMS (N= 18)	**Pilot Intervention group** (pilot ENDORSE mobile app and serious game, activity tracker, SmartPen cap/insulin pump and app, FGM/CGMS (N= 15)	**Pilot Control group** (activity tracker, SmartPen cap/insulin pump and app, FGM/CGMS) (N= 15)	**All** (N=48)
Sex (female)	12	7	9	28
Age (years) (SD)	11,09 (2,15)	12,02 (2,93)	12,55 (2,41)	11,84 (2.52)
Diabetes duration (years) (SD)	3,83 (1,46)	3,79 (2,24)	5,77 (2,4)	4,42 (2,2)
HbA1c (%) (SD)	7,7 (0,82)	7,71 (1,56)	7,64 (1,92)	7,68 (1,46)
BMI (SD)	20,08 (6,4)	18,56 (2,35)	21,23 (2,38)	19,96 (4,39)
Prepubertal	6	4	4	14
Sensor- augmented Insulin pump users	3	2	4	9

Table 2: Level of adherence

Physical activity and quality of sleep monitoring by means of activity tracker	Glucose monitoring by means of continuous glucose monitoring systems	Insulin monitoring by means of applying smart insulin pen or insulin pump	Meal monitoring by means of mobile app or insulin pump	Interaction with the ENDORSE mobile Game	Total adherence per group
Pre-pilot group					
1.91 ± 0.97	2.05 ± 0.95	1.95 ± 1.00	1.82 ± 1.01	1.45 ± 0.67	1.84 ± 0.93
Pilot Intervention group					
1.93 ± 0.88	2.13 ± 0.99	2.47 ± 0.92	2.27 ± 0.96	1.07 ± 0.26	1.97 ± 0.96
Pilot Control group					
2 ± 1.04	1.86 ± 0.86	2 ± 0.96	1.71 ± 0.99	-	1.93 ± 0.99
All groups					
1.94 ± 0.95	2.02 ± 0.93	2.12 ± 0.97	1.92 ± 1.00	1.30 ± 0.57	1.89 ± 0.94

irrespective of their baseline glycemic control. **Acknowledgements**: Supported within the framework of the ENDORSE project (Grant agreement: T1EΔK-03695)

EP338 / #356

Topic: ***AS17 COVID-19 and Diabetes***

PEDIATRIC TYPE 1 DIABETES ONSET DURING THE COVID-19 PANDEMIC: A 2-YEARs' EXPERIENCE FROM KUWAIT

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Background and Aims: There has been a considerable impact of the COVID-19 pandemic on healthcare services and the management of type 1 diabetes (T1D) at onset. The aim is to describe the clinical characteristics of children with T1D onset in Kuwait during the two years of the COVID-19 pandemic in comparison to the previous years (2017-2019)

Methods: Children aged 14 years or less diagnosed with T1D onset between the years (2017-2022) were included. Children were categorized according to the diagnosis year and during (Feb 24th- Feb 23rd,the following year)

Results: A significant increase in DKA rates was observed during the first & second years of the pandemic compared to the previous years (2020, 53.3%, 2021, 55.8% vs 2019, 39.4%, 2018,35.5%, 2017,39.1%,p-value = >0.001respectively); as well as ICU admission (26.4% in 2020,27.6% in 2021,13.9% in 2019,15.0% in 2018, and 19.7% in 2017, p-value = 0.002 respectively). Frequency of TTG-IgA antibodies was slightly higher in the second year compared to the previous years (12.4% in 2021,9.3% in 2020,8.8% in 2019,9.8% in 2018, and 6.0% in 2017,p-value = 0.06 respectively). Frequency of TPO antibodies didn't differ across the years (20.0% in 2021, 22.6% in 2020,14.8% in 2019,12.7% in 2018, and 16.0% in 2017,p-value = 0.06 respectively, p-value = 0.10, respectively)

Conclusions: DKA & ICU admission rates continue to rise in the second year of the pandemic. In 2021,celiac screening positivity was slightly higher at onset. To better understand the long-term effects of the pandemic on the clinical course of children with T1D, it is essential to evaluate further clinical presentation, autoimmune involvement & outcomes over long periods of time.

EP339 / #849

Topic: ***AS17 COVID-19 and Diabetes***

THE IMPACT OF COVID-19 PANDEMIC ON THE GLYCEMIC REGULATION OF PATIENTS WITH TYPE 1 DIABETES MELLITUS AND CONTINUOUS INSULIN INFUSION SYSTEMS

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Background and Aims: The COVID-19 pandemic severely affected the glycemic regulation of adult patients with type 1 diabetes (T1D). The aim of this study was to evaluate the impact of this pandemic on glycemic control in T1D patients with continuous insulin infusion systems (CSII).

Methods: A cohort of adult T1D patients with CSII was retrospectively evaluated. Data regarding number visits to our diabetes clinics, total daily insulin dose (TDID), blood and estimated HbA1c, time in range (TIR) (70–180mg/dl), time below range (TBR) (<70 mg/dl) time above range (TAR)(>180 mg/dl) and coefficient of variation (CV) in the pre- (March 2018-March 2020) and the pandemic (April 2020- April 2022) were collected.

Results: 66 patients were studied (32 females, mean age 44 ± 12.1 years, mean body mass index [BMI] 25.1 ± 4 kg/m2, mean bHbA1c 7.3 ± 0.9%, mean eHbA1c 7.15 ± 0.9% and average number of 8 visits in the prepandemic period). During the pandemic period, TDID and BMI remained stable. On the contrary, TIR increased significantly (65.8 ± 8.6 vs 70.2 ± 16.8%; p = 0.026) while TBR (5.8 ± 4 vs 4.9 ± 3.8%; p = 0.007) and TAR (28.4 ± 5.4 vs 24.9 ± 3.3%; p = 0.03) diminished substantially. Furthermore, mean bHbA1c (7.3 ± 0.9 vs 7.15 ± 0.7%; p = 0.01), eHbA1c (7.15 ± 0.9 vs 6.94 ± 0.65%; p = 0.005) and CV (34.1 ± 5.5 vs 31.7 ± 4.1%; p < 0.001) decreased considerably during the pandemic. Additionally, the average number of visits was reduced to 4 per person but was positively associated with greatest improvement of glycemic control.

Conclusions: Glycemic regulation of adult patients with T1D and CSII improved significantly during the pandemic, despite reduced visits to the diabetes outpatient clinics.

EP340 / #892

Topic: ***AS17 COVID-19 and Diabetes***

THE ROLE OF NEUTROPHIL INDICES IN THE PROGNOSIS OF COVID-19 WITH A FOCUS ON DIABETES MELLITUS

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Background and Aims: Many reviews show impaired response of metabolic and immune systems in patient with diabetes that leads to more severe clinical course of COVID-19. One of such early predictors could be neutrophil indices that derives from hemogram. Our study aims to investigate the predictive value of neutrophil ratios in a diabetic cohort hospitalized with COVID-19.

Methods: We retrospectively examined data from 229 diabetic patients with COVID-19 hospitalized at the regional clinical hospital of Karaganda between May and August 2021. We analyzed the relationship between inflammation markers (neutrophil-lymphocyte ratio (NLR), platelet-lymphocyte ratio (PLR), neutrophil-platelets ratio (NPR), systemic immune-inflammation index (SII)), disease severity, and early outcomes.

Results: In multivariate regression analysis, patients with high NLR (p = 0.018), NPR (p = 0.006), and SII (p = 0.022) had more severe COVID-19, an increase in NLR (p = 0.0001), NPR (p = 0.0001) and SII (p = 0.001) was associated with the development of early mortality. The role of PLR in predicting COVID-19 was not significant (p = 0.388).The ROC curve result showed that higher NLR (AUC = 0.637, 95% CI = 0.554–0.719, p = 0.002) and NPR (AUC = 0.674, 95%CI = 0.600–0.749, p = 0.0001) scores predicted the COVID-19 severity and mortality (NLR: AUC = 0.687, 95% CI = 0.587–0.787, p = 0.0001 and NPR: AUC = 0.703, 95% CI = 0.614–0.791, p = 0.0001),

increasing of SII predicted only early mortality (AUC = 0.652, 95% CI = 0.541–0.764, p = 0.004).

Conclusions: NLR and NPR can be considered as optimal and readily available parameters for predicting the severity and early mortality among diabetic patients with COVID-19.

EP341 / #332

Topic: ***AS17 COVID-19 and Diabetes***

REMOTE PATIENT MONITORING AND GLYCEMIC CONTROL TRENDS DURING THE COVID-19 PANDEMIC

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Background and Aims: COVID-19 created challenges to diabetes care and accelerated the need to optimize healthcare delivery outside of traditional settings. Due to subsequent stay-at-home orders, many clinicians sought remote patient monitoring (RPM) solutions to remain engaged with their patients with diabetes (PWD) and to provide care. This study examined RPM uptake and diabetes-related outcomes during the COVID-19 pandemic for PWD using a RPM solution.

Methods: The Glooko platform is used globally by millions of PWD and populates a real world data repository of 100+ billion data points. The analysis included diabetes device syncs from 100,000+ Glooko patient users during Year 2020. Descriptive statistics were used to evaluate trends in RPM usage and diabetes outcomes (glucose, self-monitoring, etc.).

Results: RPM uploads increased by 36% during the ''lockdown'' and remained high even as clinics reopened. Five months into the pandemic, peak glucose levels on Sundays and Saturdays increased, but remained lower than pre-pandemic levels (-1.2% and -0.7%, respectively). Average glucose levels dropped early on and gradually increased over the year but with lower weekend and holiday spikes. Self-monitoring of blood glucose (SMBG) readings were within recommended range over 50% of the time and the average number of daily SMBG checks exceeded established clinical guidelines. Additional data will be presented.

Conclusions: The Glooko RPM platform offered an important clinical tool to providers and patients during the pandemic which resulted in increased engagement, improved glucose trends, and increased self-monitoring. Remote care provided clinics and patients with necessary insights to collaborate and manage diabetes despite the lack of in-clinic visits.

EP342 / #443

Topic: ***AS17 COVID-19 and Diabetes***

''I HAVE A LOT OF CONTROL OVER MY TREATMENT'': THE ROLE OF DIABETES TECHNOLOGY ON ADOLESCENTs' SELF-EFFICACY DURING COVID-19

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Background and Aims: For adolescents with type 1 diabetes (T1D), self-efficacy in diabetes management is associated with better glycemic levels and improved health outcomes. We examined the impact of the COVID-19 pandemic on self-efficacy and diabetes management among adolescents with T1D.

Methods: We conducted semi-structured interviews with adolescents with T1D who were participating in an ongoing clinical trial. Adolescents (n = 24; mean age = 13.8 ± 2.1 years; 42% female; mean HbA1c = 8.7 ± 1.7%; 95% CGM users) described their confidence in their ability to manage diabetes during the pandemic. Interviews were transcribed and coded, establishing inter-reliability ($\kappa = .78$). Adolescents' diabetes device use and HbA1c were extracted from medical records.

Results: Most adolescents (63%) reported increased confidence over the course of the pandemic. Over half (53%) of these adolescents were already using an insulin pump, while 33% updated their method of insulin delivery over the pandemic. Many participants cited diabetes technology as an important factor in their self-management confidence. They described the additional information about blood glucose trends the technology provided as being beneficial during the pandemic, allowing them to make necessary adjustments on their own, at a time when seeing providers was inconsistent. Several participants also reported that the technology helped them adhere to recommendations regarding insulin dosing and glucose monitoring during quarantine, leading to improvements in blood glucose levels and an overall increase in self-efficacy.

Conclusions: Findings illustrate the role of diabetes technology in the daily lives of adolescents with T1D, as well as their potential benefits during the particularly unique time of COVID-19.

EP343 / #776

Topic: ***AS17 COVID-19 and Diabetes***

IMPACT OF DIABETES MELLITUS AND CARDIOVASCULAR DISEASE ON CLINICAL OUTCOME OF PATIENTS DIAGNOSED WITH COVID-19

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Background and Aims: COVID-19 patients with co-existing conditions like cardio-vascular diseases (CVD) and diabetes mellitus have reported higher fatality. With increasing circulation of new variants it is ineluctable to study the impacts of the corona virus in patients with co-existing diseases. In context with this, we propose a study that aims to analyze the impacts of CVD and diabetes on COVID-19 patients, their prognosis, and severity of diseases.

Methods: This is a multi-center retrospective observational study. 1180 patient records including clinical outcomes from multiple countries, who were diagnosed with COVID-19 by RT-PCR, based on WHO guidelines were obtained through Literature search including Pub Med and Google Scholar from December 2019-December 2021 and analysed after matching with the inclusion and the exclusion criteria.

Results: Most patients undergoing treatment are from the urban (46.61%) due to better treatment modalities than rural (22.29%). Among females (25.76%), survival rate (48.70%) is

higher compared to males. Patients above 50 years with comorbidities depict higher fatality rate. Median hospitalization duration and admission to ICU were higher for non-survivors. Oxygen saturation level and blood pressures were lower for non-survivors than for survivors incorporated with maximized cardiac biomarkers and immune-inflammatory during the first day of hospital admission.

Conclusions: CVD and Diabetes increases the risk of complications, prolong hospital stay, and death in COVID-19 patients. Patients with diabetes have higher fatality rate; however, females of all ages have a higher survival rate than males. The study found that coexisting conditions like diabetes and CVD increase risk and fatality rate.

EP344 / #779

Topic: ***AS17 COVID-19 and Diabetes***

NEW ONSET DIABETES MELLITUS IN POST COVID PATIENTS – AN OBSERVATIONAL STUDY

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Background and Aims: The novel coronavirus,binds to angiotensin-converting enzyme 2 (ACE2) receptors, which are expressed in key metabolic organs and tissues, including pancreatic beta cells, adipose tissue, small intestine and kidneys.COVID-19 is attributed to the cytokine storm, followed by pancreatic cell damage.Thus, it is plausible that SARS-CoV-2 may cause pleiotropic alterations of glucose metabolism that could complicate the pathophysiology of pre-existing diabetes or lead to new onset Diabetes Mellitus.Thus, the study aims to analyze the development of new onset diabetes in post covid patients

Methods: Serum glucose level of 500 patients, between the age of 18 to 50 who were previously normoglycemic and recovered from COVID-19 was measured and incidence of new onset diabetes mellitus was obtained.

Results: Out of 500previously normoglycemic COVID-19 patients selected for the study, 97 patients (19.4%) developed new onset diabetes mellitus after recovering from COVID-19 disease.

Conclusions: The results of this study show that a significant amount of people developed new onset type 2 diabetes mellitus after having recovered from COVID-19. Blood glucose control is important not only for prediabetics affected with COVID but also for those affected with no previous status of diabetes mellitus. The results of this paper could be useful in screening and diagnosis of new onset diabetes mellitus at an early stage can be beneficial to avoid further worsening of the patient's health.

EP345 / #932

Topic: ***AS17 COVID-19 and Diabetes***

EDUCATING EDUCATORS - RE-ADAPTATION OF QUALIFICATION COURSE IN DIABETES FOR HEALTH CARE PROFESSIONALS IN AN ONLINE FORMAT

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Background and Aims: The qualification course aims to encourage different health care professionals (HCP) to develop attitudes and educational actions in dealing with people who have diabetes, their families, and caregivers. Since 2008, more than 2000 HCP have been qualified. The activities during the course are workshops and case discussions through debates and awareness. Due to the COVID-19 pandemic, three editions of the qualification were made virtually.

Methods: This case report explores how changed the qualification course Educating Educators, through the explanation of how to apply diabetes education in health services, and teaching processes to the development and implementation of an educational project in diabetes.

Results: As of the COVID-19 pandemic, the course, which was 50% practical and 50% expository and fully face-to-face, couldn't longer be held in this format. With this continuous demand to qualify HCP in diabetes education, the course during the pandemic had participants of the 39th, 40th, and 41st editions held in a fully online format. The digital model changed the four days of the course in face-to-face modality to two days in two weeks in a virtual way, with a break between the meetings for mentoring and discussion in small groups, some orientations to turn possible the conclusion of elaboration their projects.

Conclusions: This new model of education appeared can be used to achieving people that don't can participate in face-to-face meetings. Also, the virtual model can provide a constant conversation between tutors and participants to improve their projects.

EP346 / #451

Topic: ***AS17 COVID-19 and Diabetes***

WAS COVID ERA A BLESSING IN DISGUISE FOR THE PATIENT?

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Background and Aims: In the Covid era, Continuous blood glucose monitoring(CGM) was used more frequently and it proved to be quite a helpful and accurate tool for glycemic regulation.

Methods: 75 yrs old Saudi gentleman, had Type 2 diabetes >30yrs, Hypertension, Primary Hypothyroidism, dyslipidemia, mixed polyneuropathy, Iron deficiency anemia, and benign prostatic hypertrophy. In March,2020 his BP and blood glucose readings were high at home. He had a past history of subdural hematoma with hydrocephalus(staus post-shunting). He was on Glargine, oral hypoglycemic agents, anti-hypertensives, Levothyroxine, Atorvastatin, Aspirin, iron fumarate, calcium carbonate and cholecalciferol. Fully conscious, and co-operative, of average built and height.BP 170/70 mmHg, pulse 93/m, RR 18/m,O2sat 100%, afebrile, BMI 24.96 kg/m^2. Fundoscopy normal. He had dry feet and impaired monofilament and vibration testing.

Results: Hb% 13.1g/dl(12.6 before),MCV 93.8fl,S.Ferritin 10.5ug/l(30-400),Vit.B12 270 pmol/l(145-637),HbA1c 8%(6.4 in Feb.2020).The renal, liver and thyroid functions-intact. Albumin creatinine ratio 12.23mg/g(0-30). Nerve conduction study-mixed polyneuropathy. He continued to follow-up physically even during the Covid crisis due to the elevated SMBG and BP values. Gliclazide & antihypertensive doses were optimized and Glargine was started.On patient's follow-up in August, 2020,

time in range had improved to 80%(33% in June,2020),average glucose was 147 mg/dl(200 before), glucose variability was 27.8%(28.9), hypoglycemia (54-79mg/dl) was 1%(0). On last follow-up on 27.06.2022 his HbA1c had climbed up to 8.3%(7.3 in September, 2021). He was compliant to the diabetes regime, but had stopped using the Libre sensor.

Conclusions: The case signifies the advantage of a meticulous CGM usage during the Covid pandemic, that resulted in a reasonable glycemic control.

EP347 / #574

Topic: ***AS18 Other***

ROLE OF CONTINUOUS GLUCOSE MONITORING VS HBA1C IN CYSTIC FIBROSIS RELATED DIABETES

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Background and Aims: Cystic Fibrosis Related Diabetes (CFRD) is the most common extrapulmonary comorbidity in Cystic Fibrosis (CF) and implies worst outcomes. Continuous glucose monitoring (CGM) is indicated when active treatment with multiple daily injections (MDI), monitoring patients previously with HbA1c. Due to multiple causes, HbA1c is lower in CF and not reliable in most cases. However, there are no clear definitions to guide HbA1c and glucometric objectives of follow up and treatment in CFRD. Aims To verify if there are any differences in correlation between HbA1c vs CGM metrics with CF complications.

Methods: Retrospective study including 15 patients with CFRD and follow up with HbA1c and CGM ≥14 days. Data from CGM was collected in the last appointment with a difference <1month from HbA1c measurement.

Results: Patient's mean age was 34 ± 12 years, with age at CF diagnosis of 0 (IQ range 0-3) years and evolution of CFRD of 7 (1-9) years without any microvascular complications. Glycemic control was adequate, with mean Time In Range (TIR) 90.9 ± 8.2% and mean HbA1c 5.9 ± 0.4%. Pulmonary function measured with spirometry did not correlate with HbA1c nor CGM metrics. Nevertheless, strong association exists between CF exacerbations (need of new antibiotic treatment/hospitalization) and CGM metrics: TIR 78.5 ± 12.02 vs. 92.8 ± 6.1% ($p = 0.015$), average glucose 140 ± 8 vs. 113 ± 12mg/dl ($p = 0.008$), and Glucose Management Index (GMI) 6.7 ± 0.2 vs. 6.0 ± 0.3% ($p = 0.011$), not founding this correlation with HbA1c.

Conclusions: Glucometric parameters (TIR, GMI and mean glucose), not HbA1c, are related to exacerbations of CF. Studies are needed to determine glycemic objectives in CFRD, sustained by CGM.

EP348 / #928

Topic: ***AS18 Other***

CLOSED-LOOP SYSTEMS IN PREGNANCY-THE CHESTER EXPERIENCE

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Background and Aims: There is limited research on the safety and effectiveness of closed-loop systems in pregnancy. We initiated these systems in the first and second trimesters in 6 Type 1 women who became pregnant. The aim was to improve control and reduce the risk of complications. One other patient was on a DIY system which she had initiated 12 months before pregancy. We describe the outcomes of 4 of them who have delivered,and if we are given the chance to present in the conference, we can share outcomes of 2 further pregnancies who are expected to deliver by January 2023.

Methods: We initiated 3 patients on the Tandem T-slim pump with Dexcom G6 with control-IQ, 3 patients on the Medtronic 780G with Guardian 4 sensors; all were initiated in the late first and early seccond trimesters. They had regular weekly or 2-weekly follow-up appointments until delivery. Regular monitoring of fetal well being was initiated by 28-weeks gestation.

Results: The time-in-range varied between 69-91% with an average 75%. Average period of hypoglycaemia was <6%. Total average daily insulin was 20 units+/- 9 units at the time of initiation rising to 62 units +/- 10 units at the time of delivery.There was no occurence of severe hypoglycaemia or diabetic ketoacidosis. Median gestational age at delivery was 36 weeks.Median birth weight was 3650g. Two babies were admitted to the neonatal unit for treatment of transient hypoglyceamia.

Conclusions: Our experience has shown encouraing results. Large scale trials of closed-loop therapy are required to establish safety and efficacy in pregnancy.

EP349 / #106

Topic: ***AS18 Other***

TOPIC : NEONATAL DIABETES ABSTRACT TITLE: CLINICAL FEATURES OF CHILDREN DIAGNOSED WITH NEONATAL DIABETES IN KUWAIT: A TEN YEAR EXPERIENCE

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Background and Aims: Background Reports on neonatal diabetes (ND) have been scarce regionally and internationally. **Aim** To describe the characteristics of children with ND at time of diagnosis, including gender, nationality, age, HbA1c, PICU admissions, as well as presence and severity of diabetic ketoacidosis (DKA).

Methods: Patients diagnosed with DM at less than six months of age were collected from the 'Childhood Onset Diabetes eRegistery' (CODeR). This registry includes children residing in the state of Kuwait, diagnosed with DM.

Results: Between the years 2011 and 2021, a cumulative sample of thirteen patients (0.41%) with ND were registered and collected from CODeR (n = 3135). Findings revealed that those with ND were predominantly male (84.6%), Kuwaiti (61.5%) and have a mean age of 1 month. Nine patients had information on DKA, four of whom had PICU admissions (30.7%); four no

DKA (44.4%) one mild DKA (11.1%), three moderate DKA (33.3%) and one severe DKA (11.1%). The mean HbA1c level at diagnosis was 7.18.

Conclusions: This report is the first of its kind in Kuwait to describe the clinical features of Neonatal diabetes. Subsequently, it will aid to enrich the knowledge of ND in the region. Further research on the outcome and management of ND is required to better understand the nature of the illness on affected individuals.

EP350 / #143

Topic: ***AS18 Other***

COMPARISON OF POINT-OF-CARE AND LABORATORY GLYCATED HEMOGLOBIN A1C AND ITS RELATIONSHIP TO TIME-IN-RANGE AND GLUCOSE VARIABILITY: A REAL-WORLD STUDY

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Background and Aims: The main objective of the current study was to perform a comparison of point-of-care testing for hemoglobin A1c (POCT-HbA1c) versus standard laboratory method (Lab HbA1c) and their relationship to time-in-range (TIR) and glucose variability (GV) among patients with diabetes mellitus (DM) presented to the outpatient diabetes clinics.

Methods: This single-center cross-sectional study was carried out on diabetic patients (aged ≥14 years of both genders) who undergo routine follow-up at our institution and whose physicians ordered HbA1c analysis for routine care. The included patients were using the isCGM Abbott's FreeStyle Libre system for at least three months and regular CGM users with at least 70% use.

