Continuing Medical Education

Continuous Glucose Monitoring vs. Hemoglobin A1c—Part 1

Here's why both are important in the management of diabetes.

BY JEAN CHEN-VITULLI, DPM, MS AND ANASTASIOS MANESSIS, MD

Objectives

After completing this CME, the reader will understand that:

1) There is a strong correlation between HbA1c and time in range (TIR) based on a 90-day continuous glucose monitor (CGM) data in real life conditions.

2) CGM data might provide valuable and actionable information for long-term disease management of diabetes.

3) Continuous glucose monitor data enables frequent measurement of blood glucose through minimally invasive techniques and wearable devices.

4) Continuous glucose monitoring provides information on the amount of time the blood sugar is above and below range.

5) Glycosylated hemoglobin A1c (HbA1c) is the gold standard for monitoring glycemic control.[32]

6) Diabetes mellitus (DM) is a major health problem affecting millions of people worldwide and is expected to affect 47 million people by 2045.[32]

7) Glycosylated hemoglobin A1c reflects the blood sugar control over the last two to three months. It does not provide day-to-day trends.

8) Many healthcare providers recommend using both HbA1c and CGM data for a comprehensive view of glucose control. They are complementary to each other.

9) HbA1c reflects long-term glucose control, while CGM provides immediate, real-time glucose levels.

10) Continuous glucose monitor can alert the user to high or low glucose levels, helping to prevent emergencies.

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*Following this article, an answer sheet and full set of instructions are provided (pg. 114).—**Editor***

Introduction

According to the Center for Disease Control and Prevention (CDC), 38.4 million people have diabetes (11.6% of the U.S. population). 29.7 million people, including 29.4 million adults are diagnosed with diabetes. 8.7 million people (22.8% of adults with diabetes are undiagnosed. A total of 97.6 million people aged 18 years or older have pre-diabetes (38.0% of the adult U.S. population). 27.2 million people aged 65 years or older (49.8%) have pre-diabetes.[35] Unfortunately, the incidence and prevalence of both types 1 and 2 diabetes mellitus (DM) have increased globally over the past two decades and are expected to keep rising in the future. Diabetes is associated with various chronic complications that result in increased morbidity and mortality.[3]

Persons with diabetes must receive appropriate and timely medi-

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cal management to avoid long-term complications associated with insufficient glycemic control. To evaluate glycemic control, a patient with diabetes must monitor their glycemic status. Analysis of the glucose data provides an assessment of the efficacy of therapy and guides adjustments in lifestyle and medications to achieve the best possible blood glucose control in a safe manner. One technique to assess the effectiveness of glucose control is via patient self-monitoring of blood glucose (SMBG). Another technique is through the measurement of hemoglobin A1c.[3,7]

Currently, HbA1c is recommended as a gold standard in the assessment of diabetes-related outcomes.[3,11,25]

Hemoglobin A1c (HbA1c)

Hemoglobin A1c or HbA1c is a blood test that measures the average level of blood sugar (glucose) over the past two to three months.[25] Glucose in the blood binds to a protein in the red blood cell, called hemoglobin. Red blood cells live an average of three months. The more glucose in the blood, the higher the percentage of hemoglobin that is glycated (bound to glucose). A Hemoglobin A1c (glycated hemoglobin, glycosylated hemoglobin, HbA1c, or A1c) test is used to evaluate a person's level of glucose control and represents a percentage because those red blood cells are present in the bloodstream at the time of the HbA1c test and can be used to diagnose diabetes.[3,33] The greater the amount of glucose that is in the blood, the more hemoglobin protein will become glycated by glucose, reflecting a higher A1c level.[33]

