

Impact of Professional Continuous Glucose Monitors in an Ambulatory Clinic

by Ashley Moore, PharmD, Julie Bartell, PharmD, BCACP

Continuous glucose monitoring (CGM) systems have been rapidly gaining popularity over the last few years, as they serve as alternatives to traditional self-monitoring blood glucose (SMBG) methods. CGMs automatically measure interstitial glucose levels every few minutes through a microfilament sensor inserted under the patient's skin. The capability of CGMs to provide daily glycemic trends is a valuable tool to help guide clinical decision-making. This technology can help patients and providers make informed decisions based on glucose trends and offers an advantage over SMBG, which is limited by the need for frequent testing and the difficulty of reporting accurate results.

The first CGM system was approved for professional use by the United States Food and Drug Administration (FDA) in 1999. Since then, technological advancements in accuracy, usability, and duration of wear

have given rise to a variety of CGM devices for both personal and professional use. Medicare and most private insurers have covered clinician use of professional CGMs for therapeutic management in diabetes for more than a decade; however, most professional CGM devices had historically required regular calibration with finger-stick blood glucose values to ensure their

TABLE 1. Baseline Demographics

Patients	22
Age in Years, Median (range)	60 (21-85)
Female (%)	13 (59.1)
Insulin Therapy (%)	20 (90.1)

TABLE 2. Baseline Control

	Average Hemoglobin A1c (%)	Average Hypoglycemic Events Per Week
Combined (n = 22)	8.9 ± 1.6	0.7 ± 1.2
Hemoglobin A1c		
>10 (n = 5)	11.3 ± 0.8	0.8 ± 1.6
9.0 - 9.9 (n = 5)	9.4 ± 0.3	0.0 ± 0.0
8.0 - 8.9 (n = 5)	8.4 ± 0.2	1.0 ± 1.3
7.0 - 7.9 (n = 4)	7.7 ± 0.3	1.3 ± 1.3

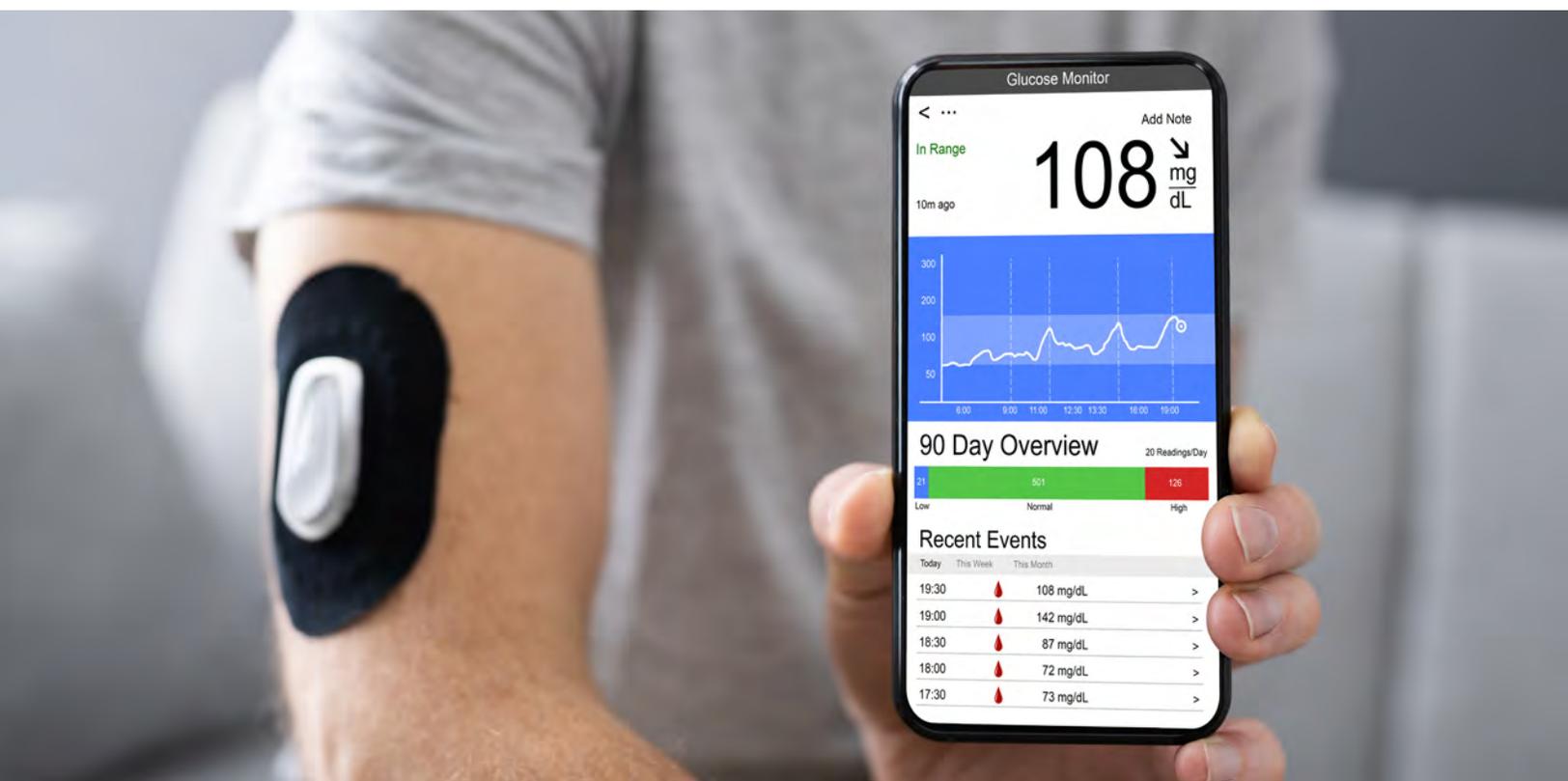
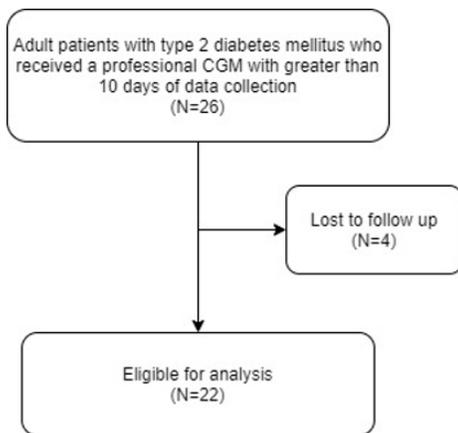


