Original Article

Glycemic Variability Using Ambulatory Glucose Profile in Type II Diabetic Patients

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Abstract

Background : Diabetes Mellitus is a chronic metabolic disorder associated with hyperglycaemia. This is due to decreased insulin secretion, decreased glucose utilization, and increased glucose production. Glycemic Variability (GV) refers to fluctuations in blood sugar levels Peaks and valleys over a period of time. To adequately understand glycemic variability is a remarkable task and it can be achieved through using of Continuous Glucose Monitoring.

Aim and Objectives : To Demonstrate the Glycemic Variability in A Group of Type 2 Diabetes Mellitus Patients Using Ambulatory Glucose Profile.

Materials and Methods : The present study was a hospital based observational study, conducted at General medicine department, Vinayaka Mission's KirupanandaVariyar Medical College and Hospital, Salem. All the Type 2 Diabetes patients with HbA1c >7.5% were included in the study. The eligible patients were selected by consecutive sampling after obtaining the informed consent.

Results : The mean age of the study participants was 58.5 (8.0) years and more than half (52%) were females with a F:M of 1.04:1. The mean fasting and postprandial blood sugar was 155.6 (21.1) mg/dl and 297.9 (58.5) mg/dl respectively. There was a mean decrease in the glycemic values from day 0 to day 14 and it was found to be statistically significant ($p<0.001$).

Conclusion : Ambulatory blood glucose monitoring is considered to be an effective tool which empowers the patients to monitor and judge their glucose levels on a daily basis which makes it more comprehensive and also makes the patient more aware on their diabetic control.

Key words : Diabetes Mellitus, Glycemic Variability, Ambulatory Blood Glucose Monitoring.

Diabetes is a metabolic disorder, which has multiple etiology. Chronic hyperglycemia is a characteristic feature and disruption of metabolism of carbohydrate, fat and protein occurs[1]. According to International Diabetes Federation (IDF) an estimated 463 million people globally had diabetes in the year 2020, out of which India contributed 77 million of the burden. With an overall prevalence of diabetes at 8.9%, after the United States of America, India has the highest number of Type I Diabetes Mellitus and 2% of mortality is attributed to diabetes in India according to World Health Organization[2,3].

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Received on : 26/06/2024
Accepted on : 02/11/2024

Editor's Comment :

- Ambulatory Glucose Monitoring (AGM) is a valuable tool for assessing glycemic variability in patients with poorly controlled Type 2 Diabetes.
- This study demonstrated that AGM not only provides detailed insight into glucose fluctuations but also significantly improves glycemic control over a short period, enhancing patient awareness and engagement in managing their condition.

Due to lack of awareness and proper patient education diabetes is usually poorly controlled and there still are many undiagnosed subclinical cases of diabetes. A good metabolic control can be achieved by a combination of regular blood glucose monitoring, good patient education and appropriate treatment. Although monitoring of glucose regularly is a key for the management of the disease, monitoring of glucose is lower than the recommended guidelines. According to Indian data, an average Indian diabetic voluntarily monitors blood glucose once a week, while Insulin dependent patient monitors three-four times

How to cite this article : Glycemic Variability Using Ambulatory Glucose Profile in Type II Diabetic Patients. Moogaambiga S, Hamsavardhini R, Kirubhakaran, Rangabashyam SR, Makina J. *J Indian Med Assoc* 2025; **123(7):** 37-40.

a week, whereas ideally they should be monitoring at least 3 to 4 times in a day[4].

HbA1c has been used to assess a good glycemic control. HbA1c is generally considered to reflect mean blood glucose over a period and is therefore not a good indicator of day-to-day diabetes control. This is of particular importance when considering the need to avoid significant extremes of glucose variability and the associated risk of hypoglycemia or hyperglycemia. There is also evidence that glycemic variability may have a greater association with the risk of diabetic complications than mean HbA1c[5].

To adequately understand glycemic variability is a remarkable task and it can be achieved only through a precise and standardized method of collection and processing of data from blood glucose[6]. Unlike HbA1c, we can directly observe and quantify glycemic variations using of Continuous Glucose Monitoring (CGM)[6]. CGM offers the possibility of recording. In spite of the fact that diurnal glucose patterns can be monitored through this method, such data often remains unmanageable. Hence, an analysis that is standardized and will produce the significant patterns of blood glucose variations which is also not complicated to understand is needed[7].

