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Pros and cons of continous glucose monitoring

Marcin Ciechański
Medical University of Lublin, Poland
https://orcid.org/0009-0001-6243-714X
Corresponding author: ciechanski@gmail.com

Edyta Witkowska
Medical University of Lublin, Poland
https://orcid.org/0009-0005-6139-5282

Agnieszka Ostańska
SP ZOZ MSWiA in Lublin, Poland
https://orcid.org/0009-0000-3830-5625

Adrianna Szafran
SP ZOZ MSWiA in Lublin, Poland
https://orcid.org/0009-0004-5723-338X

Klaudia Wiśniewska
SP ZOZ MSWiA in Lublin, Poland
https://orcid.org/0009-0004-4732-806X

Laura Piasek
SP ZOZ MSWiA in Lublin, Poland
https://orcid.org/0009-0004-3104-3393

Grzegorz Godek
City Hospital in Ruda Śląska, Poland
https://orcid.org/0000-0001-7332-9534

Kacper Więcław
Stefan Cardinal Wyszyński's Regional Specialist Hospital in Lublin, Poland
https://orcid.org/0009-0005-9959-6709

Katarzyna Stańko
The Independent Public Hospital No. 4 in Lublin, Poland
https://orcid.org/0009-0003-1097-2508

Wiktor Terelak
SP ZOZ MSWiA in Lublin, Poland
https://orcid.org/0009-0001-9429-6038

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ABSTRACT

Introduction. Diabetes mellitus is a metabolic disorder that might result in short and long-term health complications and even death if not properly managed. This disease affected 451 million people in 2017 worldwide and these figures are expected to increase to 693 million by 2045. Currently, there is no cure for diabetes. However, self-management, especially keeping BG in the recommended range, is crucial to the treatment.

Aim. The aim of this paper is to offer an overview of current literature regarding CGM technologies. We outline mechanism of action, current use of CGM and discuss pros and cons of using this method in DM management.

Material and methods. A review of the literature available in PubMed and Google Scholar databases was conducted.

Results and conclusions. Blood glucose measurement using a glucometer is an invasive method, not very comfortable for the patient, it detects only one temporary blood glucose level. This method does not reflect glucose fluctuations and trends, which makes effective diabetes management difficult. Even supplementing

this method with HbA1c measurement does not bring as much relevant information for making therapeutic decision as CGM. The abundance of data provided by CGM and the ability to analyze them in greater detail, provide additional information to help achieve glycemic goals. It is a discreet and minimally invasive method, and the reading of blood glucose values can be easily read from mobile device. Data storage allows the doctor to view the past course of the disease and modify treatment. Manufacturers are constantly improving their devices, eliminating flaws, and the benefits of CGM improve treatment outcomes, which should translate into a reduction in the long-term complications of diabetes. Further research is needed, leading to the development of CGM technology.

Introduction

Diabetes mellitus (DM) is a metabolic disorder that causes abnormal blood glucose (BG) regulation that might result in short and long-term health complications and even death if not properly managed [1]. This disease affected 451 million people in 2017 worldwide and these figures are expected to increase to 693 million by 2045 [2]. Currently, there is no cure for diabetes. However, self-management of the disease, especially keeping BG in the recommended range, is crucial to the treatment [1].

Currently, patients with diabetes may choose between two major types of system for glucose measurement: blood glucose monitoring (BGM) systems measuring glucose within capillary blood and continuous glucose monitoring (CGM) systems measuring glucose within interstitial fluid. Although BGM and CGM systems offer different functionality, both types of system are intended to help users achieve improved glucose control [3]. Moreover, patients with diabetes may use HbA1C to trace the mean blood glucose in the past 2–3 mo.

Fingerstick blood glucose can detect only one instant blood glucose; therefore, it does not represent long term day-to-week blood glucose levels. Although the HbA1c level represents the mean blood glucose in the past 3 mo, it does not reflect the fluctuations of blood glucose. To solve these shortcomings, a continuous glucose monitor is a device developed to monitor interstitial glucose levels by a mini-invasive subcutaneous sensor [4]. In this paper we focus on CGM systems. We outline mechanism of action, current use of CGM and discuss pros and cons of using this method in DM management.

