

Can Continuous Glucose Monitoring be Successful in Managing Diabetes Mellitus in the General Internal Medicine Residency Clinic

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Abstract

Objectives: This 4-year retrospective extension study aimed to determine whether continuous glucose monitoring (CGM) can be safely implemented in an Internal Medicine Residency Clinic, not just in a specialized Endocrine Clinic, for managing Diabetes Mellitus Type 1 and Type 2 in patients who used 3-4 insulin injections daily and self-monitored blood glucose (SMBG) four times a day. We extended the study by an additional year to increase the sample size and statistical power and to assess whether longer-term CGM use would result in a sustained reduction in HbA1c, which also serves as a glucose management indicator. This was applicable to the original 51 patients we followed for three years, and now the study has been extended for one more year. We added 40 more patients and followed them for an additional year. An additional parameter was the reduction of the glucose management indicator (GMI), which had been used interchangeably with HbA1c during the first four months after introducing CGM, compared to the final GMI reduction at four years. In total, we monitored 91 patients. Our internal medicine and transitional year residents transitioned patients from SMBG to CGM devices to monitor blood glucose levels due to uncontrolled diabetes. They performed these duties under the supervision of a board-certified endocrinologist who was part of the clinic. Patients were continuously monitored by sharing their 24-hour glucose data with our clinic. Each patient was assigned to specific resident, who our endocrinologist initially trained to interpret CGM data and adjust insulin treatment accordingly. The residents maintained contact with their assigned patients via phone every two weeks and made treatment adjustments as needed. Patients also visited the clinic every two months for follow-up with members of the CGM team. The CGM team consulted with the endocrinologist whenever necessary to ensure optimal management of patients' diabetes.

Keywords: Diabetes Mellitus Type and Type; Continuous Glucose Monitoring (CGM); HbA1c; Self-Monitoring Blood (SMBG); Glucose Management Indicator (GMI); Internal Medicine Residency Clinic; Board Certified Endocrinologist

1. Introduction

Diabetes Mellitus (DM) is a chronic condition that presents significant challenges in management, especially in patients who need multiple daily insulin injections. Achieving optimal glucose control is essential to prevent long-term complications of the disease. Traditional glucose monitoring depends on self-monitored blood glucose (SMBG), which provides occasional snapshots of blood glucose levels but may miss critical fluctuations, including episodes of hypoglycemia or hyperglycemia. Continuous glucose monitoring (CGM) has become a revolutionary tool in diabetes care, providing real-time data on glucose trends and allowing patients and healthcare providers to make better-informed decisions about insulin dosing and lifestyle changes [1,2]. It also serves as a motivational tool for patients to adhere to their treatment and improve their glucose control [3].

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The benefits of CGM are well-documented in specialized endocrine clinics, showing improvements in glycemic control, time in range (TIR), the Glucose Management Indicator (GMI), estimated by the CGM HbA1c, and reductions in hypoglycemic episodes [4,5,6,7]. GMI and HbA1c are used interchangeably in patients who monitor their blood glucose with CGM. However, the integration of CGM into general internal medicine residency clinics remains underexplored. Given the rising prevalence of diabetes and the need to optimize its management across various healthcare settings, there is an urgent need to assess the feasibility and effectiveness of CGM in internal medicine clinics.

This study builds on a previous investigation that was conducted in an internal medicine residency clinic, where CGM use resulted in improvements in TIR, average blood glucose, and hypoglycemia [8]. The previous study included 51 patients monitored by CGM for 3 years. To show the sustainability of using CGM and improvement of TIR, GMI, average blood glucose, and hypoglycemia over time and enhance the strength of these findings, an additional year of data was retrospectively collected to extend this study of the 51 patients. We added 40 patients using CGM followed for one year, increasing the sample size to 91 patients with uncontrolled diabetes on intensive insulin regimens. The primary aim was to determine whether CGM, managed by internal medicine and transitional year residents under endocrinologist supervision, could safely and effectively improve glycemic outcomes in non-specialist settings, which is sustainable over a longer period of time. We have enough data in specialized clinics, but as far as we know, this is the first study in an Internal medicine Clinic. Additionally, we assessed the impact of CGM on HbA1c(GMI), TIR, average blood glucose levels, and the incidence of hypoglycemia.

This study not only assesses the effectiveness of CGM in improving blood sugar control in internal medicine residency clinics but also helps lower the risk of side effects from antidiabetic drugs like insulin. CGM data enables us to monitor blood sugar levels throughout the day, giving us insight into when a patient's glucose levels are high, in range, or low. This supports better management and allows us to tailor insulin regimens for each patient.

