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Continuous Glucose Monitoring: An Overview for Nurse Practitioners

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ABSTRACT

Continuous glucose monitoring (CGM) is a revolutionary addition to diabetic management for patients with type 1 diabetes mellitus (T1DM). CGM, when used properly, improves overall glycemic control. In the short term, CGM decreases incidences of hypoglycemic events and improves day to day blood glucose control. In the long term, CGM decreases hemoglobin A1c levels and decreases incidences and severity of long term complications of diabetes. When patients are educated and supported by providers on the use of CGM, patients with T1DM can achieve optimal glycemic control.

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Introduction

The CDC National Diabetes Statistics Report (2017) states that over 1.5 million adults in the United States are living with type 1 diabetes mellitus (T1DM). With an average of 40,000 individuals newly diagnosed with T1DM each year, it is predicted that over 5 million Americans will be living with this chronic disease by the year 2050 (Centers for Disease Control and Prevention, 2017). Although these statistics are concerning, it is even more disconcerting that less than one-third of these individuals are adequately controlling their blood glucose levels to achieve target goals (Pietrangelo, 2017). As a result of poor control and high prevalence, T1DM costs the United States an average of $14.9 billion each year (Pietrangelo, 2017). Fortunately, there is something that can help. The use of continuous glucose monitoring (CGM) has recently become an important part of diabetic management and is helping to optimize the treatment of T1DM in the United States and around the world (Slattery & Choudhary, 2017).

CGM is a system that constantly measures glucose levels in real time. A small catheter containing a sensor is inserted under the skin and measures glucose levels in the subcutaneous tissue fluid. The sensor connects to a transmitter that sends glucose data wirelessly to a handheld monitoring device. Many models also have a mobile app available allowing users to see glucose readings on their handheld electronic devices (Dexcom Continuous Glucose Monitoring, 2018).

Providers caring for patients with T1DM, and specifically nurse practitioners, can greatly influence these patients' lives by increasing their knowledge of the use of CGM in diabetes management and how it can improve diabetes outcomes. CGM can be a life changing addition to a patient's diabetes management and should, therefore, be advocated by all healthcare providers

(Pickup, Holloway, & Samsi, 2015). The purpose of this article is to give nurse practitioners an overview of CGM and discuss the implications these systems can have for patients with T1DM.

History of Blood Glucose Monitoring

Blood glucose monitoring has improved greatly over the years. In the early 20th century, people with T1DM had to test their urine to determine their blood glucose level and then self-administer insulin according to the urine glucose reading (Clarke & Foster, 2012). This form of testing was very inaccurate. The time delay involved in determining the glucose by testing urine and the long-acting nature of the insulin made it nearly impossible to titrate insulin for tight glycemic control (Clarke & Foster, 2012). It was not until 1980 that home self-monitoring blood glucose (SMBG) was introduced. SMBG allows people with T1DM to test a drop of blood from a fingerstick and determine their blood glucose level at that specific point in time (Clarke & Foster, 2012). This form of testing is much more accurate than urine dips, but only allows for tight glycemic control when the blood is tested very regularly throughout the day. The emergence of CGM fills the gaps between finger sticks by relaying a continuous blood glucose trend. With increased knowledge of their current blood glucose status, patients are better able to treat their diabetes (El-Laboudi, Godsland, Johnston, & Oliver, 2016).

CGM was created to help patients with T1DM to further improve their blood glucose control. Blood glucose levels are ever changing, and CGM offers a continuum of these constantly trending values. Monitoring blood glucose with SMBG finger sticks provides only a single value on this continuum making it difficult for patients to treat their blood glucose proactively. In contrast, CGM not only provides a real-time blood glucose level, but also shows trends, direction, and speed of change. Glucose levels are updated as frequently as every five

minutes. The additional information of glucose trends allows users to treat their diabetes with precision and ultimately achieve better glycemic control (Medtronic MiniMed Inc., 2018).

