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The impact of new glucose monitoring systems on parameters of diabetes metabolic control. Literature review

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ABSTRACT

Introduction

In recent years, there has been tremendous development in medicine, including diabetology. A significant portion of these achievements pertains to pharmacological treatment. However, one should not overlook the advancement of devices necessary for monitoring glucose levels, such as glucometers or CGM and FGM systems. In this paper, I want to focus on how the use of glucose monitoring systems affects the course of diabetes.

Aim of the study

The aim of this study was to determine the impact of glucose monitoring systems (CGM and FGM) on parameters of metabolic control in diabetes.

Materials and methods

The article was created based on the PubMed and Scholar databases. The literature was analyzed using the following keywords: Continuous glucose monitor, CGM, flash glucose monitoring, FGM, type 1 diabetes, type 2 diabetes, diabetes mellitus, Metrics of Glycemic.

Results

Research has confirmed that the use of continuous glucose monitoring systems lowers HbA1c in patients with both type 1 and type 2 diabetes regardless of age and treatment modality. Furthermore, the use of CGM and FGM reduces the number of hypoglycemic episodes and increases time in range (TIR).

Conclusions

Thanks to the results obtained from numerous studies, it can be assumed that the use of continuous glucose monitoring systems is not only an adjunct to diabetes therapy but also an important component of it. With this technology combined with modern medications, we can achieve better glycemic control and, consequently, improve the quality of life of patients with diabetes.

Key words: Continuous glucose monitor, CGM, flash glucose monitoring, FGM, type 1diabetes, type 2 diabetes, Metrics of Glycemic Managment

INTRODUCTION

Diabetes is a chronic disease that affects an increasing percentage of the population worldwide year by year. In 2019, 463 million adults were affected by this disease, and according to data published by the International Diabetes Federation (IDF), by 2045, the number of people affected by diabetes could rise to 700 million. The increasing prevalence of diabetes is associated with a rise in the percentage of its complications within the population [1]. To reduce the risk of organ complications, efforts are made to achieve the best possible metabolic control of the disease. Criteria for metabolic control of diabetes are used for this purpose, which serve as treatment goals [2]. The traditional parameter for metabolic control is glycated hemoglobin (HbA1c). It corresponds to the average blood glucose levels over the past 3 months [7]. In individuals using glucose monitoring systems, it's possible to assess Time in Range (TIR), which represents the percentage of time spent within the target glucose range. For most patients, this is >70% of the time within the range of 70-180 mg/dL. Another indicator is Time Below Range (TBR), representing the time spent in hypoglycemia below 70 mg/dL, which should not exceed <4%, and the time spent in hypoglycemia below 54 mg/dL should be less than 1%. The last indicator is Time Above Range (TAR), which should be less than 25% of the time above 180 mg/dL and less than 5% of the time above 250 mg/dL. [14] Over the past few years, numerous studies have demonstrated the positive impact of continuous glucose monitoring systems on improving diabetes management and glycemic control in patients with diabetes.

Traditional methods of glycemic control

Self-monitoring of blood glucose (SMBG)

Self-monitoring of blood glucose (SMBG) by patients plays a very important role in diabetes management. Strict control of readings, along with their interpretation and appropriate response, leads to the stabilization of blood glucose levels, thereby avoiding distant complications such as microvascular and macrovascular complications [3, 4]. Unfortunately, standard blood glucose measurements using a glucometer come with many inconveniences, such as the need for frequent finger pricks and the pain associated with it [4,5]. Moreover, SMBG is not always feasible due to limited access to obtaining measurements in public places, work, or school. Measurements taken in this way are susceptible to errors caused by the presence of contaminants on the skin of the finger [6]. As a result, many patients do not adhere to their doctors' recommendations and perform glucose measurements much less frequently [5]. Another drawback of SMBG is obtaining a single glucose value only at the time of measurement, without information about trends and rate of changes. It also prevents the detection of nocturnal hypoglycemia in cases of unawareness. [7]

Hemoglobin A1c (HbA1c) testing

The measurement of glycated hemoglobin (HbA1c) reflects the average glucose concentration over the past 2-3 months. It is a useful indicator for assessing the effectiveness of treatment and can also be used to predict the risk of developing severe diabetic complications [7]. Despite being a standardized test, it may be unreliable in some patients. The results of the test may not be accurate in patients with conditions that affect the lifespan of red blood cells, such as hemoglobinopathies or various types of anemia. False results may also occur due to recent blood transfusions or pregnancy. Additionally, HbA1c does not reflect daily fluctuations in blood glucose levels, postprandial hyperglycemia, or nocturnal hypoglycemia [7]. It has also been demonstrated that the relationship between HbA1c and blood glucose levels varies significantly depending on race. In individuals of Black race, glycated hemoglobin overestimates the average blood glucose level compared to individuals of White race [8].