2. Study Design and Methods

A 4-year retrospective study was conducted using data from 91 adult patients aged 18–90 years with uncontrolled DM at an internal medicine residency primary care clinic. Of these, 51 patients were followed for four years, and 40 for one year. The participants included those diagnosed with uncontrolled Type 1 or Type 2 DM who met the inclusion and exclusion criteria (Table 1). The primary goal was to evaluate the feasibility and effectiveness of implementing CGM in this setting, under the supervision of a board-certified endocrinologist, to assess its impact on diabetes management. Specifically, the study aimed to determine whether switching from SMBG to CGM could improve diabetes control by lowering Hemoglobin A1c, reducing average blood sugar levels, increasing TIR, and decreasing both mild and more severe hypoglycemia through continuous data monitoring and timely interventions by internal medicine and transitional year residents. Hypoglycemia was measured by two variables: mild (glucose between 54-70 mg/dl) and severe hypoglycemia (glucose < 54 mg/dl). Severe hypoglycemia is life-threatening and requires an immediate and significant reduction in insulin dosage.

During the transition from SMBG to CGM, all patients were on a regimen of 3-4 daily insulin injections, with or without oral antidiabetic medications and/or GLP-1 receptor agonists. Participation in using a CGM device was voluntary, based on patient preference and insurance coverage, and patients were informed about its use. Those who met the inclusion criteria were offered the device as part of standard clinical practice.

As part of the study, patients received written instructions on insulin adjustment based on CGM data and counseling on diet and exercise. A pamphlet with information on the carbohydrate and caloric content of various foods was also provided. Before implementation, patients demonstrated their understanding of the CGM process through a "teach-back" method with the CGM team.

The Dexcom G6, G7, and FreeStyle Libre 3 devices were chosen for their accuracy, ease of use (no calibration needed), and availability of technical support. Data were collected from the Dexcom Clarity and FreeStyle Libre databases, as well as the clinic's electronic health records (EHR). Patients with compatible iPhones or Android phones received a share code for continuous monitoring, while those without compatible devices were given a receiver. Participants visited the clinic every two months for glucose data downloads, insulin regimen adjustments, and additional monitoring if using the receiver. Additionally, every two weeks, a CGM team member contacted patients to further adjust insulin doses, with oversight by an endocrinologist.

Table 1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Patients aged 18-90 years	Patients unable to understand instructions for insulin titration based on CGM data
Patients diagnosed with Type 1 or Type 2 Diabetes Mellitus	Patients wearing the CGM device less than 70% of the time
Patients with an HbA1c > 7% who are receiving primary care at the internal medicine residency clinic	Patients with impaired decision-making capacity
Patients using SMBG 4 or more times daily with uncontrolled blood glucose levels	Patients receiving primary care only at the internal medicine residency clinic
Patients who can use a CGM device	Patients missing more than 2 scheduled visits
Patients on 3-4 daily insulin injections with or without oral antidiabetic medications	Pregnant or incarcerated patients
Patients able to adjust insulin based on CGM data	Patients unresponsive to clinic contact
	Patients whose insurance does not cover the CGM device

3. Results

A paired-sample t-test was used to determine whether there was a statistically significant mean difference between A1c levels taken before and after the introduction of CGM with the support of residents. Two outliers were detected, each more than 1.5 box lengths from the edge of the box in a box plot. Inspection of their values did not reveal them to be extreme, and they were kept in the analysis. Visual inspection of QQ plots indicated the assumption of normality was not violated. Similarly, as assessed by Shapiro-Wilk's test, the post-data did not violate the assumption of normality ($p = .063$), but the pre-intervention data did ($p = .003$). However, given that t-tests are robust to non-normality, we proceeded with the analysis. Utilizing Levene's Test, variances were shown to be equal between the pre-and post-intervention timeframes ($p = .07$). Participants A1c levels prior to the intervention were higher ($M = 10.29$, $SD = 2.22$) compared to A1c levels taken after ($M = 7.04$, $SD = 1.11$), a statistically significant mean decreases of 3.24, 95% CI [-3.66, -2.76], $t(91) = -14.189$, $p < .001$, $d = 1.94$.