Results: The mean values of Lab-HbA1c and POCT HbA1c were 8.82% ± 0.85% and 8.53% ± 0.89%. The TIR, time below range, and time above range were 33.47 ± 14.38 minutes (47.78% ± 14.32%), 5.44 ± 2.58 minutes (8.41% ± 4.42%), and 28.8 ± 8.27 minutes (43.81% ± 13.22%). POCT-HbA1c values are consistent with the standard Lab-HbA1c values (SD of bias = 0.55, and 95% CI = -0.78 to 1.4). Using the univariate linear regression analysis showed a statistically significant relationship between laboratory HbA1c and POCT HbA1c ($R^2 = 0.637$, $p < 0.001$), TIR ($R^2 = 0.406$, $p < 0.001$), and GV ($R^2 = 0.048$, $p = 0.032$). After adjusting for age, gender, disease duration, diabetes type, and percentage of sensor data in a multivariable linear regression model, the linear associations remained significant (all $p < 0.05$).

Conclusions: TIR and GV have promise as preferred measures for identifying clinical trial endpoints, estimating the likelihood of DM-related complications, and gauging a patient's glycemic condition.

EP351 / #97

Topic: ***AS18 Other***

BASELINE FEATURES AND CLINICAL PRESENTATION AT DIAGNOSIS OF FAMILIAL TYPE 1 DIABETES IN KUWAIT

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Background and Aims: Studies on familial type 1 diabetes (FT1D) have been limited globally. The aim of this study is to evaluate the baseline characteristics of children with FT1D

Methods: Kuwaiti children with T1D aged ≤14 years between 2011-2021 were included. FT1D was defined as having an affected father/affected mother/or affected sibling. ST1D was defined as having no first-degree relatives with T1D

Results: 1,734 patients with T1D were included, 325 (18.74%) had FT1D and 1409 (81.26%) had ST1D. 3% (n = 65, 3.75%) had an affected father, 2.31% had an affected mother, 11.19% had an affected sibling, and 1.50% (n = 26) had two or more affected family members. ST1D group presented with DKA at a higher rate compared to the FT1D group (39.0% vs. 23.4%; p-value <0.001). Children with an affected father were more likely to present with DKA compared to the other groups (affected father 31.25%, affected mother 15.38%, affected sibling 22.92%, ≥2 affected family members 19.23%; sporadic 39%, p-value <0.001). A statistical, but not clinical, significant difference was found between HbA1c values across the groups (ST1D 11.4%, affected father 10.6%, affected mother 9.65%, affected sibling 10.5%, ≥2 affected family members 10.3%; p-value = 0.001). The FT1D group was at a lower risk of presenting with DKA at onset

Conclusions: This is the first study in Kuwait to review the characteristics of FT1D and ST1D.Further studies are needed to better understand the role of a family history of diabetes on the natural course, disease management, and outcomes

EP352 / #684

Topic: ***AS18 Other***

DETECTION OF INSULIN WITH HOECHST STAINING IN HUMAN CELLS WITH CRISPR-ACTIVATED INSULIN GENE EXPRESSION

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Background and Aims: CRISPR technology is equipping scientists with broader possibilities for editing genomes for benefit of science. There is an opportunity for a new transplantation-based therapy of type 1 diabetes which can be built on leveraging human cells with CRISPR-activated insulin gene (*INS*) expression. Human embryonic stem cells are under full scale studies now as an inexhaustible supply of differentiated β-cells for transplantation into patients with type 1 diabetes. In this journey, it will be essential to have new data obtained utilizing a recently available technology. In this work, we studied the feasibility of switching on insulin transcription in HEK 293 cells using CRISPR/Cas9 technology and we also aimed to detect insulin with lab staining.

Methods: The promoter of insulin gene in HEK 293 cells was targeted with a lentivirus-expressed guide RNA part of the CRISPR complex, while deactivated Cas9-bound VP 64

transcription factor was applied to activate the expression. *INS* mRNA was detected by qPCR and the insulin was identified using Hoechst dye.

Results: The transcription activator VP64 provided over 900x fold increase in *INS* activation comparing to a control. Expressed insulin in the *INS*-activated cells was successfully spotted with Hoechst dye.

Conclusions: Although the regulation mechanism of *INS* is complicated in nature, it turned to be feasible to activate it using CRISPR/Cas9 technology. Moreover, detecting the activated protein became also possible with Hoechst staining. These results can potentially bring light to relevant studies and also be of valuable addition to knowledge in new therapy development journeys for type 1 diabetes.

EP353 / #799

Topic: ***AS18 Other***

GLUCOSE MANAGEMENT IN PATIENTS WITH DIABETES DUE TO TOTAL PANCREATECTOMY

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Background and Aims: Glycemic control in patients with diabetes mellitus after total duodenopancreatectomy (TDPE) is a complex task requiring multidisciplinary team approach endocrinologist care at all stages of treatment.

Methods: To all patients CGM was installed. Intraoperative insulin therapy with ultra-short-acting for glycemia >10 mmol/l averaged 4-6 U every 4 hrs was administered. Postoperatively in ICU continuous intravenous insulin infusion was initiated with target glycemic level of 7-10 mmol/l. Later BB insulin therapy with glucose control by CGM was started.

Results: Initial dose of basal insulin is low- 0.08-0.1 U/kg. Mean prandial insulin dose is 0.5-0.6 U/kg/day. On average, 75,000-100,000 U of polyenzyme preparations was prescribed for each meal and 25,000 U for a snack (daily dose 300000-400000 U).

Conclusions: Insulin requirements after TDPE are lower than in T1DM even with sufficient enzyme support, and hypoglycemia is rapid and severe. Education of patients before surgery is obligatory with a focus on prevention and management of hypoglycemia. Higher glycemic goals are recommended. The use of CGM is optimal. For the exocrine insufficiency high doses of enzyme drugs are required.

EP354 / #518

Topic: ***AS18 Other***

IMPACT OF FASTING DURING RAMADAN ON CGM METRICS IN PATIENTS WITH TYPE 2 DIABETES TREATED WITH METFORMIN, SULFONYLUREA AND/OR BASAL INSULIN

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Background and Aims: Many Muslims with diabetes choose to fast during Ramadan which might impact their glycemic control. the aim of the study is to compare glycemic profiles before and during Ramadan fasting and analyse possible changes.

Methods: In this prospective cohort study, a professional blinded continuous glucose monitoring system (iPro2, Medtronic) was used before and during Ramadan to acquire data on time in range (primary outcome), time below range, frequency of hypoglycaemia, time above range, glucose variability and glucose management indicator (secondary outcomes) from a population of people with type 2 diabetes on sulfonylurea or basal insulin with or without metformin. Statistical comparison between Pre-Ramadan and Ramadan levels was undertaken using IMB SPSS Statistics (v.27). A p-value of <0.05 was considered statistically significant.

Results: 20 participants were included in this study with a female-to-male sex ratio of 1:1.22, a mean age of 60.7(±9.54) years, a mean diabetes duration of 11.1(±5.26) years and an average HbA1c of 7.4(±0.80) % at baseline. The study found a small statistically insignificant decrease in time in range in Ramadan compared with pre-Ramadan levels (-2.70 ± 24.66 %, $p = 0.63$). Ramadan fasting was not associated to any statistically significant changes in the analysed secondary outcomes in the studied population.

Conclusions: Ramadan fasting does not appear to have a negative effect on glycaemic control in people with T2DM on sulfonylurea and/or basal insulin.

EP355 / #481

Topic: ***AS18 Other***

HEALTH-RELATED QUALITY OF LIFE, GLYCEMIC CONTROL AND USE OF DIABETES TECHNOLOGY IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: The primary aim was to analyse the association between diabetes-specific health-related quality of life (HRQOL) and HbA1c in children and adolescents with type 1 diabetes. Secondary aims were to evaluate the associations between diabetes-specific HRQOL and the use of diabetes technology.

Methods: Children with type 1 diabetes and parents children completed the DISABKIDS diabetes-specific questionnaire (DDM-10) as part of the 2017 data collection for the Norwegian Childhood Diabetes Registry. The DDM-10 consists of two subscales—'Impact' and 'Treatment. We used linear regression models in order to evaluate associaions between the items and subscales as outcome variables, and HbA1c, age, sex, diabetes duration, insulin pump use, and continuous glucose monitoring (CGM) system use as predictor variables.

Results: Lower HbA1c measurements and male sex were associated with higher HRQOL scores on both DDM-10 scales in the age group 10-17 years, but not in children under 10 years. Parents gave lower HRQOL scores than children in the 10-17 age group. Insulin pump and CGM use were not significantly associated with HRQOL on the Impact and Treatment scale.

Conclusions: Low HbA1c and male sex are significantly associated with high HRQOL in children aged 10-17 with type 1 diabetes, but the use of diabetes technology is not positively associated with HRQOL. Differences in child- and parent-reported scores imply that parents might both over-and underestimate their child's HRQOL.

EP356 / #342

Topic: ***AS18 Other***

THE SIGNIFICANCE OF COEFFICIENT OF VARIATION AS A MEASURE OF HYPOGLYCEMIA RISK AND TIME IN RANGE IN REAL WORLD USERS OF THE MINIMED™ 780G SYSTEM

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Background and Aims: Advanced hybrid closed loop (AHCL) can achieve reduction in mean and standard deviation (STD) of blood glucose (BG) and mitigate hypoglycemia in people with type 1 diabetes. We assessed the significance of coefficient of variation (CV) as a predictor of hypoglycemia risk and time in range in real world users of the MiniMed™ 780G system in comparison to STD and Low BG index (LBGI).

Methods: Logistic regression was used to assess the contribution of CV to explain (1) hypoglycemia risk, measured as not reaching target <1% for time below range 54mg/dL (TBR54 < 1%), and (2) achievement of time in range 70-180mg/dL >70% (TIR >70%). Test (n = 7378) and validation (n = 3026) sets were used to identify the CV cut point that optimally discriminates between users meeting and not meeting TBR54 < 1%.

Figure 1. Coefficient of variation and its relationship with percentage time below 54 mg/dL

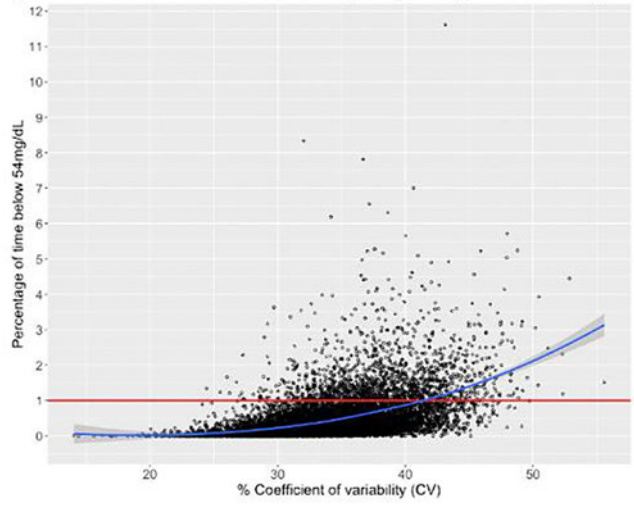

Table 1. Association with TBR54<1% target and with TIR>70% target

Association with target TB54<1%	odds ratio	95% conf interval
CV	0.51	(0.46 , 0.57)
Low BG index	0.045	(0.038 , 0.054)
In target before AHCL initiation (yes vs no)	3.65	(3.00 , 4.44)
STD	0.44	(0.40, 0.49)
Low BG index	0.031	(0.025, 0.037)
In target before AHCL initiation (yes vs no)	3.65	(3.00, 4.46)
Association with target TIR>70%		
	odds ratio	95% conf interval
CV	0.39	(0.37 , 0.41)
In target before AHCL initiation (yes vs no)	9.5	(8.00 , 11.29)
STD	0.05	(0.04 , 0.06)
In target before AHCL initiation (yes vs no)	3.45	(2.80 , 4.26)

Odds ratio in standard deviation units for Low BG index, coefficient of variation (CV) and standard deviation (STD). Given the large correlation between STD and CV (Spearman correlation=0.86), two separate models were adjusted for target TIR>70% and for target TBR54<1%.

Results: Although CV is related to TBR54 (Figure 1), the contribution of CV was the smallest on the odds of meeting TBR54 < 1% target (compared to being in target pre-initiation of AHCL and LBGI) and TIR >70% target (compared to STD) (Table 1). CV = 43.4% (95%CI: 42.9-43.9) is the cut point that optimally discriminates between users meeting and not meeting TBR54 < 1% target (correct classification rate = 87.2%).

Conclusions: With the MiniMed™ 780G AHCL system the impact of CV on hypoglycemia risk and TIR >70% is inferior to the variability metrics studied. To assess AHCL therapy, we recommend using TIR, TBR, mean BG and STD. In instances where CV is used to assess hypoglycemia risk, a cut point of 43% should be used instead of 36%.

EP357 / #142

Topic: ***AS18 Other***

MULTIVARIABLE GLUCOSE-INSULIN-PHYSIOLOGICAL VARIABLES SIMULATOR (MGIPSIM) FOR PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Simulation software can evaluate the performance of algorithms for automated insulin delivery and accelerate the development of artificial pancreas (AP) systems. Several simulators are available for Type 1 diabetes (T1D) that provide blood glucose and plasma insulin concentrations as outputs. As research on fully automated AP systems that can mitigate the effects of physical activities is progressing, simulators that provide estimates of physiological variables measured by wearable devices are needed. mGIPsim is the first simulator developed to provide wearable device variables as additional outputs for assessing the performance of fully automated multivariable AP systems.

Methods: Models describing the diverse glycemic responses to various types, intensities, and durations of physical activities are developed by incorporating new terms for endogenous glucose production (EGP) and glucose transfer and utilization. Additional signals such as heart rate, energy expenditure, accelerometer, skin temperature, and galvanic skin response are generated as outputs.

Results: mGIPsim improves simulation of glycemic dynamics during physical activities with mean absolute percentage error decreasing from 19.49 ± 5.87 to 16.11 ± 4.82 (p = 0.002). mGIPsim also generates additional signals that are useful in accelerating the development and clinical translation of multivariable AP systems. Crossover clinical experiments showed 13.33% increase in time spent in the target glycemic range for the multivariable AP system relative to the conventional glucose-only AP system.

Conclusions: mGIPsim is a novel software for *in silico* evaluation of fully automated multivariable AP systems that supplement the glucose measurements with additional signals to automatically mitigate the glycemic effects of physical activity.

EP358 / #357

Topic: ***AS18 Other***

8-HYDROXY-2-DEOXYGUANOSINE CONCENTRATION IN MEN WITH TYPE 1 DIABETES MELLITUS AND ALBUMINURIA

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Background and Aims: Currently, in all countries of the world there is a rapid increase in the incidence of diabetes mellitus (DM), which in fact becomes a global pandemic. Reactive oxygen species have a damaging effect on the structural components of the cell: lipids, proteins, enzymes and nucleic acids. 8-OHdG is a modified nucleoside base, a by-product of DNA damage. Therefore, the **aim** was to study the 8-hydroxy-2-deoxyguanosine concentration in men with type 1 diabetes mellitus and albuminuria.

Methods: A survey of 69 men with T1DM with unsatisfactory glycemic control was carried out. The patients were divided into two groups - with albuminuria A1 stage (A1) - 35 people and albuminuria A2 stage (A2) - 34 people. The concentration of the DNA destruction indicator - 8-OHdG in blood serum was measured using the commercial Assay Designs' DNA Damage ELISA Kit (USA). Enzyme immunoassay on a MultiSkan ELX808 microplate reader (Biotek, USA) was performed.

Results: Statistically higher values of 8-OH-2-deoxyguanosine were found in the group of patients with type 1 diabetes mellitus at stage A2 in comparison with the control by 1.33 times (p = 0.010). Comparison of the results between stages A1 and A2 showed increased values of 8-OHdG by 1.28 times (p = 0.010) in patients of group A2.

Conclusions: In men with T1DM, A2 study albuminuria, there are higher values of the oxidative damage DNA parameter, which can be used to develop potential strategies for the prevention and early therapy of diabetic nephropathy.

EP359 / #926

Topic: ***AS18 Other***

DIAGNOSIS OF COMORBIDITY IN PATIENTS WITH CHRONIC CARDIORENAL SYNDROME

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Background and Aims: the Charlson Comorbidity Index excludes patients with the initial stages of CKD, which make up the main percentage in the older age group population. Aim was to study the predictive capabilities of the Charlson comorbidity index when included as a ''renal'' parameter of CKD with an estimated glomerular filtration rate (eGFR) <60 ml/min/1.73 m2 in patients with chronic cardiorenal syndrome.

Methods: 472 patients (241 women and 231 men, mean age 69.6 ± 7.3 years) with stable cardiovascular pathology of elderly and senile age were examined. CKD was diagnosed according to the KDIGO Guidelines (2012). When calculating the Charlson comorbidity index, the parameter ''moderate, severe kidney disease'' additionally included CKD with eGFR <60 ml/min/1.73 m2 (invention patent RU 2706975 C1). The follow-up period was 12 months, the primary endpoint was overall mortality.

Results: CKD was diagnosed in 302 (63.9%) of 472 elderly and senile patients. CKD with eGFR less than 60 ml/min/1.73 m2 was observed in 277 (91.7%) of 302 patients with CKD, with the majority having stage 3a (185; 61.3%). High comorbidity (more than 6 points in the modified Charlson IC) is associated with the risk of death within a year in patients with stable cardiovascular pathology (RR 4.7; 95% CI 1.4-15.2; p = 0.01 against RR 1.6; 95% CI 1.08-3.35; p = 0.02 with original comorbidity index).

Conclusions: The use of the modified Charlson comorbidity index, which takes into account the presence of CKD with eGFR <60 ml/min/1.73 m2, makes it possible to more accurately assess the prognosis in elderly patients with chronic cardiorenal syndrome.

EP360 / #929

Topic: ***AS18 Other***

ADHERENCE TO LIFESTYLE MODIFICATION IN PATIENTS WITH CARDIOVASCULAR COMORBIDITY: THE ROLE OF DIABETES MELLITUS

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Background and Aims: Adherence to lifestyle modification is a leading factor in the treatment of patients with cardiovascular comorbidity. The aim of the study was to investigate the effect of diabetes mellitus on adherence to lifestyle modification in elderly comorbid patients.

Methods: 344 patients with stable cardiovascular pathology (171 women and 173 men, mean age 69.5 ± 7.6 years) were examined. Comorbidity of patients was assessed using the Charlson Comorbidity Index (CI), including age-corrected ones.To determine the level of adherence to compliance with recommendations for lifestyle modification, an integral indicator of adherence to a healthy lifestyle was assessed.

Results: In the presence of diabetes mellitus (100 (29%) patients with cardiovascular pathology out of 344 patients surveyed), high and satisfactory adherence to lifestyle recommendations was more often noted compared with patients with cardiovascular pathology without diabetes mellitus: 61 (61 %) and 23 (15.2%), respectively, $\chi 2 = 56.6$; p < 0.0001. In the group of elderly and senile patients with CKD, the presence of diabetes mellitus was associated with high and satisfactory adherence to lifestyle recommendations (OR 2.39; 95% CI 1.29–4.42; p = 0.005).When conducting a multivariate regression analysis, which, as a dependent variable, included high and satisfactory adherence to recommendations for lifestyle modification, the factor that has the greatest impact on adherence to non-drug

therapy in elderly and senile patients with stable cardiovascular pathology and CKD had diabetes mellitus (OR 2.38; 95% CI 1.23–4.61, p = 0.009) (for the $\chi 2$ model = 20.2, p = 0.0002)

Conclusions: The presence of diabetes mellitus is the most significant predictor of high and satisfactory adherence to lifestyle recommendations in elderly and senile patients with cardiovascular comorbidity

EP361 / #931

Topic: ***AS18 Other***

METABOLIC STATUS OF ELDERLY AND SENILE PATIENTS WITH CARDIORENAL SYNDROME

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Background and Aims: Metabolic disorders worsen the prognosis of patients with cardiovascular comorbidity and chronic kidney disease. The aim of the study was to investigate the metabolic status in elderly patients with chronic cardiorenal syndrome.

Methods: 227 elderly and senile patients (146 women and 81 men, mean age 71.2 ± 7.3 years) with swith cardiovascular disease and CKD were examined. CKD was diagnosed according to the KDIGO Guidelines (2012). Metabolic phenotype, presence of abdominal obesity and metabolic syndrome were assessed.

Results: The majority of elderly and senile patients with stable cardiovascular pathology and CKD (179; 78.9%) had a metabolically unhealthy nutritional status phenotype. Abdominal obesity was more common in women ($\chi 2 = 9.09$, p = 0.003); the ratio of waist circumference to height, multiplied by 100 (WT/height * 100), was greater in women than in men (p = 0.01). Half of the elderly and senile patients with stable cardiovascular pathology and CKD (104; 45.8%) had a metabolic syndrome. When assessing the i Lipid Accumulation Product Index, elderly and senile women with CKD showed a significant increase compared to men: 53.24 (33.58; 83.70) and 32.75 (19.18 ;56.88) cm*mmol/l, respectively, p < 0.0001.Elderly and senile patients with stable cardiovascular pathology and CKD had higher triglyceride levels compared to patients without CKD: 1.2 (0.87; 1.71) and 1.01 (0.5; 1.78) mmol /l, respectively, p = 0.02. When analyzing the metabolic status, depending on the stage of CKD, no differences were observed.

Conclusions: Elderly and senile patients with chronic cardiorenal syndrome are characterized by a metabolically unhealthy phenotype.

EP362 / #194

Topic: ***AS18 Other***

DISORDERED EATING BEHAVIORS IN BRAZILIAN PERSONS WITH TYPE 1 DIABETES: FREQUENCY, INSULIN OMISSION, DEPRESSIVE SYMPTOMS, BODY SHAPE CONCERNS, AND CLINICAL OUTCOMES.

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Background and Aims: To Investigate the frequency and clinical, psychological and psychiatric aspects of Disordered Eating Behaviors (DEBs) in Brazilian People with Type 1 Diabetes (PWT1D).

Methods: Two hundred and seventeen PWT1D aged 13-39 years and T1D diagnosis for 1 year completed the Diabetes Eating Problem Survey Revised-BR (*DEPS-RBR*), the Hospital Anxiety and Depression scale, and another questionnaire. Data were collected through google forms. Participants were divided into 2 groups, according to *DEPS-RBR* score (≥20, and <20). Descriptive analysis were made. Chi-Square or Mann-Whitney tests were used to compare groups, and a multivariate linear regression was performed (stepwise). Significance level was 0.05.

Results: Eighty nine % were female, age 28.5 (±6.83) years. T1D duration 13.5 (± 9.0) years, Body Mass Index (BMI): 24.4kg$^{/m2}$ (± 4.4), A1C: 7.4% (± 1.7). Sixty four % had DEPS-RBR score ≥20. DEBs' risk was associated with fixed doses of insulin (**p = 0.035**), a lower self-reported glucose monitoring (**p = 0.006**), higher anxiety (**p < 0.001),** family member with ED (**p = 0.039),** being overweight (**p = 0.025**), and diabetic neuropathy (**p = 0.016).** Higher DEPS-RBR scores were associated with: insulin restriction and omission (**p < 0.001),** comparison of one's body with other people's bodies (**p < 0.001**), family comments about one's body (**p = 0.039**), depressive symptoms (**p < 0.001**), BMI (**p = 0.007),** A1C (p = **0.001),** income above ten salaries (**p = 0.004**); and female sex (**p < 0.001**).

Conclusions: This study demonstrated a high frequency of DEBs. Changes in Insulin doses, family and shape body concerns, depressive symptoms, A1C, higher income, and female sex were associated with high DEBs scores. The detection of PWT1D at risk for DEBs is crucial for early therapeutic interventions.

EP363 / #91

Topic: ***AS18 Other***

EFFECT SIZE PREDICTION INTERVAL OF CV DEATH OR HHF IN PATIENTS WITH HFPEF: A META-ANALYSIS

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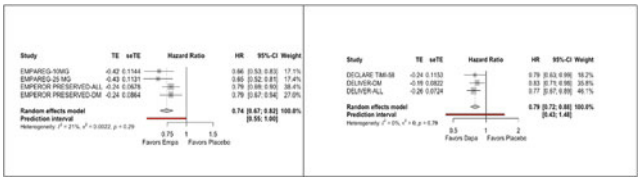
Background and Aims: The composite of cardiovascular death (CV death) or hospitalization due to heart failure (hHF) is firmly established as far as cardiovascular outcomes trial dealing with heart failure. The mean effect size of CV death or hHF was equally impressive for empagliflozin as well as dapagliflozin. However the spread of the effect size as a distribution of p-value has not been investigated. This meta-analysis attempts to match the confidence interval of mean effect size with that of its predictive interval.