Currently, HbA1c is recommended as a gold standard in the assessment of diabetes-related outcomes.[3,11,25] Historically, the elevated level of HbA1c in diabetic patients was reported first by Rahbar and associates in 1968. Over time, it became an important indicator of blood glucose control and is used widely to judge the adequacy of diabetes treatment.[3] Furthermore, three landmark trials in patients with type 2 DM (ACCORD, ADVANCE, and VADT) showed that lower HbA1c levels are associated with reduced onset or progression of some microvascular complications.[3] On the other hand, elevated HbA1c is an independent risk factor for coronary heart disease and stroke (Figure 1).[3]

Although HbA1c provides an approximate measure of glucose control, it does not address short-term glycemic variability (GV) or hypoglycemic events or hyperglycemic events linked to microvascular and macrovascular complications.[3,4,7,25,33] Hence, HbA1c may not be a good indicator of an individual patient's glycemic control because of the wide range of mean glucose concentrations and glucose profiles that can be associated with a given HbA1c level. It does not provide daily fluctuations or information of glucose levels before and after meals or how medication adjustments are affecting the treatment regimen.[3,4,7,25] It does not address postprandial hyperglycemia, which is associated with microvascular diseases and increased mortality associated with macrovascular diseases.[25]

Interventions that control postprandial glucose have been shown to improve endothelial function and reduce carotid atherosclerosis in patients with type 2 diabetes.[25] A study by Beck, et al.,[35] involving 387 participants in three randomized trials showed that not infrequently HbA1c may underestimate or overestimate mean glucose, sometimes substantially.[7] Beck, et al. recommended that if HbA1c is to be used to assess glycemic control, it is imperative to know the patient's actual mean glucose to understand how well HbA1c is an indicator of the patient's glycemic control.[7]

Estimating glycemic control from HbA1c values is in essence applying a population average to an individual, which can be misleading.[7] Furthermore, HbA1c can become a unreliable measure as it can be influenced by conditions that affect hemoglobin, such as anemia, hemoglobinopathies, liver disease, pregnancy, vitamin B12 deficiency, iron deficiency, erythropoietin administration, kidney disease, and recent blood loss.[3,4,14,25,29] Racial and ethnic differences also exist in measurement of HbA1c as the concentration is higher (by 0.2–0.4%) in U.S. African Americans and Hispanic populations than in Caucasians.[3,4,7,14,27] Inter-individual variation in red blood cell life span has also been postulated to cause mean glucose HbA1c discordance between a group versus an individual.[7] Manov, et al. also found the measured HbA1c was 0.34% (4 mmol/mol) higher than shown by the CGM-derived glucose management indicator (GMI) (Figure 2).[11]

Continuous Glucose Monitor (CGM)

Although glycemic HbA1c is still the gold standard in monitoring glycemic control, new indicators derived from continuous glucose monitoring (CGM) devices, such as time above range (TAR), time in range (TIR),

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FIGURE 1

The relationship between A1C and eAG is described by the formula 28.7 x A1C – 46.7 = eAG

A1C	eAG	
%	mg/dL	mmol/L
6	126	7.0
6.5	140	7.8
7	154	8.6
7.5	169	9.4
8	183	10.1
8.5	197	10.9
9	212	11.8
9.5	226	12.6
10	240	13.4

Figure 1: The relationship between average blood glucose and hemoglobin A1c.[2] Adapted from https://professional.diabetes.org/glucose_calc. To access scan the QR code at right.

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and time below range (TBR) have come into use in clinical practice and have established their position as more detailed short-term glycemic control indicators than HbA1c.[21] The CGM is the sensor measuring the glucose level in the interstitial fluid and converts it into the equivalent venous blood glucose value using the algorithm in the reader. However, different CGM devices use different internal algorithms. Furthermore, even in the same CGM device, the internal algorithm changes depend upon when it was launched.[21] As a result, glucose values from the same continuous glucose monitoring sensor significantly differ among readers with different generations of algorithms.[21]

