

Continuous Glucose Monitoring for Diabetes Management: Experience of an Academic Tertiary Care Hospital in Pakistan

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ABSTRACT

Background: Professional continuous glucose monitoring (pCGM) is being increasingly utilized worldwide in diabetes mellitus (DM) management. This observational study describes our institutional experience using intermittent pCGM in Pakistan.

Methodology: Data was collected from the records of patients who had Medtronic iPRO™-2 CGM wearable device placed from August 2016-September 2020 at the Endocrinology clinics of Aga Khan University Hospital, Pakistan.

Results: pCGM was utilized in 22 patients (mean age: 42.4 years) during the study period. Eleven (50%) had a diagnosis of DM2, 10 (45.5%) DM1 and 1 patient had (4.5%) GDM. Median time since diagnosis of DM was 15 years. Four patients were pregnant at time of pCGM testing. pCGM was worn on average for 6 days. Patients' pCGM glucose measurements were above the target range in 40.5% of readings and below 70mg/dL in 3% of readings. Based on report review, the treating physician recommended changes in medications, dose adjustments, or lifestyle modifications at the 1-week follow-up visit. The mean baseline HbA1c value was available in 20 patients (9.01±1.92%). Amongst patients following up after 3-6 months (n=13), HbA1c significantly decreased to 9.21±2.09% before pCGM to 7.83±1.28% after pCGM (p=0.03).

Conclusions: The use of pCGM at our institute has been limited despite a busy diabetes practice. Cost and lack of awareness amongst providers regarding the indications and benefits from pCGM are potential factors in this underutilization of technology. A significant reduction in HbA1c values was observed in patients who had pCGM.

KEY WORDS: Diabetes Technology, Lower-Middle-Income Country, Diabetes Mellitus, Continuous Glucose Monitoring, Glucose Biosensor, Implanted Devices.

INTRODUCTION

Diabetes Mellitus (DM) is a major non-communicable disease (NCD) with 422 million cases worldwide^{1,2} and it is the 7th leading cause of death with 106 million deaths reported globally.¹ The burden of disease in Pakistan totals 19 million cases of diabetes mellitus.³ Due to the associated burden on health care systems related

with DM, addressing it is a major priority as part of goal 3 of the United Nations Sustainable Development Goals (SDGs) for reduction in mortality due to non-communicable diseases, especially in lower middle-income countries (LMICs) with limited resources.⁴ Therefore, effective and early control of DM is essential to prevent the multiple complications associated with it. A key element in helping achieve glycemic control

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is consistent monitoring of blood glucose levels. This enables prompt intervention to modify management for the patient.⁵

Glycemic control can be measured by fingerstick self-monitored blood glucose monitors (SMBG), three monthly HbA1c testing and by continuous glucose monitoring (CGM) devices.⁶ CGM devices consist of a sensor which is inserted subcutaneously and measures interstitial glucose levels frequently, with the Medtronic iPRO™-2 CGM device used in our clinics recording glucose levels every 5 minutes.⁷ In professional CGM (pCGM) the glucose levels are measured over a period of days. This data is not accessible in real time but downloaded by the physician who reviews the readings and patterns from a period of time to analyze them retrospectively, consequently choosing or adjusting therapy based on this information.^{7,8}

CGM enables us to obtain multiple data points for serum glucose levels in a convenient and accurate way. While SMBG captures snapshots in time of glucose readings and HbA1c values give an “average” reading, CGM enables checking of glucose levels multiple times during the day allowing comprehensive data collection and identification of glycemic patterns. It plays an important role in enabling accurate adjustment of therapies according to the patient’s needs in both type 1 and type 2 DM.⁶ CGM enables detection of both asymptomatic hypo- or hyperglycemia,⁹ significantly reduces hypoglycemic events and helps achieve target HbA1c levels.^{7,9-11}

At our institute, the Aga Khan University Hospital, Section of Endocrinology, Department of Medicine, pCGM device service became available for patient use in 2016. In this study, data were collected from the records of patients who had Medtronic iPRO™-2 CGM device placed from August 2016-September 2020 at the Endocrine clinics of Aga Khan University Hospital, Pakistan. Our study aims to describe our experience with the use of pCGM on the outcomes of patients with type 1 and type 2 DM particularly in the setting of a lower middle-income country.