Methods: A database search was conducted using the Cochrane library to identify relevant citations. Analysis was conducted using the RevMan 5.4.1 and the R studio RStudio (2022.07.1, Build 554). Hazard ratio was used to determine the mean effect size.

Results: A pooled population of 36,431 patients from four citations were included for analysis. The Cochrane risk of bias was used to assess quality of the studies. There was a significant 21% reduction in CV death or hHF with dapagliflozin (HR: 0.79, 95% CI 0.72-0.88), and a 26% reduction with empagliflozin



(HR:0.74, 95% CI 0.67-0.82). However the prediction interval of the distribution of effect size was more impressive with empagliflozin in comparison to dapagliflozin (0.55-1.00 versus 0.43-1.48).

Conclusions: Both empagliflozin and dapagliflozin have significant impact on reduction of CV death or hHF in patients with HFpEF. However, the prediction interval is more impressive with the use of empagliflozin.

EP364 / #867

Topic: ***AS18 Other***

RETROSPECTIVE ANALYSIS OF CGM AND FGM DATA OF PATIENTS AFTER PANCREATECTOMY WITH ISLET AUTOTRANSPLANTATION AND PATIENTS AFTER PANCREATECTOMY ALONE

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Background and Aims: Patients after total pancreatectomy have extremely labile form of diabetes, due to lack of insulin and glucagon, irregular carbohydrate absorption in the gastrointestinal tract, and impaired gastrointestinal hormones secretion. Autotransplantation of pancreatic islets offers a unique possibility to prevent this therapeutically challenging type of diabetes.

Methods: To assess the impact of autotransplantation on diabetes compensation we performed a retrospective analysis of the available data from continuous and flash glucose monitoring (covering 12 months) in a cohort of patients after autotransplantation (n = 9) and patients after total pancreatectomy without autotransplantation treated in our centre (n = 9).

Results: All of the patients after autotransplantation had detectable levels of C-peptide, 3 do not need insulin therapy, and others require small doses. They had significantly better diabetes compensation compared to the cohort without autotransplantation (glycated haemoglobin 50.4 ± 8 mmol/mol vs. 66.2 ± 13 mmol/mol, p = 0.036; average glucose levels 7.4 ± 1.4 mmol/l vs. 10.2 ± 2.1 mmol/l, p = 0,004) and spent significantly more time in recommended range of glucose levels 3.9-10 mmol/l (average time in range 84 ± 15 % vs. 51.4 ± 19 % p = 0.0017), less time in hyperglycaemia and hypoglycaemia, with lower glycaemic variability (coefficient of variation 25 ± 5 % vs. 37 ± 5 %, p = 0.006) and required lower daily doses of insulin (0,25 ± 0,2 IU/kg vs 0,49 ± 0,2 IU/kg, p = 0.02).

Conclusions: Islet autotransplantation can preserve endogenous insulin and glucagon secretion and enable more stable glucose control. Therefore it should be considered in all patients referred to pancreatectomy for benign causes.

EP365 / #681

Topic: ***AS18 Other***

RACIAL-ETHNIC DISPARITIES IN HBA1C BY BMI CATEGORY IN TYPE 1 DIABETES POPULATION AT AN ACADEMIC MEDICAL CENTER

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Background and Aims: Hispanic and non-Hispanic Black (NHB) individuals with type 1 diabetes (T1D) often have lower glycemic control (i.e., higher average HbA1c) when compared to their non-Hispanic White (NHW) counterparts. However, the extent of this disparity is unclear when accounting for BMI. Using the T1D population (ages ≥14) of an academic medical center, we aimed to better understand how glycemic outcomes (using HbA1c) compare between the three most representative racial/ethnic groups by different BMI categories.

Methods: This retrospective study used de-identified data from electronic medical records (TriNetX, LLC) to analyze the relationship between race/ethnicity and HbA1c in different BMI groups of patients with T1D. HbA1c values were compared using ANOVA and Tukey HSD tests for overall and between group comparisons, respectively.

Results: Racial-ethnic differences in HbA1c were significant among individuals within the Normal ($p < 0.000$) and Overweight BMI groups ($p = 0.039$) (see Table 1). Specifically, differences in the comparison of NHW and NHB individuals were significant in the Normal ($p < 0.000$) and Overweight ($p = 0.039$) categories. HbA1c differences between the three racial-ethnic groups were not significant for individuals in the Obese category.

Conclusions: Disparities in HbA1c between NHW and NHB individuals with T1D appear to be more prominent in individuals with Normal and Overweight BMIs and less pronounced in individuals with Obesity. Future research should investigate specific confounding factors for the decreased racial/ethnic disparities in glycemic control for individuals with Obesity.

Table 1. HbA1c in Different Race/Ethnic Groups by BMI Category

BMI Group	Race/ethnicity	N	Percent	Mean	SD	Range	F	Difference between groups (p value)
Normal	NHW	410	85.4	8.24	1.94	4.6 – 13.8	-	NHW vs NHB ($p < 0.000$)*
(18.5-25.0 kg/m²)	NHB	50	10.4	9.47	2.68	4.2 – 15.2	-	NHW vs H (ns)
	H	20	4.2	9.21	2.16	6.7 – 14.0	-	NHB vs H (ns)
	Total	480	100	8.40	2.04	4.2 – 15.2	9.74	Between all ($p < 0.000$)**
Overweight	NHW	330	86.8	7.88	1.77	4.5 – 14.9	-	NHW vs NHB ($p = 0.039$)*
(18.5-25.0 kg/m²)	NHB	30	7.9	8.78	2.86	4.3 – 15.1	-	NHW vs H (ns)
	H	20	5.3	8.27	2.58	5.5 – 12.3	-	NHB vs H (ns)
	Total	380	100	7.94	1.85	4.3 – 15.1	3.34	Between all ($p = 0.039$)**
Obese	NHW	230	82.1	8.00	1.60	4.1 – 14.1	-	NHW vs NHB (ns)
(>25.0 kg/m²)	NHB	30	10.7	7.63	1.72	5.6 – 12.7	-	NHW vs H (ns)
	H	20	7.1	7.94	1.59	5.2 – 11.8	-	NHB vs H (ns)
	Total	280	100	7.98	1.61	4.1 – 14.1	0.70	Between all (ns)

Significance level at $p = 0.05$. *Significant differences as per Tukey HSD post-hoc. ** Significant differences as per ANOVA.

EP366 / #538

Topic: ***AS18 Other***

EFFECT OF SACCHARIN AND CYCLAMATE LONG TERM CONSUMPTION ON BIOCHEMICAL PARAMETERS OF HEALTHY INDIVIDUALS AND PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: Previous studies on saccharin and cyclamate were either limited to experimental animals or lacking evaluation of their long-term consumption effects in humans. The study evaluated the effect of consumption time and dose of artificial sweeteners consumed by healthy individuals and by patients with type 2 diabetes mellitus.

Methods: Healthy and diabetic individuals were classified into two groups based on whether they consumed sweeteners or not. Sweetener consumers were classified according to the amount of sweetener consumed per day: <5 tablets/day, 5-10 tablets/day, >10 tablets/day. Sweetener consumers were also classified according to time of sweetener consumption: <5years, 5-10 years and >10 years. Oxidative stress biomarkers such serum catalase activity, peroxynitrite, ceruloplasmin and malondialdehyde concentrations were determined by spectrometry. Anthropometric parameters as body mass index and waist circunference, besides systolic and diastolic blood pressure were evaluated. Biochemical parameters including glycated hemoglobin, fasting blood glucose concentration, creatinine concentration, alanine transaminase activity and lipid profile were also analysed.

Results: Saccharin and cyclamate increased HbA1C (+11.16%), MDA (+52.38%), TG (+16.74%), LDL (+13.39%) and TC/HDL (+13.11%) in healthy volunteers. Diabetic patients consuming sweetener showed increased FSG (+17.51%), ceruloplasmin (+13.17%) and MDA (+8.92%). Diabetic patients showed a positive correlation between the number of tablets consumed per day with FSG and serum creatinine. Positive correlation was also found between the duration of sweetener consumption and FSG as well as TG.

Conclusions: Consumption of saccharin and cyclamate affected biochemical parameters related to metabolic functions in a time and dose dependent manner and appear to increase oxidative stress in healthy and diabetic type 2 patients.

EP367 / #774

Topic: ***AS18 Other***

MULTIVARIATE TIME SERIES SYNTHETIC DATA GENERATION IN DIABETES CARE

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Background and Aims: Current treatments in diabetes care generate vast amounts of personal information which are highly valuable for numerous applications (e.g., software testing, machine learning). Data anonymization is a common approach for dealing with such sensitive information. However, recent advances in deep learning have raised concerns of re-identification. A promising alternative consists of generating statistically equivalent synthetic data clones which ensure a high degree of privacy. This work aims to generate individual high quality multivariate time-series synthetic data from commonly gathered data in diabetes care.

Methods: Three generative models were evaluated, including a Gaussian Copula model and two Generative Adversarial Networks models. The publicly available OhioT1DM dataset (n = 12; 6 weeks) was selected for demonstration purposes. Continuous Glucose Monitoring (CGM), insulin bolus, and carbohydrate intake were selected as target signals. To evaluate the synthetic data fidelity, diversity and generalization, 43 statistical and diabetes management metrics were employed. Utility was assessed by training a glucose prediction model with both, real data and synthetic data, and then testing the two models on real data.

Results: The Gaussian Copula model proves to perform best. Based on the selected metrics to evaluate data fidelity, the resulting synthetic dataset was statistically equivalent to its real counterpart ($p > 0.05$). Mean cross-correlation (<0.5) and visual inspection demonstrated a good degree of generalization. When trained on synthetic data, the performance of the glucose prediction model was equivalent to training on real data ($p > 0.3$).

Conclusions: It is possible to generate high-quality usable multivariate time-series synthetic data in diabetes care.

EP368 / #683

Topic: ***AS18 Other***

EFFECTS OF KB-R7943 ON DEPRESSION-LIKE BEHAVIOR IN A RAT MODEL OF STREPTOZOTOCIN-INDUCED DIABETIC NEUROPATHIC PAIN

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Background and Aims: It has been known that the glutamatergic system is involved in the pathogenesis of diabetic neuropathy. Scientific studies present that KB-R7943 compound, a Na+/Ca2+ exchanger (NCX) inhibitor, possesses antinociceptive effectiveness in animal neuropathic pain models. The aim of the present work was to study the effects of KB-R7943 on depression-like behavior in a rat model of streptozotocin-induced diabetic neuropathic pain.

Methods: Diabetis was induced by a single injection of streptzotocin (55 mg/kg). After the development of neuropathic pain, KB-R7943 was administered by oral gavage at two doses: 5 mg/kg and 10 mg/kg for 10 days. Amitryptiline (AMT) (10 mg/kg) (as an NCX blocker) was used as a positive control applied the same route as the tested drug. Behavioral tests used to test depression: forced swimming test (FST) and sucrose splash test (SSPL).

Results: Rats with neuropathic pain showed depressive behavior indicated with decreased grooming in the SSPL and increased immobility time spent in the FST, which was overturned by amitryptiline treatment. While treatment with KB-R7943 at a dose 5 mg/kg was ineffective in both tests, 10 mg/kg KB-R7943 reversed the decreased immobility time in the FST to control level. Although it was not statistically significant, the NP-KB-R7943-10mg group showed a tendency of increasing the grooming time in the SSPL.

Conclusions: The present data suggest that chronic KB-R7943 treatment can positively affects depression in a rat model of streptozotocin-induced diabetic neuropathic pain. **Acknowledgments:** This work was supported by the National Science Fund of Bulgaria (research grant # KP-06-Russia/25).

EP369 / #328

Topic: ***AS18 Other***

INEQUALITIES IN ACCESS TO DIABETES TECHNOLOGIES IN CHILDREN BY THE SOCIOECONOMIC LEVELS OF FAMILIES: A MULTICENTER, CROSS-SECTIONAL STUDY

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Background and Aims: Access to diabetes technologies is limited in developing countries. This study investigates socioeconomic factors related to technology access for families with children with T1D in Turkey where there is no reimbursement for diabetes technologies.

Methods: In this multicenter study, data on technology use, HbA1c, living arrangement, education and occupation status of parents, household income, and diabetes-related financial loss of families were collected through a questionnaire from 9 diabetes centers and online diabetes network in 65 cities of Turkey. The frequency of technology use was analyzed across the socioeconomic development ranking of the provinces.

Results: Of 882 families, 19.4% had insulin pump, 49.7% had CGM. While technology use (pump and/or CGM) provided lower HbA1c levels (7.14%vs.8.07%;p<0.001), technology using families had higher household income ($785vs.$370; p<0.001), less siblings (1vs.2;p<0.001), and less siblings with chronic medical condition (8.5%vs.17.3%;p<0.001)(**Table 1**). In logistic regression, parents with a university degree or above had higher technology adoption compared to parents who have less than a high school degree (For mothers,OR = 4.03[95%CI 2.45–6.62]; p<0.001) (For fathers, OR = 3.17[95% CI 1.91–5.26]; p<0.001) (**Figure 1**). Living in the lowest socioeconomic region was associated with lower technology adoption compared to the highest ranked region (OR = 0.20[95%CI 0.14–0.30];p<0.001). Technology users reported more ''high/severe financial loss'' (64.4%vs.49.1%;p<0.001) and less ''no/minimal financial loss'' (6.9%vs.19.8%;p<0.001) compared to non-users. Household income was inversely correlated with financial difficulty score(r = -0.405;p<0.001).

Conclusions: Although this study does not represent Turkish population, there are inequalities in access to diabetes technologies according to socioeconomic status. Children who live in a more developed city with fewer siblings, and working parents with higher education have better opportunities to access diabetes technologies.

Table 1. Characteristics of children and families (n=882)

	Technology use (n=477)	No Technology use (n=405)	p-value	Pump use (n=171)	No pump use (n=711)	p-value	CGM use (n=438)	No CGM use (n=444)	p-value
HbA1c (Mean)	7.14%	8.07%	<0.001	7.26%	7.58%	0.004	7.07%	8.06%	<0.001
Age at the diagnosis in years (mean)	6.53	7.64	<0.001	6.50	7.17	0.043	6.48	7.59	<0.001
Diabetes duration in years (mean)	3.59	3.86	0.130	5.37	3.32	<0.001	3.32	4.10	<0.001
Household Income ($) (Mean)	783	370	<0.001	747	556	0.002	807	383	<0.001
Number of siblings (Median (IQR))	1 (0-1)	2 (1-3)	<0.001	1(0-1)	1(1-3)	<0.001	1(0-1)	1(1-2)	<0.001
Sibling with a chronic medical condition	8.5%	17.3%	<0.001	10%	13.2%	0.293	7.7%	17.1%	<0.001
Living arrangement • With both parents • With single parent	%94.1 %5.9	%93.8 %6.2	0.850	93.6% 6.4%	94.1% 5.9%	0.795	94.1% 5.9%	93.9% 6.1%	0.928

Household income was converted from Turkish Lira to U.S. Dollar according to October 2022 currency rates.

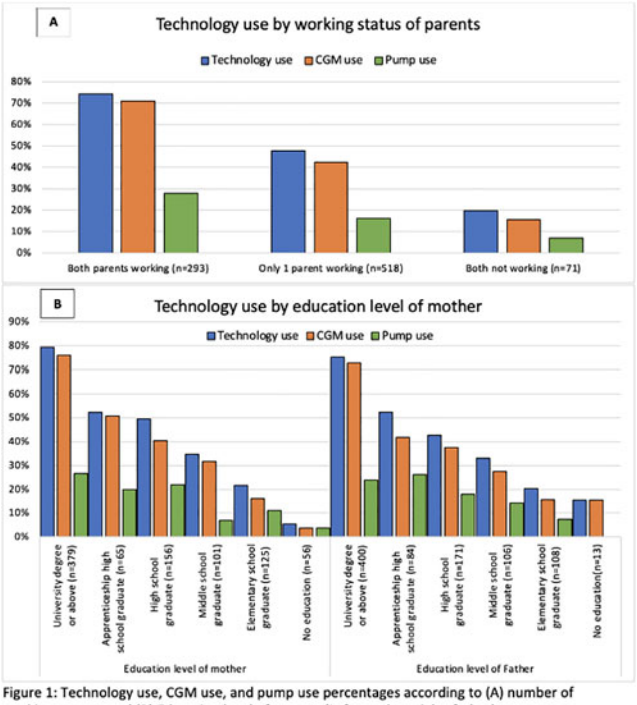

Figure 1: Technology use, CGM use, and pump use percentages according to (A) number of working parents and (B) Education level of parents (Left: mother, right: father).

EP370 / #675

Topic: ***AS18 Other***

PIZZA PERFECT BLOOD SUGARS? A QUALITATIVE EVALUATION OF THE IMPACT OF MEAL-TRACKING AND PEER SUPPORT FOR TYPE 1 DIABETES SELF-MANAGEMENT

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Background and Aims: People with T1D need to consider roughly 42 different factors that can influence BG levels in different ways. They need to constantly reevaluate different impacts in their day-to-day life, creating a vast mental load. PwD often regard medical experts' knowledge as insufficient for management and instead, value the experiential knowledge of peers. It has been called for specific intervention methods in their daily lives to improve self-management. In this study, *meala* was used as such an intervention, combining meal tracking and peer support to evaluate self-management.

Methods: 15 participants ate the same pizza twice. Inbetween, a focus group interview was conducted during which participants exchanged experience and knowledge. Using *meala* and a self-reported pre-post-survey, they were asked to indicate their self-management and whether they had adjusted their therapy in any way.

Results: On average, participants estimated carbohydrates more accurately in the second intervention. All participants reported an adjustment in self-management. 10 participants reported an improvement in their CGM data. Participants emphasized that using their own data, they were able to dare to estimate the correct amount of carbs and give the right amount of insulin.

Conclusions: Tracking one's own diabetes management repeatedly and using peer support can lead to behavioral adjustments and have positive impact on therapy outcomes in PwD. Multiple factors effect self-management outcomes and PwD need experiential expertise in order to evaluate it daily. Peer support and meal tracking were identified as important factors in the evaluation of self-management. More research should focus on providing people with those tools to improve health outcomes.

EP371 / #99

Topic: ***AS18 Other***

GLYCEMIC CONTROL DURING THE GREATEST HEATWAVE IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Effect of climate change and heatwaves over glycemic control is unknown in people with type 1 diabetes (PwT1D). This study aimed to assess the achieved glycemic control in PwT1D during the greatest heatwave on Spanish history (9^{th}-26^{th} July 2022).

Methods: Cross-sectional study from all adult PwT1D in Castilla-La Mancha (south-central Spanish region) using intermittently scanned continuous glucose monitoring (isCGM). Glycometric data from the last two weeks were anonymously gathered from Libreview website (Abbott, IL, USA).

Results: Data from 2701 patients were analyzed. Mean age was 44.2 yrs. (range 18-87 yrs.). Scan frequency was 10.8 ± 6.9 scans/day with an isCGM adherence of 88.2%. We observed the following glycometric index: Time above range (TAR) >13.9 mmol/L (250 mg/dL) 11.1%, TAR >10.0 mmol/L (180 mg/dL) 34.1%, time in range (TIR) 3.0-10 mmol/L (70-180 mg/d) 61.4%, time below range (TBR) <3.9 mmol/L (70 mg/dL) 4.6%, TBR <3 mmol/L (54 mg/dL) 1.9% and coefficient of variation percentage (CV) of interstitial glucose 36.2%. All the International Consensus on Time in Range (ICTR) goals were attained by 10.8% of the patients. Glucose management index was 55.2± mmol/mol (7.2 ± 0.8%). Patients spent 88.7 min/day in hypoglycemia and suffered from 0.6 ± 0.5 hypoglycemic events/day.

Conclusions: For the first time, we described glycemic control during a heatwave in PwT1D. Only nearly one in ten patients fulfilled the ICTR goals. Effect of climate change over health will be a major issue in the following years.

EP372 / #542

Topic: ***AS18 Other***

SHOULD YOUTH COMPETITIVE ATHLETES WITH T1DM BE TREATED DIFFERENTLY?

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Background and Aims: In 2021 we established a specialized clinic for youth with type 1 diabetes (T1DM), engaged in competitive sports, focusing on their specific needs including**:** competitive sport- oriented diabetes education, individualized treatment and nutritional requirements. Hereby we describe their clinical and occupational characteristics in a free-life setting.

Methods: We conducted a retrospective study between 2020 and 2021 of 36 patients with T1DM , who met CYA criteria. Demographic, clinical, biochemical, nutritional and exercise characteristics were evaluated. Glycemic control was compared to an age and sex-matched cohort of 864 non-athletic peers with T1D.

Results: HbA1C levels were lower in CYA's compared to non-athletic peers (7.4% vs 7.8 %, $p = 0.071$) with lower mean glucose levels in male CYA's vs. female CYA's (159 mg/dl vs 170 mg/dl, $p = 0.027$)**.** In the CYA group average time in range was 55%, with time above range of 42%, therefore not meeting recommended glycemic target criteria. Average carbohydrate consumption was 3 gr/kg/day. More female than male athletes engaged in weight-dependent sports (42% vs 19%, $p = 0.04$),

with no difference in training time (7.5hours/week) or mean training intensity (7.5 METS/hour). BMI z-score (0.637 ± 0.67SD), fat mass index z-score (-1.16 ± 1.2SD) and lean body mass index z-score (1.11 ± 0.54SD) revealed no difference between genders.

Conclusions: Personalized, gender and sport specific management strategies, which integrate glycemic parameters and body composition analysis, require routine adjustment, in order to improve glycemic control and address carbohydrate consumption. Higher than expected rates of hyperglycemia elicit further investigation. Larger scale studies are needed to assess the effects of intensive training on glycemic control in youth with T1D.

EP373 / #370

Topic: ***AS18 Other***

AGE AND SEX-RELATED CHARACTERISTICS OF OBESITY IN TYPE 1 DIABETIC SUBJECTS: THE ITALIAN AMD ANNALS INITIATIVE

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Background and Aims: To analyze potential age- and sex-differences in the prevalence of obesity, and its association with metabolic characteristics, cardiovascular risk factors and chronic complications, in adult subjects with type 1 diabetes (T1D) participating to the AMD Annals Initiative, in Italy

Methods: Major clinical variables, process indicators and outcomes were evaluated in 37.436 T1D subjects (54.7% men, 45.3% women) who attended 282 Italian diabetes clinics during 2019.

Results: Mean BMI values were higher in T1D men than in women, but the prevalence of obesity was higher in women, especially classes II and III-obesity (BMI ≥35 Kg/m2): 4.0% in women vs. 2.3% in men. The prevalence of obesity increased with age in both genders, with some sex-differences, more evident among the youngest groups (<35 years), where obesity prevailed in women. Obese women were older than men, and they showed higher values of HbA1c, total cholesterol, LDL- and HDL-cholesterol. Obese T1D subjects did not reach recommended CV risk factors targets, in spite of being more treated when compared to non-obese ones, irrespective of sex. Cardiovascular events were more frequent in obese men than women. Process indicators, outcomes and quality of care were overall worse in obese vs non-obese subjects, irrespective of sex.

Conclusions: Obesity is frequent among adult subjects with T1D, with some sex- and age-differences. In particular, class II and III obesity are more frequent in women, reaching 5% after >65 years. Obesity is associated with major cardiometabolic risk factors and a lower quality of care in both genders.

EP374 / #604

Topic: ***AS18 Other***

DRIED BLOOD SPOT GLYCATED HAEMOGLOBIN; AN ALTERNATIVE METHOD FOR MONITORING GLYCAEMIC CONTROL IN PAEDIATRIC PATIENTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Glycated haemoglobin (HbA1c) levels correspond to long-term glycaemic control in Type I Diabetes Mellitus. Elevated HbA1c levels are linked to the adverse effects of Diabetes. HbA1c levels in paediatrics are measured using point of care or whole blood samples. Dried Blood Spots (DBS) are less invasive blood collection devices and were assessed as an alternative method for monitoring HbA1c levels in paediatrics.

Methods: Paediatric patients having POC HbA1c measured at diabetic appointments in University Hospital of Limerick were recruited. DBS HbA1c samples were collected and stored at 4°C ($n = 33$), RT ($n = 27$) or under both temperature conditions ($n = 25$) for four days, before HbA1c extraction and measurement on the Tosoh HLC-723®G11 analyser. Statistical analysis included: linear regression, Bland-Altman plots and Pearson's correlation coefficient, precision, bias using external quality control material, and stability of DBS HbA1c in days.

