Continuing Medical Education

Continuous Glucose Monitoring vs. Hemoglobin A1c—Part 2

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 range and below range for blood sugar.

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. 112).—**Editor***

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

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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.

Key Points

Time Frame: HbA1c reflects long-term glucose control, while CGM provides immediate, real-time glucose levels.

Data Provided: HbA1c gives an average glucose level, whereas CGM provides detailed information on glucose trends throughout the day.

Actionability: CGM data can be used to make immediate changes in diabetes management, while HbA1c is more of a retrospective assessment.

Just like with HbA1c, CGM has a number of limitations. Insurance usually does not cover CGM monitoring for all patients. Time-consuming prior authorizations, required documentation, the fact that the patient has to be seen every six months, use of insulin, and documented hypoglycemia of 53 mg/dl or lower blood sugar may be required before it is covered. Periodic replacement of sensors is also needed and can be cost-prohibitive for those who do not qualify for insurance coverage. However, recent advancements in technology such as a new generation of insulin pumps with automated suspension of insulin infusion in response to observed or predicted hypoglycemia as well as the development of closed-loop insulin delivery systems are expected to dramatically increase the clinical utility and impact of CGM.[3] Furthermore, CGM devices measure glucose concentration in the interstitial fluid; there is an inherent lag time of several minutes in comparison to blood glucose.[14]

CGM data provides actionable data for glucose management.

This physiologic difference can lead to a delay in the detection of hypoglycemia. Therefore, patients should perform capillary BGM (finger stick) when symptoms of hypoglycemia occur, such as anxiety, shakiness, weakness, cold sweats.[14] Error also tends to be more common following the initiation of a new sensor, as each sensor requires a 'warm-up' period with sensor accuracy shown to improve after the first day of use.[14] Certain substances can interfere with the accuracy of sensor readings, such as ascorbic acid, Tylenol, and hydroxyurea.[10,14] Another source of error is the so-called 'compression artifact,' in which erroneous low CGM readings are recorded when the wearer is in a position in which the CGM and nearby local tissue get compressed, often during sleep.[14]

Device compression can result in a falsely low reading, and when the device is linked to an alarm for severe hypoglycemia, the sleeping person may awaken when the individual is not experiencing true hypoglycemia. With frequent alarms, some individuals may inactivate critical safety alarms that notify the individual about dangerous hypo- or hyperglycemia events, a protective benefit of these devices.[14,19,38] Some individuals may discontinue use of CGM as the data generated may be overwhelming to some individuals.[14,38] Others, given frequent CGM high glucose numbers, may stack their insulin doses in an attempt to bring down hyperglycemia, which can then lead to hypoglycemia.[14] Some adhesives may cause skin irritation in certain individuals.[14] Others may refuse to use CGM due to psychological stigma associated with a medical device attached to one's body.[14]

CGM use over time has helped patients improve their glycemic control.

Time Monitoring

CGM facilitates monitoring of time spent in the target blood glucose range between 70 mg/dl to 180 mg/dl, referred to as the "time in range (TIR)." Alarms are set up on patient's smart phones or sensor reader and it can warn users if the blood glucose level is trending toward hypoglycemia or hyperglycemia.[3] It provides feedback to patients and the trends can be viewed retrospectively. In addition, retrospective analysis of CGM data quantifies patterns of hypoglycemia and hyperglycemia and GV. In short, CGM helps individuals with diabetes and clinicians to personalize strategies to improve increased time in range to 70% or above and reduce incidence of severe hypoglycemia.

TIR is becoming the new standard for management of diabetes.[1,3] In the Corrida Clinical trial, the efficacy of real-time continuous glucose monitoring (rtCGM) and intermittently scanned continuous glucose monitoring (isCGM) in glycemic management was compared. Among 191 adults with type 1 diabetes, HbA1c was significantly lower with rtCGM than with isCGM (7.1% vs 7.7%) after 12 months. Hypoglycemia also decreased and time in range also increased in those on rtCGM.[6]

The glucose management indicator (GMI) is derived from an equation converting CGM-derived mean glucose.[3]

$$GMI(\%) = 3.31 + 0.02392 \times \text{meanglucoseinmg/dL}.$$

Complimentary Measurement Methods

CGM data and HbA1c are complementary to each other. Many healthcare providers recommend using both HbA1c and CGM data for a comprehensive view of glucose control. In 528 individuals with diabetes, Bergenstal, et al. showed that 19% of the measurement of the difference between the GMI calculated from CGM-derived mean glucose and laboratory-measured HbA1c in 528 individuals with diabetes who had both