Importance of CGM as a Treatment Option

Evidence shows that using CGM has both short- and long-term benefits for patients with T1DM (Floyd et al., 2012). In the short term, CGM improves day to day blood glucose control and prevents the occurrence of hypoglycemic events (Slattery & Choudhary, 2017). CGM systems are programmed to identify a downward trend in blood glucose levels and will alarm if levels drop below a programmed set point that each user can designate. CGM has also been shown to decrease hemoglobin A1c (HbA1c) levels and, therefore, decrease the long-term consequences of poor glycemic control (Lind et al., 2017). In a monumental study done in 1993 by The Diabetes Control and Complications Trial Research Group, tight glycemic control was effective at reducing kidney damage by 54%, cardiovascular damage by 41%, eye damage by up to 53%, and nerve damage by up to 41% (Shamoon et al., 1993). In addition to improving glycemic control, CGM has also been shown to decrease glucose fluctuations, reducing endothelial oxidative stress that ultimately reduces long-term complications of diabetes, especially those of a cardiovascular nature (Tumminia et al., 2015). By reducing glucose fluctuations and tightening glycemic control, CGM can reduce the incidence of long-term complications for patients with T1DM.

Many patients with T1DM use an insulin pump to deliver their insulin continuously through a subcutaneous catheter. Adding a CGM system to this regimen in conjunction with an insulin pump proves to be even more beneficial in the long-term than simply a CGM on its own (Mauras, Fox, Englert, & Beck, 2013). Patients with both devices can read their CGM meter and immediately adjust insulin delivery accordingly as the devices sit side by side. With the newest

CGM models, which are hybrid systems combining CGM with an insulin pump, glucose data and insulin delivery data can be viewed simultaneously on any smart device. In this manner, CGM use has been attributed to more frequent self-adjustments of insulin, which contributes to an overall improvement in glycemic control (Battelino et al., 2012).

Research also shows that long term use of CGM not only offers better glycemic control, but also increased patient satisfaction for patients with T1DM. The patients report an overall improvement in their quality of life when using the CGM system (Slattery & Choudhary, 2017). This satisfaction and improved outcomes may be attributed to the fact that patients with T1DM report that using a CGM system simplifies diabetic management and assists in recognizing hypoglycemia (Patton & Clements, 2016). Decreasing the fear of hypoglycemia and simplifying daily living for these patients has been shown to significantly increase the quality of life of CGM users (Chamberlain, Dopita, Gilgen, & Neuman, 2016).

An additional benefit is one of long-term economic consequence. In a study by Bronstone and Graham in 2016, a cost calculation demonstrated the estimated cost savings of CGM use: in a T1DM population of 9300, routine use of CGM would yield an annual savings of $946-$1346 per patient (Bronstone & Graham, 2016). This cost savings is primarily related to a decrease in hospitalizations and emergency treatment events related to hypoglycemic complications (Chamberlain et al., 2016).

Evidence of CGM Efficacy

Extensive research has been done on the efficacy of CGM. The results clearly indicate that CGM improves glycemic control when used appropriately. All of the research done in regards to the efficacy of CGM has concluded that it allows patients with T1DM to improve their glycemic control.

CGM provides two main outcomes for patients with T1DM: reduction of HbA1c levels and reduction of time spent in hypoglycemia (Mauras et al., 2013). A systematic review done in 2012 found that on average a reduction of 0.7% in HbA1c was seen at 3-18 months after CGM initiation (Langendam, Luijf, Hooft, DeVries, Muddle, & Scholten, 2012). Another study reported an average reduction of 0.5-0.7% in HbA1c levels over 9 months when using CGM (Parkin, Graham, & Smolskis, 2017). These levels are even further reduced for patients who use CGM consistently and proactively (Floyd et al., 2012). Another recent study found a mean reduction in HbA1c of 1.0% after 24 weeks of wearing the CGM system an average of 6 days per week (Beck et al., 2017). Additional researchers found that patients with poorly controlled T1DM taking multiple daily injections of insulin had a decrease in HbA1c from 8.35% to 7.92% over 26 weeks with the use of CGM. This shows that even those with poor control can benefit from CGM (Lind et al., 2017). A study done in an adolescent population (ages 11-20 years), with poor glycemic control, found that even while only wearing the CGM monitor an average of 4.262 days a week, there was an average reduction of 1.1% in HbA1c levels (Lewis, McCrone, Deiriggi, & Bendre, 2017). In addition to reducing HbA1c levels, CGM has also been shown to reduce the incidence of hypoglycemia. In particular, the use of CGM can nearly eliminate the occurrence of severe hypoglycemia- a blood sugar level low enough to impair daily activities (Choudhary et al., 2013).