3.1. Blood Glucose Results

A paired-sample t-test was conducted to assess whether there was a statistically significant mean difference between BG levels measured before and after the implementation of CGM supported by residents. Two outliers were identified, each exceeding 1.5 times the interquartile range from the box in a box plot. Examination of their values did not suggest they were extreme, so they were included in the analysis. Visual inspection of QQ plots indicated that the normality assumption was not violated. A Shapiro-Wilk test showed that the post- and pre-intervention data did violate the normality assumption ($p = .018$ & $p = .003$, respectively). However, because t-tests are generally robust to violations of normality, we continued with the analysis. Levene's Test showed equal variances between the pre- and post-intervention periods ($p = .07$). Participants' BG levels before the intervention were higher ($M = 247.72$, $SD = 63.81$) than after ($M = 158.10$, $SD = 27.27$), with a significant mean decrease of 89.62, 95% CI [-102.76, -76.48], $t(91) = -13.547$, $p < .001$, $d = 1.83$.

3.2. Time in Range Results

A paired-sample t-test was used to determine whether there was a statistically significant mean difference between TIR taken before and after the introduction of CGM, supported by residents. One outlier was detected, located more than 1.5 box lengths from the edge of the box in a box plot. Inspection of this value did not reveal it to be extreme, and it was kept in the analysis. Visual inspection of QQ plots indicated that the assumption of normality was not violated. However, a Shapiro-Wilk test revealed that the post- and pre-intervention data violated the assumption of normality ($p < .001$ & $p < .001$, respectively). Nonetheless, since t-tests are robust to non-normality, we proceeded with the analysis. Using Levene's Test, variances were shown to be equal between the pre- and post-intervention periods ($p = .07$). Participants' TIR before the intervention was lower ($M = 17.70$, $SD = 21.11$) compared to TIR after the intervention ($M = 62.74$, $SD = 27.70$), with a statistically significant mean increase of 45.05, 95% CI [37.49, 52.60], $t(91) = 11.84$, $p < .001$, $d = 1.83$.

3.3. Mild Hypoglycemia Results

An exact sign test was performed to assess the difference in Mild Hypoglycemia levels before and after the intervention. Among the 92 participants, 81 experienced a decrease in Mild Hypoglycemia following the intervention. Nine participants showed a positive difference, while two showed no change; however, these two participants had zero Mild Hypoglycemia both before and after the intervention. There was a statistically significant median decrease in Mild Hypoglycemia (Mdn = -0.04) compared to their pre-intervention levels (Mdn = .04) and post-intervention levels (Mdn = .00), $p < .001$.

3.4. Pronounced Hypoglycemia Results

Similarly, an exact sign test was performed to assess the difference in Pronounced Hypoglycemia before and after the intervention. Of the 92 participants in the study, the intervention resulted in a decrease in Pronounced Hypoglycemia in 65 patients compared to pre-intervention levels. Six patients showed a positive difference, while 21 patients showed no change; however, these 21 patients had zero Pronounced Hypoglycemia both before and after the intervention. There was a statistically significant median decrease in Pronounced Hypoglycemia (Mdn = -0.01) when comparing participants' pre-intervention levels (Mdn = .01) to their post-intervention levels (Mdn = .00), $p < .001$.

4. Discussion

Glucose monitoring has been a vital part of managing both Type 1 diabetes (T1D) and Type 2 diabetes (T2D), with continuous glucose monitoring (CGM) serving as one of the main methods. CGM functions as a guide, providing healthcare providers with metrics such as time in range (TIR), time in hypoglycemia, and blood glucose variability. To summarize the findings, the average reduction in HbA1c (GMI) was 3.24%, the mean blood sugar levels decreased by 89 mg/dL, and the mean time in range (TIR) increased by 45%.

Analysis of our results showed that there was not only a significant improvement in A1c, TIR levels, and average glucose levels, but also a statistically significant decrease in hypoglycemic adverse events in our patients on CGM compared to SMBG. All these findings over time demonstrated the sustainability of using CGM in an internal medicine residency clinic.

T1D and T2D management have advanced significantly in the medical field. The role of continuous glucose monitoring (CGM) in both types of diabetes is well-established for improving glycemic control and reducing hypoglycemia. With CGM, patients gain greater awareness of their glucose levels because they can self-monitor at any time. This enables patients to implement lifestyle changes effectively. Through self-knowledge of their condition, patients using CGM tend to achieve better outcomes through lifestyle modifications, such as increased physical activity, weight loss, and adherence to diet plans, compared to those using self-monitoring blood glucose (SMBG) [9,10]. CGM has demonstrated positive effects in improving glycemic control among senior patients by reducing the incidence of hypoglycemia [11]. Additionally, CGM is cost-effective and improves time in range (TIR) [12,13,14]. Recent studies have also shown that increased TIR correlates with a reduction in diabetes-related complications [15]. Conversely, decreased TIR has been associated with higher odds of developing diabetic retinopathy in patients with type 1 diabetes [16].