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values measured concurrently was identical. However, in 28% of the measurements, the difference between the two values is > 0.5%. Therefore, the introduction of GMI could be an important step for a more personalized diabetes management program. If a person has a GMI that is always considerably lower than a measured HbA1c, the healthcare professional must avoid setting the therapeutic HbA1c goal too low to avoid the risk of hypoglycemia[1,3] especially in elderly people with dementia or young children who are unable to verbalize symptoms of hypoglycemia.[1] In contrast, if the GMI is higher, targeting HbA1c lower to minimize excessive hyperglycemia is recommended.[3]

Furthermore, literature suggests the difference in laboratory-measured HbA1c and GMI remains relatively stable for each individual over time.[3,7] In a Japanese study, Babaya, et al. looking at 19 people with type 1 diabetes, found a HbA1c of approximately 7% corresponded to a TIR of 74% and a time above range (TAR) of 20%. The shorter the CGM period, the weaker was the relationship between HbA1c and CGM-related metrics. TIR, TAR, and average glucose levels accurately reflected HbA1c values in patients with type 1 diabetes with stable glycemic control.[4] Ideally, CGM data should be obtained for at least a minimum of 14 days immediately preceding the measurement of HbA1c during a period when diabetes treatment and glycemic control are reasonably stable.[7]

Discordance Factors

Glucose CV and time below range (TBR) complemented the limitation of HbA1c to detect glucose variability and hypoglycemia. Stable glycemic control with minimal hypoglycemia depended on residual β-cell function.[4,7] Manov, et al.'s article also showed a clinically significant discordance of ≥0.5% (6 mmol/mol) between HbA1c and GMI in 36-43% of the 144 patients participating in the hyperglycemic profiles in an obstructive sleep apnea (HYPNOS) trial.[11]

Factors that may cause a discordance between HbA1c and GMI include RBC turnover, such as hemolytic anemia, iron deficiency anemia, polycythemia, and B12 deficiency anemia, as well as pregnancy or glycation kinetics due to genetics, the presence of advanced chronic kidney disease, metabolic dysfunction-associated steatohepatitis (MASH), and cirrhosis of the liver, and race, among others.[11] On the other hand, Al Hayak, et al. showed that GMI derived by isCGM is 95% in agreement to lab-derived HbA1c value.[20]

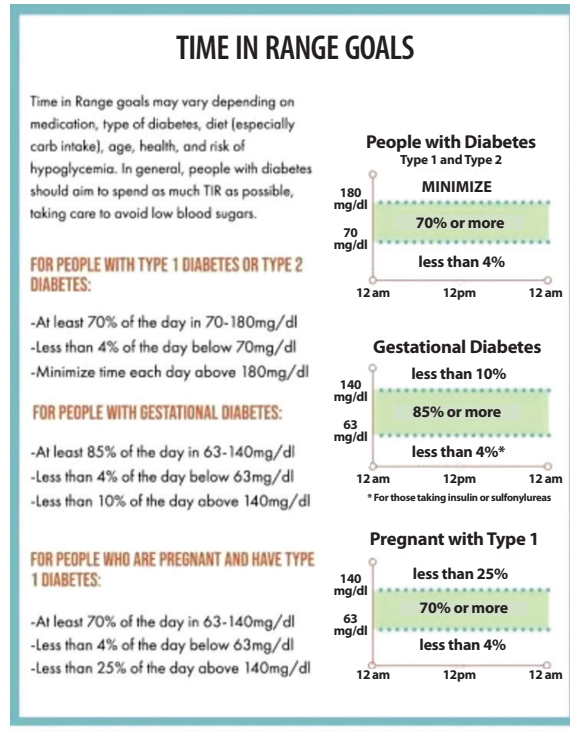

Figure 1: Adapted from DiaTribe. Goals for Time in Range varies between someone who is pregnant to elderly individuals.[36] https://diatribe.org/diabetes-management/time-range

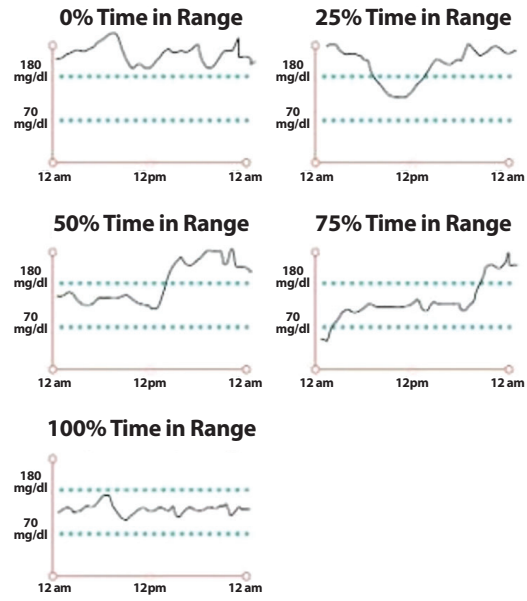

Figure 2: Explanation of Time in Range: Adapted from DiaTribe.[36] https://diatribe.org/diabetes-management/time-range

Long and Short-Term GV

GV is the degree by which a patient's blood glucose level fluctuates between high and low levels. Lifestyle, diet, comorbidities, diabetes treatment, and insulin injection technique can affect GV.[3] For instance, someone accidentally injecting insulin into muscles may be at higher risk of hypoglycemia. Also, a larger magnitude of GV is associated with higher incidence of hypoglycemia.[3] The percentage coefficient of variation (% CV) is defined as:

% CV = [(standard deviation of glucose)/(mean glucose)] × 100.

