Original Article

The association of continuous glucose monitoring with glycemic parameters in patients with uncontrolled type 2 diabetes: A prospective observational study

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Abstract

Background: Uncontrolled glycemic parameters in type 2 diabetes mellitus (T2DM) are a major concern. The present study aimed to evaluate the effectiveness of continuous glucose monitoring (CGM) on glycemic control in type 2 diabetics on insulin therapy. **Materials and Methods:** This prospective observational study was done in the Outpatient Department of General Medicine from January 1, 2021 till December 31, 2021 on patients with confirmed T2DM and on insulin therapy. Patients underwent detailed history and physical examination. The CGM device was inserted to record blood glucose levels throughout the day and night for monitoring. Parameters like glycosylated hemoglobin (HbA1c), fasting blood sugar (FBS), post-paradial blood sugar (PPBS), and lipid profile parameters [cholesterol, triglyceride (TG), and low-density lipoprotein (LDL)] were compared at baseline and after a follow-up of 3 months. *P*-value < 0.05 was used to indicate significant difference. **Results:** Of 107 patients screened, 100 were included in the study and seven were excluded. The mean age of the patients was 60.6 ± 11.1 years. Fifty-six (56%) of the patients were males, and 44 (44%) were females. The mean body mass index (BMI) was 22.9 ± 2.4 kg/m^2. Compared to baseline values, after 3 months of CGM, there was significantly decreased HbA1c (9.41 ± 0.83 vs 9.87 ± 1.16 g%, $P < 0.001$), FBS (194.640 ± 22.4587 vs 205.10 ± 35.7758 mg/dl, $P = 0.002$), PPBS (271.160 ± 29.1235 vs 299.180 ± 42.3798, $P < 0.001$), cholesterol (184.470 ± 28.5192 vs 198.430 ± 38.8367 mg/dl, $P < 0.001$), LDL (102.410 ± 22.8973 vs 112.040 ± 30.8859, $P < 0.001$), and TG (140.890 ± 18.0979 vs 146.730 ± 20.8665 mg/dl, $P < 0.001$). **Conclusion:** There was a significant improvement in the glycemic parameters and lipid profile parameters with the adoption of CGM. Overall, CGM is a novel method for practical use for management of patients with T2DM.

Keywords: Continuous glucose monitoring, diabetes mellitus, HbA1c, insulin, lipid profile

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Introduction

Diabetes is a public health issue. Approximately, 422 million individuals globally suffer from diabetes, with most of them residing in low- and middle-income countries.[1] Diabetes is a potentially epidemic health problem that is spreading fast in India. According to projections, there will be 69.9 million cases

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of diabetes in India by 2025. A recent Indian study reported the prevalence of diabetes mellitus to be 9.3%.[2]

Diabetes, as a disease, has been associated with various microvascular and macrovascular complications and cardiovascular related deaths. Management of these involves a successful and comprehensive approach beginning from lifestyle to medication, surveillance, and monitoring of glucose level on a continuous basis. Since the patients are not admitted for the whole day, the patient needs to be regularly monitored with their continuous glucose blood monitoring. For this, several monitoring tools have been devised, like continuous glucose monitoring (CGM), self-monitoring, and blood glucose monitors, which provide a regular feedback of blood glucose and help to strengthen the glucose control. CGM has been an upcoming blood glucose monitoring.[3] It provides a comprehensive and detailed blood glucose level to the patients on a continuous basis.[3]

Continuous review of CGM has brought about a vast improvement in the accuracy in glucose measurement, which has led to higher patients' acceptance and enabled the patients to reduce the capillary pricks for measuring the blood glucose. A minimum deviation of 10% has been considered appropriate for CGM monitoring, and it now remains a novel technique for self-monitoring of continuous blood glucose.[4]

Its use has been widely accepted not only in type 2 diabetes mellitus (T2DM) but also in type 1 diabetes mellitus (T1DM) in various cases where the patient is prone to higher risk of hypoglycemia.[3,4]

Since uncontrolled glycemic parameters in T2DM remain a major concern, which increases the morbidity and mortality in the patients, it demands continuous blood glucose measurements and CGM may be helpful in such cases. This may help in more intensive management of the blood glucose, allowing for prevention of the complications associated with atherosclerosis and cardiovascular events. So, not only it may help in controlling the glycemic parameters but also it may help in controlling the atherosclerotic parameters and lipid profile of the patients. In this regard, not many studies have been conducted in India, and its validity needs further information by prospective studies, which may allow for more practical use of CGM.[5]

Thus, the present study was conducted to evaluate the effectiveness of CGM on glycemic control in T2DM on insulin therapy. The results may help the primary care physicians to better monitor and manage the diabetics patients at home as well.

