Comparison of glycemic excursion using Freestyle® Libre Pro™ Flash Glucose Monitoring System in patients with type 2 DM before and after treatment with Voglibose

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BACKGROUND

- Diabetes mellitus is associated with a two to three-fold increase in the risk of cardiovascular diseases. However, intensive glucose-lowering therapy aiming at reducing HbA1c to a near-normal level failed to suppress cardiovascular events in recent randomized controlled trials.
- Glycosylated hemoglobin (HbA1c) reflects average glucose level, rather than the glycemic variability. Glycemic variability has been shown to be associated with greater reactive oxygen species production and vascular damage, compared to chronic hyperglycemia
- These findings suggest that management of glycemic variability plays an important role in diabetes management.

AIM

- The aim of this study was to determine daily glycemic excursions using Flash Glucose Monitoring in patients with type 2 diabetes receiving Voglibose as add-on therapy.

METHOD

- 100 type 2 diabetes mellitus (T2DM) patients who met the inclusion criteria were recruited from a large network of diabetes centres in India (which are all linked through a common electronic medical record system). The centres all follow the same standard protocols for diabetes management.
- The inclusion criteria were : Age 18-70 years, BMI, ≥ 23 kg/m2, HbA1c, ≥ 7% (for at least 3 months prior screening) on stable dose of Metformin only or a combination of Metformin and Sulfonylurea. Patients on Insulin and other Oral Hypoglycemic agents were excluded.(OHA's)
- At the screening visit (V1-Screening), patients were initiated on the Freestyle Libre Pro. HbA1c, lipid profile, fasting plasma glucose (FPG), and post-prandial plasma glucose (PPG) were also done during screening.
- During visit 2 (Randomization), patients with at least two postprandial glucose (within 2 hours of meal) excursions above 140 mg/dl within the 14 day period of using the Freestyle Libre Pro were randomized for the study. Voglibose was added to the existing stable dose therapy and the Freestyle Libre Pro was re-applied.
- The sensor was removed and data was collected after 14 days (Visit 3). Next the patient visited the clinic again after 12 weeks of voglibose treatment. (Visit 4). The sensor was applied for the last time at this visit and was removed 14 days later (Visit 5)
- At end of study, all relevant clinical and biochemical data were collected again.

STATISTICAL ANALYSIS

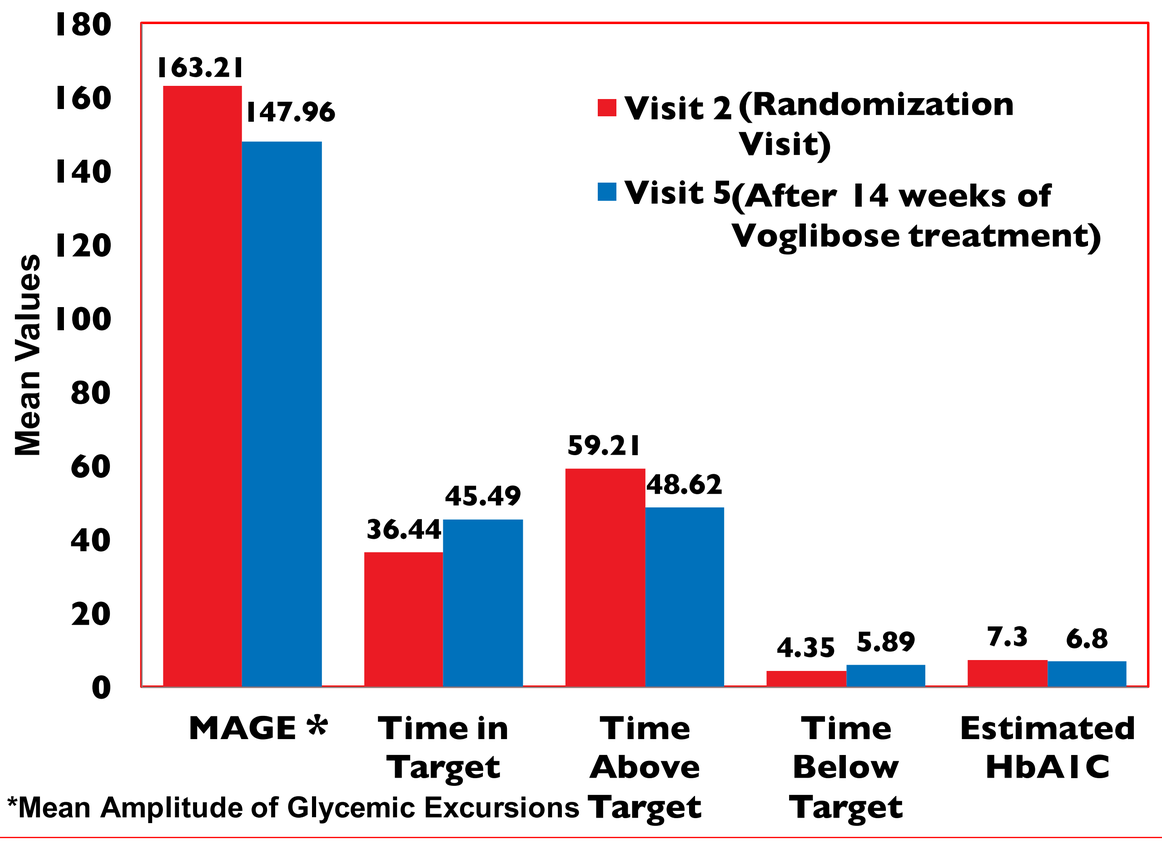
- Data was analyzed using SAS version 9.4
- The statistically significance difference between two visits were calculated by using paired t test at 5% level of significance.

RESULTS

Table 1 : Comparison of biochemical parameters at Screening and End of Study (Intervention- 6 months with Voglibose as add-on therapy)

VARIABLES	Screening Visit n=100	End of Study Visit n=100	P-value
Age (years)	50.4 ± 9.3	-	-
Male n (%)	54 (54)	-	-
Weight (kg)	71.2 ± 12.8	70.2 ± 12.9	0.001
BMI(kg/m^2)	28.0 ± 4.1	27.6 ± 4.3	<0.001
Systolic Blood Pressure (mmHg)	125 ± 13	121 ± 10	0.002
Diastolic Blood Pressure (mmHg)	78 ± 7	77 ± 6	0.162
HbA1C (%)	8.9 ± 1.4	7.9 ± 1.1	<0.001
Fasting blood glucose (mg/dl)	171 ± 52	156 ± 41	0.002
Post-prandial blood glucose(mg/dl)	279 ± 71	241 ± 59	<0.001
Total Cholesterol (mg/dl)	180 ± 37	166 ± 37	<0.001
Triglycerides (mg/dl)	154 ± 66	134 ± 56	0.001
HDL-Cholesterol (mg/dl)	39 ± 9	39 ± 9	0.706
LDL-Cholesterol (mg/dl)	110 ± 33	100 ± 32	0.001
Non-HDL-Cholesterol (mg/dl)	139 ± 37	126 ± 34	0.001

Figure 1: MAGE, Time and Estimated HbA1c between Visit 2 (Randomization) and Visit 5 (14 weeks of Voglibose treatment)



*Mean Amplitude of Glycemic Excursions

CONCLUSION

- "Time in target for glucose" improved significantly by adding voglibose to the existing stable treatment regimen in T2DM patients.
- The reduction in glycemic variability was seen within 14 days of initiating voglibose therapy and it was seen upto 14 weeks of treatment.
- In summary, voglibose reduces glycemic variabilty and thereby plays an effective role in type 2 diabetes management especially in Asian populations consuming carbohydrate rich diet.