

Benefits of self-monitoring blood glucose for patients with Type 2 Diabetes and its importance in Primary Care

Benefícios da automonitorização da glicose no sangue para pacientes com Diabetes tipo 2 e sua importância na Atenção Primária

Beneficios del auto-monitoreo de glucosa en sangre para pacientes con Diabetes tipo 2 y su importancia en la Atención Primaria

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Ana Carolina Galharo

ORCID: <https://orcid.org/0009-0000-1218-4829>
Centro Universitário Barão de Mauá, Brazil
E-mail: ana.carolina.galharo@hotmail.com

Eduarda Pereira Lima Garcia

ORCID: <https://orcid.org/0009-0000-1642-0075>
Centro Universitário Barão de Mauá, Brazil
E-mail: eduardapereiralimagarcia@gmail.com

Camille Stephani Baccarin

ORCID: <https://orcid.org/0009-0006-5992-8606>
Centro Universitário Barão de Mauá, Brazil
E-mail: camyllebacc@hotmail.com

Larissa Cocicov Gytoku

ORCID: <https://orcid.org/0009-0009-7453-4148>
Centro Universitário Barão de Mauá, Brazil
E-mail: larissa.cocicov@baraodemaua.br

Abstract

This article aims to evaluate the impact and benefit of Continuous Glucose Monitors (CGMs), specifically the FreeStyle Libre system, on the quality of life of patients with Type 2 Diabetes (T2DM), comparing the effectiveness of CGM with traditional glucose monitoring methods, like Self-monitoring Blood Glucose (SMBG) with capillary, focusing on reducing glycated hemoglobin (HbA1c) levels and reducing acute and chronic complications. The methodology used is based on a literature review with analysis of data obtained from studies and clinical trials available in the PubMed and EBSCO databases, examining the effects of CGM devices in reducing HbA1c, hypoglycemic events and vascular complications. The results indicate that the use of CGMs, such as the FreeStyle Libre, provides a significant reduction in HbA1c levels and a decrease in hypoglycemic episodes compared to traditional monitoring. Furthermore, CGM devices have been shown to be more effective in improving patients' quality of life. It is concluded that, although CGMs have a higher initial cost, they are a cost-effective option in the long term due to the reduction of severe complications and associated costs. The incorporation of CGMs in the management of type 2 diabetes is recommended to optimize glycemic control and improve patient well-being.

Keywords: Blood Glucose Self-Monitoring; Freestyle Libre; *Diabetes Mellitus*, Type 2.

Resumo

Este artigo tem como objetivo avaliar o impacto e o benefício dos Monitores Contínuos de Glicose (CGM), especificamente o sistema FreeStyle Libre, na qualidade de vida de pacientes com Diabetes Tipo 2 (DM2), comparando a eficácia do CGM com os métodos tradicionais de monitoramento de glicose, como automonitoramento da glicemia capilar (SMBG) com foco na redução dos níveis de hemoglobina glicada (HbA1c) e redução de complicações agudas e crônicas. A metodologia utilizada baseia-se em revisão de literatura com análise de dados obtidos de estudos e ensaios clínicos disponíveis nas bases de dados PubMed e EBSCO, examinando os efeitos dos dispositivos CGM na redução de HbA1c, eventos hipoglicêmicos e complicações vasculares. Os resultados indicam que o uso de CGMs, como o FreeStyle Libre, proporciona redução significativa dos níveis de HbA1c e diminuição dos episódios de hipoglicemia em comparação ao monitoramento tradicional. Além disso, os dispositivos CGM demonstraram ser mais eficazes na melhoria da qualidade de vida dos pacientes. Conclui-se que, embora os MCG

tenham um custo inicial mais elevado, são uma opção custo-efetiva a longo prazo devido à redução de complicações graves e custos associados. A incorporação de CGMs no tratamento do diabetes tipo 2 é recomendada para otimizar o controle glicêmico e melhorar o bem-estar do paciente.

Palavras-chave: Automonitorização da glicemia; Freestyle Libre; *Diabetes Mellitus* Tipo 2.