FIGURE 1. Patient Inclusion Flowchart



CGM: Continuous glucose monitor

accuracy.¹ The FreeStyle Libre Pro flash glucose monitoring system was approved by the FDA in 2016 for use by health care professionals in the management of patients with diabetes treated with insulin. It was the first professional CGM system to not require finger-stick calibration.²

The American Diabetes Association (ADA) Standards of Care state that CGMs have an important role in assessing the effectiveness and safety of treatment in subgroups of patients with type 1 diabetes mellitus (T1DM) and in selected patients with type 2 diabetes mellitus (T2DM).³ These subgroups include patients who are not achieving glycemic targets, and those with hypoglycemic unawareness and/or frequent hypoglycemic episodes. While the ADA guidelines provide data demonstrating improved hemoglobin A1c (HbA1c) lowering and reduced frequency of hypoglycemia, the evidence was mostly derived from clinical trials of T1DM patients using real-time CGM.⁴⁻⁷ 2021 ADA Standards of Care now recommend CGM as useful for people with diabetes on multiple daily injections, continuous subcutaneous insulin infusions, and other forms of insulin therapy despite age or type of diabetes.³ Guidance provided by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) 2016 Outpatient Glucose Monitoring Consensus Statement reported that data on CGM use, real-time or retrospective, in patients with T2DM using insulin, sulfonylureas, or meglitinides is limited and additional studies are recommended to evaluate its role in T2DM management.⁸ A follow-

up consensus conference by AACE/ACE concluded that the benefits of CGM in patients with T1DM are likely to be replicated in patients using intensive insulin therapy, regardless of the type of diabetes.⁹ It was also recommended that real-world analyses of health care use for acute and chronic complications affect the impact of both personal and professional CGM on potential cost savings and health-related quality of life. Consequently, clinicians would benefit from further guidance on the value of professional CGM in the management of patients with both type 1 and type 2 diabetes.

There is currently minimal research on the value of professional CGM in patients with diabetes. Furthermore, there is limited literature describing the effectiveness of clinical pharmacist-led professional CGM services in the ambulatory setting.