Materials and Methods

A prospective observational study was done in the out-patient department (Department of Medicine) of a tertiary care hospital in India over a period of 12 months from January 1, 2021 till December 31, 2021. Ethical clearance was obtained from the Institutional Scientific Research Committee. Any patient who attended the out-patient Medicine Department of the hospital with confirmed T2DM and on insulin therapy was screened for the eligibility for the study.

Inclusion criteria included all T2DM patients aged more than 18 years on insulin therapy, duration of diabetes more than 1 year, and both males and females.

Exclusion criteria included patients with T1DM and patients with cancer or immunodeficiencies, renal failure, and pregnancy.

Based on the eligibility criteria, the sample size enrolled was 50 patients. All the enrolled participants were told about the goals of the study, and an informed written consent was obtained from them. All the patients were subjected to a detailed history and thorough physical examination through a preset Performa. Demographic characteristics like age, gender, and body mass index (BMI) were noted.

Investigations

5 ml of blood was collected in a plain vacutainer, 5 ml was collected in an EDTA vacutainer, and 3 ml was collected in a sodium fluoride-coated vacutainer. The fresh morning mid-stream urine sample was collected in a vial. The samples were sent to the laboratory for processing and assessment in the Cobas® 8100 automated workflow series (Roche Diagnostics, Switzerland). The following investigations were done at baseline and at 3 months: hemoglobin, kidney function test, blood urea, serum creatinine, lipid profile, fasting blood sugar (FBS), post prandial blood sugar (PPBS), HBA1C, and urine routine and microscopy.

Technique

The CGM device was applied after wiping the patient's back of the arm with an alcohol swab.

Utilizing tiny sensors inserted under the skin, CGM systems offered continuous monitoring of glucose levels throughout the day and night, alerting users to highs and lows and enabling pro-active adjustments to insulin doses, diet, and activity levels. The data were collected using a reader, which was further connected to a desktop using a USB cable, and the data collected were saved in the desktop using compatible software.[6,7]

The follow-up was done for 3 months, and the parameters were recorded and compared with the baseline parameters.

Statistical analysis

The continuous data were shown as mean standard deviation, and categorical data were represented as absolute numbers and percentages. For continuous data, the Kolmogorov–Smirnov test was performed to assess normality of data. The data were analyzed with required descriptive statistics and statistical tests. We used Student's test for parametric and Kruskal–Wallis test/Mann–Whitney U-test for non-parametric as per study requirement. Nominal categorical data were compared by using Chi square. For all statistical significances, we took a *P*-value less than 0.05 to indicate a significant difference. We used Microsoft Excel (Microsoft Corp, Redmond, USA) and the Statistical Package for Social Sciences (SPSS) version 22.0 (IBM corp, Chicago, USA) for the analysis of data.

Results

Of 107 patients screened, 100 were included in the study and seven were excluded due to exclusion criteria. The mean age of the patients was 60.6 ± 11.1 years. Fifty-six (56%) of the patients were males, and 44 (44%) were females. The mean BMI was 22.9 ± 2.4 kg/m^2 [Table 1].

Compared to baseline values, after 3 months of CGM, HbA1c was significantly decreased (9.41 ± 0.83 vs 9.87 ± 1.16 g%, $P < 0.001$), FBS (194.640 ± 22.4587vs 205.10 ± 35.7758 mg/dl, $P = 0.002$), and PPBS (271.160 ± 29.1235 vs 299.180 ± 42.3798, $P < 0.001$) [Table 2].

Compared to baseline values, after 3 months of CGM, cholesterol was significantly decreased (184.470 ± 28.5192 vs 198.430 ± 38.8367 mg/dl, $P < 0.001$), LDL (102.410 ± 22.8973 vs 112.040 ± 30.8859, $P < 0.001$), and TG (140.890 ± 18.0979 vs 146.730 ± 20.8665 mg/dl, $P < 0.001$) [Table 3].