Glucose monitoring systems

As seen, the above methods of glucose monitoring have certain drawbacks and inconveniences. Since Medtronic released the first CGM system in 1999, we have witnessed dynamic development of this medical technology over the past years, which provides a good alternative to standard methods of glucose control [9]. Continuous glucose monitoring systems consist of a sensor and a receiver, with some requiring a special transmitter as well. The sensor is responsible for measuring glucose levels in the interstitial fluid every 1-5 minutes. Depending on the type of device, the measurements taken are received by a dedicated receiver or a smartphone with an installed application. In some cases, a personal insulin pump can also serve as the receiver [10]. The patient independently inserts the sensor under the skin using an applicator and replaces it, depending on the manufacturer, every 7-14 days [7].

There are two types of glucose monitoring systems: flash glucose monitoring (FGM) and continuous glucose monitoring (CGM). The first one available on the market is FreeStyle Libre [9]. Its advantage is the lack of need for initial calibration. It takes measurements continuously but does not transmit them automatically to the receiver. To obtain the measurement result, you need to bring the receiver close to the sensor that has been applied. At this point, the user receives the measurement data as well as information about the direction and rate of changes. Exactly, it's a system that requires minimal patient involvement [7].

The second type is a real-time continuous glucose monitoring system, which continuously transmits glucose measurement data to the receiver and automatically alerts the patient to hypoglycemia or hyperglycemia [7]. Available CGM systems on the market include Dexcom G5 Mobile, Dexcom G6 Mobile, Medtronic Guardian Connect, and Eversense [7, 9, 11].

Advantages of glucose monitoring systems

Control of glycemia using continuous glucose monitoring systems has many advantages, increasing patient safety and comfort. Among the main benefits of this method is the ability to check glucose levels 24 hours a day, in any situation and place, without the need for finger pricking. Another very important advantage is the alarms warning of hypoglycemia and hyperglycemia, which protect the patient from excessively high and low values [9]. Another benefit is visualizing the rate and direction of glucose changes, along with alarms notifying the patient about them, allowing the patient to react quickly and prevent glucose fluctuations [12].

Disadvantages of glucose monitoring systems

Unfortunately, despite the many benefits of continuous glucose monitoring systems, there is a barrier in the form of rather high costs of purchasing sensors for the patient [13]. Adverse effects may also occur, most commonly itching, redness, or rash at the site of sensor application. Additionally, during application, pain, bleeding, swelling, and bruising may occur [14].

The impact of the use of glucose monitoring systems on diabetes control parameters

In recent years, numerous studies have been conducted illustrating the positive impact of CGM systems on diabetes treatment outcomes [16-30]. Currently, most studies focus on patients with type 1 diabetes, while some involve patients with type 2 diabetes treated with insulin [17, 18, 20, 21, 23, 26, 28]. Few studies illustrate the impact of CGM and FGM systems on patients with diabetes treated with oral hypoglycemic medications [16]. One of the greatest benefits of using continuous glucose monitoring systems is a significant reduction in HbA1c levels, both in patients with type 1 diabetes and type 2 diabetes treated with insulin or oral hypoglycemic medications. A statistically significant decrease in HbA1c can be observed regardless of age, both in older individuals (above 60 years old), adults, young adults, and teenagers [16-21, 26-30]. The best effect of CGM use was achieved in patient groups with the highest baseline HbA1c values [19, 28]. In patients with well-controlled diabetes, no clinically significant change in HbA1c values was observed; however, a reduction in time spent in hypoglycemia was observed [22, 23]. In addition to improving laboratory parameters and reducing the frequency of hypoglycemia, continuous glucose monitoring systems contribute to enhancing the quality of life and increasing treatment satisfaction among patients [29, 31].

In a study conducted in five Japanese centers in 2019, involving 100 participants with type 2 diabetes not using insulin and with hemoglobin A1c levels ≥7.5% (59 mmol/mol) and <8.5% (69 mmol/mol), two study groups were distinguished. The first group (49 individuals) used CGM systems, while the second group (51 individuals) used SMBG. The study was completed by 48 participants in the first group and 45 in the second group. After 24 weeks of the study, the results clearly demonstrated the superiority of FGM systems over traditional methods of glucose measurement. A reduction in glycated hemoglobin was achieved from 7.83% (62.1 mmol/mol) to -0.47% (−5.0 mmol/mol) in the FGM group and from 7.84% (62.2 mmol/mol) to -0.17% (−1.8 mmol/mol) in the SMBG group. This gives us a difference of -0.29% (−3.2 mmol/mol) solely due to the use of different methods of glucose measurement [16].

