

# Diabetic Technology Update Continuous Glucose Monitoring Systems In The Management Of Diabetes Mellitus

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## Abstract

The term Diabetes technology is used to denote a combination of state-of-the-art hardware, newer devices and intuitive, user-friendly software that helps in the optimal management of diabetes. This term fundamentally includes two categories viz., the administration of insulin through syringes, insulin pens and precision pumps and secondly the accurate estimation of blood glucose through blood glucose monitoring (BGM) or comprehensive continuous glucose monitoring (CGM). The traditional concepts of glucose monitoring have been expanded to include the new parameters of CGM including target in range (TIR), glucose management indicator (GMI), Glycemic variability targets, time in range, time above range and time below range thereby enabling better evaluation of glycemic status and appropriate precision diabetes care. Several glucose monitoring devices including the rtCGM, isCGM and the professional CGM devices have strengthened the armamentarium of the diabetologist. CGM plays an important role in the management of T1DM, some cases of T2DM, diabetes in pregnancy and in cases of diabetes complicated by CKD.

## Introduction

In general, glycemic control may be assessed through various means including HbA1c measurement, blood glucose monitoring (BGM) and continuous glucose monitoring (CGM). The two important advances in diabetes technology include the use of continuous glucose monitoring and the deployment of insulin pumps that deliver the required insulin as and when necessary. Recently however, hybrid devices that monitor the blood sugar levels and also deliver the appropriate dose of insulin automatically, by employing suitable software, have been introduced. These advances in diabetes technology have enabled a futuristic diabetic care that is tailor made to the individual and thus has brought about a paradigm shift in the management of people afflicted with diabetes and its varied complications.

## Evaluation of glycemic control in diabetes mellitus<sup>1</sup>

Although traditionally, blood glucose has been monitored through simple blood glucose monitoring or the HbA1c measurement, CGM measurements have added a newer dimension to the management of diabetes. Recently three RCTs<sup>2</sup> involving 387 subjects have shown that laboratory measured HbA1c either underestimated or overestimated the mean blood glucose levels in comparison to the mean glucose measurements obtained from CGM. It is also suggested that a 14-day record of CGM parameters including TIR and GMI can serve as effective substitutes for HbA1c measurement in the management of hyperglycemia. CGM has thus emerged as a valuable tool in the management of several patients afflicted with T1DM and in a few patients with T2DM. The advantages of CGM include better control of diabetes with a lesser incidence of hypoglycemia and enhanced diabetic self-care.

## Types of Continuous Glucose Monitoring Devices

Recently different types of CGM devices have been introduced, including the rtCGM devices, the isCGM devices and the professional CGM devices. All these devices measure interstitial glucose levels which correlate well with the plasma glucose values. However, when there are rapid fluctuations in the blood sugar levels, the CGM values might exhibit a slight lag.

- a. rtCGM<sup>2</sup> devices: Real time continuous glucose monitoring devices, measure the glucose levels continuously without prompting and also store them appropriately.
- b. isCGM devices: Intermittent scanned CGM devices also measure glucose levels continuously, but require scanning for the memory storage of the glucose values.

A specific isCGM device called Freestyle Libre2 and another specific rtCGM device called the DexcomG6 have been designated as integrated CGM by the FDA. These devices are capable of being digitally connected with other automated insulin dosing systems reliably.

- c. Professional CGM devices: These devices are fixed on the patients in the medical institutions and are usually worn for a period of 1-2 weeks. The data obtained from these devices may be either visible or blinded to the patients wearing them. They are used to assess glycemic patterns or trends. The professional CGM devices are generally owned by the care providers while the rtCGM and the isCGM devices are generally owned by the patients themselves.

The selection of the device for the patients depends on the specific indications, the patient's particular needs, the skill levels of the user and lastly the availability and affordability of the various devices. Before prescribing a CGM device, it must be ensured that patients with diabetes or their caregivers are well trained to handle the device and also to interpret the data obtained. They should continue to receive constant support and training with re-evaluation of their techniques and review of their data interpretation skills.

The CGM devices may cause contact dermatitis when attached to the skin. This is usually due to the presence of isobornyl acrylate, a skin sensitizer that may provoke an allergic reaction. These allergic reactions must be addressed suitably to ensure continued utilization of the devices. Patch testing may be undertaken initially to identify the cause of dermatitis and in some cases, this might help in identification and elimination of the tape allergens.