Results: POC and DBS HbA1c concentrations at 4°C and RT were strongly correlated with $r = 0.695$ and $r = 0.845$, respectively, and had a linear relationship ($p < 0.05$). Under different temperature conditions, T1DM DBS HbA1c samples were stable ≤6 days, had precision ≤7.5%, increased over time (≤+12.5%). Bias ranged from -3.3%-4.8%. In contrast, non-diabetic DBS HbA1c samples were unstable, HbA1c concentrations changed from non-diabetic to diabetic levels by day four storage.

Conclusions: DBS HbA1c performance was better at 4°C than at RT. DBS HbA1c is unsuitable for use in non-diabetics. DBS HbA1c is feasible for the monitoring of T1DM in paediatric patients, however is dependent on the age of the sample (<6 days) and storage temperature, ideally 4°C.

EP375 / #316

Topic: ***AS18 Other***

DYNAMIC CHANGES IN THE LEVEL OF EXHALED ACETONE IN CHILDREN WITH TYPE 1 DIABETES MEASURED WITH A PORTABLE NONINVASIVE PHOTOCHEMICAL SENSOR

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Background and Aims: In diabetic patients acetone level in the blood is usually very low. The introduction of any simple and accurate non-invasive methods for acetone measurement may have clinical applications. Aim of the study was to find the correlation between blood glucose level and breath acetone concentration.

Methods: Children aged 7-18 with the type 1 diabetes and using Medtronic CGM with Enlite sensors were enrolled from the Children's Clinic of Tartu University Hospital. The local Ethics Committee approved the study, patients and their caregivers signed the informed consent. Patients filled sample bags with 5 non-forced exhalations. Acetone concentration in the bag was measured with the Solvax photochemical sensor.

Results: 29 patients were participating in the study. The blood sugar ranged from 3.8 to 16.0 mmol/l. Correlation curve of the breath-acetone *vs.* the CGM blood-sugar data showed two linear segments over the blood-sugar ranges of 3.8-9.2 mmol/l and 10.0-12.0 mmol/l with the correlation coefficients of $R^2 = 0.73$ and $R^2 = 0.66$ correspondingly. In the sub-group of patients with blood sugar over 13.0 mmol/l only 4 patient were presented and their where excluded from the analysis.

Conclusions: Acetone detected in the exhaled air has shown sufficient to good correlations with the blood-sugar concentration. For a better understanding of the demonstrated correlations, more statistical data is needed.

EP376 / #141

Topic: ***AS18 Other***

GROWTH STATUS OF ADOLESCENTS WITH DIABETIC TYPE 1 AND ITS ASSOCIATED FACTORS

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Background and Aims: childhood and adolescent growth is a good indicator of general health, and attaining normal growth speed is one of the goals of treating diabetic children. Diabetes mellitus type 1 (T1DM) is well known to negatively affect growth. The aim of this study is to assess the growth parameter of diabetic adolescents and related factors.

Methods: The study was conducted at Shaheed Layla Qasim Diabetic Center in Erbil City during June 2022. 160 diabetic adolescent cases were enrolled as samples for the study. Growth was assessed by taking weight and height then plotted on Centers for Disease Control (CDC) growth charts, and a blood sample to was taken to determine glycemic control (HbA1C%).

Results: 160 children participated with mean age of 13.96 ± 1.8. Mean HbA1C was 9.9 ± 2.18 %. 73.8% had poor glycemic control. 33.8% of adolescents were stunted (stature-for-age) and 56.3% of them were underweight (BMI-for-age). There was a significant association between stunting and age group also underweight (BMI-for-age) with age and gender.

Conclusions: one-third of diabetic adolescents were of short stature, and most of them were underweight.

EP377 / #527

Topic: ***AS18 Other***

CAN YOU HEAR ME? DIABETES, NUTRITION, COMMUNICATION AND HEARING LOSS

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Background and Aims: Diabetes and hearing loss. Reviewing the pathophysiology, assessment needs, impact of hearing loss on the person with diabetes, identification of hearing loss, building infrastructure and referrals, the need for hearing rehabilitation and treatment, communication-strategies, person-centered decision making and goal setting to improve quality of life, the impact of time in range (TIR) and hyperglycemia and the role of the provider the full care team!

Methods: 1. Assess the person with diabetes for hearing loss 2. Build community relationships with the audiologists being referred to and make referrals 3. Treat hearing loss with muliple treatment options 4. Continue to follow, monitor and assess levels of hearing loss and treatment plans

Results: The result of treated hearing loss includes: 1. increased cognition and ability to communicate health related goals and outcomes 2. improved lab values do to increased confidence, ability to self-care, regulated blood pressure and blood sugar, decrease social anxiety and improved quality of life. 3. decreased risks of falls due to hearing loss

Conclusions: For 11 years we worked with the American Diabetes Association to push for an addition of hearing screenings to be added to the Clinical Standards of Care. In 2021, this was finally added to table 4.4 as ''audiology if indicated.'' This was a huge step in increasing awareness of the relationship between diabetes and hearing loss. Implementing this into practice includes building relationships for referrals from providers and diabetes care and education specialist to audiologist! This also includes adding simple screenings into work flow so that hearing is discussed.

EP378 / #476

Topic: ***AS18 Other***

MORBIDITY EXPANSION IN TYPE 2 DIABETES: TRENDS OF MEDICATION PRESCRIPTIONS BETWEEN 2005 AND 2017. A GERMAN LONGITUDINAL STUDY BASED ON CLAIMS DATA

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Background and Aims: While the risk for milder cardiovascular (CVD) comorbidities is markedly increasing in Type 2 Diabetes (T2D) depicting expansion of morbidity, the risk of having myocardial infarction or stroke is not. With an attempt to understand possible mechanisms behind this development, this study examines trends of antidiabetic and CVD medication prescriptions between 2005 and 2017 in individuals with T2D.

Methods: The study is based on claims data from a large statutory health insurance provider in Lower Saxony, Germany, the AOK Niedersachsen. Period prevalence of antidiabetic and CVD medication prescriptions was examined for the periods 2005–2007, 2010–2012 and 2015–2017 in 240,241, 295,868 and 308,134 individuals with T2D respectively. Stratifying by gender and age groups, (Ordered) logistic regression analyses using predictive margins were applied to examine the effect of time period on the number and prevalence of prescribed medications.

Results: The number of prescribed agents per person has significantly increased in all examined subgroups. For the younger age groups, insulin prescriptions decreased but those of non-insulin medications increased, while both increased significantly over time for the age group 65+ years. Except for glycosides and antiarrhythmic medications, the predicted probabilities for CVD medications increased over the examined periods with lipid lowering agents demonstrating the highest increase.

Conclusions: Results point towards an increase in medication prescriptions in T2D. Although changes in T2D management guidelines play a role in this temporal developement, the increase in CVD medication prescriptions, especially lipid lowering agents, could explain the specific development of severe and nonsevere T2D comorbidities observed in this population.

EP379 / #414

Topic: ***AS18 Other***

SOCIAL MEDIA AS A TOOL TO DISCUSS EATING DISORDERS

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Background and Aims: Diabetes social media is a non-stop free educational, emotional, and supportive strategy with the possibility of reaching a wide audience. Eating disorders (ED) in persons with type 1 diabetes (PWT1D) could be an invisible and less understood condition covered by type 1 diabetes (T1D). The lack of information and stigma associated with ED prevents or delays the search for treatment, which can generate several psychological and psychiatric complications as well as worsen the clinical outcomes of T1D.

Methods: Four Instagram social media accounts compliant to Brazilian medical regulatory agency for internet use and administered by a research group specialist in diabetes (2 endocrinologists, 1 psychiatrist and 1 psychologist) with the purpose of T1D education and mental health discussion displayed medical and psychological information about ED in simple, neutral and non-judgmental language. After that, we disclosed research information about ED in PWT1D, including consent forms and questionnaires from April to July/2022. This study included persons with T1D diagnosis for more than 1 year, aged 13-39 years.

Results: These four accounts have 43.000 organic followers reaching around 10.000 people every week. The publication call for our research had 393 people engaging. 257 people completed the questionnaires with quantitative and qualitative data.

Conclusions: Social media anonymity frees the potential stigma related to T1D and ED and can facilitate PWT1Ds' engagement in education and research. It is a powerful tool for ED discussion and to support interventions and treatment in long term.

EP380 / #380

Topic: ***AS18 Other***

OPTIMAL TREATMENT REVERTS THE HYPERINFLAMMATORY STATE OF CYTOTOXIC LYMPHOCYTES IN PATIENTS WITH TYPE 2 DIABETES

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Background and Aims: Chronic systemic low-grade inflammation is an underappreciated symptom of type 2 diabetes (T2D). The inflammatory cascade is believed to be a causative factor in the development of several comorbidities associated with T2D, such as atherosclerosis, diabetic kidney disease and fatty liver disease. However, the impact of T2D on the inflammatory state of the immune system is incompletely characterized. The aim of this study is to identify diabetes-induced changes in the antiviral arm of the immune system and determine whether this can be reverted by antidiabetic treatment.

Methods: After signed informed consents were obtained, peripheral blood mononuclear cells were isolated from patients with T2D and age-/gender-matched control subjects. Multiparametric flow cytometry was used to analyze the phenotype and cytokine production by three cytotoxic lymphocyte subsets after *in vitro* stimulation with PMA/Ionomycin. In a subcohort of patients with poorly-controlled diabetes, optimization of antidiabetic treatment was made and the analysis was repeated six months after the treatment change.

Results: Phenotypic analysis showed only minor differences in the percentage of lymphocyte subpopulations between study groups. Significantly increased production of tumor necrosis factor by $CD8^+$ T cells and Granzyme B by NK cells and $\gamma\delta$ T cells was observed in patients with diabetes in comparison to the control group. Six months of optimal antidiabetic treatment decreased cytokine production by cytotoxic lymphocytes.

Conclusions: Cytotoxic immune cells change their functional profile in the context of diabetes and may therefore contribute to the development and worsening of inflammation-driven diabetic complications. Our findings suggest that optimal antidiabetic treatment may reverse these changes.

EP381 / #164

Topic: ***AS18 Other***

GLYCEMIC CONTROL OF MALE PROFESSIONAL ATHLETES WITH TYPE 1 DIABETES DURING EXERCISE, RECOVERY AND SLEEP: RETROSPECTIVE, OBSERVATIONAL STUDY OVER AN ENTIRE COMPETITIVE SEASON

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Background and Aims: To analyze glycemic control of professional athletes with type 1 diabetes during a competitive season.

Methods: We analyzed CGM data of 12 professional male cyclists with type 1 diabetes, assessing glycemic control during exercise, recovery, and nocturnal phases on days with competitive exercise (CE) and non-competitive exercise (NCE), respectively. Time in glycemic ranges was compared with general treatment guideline targets. Furthermore, we assessed whether glycemic control differed between CE and NCE days.

Results: Mean HbA_{1c} was $6.7 \pm 0.5\%$, or 50 ± 5 mmol/mol. Over the season, there were 280.8 ± 28.1 days of cycling per athlete. Overall, time in range (70–180 mg/dL) was $70.0 \pm 13.7\%$, time in hypoglycemia (<70 mg/dL) was $6.4 \pm 4.7\%$, and time in hyperglycemia (>180 mg/dL) was $23.6 \pm 12.5\%$, not significantly differing from general guideline targets. During NCE days, time in range was $71.0 \pm 13.8\%$, time in hyperglycemia was $22.2 \pm 12.1\%$, while time in hypoglycemia was $6.9 \pm 5.0\%$. The latter was related to an increased time in hypoglycemia overnight, significantly exceeding guideline targets ($10.1 \pm 7.4\%$ vs. 4%, $p = 0.008$). CE days revealed a time in range of $70.1 \pm 14.1\%$, time in hypoglycemia of $4.7 \pm 4.5\%$, but an increased time in hyperglycemia ($25.2 \pm 12.5\%$). Along with this, time in hyperglycemia during exercise was higher on CE vs NCE days ($38.5 \pm 12.9\%$ vs. $21.9 \pm 13.9\%$, $p < 0.001$), exceeding guideline targets ($p = 0.003$).

Conclusions: Overall glycemic control of these professional athletes is remarkably good and generally matches guideline targets. Further improvements could be achieved by focusing on glycemic control during competitions, as well as on the avoidance of nocturnal hypoglycemia after non-competitive exercise.

ATTD 2023 Late Breaking Abstracts

LB001 / #1042

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

A LIQUID BIOPSY BASED METHOD FOR BETA PANCREATIC CELL LOSS MONITORING

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Background and Aims: The need for minimally invasive biomarkers of early diagnosis of type 2 diabetes (T2DM) and beta-pancreatic cell loss monitoring is emerging for timely and effective interventions to preserve significant beta-cell mass. We focus on studying circulating cell-free DNA (ccfDNA) as a liquid biopsy biomaterial, in order to build accurate diagnostic/monitoring biosignatures for clinical application.

Methods: A case–control study of 96 T2DM patients and 71 healthy individuals was conducted.

Results: Total ccfDNA levels were similar between T2DM and control groups. Fragment DNA size profiling was indicative of apoptosis in T2DM. *INS* (Insulin), *IAPP* (Islet Amyloid Polypeptide-Amylin), *GCK* (Glucokinase), and *KCNJ11* (Potassium Inwardly Rectifying Channel Subfamily J member 11) ccfDNA methylation levels differed significantly between groups. Data were analyzed in combination to demographic, life-style and clinical data by Automated Machine Learning (autoML JADBio), to deliver a five-feature biosignature via Classification Random Forests algorithm, accurately discriminating T2DM patients from healthy individuals (AUC 0.927 - higher than everyone reported before). An *in silico* analysis comparing 13 pancreatic β-cell methylomes against 28 other tissues/cell types generated an optimized 4-gene beta-cell specific biosignature (AUC 0.984).

Conclusions: Our novel methodology (EP21386030) exploiting the unique tissue methylation fingerprint, liquid biopsy and ad-hoc autoML, presents a minimally-invasive T2DM diagnostic solution, with the potential to be disruptive in clinical management.

This research was co-financed by the European Regional Development Fund of the European Union and Greek national funds through the Operational Program Competitiveness, Entrepreneurship and Innovation, under the call RESEARCH – CREATE – INNOVATE (T1EDK-00940).

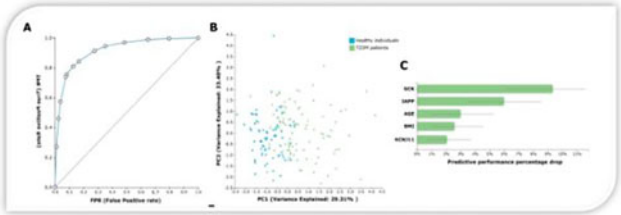

Figure 1 Best performing model via Automated Machine Learning (JADBio platform) A. ROC curve reaching an AUC of 0.927 (95%CI 0.874 - 0.967), B. Principal Component Analysis (PCA) plot depicting discrimination between T2DM patients and healthy individuals, C. Feature Importance plot, depicting the percentage drop in predictive performance when the feature is removed from the model.

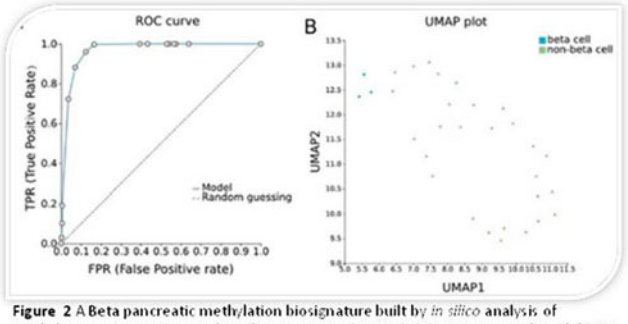

Figure 2 A Beta pancreatic methylation biosignature built by *in silico* analysis of methylomes using Automated Machine Learning (JADBio). (A) ROC curves of model (AUC 0.984 and precision 0.995) and (B) Supervised PCA plot present separation between beta cells from 28 other healthy cell types.

LB002 / #1031

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

SCREENING OF DIABETIC RETINOPATHY WITH AIREEN ARTIFICIAL INTELLIGENCE ALGORITHM PROVIDES SAFE IDENTIFICATION OF PATIENTS SUITABLE FOR EXAMINATION BY OPHTHALMOLOGISTS

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Background and Aims: The screening for diabetic retinopathy (DR) is recommended for its early diagnosis and treatment. Here we report the data on effectivity and safety of screening of DR with Aireen artificial intelligence algorithm.

Methods: Aireen (Prague, CZ) is a medical device including AI for the screening of DR. Aireen reports three outcomes: no signs of DR, signs of DR, and not suitable for analysis (picture quality issues). The aim was to identify pictures with signs of DR and compare the performance of Aireen with ophthalmologists. Pictures were taken with Canon CR-2 AF Digital Non-Mydriatic Retinal Camera (Canon, Japan) from 1274 patients with Type 1 and 2 diabetes (48% women, age 60.5 years, diabetes duration 11.0 years). Pictures were analysed by Aireen, two general ophthalmologists, and two retinal specialists. Discordant cases were adjudicated by the committee consisting of DR specialists. A two-sided 95% confidence interval was constructed for the relative frequency (%) of DR symptom captured by Aireen and by clinicians, which represented the level of agreement between Aireen and the clinical (reference) assessment.

Results: The sensitivity of Aireen, general ophthalmologists and retinal specialists for the detection of DR was 94.0%, 90.1% and 87.1%, respectively. The specificity was 90.7%, 76.6% and 81.2%, respectively. Positive predictive value was 86.3%, 70.4% and 74.1%, respectively.

Conclusions: Aireen reached the highest sensitivity, specificity, and positive predictive value among the applied DR screening approaches. The study confirms that Aireen can safely identify patients suitable for the examination with ophthalmologist and limit the burden of patients and ophthalmologists from unnecessary examinations.

LB003 / #1009

Topic: ***AS01 Big data and artificial intelligence-based decision support systems***

CONTINUOUS MONITORING OF HAEMODYNAMIC PARAMETERS IN ADDITION TO GLUCOSE VALUES IMPROVES GLUCOSE PREDICTION IN PATIENTS WITH TYPE 1 DIABETES - THE GLUCOSEML STUDY

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Background and Aims: GlucoseML study aims to develop a mobile health system for type 1 diabetes (T1D) self-management based on the use of continuous glucose monitoring (CGM), a wristband (haemodynamic and respiratory parameters), as well as carbohydrate intake and insulin dose data. We present results on short-term prediction of interstitial glucose concentration in T1D based on wearable device data.

Methods: A total of 32 persons with T1D participated in the study. The GlucoMen Day, CGM Menarini® and the Biobeat®, wrist monitor were used. The glucose predictive capacity of a univariate long short-term memory (LSTM) model using CGM data was compared with that of a multivariate LSTM model using CGM data, as well as haemodynamic and respiratory parameters. Root mean squared error (RMSE), mean absolute percentage error (MAPE) metrics, and continuous glucose error grid analysis (CG-EGA) were used to assess the predictive performance of the models.

Results: Linear correlation was observed between glucose values and heart rate and systolic blood pressure for most subjects. Both models retained the median MAPE of 30- and 60-min prediction horizons (PHs) below 5% and 7%, respectively. The multivariate model systematically improved the interquartile range of the RMSE for both PHs. The CG-EGA revealed that the addition of haemodynamic parameters reduced the percentage of erroneous predictions in hypoglycaemia from $0.30 \pm 0.36\%$ to $0.15 \pm 0.17\%$ (mean±SD) for a 60-min PH.

Conclusions: In patients with T1D using CGM, monitoring of haemodynamic parameters via a wristband device improved the short-term glucose prediction, particularly in the hypoglycaemic range.

LB004 / #1012

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

DECREASE IN HYPOGLYCEMIA EVENTS OVER A YEAR IN OLDER ADULTS WITH DIABETES MONITORING WITH DIGITAL DIABETES MANAGEMENT SYSTEM

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Background and Aims: Older adults are more likely to experience severe hypoglycemia, leading to fall-related events, ED visits, increased risk of cardiovascular events and cognitive decline. Clinical practice guidelines for the treatment of older adults with diabetes emphasize prevention of hypoglycemia. Reflecting the importance of this, in 2023 the Healthcare Effectiveness Data and Information Set (HEDIS®) added a metric related to hypoglycemia in adults age 67 and older. Dario, a digital therapeutic platform, may assist in reduction of hypoglycemia in such older adults.

Methods: A retrospective data analysis was performed on the Dario database. A cohort of 2844 users aged 67 or older with Type 1 or Type 2 diabetes and using Dario over a year was evaluated.Average numbers of Hypoglycemia Level 1 (<70mg/dL) and Level 2 (<54 mg/dL) events were observed monthly and compared to baseline (first month).

Results: Hypoglycemia level 1 events were reduced by 31% and 35% from baseline (0.54, 0.51 vs.0.78) on average within 6 months and sustained over a year ($p < 0.05$), respectively. Hypoglycemia level 2 events were reduced by 53% (0.08, 0.08 vs.0.17) on average within 6 months and sustained over a year ($p < 0.05$). The ratio of hypoglycemia readings per total measurements significantly reduced as well. Subgroup analyses (1353 patients) of Dario users with Type1 or Type2 using Insulin revealed a substantial reduction of severe hypoglycemia Level 2 of 42% (0.11 vs.0.19) ($p < 0.05$) in older adults.

Conclusions: older adults using a digital diabetes management platform have the potential to promote behavioral change and prevent hypoglycemia, demonstrating better glycemic outcome.

LB005 / #1003

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

IMPAIRED DISTAL THERMOREGULATION IN PATIENTS WITH DIABETES WITHOUT EVIDENCE OF PERIPHERAL ARTERIAL DISEASE OR PERIPHERAL NEUROPATHY

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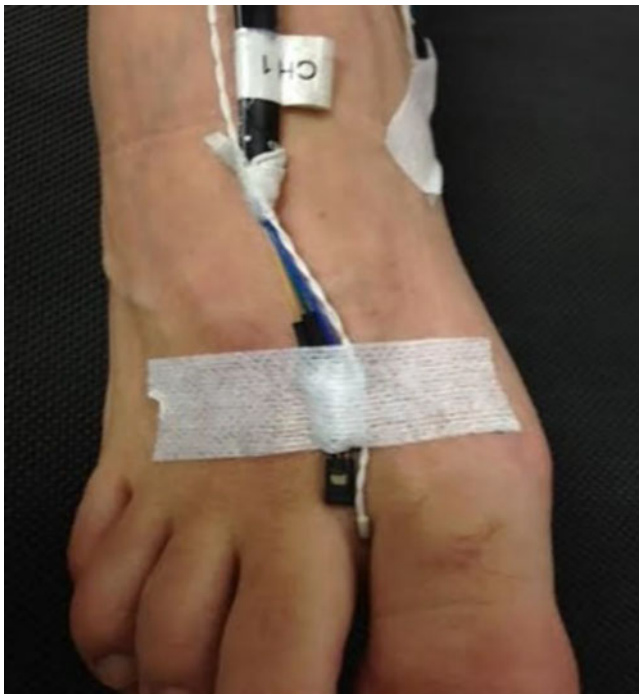
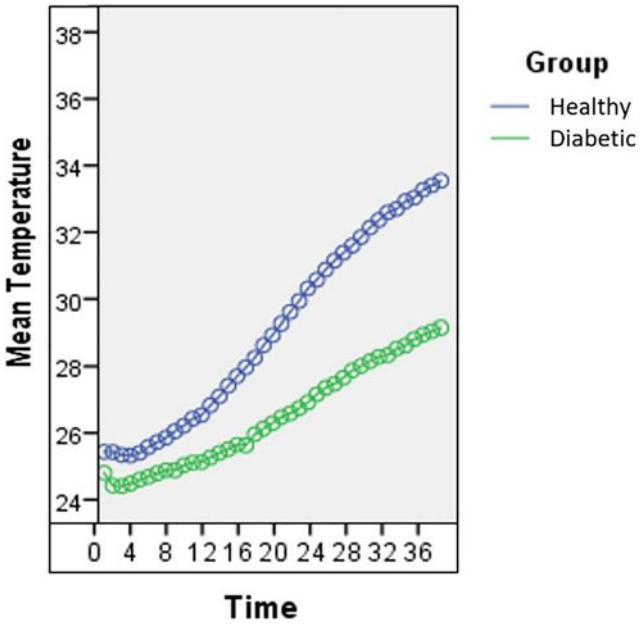
Background and Aims: Microvascular dysfunction in diabetes is associated with impaired vasodilation and abnormal thermoregulation. This study aimed to determine how thermoregulation of the feet is affected by diabetes during exercise.