In another study, concluded in 2020, conducted in 15 centers in the USA, the focus was on patients with poorly controlled type 2 diabetes. It involved 175 adult patients who were treated with 1 or 2 basal insulin injections without mealtime insulin. They were divided into two groups, with 116 patients in the CGM group and 59 in the traditional glucose meter group. The Dexcom G6 system was used for CGM in the study, which measured glucose levels every 5 minutes. The main parameter compared was the average HbA1c level. At the beginning of the study, the HbA1c level in the CGM group was 9.1%, and in the BGM group, it was 9.0%. In the first group, it decreased to 8.0%, compared to 8.4% in the second group. In addition to HbA1c, three other key parameters were evaluated: time in range (TIR) 70-180 mg/dl, time spent in hyperglycemia above 250 mg/dl, and average glucose level. Statistically significant differences were found in each of these parameters between the two groups, as shown in Table 1 [17].

	CGM group	GM group
R	%	%
ood Gucose level >250mg/dl	%	%
ean glucose level	9mg/dl	6mg/dl

Table 1 [17]

In the DIAMOND study conducted between October 2014 and May 2016, a significantly greater decrease in HbA1c was observed in patients with type 1 diabetes undergoing continuous glucose monitoring compared to self-monitoring of blood glucose (SMBG). The study involved 158 adults with type 1 diabetes treated with multiple daily insulin injections, who had HbA1c levels ranging from 7.5% to 9.9% before the study. Patients in the CGM group received the Dexcom 4G Platinum system, which measured glucose levels every 5 minutes for 7 days. Participants in the control group performed glucose measurements using a glucometer at least 4 times a day. After 24 weeks, the average reduction in HbA1c in the CGM group was 1.0%, while it was 0.4% in the control group. In the CGM group, the median time spent in hypoglycemia <70 mg/dL was 43 minutes per day, compared to 80 minutes per day in the control group. [18]

In a study conducted between January 2018 and May 2019, the focus was on teenagers and young adults aged 14 to 24 years with type 1 diabetes for at least one year. The study group comprised 153 individuals who were randomly assigned to two groups in a 1:1 ratio. Participants in the first group used a CGM system (Dexcom G5), while those in the second group monitored their glucose levels using a glucometer. The mean HbA1c value at the beginning of the study was 8.9%, and after 26 weeks, it decreased to 8.5% in the CGM group. In the BGM group, the mean HbA1c value at the beginning and after 26 weeks remained 8.9%. This represented a small but statistically significant decrease in HbA1c. Additionally, the CGM group achieved a significantly shorter duration of hypoglycemia (glucose levels below 70 mg/dL) and a longer time spent in the range of 70 to 180 mg/dL compared to the BGM group. In the CGM group, the mean time spent in the 70-180 mg/dL range was 37% at the beginning of the study and increased to 43% during the observation period, while in the BGM group, it was 36% at the beginning and 35% during the study. [20]

In 2018, a large study involving 900 patients at two university hospitals in Scotland was conducted. These were individuals with type 1 diabetes who began using flash glucose monitoring funded by the National Health Service (NHS). The introduction of NHS-funded flash monitoring had a significant effect on HbA1c levels, especially in individuals with high baseline levels of this indicator. On average, HbA1c decreased by 4 mmol/mol, with a median decrease of 14 mmol/mol in individuals with baseline HbA1c above 75 mmol/mol. Minor changes were observed in individuals with baseline HbA1c below 58 mmol/mol. Additionally, 48.8% of patients achieved an HbA1c level below 58 mmol/mol, and the number of those with HbA1c above 75 mmol/mol decreased by twofold. Importantly, flash monitoring also contributed to a reduction in the number of hospitalizations due to diabetic ketoacidosis, although there were no visible differences in the total number of hospitalizations or emergency department visits. [28]

Hypoglycemia is a common complication of diabetes that can lead to serious consequences. Severe hypoglycemia can result in seizures, loss of consciousness with falls and fractures, and even cardiac rhythm disturbances leading to sudden cardiac death [21]. Nighttime hypoglycemia is particularly dangerous, accounting for up to half of severe hypoglycemic episodes [24]. It has been demonstrated that in addition to reducing glycated hemoglobin levels, the benefits of using glucose monitoring systems also include a reduction in hypoglycemic episodes [21, 23-25].