## Monitoring of Glucose levels by CGM devices

The crucial element in the management of diabetes is the achievement of glycemic targets through accurate monitoring of the glucose levels. Blood glucose monitoring has long been established as the main method for effective diabetic management. However, in recent times, CGM parameters like Glucose management indicator (GMI) and time in range (TIR) have become standard metrics for glucose monitoring in patients with type 1 diabetes mellitus. The international Consensus on TIR has laid down standardized CGM metrics for optimal clinical care. The CGM reports with visual cues and the ambulatory glucose profile facilitate effective interpretation of the data by the patients and the providers and the initiation of suitable treatment decisions thus making the CGM metrics useful, practical and actionable. CGM has fulfilled an existing need in diabetes management by offering the possibility of automated glucose monitoring that helps improve glucose control in patients with uncontrolled T2DM and also in patients on intensive glucose lowering regimens.

## Standard CGM parameters for diabetic clinical care<sup>3</sup>

The ambulatory glucose profile (AGP) along with the percentage of TIR, TBR and TAR may be used to train and motivate patients living with diabetes. Essentially 14 days of CGM is required for the reasonable assessment of Time in range. The CGM metrics include:

1. Total number of days the CGM device is worn
2. Time duration of CGM device activity
3. Mean or average glucose levels
4. Glucose management indicator

5. Glycemic variability target (coefficient of variation) <36%
6. Time above range - time duration and the percentage of readings >250 mg/dL indicating level 2 hyperglycemia
7. Time above range – time duration and the percentage of readings between 181- 250 mg/dL indicating level 1 hyperglycemia
8. Time in range – blood sugar values 70-180 mg/dL (normal range glucose levels)
9. Time below range- time duration and the percentage of readings 54-69 mg/dL indicating level 1 hypoglycemia
10. Time below range – time and percentage of readings below 54 mg/dL indicating level 2 hypoglycemia.

## CGM goals for effective diabetic control

The time in range correlates well with the risk of microvascular complications and thus may be a useful marker in the assessment of glycemic control. TIR in addition correlates with HbA1c in many studies. Two studies have reported that a TIR of 70%<sup>4</sup> is closely aligned to a HbA1c of 7%.

The time below target and the time above target are additional CGM metrics that are also useful in diabetes management. Ideally a time below range of <4% and time <54mg/dL of <1% should be the glycemic goal. Although HbA1c remains the primary measure to guide the management of diabetes and a useful risk marker for the development of various complications, CGM metrics like TIR and GMI provide more accurate insights that helps formulate a personalized management plan. CGM metrics are slowly inching their way into clinical practice and the ability to access these data could be potentially favorable to the practice of telemedicine. The use of CGM metrics must however be guided by patient related goals and these attributes shall determine the frequency, timing and the consideration of CGM usage.

## Continuous Glucose Monitoring- Clinical applications

CGM initiation may be beneficial early on in diabetes, if tailored to the needs and preferences of the patients. This permits effective tracking of blood sugar levels, appropriate adjustment of insulin dosages, suitable lifestyle modifications and also eliminates the painful burden of frequent monitoring of blood glucose. It has also been demonstrated that cessation of CGM monitoring in patients needing it resulted in poorer outcomes thus necessitating continued access to these devices.

In January 2022, the American Diabetes Association have formulated the following recommendations for CGM in the Standards of Medical care in Diabetes<sup>2</sup>, 2022.

- i. Real time CGM or intermittently scanned CGM should be offered to adult patients with diabetes who are already on multiple daily injections or continuous subcutaneous insulin infusion (CSII).
- ii. rtCGM or isCGM should also be offered to adult diabetics taking basal insulin who have the ability to safely use these devices
- iii. rtCGM or isCGM should also be offered to younger patients with T1DM and T2DM, who are on multiple daily injections or CSII and have the capacity to safely use the devices

The ADA further recommends that in patients on multiple daily injections or CSII, the devices should be used daily and continuously. If isCGM devices are being used, the scanning must be undertaken 8<sup>th</sup> hourly. If CGM devices are not easily available then the periodic usage of rtCGM isCGM, or professional CGM devices may be helpful. In patients with type 1 DM using isCGM devices, increased frequency of scanning results in improved outcomes and better lowering of HbA1c levels. Real time systems may need to be calibrated as per predetermined time schedule. Adjunctive CGM devices are those, where the user needs to perform additional BGM measurements to make therapeutic decisions. Non adjunctive devices do not require the additional BGM measurements.