Currently, there are a variety of continuous glucose monitors (sensors) on the market. Abbott currently has Freestyle Libre 3 and Libre 2. The Pro version is for the professionals to evaluate patients. Dexcom makes G6 and G7 and recently has an FDA over-the-counter CGM sensor called Stelo.[8,9] Senseonics make Eversense and is only approved for those over the age of 18 years old.[8] Medtronics also produces the Guardian sensors.[8] Most sensors are approved for placement on the arm. However, Dexcom can be placed on the upper buttocks as well. Guardian sensors are also approved for placement on the abdomen.[8] Guardian sensors have to be replaced every seven days. Dexcom sensors are good for ten days. Abbott's Freestyle Libre sensors are good for 14 days and the new Libre 3 plus sensors are good for 15 days.[8] Only the Eversense sensors last 365 days and require a physician to insert it under the skin.[8]

Continuous glucose monitoring (CGM) is a tool which helps clinicians and people with diabetes to overcome the limitations of HbA1c in diabetes management.[3]

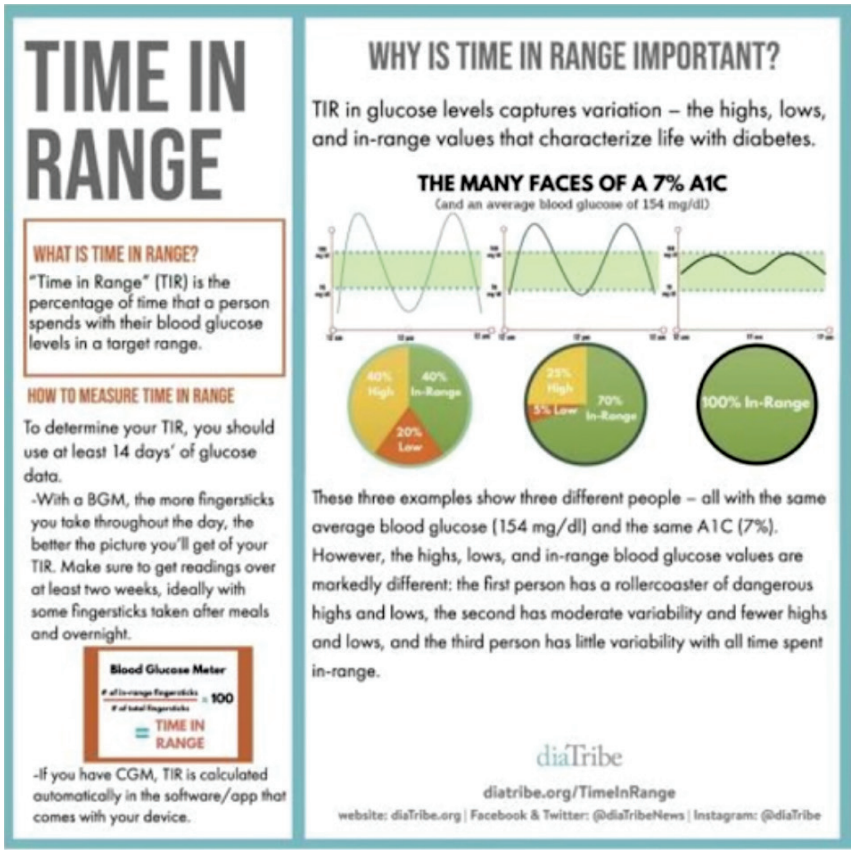

Figure 2: Time in Range concept when using a continuous glucose monitor. The goal is to aim blood glucose control between 70 mg/dl to 180 mg/dl at least 70% of the time. Adapted from Diatribe, Reference 35: https://diatribe.org/diabetes-management/time-range. To access scan the QR code at right.