Table 1: Demographic characteristics

Parameters	Mean±SD	*n* (%)
Mean age	60.6±11.1 years	
21-40		5 (5%)
41-60		37 (37%)
61-80		56 (56%)
>80		2 (2%)
Gender	-	
Males		56 (56%)
Females		44 (44%)
Mean BMI	22.9±2.4 kg/m^2	
<18.5		7 (7%)
18.5-22.9		37 (37%)
23.24.9		39 (39%)
25-29.9		17 (17%)

BMI=Body mass index

Table 2: Change in Glycemic parameters with CGM

Parameter	Baseline	3 months	*P*
HbA1c (g%)	9.87±1.16	9.41±0.83	*P*<0.001
FBS (mg/dl)	205.10±35.7758	194.640±22.4587	*P*=0.002
PPBS (mg/dl)	299.180±42.3798	271.160±29.1235	*P*<0.001

HbA1c=Glycosylated hemoglobin A1c, FBS=Fasting blood sugar, PPBS=Post-prandial blood sugar

Table 3: Change in lipid profile parameters with CGM

Parameter	Baseline	3 months	*P*
Cholesterol (mg/dl)	198.430±38.8367	184.470±28.5192	*P*<0.001
LDL (mg/dl)	112.040±30.8859	102.410±22.8973	*P*<0.001
TG (mg/dl)	146.730±20.8665	140.890±18.0979	*P*<0.001

LDL=Low-Density Lipoprotein; TG=Triglycerides.

Discussion

CGM is based on the principle of continuous monitoring of the glucose in the interstitial fluid at a rate of every 10 seconds, thereby recording the average glucose value throughout 24 hours a day at every 5 minutes. This provides accuracy in the daily fluctuation of the glucose values and allows the patient that he/she may detect the hypoglycemic episodes in glucose fluctuation in relation to the physical activity, food intake, insulin, and other medications.[6]

Though it may be based on the patients' acceptance and patients' use, over a period of 3 months, our study showed that in terms of glycemic parameters, there was a substantial control in fasting blood glucose, post-prandial blood glucose, and HbA1c levels, with significant reduction in these three over a period of 3 months. The findings were in line with various other studies,[3,6-19] which showed similar results indicating that CGM is a novel technique for controlling the glycemic parameters.

These studies mainly compared CGM and self-monitoring blood glucose (SMBG) and found a mean difference between both of them. Our study was in one way above that where we compared the baseline values and 3-month values and found that there was a significant reduction in the 3-month values over the baseline values.

A significant control in the glycemic parameters with the use of CGM as seen in our study and other studies indicates that this may be a reliable treatment option as well. Along with this, we also observed that there was a significant decrease in the lipid profile. The lipid profile was evaluated because it is closely related to glycemic control.[20] Both these are indicators for metabolic disturbances. In line with this, we observed that there was a significant improvement in the lipid profile. Similarly, the study by Taylor *et al.*[11] also observed that there was reduction in LDL-C (2.46 ± 1.02 vs 2.53 ± 1.08 mmol/L, $P = 0.152$) and triglycerides 4.29 ± 1.25 vs 4.33 ± 1.32 mmol/L, $P = 0.123$) and an increase in HDL-C (1.41 ± 0.19 vs 1.34 ± 0.16, $P = 0.619$), but the difference was not significant.

Overall, we found that CGM holds importance in controlling the glycemic parameters and lipid profile as both these need attention with regard to glycemic management in patients with T2DM.

Moreover, it needs to be stressed here that CGM allows for collection of the data in automatic fashion where glycemic excursions are observed directly. However, this technique is limited by a painful insertion, skin irritation, allergy, and adhesive problems. Moreover, the patients may have anxiety issues related to this technique and this technology is not widely available in our country. However, further trials are required to validate the use of CGM in our country.

The present study holds strength in being a prospective observational study over a period of 3 months with enrolment of 100 cases. The results hold importance in allowing the better management of T2DM at primary health care centers – allowing for home monitoring of blood glucose levels and making the patients aware of any gross fluctuations in the blood glucose levels. An immediate action or a control mechanism may be initiated by the patient to curb changes in the blood glucose levels. However, the study was limited by lack of control group. Second, long-term outcomes were not assessed. Third, we did not assess the compliance to the medications.

Conclusion

There was a significant improvement in the glycemic parameters and lipid profile parameters with the adoption of CGM. Overall, CGM is a novel method for practical use for management of patients with T2DM.

Research quality and ethics statement

This study was approved by the Institutional Review Board/Ethics Committee at Northern Railway Central Hospital, New Delhi (Approval #: NBE/CNS/DNB (Post MBBS)/4315011/UR/19660004588; Approval date: Jan 20, 2019). The authors followed the applicable EQUATOR Network (http://www.equator-network.org/) guidelines, specifically the STROBE Guidelines, during the conduct of this research project.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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