METHODS

Setting and Sample: This observational study collected from medical records and official Medtronic iPro2 CGM reports of patients with diabetes mellitus (DM) seen at the Aga Khan University Hospital, Karachi, Pakistan Endocrinology clinics that had a Medtronic iPRO™-2 CGM device placed from August 2016 till September 2020. The sampling technique was nonprobability, consecutive sampling.

Data Collection: Demographic data including age and gender was recorded, glycemic control information including Pre-CGM and Post-CGM values that were taken 3-6 months after CGM was placed were recorded, type and duration of DM as well as the pregnancy status of the patients was recorded from patient charts. Reasons for pCGM being recommended were obtained

from outpatient handwritten clinic notes. Laboratory test results were collected from the electronic laboratory health reporting system. Data obtained from CGM standardized reports included average blood sugar, percentage time in range, percentage time in target, percentage below 70 mg/dl, sensor values (highest, lowest and average) and standard deviation.

Inclusion and Exclusion Criteria: All patients of age 18 years and above who had pCGM device placed were included in the study while patients whose complete pCGM data were not available due to some technical issues were excluded. In addition, patients whose pCGM data was of less than 3 days and those with sensor values less than 288 per day were also excluded. iPro2 CGM device is worn on average for 3-6 days taking readings every 5 minutes i.e. up to 288 readings per day are required to allow physicians to assess trends in blood glucose level control.

Data Analysis: SPSS version 23 was used for data analysis. Numerical variables were presented by mean $\pm$ SD if normally distributed or median [interquartile range] if not normally distributed and compared using independent sample t-tests/Mann Whitney U-tests as appropriate. Categorical variables were presented as frequency and percentages and compared using Chi-squared tests/Fischer Exact tests. Paired t-tests/Wilcoxon tests were conducted to compare patients’ change in hemoglobin A_{1c} (HbA1c) prior to and 3-6 months after having pCGM testing.

Data Management: As no personal identifiers were recorded in the proforma, the data was anonymous. The data from the proforma was entered into Microsoft Excel and stored in a password-protected file. The digital data was accessible only by the research team. The data will be retained for 7 years post-completion of the study, after which it will be deleted.

RESULTS

A total of 23 patients had Medtronic iPRO™-2 CGM device placed from August 2016-September 2020. One patient was excluded from the study due to missing patient file. A total of 22 patients with mean age 42.41 $\pm$ 16.01 years were included in this study with the majority (68.2%) being female. pCGM was recommended to the 22 patients by a total of 7 endocrinologists with 2/7 recommending it to 11/22 patients in our study and the rest only having recommended it to 1-2 of the patients. 11 (50%) had a diagnosis of type 2 DM, 10 (45.5%) had type 1 DM and 1 (4.5%) patient had GDM.

The median duration since diagnosis of DM was 15 years. Four (18.2%) of the patients were pregnant at the time of pCGM placement with median age of gestation being 30 weeks and 3 days. Data from handwritten clinic notes showed that 15 (68.2%) of the 22 patients had poor control of diabetes, 5 (22.7%) reported hypoglycemic events, 2 (9.1%) had skin changes, 2 (9.1%) had nephropathy and 4 (18.2%) had other complications related to diabetes.

Table-I: Patient Demographics and Disease Characteristics.

Variables	Mean $\pm$ SD/n(%)/Median[IQR]
Age (years)	42.41 $\pm$ 16.01
Gender	
Females	15 (68.2%)
Males	7 (31.8%)
Type of Diabetes	
Type 1	10 (45.5%)
Type 2	12 (50%)
GDM	1 (4.5%)
Years since diagnosis	15 [5-20]
Type of anti-DM treatment	
Oral only	1 (4.5%)
Insulin only	10 (45.5%)
Oral and insulin	11 (50%)
Oral hypoglycemics	N=12
Metformin in oral	10 (83.3%)
Orals other than metformin	4 (33.3%)
Currently Pregnant	4 (18.2%)
If yes, gestational age (weeks)	30.5 [29-32]

On the next clinic visit after pCGM placement, the clinicians reviewed the data from pCGM standardized reports and made recommendations accordingly to allow better glycemic control. Medications were changed in 6 (27.3%) patients, medication doses were adjusted in 10 (45.4%) patients and lifestyle change was recommended to 8 (36.4%) patients. The mean baseline HbA1c value was available in 20 patients

(9.01 $\pm$ 1.92%). Amongst patients following up after 3-6 months (n=13), HbA1c significantly decreased from 9.21 $\pm$ 2.09% before pCGM to 7.83 $\pm$ 1.28% after pCGM (p=0.03). Patient characteristics and disease features are shown in Table-I.