Continuous glucose monitoring (CGM) is a tool which helps clinicians and people with diabetes to overcome the limitations of HbA1c in diabetes management.[3] CGM can predict HbA1c values within one month after measuring CGM in patients with DM.[5] A continuous glucose monitor is a device that estimates glucose levels every few minutes throughout the day and night and keeps track of it.[34] One can see what one's blood glucose level is at any time. This helps patients, doctors, providers, and diabetic educators spot trends such as how food, medication, and physical activity affect the blood level to help make informed decisions.[34] A major advantage of CGM technology is that the overall daily profile of blood glucose can be captured, particularly the postprandial and nocturnal blood glucose levels. Many studies have demonstrated considerable benefits of CGM in patients with insulin-dependent diabetes and those at high hypoglycemia risk.[4] However, there is inconclusive evidence to suggest that all diabetics need a CGM for glucose management.[39]

Based on the trend, medications can be adjusted to lower hyperglycemia or prevent hypoglycemia to keep glucose levels in target range to prevent complications. Time spent in the glycemic target range and time spent in hypoglycemia are the main CGM metrics that provide a more personalized approach to diabetes management.[3] The CGM also calculates the glucose management indicator (GMI), which calculates an approximate HbA1c level based on the average CGM-driven glucose level.[3] Unlike with HbA1c, CGM data also provides short-term glucose variabil-

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ity (GV), which is a measure of swings in blood glucose levels over hours or days and may contribute to diabetes-related complications.[3] The data obtained from the CGM is used for the optimization of glycemia. The degree of GV is associated with the frequency, duration, and severity of the hypoglycemic events. Many factors affect GV in a patient, including lifestyle, diet, the presence of comorbidities, and diabetes therapy.[3]

A CGM has three parts. Most sensors have a tiny sensor that can be inserted under the skin, often on your belly or arm, with an adhesive patch that helps it stay there. Depending on the manufacturer, these sensors are changed every ten to fifteen days.[3,34] These are called disposable sensors. Another type of CGM sensor, called Eversense, is an implantable sensor placed inside the patient's body by the endocrinologist.[34] It is replaced every twelve months. CGM sensors estimate the glucose level in the interstitial fluid between the cells and do not measure blood sugar concentrations.[3,34] CGM data for a period of 10–15 days provides a good estimate of CGM metrics for a 3-month period. HbA1c can be estimated (eA1c) if 70% of the CGM data are available.[3] However, CGM data do not always match finger stick blood glucose readings, as interstitial glucose readings have a time lag of approximately 15 minutes as compared to blood glucose readings.[3]

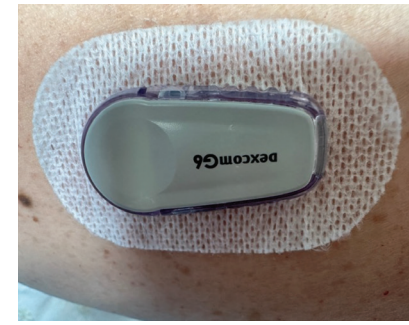

Figure 3a: A Dexcom G6 sensor is inserted into the skin testing the interstitial blood glucose on the patient's arm. A transmitter sending signals to a receiver or a cell phone to track the blood sugar trend. In addition, the transmitter can send signals to an insulin pump using a closed loop system to act like an artificial pancreas.

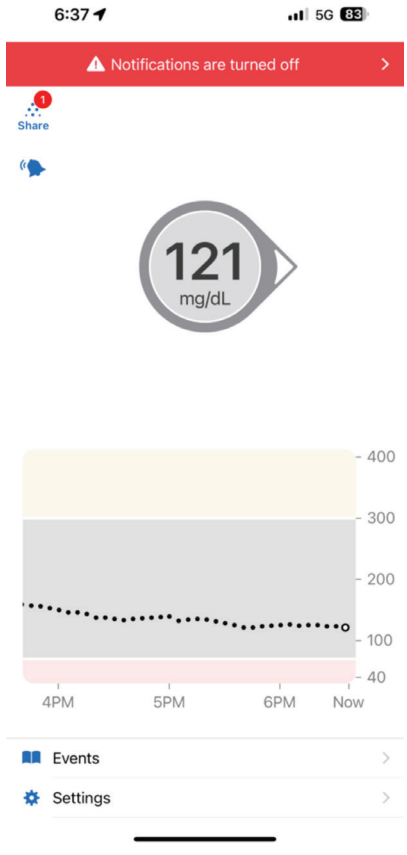

Figure 3b: The transmitter is sending the blood sugar information to the Dexcom G6 app on the patient's mobile phone.

