

Continuous Glucose Monitoring—Purposes, Benefits, and Problems: A Review of the Indian Scenario

Anushtha Kushwaha^{1*}, Aarti Niveditha Kodirekkala², Aruna Saharawat³, Rashi Jaiswal⁴

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ABSTRACT

One of the global epicenters of the diabetes mellitus pandemic is India. Over the past 40 years, there has been a sharp rise in the prevalence of diabetes mellitus in India due to rapid socioeconomic development, demographic shifts, and increasing susceptibility in the Indian population. Diabetes affects 74.2 million individuals in India, which places a significant strain on the country's economy and healthcare system. A patient's diet, lifestyle, medication, and glucose monitoring must all be customized for optimal diabetes control. The rates of glucose monitoring in India are abysmal. Most of the monitoring methods currently in use are based on single-point-in-time readings, which may not be totally indicative of the state of diabetes control. This presents problems. With advancements in technology, the new monitoring tool—continuous glucose monitoring (CGM)—provides visibility into the glycemic profile 24 × 7 with user-friendly reports that provide information much beyond glycated hemoglobin (HbA1c) and self-monitoring of blood glucose. This device also detects the time spent in range by the individual with diabetes. This review article discusses CGM in terms of its purposes, technologies, accuracy, clinical indications, benefits, and problems associated with it.

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INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic noncommunicable disease that has attained epidemic proportions worldwide. Diabetes is primarily caused by genetic factors, immune disorders, and other influences impacting the human body. These elements cause insulin resistance and a decline in islet function, which throws off glucose homeostasis. The manifestation of this imbalance is seen as a failure in glucose metabolism and the presence of hyperglycemia.¹ Diabetes is classified into two main types: type 1 and type 2. Diabetes type 1 is caused by a scarcity of insulin secretion in the pancreas. Type 2 DM, however, primarily occurs when patients experience a reduction in insulin sensitivity and an increase in insulin resistance, leading to ineffective insulin use.² More than 415 million persons in the world had diabetes mellitus in 2015; by 2040, that figure is expected to rise to 642 million.¹ As per the Indian Council of Medical Research–India Diabetes (ICMR INDIAB) study published in 2023, the prevalence of diabetes is 10.1 crores. The Indian Council of Medical Research (ICMR) in 1971 initiated the first multicenter study on diabetes mellitus. The prevalence of the disease was found to be 2.1% in the urban areas and 1.5% in the rural areas.³

Research on diabetes mellitus and its complications has expanded in tandem with the disease's rising incidence in India. There are several different types of diabetes

technology, including continuous glucose monitoring (CGM) and insulin pumps. Insulin pumps have made insulin delivery more convenient, while CGM has replaced finger pricks in diabetes management. In this review, we discuss the complications of diabetes mellitus in India, focusing on the purpose, technology, accuracy, indications, and outcomes of CGM.

NEED FOR GLUCOSE MONITORING

Diabetes has a natural progression to end-stage complications. Thus, maintaining good glycemic control is critical in the management of diabetes, especially in its initial stages, as this leads to what is known as a “good glycemic legacy.” Good control is associated with a reduction in both macro- and microvascular complications of diabetes. Diabetes control is assessed by several monitoring techniques, i.e., self-monitoring of blood glucose (SMBG) and laboratory tests, including hemoglobin A1c (HbA1c) and fasting and postprandial blood glucose levels. Unfortunately, monitoring is not given the importance it deserves within the diabetes management domain.⁴

The gold standard in diabetes management is glycated hemoglobin (HbA1c), which indicates the average blood glucose level over a span of 2–3 months. Although it offers a great measure of long-term control, it lacks any information about the daily aspects. Glucose levels

can fluctuate. In addition, research has shown that individuals with identical levels of HbA1c may experience varying levels of fluctuating glucose. Laboratory tests such as fasting plasma glucose (FPG) and postprandial plasma glucose (PPG) are commonly prescribed, but they solely indicate the glucose levels for that particular day. In a country such as India, where people traditionally consume high-carbohydrate meals three times a day, the sporadic information provided by FPG and PPG does not accurately reflect the actual state of diabetes control. The introduction of continuous glucose monitoring brought about a significant advancement in glucose monitoring in this scenario (Table 1).⁵

Table 1: Differences between CGM and IGM⁷

Continuous glucose monitoring	Intermittent glucose monitoring
Provides multiple glucose levels of fair accuracy	Measures discrete glucose levels extremely accurately
Trends in glucose levels do have this predictive capability	Current blood glucose levels do not indicate future glucose levels
Too much data is generated to study all data points	Studying each measured blood glucose value throughout various time periods is simple
Blood glucose monitoring does not require effort to operate	Blood glucose monitoring requires effort to operate

IGM, intermittent glucose monitoring

¹MDS, Department of Public Health Dentistry;

²MDS, Department of Oral and Maxillofacial Pathology; ³BDS, Treble Aesthetics; ⁴MDS, Department of Oral Medicine and Radiology, Greater Noida, Uttar Pradesh, India;

*Corresponding Author

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CONTINUOUS GLUCOSE MONITORING: PURPOSES

The commercial availability of CGM began in 2000. It provides information unattainable by intermittent capillary blood glucose, including instantaneous real-time display of glucose levels and rate of change of glucose, alerts and alarms for actual or impending hypo- and hyperglycemia, “24/7” coverage, and the ability to characterize glycemic variability. CGM has the capability of informing, educating, motivating, and alerting people with diabetes. CGM is medically indicated for patients with frequent, severe, or nocturnal hypoglycemia, especially in the presence of hypoglycemia unawareness.⁶ Continuous glucose readings that supply trend information can help identify and prevent unwanted periods of hypo- and hyperglycemia.

