



Continuous Glucose Monitoring: changing the landscape of diabetes mellitus management

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Abstract

The human body is made up of many different organs that each have a very important role in keeping us healthy. Diabetes is a chronic disease that affects the pancreas and the ability for it to properly regulate insulin production and/or release. There is no cure for diabetes, but there are ways to help the body compensate for the lack of insulin production or regulation. Lifestyle changes can make a major difference and these include exercise, a healthy diet, and staying educated on the condition. Additionally, many patients have to take oral diabetes medications, injectable agents, or insulin. Along with this, patients need to check their blood sugars routinely and do so via fingerstick. Continuous glucose monitors (CGMs) are devices that allow digital blood glucose readings and ultimately fewer finger sticks. Constant monitoring can help patients see the change in their daily glucose readings and help them make changes to keep their sugars in a good range. While CGMs are very helpful for patients with diabetes, they are used by less than 50% of diabetic patients. The reasons behind this can widely vary, but lack of provider and patient education, lack of access to the devices, and cost may be deterrents in the process of patients using a CGM.



Diabetes Mellitus is a disease that affects about 1 in 10 people, which is approximately 34 million Americans.¹ It is diagnosed using one or more glucose tests. Most commonly, an A1C greater than 6.5% or a fasting plasma glucose of greater than 126 mg/dl is what is used to determine if a patient has diabetes.² It is then classified into 3 main types: type 1, type 2, or gestational.

Types of Diabetes

Type 1 diabetes is where the body does not produce any insulin.³ This typically occurs at a young age, but can ultimately happen to anyone. It is an autoimmune disorder, where the T-cells destroy the pancreatic B-cells.³ Both genetic and environmental factors could be a cause. This type of diabetes is managed by insulin therapy and a healthy lifestyle.³

Type 2 diabetes is the most common type of diabetes. In this type the body does not use insulin properly. This can either be from insulin resistance or B-cell dysfunction.³ This type has a slow onset and can be caused by lifestyle factors, such as obesity, age, inactivity, or other factors, like genetics.³ Some patients may just need lifestyle changes, but others may require pharmacological therapy.³

Gestational diabetes occurs in pregnancy with an unknown cause, typically in the second or third trimester.³ It has shown to increase the risk of developing type 2 diabetes.³ This type

may require more rigorous monitoring to make sure that both the mother and the baby stay healthy.³

Pathophysiology

Insulin is a hormone that helps maintain blood glucose levels and is not regulated properly in patients with diabetes.³ When there is a decreased amount of insulin produced or released blood sugar levels remain high, also known as hyperglycemia.³ For people with diabetes and are not pregnant, hyperglycemia can be defined as fasting blood glucose greater than 130 mg/dl and a blood glucose above 180 mg/dl two hours after meals.⁴ Hyperglycemia can be very dangerous and could lead to a condition called diabetic ketoacidosis (DKA).⁵ DKA is a medical emergency and is where ketones are produced too quickly.⁵

Patients with diabetes may also experience hypoglycemia, also known as a blood glucose level less than 70 mg/dl.⁴ This is also very dangerous and can be caused by many reasons, such as eating habits, medications, or taking too much insulin.

Patients need to identify what factors change their blood sugar the most so that they can avoid or at least be aware of it. Blood sugar monitoring is one of the most important things for patients with diabetes to prioritize.⁴ This is considered a priority because out-of-range levels could eventually lead to other health problems, such as neuropathy and





retinopathy. Short term, it is important for patients to monitor for hypoglycemic and hyperglycemic events.⁴

This is most often done by the use of a blood sugar meter, also known as a glucometer, which is a very common device used in the home and healthcare settings.⁶ Meters require the collection of capillary blood, usually obtained by pricking the end of a finger with a lancet, so that blood can be put on a test strip for the device to read.⁶ Many patients are asked to test their blood sugar several times a day to monitor their blood glucose. Because this type of testing may be uncomfortable and cumbersome, it can lead to poor compliance and blood sugar control.⁶

What are CGMs?