Figure 3c: The Dexcom G6 transmitter is also sending blood sugar information to the patient's Tandem T-Slim insulin pump to maximize blood sugar control.

The second part of the CGM is a transmitter that sends the information on the blood glucose level, without using wires, to the third part, a software program that is stored on a smartphone, a reader device called a receiver, or to an insulin pump.[34] The real-time data gathered by the software program can be connected to an endocrinologist's office, and the blood sugar can be monitored remotely by the endocrinologist and his care team to adjust medications to keep the patient safe.(Figures 3 a-d)[37]

In the Gold randomized trial, among patients with inadequately controlled type 1 diabetes treated with multiple daily insulin injections, the use of continuous glucose monitoring compared with conventional treatment for 26 weeks resulted in lower HbA1c.[22] Compared with a glucometer, using a CGM can help patients manage blood glucose levels more effectively by providing a feedback on how activities such as exercise, stress, and food affect the blood sugar.[3,34] The use of a CGM becomes an invaluable tool as the patient learns how one's body tolerates certain food and learns to eat in moderation. If a peach causes one to have a blood sugar spike at two hours post-prandial (above 180 mg/dl per ADA guideline), next time, the patient knows to eat a smaller peach or share half of the peach with someone else. Most patients also prefer fewer finger sticks. Patients and providers can also set a reasonable target to achieve in their glycemic control.[37]

A CGM has three parts. Most sensors have a tiny sensor that can be inserted under the skin, often on your belly or arm, with an adhesive patch that helps it stay there.

The CGM will create an alert and might display a graphic that shows whether your glucose level is rising or dropping, and how quickly. It helps prevent hypoglycemic emergencies when an alarm goes off as blood sugar is dipping and rapidly approaching 70 mg/dl.[34] CGM can also be of particular

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benefit to older adults, who may be more susceptible to episodes of hypoglycemia and hypoglycemia unawareness.[14] While there can be challenges in technology use in this population related to cognitive or physical (visual, hearing, dexterity) impairments, it gives a caregiver access to glucose data through the CGM system share feature and reduction in glucose variability, hyperglycemia, hypoglycemia, and need for finger stick measurements.[14]

Riddlesworth, et al. and the "Beyond A1c Writing Group" declared that HbA1c does not accurately reflect the glucose pattern at the individual level. The Steering Committee of decision-making for the "Type 1 Diabetes Outcomes Program" recommended the use of defined clinically meaningful outcomes beyond HbA1c in research, development, and evaluation of therapies for type 1 DM.[3] The most basic definitions are summarized in Figure 4.

In addition, CGM data provide additional details on the patterns of glycemic excursions, as well as potentially dangerous high or low glucose concentrations that are often missed with SMBG.[3]

CGM provides continuous monitoring, with readings available every few minutes, providing valuable information unattainable by SMBG, including