CONTINUOUS GLUCOSE MONITORING: TECHNOLOGY

The CGMs that are now on the market monitor blood glucose either noninvasively

Table 2: Differences between the two types on CGM⁵

Parameters	Professional CGM	Personal CGM
Owned by	Healthcare professionals	Patients him/herself or caregivers
Real-time readings	No	Yes
Analysis	CGM data analyzed by healthcare professionals	Patients can take decisions according to hypo/hyperglycemia
Advantages	It gives a clear picture of the most probable behavior of blood glucose and outliers	Increases TIR
	Helps HCPs and patients to discuss intervention areas through diet and lifestyle	Shows daily variability of glucose levels. Reduction in HbA1c, hospitalization, and work absenteeism
	Allows detection of unknown hypoglycemia	Provides a detailed view of day-to-day glucose readings that help patients

HbA1c, glycated hemoglobin

by delivering electromagnetic radiation via the skin to the body's blood vessels or minimally invasively by continuously measuring interstitial fluid (ISF). To establish a connection between a sensor and ISF, different technological approaches can be employed. These methods involve either implanting a sensor under the skin (such as in the abdominal wall or arm) to directly measure ISF in its natural location, or utilizing techniques that disrupt the skin barrier to gather the fluid and transfer it to an external sensor.

In the United States, the US Food and Drug Administration has granted approval for five CGM devices, while in Europe, these devices have obtained the CE mark for utilization. The Continuous Glucose Monitoring System-Gold (CGMS-Gold) from Medtronic MiniMed, located in Northridge, CA, is one of the devices included in this collection. Another device is the GlucoWatch G2 Biographer (GW2B) from Cygnus in Redwood City, CA. Medtronic MiniMed also offers the Guardian Glucose Monitoring System. Lastly, there is GlucoDay from a currently unspecified location. Menarini Diagnostics is based in Florence, Italy, and Pendra (Pendragon Medical) is located in Zurich, Switzerland. The FreeStyle Navigator Continuous Glucose Monitor, produced by Abbott Laboratories in Alameda, CA, is the sixth monitor to undergo FDA premarket approval.⁷

Continuous glucose monitors can be classified into professional and personal CGMs. See Table 2 for differences enumerated between these two CGM types. As the name suggests, a professional CGM is meant for use by the treating healthcare professionals (HCPs), and it provides a set of reports that can be downloaded for discussion between the HCP and the patient. In contrast, the personal version is designed to be a personal device specifically for patients, enabling them to monitor their own glucose levels. There are two versions of CGM available in India: one for HCPs and the other for patients to monitor their diabetes control.⁵

Real-time Continuous Glucose Monitoring

The real-time continuous glucose monitoring (RT-CGM) is a compact, hassle-free system that avoids finger pricks and provides 288 glucose readings in a single day. There is a 20-minute delay in the glucose concentrations in the interstitial fluid compared to the glucose concentrations in the blood. RT-CGM is immensely advantageous and the preferred method for detecting nocturnal or unidentified hypoglycemia and glycemic variability (GV). The range of RT readings offered extends from 5 to 6 days up to 10–14 days. The incidence

of hyperglycemia can be reduced by using RT-CGM. The mean absolute relative difference (a measure of the accuracy of the CGM systems) of the latest device is extremely low, showing its precision and accuracy.^{8,9} It is now universally agreed that maintaining a time in range (TIR) of at least 70% (i.e., blood glucose is under control for 70% of the time in a day—which represents good glucose control for 16.8 hours within 24 hours) would effectively prevent the complications of diabetes. TIR has a direct correlation to HbA1c in both type 1 diabetes (T1DM) and type 2 diabetes (T2DM). Every 10% increase in TIR brings a ~0.5% reduction in HbA1c in T2DM and a ~0.8% reduction in HbA1c in T1DM and T2DM. In various published studies, the use of TIR is effective at improving diabetes outcomes through the benefits offered.¹⁰