CGM description

The CGM system is mainly comprised of 3 components: a) biosensor, b) transmitter and c) monitor. The biosensor is a tiny cannula inserted into the subcutaneous fatty tissue and continuously measures glucose concentration in the interstitial fluid. The glucose sensor is based on a glucose oxidase (GOD). The biosensor must be changed every 7–14 d, and some biosensors can be used for a maximum of 180 d (Eversense). The transmitter is a small, reusable device that is connected to the biosensor to send the measured data of interstitial glucose levels wirelessly. Finally, the monitor receives the wireless real-time interstitial glucose signal. The monitor function can be performed by a special mobile device, smartphone using an dedicated application, and some systems allow data to be sent directly to the insulin pump. That provides easy mobile acces to real-time glucose levels and provide feedback with many smart features, such as arrows depicting the current glucose trends and smart alarms for impeding hypo- hyperglycemic events, improving patient self-management [5]. The smartphone can also send glucose readings to the cloud, and the medical staff can access them. The large amount of data of glucose levels can be analyzed to produce an output that combines the glucose readings and suggested medications, diet and exercise amount through the cloud system [5, 6]. Currently, two different types of CGM systems are available on the market: real-time continuous glucose monitoring (rtCGM) systems and intermittently scanned continuous glucose monitoring (iscCGM), flash glucose monitoring [FGM]) systems. rtCGM systems measure the glucose values and automatically display, every 5 min, a recent value.

In contrast, the sensor of iscCGM systems measures glucose levels every minute and stores one value every 15 min. iscCGM systems need to be actively scanned to obtain glucose information and to show it on the device display. The scans have to be performed at least every 8 h to retain the whole daily glycemic data [7]. Scanned glucose values of iscCGM systems can be either downloaded to a personal computer or uploaded to a cloud-based system [8, 9].

Mechanism of action

Glucose concentration is estimated based on the production of hydrogen peroxide by GOD and the associated release of electric current, which is directly proportional to the concentration of glucose in the interstitial fluid. In detail, GOD and its cofactor, which works as the initial electron acceptor, catalyze the oxidation of glucose to hydrogen peroxide (H_2O_2) and gluconic acid, whereas the cofactor is reduced: glucose + GOD – cofactor$_{(oxidized)}$ → gluconic acid + GOD – cofactor$_{(reduced)}$. The cofactor is regenerated in a reaction with oxygen (O_2), which leads to the formation of H_2O_2:GOD – cofactor$_{(reduced)}$ + O_2 → GOD – cofactor$_{(oxidized)}$ + H_2O_2. H_2O_2 is oxidized at a catalytic electrode where the amount of transferred electrons is detected: $H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$. This electron flow is proportional to the glucose concentration in the interstitial fluid [8].

Accuracy and precision

High-quality performance of medical devices for glucose monitoring is important for a safe and efficient usage of this diagnostic option by patients with diabetes. In the literature, BGM system accuracy is assessed mainly according to ISO15197:2013 accuracy requirements, nor requirements to determine and compare the accuracy of CGM systems reproducibly [8]. CGM accuracy has hitherto mainly been assessed by MARD. The mean absolute relative difference (MARD) parameter is used most often to characterize the measurement performance of CGM systems. Many patients with diabetes routinely use CGM systems as the diagnostic cornerstone of their diabetes treatment and they make insulin dosing decisions based on the determined readings. It's important to note that MARD is just one of several metrics used to evaluate CGM systems performance. Other metrics, such as mean absolute difference (MAD), time-in-range (TIR), and continuous glucose error grid analysis (CG-EGA), provide complementary information and a more comprehensive understanding of device performance. In this paper we focus only on MARD and we briefly describeTIR [10].

