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Glucose management indicator – potential factors affecting differences in comparison with HbA1c and clinical significance of this phenomenon

Wskaźnik kontroli glikemii – potencjalne czynniki wpływające na różnice w porównaniu z HbA1c i kliniczne znaczenie tego zjawiska

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Abstract
HbA1c and the glucose management indicator (GMI) are now widely recognized as the gold standard for assessing the effectiveness of diabetes therapy. The GMI is a result of a mathematical formula used to estimate HbA1c with continuous glucose monitoring (CGM) data in patients with diabetes. It is a useful parameter providing a good estimate of CGM metrics for a 3-month period with just 10–14 days of data. It can reflect the effectiveness of administered/modified therapy of insulin faster than traditional measurements of laboratory HbA1c and can be used as an educational tool and in telemedicine. Unfortunately, there are significant discordances between GMI and laboratory-measured HbA1c, reaching as much as 0.5–1% in many patients. It may be caused by well-known factors influencing HbA1c measurement and red blood cell turnover like anaemia, haemoglobinopathies, or certain medications, but these causes of potential errors are too rare in everyday practice to account for the amount of discrepancy reported in the literature. In this article we would like to review other new potential factors that may influence HbA1c estimation based on GMI and cause potential differences between results calculated from CGM and those measured in the laboratory. In addition, we will present clinical implications of the observed differences between GMI and HbA1c. Recognizing the factors that cause such differences is an important clinical skill. Moreover, understanding the principles of evaluating paired measures of these parameters will allow us to individualize the treatment of each person with diabetes.
Key words: diabetes, HbA1c, GMI, CGM.

Streszczenie
HbA1c i wskaźnik kontroli glikemii (GMI) są powszechnie uznane za złoty standard w ocenie efektywności terapii cukrzycy. Wskaźnik kontroli glikemii jest wynikiem obliczeń z użyciem formuły matematycznej stosowanym w celu oszacowania HbA1c przy użyciu danych z CGM u pacjentów z cukrzycą. Jest to użyteczny parametr, zapewniający dobre oszacowanie 3-miesięcznych odczytów z CGM przy użyciu danych tylko z 10–14 dni. Może wykazać skuteczność zastosowanej lub zmodyfikowanej terapii insulinowej szybciej niż tradycyjne pomiary HbA1c w laboratorium. Poza tym GMI może być użyty jako narzędzie edukacyjne w telemedycynie. Niestety, istnieją znaczące rozbieżności pomiędzy GMI i HbA1c zmierzoną w laboratorium, osiągające u wielu pacjentów nawet 0,5–1%. Przyczyną mogą być powszechnie znane czynniki wpływające na pomiar HbA1c i obrót czerwonych krwinek, np. anemia, hemoglobinopatie, niektóre leki, jednakże są to zbyt rzadkie w codziennej praktyce przyczyny, aby wytłumaczyć nimi liczbę nieścisłości opisywanych w literaturze.
W tym artykule chcemy omówić nowe potencjalne czynniki, które mogą wpływać na szacowanie HbA1c na podstawie GMI i powodować potencjalne różnice między wynikami obliczonymi przez CGM i tymi zmierzonymi w laboratorium. Dodatkowo wskażemy kliniczne implikacje zaobserwowanych różnic między GMI i HbA1c. Identyfikacja czynników powodujących takie różnice jest ważną umiejętnością kliniczną. Co więcej, zrozumienie zasad wspólnej oceny tych parametrów pozwoli zindywidualizować terapię każdej osoby z cukrzycą.
Słowa kluczowe: diabetes, HbA1c, GMI, CGM.

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Introduction

HbA1c is widely recognized as the gold standard in assessing the effectiveness of diabetes therapy. It is a laboratory measurement introduced into clinical use in the 1980s corresponding with vascular complications of diabetes. With the development of continuous glucose monitoring (CGM) systems and their widespread availability, a new parameter was created: estimated HbA1c (eHbA1c). In a 2017 consensus, researchers concluded that 10–14 days (with the current standard being >70% of sensor usage) of CGM data based on mean glucose levels provides a good estimate of CGM metrics for a 3-month period [1]. Linear regression analysis of HbA1c and average glucose was used to develop a standard formula whereby mean glucose values could be correlated with long-term HbA1c. Potentially this could more rapidly reflect the effectiveness of administered or modified therapy. Based on large studies, the estimated HbA1c was recommended by the international consensus group as a part of CGM reports [2] and supplementary glucose monitoring indicator. It was also found useful by physicians and patients, as an education tool or telemedicine parameter (e.g. during the COVID-19 pandemic) [3]. However, similar nomenclature led to misinterpretations, and some clinicians and their patients were disappointed with the results. It was recognized that eHbA1c, which is based on a mathematical formula, and laboratory-measured HbA1c may differ for any person with diabetes because of the number of non-glycaemic factors involved in each calculation [4]. That is why glucose management indicator (GMI) has been established as a new term for eHbA1c, and this wording should be used in the current medical nomenclature [5].

