Successful implementation of Continuous Glucose Monitoring in an Internal Medicine Residency Community Continuity Clinic.

Abstract: Diabetes mellitus (DM) is the leading cause of blindness, non-traumatic amputation, and end-stage renal disease in the US. Continuous Glucose Monitoring (CGM) is an advancement in diabetes technology that continuously and automatically tracks blood glucose throughout the day and night. When combined with proper education, follow-up, and support, CGM has proven effective at improving the management of insulin-dependent diabetics. Our study aims to implement CGM in a resident-run internal medicine clinic, not specialized in endocrinology, to improve the quality of care for diabetic patients using 3-4 insulin injections daily.

Methods: Twenty-five patients (n= 25) at our Internal Medicine Residency Clinic with Type-I or Type-II DM on at least 3-4 insulin injections were provided with a CGM Dexcom 6 device and assigned to a resident who assesses their glucose management and subsequently adjusts their treatment regimens on a biweekly basis after consultation with board Certified Endocrinologist. Data were collected from the Dexcom Clarity database and the clinic EHR to assess changes in the following endpoints before and after implementation of CGM: average Hba1c/glucose management indicator (GMI), blood glucose, the incidence of low blood glucose (55-70 mg/dL), the incidence of very low blood glucose (<54 mg/dL), percent time in range (70-180 mg/dL), and satisfaction measures on quality of life questionnaire.

Results: Average Hba1c/GMI was reduced to 7.04% from 11.21%, average blood glucose decreased to 158 mg/dL from 286 mg/dL, and incidence of low blood glucose < 70 mg/dl was reduced to 11-minutes per day from 1 hour and 14 min per day, the incidence of very low blood glucose less than 54 mg/dl was reduced to 3 minutes per day from 29 minutes per day, and time in range increased to 74% per day from 18%. A questionnaire given to patients after they started CGM also showed an improvement in their quality of life compared to self-monitoring blood glucose. Furthermore, 16% of the patients in this study eventually discontinued their insulin and controlled it with only perioral medications and an injectable once a week.

Conclusion: This study shows that CGM devices can be successfully utilized in a resident-run clinic to improve the management of diabetic patients administering insulin multiple times a day.

Comment [DNA1]: Type 1 diabetes

Comment [DNA2]: Oral anti-diabetic

Key Words: Diabetes Mellitus type 2, Continuous glucose monitoring (CGM), HbA1c, Self-Monitoring Blood Glucose (SMBG), Internal Medicine Residents, Board Certified Endocrinologist

Comment [DNA3]: community clinic

Introduction:

Over 34 million people in the USA have diabetes mellitus (DM). 90% of them are Type II, whereas 10% are Type I DM (1). The stress of managing diabetes can overwhelm individuals, resulting in inadequate effort and subpar results. DM is the leading cause of ESRD, non-traumatic extremity amputation, and blindness in the USA (1,2). From the time of diagnosis, patients with DM require a wealth of new knowledge to maintain a healthy lifestyle and avoid unintended complications. Appropriate management comprises a range of methods that assist in sustaining excellent outcomes

Comment [DNA4]: Type 2

One such modality that has emerged as one of the most significant parts of treatment is continuous glucose monitoring (CGM). Unlike traditional self-monitoring of blood glucose (SMBG), which only measures blood glucose at four points in time, CGM data can give a snapshot of blood glucose readings throughout 24 hours. Since DM is a chronic condition, managing it without CGM is equivalent to embarking on a long journey without a map. Compared to SMBG, CGM systems have become far more patient-friendly and preferred (1,2). SMBG does not provide a complete picture of blood glucose fluctuations, nor does it reveal daily, weekly, or monthly blood glucose trends, making diabetes management extremely challenging in the absence of a proactive approach (2,3,4,5,6). Thus, one of the most significant developments in diabetes medicine within the last 10 years is the adoption of the CGM. It is now considered the standard of treatment for individuals with type I and type II diabetes who receive numerous insulin injections daily (2).

