World Journal of Advanced Research and Reviews
eISSN: 2581-9615 CODEN (USA): WJARAI
Cross Ref DOI: 10.30574/wjarr
Journal homepage: https://wjarr.com/

(RESEARCH ARTICLE)

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The Impact of remote Continuous glucose monitoring and Insulin management performed by resident physicians under the supervision of endocrinologists on serum HbA1c

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World Journal of Advanced Research and Reviews, 2025, 27(03), 1947-1951

Publication history: Received on 20 August 2025; revised on 25 September 2025; accepted on 29 September 2025

Article DOI: https://doi.org/10.30574/wjarr.2025.27.3.3344

Abstract

In our article, we describe what we believe to be the first prospective trial in the USA evaluating the impact of continuous glucose monitoring (CGM) and insulin management performed by resident physicians under the supervision of an endocrinologist on serum HbA1c. We have previously published our experience with a retrospective, cohort observational study, and now we aim to validate our concept through a prospective trial. The study aims to demonstrate that, with appropriate education and supervision by an endocrinologist, internal medicine residents in both specialized endocrinology and general internal medicine clinics can effectively interpret CGM data and improve patients' HbA1c levels by adjusting their treatment. We plan to recruit patients with Type 1 and Type 2 diabetes who are using 3-4 insulin injections per day, possibly combined with other antidiabetic medications, and who self-monitor their blood glucose (SMBG) at least four times daily. These patients typically have poor glycemic control, with HbA1c levels ranging from 7.5% to over 14%. The goal is to show that switching from SMBG to CGM, with residents monitoring and adjusting insulin doses, leads to improvements in HbA1c, time in range (TIR), hypoglycemia frequency, average blood glucose levels, hyperglycemia, and patient satisfaction with the CGM device. Ultimately, we aim to demonstrate that CGM can be safely integrated as a management tool in general internal medicine residency clinics across the USA, incorporated into the internal medicine residency curriculum, and help improve diabetes care and education for internal medicine residents.

Keywords: Continuous Glucose Monitoring (CGM); Hba1c; GMI; Self-Monitoring of Blood Glucose (SMBG); Internal Medicine Residents; And Endocrinologists

1. Introduction

Diabetes Mellitus (DM) is a leading cause of illness and death worldwide, with poor blood sugar control leading to long-term microvascular, macrovascular, and metabolic complications. Continuous glucose monitoring (CGM) has revolutionized diabetes management by providing real-time glucose data, enabling patients and healthcare providers to identify patterns, track trends, and tailor treatments through continuous blood glucose monitoring—unlike the traditional method of four daily self-monitoring blood glucose (SMBG) measurements. The intensive use of glucose control with CGM impacts macrovascular complications of DM. CGMs offer valuable information, including the Glucose Management Indicator (GMI), which estimates HbA1c and the percentage of time the patient's blood glucose remains within the range of 70-180 mg/dL, above 180 mg/dL, or below 70 mg/dL. Past studies have shown that CGM effectively improves glycemic control, and intensive glucose management in type 2 DM reduces macrovascular complications [1-2].

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However, limited prospective evidence exists on whether resident physicians in Internal Medicine residency clinics can successfully implement structured, clinician-guided review of CGM data and corresponding insulin adjustments.

In Manov et al. [3], a retrospective study confirmed the effectiveness of CGM in managing uncontrolled Diabetes Mellitus in patients with DM at an internal medicine residency clinic. This is an essential tool for improving glucose control in the most difficult-to-treat patients with DM.

Additionally, CGM has recently been studied as a method to prevent DM type 2 in prediabetic patients and to assess how different types of food affect blood sugar levels in individual patients.

The benefits of CGM are well-documented in Jan apala et al. [4], a systematic review and meta-analysis of patients with type 2 DM. CGM, when compared to SMBG in multiple studies, shows improvements in glycemic control, time in range (TIR), and the GMI estimated by CGM, along with reductions in hypoglycemic episodes initially in patients with type 1 and type 2 DM.

However, integrating CGM into general Internal Medicine residency clinics remains underexplored. With the rising prevalence of diabetes and the need to enhance its management across various healthcare settings, it is essential to evaluate the feasibility and effectiveness of CGM in Internal Medicine clinics and to consider its potential as a tool for improving Internal Medicine residents' education. Clinical targets for CGM interpretation are based on the international consensus on time in range.

Our prospective study aims to determine whether insulin-treated patients on multiple daily injections who use SMBG and have uncontrolled DM can be effectively managed, resulting in improved DM control after implementing CGM in our outpatient Internal Medicine residency clinic. This project was mainly designed for Internal Medicine Residents to focus on insulin management and other diabetic care tasks, utilizing CGM data after patient education and consultation with an endocrinologist who is part of the clinic.

This study builds on a previous retrospective trial conducted at an Internal Medicine residency clinic, where the use of CGM improved TIR, average blood glucose levels, and hypoglycemia. Earlier studies involving patients with Type 1 and Type 2 DM showed better glucose control with CGM.

The current study will follow consensus guidelines for managing DM with CGM, focusing specifically on TIR, which is associated with diabetic eye complications. The primary aim is to determine whether CGM, overseen by Internal Medicine residents under an endocrinologist's supervision, can safely and effectively improve glycemic outcomes in non-specialist settings, this time through a prospective trial rather than a retrospective one.