The mean average glucose level during pCGM was 150.73 $\pm$ 42.52 mg/dL, with minimum average glucose level being 87 mg/dL and maximum average glucose level being 239 mg/dL. The time in the targeted range was 49.86 $\pm$ 24.51%. The readings were found to be below 70 mg/dL 3 [0-7.25] % of the times and were above range 40.51 $\pm$ 25.40 % of the times with the highest and lowest sensor values being 303.86 $\pm$ 79.73 mg/dL and 58.41 $\pm$ 18.24 mg/dL respectively.

In comparison to patients with type 1 DM (163.60 $\pm$ 46.40 mg/dL), patients with type 2 DM had an average blood glucose sugar of 144.73 $\pm$ 35.50 mg/dL during pCGM monitoring. The percentage of times readings were within target range was 40.10 $\pm$ 25.11 % in type 1 diabetics and 55.36 $\pm$ 20.68 % in type 2 diabetics. The percentage of times readings were below 70 mg/dL in type 1 and type 2 diabetics was 4.5 [1-10.25] % and 2 [0-7] % respectively, while the percentage of times readings were above range in type 1 and type 2 diabetics were 48.90 $\pm$ 26.57 % and 36.40 $\pm$ 29.96 % respectively. pCGM standardized report data is shown in Table-II.

DISCUSSION

Continuous glucose monitoring (CGM) has drastically improved the management of DM over the past few years. It is especially beneficial in diabetic patients with frequent hypoglycemia and/or uncontrolled DM and helps physicians in evaluating the risk of blood glucose variability and managing these patients accordingly. Our study aimed to describe our experience with the use of pCGM on the outcomes of patients with DM particularly in the setting of a low resource country.

Table-II: pCGM Standardized Report Data.

Variables	Mean $\pm$ SD/n (%) / Median [IQR]		
	Overall (N=22)	T1DM (N=10)	T2DM (N=11)
Average Blood sugar during CGM (mg/ dL)	150.73 $\pm$ 42.52	163.60 $\pm$ 46.40	144.73 $\pm$ 35.50
CGM Period (days)	6 [5-7]	5.5 [4.75-6.25]	6 [6-7]
Time in target (%)	49.86 $\pm$ 24.51	40.10 $\pm$ 25.11	55.36 $\pm$ 20.68
CGM Readings			
Times readings below 70mg/ dL (%)	3 [0-7.25]	4.5 [1-10.25]	2 [0-7]
Times readings above range (%)	40.52 $\pm$ 25.40	48.90 $\pm$ 26.57	36.40 $\pm$ 29.96
Number of sensor values	1304.7 $\pm$ 341.23	1236.40 $\pm$ 418.72	1355.00 $\pm$ 278.53
Highest sensor value	303.86 $\pm$ 79.73	341.10 $\pm$ 69.74	284.18 $\pm$ 68.76
Lowest sensor value	58.41 $\pm$ 18.24	56.60 $\pm$ 20.52	60.91 $\pm$ 17.35

A statistically significant lowering of HbA1c was seen over 3 to 6 months after measures were taken to improve glycemic control post-pCGM.

Previous literature has shown a 0.5 unit decrease in HbA1c and a mild decrease in the incidence of hypoglycemia after use of CGM.¹² Our study demonstrated a reduction in HbA1c from 9.01 ± 1.92 to 7.83 ± 1.28 3 to 6 months after the use of pCGM. Similarly, a retrospective study from India showed a reduction in mean HbA1c from 8.6 to 8% in a period of 3 months owing to changes in therapy of patients using data from Medtronic iPRO™-2 CGM device (10). Another similar study re-demonstrated a reduction in HbA1c levels from 7.5 to 7% in a period of 6 months as well as detection of previously unknown hypoglycemic events in 38% of patients.¹¹ These findings suggest potential for significant reduction in HbA1c after use of pCGM making it an effective tool for improving diabetes management in developing countries of DM and reduce complications in the long run.