Resumen

Este artículo tiene como objetivo evaluar el impacto y beneficio de los Monitores Continuos de Glucosa (MCG), específicamente el sistema FreeStyle Libre, en la calidad de vida de pacientes con Diabetes tipo 2 (DM2), comparando la efectividad de los CGM con los métodos tradicionales de monitoreo de glucosa, como Autocontrol de la glucosa en sangre (SMBG) con capilar, centrándose en reducir los niveles de hemoglobina glucosilada (HbA1c) y reducir las complicaciones agudas y crónicas. La metodología utilizada se basa en una revisión de la literatura con análisis de datos obtenidos de estudios y ensayos clínicos disponibles en las bases de datos PubMed y EBSCO, examinando los efectos de los dispositivos CGM en la reducción de la HbA1c, los eventos de hipoglucemia y las complicaciones vasculares. Los resultados indican que el uso de MCG, como el FreeStyle Libre, proporciona una reducción significativa de los niveles de HbA1c y una disminución de los episodios de hipoglucemia en comparación con la monitorización tradicional. Además, se ha demostrado que los dispositivos CGM son más eficaces para mejorar la calidad de vida de los pacientes. Se concluye que, aunque los MCG tienen un costo inicial mayor, son una opción costo-efectiva a largo plazo debido a la reducción de complicaciones graves y costos asociados. Se recomienda la incorporación de MCG en el tratamiento de la diabetes tipo 2 para optimizar el control glucémico y mejorar el bienestar del paciente.

Palabras clave: Automonitorización de la Glucosa; Freestyle Libre; *Diabetes Mellitus* Tipo 2.

1. Introduction

During the current 21st century, *Diabetes Mellitus* (DM) has become one of the most recurrent public health emergencies, with an estimated growing number of affected people of 643 million people between 2021 and 2030 (Gao; Zhou; Xu & Chen, 2022). In this context, new technologies for glucose meters, smaller and more accurate, allowed self-monitoring, optimizing glycemic control and reducing long-term complications (SMBG) (Gao et al., 2022).

Monitoring by capillarity through portable glucometers presents benefits such as ease of handling, quick results and less demand for blood samples. These devices use reflection photometry or electrochemical amperometry on disposable reagent strips. Furthermore, they present a variation of less than 15% when compared to laboratory tests of plasma glucose (Oliveira, Júnior, Santos-Leonardo & Morais, 2015)

On the other hand, there is the continuous monitoring of interstitial glucose (CGM) from systems such as Freestyle Libre Pro and Freestyle Libre with 14 days of use and without the need for calibration. The difference between them is that the Freestyle Libre Pro system has an accuracy (MARD) of 12.3% and a frequency of glucose reading every 15 minutes and the Freestyle Libre system has an accuracy (MARD) of 9.4% and a frequency of reading every 1 minute, being automatically recorded every 15 minutes (Unger, Kushner & Anderson, 2020). The use of these devices, however, is still restricted to only a portion of the population, mainly those with type 1 diabetes mellitus (DM1) due to their high cost (Haak et al., 2017).

Barriers to realizing the clinical benefits of continuous glucose monitoring (CGM) in daily diabetes management are being overcome with the advancement of more accessible and user-friendly technologies. The new category of CGM, known as 'flash,' enables more frequent use of continuous data by a greater number of patients in primary care (Hirsch & Wright, 2019).

Given the above, it is relevant to compare the portable method of measuring capillary blood glucose and the CGM Freestyle Libre system to assess the impact on the quality of life of patients with DM.

In this regard, the present review study aims to synthesize current information on the use of Libre-type CGM with emphasis on its benefits in controlling glycated hemoglobin (HbA1c) and reducing acute and chronic micro and macrovascular

complications in individuals over 18 years of age with a previous diagnosis of type 2 diabetes mellitus (DM2) and using insulin therapy.

2. Methodology

Scientific Methodology is important to achieve reproducibility in studies (Pereira et al., 2018). In the present study, the descriptive methodology was adopted, of a qualitative nature and of the narrative review type (Cavalcante & Oliveira, 2020).

This literature review explores the beneficial evidence of the use of CGM Libre devices, on the reduction of HbA1c, hypoglycemic events and chronic micro and macrovascular complications. As a research resource, the *National Library of Medicine (PubMed)* and *EBSCO Information Services (EBSCO)* databases were used, where articles were selected using the descriptors *DIABETES TYPE 2 AND SELF MONITORING BLOOD GLUCOSE*.

3. Results and Discussion

Glycemic monitoring aims to help and educate patients with DM on glycemic control, mainly by showing results in real-time. Both CGM devices and the use of capillarity have been shown to have a significant effect in reducing complications such as retinopathy, nephropathy, neuropathy, coronary disease, ischemic stroke and peripheral vascular disease (Demidov, 2021).

A study by a group of researchers developed and evaluated a structured education and treatment program called FLASH to help patients that use FSGM (flash sensor-based glucose monitoring) understand and use available glycemic information to optimize DM treatment. It involved 216 eligible participants (aged 16-75 years) on intensive insulin therapy - consisting of either injections (MDI) or continuous subcutaneous insulin infusion therapy - and presented as a result significant reduction in HbA1c, longer time on target glucose, improved quality of life questionnaires, diabetes-related distress scores, and satisfaction with the glucose monitoring method in the group that received FLASH compared to the control group. FLASH has also resulted in improvements in the use of glycemic information provided by the FSGM and reduced need for capillary blood measurements for self-monitoring of blood glucose (SMBG) (Hermanns et al., 2019).