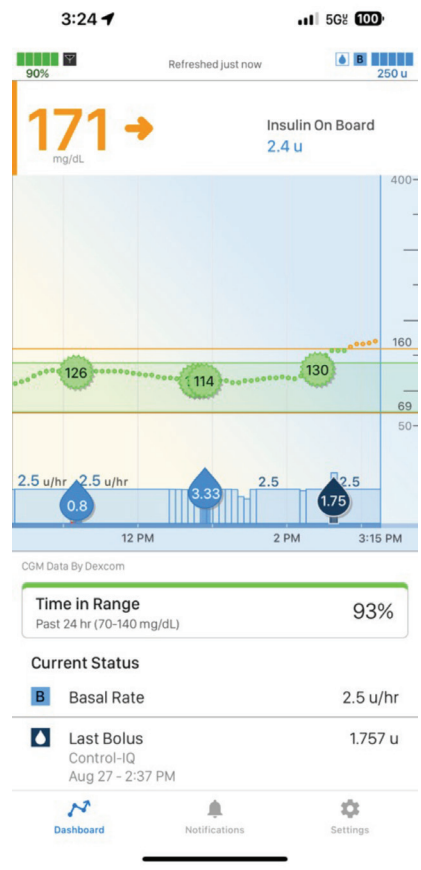

Figure 3d: The Dexcom G6 transmitter is sending information to the patient's Tandem T-Slim insulin pump app. As blood sugar decreases, the insulin pump automatically decreases the rate of basal insulin. As blood sugar rises, the insulin pump automatically increases the rate of basal insulin.

The CGM will create an alert and might display a graphic that shows whether your glucose level is rising or dropping, and how quickly.

New definitions of hypoglycemia, hyperglycemia, and time in glycemic range

Outcome	Definition
Hypoglycemia	Level 1: glucose < 70 mg/dL (3.9 mmol/L) and glucose ≥ 54 mg/dl (3.0 mmol/L)
	Level 2: glucose < 54 mg/dL (3.0 mmol/L)
	Level 3: a severe event characterized by altered mental and/or physical status requiring assistance
Hyperglycemia	Level 1 (elevated glucose): glucose > 180 mg/dL (10 mmol/L) and glucose ≤ 250 mg/dlL(13.9 mmol/L)
	Level 2 (very elevated glucose): glucose > 250 mg/dL (13.9 mmol/L)
Time in range	Percentage of readings in the range of 70–180 mg/dL (3.9–10.0 mmol/L) per unit of time

Figure 4: Definition of hypoglycemia, hyperglycemia and time in range in CGM readings.[3]

detection of glycemic variability (GV) and the rate of change over time, as well as time spent in hypoglycemia and hyperglycemia. CGM can be considered for patients with severe or nocturnal hypoglycemia, especially those with hypoglycemia unawareness or when HbA1c does not match the finger stick values.[3] Hence, SMBG has been shown to be less helpful for reaching glycemic goals unless the data are being used to make lifestyle changes or manage medications through active, shared decision-making between patients and healthcare providers.[12] Furthermore, another limitation to using SMBG is that it only provides a static point-in-time glucose value. To achieve glycemic control and medication adjustments, and lifestyle and activity changes, it requires frequent painful finger sticks, and insurance coverage for test strips is limited for most people who do not take insulin.[12] Also, the GOLD and DIAMOND trials showed that among patients with type 1 DM treated with multiple daily insulin injections, the use of CGM resulted in better glycemic control than did conventional treatment.[3] Several studies have also shown that the use of CGM can improve the mean amplitude of glycemic excursion (MAGE) and result in better glycemic control in persons with type 2 DM.[3] Hence, the use of CGM monitoring in both patients with type 1 diabetes and type 2 diabetes could reduce HbA1c levels and time spent with hypoglycemia.[3,26] Finally, CGM data can be used as a valuable tool for patient education.[3,12]

Comparison

There is also a difference in real-time CGM (rtCGM) and intermittent scanning CGM (isCGM). rtCGM systems such as the Guardian Connect Mobile (Medtronic, Inc., Northridge, CA) and Dexcom systems (Dexcom Inc, San Diego, CA) automatically transmit a continuous stream of real-time numerical and graphical information about the current glucose level and direction/velocity of change to the user's receiver or smartphone. These systems also feature active alerts/alarms that warn users of immediate and/or impending hypoglycemia or hyperglycemia. The FreeStyle Libre Flash