Monnier, et al. showed that a CV of 36% or greater is associated with increased risk of hypoglycemia in insulin treated patients.[3]

GV can be categorized from short-term to intermediate to long-term. A GV of 24-72 hours duration is referred to as short-term GV. Intermediate-term GV is defined as GV of three days to one month duration. Long-term GV refers to GV of one month to years. Research has shown that long-term GV and longitudinal variations in HbA1c are related to microvascular and macrovascular complications.[3] Currently, the association of varying duration and magnitude of GV with diabetes-related complications is unclear and further research is needed (Figures 1,2).[3]

Large fluctuations in blood glucose are considered an important treatment target as they can be dangerous. Newer agents to lower glucose, such as incretin hormones or sodium glucose cotransporter 2 (SGLT-2), rapid-acting prandial insulins, and stable long-acting insulins with

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CGM use in patients with type 1 and type 2 diabetes, are used to achieve treatment target.[3] For instance, in the DEVOTE trial, insulin degludec ultra-long-acting basal insulin had lower risk of severe hypoglycemia, in day-to-day variation in glucose level when compared to insulin glargine.[3] Furthermore, there is lower incidence of nocturnal hypoglycemic events in patients with high GV when patients were treated with insulin degludec compared to insulin glargine.[3] Likewise, in the VARIATION study, patients with type 2 DM using a combination of basal insulin with a glucagon-like peptide-1 receptor agonist (GLP-1RA) have the lowest GV and lowest hypoglycemia.[3] Another study showed treatment with exenatide led to improvement in glycemic excursions in patients with type 2 diabetes.[3]

Average glucose, GMI, time spent in hyperglycemia, TIR, time spent in hypoglycemia, and GV provide patient and healthcare providers with information beyond the HbA1c value. Data can be obtained to address safety concerns in the diabetes management plan.[3]

As one can see, compared to self-monitoring of blood glucose and HbA1c, CGM profiles provide far more information than just the mean glucose concentration by identifying patterns of hyperglycemia and hypoglycemia as well as potentially dangerous high or low glucose concentrations. The results of secondary analyses of two major studies (the Examination of Cardiovascular Outcomes with Alogliptin versus Standard of Care [EXAMINE] trial and the Atherosclerosis Risk in Communities [ARIC] Study) found an association between hypoglycemia and cardiovascular events. Both studies emphasize the importance of understanding a patient's glucose profile with CGM to potentially identify patients who may be at high risk for cardiovascular events. Thus, CGM, by providing more clinical insights than HbA1c or self-monitoring of blood glucose measurements, and the information of patient profile can help optimize and personalize glucose control and diabetes management.[7]

Yoshii, et al.'s study also showed that higher Hba1c levels do not always protect against hypoglycemic episodes. Their data demonstrate that the use of CGM metrics to complement HbA1c is beneficial, particularly in those on insulin, sulfonylureas, the elderly, and those with chronic kidney disease.[16] In addition, according to Huang, et al., CGM can predict HbA1c values within one month after CGM in patients with DM.[18]

Conclusions

In summary, hemoglobin A1c is the current gold standard for assessing glycemic control. It only provides, however, an average measure of glycemic status over a two-to-three-month period. HbA1c and CGM serve different but complementary roles in the management of diabetes. HbA1c provides a long-term overview, while CGM offers detailed, real-time insights, allowing for better day-to-day control of blood sugar levels. Combining both gives a more complete picture of an individual's glucose control and can lead to more tailored and effective diabetes management strategies to achieve efficacy and safety for patients. Research also showed a strong linear correlation between HbA1c and TIR based on 90-day CGM data in real-life conditions.[13] CGM system-based blood glucose monitoring is more effective for glycemic control in patients with type 1 and 2 DM than self-monitoring of blood glucose.[18]

Furthermore, GV is potentially associated with severity of hypoglycemic events and may be linked to development of diabetes-related complications that may impact a patient's quality of life. Newer medications such as the SGLT-2, GLP-1RA, and newer insulins can reduce the magnitude of GV and reduce the risk of hypoglycemia. **PM**

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CME **EXAMINATION**

SEE ANSWER SHEET ON PAGE 113.

