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Transformative Advances in Continuous Glucose Monitoring and the Impact of FDA Over-the-Counter Approval on Diabetes Care

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ABSTRACT

Introduction: Continuous glucose monitoring (CGM) has significantly advanced diabetes management, evolving from early glucose testing methods to modern, FDA-approved systems. Despite its benefits, challenges related to data security, affordability, and awareness of CGM devices remain.

Aim: This article explores the historical development, current advancements, and ongoing challenges of CGM systems in diabetes management. It aims to provide insights into how these technologies have transformed patient care and highlight areas needing further improvement.

Methods: A comprehensive literature review was conducted, focusing on advancements in CGM technology. Sources included PubMed, Google Scholar, and recent guidelines and reviews on CGM systems and their impact on diabetes management.

Results: The evolution from the Dextrostix test strip to modern CGM systems, including over-the-counter devices, has enhanced glucose monitoring and patient outcomes. Recent innovations, such as machine learning models for predicting glucose fluctuations, promise to improve diabetes management. However, issues like data security and device accessibility persist.

Conclusion: To maximize the benefits of CGM systems, addressing data security, improving affordability, and increasing awareness of CGM devices are crucial. Continued advancements in CGM technology and supportive policies are essential for enhancing diabetes care and patient outcomes globally.

Diabetes mellitus (DM) is a group of metabolic disorders characterized by disturbances in insulin secretion or its effects [1, 2]. The first documented case of diabetes dates back to 1552 B.C. when a physician named Hesy-Ra observed the condition [3]. Since then, the global burden of diabetes has escalated, particularly in developing countries. The prevalence of DM has surged from 108 million cases in 1980 to 422 million in 2014, and it is now estimated that 9.3% of adults aged 20–79 may develop diabetes due to genetic or lifestyle factors. This figure is expected to exceed 700 million adults globally by 2025 [4].

DM's effects are far-reaching, ranging from hypoglycemia and hyperglycemia to more severe complications like myocardial infarction, diabetic neuropathy, and diabetic retinopathy, which accounts for 2.6% of global blindness [2–4]. Additionally, these patients were at high risk during the COVID-19 pandemic [5]. To manage these complications, patients must adhere to dietary plans and regularly monitor their blood glucose (BG) levels. Insulin therapy has been the most effective treatment for some patients for over a decade, helping to control BG levels within the normal range [3, 5].

Ames developed the first glucose oxidase blood glucose test strip, the Dextrostix, in 1965. A huge drop of blood washed off the strip after 60 s [6]. The early system relied on finger pricking to measure BG concentration, providing only a snapshot of the BG level. The FDA approved the first CGM system in 1999 to address this limitation, allowing continuous glucose monitoring through interstitial fluid [2].

CGM technology marked a significant advance, but it is important to note that intermittent monitoring systems, such as the widely-used FreeStyle Libre 2, are still crucial for managing type 1 diabetes [7]. By 2004 and 2006, newer CGM systems could monitor glucose levels every 5 min for several days, with alerts for high or low glucose levels [8, 9]. The FDA's approval of Dexcom's G5 mobile CGM system in 2016 extended these benefits to toddlers and older individuals, further expanding the use of CGM technology [10].

Recent studies have highlighted the effectiveness of CGM systems, particularly among adolescents. These systems can predict hypo- and hyperglycemic events during and after physical activity [11]. The precision of CGM is measured using the mean absolute relative difference (MARD) metric, which calculates the average percentage difference between CGM readings and reference glucose values. For instance, the Medtronic Enlite CGM system achieved a MARD of 13.6%, showcasing improvements in accuracy, wearability, and comfort [9].

Machine learning (ML) models have been incorporated into CGM systems to predict hypoglycemia risk, providing patients with actionable insights into their glycemic patterns [12]. According to the Type 1 Diabetes Exchange Registry, approximately 30% of participants between 2016 and 2018 utilized CGM [13]. The popularity of systems like Senseonics Eversense, Medtronic Enlite and Guardian, and Dexcom G5 Mobile and G6 underscores CGM's pivotal role in helping patients monitor glucose levels in real time and avoid complications [14]. The recent progress regarding the development of various ensemble learning methods has also shown excellent performance in predicting hypoglycemic events, further improving the safety and accuracy of the CGM systems [15].

CGM devices have also demonstrated their ability to reduce healthcare costs by improving glycemic control in hospitalized patients, leading to fewer hypoglycemic and hyperglycemic events. This, in turn, reduces complications, hospital readmissions, and the need for expensive interventions related to poorly managed diabetes [5, 16]. For example, Galindo et al. confirmed the reduction in hypoglycemic episodes in hospitalized patients using CGM [16].