This study aimed to use this novel and comprehensive tool for the doctor to understand the patient's complete glycemic picture. AGP will be an effective basis for education, helping achieve better understanding of glycemic variability and increase involvement in self-management. There is a scarcity in knowledge of Ambulatory glucose profiling in the Indian population. Hence, this study will be able to bridge that gap.

Materials and Methods

The present study was a hospital based observational study, conducted at General Medicine Department, Vinayaka Mission's KirupanandaVariyar Medical College and Hospital, Salem. The study period was performed between January, 2021 and September 2022. All the Type 2 Diabetes patients with HbA1c >7.5% were included in the study. Type 2 Diabetic patients with HbA1c less than 7.5%, Type 1 Diabetic patients, Non diabetic patients, Gestational patients, Type 2 Diabetes with Sepsis, Chronic Kidney Disease, coronary artery disease, Hypertensive emergency, urgency, malignant hypertension and Preoperative, perioperative and postoperative patients were excluded from the study. A total of 50 patients with Type 2 Diabetes Mellitus were needed for assessing Glycemic variability using ambulatory glucose profile. The eligible patients were selected by consecutive sampling after obtaining the informed consent until the sample size was reached. Written informed consent was obtained from all the patients in the study. A pre-designed, semi-structured questionnaire was used for interviewing the patients in the study. The data was entered in MS EXCEL 2019 and analyzed using SPSS statistics 16.0. Quantitative variables were expressed in mean standard deviation and qualitative variables were expressed in proportions. The differences between proportions were analyzed using Chi-Square test. A probability value of less than 0.05 was considered to be statistically significant.

Results

A total of 50 eligible patients with Type 2 Diabetes Mellitus were included in the study. The mean age of the study participants was 58.5 (8.0) years. The median age of the study participants was 58.0 (52.0-64.25) years with a minimum of 45 years and a maximum of 76 years. In the present study, majority (64.0%) of them were ≤60 years and little more than half (52%) females with a Female : Male of 1.04:1. The mean fasting and postprandial blood sugar was 155.6(21.1) mg/dl and 297.9(58.5) mg/dl respectively. Similarly, the mean HbA1c was 9.6(1.7)%(Tables 1,2).

Table 3 shows the repeated measures ANOVA analysis for the change in the mean glycemic values among the study participants. It can be seen that there was a mean decrease in the glycemic values from day 0 to day 14. Tests for within subject effects by Greenhouse-Geisser test shows a F value of 26 and

Table 1 — *Distribution of Study Participants by Age Category (N=50)*

Variables		Frequency (n)	Percentage
Age category in years	≤60	32	64.0
	>60	18	36.0
Gender	Males	24	48.0
	Females	26	52.0

Table 2 — *Distribution of Study Participants by their Blood Sugar Status (N=50)*

	Fasting Blood Sugar (mg/dl)	Postprandial Blood Sugar (mg/dl)	HbA1c%
Mean (SD)	155.6 (21.1)	297.9 (58.5)	9.6 (1.7)
Median (IQR)	155.5 (139.75-172.5)	285.5 (253.5-340.5)	9.6 (8.0-11.0)
Minimum	102	209	8
Maximum	193	454	14

Table 3 — *Repeated measures ANOVA showing the Glycemic Variability Over the TIme (N=50)*

Day	Mean Glycemicvalues (mg/dl)	F value	p value
0	301.8		
1	258.4		
2	248.4		
3	244.1		
4	237.2		
5	233.1		
6	229.9		
7	224.8	26.8	<0.001
8	218.7		
9	211.9		
10	204.3		
11	192.9		
12	189.6		
13	186.8		
14	178.7		

it was found to be statistically significant (p<0.001). Post hoc analysis using Bonferroni test (Pairwise comparison) shows that there was a significant decrease in the glycemic values from day 0 with all the time periods till day 14. Similar association was found for all the days with day 14 of the follow-up.

In the current study nearly $^{2}/_{3}^{rd}$ (66.0%) patients had high glycemic variability and 32.0% patients had moderate glycemic variability. There was no association between the age of the study participants and glycemic variability (p=0.452) and there was no association found for gender with the glycemic variability among the study participants (p=0.616)(Tables 4,5).