MARD is calculated by averaging the absolute values of relative differences between CGM/BGM system measurement results and corresponding comparison method results. In this case, "absolute" means each individual relative difference value is considered a positive value, irrespective of whether the calculated difference with respect to the comparison result is positive or negative. Reported as a percentage, MARD is the average of the absolute difference between these values. The less the MARD is, the closer are the CGM readings to the comparison values. Current CGM systems reach MARD values in the range of approximately 8%–12%. Using CGM for insulin dosing decisions is feasible below a certain level of sensor error, estimated at MARD = 10%. Further accuracy improvement did not contribute substantively to better glycemic outcomes [10].

Accuracy and precision have improved dramatically [7,11,12]. For a wide range of glucose values, CGM data are accurate enough to use for self-adjustment of insulin dosage, detection of hypoglycemia, and evaluating response to therapy. Accuracy is strongly dependent on the glucose level [13], rate of change of glucose and number of other factors [9]. MARD should be considered alongside other metrics and clinical outcomes to gain a comprehensive understanding of a device's performance [3,8,14].

The systems currently available on the market offer a MARD of 8–12%, examples:

- Dexcom G6: The Dexcom G6 CGM system has been reported to have a MARD value of around 9%-10%.
- Medtronic Guardian Sensor 3: The Medtronic Guardian Sensor 3 CGM system has reported MARD values in the range of 8%-12%.
- Abbott FreeStyle Libre: The FreeStyle Libre CGM system by Abbott has reported MARD values ranging from approximately 9%-11%.
- Eversense CGM system had reported MARD values in the range of 9%-12%.

PROS

Approval for non-adjuvant use

There has been steady improvement in the accuracy of glucose sensors (±10% MARD), which has led to greater acceptance by patients and physicians and has enabled users of CGM to reduce the number of measurements of capillary blood glucose (CBG). It is proved that a 10% MARD should be sufficient to permit self-adjustment of insulin dosage without the need for a confirmatory CBG. Thus, CGM is ready for non-adjuvant use—no longer just an adjuvant to self-monitoring of blood glucose (SMBG) [10,15,16]. The ability of CGM devices to accurately collect and document glucose levels is accepted by the clinical community [17,18]. Several CGM devices are authorized by regulators to replace SMBG testing for diabetes treatment decisions, which is the so-called non-adjunctive use of these devices. In addition, a specific category of FDA class 2 device type, known as an integrated CGM (iCGM) device [23], is used by the FDA to refer to CGM devices that are suitable for use with digitally connected medical devices, including automated insulin delivery systems [19,20].

Better insight into the disease and smart features

Use of CGM continues to expand in clinical practice. As a component of diabetes self-management, daily use of CGM provides the ability to obtain immediate feedback on current glucose levels as well as direction and rate of change in glucose levels [21]. Smart features such as alert, alarms and trend arrows which warn of impending or occurring hypo- or hyperglycemia events. As a result, rapidly increasing or decreasing glucose levels can be noticed and subsequently counteracted. Through the early perception of changing glucose levels, the probability of nocturnal hypoglycemic events [22], as well as missed bolus insulin injections for meals, can be reduced. Nonetheless, excessive occurrence of alarms can also lead to reduced compliance in patients ("alarm fatigue") [23]. Also trend arrows in CGM systems serve as an early warning for impending hypoglycemia and hyperglycemia events. Downward trend arrows appear when glucose level is falling, whereas upward arrows appear when it is rising. Consequently, the trend arrows may indicate the need to ingest carbohydrates or for correcting insulin dose. CGM provides a much larger number of glucose readings than occasional SMBG, whereby a comprehensive picture of daily glucose course is obtained. Up to 288 glucose measurement results every day (within a 5-min interval) make the use of easy understandable and standardized data readouts and graphical presentations necessary. Retrospective CGM data enable patients to enhance their glycemic management by adjustment of their therapy and behavior with the help of their clinicians under consideration of supplementary disclosures, such as insulin dosing and carbohydrate intake. These data, for example, can enable insights into the patterns of hypo- and hyperglycemia events that occur over time and lead to a change in their therapy to avoid such events in the future [24]. This information allows people with diabetes to optimize dietary intake (e.g. adjustments in pre-bedtime snacks to reduce nocturnal hypoglycemia) and exercise, make informed therapy decisions regarding mealtime and correction of insulin dosing, and, importantly, react immediately and appropriately to mitigate or prevent acute glycemic events [25–27].

