P-0340 – Evaluation of 24 hour glycemic control in T2DM patients receiving the novel formulation of U-200 human pre-mix insulin

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BACKGROUND
Effective glycemic control and achieving minimum glycemic variability is the main goal of diabetes management. Patients with type 2 diabetes will need insulin replacement at some stage of the disease. Premix insulin formulations provide basal and prandial components which can be administered before meals. In those patients with predominant insulin secretory deficiency and those with obesity, the dosage requirements can vary and many times patients get annoyed with the large volume of injections. U-200 is a new r-DNA Human Insulin Premix 30/70 - 200IU/mL available in India for use in patients with diabetes mellitus. It is first of its kind and introduced with an objective to address several unmet needs of patients on insulin therapy.

AIM
To assess glycemic control and variability over 6-7 days in type 2 diabetes mellitus patients treated with novel formulation of high concentrated human premix insulin U-200 (r-DNA Human Insulin Premix 30/70 - 200IU/mL) using a continuous glucose monitoring device.

METHOD
In this prospective, open label study, adult patients with type 2 diabetes mellitus requiring regular / NPH or premixed human insulin were treated with the new high concentrated human premix insulin (r-DNA Human Insulin Premix 30/70 - 200IU/mL). Glycemic control was assessed for 6-7 days with a professional 24-hours continuous glucose monitoring device. Percentage of time in normal glycemic range, mean amplitude of glucose excursions (MAGE), duration and frequency of hypoglycemic (<70 mg/dl) and hyperglycemic (>150 mg/dl) episodes were recorded. Assessments were done at baseline and seven days of treatment

RESULTS

- Thirty patients (N=30, mean age 55.10years; male 19, female 11) were included.
- The mean glucose level was 154.57 mg/dl whereas mean daily dose of insulin was 20+4.95 IU.
- Glucose levels were within the acceptable range 62.4% of time(duration of 5 Days- day 2 to day 6)
- The mean numbers of hyperglycaemia and hypoglycemia episodes were 2.46 and 0.19 respectively with a mean duration of 156.40 and 25.60 minutes respectively.
- Mean amplitude of glucose excursions was 76.78 (+17.97) mg/dl.
- The mean sugar levels before breakfast, after breakfast, before lunch and after lunch were 138.21, 168.38, 152.60 and 161.73 mg/dl respectively with a mean HbA1c of 7.04 ± 0.61.
- The study medication was well tolerated without any serious adverse event

PROFILE OF MEAN BLOOD GLUCOSE BY MEAL

Periods	Mean Values
Sleeping	135.63
Before Breakfast	138.21
After Breakfast	168.38
Before Lunch	152.60
After Lunch	161.73
Evening	164.63
After Dinner	153.50
Before Dinner	171.83

ESTIMATED MEAN HBA1C LEVELS FROM CGMS DEVICE

Parameters	Mean HbA1c (%)
Mean ± SD	7.04 ± 0.61
Range (Min – Max)	(5.9 – 8.2)

PROFILE OF MEAN AMPLITUDE OF GLUCOSE EXCURSIONS

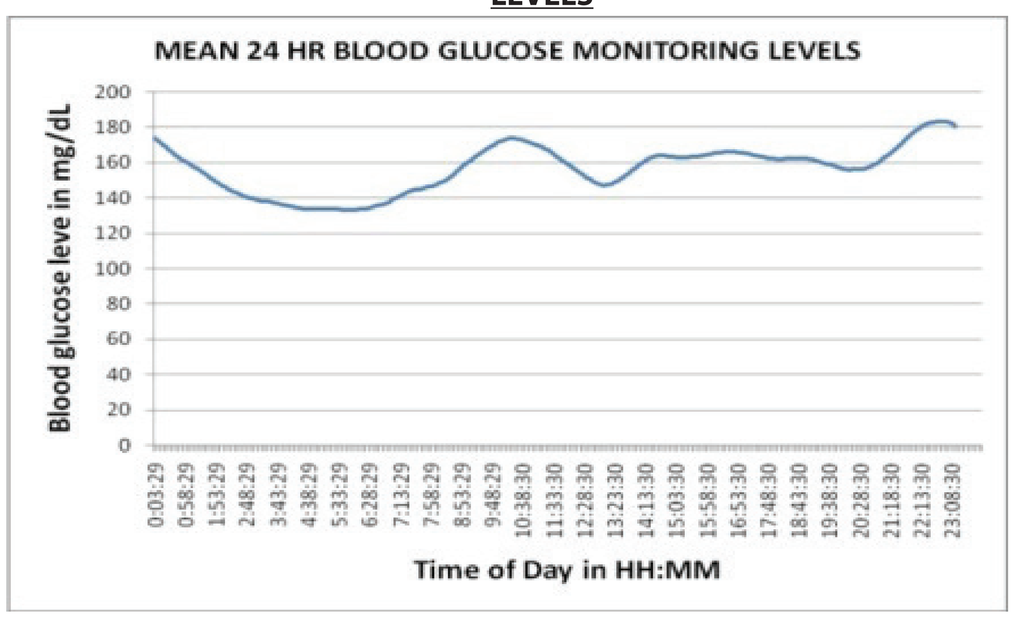
Parameters	Mean MAGE (mg/dl)(N = 30)
Mean	76.78
SD	17.97
Range (Min – Max)	(46.81 – 114.51)

OVERALL STATUS OF BLOOD GLUCOSE AMONG STUDY CASES

Parameter	Total (N = 30) (%)
% of time with BG < 70 mg/dL	01.90
% of time with BG > 150 mg/dL	35.70
% of time with BG in Normal Range (70 -150 mg/dL)	62.40

Average 62.40% times of the total study cases had Blood Glucose levels with in Normal range of 70 – 150 mg/dL.

MEAN 24 HR BLOOD GLUCOSE MONITORING LEVELS



DISCUSSION
Continuous glucose monitoring data confirms that the novel formulation of U-200 (r-DNA Human Insulin Premix 30/70 with concentration of 200IU/mL) containing regimen is effective, safe and well tolerated in type 2 diabetes patients.

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