Methods: Healthy participants and participants living diabetes without clinical evidence of peripheral arterial disease (PAD) or neuropathy, having triphasic Doppler waveforms and ankle-brachial pressure index >0.9 underwent in-shoe foot temperature monitoring during a 38-minute treadmill walk at standardised speed. Following a 15-minute acclimatisation period, pre-calibrated thermistors (TSD202A model) were placed on the dorsal aspect of the hallux (Fig 1) using standard socks and footwear. Data were recorded in real time using a physiological data monitoring system (Biopac Systems Inc., USA) in a laboratory with controlled ambient temperature.





Results: Nine participants living with diabetes and 14 healthy individuals participated. No difference was observed in the first 14 minutes, after which a statistically significant difference ($p < 0.05$) was achieved between the 15th and 35th minute where the healthy participants showed an enhanced temperature increase which was not manifested in the diabetic group. Healthy participants demonstrated typical S-shaped temperature kinetics while the diabetic participants demonstrated a delayed temperature increase shown by a more linear graph of temperature kinetics (Fig 2).

Conclusions: The temperature kinetics recorded are suggestive of a delayed threshold for vasodilation and impaired vasodilation response in diabetic patients without clinical evidence of PAD. Microvascular abnormalities, which can be manifested as abnormal thermoregulation in diabetic patients, is associated with failure of microvascular perfusion to meet the requirements of increased skin metabolism in cases of tissue injury.

LB006 / #1016

Topic: ***AS03 Closed-loop System and Algorithm***

GLYCAEMIC AND METABOLIC CONTROL AFTER 3 MONTH OF STARTING ADVANCED HYBRID CLOSED-LOOP SYSTEM IN TYPE 1 DIABETES MELLITUS PATIENTS

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Background and Aims: The aim was to evaluate effectiveness of the Advanced hybrid cloosed-loop (AHCL) (Minimed 780G ™) in glycaemic control in a group of patients with type 1 diabetes (T1D) during the first three month.

Methods: Longitudinal multicenter study in patients with T1D who started a AHCL between May and July 2022. Baseline characteristics and glucometric data were evaluated at the beginning of the treatment and at three-month's.

Results: 27 patients was studied, 19 (70.4%) female, 8 (29.6%) male. The median age 27.5 years-range (7-62). Type of training was on-site (77.8%), virtual (14.8%). The most frequent previous treatment was Minimed 640G (33.3%), Minimed 670G (25.9%) MDI (22,1%). An increase was observed between baseline and 3 months in: **Weight**: 58kg vs. 63.52 (P 0.0027), **daily carbohydrates (CH):** 139.7gr vs.172.3 (P 0.0014), **Bolus:** 49.95 vs. 58.3 (P 0.0004) **TIR**: 67.28% vs. 79.19% (P < 0.0001). And a significantly decreasedwas observed in **HbA1c:** 7.29 vs. 6.67(P 0.0019) **TAR 180:** 28.19 vs. 18.41 (P 0.0044). No differences were found in **DDT, Basal, TBR 70**. Differences between sexes were an increased average of 24 gr CH daily in women, while men increased an average of 70 gr (p = 0.0297). Autobolus in women decreased by an average of 1.11%, in men decreased 7.0%(p = 0.0029) between month 1 and 3 of automatic mode. When comparing between adult and pediatric patients, no significant differences were observed. .

Conclusions: With AHCL glycaemic outcomes improved with an increased in TIR and a decreased TAR. A significantly increase was observed after 3 months in weight, carbohydrates intake and in total insulin bolus.

Variable	BASELINE Media	D.E.	1 MONTH Media	D.E.	3 MONTH Media	D.E.	Diference media (3 Meses – AC)	Valor p
Weight KG	58	20,73	59,53	16,41	63,52	20,86	5.52	0.0027
HbA1c	7,29%	0,75	6,69%	0,21	6,67%	0,25	-0.58	0.0019
HC Daily	139,77	49,09	160,67	42,24	172,3	60,13	36.38	0.0014
DDT INSULIN	44,11	21,56	41,75	21,26	41,37	17,84	-1.65	0.5306
BASAL	45,28%	15,89	42,31%	7,67	41,7%	5,35	-3.48	0.2478
BOLUS	49,95%	11,53	57,67%	7,52	58,3%	5,35	8.67	0.0004
AUTOBOLO*			31,59%	10,77	28,74%	10,21	-2.85*	0.0324
TIR 70-180	67,28%	9,47	79,15%	6,92	79,19%	6,95	11.88	<0.0001
TAR 180	28,19%	9,66	18,74%	6,56	18,41%	7,54	-8.56	0.0044
TBR 70	1,94%	2,08	2,11%	1,69	2,52%	2,75	0.94	0.1527

LB007 / #1007

Topic: ***AS03 Closed-loop System and Algorithm***

SAFETY AND GLYCEMIC OUTCOMES OF ADVANCED CLOSED LOOP SYSTEM FROM ONSET IN VERY YOUNG CHILDREN (9 MONTHS-6 YEARS) WITH 1 DIABETES: CASE SERIES

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Background and Aims: Highly variable insulin sensitivity, low insulin doses, susceptibility to hypoglycemia and inability to effectively communicate hypoglycemic symptoms pose significant challenges for very young children with type 1 diabetes (T1D). Herein, outcomes during hybrid closed cloop system use were evaluated in these T1D patients.

Methods: Participants (N = 15, mean age: 4.4 ± 2.1 years) used Tandem t:slim X2 Control IQ (CIQ) system from T1D onset. Safety events, mean A1C, Glucose Management Indicator (GMI), insulin total daily dose and percentage of time in (TIR, 70-180 mg/dl), below (TBR, <70 mg/dl) and above (TAR, >180 mg/dl) range were assessed after 1 month of CIQ use.

Results: 12 males and 3 females (26% ≤ 2 years old; mean weight: 16.5 ± 6.5 kg) were enrolled at onset. Diabetic ketoacidosis (DKA) at onset was reported in 41% with mean A1C of 9.7 ± 1.9%. After 1 month of CIQ use, patients reported mean glycemia 143 mg/dl, CV was 37.5 ± 7.4%, total daily dose of insulin 11.2 ± 5.9 U/die (0.7 ± 0.4 U/kg/die, basal (U)/die: 4.2 ± 1.9, bolus (U)/die: 7.0 ± 4.2). Reported TIR was 75.0 ± 12.1%, TBR (70-54 mg/dl) 3.2 ± 2.3% and TBR (<54 mg/dl) 1.1 ± 1.0%. TAR >250 mg/dl was 6.5 ± 7.4%, TAR 250-180 mg/dl was 14.5 ± 6.1%. GMI mean value after 1 month of CIQ use was 6.7%. No episodes of severe hypoglycemia, DKA, no serious adverse device-related events were described.

Conclusions: Diabetes management in very young children is complicated by higher variability in insulin requirements. CIQ use could safely allow achievement of optimal glycemic control even in children less than 2 years old, despite administration of very low insulin doses.

LB008 / #986

Topic: ***AS03 Closed-loop System and Algorithm***

WITH HYBRID CLOSED-LOOP SYSTEM DBLG1, THE CLINICAL IMPROVEMENT OBTAINED IS ALL THE MORE IMPORTANT AS THE INITIAL CLINICAL SITUATION WAS MORE DETERIORATED.

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Background and Aims: Does automatised insulin administration in closed-loop (CL) with DBLG1 system improve TIR (time in range 70-180mg/dl) and TBR (time below range <70) in all adult patients affected by Type 1 diabetes (APT1D) ?

Methods: 140 APT1D, HbA1c > 8%, 43,3 ± 13,0 years, treated with Dana insulin pump were randomised to either receive after 2 weeks in open loop (OL), CL treatment with the DBLG1 algorithm, or continue in OL, with a 4 CL/1 OL ratio. COVID health crisis prematurely terminated the study. Nonetheless, 99 patients received at least 14 days of treatment with CGM data ≥75% of the time (88CL, 11 OL).

Results: After adjusting on baseline HbA1c and centers, patients in CL versus OL, spent 12min less per 24h in hypoglycemia <70 mg/dl ($p < 0.01$), 3h12 more in target 70-180 ($p < 0.001$), 3h less in hyperglycemia >180 mg/dl ($p < 0.0007$). These improvements were primarily nocturnal. Significative ($p < 0.0001$) linear correlations were observed between: 1 - TIR baseline/Delta-TIR: patients with the lowest TIR at T0 are the ones who increase it the most. 2 - TBR baseline/Delta-TBR: patients with the highest TIR at T0 are the ones who lower it the most. The patients who were initially the most hyperglycemic, and therefore had the least hypoglycemias, are the ones who gained the most in TIR, without deteriorating their TBR.

Conclusions: The DBLG1 system is likely to benefit the entire spectrum of metabolic disorders in Type 1 diabetes, either by improving TIR70-180 or decreasing TBR70, depending on the situation at initiation.

LB009 / #973

Topic: ***AS06 Glucose sensors***

THE FEASIBILITY OF NON-INVASIVE CONTINUOUS GLUCOSE MONITORING WITH THE NOVEL LIFELEAF WRISTWATCH AND PLATFORM

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Background and Aims: Reliable, non-invasive methods of continuous glucose monitoring (CGM) may simplify and reduce the burden of diabetes management compared to more invasive capillary BGM or interstitial CGM. We investigated the reliability of a novel spectroscopic CGM technology compared to standard BGM- and CGM-based references and report the findings of these feasibility studies.

Methods: The LIFELEAF® wristwatch (LifePlus, Inc., San Jose, CA) uses novel machine learning (ML) algorithms to amplify glucose absorption peaks in the near-infrared/short-wave spectrum from photoplethysmography (PPG) signal derived from a conventional optical sensor. The device comes pre-calibrated and has a 70-240 mg/dL (3.9-13.3 mmol/L) dynamic glucose range. Our first patient study compared LIFELEAF® versus BGM measurements in 164 subjects (with and without diabetes). The second compared LIFELEAF® versus Dexcom G6 CGM measurements in 66 patients with Type 1 diabetes over 20 consecutive days. All datasets were paired and split for model training and prediction in randomized fashion (60:40 and 70:30 in first and second studies, respectively).

Results: LIFELEAF® non-invasive glucose prediction metrics:

	Study 1 (versus BGM)	Study 2 (versus CGM)
Subjects enrolled	164	66
#Datapoints in 70-240 mg/dL range used for glucose prediction	706	10905
Mean Absolute Relative Difference (MARD)	14.4%	10.8%
Accuracy Rate (AR20)	73.1%	85.3%
Outlier Rate (% predictions over/under 40% of corresponding study reference)	4.5%	3.0%

Conclusions: Accurate, meaningful non-invasive continuous glucose predictions in a relevant dynamic range of 70-240 mg/dL can be obtained via specialized signal processing, signal amplification and ML applied to conventional wrist-based PPG signal. This demonstrates the feasibility of a non-invasive spectroscopic approach to CGM.

LB010 / #997

Topic: ***AS06 Glucose sensors***

CLINICAL PERFORMANCE OF A CGM USING DIRECT ELECTRON TRANSFER TECHNOLOGY WITH ASCORBIC ACID AND EXERCISE CHALLENGES

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Background and Aims: Sinocare i3 (US commercial name TrueVie), the first commercial factory-calibrated continuous glucose monitoring (CGM) system using direct electron transfer technology, has a 15-day wear life and provides glucose values every 3 minutes. In this study, we evaluated the effect of ascorbic acid and exercise on i3 sensor accuracy in people with Type 1 diabetes.

Methods: We enrolled sixteen adult participants with T1D. Each participants wore three sensors, one on the upper arm and two on the abdomen for 15 days. Each participant completed 3 in-clinic visits of 8-hour duration on days 1, 8, and 15. Frequent blood sampling was done every 15 minutes to compare the sensor values to a standard reference plasma glucose measurement using a YSI 2300 Stat Plus glucose analyzer. There were no glucose manipulation throughout the study. The mean absolute relative difference (MARD), Clarke, Parkes, and surveillance error grid analysis were evaluated between the i3 readings from all three insertion sites and YSI reference values. The interferent and exercise challenges were randomly assigned on days 8 and 15.

Results: The accuracy analyses were based on 2168 matched pairs over 15 days. Percent CGM readings within 15/15% and 20/20% of YSI values was 77.7% and 89.5%, respectively, and the overall MARD was 10.5%. Neither ascorbic acid nor exercise had a significant effect on sensor accuracy.

Conclusions: Sinocare i3 factory-calibrated real-time CGM system demonstrates accuracy and safety over 15-day wear with no significant inference from ascorbic acid or exercise.

LB011 / #1036

Topic: ***AS06 Glucose sensors***

FLASH GLUCOSE MONITORING: A RELIABLE TOOL TO MONITOR DIET ADHERENCE

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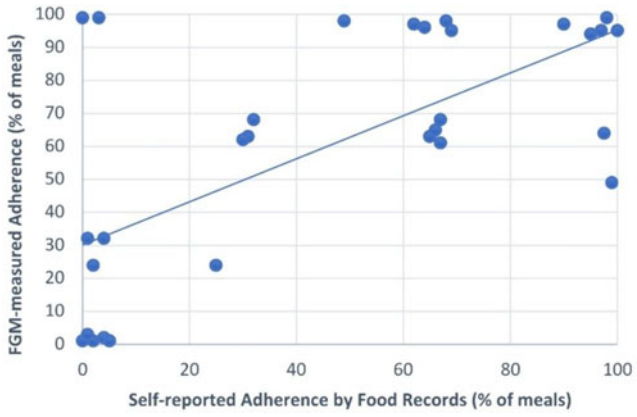
Background and Aims: Nutrition therapy and specifically carbohydrate restriction is essential for the management of type 2 diabetes. Measuring adherence to nutritional interventions is challenging and commonly relies on self-administered food records, which are time-consuming, prone to bias, and impose a significant patient burden. We examined whether flash glucose monitors (FGM) can provide an alternative reliable instrument to measure patients' adherence to a carbohydrate restricted diet.

Methods: In this pilot study, patients with type 2 diabetes were prescribed a 12-week, low-calorie dietary regimen with carbohydrate restriction after noon. Diet adherence was measured every 4 weeks by 2-week FGM and by quantitative, self-reported, 3-day food records

Results: Complete FGM and food record data were collected in 9 patients followed for 12 weeks (6 males and 3 females, age 70.8 ± 7.1 years, BMI 28.2 ± 2.3 kg/m2, diabetes duration 6.8 ± 2.2 years, diet and metformin treatment only). Self-reported and FGM-measured adherence to carbohydrate restriction ranged widely, being on average 46% and 63%, respectively, with an average interindividual coefficient of variability (CV) of 0.79 and 0.52 and intraindividual CV of 0.38. Patients were classified as non-adherent based on self-reported intake of small amounts of carbohydrates in the evening (e.g. one fruit), which however did not cause significant glycemic variations at FGM.

Conclusions: There is a good level of agreement between self-reported food records and FGM to assess the adherence to carbohydrate restriction in patients with type 2 diabetes. FGM may offer new opportunities to measure objectively patients' compliance to nutritional interventions.



LB012 / #1006

Topic: ***AS06 Glucose sensors***

EFFICACY OF A TELEMEDICINE SYSTEM ON GLYCEMIC CONTROL IN ELDERLY PATIENTS WITH TYPE 2 DIABETES MELLITUS AND FLASH GLUCOSE MONITORING

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Background and Aims: Flash glucose monitoring (FGM) has shown to improve glycemic control in patients with type 2 diabetes mellitus (T2DM) treated with multiple daily injections of insulin (MDI) therapy. The aim of this randomized controlled trial is to evaluate the efficacy of a telemedicine system in the management of MDI therapy based on data from FGM in frail elderly patients in nursing homes.

Methods: This is an interim analysis: 32 patients were assigned to intervention (n = 20) or to control group (n = 12) and followed for 3 months. The intervention group used FGM system and insulin doses were modified weekly by diabetologists; the control group maintained standard therapy and blood glucose monitoring (BGM) as usual, and an Holter-like FGM was applied. Differences in parameters of glucose variability and control between last two weeks and first two weeks of treatment were evaluated.

Results: Among intervention group, time in range (TIR) and HbA1c improved significantly ($p = 0.016$ and $p = 0.006$ respectively), while hypoglycemic events decreased significantly ($p = 0.017$). In the control group, HbA1c improved ($p = 0.003$) but a significant increase in hypoglycemic events and in time below range (TBR) was observed ($p = 0.012$ and $p = 0.005$ respectively). In the comparison between the two groups, a significant variation in TBR ($p < 0.001$) and in number of hypoglycemic events ($p < 0.001$) emerged.

Conclusions: Telemedicine and FGM systems seem to be associated to reduction of hypoglycemic risk in elderly patients with T2DM in MDI therapy.

LB013 / #991

Topic: ***AS06 Glucose sensors***

DRUG INTERFERENCE IN GLUCOSE MEASUREMENT AND ITS IMPACT ON PATIENT SAFETY

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Background and Aims: Even in the best-cared for people with diabetes, comorbidities are common, and so is polypharmacy. However, depending on the specific chemistry of the glucose sensor, the presence of various substances can confound the reading and lead to false high or low measurements. This, in turn, can lead to inappropriate amounts of insulin being given. For self-monitoring of blood glucose, distinct protocols are being required by ISO and the FDA. For the increasingly common continuous glucose monitoring, however, interference testing is in its infancy. Assessing the risk of unreliable measurements is thus important.

Methods: We searched the guidelines and the literature for information on the risk of interference in blood glucose measurements in general, existing protocols and information on gaps in interference testing, including differences between SMBG and CGM.

Results: Interference testing is mandatory for SMBG devices, with some manufacturers testing a continuously expanding catalogue of 200+ substances. Others complement the mandatory methods mandated by ISO and the FDA with methods based on real-world data, that address some of the limitations of the bench methods. However, for CGM, protocols to test for interference have only recently been suggested in literature and official regulations are in their infancy.

Conclusions: Distinct measurement technologies are used in distinct body compartments (blood and interstitial fluid), presenting different scenarios for potential interferences, while actual verification and labeling are often limited and sometimes even wrong. This poses a substantial risk for precipitating hypo- or hyperglycemic events with the very technology meant to avoid them.

LB014 / #983

Topic: ***AS06 Glucose sensors***

THE RELATIONSHIP BETWEEN HEMOGLOBIN A1C AND GLUCOSE MANAGEMENT INDICATOR (GMI) IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Despite its limitations, HbA1c is still used to monitor diabetic patients due to its relationship with microvascular complications. Several studies have explored the differences between HbA1c and GMI, establishing a difference of ≥0.1% in up to 81% of patients. The aim of our study was to examine this discordance in patients attended in a tertiary Spanish hospital.

Methods: A retrospective review of 497 patients with type 1 diabetes using Freestyle-Libre2 was conducted. The most recent HbA1c determined by high-performance liquid chromatography method was collected, as well as glucose monitoring data from two weeks prior to HbA1c determination (Libreview platform). Only patients with >70% of data were included. Pearson correlation was used to determine the relationship between parameters.

Results: 322 patients were included with mean HbA1c 7.41 ± 0.86%, GMI 7.24 ± 0.67% and Time-in-Range (TIR) 61.5 ± 15.8%.

Relationship	Correlation	p
HbA1c-GMI	r=0.745	p<0.001
HbA1c-TIR	r=-0.705	p<0.001

An estimated HbA1c was calculated for every TIR with a result of 7.1% for TIR of 70%. The HbA1c-GMI discordance (the absolute difference between the two) was analyzed in subgroups.

% of patients	Discordance
84.2%	≥0.1%
38.5%	≥0.5%
10.2%	≥1%

To analyze the influence of glycemic variability on GMI-HbA1c relationship, the group was split according to coefficient of variation (CV).

Coefficient of variation	Correlation GMI-HbA1c	P
CV<36%	r=0.784	p<0.001
CV≥36%	r=0.671	p<0.001

Conclusions: A significant discordance was found between GMI and HbA1c that should be taken into account while adjusting diabetic treatment. A higher discordance can be expected with higher glycemic variability.

LB015 / #999

Topic: ***AS06 Glucose sensors***

WHAT IS THE FAIR PRICE OF A NON-INVASIVE GLUCOSE METER? AN EXPLORATORY STUDY OF THE COSTS OF INPUTS IN DIABETES HEALTH CARE IN BRAZIL

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Background and Aims: The health care costs (HCC) in Diabetes progresses exponentially affecting half a billion people. Uncontrolled Diabetes increases complications and the HCC. Daily finger pricks contribute to poor Diabetes compliance and control. Non-invasive glucose meter devices (NIGMD) have a potential to improve the Diabetes outcomes and cost through compliance. Our goal is to plan a fair cost for a NIGMD to ease the public health care implantation and supply support for technical specifications.

Methods: In twelve months, from April 2021 to 2022, the cost of bids to buy devices and supplies to standard invasive point of care glucose meter (SIPCGM) for diabetes patients was considered in Brazil, through a free online search tool. Finally, we exchange the values to EUR on the October 6th.

Results: The median price for a standard invasive glucose meter was 14,48 EUR, covering nineteen bids. The lancing median price was 1,06 EUR covering three bids. The lancet median price was 0,03 EUR covering thirty-seven bids. The strips median price was 0,19 EUR covering 53 Bids. The cost for one glucose measurement was 15,79 EUR. Three times a day measurement for one year totaled 264,53 EUR.

Conclusions: The future technology must be comparatively less expensive. It is to be expected the same price (15 EUR) for SIPCGM and the NIGMD measurements. Considering one year-long cumulative values for SIPCGM, one NIGMD at 260 EUR would still prove a comparative advantage with an increase in patient adhesion to medical recommendations, reducing long-term complications and costs.

LB016 / #1039

Topic: ***AS06 Glucose sensors***

PREDICTION OF HYPOGLYCAEMIA DURING EXERCISE IN PEOPLE WITH TYPE 1 DIABETES: DATA FROM THE PACE STUDY.

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Background and Aims: Exercise uptake is low in people with type 1 diabetes (T1D), with fear of hypoglycaemia cited as the main barrier. We aimed to establish factors that predict hypoglycaemia during exercise.

Methods: People with T1D who exercised regularly (minimum 150min/week) recorded the type, timing and duration of exercise for 80 days using a GPS watch which measured heart rate. Participants used Dexcom G6 CGM throughout. Univariate analyses were undertaken looking at the impact of the recorded variables on hypoglycaemia <70gm/dL, followed by multivariate analysis.

Results: 24 participants (8 men, 16 women) had a mean (SD) age of 35 (11) years, duration of diabetes of 14 (7) years, BMI 26 (4.7) kg/m2 and HbA1c of 58 (12) mmol/mol) recorded 1454 activities with complete CGM. In univariate analysis participants had higher exposure to hypoglycaemia if they exercised in the afternoon, compared with the morning (OR 1.85 (95% CI 1.22 – 2.81), $p = 0.004$); and during cycling compared with walking (OR 2.51 (1.61-3.92), $p < 0.001$). Cardiovascular exercise in the gym was associated with lower exposure to hypoglycaemia compared with walking (OR 0.33 (0.16-0.37), $p = 0.002$). The OR for hypoglycaemia was 1.014 for each minute exercised ($p < 0.001$) and 1.02 for every 1 bpm increase in maximum HR. In multivariate analysis, the timing ($p < 0.001$), duration ($p < 0.001$), activity type ($p = 0.004$) and maximum heart rate ($p < 0.001$) are significant predictors of hypoglycaemia during exercise.

Conclusions: To empower adults with T1D to exercise without hypoglycaemia, education and support should focus on the timing, duration, activity and intensity.

LB017 / #1022

Topic: ***AS06 Glucose sensors***

CGM PARAMETERS AS POTENTIAL PREDICTORS OF PREGNANCY-RELATED COMPLICATIONS IN PATIENTS WITH TYPE 1 DIABETES: A RETROSPECTIVE COHORT STUDY.

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Background and Aims: The primary study objective was to analyze the relationships between the numerous continuous glucose monitoring (CGM) parameters and the following gestational complications: large-for-gestational-age (LGA) neonates, neonatal hypoglycemia, hyperbilirubinemia, transient breathing disorders, preterm births, and pre-eclampsia.