The average reduction seen throughout the research is around 0.7%, which is equivalent to decreasing the average blood sugar by 20mg/dL. For example, a patient with a HbA1c of 8.6% has an average blood glucose of 200mg/dL, while a patient with a HbA1c of 7.9% has an average blood glucose of 180mg/dL. Even a 1.0% decrease in HbA1c reduces the risk of death

related to diabetes complications by 21% and has also been shown to reduce microvascular complications by 37% and risk of heart attack by 14% (Stratton et al., 2000).

Another benefit of CGM is the use of nocturnal data to treat glucose trends. Prior to CGM, the only data available to analyze glucose trends were the SMBG levels provided by the patient and the HbAlc blood level tested by the provider. SMBG and HbAlc alone cannot provide a picture of hypoglycemia duration or nocturnal hypoglycemia, as patients do not typically test their blood while sleeping (Kusunoki et al., 2015). With CGM, data are provided about glucose trends during sleep and can, therefore, be used by a provider to adjust insulin delivery accordingly. These data are particularly useful in conjunction with insulin pump therapy as the basal rate delivery of insulin can be adjusted to fit the individual glucose patterns of the patient. The use of nocturnal data ultimately increases the amount of time the patients spend within their target blood glucose range (Sharifi et al., 2016).

Identifying Candidates for CGM

Ideally, all patients with T1DM would be candidates for CGM; however, this is not the case. Socioeconomic factors are paramount in identifying potential candidates for a CGM system. One study indicated that low-income patients with minimal diabetes education do not achieve any improvement in HbAlc levels when using CGM (Sequeira, Montoya, Ruelas, Xing, Chen, Beck, & Peters, 2013). Although unable to achieve improvement in glycemic control, the subjects in this study did indicate that the CGM made it easier for them to adjust their insulin dosing and the majority wanted to continue with CGM (Sequeira et al., 2013).

Unfortunately, insurance companies' reimbursement policies dictate how patients receive healthcare. Each insurance company has its own set of qualifications for CGM coverage. Without insurance, a CGM system is unaffordable for many patients, and some insurance

companies may not provide adequate coverage to make using the CGM system an economical option. Historically, insurance companies have generally provided just minimal coverage for CGM. Medicare, for example, has not until recently covered the cost of CGM systems, but in 2017 Medicare announced it will cover the Dexcom G5 CGM system (Shifflett, 2018). This announcement will open the opportunity for CGM to many patients with T1DM. Another economic barrier is the need for continued supplies, which can also be costly with or without insurance coverage (Shifflett, 2018). The CGM meter, insertion sites, transmitter, and site adhesives must be purchased by the patient on a regular basis. Candidates for a CGM system must have the means to replenish these supplies consistently in order to achieve the maximum benefit of CGM. A CGM meter itself can cost anywhere from $200 - $1000, not including the supplies needed to run the CGM system which can cost an average of $75 - $150 a month (Scheiner, 2018). All of these costs are out of pocket for the patient after insurance. A patient without insurance, paying cash for the meter and supplies, can expect to pay even more. For example, the Dexcom G6, one of the newest CGM models, has a retail cost of $365 for the receiver, $475 for a bundle of two transmitters, and $349 for a monthly supply of sensors (Hoskins, 2018). In comparison, a SMBG kit can be purchased over-the-counter for an average of $20, without insurance, and free for patients with insurance coverage. The testing strips for a SMBG kit are even more economical at around 25 cents each with insurance coverage and $2 each without insurance. Nurse practitioners can assist patients with T1DM progress towards qualifying for a CGM by being informed about the different insurance companies' parameters and helping patients to understand these qualifications.