Today, both professional and personal CGMs are available to the general public. One of the largest drawbacks of a CGM is cost. Professional CGM placements are billed as a procedure through medical insurance, while personal CGMs are typically billed through drug insurance. Patients' out-of-pocket costs can vary based on their insurance plans. When affordable, professional CGMs are an effective way of getting a two-week snapshot of a patient's glycemic control when a personal CGM is not an affordable option. In addition, they can be used as a bridge until a patient is approved for a personal CGM. For more

information on CGMs in general, please refer to the continuing education available in the July/August 2021 issue of The Journal of the Pharmacy Society of Wisconsin.¹⁰

SSM Health Monroe Clinic is a rural health system located in southern Wisconsin, which consists of a 58-bed hospital and several multispecialty clinic practices. There are seven satellite branch clinics located throughout southern Wisconsin and northern Illinois. Ambulatory care pharmacists (pharmacotherapists) at the Monroe Clinic are uniquely positioned in the pharmacotherapy department to manage chronic disease states, including diabetes. This is achieved through broad scopes of practice and collaborative practice agreements (CPAs), allowing the pharmacotherapists to adjust medications, order labs, and follow up with the patients at their discretion.

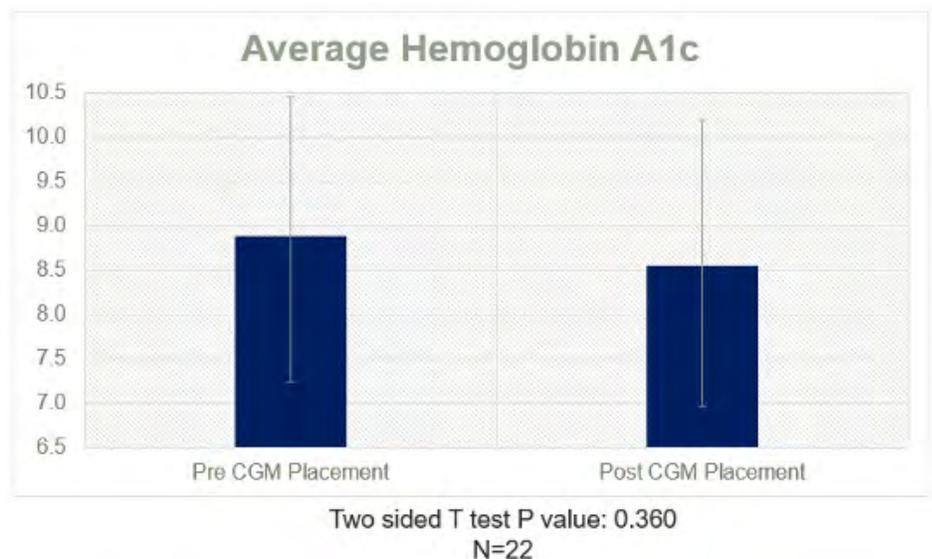
Methods

This is a retrospective, pre-post, cohort analysis conducted from September 1, 2020–February 28, 2021 at the SSM Health-Monroe Clinic pharmacotherapy department. This study was determined to be exempt from IRB review.

Outcomes

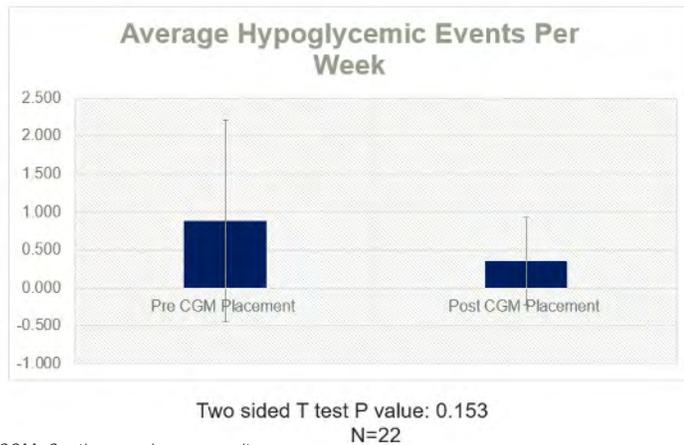
The objective of this project was to evaluate the clinical and economic impact of professional CGMs on the management of patients with type 2 diabetes by ambulatory