What is a glucose management indicator?

Glucose management indicator has been proposed by Bergenstal [5] as a new term replacing eHbA1c, to avoid misinterpretation that it should always closely match HbA1c. It is calculated with the following equation:

$$GMI(\%) = 3.31 + 0.02392 \times [\text{mean glucose in mg/dl}]$$

A calculator to compute GMI is available at: www.jaeb.org/gmi.

Researchers explained that this formula was based on several randomized trials conducted in different patient populations that used DEXCOM sensors. It is assumed that equations for measurements collected with different devices may be similar, but not necessarily the same.

Is glucose management indicator perfect?

In Bergenstal's report 19% of the time the GMI and laboratory HbA1C have an identical value, while 51% of the time they differ by 0.3% (HbA1C points) or more, and 28% of the time they differ by 0.5% or more [5].

It is worth mentioning that GMI is not the only parameter for CGM systems evaluation. For example, Chrzanowski *et al.* proposed 2 other statistical models of HbA1c estimation from CGM and validated them in real-life conditions with a large population of patients with DM1 (723 results of HbA1c-CGM pairs from 174 patients) [6]. In external validation, both of them produced better estimations than GMI (accuracy of 87.5% and 91.0% vs. 73.8%, respectively). In another study it was reported that machine learning and linear regression models using CGM and participant data reduced HbA1c estimation error by up to 26% compared to the GMI formula [7]. While these works represent only a proposal, which has not found its way into a common use, they are a confirmation that GMI is not perfect.

There are many established reasons why HbA1c in itself may misrepresent the mean glucose level [8]. However, known causes of potential errors are too rare in everyday practice to account for the discrepancy reported in the literature. In a study based on older CGM systems (mainly Dexcom G5 requiring calibration, used in 2012–2019), disagreement between GMI and HbA1c was documented at levels higher than seen in Bergenstal's report: respectively, 50% and 22% of adult patients with long diabetes duration had differences of ≥ 0.5% and ≥ 1% [8]. In more recent observations these differences are usually smaller: GMI could be meaningfully discordant with HbA1c in more than a third of children/adolescents with type 1 diabetes (T1D) (differences > 0.5%) [9]. As many authors suggest, there is still no obvious physiological reason for the increased discordance seen in many patients with diabetes. Therefore, additional research on other clinical factors explaining these effects would be important and potentially interesting.

Aim and methodology

The aim of our review is to determine potential factors that lead to discordances in laboratory measurement of HbA1c and GMI. To do that we examined recently published articles regarding GMI available in the PubMed database. We searched for articles from 2017 to 2022 using keywords such as "CGM GMI" – 54 results, "GMI diabetes" – 87, "GMI HbA1c" – 56, and "eHbA1c" (several of those articles overlapped with each other). Because our research field is narrow, only 24 of them were viable. We found studies that connected GMI with the following clinical factors: race, adipose tissue, glycaemic variability, age, and clinical aspects such as pregnancy or patients with chronic kidney disease. In this short review we would like to focus on the aforementioned factors. We emphasize that most of the cited studies used readings with at least 70% of CGM data available as an inclusion criterion.

Factors influencing HbA1c

Before we dive deeper into GMI we would like to recall factors influencing HbA1c for a better understanding of our article. Blood glucose levels strongly affect HbA1c levels – the more glucose is in blood, the higher HbA1c levels are. Red blood cell (RBC) turnover is very individual, influenced by many known factors, such as pregnancy, iron deficiency, and haemolytic anaemia (including sickle cell anaemia and thalasse-

mia), and it might influence HbA1c levels. It is also established that medications such as glucocorticosteroids can elevate HbA1c [10, 11].