CGM has been described to be one of the most effective methods to monitor glycemic control in almost all types of DM including type 1, type 2, and gestational DM.¹³ In previous studies, CGM has mostly been used in type 1 DM. In comparison the majority (50 %) of patients in our study had type 2 DM while 45.5 % had type 1 DM¹⁴ signifying the utility of pCGM testing in several types of DM.

SMBG along with HbA1c can predict glycemic control but these methods can not foresee hypoglycemia or alert about hypoglycemia^{15,16} which highlights yet another major benefit of CGM when compared to traditional methods of blood glucose monitoring. In our study, a positive history of hypoglycemic events was an indication for pCGM use in 22.7 % of the patients. Studies have reported that hypoglycemia causes not only economical but also psychological burden on patients and therefore it is vital to modify management in these patients with the help of data from pCGM standardized reports to prevent hypoglycemia and improve the overall control of DM.¹³

At our institute, since the introduction of pCGM, only 23 patients underwent a pCGM study in a duration of 4 years which is likely due to several factors. These include the high cost, lack of awareness and training regarding use and interpretation of pCGM data as well as limited availability of pCGM sensors in resource limited countries. The cost of pCGM ranged from 12,000 to 15,000 PKR in the time duration that the data for this study was collected. Data shows that the average monthly wage of an individual working in Pakistan was 18,754 PKR in 2018 meaning that the cost of pCGM makes up most if not the entire percentage of an average person's monthly wage and with most people in Pakistan paying for medical expenses out of their own pocket, it becomes a major contributing factor to the underutilization of pCGM.¹⁷ These reasons should be considered, and appropriate measures should be taken so that utilization of pCGM can be increased for maximum benefit patients with diabetes. Guidelines should be introduced to outline indications, interpretation, and follow-up strategies, interpretations

and post-pCGM measures to make pCGM usage more effective and standardized.

pCGM data helps physicians in adjusting treatment options for appropriate management of DM to prevent complications. In our study based on pCGM results, following interventions were recommended by primary physicians for achieving better glycemic control; dose adjustment (45.5%), lifestyle changes (36.4%) and change in medications (27.3%). Most of the patients in our study had DM for a median duration of 15 years signifying that even after being diagnosed with DM for a long duration, they still had either poor glycemic control or episodes of hypoglycemia ultimately affecting their quality of life and increasing likelihood of suffering from associated complications. pCGM significantly improved their glycemic control which highlights the benefits of pCGM.

All pCGM devices used in our study participants were prescribed by endocrinologists and none by physicians from other specialties such as family medicine, internal medicine etc. This emphasizes the need of training internists and general physicians in this domain that would allow benefit to a wide range of patients since most patients with DM are usually managed by general physicians or family medicine doctors. It would also encourage use of pCGM in hospitalized patients, especially in patient populations who are at high risk of developing hypoglycemia and variability in blood glucose levels particularly in the ICU.¹⁸

Some limitations have been identified in our study including small sample size, availability of only outpatient data and inability to account for confounding factors. A future study needs to be conducted on a larger sample size with pCGM being used in both inpatients and outpatients.

CONCLUSION

Although professional CGM offers proven benefits, its use at our institute remains limited despite the proven benefits of professional continuous glucose monitoring (pCGM) in diabetes management, its use at our institute remains limited, despite a high patient volume (>150/day) and availability of the technology since 2016. Key barriers include cost, limited awareness among providers and patients, and inconsistent sensor availability. Among patients who underwent pCGM, a significant HbA1c reduction was noted following treatment adjustments based on the reports. These findings highlight the need to increase pCGM utilization through improved education for physicians and patients.

Declarations:

Ethics approval and consent to participate: Ethical approval for this study was waived by the Ethical Review Committee.

Consent for publication: Not applicable

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests

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Authors' Contributions:

SN conceived the original idea. SN, SB and AA worked collectively on the methodology of the study. Once the study was approved by the Ethical Review Committee, IA worked on the data collection from patient charts, while SB and AA worked on data collection from CGM standardized reports. Once data was collected, IA, HR and RSM worked on refining and analyzing the data. IA, AA, and SB contributed significantly to drafting the main text, while SN substantially revised the manuscript. HR and RSM also helped in writing parts of the paper. The final version of the study has been approved by all authors.

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