Sleep Quality

Many factors contribute to insufficient sleep duration and poor sleep quality in people with T1D. Nocturnal diabetes management tasks, such as glucose testing and insulin administration, may be necessary for routine diabetes care. In addition, hypoglycemia, rapid changes in glucose levels, and fear of hypoglycemia can delay sleep onset and cause frequent night awakenings.

CGM use has been associated with improved subjective sleep quality, especially for parents of children with T1D and spouses/partners of people with T1D [28,29]. Sharing of real-time glucose data, has transformed T1D care for many people. This is especially true in the pediatric population because parents can view their child's glucose levels at all times including overnight, without disrupting the child's sleep. In addition to improved sleep, fear of hypoglycemia, health-related quality of life, stress, and anxiety, have been shown to be better among parents of children using a CGM [30].

However, CGM devices can also disrupt sleep due to alarms and increased anxiety which can lead to nocturnal awakenings [31,32]. Fre-

quent alarms, whether nocturnal or throughout the day, often lead people to discontinue use of CGM, an experience known as "alarm fatigue" [32]. Although many parents have benefitted from their child's use of CGM, some parents of young children with T1D may continuously monitor their child's CGM glucose level due to fear of hypoglycemia. This can result in parents having greater sleep disturbances than the child, whose sleep disruptions are decreased due to fewer finger stick glucose tests during the night [33].

Integrating the CGM system with an insulin pump and an internal algorithm allows to create a hybrid closed-loop system that automatically adjusts insulin delivery based on glucose values and trends from the CGM sensor. HCL system studies highlighted significant improvement in nocturnal glucose levels [34–37].

A number of controlled clinical trials have evaluated sleep outcomes in patients using HCL systems. Although objectively assessed sleep (e.g., actigraphy) has shown neither improved or impaired sleep with the use of HCL systems compared to sensor augmented pumps or the previously used diabetes regimen [38–42], multiple studies have found improvements in subjective sleep quality [38,40,43–45], likely related to trust in the system to manage blood glucose levels and decreased fear of hypoglycemia [46]. In a qualitative study, participants reported that overnight increase in time spent in range (between 70 mg/dL and 180 mg/dL) and improved sleep quality led to reported improvements in daily functioning (improved energy level, feeling better) and overall glucose regulation [47].

Overwhelmingly, patients and families report improvements in diabetes glycemic outcomes with device use; however, there remain concerns about how devices impact sleep, with CGM alarms as a common reason for nocturnal disruptions. Use of a device often requires weighing the benefits versus the burden, which can vary greatly from person to person [48].

Decreased HbA1c with lower risk of hypoglycemia

HbA1c is currently recognized as the key surrogate marker for the development of long-term diabetes complications in people with type 1 and type 2 diabetes and has been used as the primary end point for many CGM studies [49,50]. While HbA1c reflects average glucose over the last 2–3 months, its limitation is the lack of information about acute glycemic excursions and the acute complications of hypo- and hyperglycemia. HbA1c also fails to identify the magnitude and frequency of intra- and inter-day glucose variation [51,52]. Despite some limitations, HbA1c is the only prospectively evaluated tool for assessing the risk for diabetes complications, and its importance in clinical decision making should not be undervalued. Rather, the utility of A1C is further enhanced when used as a complement to glycemic data measured by CGM [21].