Scientists from the USA and UK derived a novel kinetic model that takes the aforementioned RBC turnover as well as cross-membrane glucose transport and haemoglobin glycation processes into account to individualize the relationship between glucose levels and HbA1c. This data was used to project future HbA1c, creating a new individualized marker: calculated HbA1c (cHbA1c). It gave an accurate estimation of laboratory HbA1c across individuals in contrast to eHbA1c. The model and data showed that glycation status is modulated by age – the oldest group in the study had a significantly higher apparent glycation constant [12].

Ethnic and racial genotype

Studies suggest that GMI will typically be higher than HbA1c in white people but lower than HbA1c in Chinese Asians or in black African Americans [4]. This may indicate a difference in the glycation kinetics in each of these populations, alongside other non-glycaemic genetic factors. Yoo *et al.* conducted a 24-week prospective, observational study on 106 Korean subjects with type 1 diabetes using Dexcom G5. They concluded that each 25 mg/dl increase of mean glucose resulted in a 0.7% increase of GMI, which was higher than the previously published value of 0,6% [13]. Additionally, we decided to include 2 studies using eHbA1c, due to the small number of articles concerning GMI. The first of them showed that in the Chinese population eHbA1c tends to be lower than lab-measured HbA1c [14]. Another study in China using GMI drew similar conclusions [15]. On the other hand, an article regarding analysis of a mainly Caucasian population revealed that eHbA1c was higher than measured HbA1c in 57% of their reports [16]. All those studies may prove that race is a factor influencing GMI – the authors believe the development of race-specific regression equations for GMI may be warranted [17].

Adipose tissue

Year after year there are more patients suffering from obesity, both adults and children. Obesity in patients with diabetes adversely affects many aspects of therapy, including among others the assimilation and absorption of drugs or the way devices work. Fellinger *et al.* compared HbA1c and GMI in 278 patients using Freestyle Libre 1 systems with different types of diabetes and BMI. The discordance between calculated GMI and HbA1c was greater with increased BMI and in type 2 diabetes. The authors believe those factors should be considered when using GMI [18]. The aforementioned discordance might be explained by a reduction in circulation of subcutaneous fat tissue leading to less diffusion in the sensing area [19, 20]. The other hypothesis is that it is due to interstitial oedema and increased tissue inflammation associated with obesity and T2D [21, 22]. Both hypotheses indicate the need to take into account excessively developed adipose tissue in patients in the context of GMI reliability.

Glycaemic variability

Another important parameter that has a significant influence on the relationship between glycosylated haemoglobin and GMI is glycaemic variability (GV). It was shown in studies among both groups of patients with type 1 [23, 24] and type 2 diabetes [25] that higher unsteadiness of blood glucose level (measured by coefficient of variation [CV] / standard deviation [SD]) leads to increased discordance between measured HbA1c and data calculated with the help of CGM. The authors proposed drawing practical conclusions from these observations – GV should be taken into consideration when applying GMI or laboratory HbA1c for the personalized management of diabetes. For example, patients with stable glucose can choose either GMI or laboratory HbA1c for individual management, while those with large glucose fluctuations would need a combination of GMI and laboratory HbA1c to help set individual goals [24].

Age

We expected that age could be a significant factor because it influences many metabolic processes, hormonal and haemoglobin levels, etc. We believe that children comprise the group that may present the biggest differences when it comes to the aforementioned factors. They also tend to have rapid changes in their emotional state, diet, and activity, which may significantly affect glycaemic control. A group of scientists noticed that Bergenstal's study regarding GMI formula did not include patients under the age of 6 years. An examination of GMI among 215 children with type 1 diabetes aged 0–6 years led to the conclusion that younger children's GMI may be more accurate when the calculation is based on a longer period and when the data collection period for CGM values is less than 18 days, researchers recommend considering utilizing the young child-specific GMI formula [26]. The authors believe that those differences might be connected with increased insulin sensitivity and glycaemic variability typically observed in younger children with T1D [27].

While there have been a few studies on this topic in children, the only extensive study was performed by Piona *et al.* [9]. The authors collected measurements of different types of CGM from 805 children/adolescents and looked for a discordance between GMI and HbA1c measurement. Scientists stratified discordant patients by age, gender, BMI, CGM type, insulin therapy, haemoglobin, anaemia, and coexistent autoimmune diseases, none of which explained the differences. The authors concluded that GMI could be meaningfully discordant (> 0.5%) with respect to HbA1c in more than a third of children/adolescents with T1D. This discretion should be taken into consideration when the 2 indices are directly compared in daily clinical practice.