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Glucose Monitoring 14 day and FreeStyle Libre 2 systems (Abbott Diabetes Care, Alameda, CA) are isCGM systems. These systems provide the same glycemic information as rtCGM devices but require users to consciously scan the sensor to obtain glucose data. Only the FreeStyle Libre 2 and Libre 3 systems provide optional alarms/alerts.[10]

Both rtCGM and isCGM help patients improve glycemic control by decreasing time spent in hyperglycemia and hypoglycemia range.[10] The Hoskova, et al. study showed that in 60 participants with type 1 diabetes mellitus, for patients with the rtCGM, the percentage of time spent in hypoglycemia was less than those using the isCGM system. Hypoglycemia is less in those using rtCGM and during exercise compared to those who used isCGM.[10] Fear of hypoglycemia has also been an issue in having patients exercise. Hypoglycemia is a common and significant acute complication of type 1 diabetes and those on insulin therapy, and remains the primary obstacle to achieving glycemic control. The risk of severe hypoglycemia is increased during and up to 24 hours after extended periods of physical activity due to increased glucose uptake and insulin sensitivity.[10]

Recent advances in continuous glucose monitoring (CGM) technologies have prompted their increased adoption by individuals with insulin-treated diabetes and non-insulin dependent diabetics on multiple glucose management therapeutics to minimize or avoid severe hypoglycemia as they achieve desired glycemic control.[10,12]

Summary

Monitoring hemoglobin A1c (HbA1c) has long been considered the gold standard in diabetes mellitus (DM) management, and as an indicator of average glycemia. High HbA1c also serves as a predictor of long-term complications among people with DM. However, HbA1c is subject to non-glycemic influences such as anemia and liver disease. It is only a measure of average glycemia, which does not provide information regarding glucose trends or information about the occurrence of hypoglycemia and/or hyperglycemia episodes. Hence, use of HbA1c alone without accompanying glucose data does not convey actionable information that can be harnessed to guide targeted therapy in many patients with DM.

While conventional capillary blood glucose monitoring via fingerstick only shows blood glucose one moment in time, the data inherent in them precludes elucidation of glycemic trends or reliable detection of hypoglycemia or hyperglycemia episodes. In contrast, continuous glucose monitoring (CGM) data reveals glucose trends and potentially undetected hypo- and hyperglycemia patterns that can occur between discrete BGM measurements. The use of CGM has grown significantly over the past decades as an ever-expanding body of literature, demonstrating a multitude of clinical benefits for people with DM with improvement in glycemic control. Here, we will explore the benefits and limitations of CGM use, the use of CGM in clinical practice, and the application of CGM to advanced diabetes technologies. **PM**

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Dr. Jean Chen-Vitulli is a podiatrist who obtained her Master's Degree from Roswell Park Cancer Institute. specializeing in wound care and limb salvage. She trained under Anastasios Manessis, MD to become a certified diabetic educator and is now involved in interdisciplinary research. She also enjoys mentoring NYCPM students and is also actively involved with the American Podiatric Medical Association.

Dr. Manessis, is a double-board certified physician at Endocrine Associates of West Village PC in Murray Hill, Manhattan, and Long Island City, NY, specializing in endocrinology, diabetes, and metabolism and obesity medicine. He has an endocrine certification in neck ultrasounds and has extensive experience in diagnosing, treating, and managing endocrine disorders, including diabetes, thyroid disorders, hormonal dysfunction, and obesity. Dr. Manessis earned his medical degree from the State University of New York at Buffalo and completed a combined residency in internal medicine and pediatrics at New York Medical College at Saint Vincent's Hospital in New York. Following a year as chief medical resident, he completed a two-year clinical fellowship in endocrinology, diabetes, and metabolism, where his research interest, among others, involved the use of insulin pumps in patients with Type II diabetes.

CME **EXAMINATION**

SEE ANSWER SHEET ON PAGE 115.

1) Which of the following is the gold standard for monitoring glycemic control?