Intensive glucose-lowering treatments to achieve or maintain glycemic goals can raise the risk of hypoglycemia (7,8,9). Continuous hypoglycemia has been shown to increase the risk of severe life-threatening hypoglycemia due to impaired glucose awareness (7,8,9). Compared to conventional self-monitoring of blood glucose (SMBG) measurements alone, both randomized and observational studies of early and more recent real-time CGM (RT-CGM) systems demonstrated improved glycemic control (ie, reduced glucose variability, hypoglycemia, severe hypoglycemia, fear of hypoglycemia, and even impaired hypoglycemia awareness). Frequent hypoglycemia in patients receiving multiple daily insulin injections is now an indication of CGM. The use of a standalone RT-CGM system has been associated with improved quality of life, psychological well-being, and cost-effectiveness. (10,11,12). Individuals with type-I and type-II diabetes (T2D) treated with MDI have shown a similar trend of glycemic improvement with RT-CGM compared to SMBG, which has been documented by several studies (10,11,12,13,14,15,16,17,18). Bailey and Yooalso showed that patients with type 2 diabetes mellitus with poorly controlled diseases had lower HbA1c levels (18,19).

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Given all this information, using CGM as opposed to SMBG is the most practical option for treating patients with type I and type II diabetes who require numerous daily insulin injections (3,4,5,6,7,8,9,10). Prescribing CGM and management of diabetes with CGM data is often linked to specialty providers and often not known to be done at a primary care level. The present study

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the aim was to show that the use of CGM could be implemented successfully in a resident-run clinic with proper guidance.

Methods:

A longitudinal retrospective study was conducted for twenty-five (n = 25) patients between 42 and 75 years of age with uncontrolled diabetes recruited by a team of internal medicine residents, transitional year residents, and a board-certified endocrinologist at the internal medicine resident clinic at MountainView Hospital in Las Vegas, Nevada. The patients had either Type 1 DM (15%) or Type 2 DM (85%). At the time of recruitment, all patients were using 3-4 injections of insulin a day in addition to oral antidiabetic medications or GLP1-RAG. Patients were self-monitoring their blood glucose at least four times a day. All subjects were current patients at the resident clinic and were given information regarding CGM if they met the inclusion criteria for the study. Patients who expressed an interest in CGM instead of self-monitoring blood glucose (SMBG) signed a consent form for implementation of CGM, which explained the usage of CGM and the possible risks and benefits of participation in our study. No coercion or forceful behavior was used to convince patients to sign the form. The decision to use CGM and participate in the study was entirely voluntary, and patients could leave the study at any point.

In the clinic, diabetic patients were given pamphlets describing how to adjust their insulin at home. They were also counseled about diet and exercise and provided a pamphlet containing different foods and meals' carbohydrate and caloric content. Patients needed to show understanding of the procedure and teach back this understanding before implementation of CGM. The CGM Dexcom G6 device was used in our study due to the availability of the device, the availability of technical team support, and the device not requiring calibration. The data was collected from the CGM Dexcom database through the Dexcom G6 Clarity database and the clinic EHR. Patients with device-compatible iPhones or Android phones were given a share code by the CGM team so that the research team could monitor their blood glucose data continuously. Patients who did not have compatible phones were given a receiver and were seen at the clinic at least once a month. Patients' data were downloaded at the clinic visit so that their insulin regimen could be adjusted appropriately, and additional data could be collected for the study. All patients were seen at least once a month at the internal medicine residency clinic. They were also contacted by a member of the CGM team biweekly, and their insulin regimens were adjusted based on their blood glucose readings with the help of our board-certified endocrinologist.

Inclusion Criteria	Exclusion Criteria
Patients ages 18-80 years old	Patients who were non-compliant with dietary and exercise recommendations
Patients with the diagnosis of Type - I or - II Diabetes Mellitus	Patients are unable to understand the instructions for the titration of insulin

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Patients with HbA1c > 7%	Patient's wearing their CGM device <70% of the time
Patients with uncontrolled blood glucose levels while using SMBG for equal or greater than four times daily	Patients with impaired decision-making capacity
Patients receive their primary care only at the IM Resident Clinic at MountainView Hospital	Patients missing >2 scheduled visits
Patients can use a CGM device	Patients who are pregnant or incarcerated
Patients on 3-4 injections of insulin +/- oral medications	Patients unresponsive to calls from the clinic
The patient can adjust their insulin based on the CGM data	Patients whose insurance did not cover the CGM device