Recent advancements in CGM technology have revolutionized diabetes management, offered real-time insights, and improved glycemic control. The FDA's approval of over the counter (OTC) CGM devices is a significant development in this evolution. This approval marks a transformative shift in diabetes care, significantly improving patient access to these life-changing technologies. By removing the need for a prescription, OTC availability empowers individuals to take charge of their diabetes management, facilitating more frequent monitoring and timely intervention. This increased accessibility is especially important for underserved populations and those facing prescription barriers [17, 18].

In clinical research, numerous randomized controlled trials and cross-sectional studies have demonstrated that CGM systems are more effective than traditional self-monitoring methods for managing diabetes. Studies by Beck et al. and Lind et al. have shown that sensor-augmented pump therapy significantly improves glycemic outcomes compared to multiple daily injections [19–21].

Several studies conclude that the use of continuous glucose monitoring (CGM) in type 2 diabetes mellitus is beneficial, as it significantly reduces HbA1c compared to self-monitoring of blood glucose, demonstrating significant improvements in glycemic control and highlighting the potential of CGM devices to optimize diabetes management [22, 23].

Data security and privacy concerns have been raised with the increasing use of cloud-connected CGM devices. While some of these concerns are based on user perceptions, documented data breaches and vulnerabilities in digital health systems, highlight the importance of robust security measures. Manufacturers and healthcare providers must implement stronger encryption, regular security audits, and clear data usage policies to protect patient information and build trust in CGM technology [24].

Moreover, Cost and access to CGM systems continue to be significant barriers; however, public funding initiatives have helped reduce socioeconomic disparities in managing both type 1 and type 2 diabetes, making these life-saving technologies more accessible to diverse populations [25, 26]. Public funding has been instrumental in making these life-saving technologies more accessible to lower-income populations, helping to close the gap in diabetes management [25, 26].

Another notable advancement in CGM systems is their ability to detect high ketone levels during hyperglycemic events, which can significantly reduce the incidence of diabetic ketoacidosis (DKA) [27]. However, current ketone detection methods face limitations, including delays in detection and challenges in integrating ketone monitoring into CGM devices. These issues highlight the need for further research into more innovative glucose sampling techniques to address these gaps and enhance the accuracy and timeliness of DKA prevention [27].

In addition, inadequate insurance coverage and affordability continue to hinder the widespread adoption of CGM systems, particularly for type 1 and type 2 diabetes patients from lower-income backgrounds. To improve precision, reducing the lag time between blood glucose fluctuations and interstitial fluid detection is necessary [9, 28]. Increasing awareness about the benefits of CGM among type 1 and type 2 diabetes patients is also essential for expanding the use of this technology and ensuring more equitable access to its advantages.

Although recent reports indicate that only a small percentage of type 1 DM patients (0.5% of all diabetic patients) use CGM systems [29], efforts by the U.S. and European countries to promote CGM adoption are expected to benefit a substantial portion of the population [30]. Additionally, around 12.3% of people with type 2 diabetes are currently using CGM systems. As CGM technology continues to evolve, it holds the potential to revolutionize diabetes management for millions of people worldwide [31].

In conclusion, CGM technology has transformed diabetes management by offering continuous, real-time insights into glucose levels, helping to prevent complications associated with hypo and hyperglycemia. The recent FDA approval of over-the-counter CGM devices represents a significant milestone, making this technology more accessible to a broader range of patients. However, challenges such as data security, affordability, and precision remain. Ongoing efforts to raise awareness of CGM devices and address these barriers, coupled with advancements in machine learning and predictive analytics, will further enhance the role of CGM in improving diabetes care and patient outcomes globally.

Author Contributions

Zain Afridi: conceptualization, investigation, writing – original draft, methodology, validation, visualization, writing – review and editing, resources, data curation, formal analysis. **Sameer Abdul Rauf:** investigation, writing – original draft, methodology, validation, visualization, writing – review and editing, resources, data curation, formal analysis, software. **Syed Muhammad Nabil Ashraf:** investigation, writing – original draft, writing – review and editing, visualization, methodology, software, formal analysis, resources, data curation, validation. **Md Ariful Haque:** investigation, funding acquisition, writing – original draft, writing – review and editing, supervision, project administration, methodology, visualization, formal analysis, resources.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The authors have nothing to report.

Transparency Statement

The lead author, Md Ariful Haque, affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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