- **A) Glycosylated Hemoglobin A1c (HbA1c)**
- **B) Time in Range**
- **C) Estimated Hemoglobin A1c**
- **D) Glycemic variance**

2) Which of the following is a benefit of using a continuous glucose monitor?

- **A) Alert for hypoglycemia**
- **B) Alert for hyperglycemia**
- **C) Improved glycemic control**
- **D) All the above**

3) High glycosylated hemoglobin A1c (HbA1c) is associated with:

- **A) Increased risk of macrovascular disease**
- **B) Increased risk of microvascular disease**
- **C) No risks**
- **D) A & B**

4) Which of the following is NOT true?

- **A) Certain medications can affect CGM readings**
- **B) CGM readings tests the blood sugar in the interstitial fluid.**
- **C) CGM has no place in management of a diabetic patient.**
- **D) CGM readings is not complementary to HbA1c in management of a diabetic patient.**

5) Which of the following IS true?

- **A) CGM data provides actionable data for glucose management.**
- **B) CGM data does not give information on a patient's blood glucose profile trend.**
- **C) HbA1c data is more important in management of blood sugar in a patient with diabetes.**
- **D) CGM data allows a patient to learn to cheat on food consumption.**

6) CGM helps a patient improve glycemic control by:

- **A) Decreasing time spent in hyperglycemia**
- **B) Decreasing time spent in hypoglycemia**
- **C) A & B**
- **D) None of the above**

Continued on page 114

Continuing Medical Education

CME EXAMINATION

(Continued from page 113)

7) CGM trend is helpful in behavioral modification because:

A) Patients can see the effect of food on blood sugar
B) Patients can see how exercise activity decreases blood sugar
C) It is not helpful but a waste of healthcare dollars
D) A & B

8) CGM data is helpful in counseling patients because:

A) Patients can be counseled to eat smaller amounts of food that drives blood sugar up
B) It is not helpful in adjusting insulin dose
C) Provide positive reinforcement for behavioral change
D) A & C

9) Fear of hypoglycemia is a barrier to glycemic control

A) Patients are not afraid of low blood sugar because they want lower HbA1c
B) Insulin use and exercise
C) Use of CGM does not alleviate fear of hypoglycemia
D) None of the above

10) Advantages of using CGM data include:

A) B & C
B) Patient scan be remotely monitored to adjust medications
C) Minimize hyperglycemia and hypoglycemia
D) Data is too difficult to interpret

SEE ANSWER SHEET ON PAGE 115.

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ENROLLMENT FORM & ANSWER SHEET *(continued)*

EXAM #3/25
Continuous Glucose Monitoring vs. Hemoglobin A1c—Part 1
(Chen-Vitulli and Manessis)

Circle:

1.	**A**	**B**	**C**	**D**	**6.**	**A**	**B**	**C**	**D**
2.	**A**	**B**	**C**	**D**	**7.**	**A**	**B**	**C**	**D**
3.	**A**	**B**	**C**	**D**	**8.**	**A**	**B**	**C**	**D**
4.	**A**	**B**	**C**	**D**	**9.**	**A**	**B**	**C**	**D**
5.	**A**	**B**	**C**	**D**	**10.**	**A**	**B**	**C**	**D**

Medical Education Lesson Evaluation

Strongly agree [5]	Agree [4]	Neutral [3]	Disagree [2]	Strongly disagree [1]

1) This CME lesson was helpful to my practice ____

2) The educational objectives were accomplished ____

3) I will apply the knowledge I learned from this lesson ____

4) I will makes changes in my practice behavior based on this lesson ____

5) This lesson presented quality information with adequate current references ____

6) What overall grade would you assign this lesson?

A B C D

7) This activity was balanced and free of commercial bias.

Yes _____ No _____

8) What overall grade would you assign to the overall management of this activity?

A B C D

How long did it take you to complete this lesson?

_____hour _____minutes

What topics would you like to see in future CME lessons ? Please list :

_____

_____

_____

_____

_____