Several other factors are also important in considering potential candidates for CGM. Research has shown that CGM systems work best in highly motivated patients of all ages. With

appropriate support, these patients can proactively calibrate their meter, use their meter consistently, and take action according to glucose trends (Mauras et al., 2013). Research has also shown that patients who participate in frequent and high intensity exercise can benefit from CGM as its accuracy and effectiveness is not altered my metabolic changes (Bally, Zueger, Pasi, Carlos, Paganini, & Stettler, 2016).

An additional consideration is the predicted compliance of the patient. High levels of compliance and frequent interaction with the CGM system is essential to reaping the benefits. Patients with low compliance and low motivation do not appear to benefit significantly from a CGM system (Slattery & Choudhary, 2017). However, several studies have indicated that even patients with poorly controlled diabetes benefit from CGM use as even minimal use of CGM results in a lower HbA1c level (Lewis et al., 2017). Poorly controlled diabetes, therefore, does not rule out a patient from CGM benefits (Lind et al., 2017).

Potential Barriers to CGM Use

Even among ideal candidates, there are still several barriers to appropriate CGM use. The meter must be plugged in once daily to recharge, making CGM an impractical option for homeless or transient populations. Also, one study concluded that CGM use was most appropriate and effective in patients with higher education, higher household income, private health insurance, longer duration of diabetes, and concurrent use of an insulin pump (Wong et al., 2014).

An additional challenge with CGM is wearing the transmitter and the complexity of the system. The insertion site can be uncomfortable and requires frequent changing. Patients also complain of the nuisance of wearing two separate insertions sites, one for their insulin pump and one for their CGM sensor, as CGM is most frequently used in conjunction with insulin pump

therapy (Giani, Snelgrove, Volkening, & Laffel, 2017). With the two insertion sites also comes the added burden of carrying two devices: a pump and a CGM receiver (Giani et al., 2017). For example, patients with T1DM must keep track of the two devices at all times and adjust their wardrobe so that they have pocket space to keep these devices on their person at all times as well. The hassle of having another inserted device and negative associations with the device being on the body are additional common barriers seen particularly in young adults (Tanenbaum, Adams, Hanes, Barley, Miller, Mulvaney, & Hood, 2017). Some patients also report increased anxiety with using a CGM system related to the complexity of the system, frequent alarms, and sleep disturbances (Patton & Clements, 2016).

Types of CGM

There are three major companies that currently supply CGM systems: Dexcom, Abbott, and Medtronic. Dexcom was the first to come out with CGM and they have continued to release new and improved models since they went public in 2005 (Dexcom Continuous Glucose Monitoring, 2018). Their most recent model is the Dexcom G6. Abbott's CGM system, the FreeStyle Libre, became available in the United States in December of 2017. While superbly accurate, the Libre only displays glucose data when the transmitter is scanned across the sensor, and does not transmit data continuously like the other models (FreeStyle Libre Inc., 2018). Medtronic offers a CGM system called Guardian Connect that has previously only been available as an integrated piece of their most recent insulin pump models- the MiniMed 630G and MiniMed 670G (Medtronic MiniMed Inc., 2018). In March 2018, the Guardian Connect system became available to the public for use as a CGM only, not linked to a pump, and is geared towards use in patients on multiple daily injections (Medtronic MiniMed Inc., 2018).

Research has been done comparing the Abbott and Dexcom systems, but none has been done yet concerning the Guardian Connect CGM system on its own. The FreeStyle Libre and Dexcom G4 Platinum have comparable accuracy and agreement with true blood glucose values (Bonora, Maran, Ciciliot, Avogaro, & Fadini, 2016). However, another study found that the Libre had greater precision in hypoglycemia, hyperglycemia, and during exercise (Aberer et al., 2017). Each of the CGM systems has its pros and cons which should be considered and catered to each individual patient.