1) 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.**

2) Which of the following is an advantage for a patient in using a CGM?
- **A) Alleviates fear of hypoglycemia**
- **B) Sees the effect of certain food on blood glucose and helps patient learn portion size**
- **C) Sees the effect of exercise on blood sugar.**
- **D) All of the above**

3) Glycosylated HbA1c can be affected by:
- **A) Ethnicity**
- **B) Anemias**
- **C) Kidney disease**
- **D) All of the above**

4) CGM is beneficial in managing blood sugar because
- **A) Patients can avoid multiple painful finger sticks per day.**
- **B) CGM readings may alert a patient of potential hypoglycemia in real time.**
- **C) CGM gives a patient the convenience of knowing their blood sugar without a fingerstick.**
- **D) All of the above.**

5) Which of the following is true?
- **A) Insurance covers CGM for everyone.**
- **B) CGM use over time has helped patients improve their glycemic control.**
- **C) CGM is inexpensive and everyone can afford it even if there is no insurance coverage.**
- **D) Estimated HbA1c from CGM data should replace HbA1c in management of blood glucose in patients living with diabetes.**

6) Which of the following is part of a CGM?
- **A) Sensor**
- **B) Transmitter**
- **C) Receiver**
- **D) All of the above.**

7) Medicare patients who are not on insulin may qualify to receive a CGM if:
- **A) Every Medicare patient can get a CGM.**
- **B) There is a documented low blood sugar of < 53 mg/dl in the past year.**
- **C) Medicare does not cover CGM due to high cost.**
- **D) Medicare covers CGM only if a patient is afraid of poking their finger for a drop of blood to check blood glucose level.**

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8) Which groups of people may an endocrinologist target for higher HbA1c per American Diabetes Association Guidelines?

A) Everyone should be targeted for HbA1c at 6.5 or less to avoid microvascular and macrovascular complications.
B) Elderly patients with dementia should be targeted for higher HbA1c for safety reason.
C) Young children who may not be able to verbalize signs and symptoms of hypoglycemia should be targeted at higher HbA1c for safety reasons.
D) B & C

9) When counseling patients with type 1 diabetes or type 2 diabetes) non-pregnant and non-gestational):

A) The blood sugar should be between 70–180 mg/dl at least 70% of the day.
B) You need to make sure blood sugar below 70 mg/dl or under occurs less than 4% of the day.
C) You need to minimize the amount of time each day where the blood sugar is above 180 mg/dl
D) All of the above

10) Blood sugar target

A) Is the same for everyone at 70-180 mg/dl regardless of their medical co-morbidities
B) Due to the risk for developing fetal abnormalities, blood sugar in pregnant individuals is targeted at least 70% of the time between 63-140 mg/dl.
C) People with gestational diabetes should not fear weight gain and lack of exercise because they have lower risks of developing type 2 diabetes.
D) Blood sugar target goals are not useful, especially because blood sugar level can be influenced by food, stress, and pain.

SEE ANSWER SHEET ON PAGE 113.

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If you are *not* enrolled in the 10-exam CME program, the fee is $35 per exam.

Phone-In Grading

You may also complete your exam by using the toll-free service. Call 516-521-4474 from 10 a.m. to 5 p.m. EST, Monday through Friday. Your CME certificate will be dated the same day you call and mailed within 48 hours. There is a $2.95 charge for this service if you are currently enrolled in the 10-exam CME program, and this fee can be charged to your Visa, Mastercard, American Express, or Discover. If you are not currently enrolled, the fee is $35 per exam. When you call, please have ready:

1. Program number (Month and Year)
2. The answers to the test
3. Credit card information

In the event you require additional CME information, please contact PMS, Inc., at **516-521-4474**.

ENROLLMENT FORM & ANSWER SHEET

Please print clearly...Certificate will be issued from information below.

Name _____ Email Address_____
Please Print: FIRST MI LAST

Address_____

City_____ State_____ Zip_____

Charge to: _____Visa _____ MasterCard _____ American Express

Card #_____Exp. Date_____ Zip for credit card_____

Note: Credit card is the only method of payment. Checks are no longer accepted.

Signature_____ Email Address_____ Daytime Phone_____

State License(s)_____ Is this a new address? Yes_____ No_____

Check one: _____ I am currently enrolled. (If faxing or phoning in your answer form please note that $2.95 will be charged to your credit card.)

_____ I am not enrolled. Enclosed is my credit card information. Please charge my credit card $35.00 for each exam submitted. (plus $2.95 for each exam if submitting by fax or phone).

_____ I am not enrolled and I wish to enroll for 10 courses at $299.00 (thus saving me $51 over the cost of 10 individual exam fees). I understand there will be an additional fee of $2.95 for any exam I wish to submit via fax or phone.

Over, please

ENROLLMENT FORM & ANSWER SHEET *(continued)*

EXAM #4/25
Continuous Glucose Monitoring vs. Hemoglobin A1c—Part 2
(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 :

_____

_____

_____

_____

_____