Table 1: Inclusion and Exclusion Criteria

Data Evaluated:
Mean A1c/GMI before and after CGM
Avg Blood Glucose
Percentage of TIR before/after CGM
Percentage of Mild Hypoglycemia (blood glucose 55-70 mg/dl)
Percentage of Severe Hypoglycemia (blood glucose <54 mg/dl)
Patients' Medications
Quality of Life Questionnaire

Table 2: Data of Study

Results:

A total of 25 patients were included in this study. They were divided into DM2 (85%) or DM1 (5%). All the subjects did SMBG 3-4 times daily before starting the CGM. The patients were between 42-75 years of age. The mean HbA1c recorded before the switch from SMBG to CGM was 11.21%. After starting the CGM, the patient's Average HbA1c/GMI improved to 7.04%. Similar effects were also noted in the average blood glucose, the number of hypoglycemic

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Comment [DNA11]: Type 2 DM

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events, and time in range. The average blood glucose decreased from 286 mg/dl to 158 mg/dl by switching from SMBG to CGM. (Figure 2) Before CGM, the patients had 1-3 on average daily episodes of mild hypoglycemia lasting 1 hour and 14 min per day (4.75%) and around one pronounced hypoglycemia per day lasting 29 min (3.01%). After the Dexcom G6 was inserted, there was less than one mild hypoglycemic episode per day lasting on average 11- minutes (0.78%) and less than one more pronounced hypoglycemic episode per day lasting 3 minutes (0.2%). (see Figures 3 and 4) This study meets the ADA goal for the percentage of mild hypoglycemia episodes to be less than 4% and severe hypoglycemia episodes to be less than 1% per day.

Time in range (TIR) of blood glucose ranging from 70-180 mg/dl per day improved from 18% on SMBG to 74% on CGM, surpassing the goal of 70%. The coefficient of variation before the switch to CGM was 39%, and after the introduction of CGM decreased to 29%, with the goal below 36%. (Table 4) Four of the patients with type DM type- 2 (16%) stopped their Rapid Acting Insulin before meals and could control their Diabetes mellitus type- 2 only with oral anti-diabetic medications and/or injectable weekly GLP-1 RAG after switching from SMBG to CGM.

Patient satisfaction was found to be improved after CGM was implemented, likely due to their being better glycemic control through healthier lifestyles and improved physical activity. (Figure 5)

	Before CGM Device insertion	After CGM Device insertion
Patients' Average HbA1c/GMI	11.21%	7.04%