Continuous glucose monitoring (CGM) is a device that allows a patient's blood glucose levels to be read constantly and that information is made easily accessible.⁷ This is accomplished using technology that can be connected to one's mobile device.⁷ The glucose is measured in the interstitial fluid using a sensor that is placed under the skin.⁷ The sensor penetrates the skin using a small needle that inserts a cannula (a small, flexible tube) under the skin and then retracts.⁷ It can be placed on the buttocks, back of the arm, or the abdominal area.⁷ CGMs are used by less than 50% of diabetic patients.¹

There are many different models, but the majority of CGM's work in the

same way. Glucose levels are taken every couple of minutes and that is recorded using a separate monitor, or directly to a mobile device.⁷ The information can be shared with others as well. For young children and other patient populations, this is a great way for their caretakers to be able to monitor their health and be alerted when something is out of balance.

Typically, CGMs have to be replaced about every week.⁷ It is also important that accuracy checks are done to ensure that the sensor is reading correctly by using a standard glucose meter and comparing the results.⁷ The timing of these checks differs for each CGM, but it is important for the patient to perform an accuracy check if they feel the CGM's reading does not match how they are feeling.⁷

The CGMs on the market include the FreeStyle Libre, Dexcom G4, Dexcom G5, Dexcom G6, and the Medtronic model.⁸ All of these have an iOS and android app available. FreeStyle Libre is the only model that does not have automatic glucose data sharing.⁸

1. FreeStyle Libre: approved for use in patients 18 years old or older.⁸ It has a 12-hour warm-up period before it produces accurate readings, but can be used for up to 10 days with no calibration needed.⁸ The reader shows a trend graph for the previous 8 hours, but this CGM does not have an alarm for when the levels get too high or low.⁸





2. Dexcom G4, G5, and G6: approved for use in patients at least 2 years old.⁸ They only need a 2-hour warm-up period to provide accurate readings, but only last 7 days and need to be calibrated every 12 hours.⁸ The G4 was the first Dexcom monitor to be released and can show glucose trends, share data with others through the app, and has alarms for high and low glucose alerts.⁸ The G5 is the most popular due to it being more accessible via the app or the display device.⁸ The G6 is the most recent of the Dexcom monitors to come out and it has some upgrades.⁸ This Dexcom does not require calibration and it lasts for 10 days.⁸ Unless the patient feels that the readings are inaccurate, they do not need to confirm the accuracy using a standard glucose meter.⁸
3. Medtronic: this is the newest of all of the CGMs discussed and is for patients 14-75 years old.⁸ It does not come with a reader device but sends the readings to the app that can be shared with others.⁸ This monitor has to be calibrated every 12 hours.⁸ The main benefit of this meter, over the others, is that it collects data to provide the patient information regarding what is affecting their blood sugar throughout the day. In turn, these

extra benefits make this monitor the most expensive.⁸

In addition to these monitors, there are also combination CGM+insulin pumps that are available for patients who qualify for a pump.⁸ These devices have the ability for the monitor to control the amount of insulin the patient gets based on their readings. The combination pumps available are the MiniMed 630G and 670G by Medtronic and the t:slim X2 by Tandem, which is compatible with the Dexcom G6 monitor.⁸

Benefits of CGMs

CGMs allow patients to track their blood sugar levels more conveniently. Long term, the goal is to regulate the patient's blood sugar enough to lower their hemoglobin A1C levels to goal and decrease the amount of diabetes-related complications.⁹

One of the major advantages of a CGM is visually seeing the trends in glucose levels throughout the day.⁹ Patients can see what times their blood sugar increased or decreased the most, what activities may have caused a drastic change, and many other factors.⁹