In randomized, controlled trial, was observed that the benefit associated with continuous glucose monitoring was strongly related to age. In patients 25 years of age or older, substantially tighter glycemic control was evident in the continuous-monitoring group in both glycated hemoglobin levels and sensor glucose results. More patients in the continuous-monitoring group than in the control group had a glycated hemoglobin level of less than 7.0% without having a severe hypoglycemic event. The results of this study indicate that continuous glucose monitoring improves glycated hemoglobin levels and may enhance the management of type 1 diabetes in adults who have the motivation to use this technology and the capability to incorporate it into their own daily diabetes management [53].

Another randomized trial among adolescents and young adults with type 1 diabetes showed a small but statistically significant lowering of HbA1c over 26 weeks of CGM use compared with standard BGM. This finding offers potential for clinical importance with a meaningful shift in the HbA1c distribution toward improved glycemic control; however, further research of longer duration and with clinical outcomes is needed before reaching definitive conclusions about the clinical value of the study's findings [54].

In another systematic review and meta-analysis of RCTs comparing CGM with conventional therapy, use of CGM led to a modest 0.17% reduction in HbA1c, with a 70.74 min increase of time spent in the target range. Moreover, CGM provided additional benefits in glycemic control, including the significant reduction of TBR, TAR, and CV, thus suggesting an improvement of glucose variability compared with usual care. Such a result may appear insufficient for the great majority of

people with diabetes; on the other hand, it may also reflect a more intense effect in reducing hypoglycemia, thus expressing the effort in ameliorating glucose control while reducing glucose variability [55].

TIR

In clinical practice, time in rangeis both appropriate and useful as clinical targets and outcome measurements that complement HbA1C for a wide range of people with diabetes and that the target values should be considered an integral component of CGM data analysis and day-to-day treatment decision making. To streamline data interpretation, the ATTD [56] consensus panel identified "time in range" as a metric of glycemic control that provides more actionable information than HbA1C alone. The metric includes three key CGM measurements: percentage of readings and time per day within target glucose range (TIR), time below target glucose range (TBR), and time above target glucose range (TAR). The primary goal for effective and safe glucose control is to increase the TIR while reducing the TBR. The consensus group agreed that expressing time in the various ranges can be done as the percentage (%) of CGM readings, average hours and minutes spent in each range per day, or both, depending on the circumstances [21].

CONS

Cost

Continuous glucose monitoring devices are costly, with inconsistent reimbursement across government bodies. Many countries, including Australia and America, offer reimbursement for people with type 1 diabetes mellitus, with limited subsidization for people with type 2 diabetes mellitus. Germany reimburses real-time CGM for all types of diabetes, whereas Spain offers no reimbursement at all. Most CGM systems require sensor changes every 6–14 days, which generates significant costs [57]. CGM appears to be a cost-effective intervention for individuals with type 1 diabetes. Key drivers of CGM cost-effectiveness include reduction of chronic complications through improvement in glycemic management, and reduction in frequency and duration of hypoglycemic episodes [58]. These studies also highlight the rapidly evolving nature of CGM which has driven down usage costs and may continue to do so with further advances [59]. One also needs to consider costs to society for failure to implement CGM, including costs of emergency management of severe hypoglycemic episodes (emergency room visits, hospitalizations, mortality, and morbidity), the costs of failure to achieve the optimal level of glycemic control in terms of quality of life, and long-term complications [9].

Lag time of interstitial fluid glucose relative to blood glucose

There is a delay as glucose is transported from blood to interstitial fluid. This delay could be appreciable in early forms of CGM (e.g., 15 min). Largely because of improvements in algorithms for computing glucose from the raw electrical signal from the sensor, this problem has been dramatically reduced to only a few minutes for several systems [9]. The new glucose algorithm reduces the time lag for FreeSyle Libre System to about two minutes (2.4 minutes for adults and 2.1 minutes for pediatric population) compared to the previous-generation the product (4.5 minutes, in a study without glucose manipulation) [60, 61] the drop in CGM lags behind the drop in blood glucose during prolonged aerobic exercise by 12 ± 11 min, and MARD increases to 13 (6–22)% during exercise as well. Therefore, if hypoglycemia is suspected during exercise, individuals should confirm glucose levels with a capillary glucose measurement [62].