Table 4 — *Association of age with High Glycemic Variability (N=50)*

High glycemic variability	Age in years		p value
	Mean	SD	
Yes	57.9	8.2	0.452
No	59.7	7.7	

Table 5 — *Correlation of Baseline Fasting Blood Sugar with Glycemic Variability (N=50)*

	Correlation Coefficient (r)	p value*
Baseline Fasting Blood Sugar (mg/dl) *versus* Average Glycemic Variability (mg/dl)	0.467	<0.001
Baseline Postprandial Blood Sugar (mg/dl) *versus* Average Glycemic Variability (mg/dl)	0.251	0.048
Baseline HbA1c% *versus* Average Glycemic Variability (mg/dl)	0.915	<0.001

*Pearson correlation

Discussion

Diabetes Mellitus is one of the important metabolic disorders which warrant apt metabolic control for proper monitoring of the blood sugar. Ambulatory blood glucose monitoring is considered to be an effective tool which empowers the patients to monitor and judge their glucose levels on a daily basis which makes it more comprehensive and also makes the patient more aware on their diabetic control. Furthermore, it can also help the physicians for taking future treatment decisions. Hence, this study was conducted among the patients with Type 2 Diabetes Mellitus attending a Tertiary Care Centre to demonstrate the glycemic variability with the use of ambulatory glucose profile.

The mean age of the study participants was 58.5 (8.0) years. The median age of the study participants was 58.0 (52.0-64.25) years with a minimum of 45 years and a maximum of 76 years. In the present study, majority (64.0%) of them were ≤60 years and little more than half (52%) females with a Female: Male of 1.04:1. The mean fasting and postprandial blood sugar was 155.6(21.1) mg/dl and 297.9 (58.5) mg/dl respectively. Similarly, the mean HbA1c was 9.6(1.7)%. A study done by Kim S, *et al*[8] observed that the mean glucose value during CGMS was 157.7 mg/dL and 24 patients (37%) experienced the hypoglycemia events during CGMS.

The mean glycemic variability over the 14 days of follow-up of the study participants and there was a gradual decrease in the glycemic values over the two weeks of follow-up. There was a mean decrease in the glycemic values from day 0 to day 14 and it was found to be statistically significant (p<0.001). A study conducted by Saboo B, *et al*[9] also had shown that there was a gradual decrease in the glycemic values during the period of follow-up in their study. The study also took the medications into consideration and there were various changes made to the medications by which they were able to monitor the changes due to the diabetic medications and also were able to change the type of medication (OHA or insulin) and their dosage. Similarly, study done by Kohnert K, *et al*[10] had concluded that continuous glucose monitoring were better in the assessment of glucose variability and a weak correlation was shown between HbA1c and glucose variability indices. It was also concluded by the same study that the frequency, duration and the fluctuations of the blood glucose would have been undetected without Continuous Glucose Monitoring

(CGM). It could also be well noted in our study that nearly $^{2}/_{3}$rd (66.0%) patients had high glycemic variability and 32.0% patients had moderate glycemic variability.

In the current study nearly $^{2}/_{3}$rd (66.0%) patients had high glycemic variability and 32.0% patients had moderate glycemic variability. A study done by Skyler JS, *et al*[11] and Bergenstal, *et al*[12] results were correlates with our study.

The present study result showed that there was a strong positive correlation for the fasting blood sugar, postprandial blood sugar and HbA1c with the average glycemic variability and it was found to be statistically significant (p<0.001). Similarly a study by Kohnert K, *et al*[93], there was a strong correlation between the glucose variability and postprandial blood glucose level and a study done by Young L, *et al*[13] also showed a positive correlation between the glucose variability and HbA1c.

Conclusion

There was a strong positive correlation for the fasting blood sugar, postprandial blood sugar and HbA1c with the average glycemic variability and it was found to be statistically significant (p<0.001). Hence it is recommended that further studies with a larger sample size and a longer duration of follow-up, in particular a clinical trial could add more robustness to our study findings and add more value for the utility of the continuous glucose monitoring which could help in the better management of the patients with Type 2 Diabetes Mellitus.

Funding : None

Conflict of Interest : None

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