Methods: We conducted a single-center retrospective cohort study. We recruited a group of 132 eligible pregnant women with type 1 diabetes (T1D) who were treated with insulin pumps paired with CGM devices. Pregnant patients were admitted for at least one control hospital visit in each trimester of gestation to undergo routine anthropometric and laboratory measurements and collection of sensor data.

Results: Most of the patients from our study cohort met the criteria of well-controlled T1D defined by the mean HbA1c and time-in-range (TIR) values specific for the diabetic pregnant population. Despite achieving optimal glycemic targets in each trimester of pregnancy, numerous pregnancies were complicated by the listed adverse pregnancy outcomes. Worse glycemic control and more glycemic fluctuations in the second and third trimesters, rather than early pregnancy metabolic control, were mainly associated with the increased risk of transient breathing disorders, hyperbilirubinemia, and preterm births.

Conclusions: Several novel CGM parameters could serve as an additional tool in the prediction of pregnancy-related adverse outcomes, such as transient breathing disorders, hyperbilirubinemia, and preterm births. However, we did not find evidence that a range of novel CGM indices could be more clinically useful compared to commonly used CGM parameters such as TIR, TAR, mean glucose values, or HbA1c measurements.

LB018 / #998

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PATIENT AND PHYSICIAN PERSPECTIVES ON THE USE OF A CONNECTED DIGITAL ECOSYSTEM FOR TYPE 2 DIABETES MANAGEMENT: INTERNATIONAL CROSS-SECTIONAL SURVEY STUDY

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Background and Aims: Interconnected digital technologies could unite healthcare-related devices and platforms into connected digital ecosystems (CES) to better manage Type 2 diabetes (T2DM), but attitudes about CES are unknown. We conducted a survey to understand which patients are likely to 1) participate in a CES (patient survey) and 2) benefit medically from CES participation (physician survey).

Methods: We surveyed 197 insulin-dependent adults with T2DM and 33 physicians who treat T2DM in the US, France, and Germany. We characterize associations of patient self-report of likelihood for participating in a CES with patient characteristics. We also report descriptive characteristics of patients whom physicians believed would most benefit from CES use.

Results: 44.7% of US patients, 36.4% of German patients, and 46.3% of French patients expressed strong interest in CES. 78.7% reported using ≥1 connected device/app, yet physicians reported between 11.3%–19.2% of their patients were using a device/app for disease management. Physicians infrequently prescribed devices, although ≥80.0% thought that a CES could support their patients. Patient predictors of participating in a CES were cost, medication reminders, and linking blood glucose levels to eating and exercise. Physicians reported that newly diagnosed or sicker patients, and those non-adherent to treatment would benefit most from CES.

Conclusions: Although interest in CES use was strong, additional education is needed among patients with T2DM and their physicians to achieve the full potential of such systems to improve self-management and clinical care for the disease.

LB019 / #1037

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A CGM-ASSISTED LIFESTYLE INTERVENTION IMPROVES GLYCAEMIC METRICS AND PROMS IN PATIENTS WITH TYPE 2 DIABETES: A 3-MONTH PILOT OF UNA HEALTH

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Background and Aims: Lifestyle interventions in type 2 diabetes (T2D) often fail, possibly due to a lack of personalisation and absence of immediate feedback on effects of behaviour change. Use of continuous glucose monitoring (CGM) in these patients may help address these shortcomings. We have previously shown the efficacy of such a CGM-assisted lifestyle intervention over four weeks. We conducted a three-month pilot to assess whether improvements in glycaemic control and patient-reported outcome measures of diabetes-related well being are sustained over a longer time period.

Methods: Adult patients diagnosed with T2D who were not treated with insulin were recruited to a single-group assignment, open label clinical pilot. The intervention was use of the Una Health application over 3 months. This smartphone application allowed participants to log meals and exercise, and provided information on postprandial glycaemic response to logged meals based on analysis of CGM data. CGM-derived glycaemic control outcome measures and PROMs were compared between the beginning and the end of the intervention.

Results: Completion of the 3-month Program was associated with absolute reduction of 1.4% between pre-study HbA1c and Glucose Management Indicator at the end of the pilot ($p < 0.01$). Time in hyperglycaemia fell by 3.5% ($p < 0.05$). Median iAUC decreased by 365.3 mg/dl.min (relative reduction 17.0%), but this change was not statistically significant. 48.8% of participants reported a reduction in anxiety about their blood sugars ($p < 0.05$).

Conclusions: Given the preliminary evidence for efficacy of Una Health in T2D, we are now conducting a controlled trial of this CGM-assisted lifestyle intervention.

LB020 / #987

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

LIMITED EFFECTIVENESS OF ESTABLISHED STRATEGIES TO SUPPORT BASAL INSULIN (BI) TITRATION: PERSISTENCE, ADHERENCE AND HBA1C OUTCOMES IN TYPE 2 DIABETES (T2D) IN THE US

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Background and Aims: Effective titration and continuous support for people with T2D initiating BI is essential to achieve optimal glycemic control. In a US survey of people with T2D

Table: Survey-linked claims data in adults with T2D initiating BI for total sample and according to titration resources offered

	Total (N = 375)	Resources offered (n = 297)	No resources offered (n = 78)	p-value
Baseline Characteristics				
Mean age[1], yrs (SD)	70.1 (9.4)	70.1 (9.5)	69.9 (9.3)	0.821
Gender, n (%) Male	184 (49.1)	144 (48.5)	40 (51.3)	0.703
Charlson comorbidity score (continuous) Mean (SD)	2.3 (2.0)	2.1 (1.8)	2.9 (2.4)	**0.016**
Diabetes-related Health Care Resource Utilization[2] Counts, Mean (SD)				
Office visits	3.2 (3.2)	3.3 (3.3)	2.6 (2.8)	0.088
Outpatient visits	1.4 (3.5)	1.3 (3.1)	1.7 (4.8)	0.467
Emergency room visits	0.1 (0.4)	0.1 (0.4)	0.03 (0.2)	**0.005**
Inpatient stays	0.1 (0.3)	0.1 (0.4)	0.04 (0.2)	**0.023**
Inpatient days	1.0 (5.3)	1.2 (5.9)	0.2 (0.9)	**0.003**
Pharmacy fills	7.5 (5.8)	7.7 (6.0)	6.8 (4.9)	0.171
6-month follow-up				
Persistence and Adherence, Mean (SD)				
Persistence in days with BI index therapy (using a 60-day gap)[3]	140.1 (57.3)	140.6 (57.5)	138.3 (57.1)	0.754
Proportion of days covered (PDC) with BI index therapy[4]	0.7 (0.3)	0.7 (0.3)	0.7 (0.3)	0.315
PDC≥0.80, n (%)	177 (47.2)	148 (49.8)	29 (37.2)	0.056
HbA1c Lab Results (for patients with baseline and follow-up results), Mean (SD)				
	n=186	**n=150**	**n=36**	
Baseline period	8.7 (1.8)	8.8 (1.9)	8.2 (1.6)	0.090
Follow-up period	7.8 (1.5)	7.8 (1.5)	7.7 (1.5)	0.550
Change in HbA1c	-0.9 (1.9)	-1.0 (2.0)	-0.6 (1.5)	0.175

BI, basal insulin; HbA1c, hemoglobin A1c; PDC, proportion of days covered; SD, standard deviation
[1]Claims-based age defined as of the index year.
[2]Utilization defined as diabetes-related if the claim had a diagnosis for T2D in the primary position, or if the pharmacy claim was for a treatment for T2D.
[3]Persistence with BI index therapy defined as the total number of uninterrupted days on therapy without discontinuation or switching.
[4]Adherence with index therapy assessed using the PDC. The PDC represents the proportion of time over the course of a patient's treatment that he/she theoretically was in possession of the medication. PDC is calculated by dividing the total number of days on which a medication was available (based on filled prescriptions) by the number of days between the earliest prescription claim in the observation period through the end of the observation period. This calculation was not corrected for inpatient events. Days' supply were added together (overlapping days were counted once). The pharmacy fill for the longer days' supply was retained for pharmacy fills for the same medication on the same date of service. Patients who were perfectly compliant had a PDC of one, while those who were less than fully compliant had PDCs less than one.

initiating BI, most were offered resources to support titration (including in-office training, educational materials, paper/digital tools, access to a certified diabetes educator). We evaluated whether these resources impacted persistence, adherence and HbA1c.

Methods: Adults with T2D and ≥2 claims (≥30 days apart in most recent 12-month period) in the Optum Research Database, who initiated a BI analogue between February and April 2021, were asked to complete a one-time, mailed survey. Survey-linked longitudinal claims data (during 12-month baseline and 6-month follow up) were analysed. Charlson comorbidity score, diabetes-related health care resources utilization, HbA1c and BI adherence were compared in patients who were/were not offered resources for BI titration.

Results: Among 375 evaluable respondents, 297 were offered BI titration resources (**Table**). At baseline, patients with resources offered had a significantly lower mean Charlson comorbidity score, and more diabetes-related emergency room visits and inpatient stays compared with the group not offered resources ($p < 0.05$). During follow-up, there were no statistically significant differences in persistence or adherence to BI index therapy between groups. Although not statistically significant, the greater HbA1c reduction in the resources-offered group (1.0%) versus the group not offered resources (0.6%) may be clinically relevant.

Conclusions: These results suggest that conventional BI titration resources do not obviously impact BI persistence/adherence and HbA1c change, highlighting the need for more innovative strategies.

Intervention category *Characteristics of category*	No. of studies	No. of studies (%) with significant results
High intensity *Patient data automatically uploaded to the cloud in regular intervals. The coaching includes personalized motivational and goal-setting components based the most recent data and delivered by dedicated staff. The communication can be either in-person or remote, however the communication happens regularly, at least once a week. Education includes specific modules explaining the disease, behavioral strategies, and psychological coping.*	8	7 (87.5)
Medium intensity *Patient data are manually uploaded. Coaching includes personalized advice based on patient data but not a behavioral advice in terms of motivational and goal-setting component. The communication is ad-hoc, initiated by the HCPs. Education includes general information about the disease and technical information about the use of the device(s).*	16	12 (75)
Low intensity *Limited data sharing. Generic feedback using pre-existing templates. The communication is asynchronous or delayed (e-mail or follow-up phone call). Limited or no education.*	4	2 (50)

LB021 / #959

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DIGITAL INTERVENTIONS FOR SELF-MANAGEMENT IN TYPE 2 DIABETES MELLITUS (T2DM): A SYSTEMATIC LITERATURE REVIEW

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Background and Aims: Our goal was to characterize the evidence landscape on the relative efficacy of digital interventions for self-management of T2DM, specifically glucose monitoring and coaching, as measured by changes in HbA1c and patient engagement via a systematic literature review.

Methods: Relevant studies were identified by searching MEDLINE®, Embase, and CENTRAL databases on April 5, 2022. Conference abstracts from 2018-2022, selected company websites, and the US clinical trials registry were also searched.

Results: From an initial 6,288 records, 28 studies were included. Within the evidence base, the basic form of all interventions included two components: technology (personal glucose meters and other devices) and human component (coaching). The coaching component varied considerably both in terms of quantity (frequency and length of patient-healthcare practitioner interactions) and quality (personalized vs. generic advice, goal setting, problem solving). Effectiveness of the interventions was assessed using a three-tier classification of the digital interventions based on the quality and intensity of the coaching component (high, medium, and low intensity). Overall, 19 out of the 28 studies reported significant improvement in HbA1c levels and two out of three studies targeting patient engagement achieved significant improvement as well. When separated into the three intervention categories, success of the intervention was proportional to the intensity of coaching (see table).

Conclusions: Our findings suggest that higher intensity of coaching in digital interventions for the self-management of T2DM, defined by availability and level of personalization, is more likely to produce significant results in HbA1c improvement.

LB022 / #957

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EFFECTIVENESS OF THE NOVEL GLUCARE.HEALTH CARE MODEL IN TYPE 2 DIABETES MEDICATION REDUCTION AND MANAGEMENT OVER A YEAR

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Background and Aims: Implementation by health care providers (HCPs) of remote monitoring programs combined with digital health solutions suggests a promising direction in medication regimen simplification and adherence in improving chronic diseases such as type 2 Diabetes Mellitus (T2D) and complications. The primary goal of this study is to assess the effectiveness and safety of a novel continuous GluCare.Health care model for the management of T2D over one year. The study assesses the model's association with medication reduction, increased medication adherence, and improved clinical biomarkers related to T2D and glycated hemoglobin reduction over one year.

Methods: A retrospective study including 71 T2D patients was conducted. Medication records were analyzed and statistically compared between the baseline and 3, 6, 9, and 12 months after the intervention. T-tests and nonparametric Wilcoxon were applied. Statistically significant results were set at 5% and 10% levels. We used a two-tailed p-value as a more conservative approach than a one-tailed one. Additionally, an effect size analysis was conducted to make judgments about the magnitude of medication reduction.

Results: The results suggest that the effect of the GluCare intervention in medication reduction is already significant at 3 months follow-up ($p = 0.002$) and are also relevant after one year ($p = 0.02$).

Conclusions: Among T2D patients, the strategy of medication reduction guided by continuous monitoring and engagement via the hyper-personalized, technology-enabled GluCare.Health model of care had a positive impact within a 3-month period. The intervention improved medication adherence and it may be a cost-effective and cost-saving solution for the management of T2D.

LB023 / #984

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

REAL WORLD EFFECTIVENESS OF FITTERFLY DIABETES CGM DIGITAL THERAPEUTICS PROGRAM FOR IMPROVEMENT IN GLYCEMIC CONTROL AND METABOLIC PARAMETERS

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Background and Aims: The study aims at analyzing the effectiveness of the Fitterfly Diabetes CGM digital therapeutics program for improving glycemic control and metabolic parameters among people with T2DM.

Methods: De-identified data of 145 participants with T2DM and BMI $\geq 25.0\ kg/m^2$ (Mean age: 47.45 ± 12.71 years, Females: 56.97 % (94/145)) was analyzed. The participants had access to continuous glucose monitoring (CGM) in the first 14 days of the program. Based on usual lifestyle in week-1, a modified lifestyle plan was introduced from week 2 till program completion (day 90). HbA1c, weight, and BMI was analyzed pre and post the program. Wilcoxon signed rank test was used for statistical analysis. All data has been reported as median (IQR).

Results: In the week-2, a significant median reduction in average blood glucose and time-above-range was observed by -8.00 (-23.00, -0.50) mg/dl and -5.40 (-16.00, 0.00) % from week-1 baseline of 140.00 (115.00, 170.00) mg/dl and 27.60 (11.10, 48.50) % respectively ($p < 0.0001$ for both). Time-in-range significantly increased by 6.00 (-2.00, 14.00) % from a baseline of 66.00 (48.60, 79.00) % ($p < 0.0001$). After the program, a significant median reduction in HbA1c, weight and BMI was observed by -1.00 (-2.00, -0.30) %, -2.30 (-5.00, -1.00) kg, and -0.80 (-1.70, -0.20) kg/m^2 from a pre-program baseline of 8.10 (7.20, 9.10) %, 80.00 (72.00, 90.50) kg and 28.80 (26.50, 31.70) kg/m^2 respectively ($p < 0.0001$ for all).

Conclusions: CGM based Fitterfly Diabetes CGM program can help in improved diabetes management, as significant improvement in glycemic control and metabolic parameters was observed after program completion.

LB024 / #1019

Topic: ***AS07 Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PREDICTIVE MODEL FOR ESTIMATING FASTING AND POSTPRANDIAL CGM READINGS BY USING BASELINE HBA1C VALUES: ANALYSIS OF REAL-WORLD DATA IN FITTERFLY DIABETES DIGITAL THERAPEUTICS PROGRAM

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Background and Aims: Continuous glucose monitoring (CGM) enables real-time glucose monitoring, glycemic awareness, and control. Newer CGM devices do not require calibration using SMBG readings. The present study leverages participant's baseline characteristics to predict blood glucose levels. This will help reduce the need for SMBG and fingerstick testing while instilling confidence in CGM among patients.

Methods: A multiple linear regression model was used to examine the influences of baseline HbA1c level on CGM based fasting blood glucose reading (CGM-FBS, 5 am) and postprandial blood glucose reading (CGM-PPBG, 2h post lunch and

dinner) after controlling for baseline factors of age and gender. All participants (n = 237) were enrolled in the Fitterfly Diabetes program (Fitterfly Healthtech Pvt Ltd, Mumbai) with CGM sensors (FreeStyle Libre Pro, Abbott Diabetes Care) being applied on day 1 of the program. Statistical analysis was performed using R-software (Version 4.1.2).

Results: CGM-FBS reading was found to be significantly associated with HbA1c ($\beta = 14.894$, $P < 0.001$) with an intercept of 23.638 ($P = 0.199$). No significant association was observed for age ($\beta = -0.148$, $P = 0.578$) and gender (male, $\beta = -8.225$, $P = 0.188$). CGM-PPBG reading was found to be significantly associated with HbA1c ($\beta = 19.101$, $P < 0.001$) and gender (male, $\beta = -16.996$, $P = 0.040$) with an intercept of 48.115 ($P = 0.048$). No significant association was observed for age ($\beta = -0.136$, $P = 0.697$).

Conclusions: HbA1c values along with baseline parameters can help in prediction of FBS and PPBS readings on a CGM device, thus helping in more informed use of CGM sensors. This data can also be used for assessing the need for calibration of CGM sensors.

LB025 / #965

Topic: ***AS08 Insulin Pumps***

COMMON MISTAKES OF ADOLESCENTS AND CAREGIVERS ON CSII MANAGEMENT

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Background and Aims: Insulin pumps supported by continuous glucose monitoring(CGM) are the most effective forms of insulin delivery in type 1 diabetes(TID).Essential requirement for the use of CSII-CGM is the intensive training of the patient and the family on its management.

Methods: To present the commonest pitfalls of adolescents and their parents-caregivers on CSII-CGM management. Six-month data from CSII- CGM open and closed loop systems were analyzed from 11 children and adolescents with T1D aged 6-17 years old. Male to Female ratio was 5:6(M:45%, F: 65%,mean duration of diabetes 7.5 years, mean HbA1c 7,2%(55mmol/mol), mean of BMI:20.3Kg/m2,TIR: 67%,CV: 36.6%.

Results: 6 of 11(55%) patients were omitting the meal insulin bolus resulting in significant postprandial hyperglycemia. The insulin-carbohydrate(ICR) ratio was frequently underestimated by the adolescent users. Dual boluses for mixed meals were not used by the majority. 4 out of 11(36%) of the patients were changing the cannula set every 4.5 days with resulting hypertrophy at the entry points. one family was using temporary basal rate to correct hyperglycaemia.Only 4 out of 11 (36%) children aged 6-12y old were correctly managing the pump due to adequate training and education of their parents. Social media negatively influenced some families on CSII-CGM management.

Conclusions: The majority of patients and their families did not have adequate training on ICR to manage the pumps satisfactory. It is required that health professionals(paediatric diabetologists, diabetes educators) thoroughly assess families who will use the insulin pumps and help them to achieve the essential skills to improve glycaemic control.

LB026 / #1025

Topic: ***AS08 Insulin Pumps***

FEASIBILITY STUDY OF AN OCCLUSIVE SKIN PATCH TO TREATMENT OF IRRITANT CONTACT DERMATITIS CAUSED BY DIABETES DEVICES

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Background and Aims: In children and adolescents with type 1 diabetes, irritant contact dermatitis (ICD) is frequent to diabetes devices, but no consensus guidelines for treatment nor prevention exist. Since next device needs intact skin quick healing is crucial. Therefore, the aim of present study is to investigate the efficacy and safety of an occlusive hydrocolloid-based patch as therapy of ICD.

Methods: This study was a single-center cross-over study investigating the efficacy and safety of an occlusive hydrocolloid patch versus non-occlusive treatment of ICD. Study participants were in the age of 6-20 with active ICD caused by diabetes device. First study period was with patch for three days. A control arm was initiated if a new ICD arise in 30 days. Clinical evaluation of skin sites and safety data were obtained at day 1, 4 and 8.

Results: Seventeen study subjects in age 6-18 years were included in patch-arm with five included in control-arm. ICD-severity score was improved in 93% of all patch-users and in 75% of control-users at day 4, with complete healing of ICD in 21% of patch-users but none in control arm. The patch adhered for full study period in 70% of users, with itching and scratching as reason for performance fail. Itching was reported as adverse events in both arms, but additionally only one adverse event in patch-arm was seen: an infection though not at site of patch.

Conclusions: The hydrocolloid-based patch is both effective and safe as treatment of ICD, but larger studies are needed.

LB027 / #1015

Topic: ***AS08 Insulin Pumps***

EFFECT IN GLYCEMIC CONTROL OF CHILDREN AND ADOLESCENTS WHO SWITCHED TREATMENT FROM MULTIPLE INJECTIONS (MDI) OR MINIMED 640G TO 780G IN A CLINIC IN CHILE

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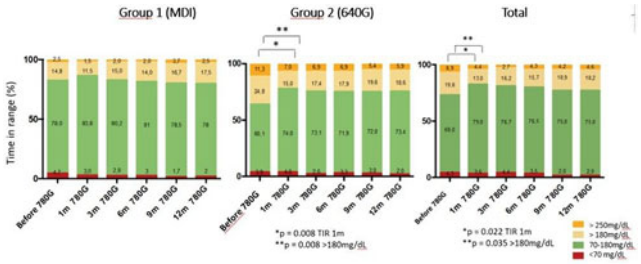
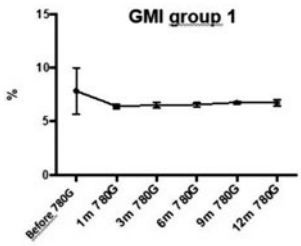
Background and Aims: The use of hybrid closed loop systems has significantly grown to improve glycemic control. The aim of this study is to evaluate the impact of switching from MDI or 640G to a Minimed 780G and its effect on time in range (TIR, 70-180mg/dL) in a group of type 1 diabetic children and adolescents.

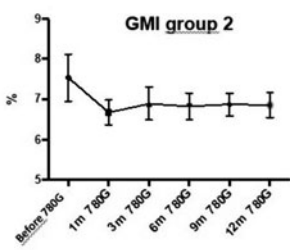
	Group 1 (MDI to 780G)	Group 2 (640G to 780G)	Total
N	6	8	14
Age (years)	6.9 ± 2.05 (4.9-11.5)	11.3 ± 3.9 (6.82-18.5)	9.7 ± 2.1 (4.9-18.5)
Male/ Female (n)	4 / 2	5 / 3	9 / 5
Age at DM1 diagnosis (years)	4.3 ± 3.4 (1.4-9.9)	4.9 ± 2.1 (5.2-11.6)	4.9 ± 3.4 (1.4-11.6)
Time from diagnosis (years)	1.9 ± 1.9 (0.2-4.7)	6.2 ± 3.0 (1.8-9.0)	4.4 ± 1.9 (0.2-9.0)
HbA1c before study (%)	6.6 ± 0.6 (6.2-11)	7.7 ± 0.2 (6.4-7.9)	7.8 ± 0.6 (6.2-7.9)
Insulin Aspart/ Rapid Aspart	1 / 5	1 / 7	2 / 12

Methods: Prospective study. Recruitment of 14 patients, 9.7 ± 2 years of age and 31.3% female. Clinical characteristics described in table 1. They were separated into two groups: MDI (G1; n = 6) and 640G users (G2; n = 8). Both groups changed their therapy to 780G. Changes in TIR, frequency of hypo and hyperglycemia, insulin/kg dose and GMI were evaluated at 1, 3, 6, 9 and 12 months using it. Comparisons determined using ANOVA test.

Results: TIR increased, time spent >180mg/dL decreased significantly and hypoglycemia showed lower frequency for all patients. G2 patients presented higher improvement in TIR in the first month and continued afterwards. (Figure 1. Variation in TIR during study).







GMI was reduced only in G2 (7.3 ± 0.4% before study and 6.7 ± 0.3% after one month using 780G (p = 0.018) and stabilized during follow-up (Figure 2. Variation of GMI during study in G1 and G2).

G1 increased progressively insulin/kg from 0.4 ± 0.2U/kg to 0.7 ± 0.1U/kg at 12 months (p = 0.05). Patients spent 90.4 ± 1.2% (range 64-100%) of the time in Smart Guard mode during study.

Conclusions: Switching therapy from MDI or 640G to 780G improved TIR and reduced hyperglycemia, without increasing hypoglycemia, in this group of children and adolescents from Chile.