Table 3: CGM device Impact on A1c

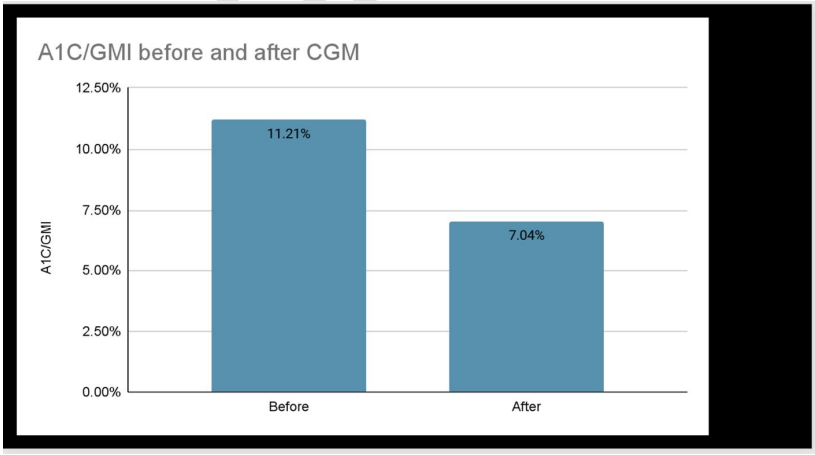

Figure 1: Reduction of Alc following the implementation of CGM Dexcom G6 Device

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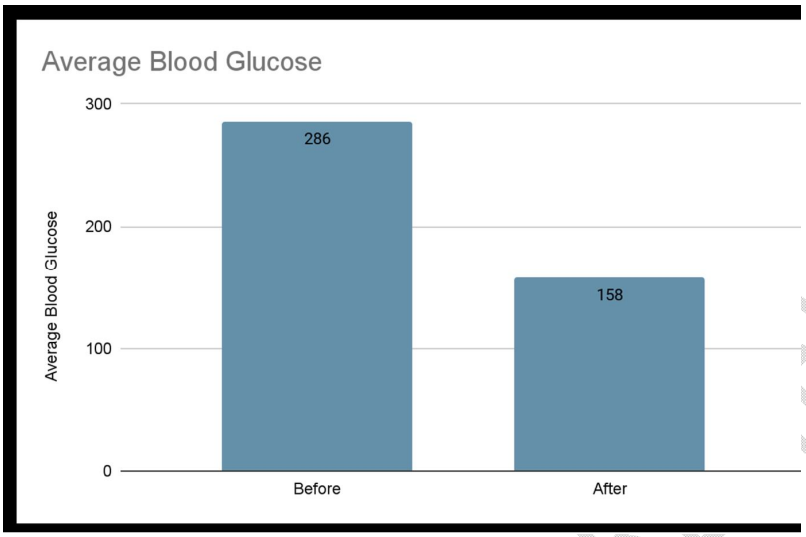

Figure 2: Reduction of Average Blood Glucose Following CGM

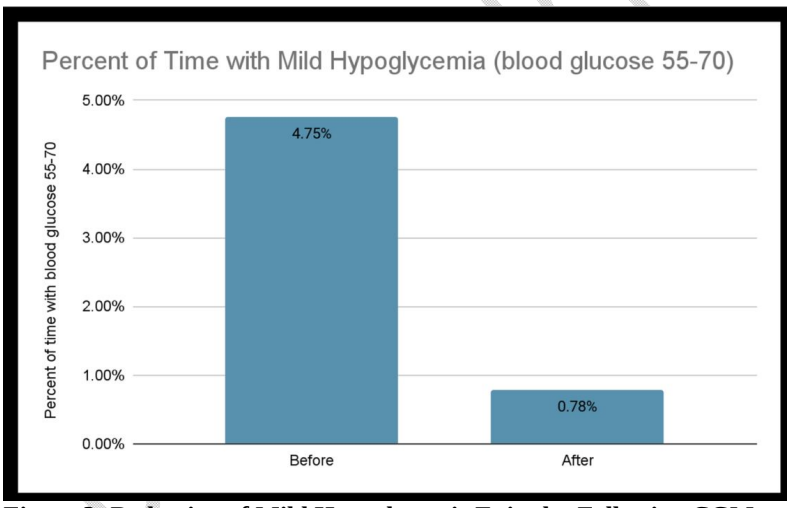

Figure 3: Reduction of Mild Hypoglycemic Episodes Following CGM

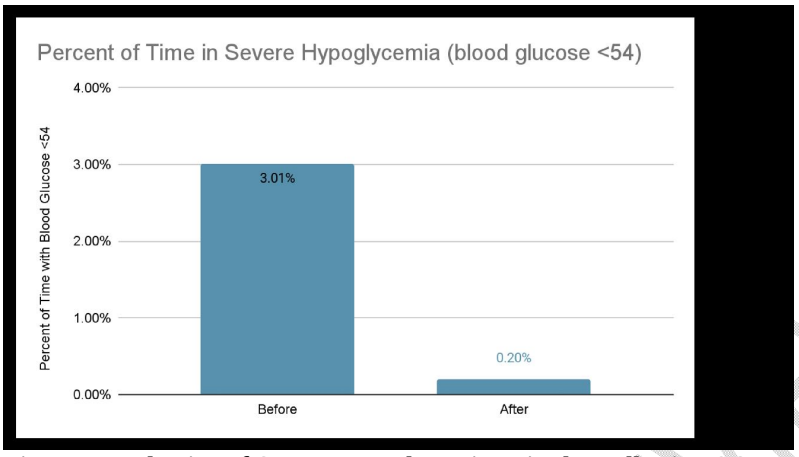

Figure 4: Reduction of Severe Hypoglycemic Episodes Following CGM

Table 4: TIR of blood glucose

	SMBG	CGM
Time In Range*	18%	74%
Coefficient of Variation*	39%	29%

Table 4: TIR of blood glucose (* indicates areas that have met objective goals)

CGM Quality of life Questionnaire Pre and Post CGM

	Pre-CGM	Post-CGM
Diabetes control	Poor	Improved
Physical activity	Poor	Improved
Healthier Lifestyle	Poor	Improved

Figure 5: Patient Questionnaire Pre and Post CGM

Discussion:

Technological advancements have significantly impacted diabetes management over the past decade, particularly with the use of continuous glucose monitoring (CGM) devices. These devices are now more compact and accessible through a wider range of insurance plans. Studies conducted on patients with type 1 diabetes mellitus (T1DM) have indicated that using CGM devices resulted in a significant reduction in patients' HbA1c levels compared to self-monitoring of blood glucose [7-9]. Both randomized and observational studies have shown that real-time CGM systems lead to better glucose control, as measured by time in range (TIR), reduced glucose variability as measured by the coefficient of variation (CV), and a reduction in both hyperglycemia and hypoglycemia for individuals with type 1 and insulin-requiring type 2 diabetes who receive multiple insulin injections daily [7-11].

The Glycemic Management Indicator (GMI), which is derived from average glucose readings, provides an estimation of HbA1c levels that is less susceptible to interference from conditions such as anemia, chronic kidney disease, polycythemia, and liver cirrhosis [11]. The American Diabetes Association (ADA) recommends using CGM for blood glucose control [12,13]. The goal is to maintain a TIR between 70 and 180 mg/dL, which should account for 70% of the time, except for older or pregnant patients. Studies have demonstrated a correlation between TIR and the development of microvascular complications, such as retinopathy and diabetic nephropathy, as indicated by microalbuminuria in patients with diabetes mellitus [14].

CGM devices have proven to be valuable tools for 24-hour blood glucose monitoring, leading to improvements in average HbA1c levels by 0.3-0.6% and a decrease in the incidence of hypoglycemia in insulin-dependent patients [15,16]. Furthermore, compared to traditional self-monitoring of blood glucose (SMBG) using fingerstick daily, CGM devices have significantly improved patient satisfaction. Real-time glucose monitoring via CGM devices has resulted in patients improving their eating patterns, physical activity, and overall quality of life [17-21].

Our study found that switching from self-monitoring of blood glucose (SMBG) to continuous glucose monitoring (CGM) significantly improved the health outcomes of 25 patients with type 1 or type 2 diabetes. We observed significant improvements in HbA1c levels, blood glucose levels, number of hypoglycemic events, time in range, and patient satisfaction. The average HbA1c reduction was from 11.21% to 7.04%, and the average blood glucose decreased from 286 mg/dl to 158 mg/dl, achieving a TIR of 74%, which is in line with recommended guidelines. Our findings suggest that using CGM instead of SMBG methods can lead to better glycemic control, fewer side effects, and lifestyle improvements. Additionally, four type 2 diabetes patients could transition to only oral anti-diabetic medications or GLP-1 RAG after switching to CGM from SMBG. Furthermore, we were able to successfully implement CGM in a continuity clinic managed by residents and supervised by a board-certified endocrinologist, indicating the potential for widespread adoption of this approach, which may provide educational benefits for future healthcare providers.

Conclusions:

This longitudinal study shows the significance of CGM in the management of both type 1 and type 2 diabetes mellitus. By providing real-time glucose data and trends, CGM enables patients and physicians to make informed decisions about their diet, exercise, and medication regimens, ultimately leading to better health outcomes. In addition, the data collected through CGM can help healthcare providers personalize treatment plans and make necessary adjustments.

The successful implementation of CGM in a residency clinic under the supervision of a board-certified endocrinologist offers a promising model for other residency programs to follow, not only improving patient care but also providing valuable educational opportunities for future healthcare providers. By utilizing CGM-guided diabetes management, healthcare providers can play a significant role in improving the management of this disease. Funding from the US government for similar pilot programs would be valuable in validating this approach and expanding its implementation in residency clinics. Further, randomized controlled studies and research with larger sample sizes are needed to fully assess the potential of CGM-guided treatment of diabetes mellitus.

Disclaimer: This research was supported (in whole or part) by HCA Healthcare and/or an HCA Healthcare-affiliated entity. The views expressed in this publication represent those of the authors and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities. The information provided in this case series is based on the results obtained from patients using the Dexcom 6 continuous glucose monitoring (CGM) device. Our study does not evaluate the efficacy of other similar CGM devices and does not endorse the use of a particular CGM device. Further research is necessary to understand CGM devices' use and effectiveness fully. The results of this evaluation should not be used to make any medical decisions and should be considered in conjunction with professional medical advice.

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