According to the open-label randomized controlled trial conducted during a 2-week blinded use of the sensor, which recruited adults with T2DM on intensive insulin therapy from 26 European diabetes centers, the use of flash technology is safe and effective and can replace SMBG, as there is no significant difference in HbA1c or reduction of hypoglycemia, mainly in groups <65 years (-5.7 ± 0.96 mmol/mol ($-0.53 \pm 0.09\%$) and -2.2 ± 1.31 mmol/mol ($-0.20 \pm 0.12\%$), respectively; $p = 0.0301$) (Haak et al., 2017). Additionally, the application of the flash glucose sensing technology for glycemic management over a 12-month period in individuals on intensive insulin therapy was linked to a sustained decrease in hypoglycemia, also corroborating with the evidence of a reliable and efficient replacement of self-monitoring of blood glucose (Haak et al., 2017).

The German Diabetes Association led a randomised controlled trial, which pointed out that weekly SMBG profiles, or revealing HbA(1c) results did not enhance glycemic control in patients with type 2 diabetes receiving conventional insulin treatment. However, signs of hyperglycemia increased the probability of intensifying the therapy (Nauck et al., 2014).

Furthermore, a multicenter, randomized, controlled study evaluated 148 patients with DM2, dividing them into three groups: (A) self-monitoring of blood glucose, (B) self-monitoring of blood glucose and two wears of the Libre Pro sensor, and (C) self-monitoring of blood glucose and four sensor wears, thus, comparing groups A and C it was observed that the HbA1c was lower in the second group with 5.4 ± 1.79 mmol/mol ($0.48\% \pm 0.16\%$; $p = 0.0041$, significant adjustment \pm SE), without increasing hypoglycemia time ($p = 0.1795$). Finally, it was concluded that Libre Pro can improve HbA1c without increasing

hypoglycemia rates in individuals with T2DM treated with insulin in primary and secondary care centers (Ajjan, Jackson, & Thomson, 2019).

An open-label randomized controlled trial randomly assigned 101 patients with type 2 diabetes on multiple daily insulin injections (MDI) for at least 1 year to the Flash Glucose Monitoring (FGM) intervention or the standard care (control) group and followed for 10 weeks. The changes in HbA1c were -0.82% (9 mmol/mol) for the intervention group compared to -0.33% (3.6 mmol/mol) for the control group ($P = 0.005$). In a non-prespecified post hoc analysis, 68.6% of patients in the intervention group experienced a reduction in HbA1c of $\geq 0.5\%$ (5.5 mmol/mol), whereas only 30.2% in the control group achieved this ($P < 0.001$). Additionally, 39.2% of the intervention group saw a reduction of $\geq 1.0\%$ (10.9 mmol/mol) compared to 18.6% in the control group ($P = 0.0023$), with no increase in the frequency of hypoglycemia. In conclusion, FGM might cause betterment to glycemic control in patients with type 2 diabetes on MDI, all while not increasing the frequency of hypoglycemia (Yaron et al., 2019).

Japanese type 2 diabetes patients, which were part of a prospective study, treated with basal-bolus insulin therapy showed a low baseline of hypoglycemia, and enabled improved glycemic control and treatment satisfaction under the use of FreeStyle Libre. In conclusion, it could be inferred that there was an increased time in range and decreased time in hyperglycemia without increasing hypoglycemia (Ogawa et al., 2021).

In a meta-analysis, individuals over 18 years of age with T2DM on the treatment of any type who received CGM had, in most randomized trials, a significant reduction in HbA1c of 0.20% (95% confidence interval [CI] -0.31 to -0.09) compared with the control group (Park & Le, 2018).

In another study, adults aged between 35 and 79 years with a mean time since DM2 diagnosis of 17 years were randomized and evaluated to the application of multiple daily insulin injections and their hemoglobin A1c (HbA1c) levels. As a result, the subgroup that received multiple daily insulin injections and used CGM daily for 24 weeks had better glycemic control with HbA1c levels decreasing to 7.7% compared to the control group that had 8.0% (adjusted difference in mean change, -0.3% [95% CI, -0.5% to 0.0%]; $P = 0.022$). Thus, the treatment of patients with DM2 on insulin therapy associated with CGM can benefit these patients despite the small difference in HbA1c (Beck et al., 2017).