CGMs are also beneficial when it comes to drastic blood sugar highs or lows because they can send an alarm to the device that alerts the patient of their blood sugar level.⁹ Instead of a patient relying on seeing or feeling the signs that their blood sugar is going low, the CGM would be able to alert them, so that they could hopefully avoid reaching the point





of emergency.⁹ This can help decrease the number of hospital visits related to blood glucose emergencies by helping people be more aware and not requiring them to rely on how they are feeling and then testing themselves.⁹

Without a CGM, a patient may only see that their level is high or low, but have no knowledge of how fast or slow the level is changing or how long it has been at that level.⁹ With a CGM, it shows how quickly the level is rising or falling, which can help the patient decide the best course to take to manage the level.⁹ It is very important for the overall health of the patient to keep their blood glucose within the desired range throughout the course of the day and CGMs are a valuable tool to manage that.⁹

Drawbacks of CGMs

CGMs are a great resource, but they are not always the most desirable for several reasons. Some obvious reasons involve the fact that the CGM is attached to the patient's skin via a cannula and is worn constantly.⁹ This can create issues with someone who is in water a lot, or is active and sweats a lot. The adhesive that holds the CGM can start to prematurely fall off the skin, or if it gets snagged it could possibly come off completely. This may throw off the normal rotation of when the patient is supposed to change the CGM and will also require the placement of a new device.⁹ Also, if the patient is already using an insulin pump, this is another bulky item that they would

be wearing, which may be uncomfortable or inconvenient.⁹

Cost is one of the main factors that impede CGM usage. Due to CGMs being a newer healthcare advancement, many insurance companies do not cover them for all patients. For many, the out-of-pocket costs would be unattainable without the help of insurance.

Currently, The Centers for Medicare and Medicaid Services have revised criteria for covering CGMs. Based on these criteria, the patient must have diagnosed diabetes mellitus, be treated with insulin multiple times a day or with a continuous infusion, and the treatment regimen requires adjustments.¹⁰ Also, the practitioner must have an in-person visit regarding blood glucose control within 6 months before prescribing the CGM and every 6 months after to assess adherence.¹⁰ When all of the criteria are met and a CGM is covered, all of the supplies, including sensors and transmitters, are also covered.¹⁰

For a patient to get a CGM initially, it must be sent to get prior authorization from the insurance company.¹¹ This is so insurance can determine the necessity for what the prescriber wants to start the patient on, which would be a CGM in this case.¹¹ This will reveal to the prescriber and the patient which specific CGMs will be covered and how much.¹¹ Overall, the cost is a major factor that can affect everyone involved in the CGM enabling process.¹²





The CGM devices that send alerts for high and low blood sugar levels may become overwhelming to the patient and others who get the data. It is great to receive notifications, but the notifications could cause extra stress if they are receiving the notifications frequently. Some of these issues can be overcome with time and experience, especially once the patient finds the CGM that works best for them.¹²

There is currently a shortage of primary care physicians, so physicians may not have the time to review these devices, teach their patients, analyze collected data, and utilize all of the information to discuss results with the patient and what to do moving forward.¹²⁻¹³

Discussion

CGMs can help bridge the gap between patient, physician, and caretaker because the physician can see the readings using a 24/7 visual of the patient's blood sugar levels in comparison to a snapshot provided by a typical blood sugar log provided by the patient. This could ultimately help with improving a treatment regimen for a patient.

Many factors are standing in the way of CGMs being implemented into more patients' treatment regimens. Cost is a major factor and can be the sole reason that some patients may not be able to utilize a CGM. In the end, the main goal is to improve the lives of patients with

diabetes and the people who care about them.

Conclusion

Patients with diabetes are burdened with having to manage their blood glucose levels and the many factors that can affect it. The introduction of CGMs has allowed the opportunity for these patients to take some of that burden off of themselves. Overall, CGMs have proven to be a great resource, but some elements are impeding their use. With this being a newer healthcare device, there is a very positive outlook on the future and the improvements that can be made. With focus on improving access to materials, education, and costs, CGMs can be made more attainable for patients and easier for physicians to prescribe.





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