2. Study Design and Methods

Eligible patients (Table 1) using CGM devices, including Dexcom G6, G7, or Freestyle Libre 3 systems, will be recruited during routine clinic visits and asked to provide consent for enrollment. Once enrolled, participants will complete a baseline HbA1c test and the CGM-Satisfaction (CGM-SAT) survey. These patients will have uncontrolled diabetes mellitus with HbA1c levels ranging from 7.5% to over 14%, are on multiple daily insulin injections (3-4), and may be taking other antidiabetic medications. They should have also performed self-monitoring of blood glucose (SMBG) at least 4 times a day prior to switching to the CGM device. Patients will receive education on diet, exercise, and medication adjustments, and will be transitioned to CGM in the clinic. Data will be shared from Dexcom Clarity or Free Style Libre databases with the clinic for 24 months. Participants will receive bi-weekly calls from a CGM team member to review diabetes management over the past 14 days based on CGM data. They will also attend bi-monthly clinic follow-ups, which include HbA1c testing and medication adjustments guided by CGM data monitored through Dexcom Clarity or Free Style Libre portals. At baseline and every six months, participants will complete the CGM-SAT survey. Residents will be supervised by endocrinologists on how to interpret CGM data and receive recommendations for insulin regimen adjustments during bi-weekly calls. Additionally, quantitative and qualitative data on patient adherence and glucose control will be recorded and analyzed.

Table 1 Inclusion and exclusion criteria for study patients. CGM – continuous glucose monitor

Inclusion Criteria	Exclusion Criteria
Patients aged 18 to 95 with diagnosed Type 1 and Type 2 DM	Pregnant patients
English speaking patients (proficient)	Incarcerated patients
Patients treated for DM with 3-4 injections of Insulin per day plus /minus other diabetic medications and SMBG at least 4 times a day	Patient's whose insurance does not cover the CGM device
Patients whose DM is only being managed in the Internal Medicine Residency Continuity Clinic	Patients who are non-compliant with the clinical visits
Patients Using CGM: Dexcom G6/G7 or Free Style Libre 3 as part of standard care	Patients non-compliant with lifestyle interventions, who were unable to understand, or unwilling to wear the CGM device at least 70% of the day
Patients who can understand the CGM data and adjust their Insulin based on instructions from the CGM team	Patients who are unable to understand the instructions regarding treatment based on the CGM data.
Patients available to speak to medical residents every 2 weeks via telephone about adjusting their insulin dosages.	Non-compliant with telephone calls and follow ups
Patients with insurance coverage of their CGM devise	Homeless patients

3. Analysis

We plan to collect 11 different data points every two months after patient enrollment in the study (Table 2). These will be compared to pre-enrollment data using either a paired t-test or a Wilcoxon signed-rank test, depending on the data's normality.

We will also use qualitative metrics (Table 2) collected during bi-weekly phone calls about diet and lifestyle changes. These metrics will be analyzed to identify potential trends affecting glucose control, including the time spent exercising, types of exercise, dietary habits, and the influence of support systems.

Table 2 Data points used in our study. HbA1c – hemoglobin A1c, GMI – glucose management indicator, CGM – continuous glucose monitor, CGM-SAT – CGM satisfaction survey

Quantitative Data Points	Qualitative Data Points
HbA1c/GMI	Diet modifications
Average blood glucose	Types of exercise
Time spent (%) in severe hypoglycemia (< 54 mg/dL)	Presence of support system
Time spent (%) in mild hypoglycemia (54-89mg/dL)	
Time spent (%) in goal range (70-180mg/dL)	
Time spent (%) in hyperglycemia (> 180mg/dL)	
CGM-SAT scores	
Compliance (%) with insulin regimen	
Compliance (%) with CGM usage	
Compliance (%) with non-insulin diabetes medication	
Compliance (%) with bi-monthly clinic visits	
Minutes of exercise per week	

4. Discussion

This study is the first prospective research in which internal medicine residents will use CGM technology to manage the most complex and difficult-to-treat diabetes patients who are not controlled with SMBG, under the supervision of a board-certified endocrinologist. It is also the first prospective study conducted in an internal medicine residency clinic in the USA focusing on the role of CGM in managing the most challenging patients who used SMBG and received three or more insulin injections per day but remained uncontrolled before switching to CGM. The goal is to demonstrate that successful management can be achieved for patients in the Internal Medicine Residency clinic, not just in specialized endocrinology clinics. If successful, we aim to show that CGM data can be effectively used by supervised Internal Medicine residents for diabetes management in these complex cases, without needing to refer patients to specialized endocrine clinics. The results could support wider adoption of CGM in IM residency clinics and potentially be incorporated into the teaching curriculum of other Internal Medicine residency programs across the United States.

Until now, there have been studies in type 1 DM with CGM vs SMBG in patients on multiple injections of insulin showing improved blood glucose control [5]. Also, CGM improved quality of life in adults with type 1 DM [6].

Also, there have been studies in patients with type 2 DM about the clinical use of CGM [7].

Also, Pratley et al. study using CGM showed the investigation of hypoglycemia incidence in older patients with type 1 DM with favorable results [8].

Further investigations confirmed the usefulness of real-time CGM in patients with type 2 DM as well [9].

The systematic review and meta-analysis again supported the use of CGM [10].

Clinical targets based on the International Consensus on time in range (TIR) as one of the most important measures were followed [11]. Low TIR was associated with incident retinopathy in adults with type 1 DM [12].

5. Conclusion

In this prospective study, we aim to demonstrate for the first time that the most difficult-to-treat patients with DM, who are on 3-4 insulin injections per day and are not well controlled, can be transitioned from SMBG to CGM with significant improvements in their glucose management, as indicated by a reduction in HbA1c in an internal medicine residency clinic. Internal medicine residents can safely interpret CGM results and adjust insulin therapy after receiving proper education and supervision from an endocrinologist. This strategy will improve the quality of care for patients with DM and enhance the educational experience of internal medicine residents in the USA, potentially becoming part of the internal medicine residency curriculum.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed

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