In a clinical study conducted in the United States, 203 individuals aged 60 and older with type 1 diabetes and glycated hemoglobin levels below 10.0% participated. Participants were divided into two groups in a 1:1 ratio, with one group using the Dexcom G5 CGM and the other group using a glucometer. In the CGM group, the median time spent in hypoglycemia below 70 mg/dl was 5.1% at the beginning of the study and 2.7% over 6 months of observation. In the glucometer group, it was 4.7% at the beginning and 4.9% during the study. The difference between the groups amounted to 27 minutes per day. Significant improvement in the duration of hypoglycemia was most noticeable at the beginning and remained at a similar level throughout the study in the CGM group. The treatment effect was observed both during the day and at night, in patients using insulin pumps as well as those using multiple daily insulin injections. In addition to reducing time spent in hypoglycemia, a significant increase in time in range (TIR) and a decrease in glycated hemoglobin were also observed. [21]

The decrease in the duration of hypoglycemia was also observed in the IMPACT study conducted in 23 European centers. The FreeStyle Libre system was used in the study. Individuals aged 18 and older, diagnosed with type 1 diabetes for a minimum of 5 years, with an HbA1c level of 7.5% or less, were included in the study. Individuals with diagnosed hypoglycemia unawareness were excluded from the study. In the group using FGM, a reduction in both daytime and nighttime hypoglycemia duration was evident from the beginning of the study. The duration of hypoglycemia in the FGM group was shortened from 3.44 hours/day to 1.86 hours/day. In the control group, the duration of hypoglycemia at the beginning of the study was 3.76 hours/day, and after the study concluded, it was 3.66 hours/day. [23]

The effectiveness of CGM systems in preventing hypoglycemia episodes in individuals with hypoglycemia unawareness has also been demonstrated [24, 25]. In the HypoDe study conducted in 12 German clinics, participants were patients over 18 years old with type 1 diabetes and impaired awareness of hypoglycemia or severe hypoglycemia in the last year. A decrease of 72% in hypoglycemia episodes was achieved in the CGM group, while in the control group, the reduction in hypoglycemia was minimal. [24] Similar results were obtained in the IN CONTROL study conducted at two centers in the Netherlands. Patients recruited for the study had type 1 diabetes, were aged 18-75 years, treated with continuous subcutaneous insulin infusion or multiple daily insulin injections, and performed a minimum of three blood glucose measurements per day. Another inclusion criterion was hypoglycemia unawareness, confirmed by a Gold score of at least 4 points. After the study concluded, it was determined that while using the CGM system, the number of severe hypoglycemic events was 14, whereas with only self-monitoring of blood glucose (SMBG), there were 34 events. Additionally, the duration of normoglycemia was higher, and the time spent in hypoglycemia and hyperglycemia decreased during CGM use. [25]

In a study conducted between 2016 and 2017 in Israel, the impact of FGM on treatment satisfaction in patients with type 2 diabetes was evaluated. The study included 101 individuals aged 30-80 years who were treated with two or more insulin injections per day, with HbA1c levels ranging from 7.5% to 10%. After 10 weeks, patients in the FGM group rated their treatment as more flexible than those in the control group, and the perceived frequency of hypoglycemia improved in the intervention group. [31]

Conclusions

Diabetes management has evolved significantly with the advent of continuous glucose monitoring (CGM) systems, offering real-time insights into glucose levels and trends. Traditional methods such as self-monitoring of blood glucose (SMBG) and HbA1c testing have limitations in providing comprehensive data on glucose fluctuations, especially in detecting hypoglycemic events. CGM systems offer numerous advantages over traditional methods, including continuous monitoring, alerts for hypo- and hyperglycemia, and visualization of glucose trends. Studies have consistently demonstrated the efficacy of CGM in improving glycemic control, reducing HbA1c levels, and minimizing hypoglycemic episodes across diverse patient populations with type 1 and type 2 diabetes. The impact of CGM extends beyond glycemic control, with studies highlighting improvements in quality of life, treatment satisfaction, and reduction in diabetes-related complications. Furthermore, CGM systems have demonstrated efficacy in preventing hypoglycemic episodes, particularly in patients with hypoglycemia unawareness. While CGM systems offer substantial benefits, challenges such as cost and potential adverse effects remain. However, ongoing advancements in technology and increasing accessibility may address these barriers, further enhancing the utility of CGM in diabetes management. In conclusion, continuous glucose monitoring (CGM) systems mark a significant advancement in diabetes treatment, providing a holistic method for managing blood sugar levels and enhancing the well-being of individuals with diabetes. Ongoing research and advancements in this area offer hope for even better diabetes management and improved quality of life for patients worldwide.

Author's contribution

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Investigation, Weronika Salasa and Justyna Marcicka; Resources, Aleksandra Mazurkiewicz; Data Curation, Wojciech Mądry; Writing -Rough Preparation, Tomasz Seredyński; Writing - Review and Editing, Michał Andrzej Kozicz and Weronika Salasa; Visualization, Tomasz Seredyński; Supervision, Magdalena Kołodziej; Project Administration, Joanna Męczyńska; Receiving Funding, Aleksandra Mazurkiewicz.

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