LB028 / #1018

Topic: ***AS08 Insulin Pumps***

EFFICACY AND SAFETY OF AUTOMATED INSULIN DELIVERY SYSTEMS AND SENSOR-AUGMENTED PUMP THERAPY WITH PREDICTIVE LOW GLUCOSE MANAGEMENT IN AN ELDERLY POPULATION WITH TYPE 1 DIABETES.

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Background and Aims: Evidence for the benefits of automated insulin delivery systems (AIDs), sensor-augmented pump therapy with predictive low glucose management (SAPT-PLGM), as well as achieving strict glycemic control goals in older adults diagnosed with type 1 diabetes (T1D) is limited. The objective of this study is to describe the efficacy and safety of this technology in the elderly population with T1D.

Methods: Cross-sectional study. Adults with T1D ≥60 years without geriatric syndromes using AID or SAP for more than three months were included. Comprehensive geriatric assessment variables, time in range (TIR%), time above range (TAR%), time under range (TBR%), coefficient of variation (CV%) and adherence were analyzed.

Results: 45 patients were included (53.3% men, mean age 67.1 years, mean duration of diabetes 24.7 years, Hb1Ac 7.47 ± 0.6%). 13 patients were SAPT-PLGM users and 32 patients used AIDs (46.7% Minimed 670G, 24.4% Minimed 780G). TIR% was 75.4% ± 9.9, TBR% <70 mg/dL and <54 mg/dL were 2.4% ± 2.3 and 0.47% ± 0.81, respectively. The TIR% of AID users were higher compared to SAPT-PLGM (Mean difference 4.6%, p = 0.04), with no difference for TBR% <70 and <54 mg/dL. 97.8% and 43% of the patients met the goals established for older adults defined by TIR%>50% and TBR%<1% for 70 mg/dL, respectively. The factors associated with TBR%>1 were a lower percentage of muscle mass and CV >36%, regardless of the type of technology used.

Conclusions: The use of AIDs and SAPT-PLGM in the elderly population without geriatric syndromes makes it possible to achieve stricter goals of metabolic control without an increase in hypoglycemia.

LB029 / #1026

Topic: ***AS08 Insulin Pumps***

IMPROVED GLYCAEMIC CONTROL IN CHILDREN AND YOUNG ADULTS WITH TYPE 1 DIABETES USING TUBELESS INSULIN PUMPS VS MULTIPLE DAILY INJECTIONS IN COMBINATION WITH GLUCOSE SENSORS

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Background and Aims: To study metabolic control in children and young adults with type 1 diabetes using tubeless insulin pumps (Omnipod/Omnipod DASH ® Insulin Management Systems) in combination with continuous glucose monitoring systems (pump+CGM, without constant communication). Multiple daily injection therapy with CGM (MDI+CGM) was used as the control group.

Methods: Individuals <25 years of age (diabetes duration ≥1 year), registered in DPV as of 2015 were included. Propensity score was used to match individuals with pump+CGM for at least 3 months to individuals with MDI+CGM with sex, age at T1D onset, current age and migratory background as covariates. HbA1c, time in range (TIR 70-180 mg/dl; 3.9-10.0 mmol/L) and the proportion of individuals reaching an TIR >70% was studied with linear, fractional and logistic regression models.

Results: 2,480 individuals using pump+CGM were identified and matched one-to-one to MDI+CGM controls. In the matched cohort, HbA1c was significantly lower in the pump+CGM group (7.6% (95%-CI: 7.5-7.6)) compared to MDI+CGM (7.8% (7.7-7.8), $p < 0.001$). Pump+CGM was associated with a higher percentage of TIR (52% (48-56) vs. 48% (45-52), $p = 0.151$). The proportion of individuals with TIR >70% was 14.2% (12.5-16.9) with Pump+CGM and 11.0% (9.0-13.4, $p = 0.058$) in the control group.

Conclusions: Real-world data from the multicentre DPV registry shows that tubeless pump therapy in association with CGM might result in beneficial effects on metabolic control in children and young adults with type 1 diabetes.

LB030 / #993

Topic: ***AS09 New Medications for Treatment of Diabetes***

EFFECTS OF SOTAGLIFLOZIN ON CLINICAL FACTORS ASSOCIATED CARDIORENAL OUTCOMES: A POST HOC ANALYSIS OF THE INTANDEM 3 TRIAL IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Mediators of cardiorenal benefits with SGLT2 inhibitors have been identified from cardiovascular (CV) outcomes trials in patients with type 2 diabetes (T2D). CV outcomes trials have not been performed with an SGLT inhibitor in people with type 1 diabetes (T1D). We evaluated the effects of sotagliflozin on clinical factors associated cardiorenal benefits in adults with T1D.

Methods: Data from a 24-week, randomized, double-blind trial evaluating sotagliflozin 400 mg/d or placebo as an adjunct to insulin in 1402 adults with T1D were used for this post hoc analysis. Change from baseline was assessed in the metabolic, renal, and hemodynamic factors associated with cardiorenal benefits with SGLT2 inhibitors in patients with T2D.

Results: Compared with placebo, sotagliflozin significantly ($p < 0.001$) improved clinical factors previously associated with cardiorenal benefits (Table). In these prior T2D analyses, variables associated with changes in plasma volume, hematopoiesis, and serum uric acid were the strongest mediators of clinical

Table. Effect of sotagliflozin on clinical factors associated with cardiorenal benefits

Variables	Baseline mean (SD)		
	Sotagliflozin	Placebo	Difference in LS mean change from baseline at Week 24 (95% CI)
HbA1c, %	8.3 (1.0)	8.2 (0.9)	**-0.46 (-0.54, -0.38)**
Vascular tone			
SBP, mmHg	122.0 (15.3)	121.8 (14.8)	**-3.3 (-4.5, -2.1)**
DBP, mmHg	76.4 (8.8)	76.7 (9.1)	**-1.6 (-2.3, -0.8)**
Pulse rate, bpm	75.0 (11.5)	75.2 (11.2)	-0.5 (-1.4, 0.4)
Renal			
UACR, mg/g*	11.8	11.7	-2.0 (-8.9, 5.3)
eGFR, mL/min/1.73 m^2	91.5 (19.8)	92.5 (21.9)	-0.2 (-1.5, 1.0)
Weight, kg	82.4 (17.1)	81.6 (17.0)	**-3.0 (-3.3, -2.7)**
Volume Status and Hematopoiesis**			
Hematocrit, %	42.2 (3.9)	42.2 (3.9)	**1.9 (1.6, 2.2)**
Hemoglobin, g/L	140.8 (14.0)	140.7 (13.8)	**5.3 (4.5, 6.1)**
Serum Albumin, g/L	43.2 (2.7)	43.3 (2.7)	**0.6 (0.3, 0.8)**
Serum uric acid, µmol/L	265.5 (73.3)	264.0 (76.0)	**-14.6 (-19.2, -10.1)**

* Baseline UACR values are geometric means and difference value is percentage of treatment difference in LS geometric means; in cohort with baseline UACR ≥30 mg/g, the treatment difference = -20.3% (-37.2, 1.1).
** For reference, change from baseline in hematocrit = 2.3%, hemoglobin = 6.6 g/L, serum albumin = 0.6 g/L, and serum uric acid = -23.2 µmol/L with canagliflozin in the CANVAS Program (Li et al. JACC HF 2020).
P < 0.001 vs placebo for variables with bolded results.

benefit. This T1D study analysis showed the magnitude of change from baseline in these variables with sotagliflozin (hematocrit = 2.3%, hemoglobin = 6.6 g/L, serum albumin = 0.6 g/L, and serum uric acid = -23.2 μmol/L) was similar to that observed in the CANVAS program (Table).

Conclusions: In patients with T1D, sotagliflozin significantly improved several factors associated with cardiorenal benefits in patients with T2D treated with SGLT2 inhibitors. We conclude that patients with T1D may also experience cardiorenal benefits with SGLT inhibitors, however long-term prospective studies need to be performed.

LB031 / #972

Topic: ***AS12 Advanced Medical Technologies to Be Used in Hospitals***

MATERNAL HYPOGLYCEMIA PREVALENCE DURING FIRST-TRIMESTER PREGNANCY IN TYPE 1 DIABETES INCREASES THE RISK FOR OVERWEIGHT NEONATES

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Background and Aims: Tight glycemic control improves the outcome of T1DM pregnancy; however, it increases the risk of hypoglycemia. This study aimed to determine the risk of neonatal overweight by maternal age, type 1 diabetes mellitus duration (T1DM), BMI, hypoglycemia, HbA1c, leptin, and brain-derived neurotrophic factor (BDNF) in the first trimester of diabetic pregnancy.

Methods: In the prospective observational cohort study, part of the scientific project PRE-HYPO No. IP2018-01-1284, we included 66 women with T1DM. According to the z-score for neonatal weight, we divided patients into two groups: Healthy weight neonates (HWN) (n = 47, 71.2%) and Overweight neonates (ON) (n = 19, 28.8%). CGM measurement was done on the iPro2 device (professional CGM system ''Blinded''). The iPro2 sensor provides a retrospective picture of glycemia for seven days without alarm or monitor. The maternal vein sera were analyzed for fasting leptin and BDNF concentration, and the HbA1c percentage was measured in maternal blood only. We studied whether ON was associated with age, T1DM duration, BMI before pregnancy, HbA1c, leptin, and BDNF in T1DM mothers with the logistic regression model.

Results: The percentage of maternal glucose concentration in the first trimester of pregnancy less than 3.9 mmol/L was significantly higher in the group of ON than in HWN (26.6 ± 13.1:19.2 ± 12.0; p = 0.044). Increased risks for ON were BMI before pregnancy (OR 2.012, 95% CI 1.163-3.481), CGM <3.9 mmol/L (%) (OR 1.082, 95% CI 1.082 (1.029–1.176), BDNF (OR 1.003, 95% CI 1.001–1.005).

Conclusions: Higher BMI, BDNF, and prevalence of maternal hypoglycemia during the first trimester of diabetic pregnancy increase the risk for overweight neonates.

LB032 / #1024

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

A NOVEL COMMUNITY PHARMACY SERVICE MODEL FOR TYPE 2 DIABETES CARE USING DIGITAL TECHNOLOGY; A SINGLE-ARM PILOT STUDY IN SOUTH KOREA.

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Background and Aims: Type 2 diabetes mellitus is a disease with a very low disease control rate despite pharmacotherapeutic management, and therefore research on the management of diabetic patients using digital technology is being actively conducted in the medical field. In this study, a novel management system using internet of things (IoT) linked digital platform technology was introduced to community pharmacies and it's effectiveness was evaluated.

Methods: 28 patients with Type 2 diabetes and 17 community pharmacies participated in the community pharmacy diabetes care program. The service was provided by IoT-linked digital platform at 2 weeks intervals for 24 weeks, which comprises medication counseling and support for self-monitoring of blood glucose and life style management.

Results: The mean of HbA1c was decreased significantly by 0.81% from 8.11 ± 1.10 to 7.30 ± 0.86 ($p < 0.001$) and fasting blood glucose level was decreased significantly ($p = 0.024$) at the end of the study. And the mean of triglyceride level was decreased with marginal significance ($p = 0.062$) over the service. The effect was shown at 12 weeks and it was lasted to the end of the study. These effect was faster than the past results of 30 weeks usual pharmacy care service research program.

Conclusions: The community pharmacy service using digital technology for type 2 diabetes care resulted in significant improvements in clinical outcomes for the first time. Further expanded and randomized controlled studies need to be done for the development of community pharmacy diabetes care service.

LB033 / #1002

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

ASSOCIATION BETWEEN MAXIMUM LIFETIME BODY MASS INDEX, BODY MASS INDEX AT SURVEY, AND CROSSING CAPILLARIES IN THE FINGER NAILFOLD IN TYPE 2 DIABETES MELLITUS

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Background and Aims: Increased capillary crossing in the finger nailfolds may be a new visual indicator of early microvascular damage in patients with type 2 diabetes mellitus (T2DM).

Methods: We conducted a cross-sectional and single-center study to examine the association between maximum lifetime body mass index (BMI) and BMI at survey, and the percentage of crossing capillaries in the finger nailfold in patients with T2DM (Table 1). Obesity was defined as a BMI ≥25 kg/m^2. Based on the simple capillaroscopic definitions provided by the European League Against Rheumatism Study Group, capillary morphology was evaluated using nailfold capillaroscopy.

Results: We included 60 T2DM patients (age, 40–75 years) in this analysis. In multiple linear regression analysis, patients categorized as obese at maximum lifetime and time of the survey had a significantly higher percentage of crossing capillaries compared with those without obesity at maximum lifetime and time of the survey. When compared to patients who were not obese at both the maximum lifetime and the time of the survey, those who were obese at the maximum lifetime but were not obese at the time of the survey tended to have a higher percentage of crossing capillaries.

Conclusions: The increase in the proportion of crossing capillaries in the finger nailfold in patients with T2DM may be significantly influenced by a history of obesity.

Table 1 Association between maximum lifetime body mass index, body mass index at survey, and crossing capillaries in the finger nailfold in type 2 diabetes mellitus

Maximum lifetime BMI (kg/m^2)	BMI at survey (kg/m^2)	Number	Crossing capillaries (%)	Model 1	Model 2	*p* value*
				β(95% CI)	β(95% CI)	
<25	<25	6	53.1 ± 11.6	Reference	Reference	
≥25	<25	17	63.1 ± 10.8	9.5 (−1.4–20.4)	8.1 (−2.9–19.1)	0.15
≥25	≥25	37	64.0 ± 11.3	11.5 (1.4–21.6)	12.8 (2.5–23.2)	0.03

Crossing capillaries (%) are presented as mean ± standard deviation.

Hypertension was defined as systolic blood pressure ≥140 mmHg, diastolic blood pressure ≥90 mmHg, and/or use of antihypertensive drugs.

Dyslipidemia was defined as low density lipoprotein cholesterol ≥140 mg/dL, high-density lipoprotein cholesterol <40 mg/dL, triglycerides ≥150 mg/dL or use of antilipidemic medications.

Model 1: Adjusted for age and sex

Model 2: Adjusted for age, sex, regular exercise, duration of diabetes, glycated hemoglobin, hypertension, and dyslipidemia

BMI, body mass index; CI, confidence interval

*p value from Model 2

LB034 / #981

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

PHARMACOLOGICAL INHIBITION OF A-FABP ALLEVIATES GLUCOSE INTOLERANCE THROUGH PROMOTING GLUCOSE UPTAKE IN BAT IN MICE WITH GESTATIONAL DIABETES MELLITUS

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Background and Aims: Gestational diabetes mellitus (GDM) characterized by adipose dysfunction is associated with considerable risks to both the mother and developing fetus. Current treatments for GDM are suboptimal owing to insufficient response in long-term outcomes in mother and infant. Adipocyte fatty acid binding protein (A-FABP) is an adipokine with pleotropic pathogenic effects on disordered glucose and lipid metabolism. This study aims to preclinically evaluate the effects of pharmacological inhibition of A-FABP on glucose intolerance and impaired glucose uptake in brown adipose tissue (BAT) in mice with GDM.

Methods: Experimental GDM was induced in 14-week-old female C57 BL6/J mice by high-fat diet feeding for 6 weeks prior to mating in combination with peritoneal injection of streptozotocin (100 mg/kg body weight) at day 6 and day 9 during pregnancy. A-FABP inhibitor BMS309403 was administrated in mice through daily oral gavage (15 mg/kg body weight) while control mice were treated with PBS as vehicle.

Results: Fasting blood glucose level in the second trimester during the pregnancy was significantly lowered in BMS309403 treatment group when compared to vehicle controls. Further, oral glucose tolerance test showed that hyperglycemia was substantially alleviated in mice received BMS309403 treatment. Additionally, *ex vivo* assay of glucose uptake in various white adipose tissues and BAT demonstrated that GDM-induced impairment in glucose uptake in BAT was specifically and markedly attenuated following BMS309403 treatment.

Conclusions: Our findings demonstrate that BMS309403 treatment alleviates glucose intolerance in close association with potentiated glucose uptake in BAT in mice with GDM, and suggest targeted A-FABP as promising therapeutic approach for GDM.

LB035 / #1023

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

ASSOCIATION BETWEEN FRUCTOSAMINE, INDEPENDENT OF HBA1C AND INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING METRICS: A SINGLE-CENTRE STUDY FROM THE MIDDLE EAST

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Background and Aims: Fructosamine can estimate glycaemic status where HbA1c measurement is potentially inaccurate. We investigated relationships between fructosamine, HbA1c and FreeStyle Libre-estimated Glucose management indicator (GMI) in a population with high prevalence of undiagnosed variant haemoglobin.

Methods: Persons with type 1 (T1DM) or type 2 (T2DM) diabetes on FreeStyle Libre whose sensor was active >50% of the time were included. Ambulatory glucose profile data from 30 days prior to fructosamine measurement were collected from LibreView. In these selected patients where there was a clinical decision to use fructosamine to assess glycaemic control, fructosamine (Cobas c501) was not significantly associated with simultaneously-measured HbA1c (Variant) ($p = 0.16$).

Results: Twenty-three [9 (39%)females, median age 36.6 (28.3-53.9) years, 12 T1DM, days worn 28.0 (23.5-29.5), sensor coverage 85% (71.0-97.0%)] patients were included. Median (IQR) fructosamine and HbA1c were 348 (296-391) umol/L, 7.2% (5.2-8.7)% respectively. Fructosamine was positively associated with GMI adjusted for diabetes type and HbA1c (Fructosamine 0.020 ± 0.004, $p < 0.0001$), T2DM 1.378 ± 0.517, $p < 0.015$, HbA1c n.s.) and negatively associated with both hypoglcyaemic events (glucose <70 mg/dL) per day (Fructosamine -0.004 ± 0.002 $p = 0.016$, T2DM -0.950 ± 0.634, $p < 0.001$, HbA1c n.s.) and time in range 70-180 mg/dL (-0.296 ± 0.063, $p < 0.001$, HbA1c n.s.). Adjusting for diabetes type, a fructosamine <300 umol/L was significantly associated with increased hypo frequency (0.59 ± 0.17, $p = 0.003$).

Conclusions: In this selected population, fructosamine was a significant and independent predictor of objectively-measured TIR and hypo frequency while HbA1c was not.

LB036 / #980

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

PROFILES OF GLYCEMIC CONTROL IN PEOPLE WITH TYPE 1 DIABETES USING CGM: A CLUSTERING APPROACH IN THE SFDT1 STUDY

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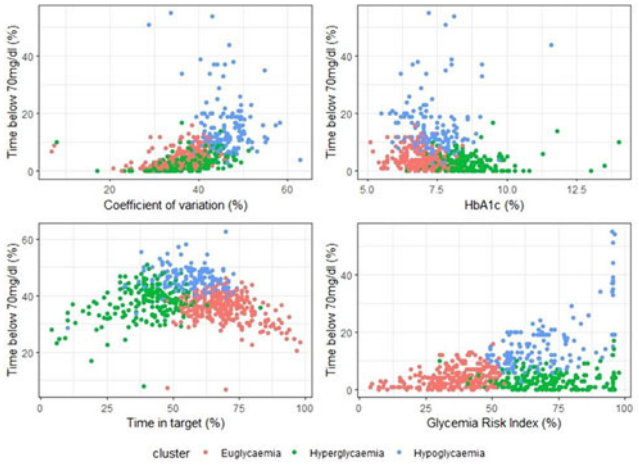
Background and Aims: Continuous glucose monitoring (CGM)-derived data are usually analysed in silos, metric by metric, for diabetes care or therapeutic strategy. Simultaneous analysis of the various dimensions of glycemic control in people with type 1 diabetes (PWT1D) would allow a more comprehensive overview.

Methods: We analysed data of PWT1D in the SFDT1 cohort study. A K-means clustering model was developed with HbA1c, coefficient of variation (CV), time in range (TIR), time below 70 mg/dl (TBR), Gold score and Glycemic Risk Index (GRI).

Results: We included 618 participants (53% men, age 41 years (SD 14)) from 20 centres in France. The optimal model was with 3 clusters and was highly stable (average Jaccard <0.9). The ''Euglycemia'' cluster (n = 280, 45%) was characterised by a high TIR (mean 69.3%), and low TBR (4.2%), TAR (time above 180 mg/dl: 26.5%), CV (35.7%), HbA1c (7.0%) and GRI (36.4) values. The ''Hyperglycaemia'' cluster (n = 197, 32%) was characterized by high TAR (56.5%), GRI (71.8) and HbA1c (8.5%) and low TIR (40.3%), TBR (3.2%) and Gold score (2.3). The ''Hypoglycemia'' cluster (n = 141, 23%) was characterized by high TBR (15.8%), CV (46.1%), GRI (69.2) and Gold score (3.0) **(Figure 1)**. Participants in the ''Hyperglycemia'' cluster were younger, socially vulnerable, and had more frequent hypertension than those in the ''Euglycemia'' cluster.



Conclusions: In a large population of PWT1D, we identified three distinct, clinically relevant glycemic control profiles, enabling better characterization of PWT1D and, thus, more personalised management. Figure 1

LB037 / #994

Topic: ***AS15 Human factor in the use of diabetes technology***

GLUCOSE CONTROL OF MIGRANT CHILDREN WITH TYPE 1 DIABETES IN LOMBARDY.

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Background and Aims: Migrant status may obstacle the management of type 1 diabetes (T1D) and the use of diabetes technologies. Patients at our center represent approximately 50% of children with T1D in Lombardy. Our aim was to compare glucose control and treatment choice of migrant children with T1D vs all patients followed at our center in 2021.

Methods: Auxological parameters, HbA1c (%), type of glucose monitoring [by blood (BGM), flash (FGM) or continuous (CGM) glucose monitoring], and treatment modality [multiple daily injection (MDI) insulin therapy, sensor augmented pump (SAP), advanced hybrid closed loop (AHCL)] were recorded.

Results: Migrant population: 54 patients (23F, 31M), mean age 14yrs ±4, mean BMI-SDS 0.79, median T1D duration 4yrs, mean age of onset 8.9yrs ±4.5. Mean HbA1c 7.8 ± 1.5. Of these, 45 (83%) use MDI (2 use BGM, 43 use FGM) and 9 (17%) use pumps (2 SAP, 6 AHCL, 1 pump user with BGM). HbA1c is not significantly different between pump and MDI users (7.3 ± 1.4 vs 7.9 ± 1.5). Regarding all 994 children with T1D followed at our center: mean BMI-SDS 0.61, mean age 13.5yrs, mean age of onset 10.9yrs ±4.7, median T1D duration 4yrs. Mean Hb1Ac 7.2 ± 1.1. Of these, 44% are pump users and 56% MDI users. HbA1c is significantly higher in migrant children vs overall (p = 0.0001). There is no significant difference in HbA1c between migrant pump users vs overall. Other parameters are not significantly different.

Conclusions: Migrant children are less likely to use technology and consequently have suboptimal glucose control.

LB038 / #1017

Topic: ***AS15 Human factor in the use of diabetes technology***

SITUATIONAL AWARENESS INDEPENDENTLY PREDICTS TIME IN RANGE IN ADOLESCENTS AND YOUNG ADULTS USING THE T:SLIM X2 WITH CONTROL-IQ SYSTEM ON A DAILY BASIS

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Background and Aims: Adolescents and young adults (AYA) with type 1 diabetes have competing demands for attention and struggle with diabetes self-management (DSM). A salient pyschocognitive construct may be their situational awareness of diabetes, which is the ability to recognize and interpret current health status and to successfully execute DSM behaviors. We sought to measure AYAs' situational awareness and DSM behaviors to determine predictors of Time-in-Range (70-180 mg/dl, 3.9-10.0 mmol/L, TIR) in advanced hybrid closed loop users (t:Slim X2 with Control-IQ technology, Control-IQ).

Methods: 14 AYAs (18 ± 1.86 years, 86% White non-Hispanic, HbA1c 7.9% ± 1.2, diabetes duration 8.0 ± 2.1 years) using Control-IQ participated in a 2-week study. Situational awareness was assessed at varying times 2-3 times/day by asking participants to report their perceived glucose levels and trends without checking their CGM. Additionally, Control-IQ system engagements (boluses, alerts, etc.) were collected. A multivariate model was used to determine factors that predict day-by-day TIR.

Results: In multivariable modeling, underestimating current glucose levels predicted lower TIR daily, independent of DSM behaviors (r = -0.22, Table). Acknowledging CGM alerts (r = 0.20) and having higher percentages of boluses with carbohydrates (r = 0.49) both predicted higher daily TIR. Number of CGM alerts, pump engagements, and percent of boluses with carbohydrates predicted both same-day and next-day TIR (table).