Calibration

The improvement in accuracy of CGM sensors has been accompanied by a reduced need for frequent calibration (Eversense- one per day [63]) or any calibration (Abbott FreeStyle Libre, Dexcom G6, Medtronic Guardian Sensor 4) by the user [61,64,65].

Sensor lifetime

Sensor lifetime is another factor that contributes to cost, inconvenience, and slow user acceptance. Even the durability of the adhesive used for attachment of the sensor to the skin is a matter of concern. One can expect that user acceptance will continue to improve as sensor lifetime increases and ease of sensor insertion improves [9]. Companies are trying to meet customer expectations,

and currently available sensors on the market offer operating times from 7 (Medtronic Guardian 3) to even 180 days (Eversense) [5].

Poor adhesion, sweating and skin irritation

When we talk about medical devices for diabetes treatment, the focus is usually on scientific aspects and clinical efficacy. Safety issues are largely discussed in terms of hypoglycemic events, devices failures, and so on. However, in practice other aspects, like rashes, itching, site reactions, pulling off, falling off, sweating off, losing a transmitter or receiver and so on are often of concern for patients and diabetologists. One area that does not get much attention involves the adhesives used to attach devices to the human skin. There is a trend for the extension of glucose sensor wearing time of continuous glucose monitoring systems (CGM). Longer wearing time means less injuries of the skin, less hassle for sensor change and lower sensor costs per day. However, longer wearing time of glucose sensors or insulin infusion sets means also higher challenges for the adhesive material used. The consequence of longer usage time might be that we see in more patients allergic skin reactions (contact dermatitis) [66]. This is especially significant for individuals with skin sensitivities, pediatric patients, and those who use devices chronically. Dermatological complications are often cited as a barrier to device use and a reason for device discontinuation. Furthermore, it is a frequent topic of discussion in diabetes follow-up visits, although little evidence-based literature exists to guide providers in managing skin integrity issues [67].

Conclusions

CGM has emerged as a valuable tool to assess the effectiveness and safety of treatment in many patients with type 1 diabetes and in selected patients with type 2 diabetes treated with intensive insulin regimens [68]. Applying these technologies to diabetes management results in immediate information regarding glucose levels to the user, as well as glucose trend, its current direction, and rate of change, leading to an increased time in the target glucose range by reducing hyperglycemia and minimizing the occurrence of hypoglycemia [69,70]. In previous meta-analyses of randomized controlled trials conducted in patients with both type 1 [71–73] and type 2 diabetes [74,75], the use of CGM provided a reduction in HbA1c of ~0.3%, with less hypoglycemia [71,72], compared with usual care. The large quantity of glucose readings collected by CGM allows users to obtain a more complete profile of the glycemic status over the entire day, including the time spent in the target ranges and the time spent in hypo- and hyperglycemia, as well as measures of glucose variability, adding some useful information for assessment of the current glycemic profile in addition to what is provided by the HbA1c [56,76]. A recent international consensus on the use of CGM highlighted the importance of assessing and reporting the percentages of TIR, TBR and TAR in conjunction with measures of glucose variability as key metrics for the evaluation of glucose control in clinical studies [55,56]. The pace of development in diabetes technology is extremely rapid. New approaches and tools are available each year. It is hard for research to keep up with these advances because by the time a study is completed, newer versions of the devices are already on the market. The most important component in all of these systems is the patient. Technology selection must be appropriate for the individual. Simply having a device or application does not change outcomes unless the human being engages with it to create positive health benefits. This underscores the need for the health care provider to assist the patient in device/program selection and to support its use through ongoing education and training. Expectations must be tempered by reality—we do not yet have technology without flaws that completely eliminates the self-care tasks necessary for treating diabetes, but the tools described in this paper can make it easier to manage [77].

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Conflict of interest statement
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