## Advantages of continuous Glucose monitoring

Several RCTs have shown that regular usage of rtCGM devices have resulted in considerable lowering of the HbA1c levels and also decreased the incidence of hypoglycemia. The studies initially demonstrated the benefit of CGM in young individuals and adults with T1DM who were on MDI or CSII. Subsequently, it was shown that even in T2DM, the use of rtCGM caused a significant improvement in HbA1c, although there was no reduction in the rate of hypoglycemic attacks. Surprisingly, these changes were achieved without much changes in the anti-diabetic medications.

The data from RCTs is limited in case of isCGM devices and the results not very promising. A few studies showed decrease in HbA1c, while others showed reduced hypoglycemic attacks. However, observational or retrospective studies in T1DM patients using isCGM devices demonstrate improvement in HbA1c levels in addition to reduction of acute complications like ketoacidosis or hypoglycemia. T2DM patients on MDI or basal insulin also show improvement in HbA1c levels with usage of isCGM devices.

A few RCTs have compared the advantages of rtCGM with that of isCGM concluding that the time spent in hypoglycemia was lesser with rtCGM usage. Another study demonstrated an improvement in TIR with rtCGM usage. CGM is thus useful in the creation of an ambulatory glucose profile in addition to some highly useful metrics like, TIR, time spent above and time spent below range along with glucose variability.

### Real time continuous glucose monitoring in the antenatal period

A RCT study by Feig et al<sup>5</sup> showed a reduction of HbA1c levels in pregnant women on MDI or CSII who were using rtCGM in addition to standard care. This improvement was achieved without an increased risk of hypoglycemia or neonatal hypoglycemia and also reduced the incidence of large for gestational age births. Real time CGM reported mean glucose levels, are superior indicators of glucose control in pregnancy as compared to HbA1c. But, isCGM device usage did not decrease the adverse neonatal outcomes as per published studies.

### CGM technology application in prevention of Hypoglycemia

The usage of CGM and CGM assisted pump therapy introduced the possibility of alarm-based prevention of hypoglycemia. RCTs done amongst Type 1 diabetics using rtCGM showed reduction in the time spent in the range of 54-70 mg/dL. However, rtCGM usage does not reduce the incidence of hypoglycemia in type 2 diabetics although it improves the HbA1c levels.

### Professional Continuous Glucose monitoring

In situations where rtCGM or isCGM are not available or if the patient chooses to opt for the blinded analysis of his glucose values, professional CGM may be a viable option. These professional CGM devices are also useful to identify patterns and trends of hypoglycemic or hyperglycemic events. Professional CGM usage is inevitably linked with detailed analysis and interpretation by the medical provider leading to suitable medication alterations and life style adjustments.

### Continuous Glucose monitoring in the hospital settings

In general, point of care glucose monitoring at any given time may lead to increased risk of missing out on the detection of asymptomatic or nocturnal hypoglycemia. This is countered to a large extent by the usage of CGM that measures glucose continuously and also documents the trend and direction of change over time. The ADA recommends that patients already using CGM may be permitted to continue the same under supervision<sup>6</sup>. The American Association of Clinical Endocrinologists permits continuation of CGM in hospitalized patients if they have intact cognition and if the hospital has a specialized diabetes in-patient consultation team. The Diabetes Technology society suggests that CGM may be started during hospitalization, to reduce the need for point of care measurements in highly contagious patients in isolation facilities.

In conclusion, it is pertinent to state, that continuous glucose monitoring systems have opened up exciting new possibilities for better management and control of diabetes. The CGM parameters like Glucose management indicator, time in range, time below range and time above range are novel criteria that facilitate a better reduction of

HbA1c levels even while reducing the incidence of hypoglycemia. Additionally, CGM seamlessly slips into the domain of telemedicine facilitating round the clock diabetic care. Diabetes technology thus strives to take us closer and closer to the state of physiological glucose homeostasis.

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