Moreover, a literature search reveals substantial evidence that supports the use of CGM in people with type 1 diabetes, demonstrating benefits such as reduced glycated hemoglobin and hypoglycemia, as well as increased time in range. Although the evidence for CGM use in type 2 diabetes is less robust, similar benefits have also been demonstrated. In brief, continuous glucose monitoring is transforming the management of diabetes. As a cost-effective addition to diabetes care, it has the potential to enhance glycemic control and improve the quality of life for people with diabetes (Lin, Brown, James, Jones & Ekinici, 2021).

Considering the statistics from a randomized clinical trial, it can be concluded that administrative claims data identified changes in health services utilization associated with professional flash glucose monitoring, despite minimal changes in glycaemic control, based on the finding of small increase in primary care health service utilization associated with professional flash glucose monitoring. As a result, this study adds to the evidence surrounding professional flash glucose monitoring use in primary care by people with T2D (McMorrow, Thuraisingam, Furler & Manski-Nankervis, 2021).

According to a systematic review of ten studies and 4006 participants, when compared to usual, intermittently scanned CGM/CGM (is-CGM) can reduce HbA1c levels (WMD -0.43%) and hypoglycemic events. However, due to the presence of notable biases, industry sponsorship, open and short-term studies, new data are needed to confirm the long-term benefits in primary care (Kieu, King, Govender & Östlundh, 2023).

Corroborating with the findings, a novel flash continuous glucose monitoring (FCGM) device used for a single 2-week period with a readily interpretable data report known as the ambulatory glucose profile (AGP) is gaining attention.

Increasing evidence suggests that intermittent use of factory-calibrated professional FCGM with AGP provides a practical option for continuous glucose monitoring in primary care settings. Utilizing standardized AGP displays, clinicians could achieve a more effective consultation experience, assisting patients in converting the long-term advantages of informed self-care (such as preventing vascular complications) into tangible short-term benefits, like safely extending time in range. In sum, intermittent continuous monitoring with AGP downloading may encourage patients to take a more active role in managing their diabetes, in addition to having the potential to address the shortcomings of traditional technologies, offering reduced costs and enhanced convenience, justifying the use of intermittent FCGM as a supplement to A1C in primary care (Hirsch, 2017).

Given this points, when utilized correctly, real-time and intermittently scanned continuous glucose monitors, along with insulin therapy, can effectively help reduce A1C levels and/or decrease hypoglycemia in adults with type 2 diabetes who are not attaining their glycemic targets (American Diabetes Association, 2020).

Based on data from a literature review in Spain, the FreeStyle Libre system used in monitoring DM2 patients on a basal-bolus insulin regimen is a potential cost-saving strategy considering the reduction in the management of cases of severe hypoglycemia (− 48.8%). The estimate includes annual consumption for glucose monitoring (strips, lancets and sensors) and management of severe hypoglycemic events (SHE), potentially generating cost savings of up to €580,953/year versus SMBG (− 21.5%) (Oyagüez et al., 2021).

Furthermore, another study conducted in Sweden also presents the CGM Flash FreeStyle Libre as a cost-effective glucose monitoring alternative to SMBG for insulin-treated DM2 patients, with a probability of more than 50% of being a cost-effective option compared to SMBG, in addition to demonstrating improvements in clinical outcomes (Jendle et al., 2021).

4. Conclusion

Recent evidence suggests that the use of new continuous glucose monitoring technologies, such as FreeStyle Libre CGM devices, significantly reduces HbA1c levels and hypoglycemic events, in addition to being more cost-effective compared to SMBG. It is also known that the FLASH program improved the management of glycemic data provided by the FSGM, reflecting a decrease in the number of SMBG. However, further studies and comparative clinical outcomes are needed between these devices and their impacts on future complications for patients with DM2. To deepen the understanding of the impact of continuous glucose monitoring technologies, future research could explore the effectiveness of different CGM devices in diverse populations of patients with type 2 diabetes, taking into account variables such as age, comorbidities, and levels of health literacy. Additionally, longitudinal studies that assess not only the reduction of HbA1c levels and hypoglycemic events but also the long-term effects on diabetes-related complications would be essential to validate the benefits of CGM. Investigations into the integration of these technologies into the public health system, including barriers and facilitators to adoption in primary care sectors, are also crucial to ensure equitable access for patients to these innovations.

Finally, this research presents evidence that supports the insertion of CGM in the Brazilian public health system, mainly in primary care sectors, considering the cost-effectiveness of its use and the improvement of well-being in patients with DM2.

Conflict of Interest

The authors have no conflicts of interest to disclose.

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