Pregnancy

Diabetes in pregnant women has always been a therapeutic challenge, primarily due to the very high dynamics of metabolic and hormonal changes directly affecting glycaemic

control and insulin treatment. Because the 3 months leading to HbA1c measurement is equal to a whole trimester (which is a long period), it is not a perfect tool for use in pregnancy, which is why, theoretically, GMI may be especially useful in this clinical situation. Different therapeutic recommendations in terms of target glycaemic values (adjusted to the safe development of the foetus) resulted in the design of a specific study for pregnant women, taking into account an additional parameter from the CGM report: time in range (TIR). Viral N Shah *et al.* tried to evaluate how Hba1c and GMI correlates to the changes in TIR (63–140 mg/dl) in pregnant women with T1DM [28]. The number of patients included in this study was low, but the authors noticed significant negative correlation between TIR and HbA1c – during the first trimester it was lower than in the second and third. Simultaneously, there was a strong correlation between TIR and GMI during each trimester. The authors concluded that GMI may be a better reflection of glycaemic control in early pregnancy, but they mentioned the need for further studies. The researchers suggested a few possible factors explaining the differences: rapid change in glucose during the first trimester due to intensive insulin treatment, physiological changes regarding red blood cells, and the role of iron deficiency or supplements, which directly influence HbA1c. They also noted that GMI is a result of a mathematical formula and therefore might not be influenced by such factors.

Chronic kidney disease

The kidneys play an important role in glucose metabolism and haematopoiesis. Chronic kidney disease (CKD) may lead to impaired removal of waste products, resulting in higher glucose levels. It can also alter red blood cell turnover and lifespan, which can affect the accuracy of HbA1c measurements. On the other hand, diabetes can lead to chronic kidney disease. Jordan Perlman and his team highlighted the role of kidney function – the HbA1c-GMI discordance was higher in patients with advanced chronic kidney disease [8].

Another study showed the discordance between glycated haemoglobin A1c and the glucose management indicator in people with diabetes and chronic kidney disease [29]. These results suggest that we should take GFR into consideration when using GMI in assessment of glycaemic control.

Clinical implications of differences between GMI and HbA1c

Recognizing and understanding the factors that cause differences between HbA1c and GMI is an important clinical skill. For example, when HbA1c is elevated above GMI, further attempts at intensification of therapy based solely on the HbA1c value may increase the risk of hypoglycaemia. As a rule, the evaluation of these 2 parameters should be highly personalized. Undoubtedly, red blood cell lifespan and individual glycation rates are the main factors determining HbA1c formation. Different glycation rates will generate different HbA1c readings for the same mean glucose value. When HbA1c is consistently higher than the GMI, these individuals are likely to be "high" glycators as opposed to "low" glycators whose HbA1c is consistently lower than the GMI. High glycators have the potential for more glucose-mediated organ damage despite the same average glucose levels as measured by GMI. Hence, "high glycators" must strive for tighter glycaemic control to avoid chronic complications [4].

In the clinical assessment of the usefulness of the GMI, it is also worth noting the imperfection of the mathematical methodology – HbA1c reflects the last 3 months, and the GMI is calculated mainly from the last 2 weeks [30]. This may be important, for example, in specific circumstances: during illness, puberty, and in some women due to their menstrual cycle. Taking all this into account, we believe that new, larger research to determine the causes of non-compliance, particularly in the paediatric population, would be beneficial in clinical practice because it would help to further refine an already useful therapeutic and diagnostic tool.

Summary

Despite our intensive search in the available literature (PubMed), we think that there are still too few new valuable articles regarding factors explaining differences between HbA1c measurements and GMI. Studies confirming the impact of some clinical factors are scarce and have been conducted in small research groups. We found no studies linking GMI to the type and duration of diabetes, degree of metabolic control (HbA1c value), or gender.

During the days of common CGM usage, we wish to emphasize that for now GMI should supplement lab HbA1c, which is still an important marker of long-term diabetes control. In the author's opinion of this review, considering the simplicity of the CGM reading and its interfering factors, it is essential to individualize the assessment the time period of the patient's glycaemia, e.g. from 14 to 30 or 60 days. Clinicians should exercise caution when using the GMI to evaluate their patients' outcomes, especially those with high levels of GMI-HbA1c non-compliance.

Understanding the principles of evaluating paired measures of GMI and HbA1c will allow us to individualize the treatment of each person with diabetes.

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