Conclusions: AYA who demonstrate lower situational awareness have lower TIR on a daily basis. This glycemic predictor is independent of DSM practices and may provide a new target for influencing glycemic outcomes in adolescents.

Table 1: Final multivariate model predicting day-by-day Time-in-Range (70–180 mg/dl, 3.9-10.0 mmol/L) in adolescents and young adults with Type 1 Diabetes

	Prediction of same-day TIR			Prediction of next-day TIR		
	Effect size *	*t*	*p*	Effect size *	*t*	*p*
% Underestimate glucose (Q2)	-0.22	-2.73	0.007 **			
# CGM alerts received/day	-0.31	-3.43	<0.001 ***	-0.29	-2.71	0.008 **
% CGM alerts acknowledged	+0.20	2.31	0.02 *			
Mean # pump engagements /day	-0.27	-3.00	0.003 **	-0.24	-2.59	0.011 *
# Boluses given/day				+0.28	3.31	0.001 **
% boluses that included carb entry	+0.49	5.75	<0.001 ***	+0.49	4.89	<0.001 ***

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

LB039 / #1001

Topic: ***AS15 Human factor in the use of diabetes technology***

265KM-EFFORT ULTRA-TRAIL (165KM, 9980M ELEVATION) WITH HYBRID CLOSED LOOP – 100% TIME IN RANGE - NO LIMIT FOR ME AND MY DIABETES TEAM

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Background and Aims: The use of Hybrid closed loop (HCL) by competitive athlete living with type 1 diabetes (T1DM) in extreme sports including ultra-trail running races has not been described. We present the performance of a 265km-effort (165km, 9980m elevation) ultra-endurance race with HCL on October 20-23, 2022 on Réunion Island.

Methods: A 59-year-old male athlete on HCL (Medtronic, Minimed780G, Guardian Sensor3) since January 2021 with total daily insulin(TDI) 16-21UI/day, Blood glucose(BG) target: 100mg/dl, active insulin time: 2h.Temporary target(150 mg/dl) was set 60min before the race. BG and ketones levels were controlled at 50,72,92,127,135,144 and 152km. Time in, below and above range (TIR,TBR, TAR); insulin delivery, nutritional and fluids intake were monitored. Biological analyze of muscle damage, inflammation, hepatic and renal function were performed before and post-race.

Results: Athlete ran continuously during 152km(9063m elevation), 57hours20min, then stopped as arrived at the chekpoint 1min after the cut-off time, due to lumbar pain.TIR was 100% (100% time in HCL, 100% sensor use), 0% TBR, 0% TAR. Mean sensor glucose 126+/-21mg/dl. BG and capillary ketones were 172-108-164-217-129-150-180mg/dl and 1.3-0.8-1.3-1.0-1.6-0.5-1,4 mmol/l respectively at medical checkpoints. The athlete consumed 1204g of CHO(21g/h) from which 96% were not declared to the algorithm and 7.5liters of drinks. TDI during race was 7.0UI/d (16.6UI/57h) vs 16.9UI/d the day before the race. Body weight decreased from 64.5 to 62 kg. There were no technical issues. Biological analysis found important and reversible muscle and hepatic abnormalities.

Conclusions: HCL use during ultra-endurance race is possible with good glycemic control in patients with appropriate physical and educational preparation.

LB040 / #1008

Topic: ***AS15 Human factor in the use of diabetes technology***

SIX MONTHS IN ADVANCED HYBRID CLOSED LOOP SYSTEM IN THE REAL WORLD: PSYCHOSOCIAL OUTCOMES IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: Advanced hybridclosed-loop systems(a-HCLS) only automate some aspects of diabetes care, psychosocial factors remain an important consideration in their use.We examined psychosocial and human factors of a-HCLS

Methods: Prospective data collection occurred during routine clinical care and included glycemic variables and psychosocial variables (Pediatric Quality of Life InventoryTM (PedsQL) diabetes module 3.0 child and parents (8-12 yrs); Quality of Life for Youth (13-18 yrs), Strengths and Difficulties Questionnaire (SDQ);Hypoglycemia Fear Survey (HFS) for Children,The Revised Child Anxiety and Depression Scale(R-CADS) and a-HCLS specific expectation and satisfaction survey).

Results: Sixty youth started HCL for their diabetes care.46 (67%) completed 6th month follow-up. 4 of the patients refused to fill the 6th month survey and 1 patient due to a psychiatric diagnosis were excluded.A total of 41 participants (23 females), mean age 12.5 years ±3.2 yrs (6.7–18 yrs) and diabetes duration of 5.5 ± 5.0 yrs completed the questionnaires. aHCL use mean age: 11.4yrs (6-17 yrs). Sensor time in range increased from 76.9 ± 9% at baseline to 80.4 ± 5% at 6 months ($P = 0.034$). HbA1c decreased from 7.1% ± 0.7% at baseline to 6.8% ± 0.8% after 6 months of use ($P = 0.031$) with the greatest HbA1c decline in participants with high baseline HbA1c.

Conclusions: To our knowledge, this is the first study to compares the psychological characteristics of T1D patients and parents starting on a-HCL.Although these technologies provide patients with more flexibility in their daily life and information about glucose fluctuations the use of the a-HCL in our practice resulted in a TIR above the recommended target without psychosocial variables of children.

LB041 / #992

Topic: ***AS15 Human factor in the use of diabetes technology***

TRUST BUILDING MECHANISMS IN DIGITAL HEALTHCARE DATA RECORDING AND MEASURING FOR ADULTS WITH TYPE 2 DIABETES

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Background and Aims: Insulin pen connected caps (IPCC), associated with digital support platforms, are potent tools to improve glycemic control through titration support for people with type 2 diabetes (PWT2D). This research aimed to develop an understanding of the trust building process in relation to digital health measuring tools, with the view of leveraging this knowledge for the successful initiation of IPCCs.

Methods: We conducted a multi-method qualitative study with a behavioural science approach, including 1) one-on-one interviews with diabetes support system experts, 2) dyad interviews with PWT2D with different behavioural mind states (struggling, juggling, controlling) and informal carer persons, and 3) focus groups with healthcare professionals (HCPs) representing conservative or innovator personae (general physicians, specialists, nurses).

Results: From June-2022 to August-2022, we conducted nine interviews with experts, 28 dyad interviews with PWT2D and carers, and focus groups with 59 HCPs. Findings show that trust in digital healthcare measuring and tracking devices is not a given. It operates differently from building trust in medications and requires activating, motivating and sustaining desired behavior change. To create acceptance and engagement, trust needs to be built systematically with messages that leverage data to 1) support self-efficacy and individual balance, 2) empower personal goals via data collection, and 3) showcase progress of data collection routines as life-long chronic care learning.

Conclusions: People with trust built on all three levels felt in control of their diabetes, motivated and engaged in digital healthcare solutions. Focus on trust building is critical for digital healthcare launch strategies, particularly in user conversion and initiation phases.

LB042 / #1030

Topic: ***AS15 Human factor in the use of diabetes technology***

EATING DISORDERS IN SUBJECTS WITH T1DM: COMPARISON BETWEEN MDI VS CSII

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Background and Aims: To evaluate the predisposition to eating disorders (ED) in subjects with type 1 diabetes mellitus (T1DM) and to compare possible differences between subjects on multiple daily injections (MDI) vs insulin pumps (CSII).

Methods: We enrolled subjects with T1DM, both on MDI and CSII, age >18 years old. To all participants 34 items Body Shape Questionnaires (BSQ) and Eating Disorder Inventory (EDI)-3 questionnaires were administered. In all subjects data about HbA1c and body mass index (BMI) were collected.

Results: 126 subjects (66 women, age 41 ± 12 years), 51% on MDI e 49% on CSII, were enrolled. Subjects on MDI and CSII were comparable for HbA1c and BMI. 23% of participants presented BSQ score compatible with ED predisposition or overt ED. Subjects on MDI had more pathological scores than those on CSII (26.4% vs 16.3%). Subjects on MDI presented also EDI-3 scores compatible with tendency to perfectionism more often than those on CSII

Conclusions: In our population we observed in subjects with T1DM high prevalence of ED predisposition or overt ED (23%).

ED seem to be more frequent in subjects on MDI than on those on CSII. Subjects on MDI have more frequently a perfectionist personality

LB043 / #982

Topic: ***AS15 Human factor in the use of diabetes technology***

COGNITIVE ASSESSMENT IN ELDERLY WITH TYPE 1 DIABETE MELLITUS: A CROSS SECTIONAL OBSERVATIONAL STUDY

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Background and Aims: To investigate cognitive performance in elderly with type 1 diabetes(T1DM) on insulin pump(CSII) and the correlation between time in range(TIR) and cognitive scores(CS). Differences in CS according to duration of disease were also investigated.

Methods: Subjects with T1DM aged >65 years on CSII were included. Participants underwent following tests:Rey Auditory Verbal Learning Test(RAVLT), Rey-Osterrieth Figure Test, Verbal Fluency Test, Stroop Color and Word Test and Trail Making Test(TMT) A and B. At visit data from continuous glucose monitoring, according to 2019 ATTD Consensus, diabetic history and blood tests were collected.

Results: We enrolled 45 subjects, 22 women(49%), mean age 69.5 years. Median duration of disease was 30 years; mean HbA1c was 58 mmol/mol(7.4%). Mean TIR was 66%, mean time below range was 2.62% and time above range (TAR) 29.9%. 5 subjects(11%) presented CS compatible with mild cognitive impairment. No correlation between TIR and CS was detected. Based on median duration of disease, subjects with longer history presented lower TIR(59.7 %(20.2) vs 71.1% (16.3), $p=0.05$) and higher TAR(35.7% (17.8) vs 25.2% (15.3), $p=0.05$). Subjects with longer history presented lower scores at RAVLT-Immediate recall (30.1(12.6) vs 39.3(13.4), $p<0.001$) and RAVLT-Accuracy (0.89(0.09) vs 0.93(0.05), $p=0.08$) and longer time at Stroop-Test (28.8(8.13) vs 20.0(7.36), $p<0.001$) and TMT-B (131(64.2) vs 104(32.2), $p=0.08$) test. Groups were comparable for school age(>30 years 12.9 vs <30 years 13.1, $p=0.80$).

Conclusions: Elderly with T1DM presented good TIR and good CS. Those with longer history presented lower CS in executive and attentive functions, expression of subcortical damage. No association between TIR and CS was detected.

LB044 / #996

Topic: ***AS15 Human factor in the use of diabetes technology***

GROUP EDUCATION ON CARBOHYDRATE COUNTING INCREASES TIME IN RANGE

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Background and Aims: Carbohydrate counting(CHOc) is the most effective nutritional strategy to improve glycemic control in subjects with type 1 diabetes mellitus(T1DM), both on multiple daily injections (MDI) and insulin pump (CSII). Participation in a CHOc group-education program showed significant reduction of glycated hemoglobin (HbA1c). Aim of this study is to evaluate the effect of CHOc group-education program on time in range(TIR).

Methods: In a prospective, observational, case-control study subjects with T1DM, aged ≥18 years, on MDI or CSII, participating in a 3 weeks CHO-c group-education course (study group) were compared to those receivingstandard education (control group). For all subjects at enrollment and after 24 weeks, TIR, time below range (TBR), time above range (TAR) were evaluated accordingly to 2019 ATTD Consensus through retrospective CGM. Blood tests were recorded at both timepoints.

Results: 80 subjects(57 males, mean age:45,3 years, 48 CSII) were included in study group and 32(15 males, mean age:42,5 years, 30 CSII) in control group. At enrollment groups were comparable for CGM and laboratory parameters. After 24 weeks in the study group TIR increased(enrollment $57.2\pm14.4\%$ -after 24 weeks $62.3\pm16.6\%$, $p=0.013$) while it did not change in the control group ($p=0.627$). Study group showed a significant decrease of Level1 TBR(enrollment $2.9\pm3.3\%$ – after 24 weeks $2.5\pm2.9\%$, $p=0.021$)and a not significant decrease of Level1 TAR ($p=0.07$). In both groups a significant reduction of HbA1c has been detected.

Conclusions: Group education on CHO-c is associated with significant increase of TIR. Further data are required especially with advanced hybrid closed loop where basal infusion is automatically delivered and CHO-c is essential.

LB045 / #1010

Topic: ***AS18 Other***

CD36-OXLDL AXIS PLAYS A MAJOR ROLE IN PLATELET ACTIVATION AND THROMBOSIS IN TYPE 2 DIABETES

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Background and Aims: Type 2 diabetes (T2D) is a chronic disorder affecting more than 500 million people worldwide. Platelet activation and thrombosis have been demonstrated in this disease which may eventually lead to cardiovascular disorders. We aim to find a novel pathway that promotes platelet activation in patients with chronic T2D.

Methods: Platelets were collected from patients with chronic T2D and from non-diabetic healthy individuals. Platelet activation was assessed using measurement of surface expression of P-selectin, phosphatidyl serine (PS) and CD41a+ microparticle release. LC-MS/MS was used to identify the glycosylated proteins involved in platelet activation using whole platelet proteome. Western blot was used to validate the data.

Results: Proteomic analysis indicated an elevated level of total CD36 and its glycosylated forms in platelets of T2D patients than healthy individuals. We observed an elevated plasma levels of oxLDL, ligand of CD36 in T2D patients. We further validated that oxLDL or T2D patients' plasma containing high oxLDL significantly activated platelets *in vitro*. Both forms of OxLDL

increased platelet activation alongside signaling adopter molecules like p-Src, p-Lyn and phospho(p)-JNK. The supplementation of sulfo-n-succinimidyl oleate (SSO), a known inhibitor of CD36, significantly inhibited oxLDL-mediated platelet activation *in vitro*.

Conclusions: Our data suggest that elevated expression of CD36 and its glycosylated forms in platelets increase the risk of oxLDL mediated hyperactivation of platelets in T2D patients. The CD36-oxLDL axis may act as a potential target to inhibit thrombotic complications in T2D.

LB046 / #958

Topic: ***AS18 Other***

FUNCTIONAL STATE OF THE KIDNEYS IN PATIENTS WITH TYPE 2 DIABETES

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Background and Aims: Kidney damage in type 2 DM is one of the significant complications of this disease. CKD develops in approximately 15% of individuals in the general population and in every 2 patient with AH and DM. Determining the level of cysC in DN in the initial stages of the disease will allow early diagnosis and timely therapy, delay the development of the terminal stage of CKD. Aim: To study the effect of cysC on the functional state kidneys in patients with DN.

Methods: 120 patients with type 2 diabetes were under observation, which were divided into two groups depending on the stage of DN. A1. Group 2 consisted of patients with diabetic nephropathy with microalbuminuria and impaired renal function DN C2, A2. Average GFR cr. amounted to 73.5 ± 10.81 ml/min/1.73 m2, albuminuria - 36.50 ± 3.4 mg/g, mean age 59.3 ± 6.5 years, HbA1C-9.3 ± 1.82%, type 2 diabetes experience – 7 ± 3.16 years.

Results: Study showed that in patients with type 2DM with DN. The level of serum cysC and the calculated eGFRcys in this group differed from the control. The serum concentration of cysC was higher (0.64 ± 0.09 mg/ml versus 1.07 ± 0.08 mg, $p < 0.05$), the eGFRcys was lower (81.32 ± 6.31 ml /min versus 96.60 ± 5.22 ml/min, $p < 0.05$) in healthy individuals. In patients with DNC2,A2, compared with the ctr and the 1 grp of patients, the eGFR index was reduced by 24.2% and 18.3%, respectively ($p < 0.0$,$p < 0.05$), which indicates a pronounced decrease in kidney function in this category of patients with type 2 DM.

Conclusions: The results showed that in patients with subclinical course of DN, a decrease in GFR, determined by the level of cysC.

LB047 / #969

Topic: ***AS18 Other***

MACROPHAGE DERIVED MIR-210-3P CAUSES ADIPOCYTE INSULIN RESISTANCE IN OBESITY

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Background and Aims: Obese pathophysiological adipose tissue microenvironment (ATenv) enriched with high free fatty acids (lipids) and low oxygen tension (hypoxia), facilitates macrophage accumulation and proinflammatory switching followed by chronic low-grade inflammation leads to adipose tissue dysfunction. miRNAs generated from ATenv dynamically regulate tissue homeostasis and impact pathophysiology development. Our aim is to find out the role of adipose tissue macrophages (ATMs) secreted miRNAs in the fat pad during chronic obesity.

Methods: Human subject: Visceral adipose tissue was collected from obese diabetic ($n = 8$, BMI: 32.2-44 kg/m^2) and lean non-diabetic ($n = 5$, BMI: 22.2-27.4 kg/m^2) patients. ***In-vivo*:** HFD-fed diet-induced obese mice model was generated for the intervention study. ***In-vitro*:** Monocyte, macrophage and adipocyte cells considered for miRNA silencing/upregulation, co-culture experiments and insulin sensitivity determination studies.

Results: The pathophysiological lipid-rich hypoxic (HL) environment exhibits marked induction of *miR-210-3p* expression in ATMs in obese diabetic patients and in diet-induced obese mice (HFD) compared to controls. Co-cultured experiments elucidate ATMs-driven miR-210-3p potentiates adipocyte glucose intolerance. miR-210-3p mimic (MM) transfected adipocytes significantly reduce glucose uptake. Interestingly control(CI) or miR-210-3p inhibitor(MI) transfected macrophages when cocultured with adipocytes in the presence or absence of HL, showed adipocytes with MI macrophages increasingly uptakes glucose compared to CI-macrophages under HL conditions. Furthermore, Anti-miR-210-3p LNA administered HFD mice showed a sharp decrease in *miR-210-3p* expression in the VAT-isolated ATMs and strikingly improved systemic insulin sensitivity.

Conclusions: Macrophage-driven *miR-210-3p* holds a critical role in adipocyte functionality by abrogating insulin-stimulated glucose uptake in adipocytes at the onset of obese diabetic conditions and holds formidable potential as a therapeutic candidate.

LB048 / #988

Topic: ***AS18 Other***

IMPACT OF NOCTURNAL SYMPTOMATIC AND ASYMPTOMATIC PERSON-REPORTED HYPOGLYCAEMIA ON MORNING FUNCTIONING AMONG ADULTS WITH INSULIN-TREATED DIABETES: THE HYPO-METRICS STUDY

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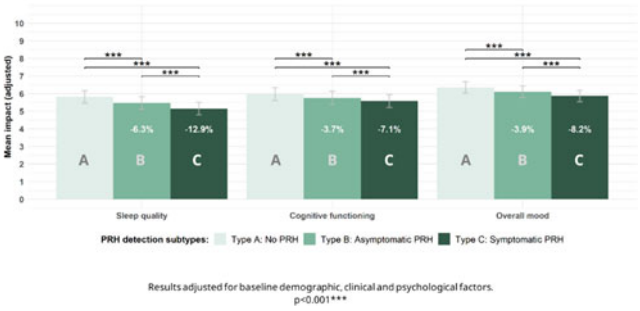
Background and Aims: To examine the impact of nocturnal hypoglycaemia on self-reported sleep quality, cognitive functioning, and mood.

Methods: On 70 consecutive mornings, adults with insulin-treated diabetes self-reported their morning functioning (sleep quality, cognitive functioning, and mood), via the Hypo-METRICS smartphone app. Participants also recorded nocturnal person-reported hypoglycaemia (PRH) including whether they recognised the episode via symptoms (symptomatic PRH) or via their own glucose monitoring system (asymptomatic PRH) (see Figure 1, Type A-C). Multilevel regression assessed associations between type of hypoglycaemia and morning functioning (percentage change on original 0-10 scale).

Results: Among 408 adults (44% female, age[M±SD]: 55 ± 15 years; n = 207 with type 1; n = 201 with type 2 diabetes), PRH (Type B & C, Figure 1) was associated with lower ratings in subjective sleep quality (B: -6.3%, C:-12.9%), cognitive functioning (B: -3.7%, C: -7.1%) and mood (B: -3.9, C: -8.2%) (all $p < 0.001$) compared to nights without PRH (Type A). For all domains, symptomatic PRH (Type C) was associated with significantly lower ratings in morning functioning compared to asymptomatic PRH (Type B) (all $p < 0.001$).

Conclusions: Recognition of nocturnal hypoglycaemia, from either symptoms or one's own glucose monitoring system, is associated with worsening of sleep quality, cognitive functioning, and mood assessed the following morning.

Figure 1: Impact of nocturnal hypoglycaemia on subjective morning functioning



Results adjusted for baseline demographic, clinical and psychological factors.
p<0.001***

ATTD 2023 Read by Title

R001 / #954

Topic: ***AS02 Clinical Decision Support Systems/Advisors***

ALIGNING CONSENSUS: A HARMONISED GUIDE FOR THE DIAGNOSIS AND GLYCAEMIC TREATMENT OF DIABETES TYPES 1, 2, AND LADA

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R002 / #160

Topic: ***AS06 Glucose sensors***

USE OF AGP IN GDM - IMPROVED PATIENT SATISFACTION AND GLYCEMIC CONTROL

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R003 / #1032

Topic: ***AS06 Glucose sensors***

REACHING CONTINUOUS GLUCOSE MONITORING TARGETS WITH SENSOR-AUGMENTED PUMP: A CASE REPORT

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R004 / #695

Topic: ***AS09 New Medications for Treatment of Diabetes***

NEUROPROTECTIVE EFFECT OF PRAMIPEXOLE IN EXPERIMENTAL MODEL OF DIABETIC NEUROPATHY: EFFECT ON TLR4/IRAK1/TRAF-6/ ICAM-1 AXIS

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R005 / #86

Topic: ***AS09 New Medications for Treatment of Diabetes***

ANTIDIABETIC ACTIVITY OF RECYCLED SODIUM POLYACRYLATE FORMULATED NANOCELLULOSE EXTRACTED FROM INVASIVE PLANT

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R006 / #970

Topic: ***AS09 New Medications for Treatment of Diabetes***

PHARMACOLOGICAL EVALUATION OF INVIVO HYPOGLYCEMIC ACTIVITY OF LEAF EXTRACT AND SOLVENT FRACTIONS OF DORSTENIA BARNIMIANA IN MICE: A SINGLE DOSE STUDY

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R007 / #1027

Topic: ***AS09 New Medications for Treatment of Diabetes***

HYPOGLYCEMIC EFFECT OF COFFEA ARABICA LEAF EXTRACTS AND MAJOR BIOACTIVE CONSTITUENTS

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R008 / #691

Topic: ***AS11 Devices Focused on Diabetic Preventions***

CONTINUES GLUCOSE MONITORING AFFECTS TO POOR DIABETES CONTROL: A CASE REPORT

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R009 / #87

Topic: ***AS13 New Technologies for Treating Obesity and Preventing Related Diabetes***

PREVENTABLE RISK FACTORS FOR TYPE 2 DIABETES CAN BE DETECTED USING NONINVASIVE SPONTANEOUS ELECTRORETINOGRAM SIGNALS

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R010 / #718

Topic: ***AS14 Blood Glucose Monitoring and Glycemic Control in the Hospitals***

A TELL-TALE TOOL FOR BOTH HYPERGLYCEMIA & HYPOGLYCEMIA

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R011 / #925

Topic: ***AS15 Human factor in the use of diabetes technology***

CONTINUOUSLY REFRESH KNOWLEDGE OF INSULIN PUMP TECHNOLOGY

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R012 / #788

Topic: ***AS16 Trials in progress***

DETECTION OF HYPOGLYCEMIA IN PEOPLE WITH T2DM IN PRIMARY CARE THROUGH CONTINUOUS GLUCOSE MONITORING. DESIGN AND OBJECTIVES OF THE GPDETECT STUDY

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R013 / #607

Topic: ***AS18 Other***

COMPARATIVE STUDY OF THE ANALGESIC EFFECT OF THE SODIUM-CALCIUM REVERSE-MODE EXCHANGER (NCX) KB-R7943 AND AMITRIPTYLINE ON DIABETIC NEUROPATHY MODEL IN RATS

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R014 / #930

Topic: ***AS18 Other***

DIABETES TECHNOLOGY: YEA OR NAY?

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R015 / #1035

Topic: ***AS18 Other***

RISK REDUCTION INTERVENTION TO REDUCE CORONARY ARTERY DISEASE AMONG HIGH RISK WOMEN

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R016 / #72

Topic: ***AS18 Other***

HYPERGLYCEMIA IN THE FIRST WEEK OF LIFE, A CASE OF NEONATAL DIABETES MELLITUS

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