FIGURE 2. Change in Hemoglobin A1c



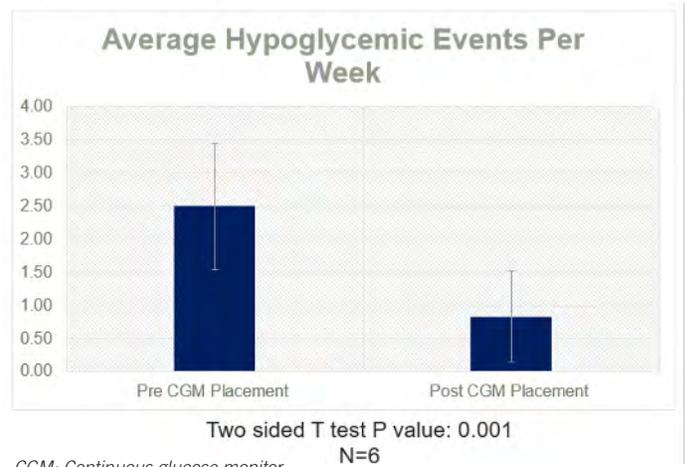
CGM: Continuous glucose monitor

FIGURE 3. Overall Change in Hypoglycemic Events



CGM: Continuous glucose monitor

FIGURE 4. Change in Hypoglycemic Events in Patients Experiencing Hypoglycemia



CGM: Continuous glucose monitor

care pharmacists. Clinical impact was measured through glycemic control and change in hypoglycemic events. Glycemic control was defined as the change in the most recent HbA1c prior to CGM placement, and the first HbA1c after CGM placement. The change in incidence of hypoglycemia was defined as any patient-reported episodes requiring treatment or self-monitored blood glucose of less than 70 mg/dL reported within a timeframe of 3 months prior to and 3 months post CGM placement. Paired t-tests were used to compare the change from baseline to post-intervention HbA1c and hypoglycemic events.

Data collection

Starting in September 2020, pharmacotherapists began offering FreeStyle Libre Pro CGM devices for professional use to patients with type 2 diabetes over the age of 18 years. A nurse-only encounter was scheduled for CGM placement by nursing staff, and a follow up appointment for CGM removal and data download by nursing staff was scheduled approximately 14 days later. Pharmacotherapists then met with patients to discuss CGM results and adjust antihyperglycemic therapy based on interpretation of the ambulatory glucose profile (AGP). Current Procedural Terminology (CPT) code 95250 was used within the EHR to bill for professional CGM placement.

All clinical data was extracted from patients' electronic medical records, while reimbursement data was provided by the Monroe Clinic's billing department. Insurance reimbursement to the healthcare

system was also collected and analyzed.

Results

Upon review of electronic medical records, 26 patients had a professional CGM placed within the 6-month study period. A total of 22 patients were included for analysis (Figure 1). The majority of the study population was female and had a mean age of 60 years, with most patients receiving supplemental insulin. (Table 1).

The primary outcome of glycemic control is summarized in Figure 2. The mean difference between pre- and post-intervention HbA1c was 0.3% ($p=0.360$). Overall, there was a decline in weekly hypoglycemic events (Figure 3). A subgroup analysis (Figure 4) was performed on six patients experiencing hypoglycemic events prior to CGM placement which showed a statistically significant decrease from 2.5 to 0.8 weekly events ($p=0.001$).

All CPT codes associated with the professional CGM placement were submitted by the pharmacotherapists. Reimbursement data for CPT code 95250 was available for all patients and the mean payment amount was $\$107.42 \pm \157.12 per patient, which was greater than CGM unit acquisition costs and encounter expenses.

Discussion

Adjustment of antihyperglycemic therapy was implemented in 21 of the 22 patients during the study period, demonstrating a mean decrease in HbA1c of 0.3%. While this was not a statistically significant difference, it did show clinical

improvement. More significantly, pharmacotherapists were able to use CGM data to make medication adjustments, which resulted in reducing hypoglycemic events by over 65%. Professional CGMs also created a new form of revenue for the department. This study supports that CGMs are a beneficial tool in patients with T2DM.

These documented medication interventions did not include lifestyle recommendations that were implemented as a result of professional CGM use. While not measured directly, patients were able to visualize how lifestyle habits, such as dietary choices or medication adherence, impacted blood glucose levels throughout the day when reviewing CGM reports with their pharmacotherapist. These variations in glycemic control that would have been otherwise undiscovered by intermittent SMBG values allowed patients to recognize the effects of positive and negative lifestyle habits and implement behavioral changes with the pharmacotherapist's guidance.

Patients with T2DM have become a substantial portion of patients seen in the pharmacotherapy department at SSM Health- Monroe Clinic. This number will continue to grow through the roll out of the Diabetes Center for Excellence. With this program, any patient who is referred to diabetes education with an HbA1c greater than 8 is automatically referred to the department and seen by a pharmacotherapist.

A limitation of this study was the small sample size and short timeframe. It is likely that all results would reach statistical

significance given more time and CGM placements.

Conclusion

A major barrier in clinical practice is motivating patients to perform SMBG at appropriate and consistent intervals that allow for effective adjustments to antidiabetic regimens. This gap in care has prompted the expansion of both professional and personal-use CGMs in clinical practice. Professional CGMs can provide a useful bridge for patients and providers to improve patient care and are covered under patients' insurance plans as a medical procedure. Overall, professional CGMs are a financially beneficial tool to guide medication adjustments for patients with T2DM to improve glycemic control.

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