CONTINUOUS GLUCOSE MONITORING: CLINICAL INDICATIONS

Continuous monitoring of blood glucose is necessary in various situations that demand specific and detailed information. These situations include adjusting therapy to manage diabetes effectively, evaluating the effectiveness of a diabetes treatment through trials, determining the influence of lifestyle changes on glycemic control, monitoring conditions that require strict control without risking low blood sugar levels (such as gestational diabetes, pediatric diabetes, or patients in the intensive care unit), identifying and preventing hypoglycemia during sleep or in cases of hypoglycemia unawareness, and diagnosing and managing postprandial hypoglycemia. Continuous blood glucose monitoring is mostly used to support therapeutic modifications aimed at enhancing control. Specific therapeutic adjustments include changing from regular to a synthetic ultra-short-acting insulin analog at mealtime, changing from NPH to synthetic ultra-long-acting insulin once or twice per day, varying the insulin bolus amount given at mealtime and varying the basal insulin rate, modifying the insulin to glucose adjustment algorithm for premeal hyperglycemia, as well as the way that intermittent hypoglycemia or hyperglycemia are treated, changing the insulin-to-carbohydrate ratio at mealtime, changing the method for counting carbohydrates, changing the carbohydrate composition of the diet, changing the discount in short-acting insulin dosage for exercise, changing the nighttime regimen because of the dawn phenomenon, modifying the desired preprandial or postprandial blood glucose levels, or prior to recommending

psychological counseling for a patient in order to enhance treatment regimen adherence.⁷

CONTINUOUS GLUCOSE MONITORING: LIMITATIONS

One major problem is their lack of accuracy for each single data point compared with the accuracy of simultaneous intermittent blood glucose measurements. CGMs are generally the least accurate in the hypoglycemic range.¹¹ As CGM sensors detect the glucose level in interstitial fluid rather than in the blood, there are concerns about the lag time resulting in differential readings between the two media. However, this slight delay does not diminish the usefulness of the device. It is crucial to remember that it is currently not possible to stick a sensor into a blood vessel periodically to get blood glucose readings, as it could lead to serious clot formation.¹²

The following are some of the challenges of CGM use:

- Requires patients to insert sensors every 10–14 days, which requires both adequate dexterity and cognitive function.
- Visual impairment may make it difficult for patients to view their CGM data.
- Hearing impairment may make it difficult for patients to detect alarms/alerts when they occur.
- Perceptions of data overload may cause or increase patient anxiety.
- Frequent alarms/alerts can cause “alarm/alert fatigue.” This may cause patients to ignore their alarms/alerts or discontinue CGM use.
- Requires patients or their caregivers to learn how to accurately interpret and appropriately respond to the CGM data.
- It may involve significant out-of-pocket expenses or copays, depending on insurance coverage.¹³
- It reduces hypoglycemia.
- Improves HbA1c.
- The need for fingerstick testing is reduced or eliminated.
- Long-term exposure to midrange glycemia may prove to be more beneficial in preventing complications than experiencing numerous upward hyperglycemic spikes and downward hypoglycemic spikes. This is because it reduces glycemic variability.⁷
- Provides audible alarms/alerts for current and impending hyperglycemia and hypoglycemia.
- Provides downloadable reports that facilitate data interpretation and patient learning.

- Provides features that share data and allow caregivers to view patients’ glycemic status in real-time.
- Rather than relying on a single data point such as HbA1c or fructosamine, continuous glucose monitoring provides valuable information about the time spent in normal, low, and high glucose ranges.
- In addition, continuous glucose monitoring presents the opportunity to express the average blood glucose level in innovative ways. Treatment can cause a rapid shift in the average blood glucose level.¹³

CONCLUSION

Diabetes is a long-term condition that significantly adds to sickness and death rates. In India, the management of diabetes is disappointingly inadequate, as only one-third of individuals with diabetes are able to reach the desired HbA1c level of less than 7%. As a result, the burden caused by both macro- and microvascular complications remains substantial. Thus, it is imperative to prioritize maintaining optimal glycemic control in all individuals diagnosed with diabetes. The use of innovative technologies such as CGM with real-time readings can aid in enhancing metabolic control, minimizing hypoglycemic episodes, and elevating the overall quality of life. CGM, in the long run, may contribute to minimizing the occurrence of chronic diabetes complications and potentially even lower the rates of morbidity and mortality associated with the condition, resulting in reduced expenses in the healthcare sector. These measures would, in turn, enhance the quality of life for diabetes patients in India. Further investigation is required to accurately record these findings among diabetic patients in India.⁵ CGM has several advantages over intermittent glucose monitoring, especially in situations where glycemic patterns are not well understood. With intermittent blood glucose monitoring, one cannot access the information pertaining to the direction, magnitude, duration, frequency, and underlying causes of fluctuations in blood glucose levels, as provided by continuous glucose monitoring. CGMs have proven to be useful when it comes to adjusting therapy or documenting the state of physiology that requires retrospective patterns. A real-time CGM is an abundant resource when one requires simultaneous monitoring of both the absolute level and trend patterns of glycemia.⁷

In today’s era of information overload, it seems highly probable that continuous glucose monitors (CGMs) will soon become

a standard tool for managing diabetes. They will initially cater to individuals struggling to control their diabetes, eventually extending their benefits to the majority of diabetes patients. With the continuous advancement of minimally invasive and non-invasive monitoring methods, diabetic patients will increasingly incorporate this technology into their regular routines. In the 21st century, data printouts emerging from CGMs will serve as a valuable tool for navigating diabetes management more effectively.

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CONFLICT OF INTEREST

None.

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