Patients with diabetes are at risk of experiencing hypoglycemic episodes because of multiple insulin injections throughout the day. CGM is a device that monitors blood glucose levels, alerting users when they enter a hypoglycemic state, unlike SMBG. Additionally, CGM enables physicians to better manage diabetes to prevent further hypoglycemic episodes [11].

CGM detects around 56.9% of hypoglycemic episodes compared to only 26.4% in SMBG [10]. Given this, physicians and patients can intervene and prevent further hypoglycemic episodes.

The study had several limitations. Since this is a retrospective observational study, we were unable to adjust for confounding variables such as lifestyle modifications (diet and exercise), co-morbid conditions that can affect A1c readings (CKD, anemia – described below), those with other causes contributing to hyperglycemia (steroid use, Cushing's disease), the duration and type of diabetes mellitus.

The patients' adherence to diet and lifestyle interventions varied, with follow-up lasting up to 4 years for 51 of them. All patients in the clinic receive counseling on the standard diabetic diet for patients with Diabetes Mellitus who are on insulin and exercise. Not all patients adhered to these recommendations to the same extent, which may confound our results. Those with better compliance to diet and exercise likely have better A1c and blood sugar levels than those with poorer adherence.

The study was conducted in only one clinic, which may hinder the generalizability of our data to a larger population. Around 6% of the patients had anemia of inflammation, 10% had chronic kidney disease (CKD) stage-3A, and 2% had CKD-4. These conditions may have influenced the measured HbA1c before the start of the CGM while patients were still using the SMBG technique. Although we still used A1c in our analysis, other data provided by the CGM, including average blood sugar levels and TIR levels, are less likely to be influenced by the above co-morbidities and can give us a more accurate understanding of blood sugar control in these individuals.

The strength of the study was the use of CGM in an Internal Medicine Residency Primary Care Clinic. It involved managing the most difficult-to-control patients with DM by internal medicine and transitional year residents after receiving appropriate education and supervision from endocrinologists. The endocrinologists also participated in patient follow-up and helped the medical residents manage the CGM data. This use of CGM not only improved the quality of care for diabetic patients but also reduced the incidence of hypoglycemic adverse events. Another strength of the study is demonstrating the sustainability of improved glucose control with CGM over a longer period compared to our previous studies.

Although not examined in this research article, CGM usage in resident clinics may enhance residents' familiarity with the most advanced technology used in DM management and encourage the adoption of this tool in their future clinical practice. Further prospective studies are necessary to assess how using CGM in residency clinics affects residents' familiarity and their future use of this tool as primary care physicians. These studies will help confirm our findings.

As far as we know, this is the first study using CGM in an Internal Medicine Residency clinic, and future research will examine its role in enhancing the education of medical residents. Our results showed a significant improvement in HbA1c levels compared to patients treated in specialized settings. This was because our patients initially had less controlled diabetes than those in specialized endocrine clinics. The HbA1c improvement in endocrine clinics was around 0.5-0.6%, which is lower than in our patient group, likely due to selection bias. Patients in endocrine clinics were much better controlled from the start compared to our community patients. This created a larger opportunity for improvement in their HbA1c levels. Additionally, we demonstrated sustainable glucose control with CGM over an extended period.

The results showed that internal medicine and transitional year residents can provide and manage CGM for T1D and T2D patients, with improvements seen in HbA1c, average blood glucose, TIR, and a reduction in hypoglycemic episodes compared to SMBG. CGM offers the tools necessary for patients to manage their glucose safely and effectively. The findings also indicate that this can be implemented in an internal resident's continuity clinic, which may enhance medical residents' education. Future prospective trials can further explore these outcomes.

5. Conclusion

This extension of our previous study reaffirms, in this larger group of patients, the role of CGM in managing DM within internal medicine residency clinics. The significant improvements in glycemic control, hypoglycemia reduction, and TIR demonstrate the feasibility of implementing CGM not only in specialist settings. The improvement of glucose control using CGM was sustained over a longer period of time. Moreover, the study highlights the potential of CGM to enhance medical residents' education, a potential that larger prospective trials will further determine. Expanding CGM usage across residency programs in the US could elevate the standard of diabetes care nationwide.

Compliance with ethical standards

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Disclosure of conflict of interest

None to be disclosed for any of the authors.

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The information provided in this research 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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