Table 1
Comparison of CGM systems

	Dexcom	Abbott	Medtronic
Calibration by fingerstick	Not needed, but can be done if desired	No, not able to receive calibrations. Factory calibrated prior to purchase.	Yes, demands calibration 3-4x/day
Cost per year with insurance	≈ $4700	≈ $730	≈ $5200
Covered by Medicaid	Yes for the G5 model	Yes	No
Life of sensor	Approved for 10 days	Approved for 14 days	Approved for 7 days
Life of transmitter	3-month battery life	Approved for 10 days	7 days and then must be removed and recharged
Display options	App on smart device, Tandem pump, or handheld receiver	Handheld receiver, must be touched to sensor to receive data	App on smart device or Medtronic pump
Warm up time	2 hrs.	12 hrs.	2 hrs.
FDA approval	Age 2 years and up	Age 18 years and older	Age 14-75 years

*Information gathered from FreeStyle Libre, Inc., Dexcom Continuous Glucose Monitoring, Medtronic MiniMed Inc., and Scheiner (2018)

Evolution of CGM

CGM has evolved significantly in the last decade. Since the first CGM system was available to the public in 2005, the performance of these systems has only improved in consistency and accuracy (Dubois, 2010). In 2016, a new device was released by Medtronic that

is a combination CGM device and insulin pump (Medtronic MiniMed Inc., 2018). This device, called the MiniMed 670G, is a hybrid closed loop system and the first of its kind in that it automatically takes action for the patient in adjusting insulin delivery according to the CGM values. For instance, if glucose levels go above or below designated values, the device will increase or decrease the basal rate of insulin delivery to treat the glucose trend (Rossetti et al., 2017). This new technology is monumental for people with T1DM and holds great promise for the future of diabetic care. As technology continues to improve, it is likely that CGM will become part of mainstream treatment for patients with T1DM. This will ultimately eliminate the need for painful finger sticks and improve glycemic control in the short- and long-term (Forlenza, Argento, & Laffel, 2017).

Monitoring and Evaluating Effectiveness of CGM Therapy

Data from a CGM system reach optimal effectiveness when it is accessed and analyzed. Data can be downloaded to a computer directly from the meter and glucose trends evaluated in order to make changes to the patient's practices. Each type of CGM system has its own program or website with a method of displaying the glucose values (Scheiner, 2018). Graphs of trends are especially useful in discussing necessary changes with patients. When patients can see their own glucose data in graphical form, their understanding and motivation for change increases.

Quarterly visits are recommended for ideal diabetes management. At these visits, providers can encourage patients with T1DM to wear their meter more often, ideally all the time. Although benefits from the system are seen with only 40% compliance, the benefits increase with increased compliance (Tumminia et al., 2015). Providers can also address barriers to CGM system use and discuss ideas for improving compliance with the system (Pickup et al., 2015).

Providers should also take time during these visits to educate how CGM use is linked to improved HbA1c levels and overall improved glycemic control (Tanenbaum et al., 2017).

Patient Teaching

Several points of education should be addressed with patients about their CGM system. It is important to educate patients that although undoubtedly helpful, CGM does not replace their need to critically think (Giani et al., 2017). Technology is not always perfect, and, therefore, patients must trust how they feel and test their blood if they feel their blood glucose level is different from what the meter is reporting. Each CGM system also comes with a manual that can assist the patient in troubleshooting the meter if it reports an error or is malfunctioning (Shifflett, 2018). Patients should be directed towards these manuals and individual education provided as needed. In a qualitative study conducted to analyze the experiences of patients with CGM, it was found that a lack of knowledge about CGM was a common theme among general practitioners. Healthcare providers must educate themselves on CGM in order to enhance the efficacy of its use for patients with T1DM (Pickup et al., 2015).

Conclusion

CGM improves overall glycemic control in both the short and long term and also decreases incidence and severity of diabetes related complications for patients with T1DM. CGM is most beneficial when properly used by motivated patients of all ages. When a healthcare provider appropriately educates and supports patients and patients comply with the established plan of care, optimal glycemic control can be achieved for patients with T1DM using CGM.

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