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CGM use with interprofessional therapy management improves HbA1c levels in T2DM patients

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CGM use with interprofessional therapy management improves HbA1c levels in T2DM patients

Abstract

Background

Type 2 Diabetes Mellitus (T2DM) is a chronic disease state with increased complications over time from uncontrolled glucose. Significant data has shown benefits of continuous glucose monitoring (CGM) in reducing glycated hemoglobin (HbA1c) levels of Type 1 Diabetes Mellitus (T1DM) patients, but a lack of robust evidence is seen in T2DM. This study assessed the impact of short-term CGM placement on HbA1c levels in T2DM.

Objectives

The primary outcome was the change in baseline HbA1c levels in patients with T2DM up to six months after CGM placement. Secondary outcomes assessed intensification of diabetes medications made by an interprofessional team at a family medicine clinic.

Methods

This retrospective study evaluated changes in baseline HbA1c after short-term CGM placement in patients with T2DM between June 2017 and May 2020. Single-center data was collected from patients with T2DM who were ≥ 18 years old and HbA1c ≥ 6.5%. Participant data included age, sex, race, weight, blood pressure, heart rate, pre-/post-CGM HbA1c, and number and type of diabetes medications used before and after CGM placement. Medication regimen changes were made by a team of healthcare providers that included medical residents, a nurse who is a certified diabetes educator, clinical pharmacist and pharmacy students, and attending physicians. Descriptive statistics were used for patient demographics, and paired t-tests analyzed primary and secondary outcomes.

Results

115 patients were included in the study and had a mean baseline HbA1c of 9.9%. Upon review of HbA1c levels post-CGM placement, mean HbA1c was 8.8% (p=

Conclusions

This study showed a statistically and clinically significant reduction in HbA1c, most likely from an improved guidance of therapeutic decision making made by the healthcare team. Based on study results, CGM placement may be most useful for those T2DM patients unwilling or unable to adequately monitor blood glucose multiple times per day or in those who experience inadequate responses to their currently prescribed diabetes medications.

Keywords

CGM, Interprofessional management, diabetes

An SLP Graduate Student's Analysis of Language in Children with Speech Sound Disorders

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Introduction

The incidence of Type 2 Diabetes Mellitus (T2DM) in America has continued to rise over the last few decades coinciding with a similar rise in obesity rates.[1] The micro and macrovascular complications that have been long recognized in patients with T2DM, such as heart disease, stroke, chronic kidney disease, diabetic foot infections, amputations, diabetic retinopathy, and diabetic peripheral neuropathy, come from a lack of glucose control over time.[2] For many patients with T2DM long-term multiple fingersticks per day to monitor blood glucose levels is not feasible due to cost, time, lack of education, unwillingness, or some combination of these factors.[3] However, new technologies in the blood sugar monitoring devices field have been made, in particular, significant improvements in the accuracy and reliability of continuous glucose monitors (CGMs) for monitoring blood glucose have led to more widespread use. The direct measurement of glucose levels allows for fewer finger sticks per day for patients and allows practitioners to view a wider range of metrics such as the percentage of time within and outside of the normal blood glucose range. There is substantial data showing the benefits of CGMs in Type 1 Diabetes Mellitus (T1DM) patients, but a lack of robust evidence exists regarding their benefit in T2DM patients. Randomized controlled trials utilizing CGMs in persons with T1DM have been shown to decrease hemoglobin A1c (HbA1c) levels, decrease glycemic variability, increase time in normal blood glucose range, decrease time in hypoglycemia, and reduce the number of hypoglycemic episodes.[4-14] A few studies have shown a modest decrease in HbA1c levels in patients with T2DM, and the utilization of CGMs have been established as a behavioral modification tool as well in these patients. Additionally, CGMs

have shown to be a valuable tool in patients withT2DM by detecting silent/unknown hyper- and hypoglycemia by directly measuring the glucose level rather than through the measurement of HbA1c.[15-19]

This study evaluated retrospective data to assess whether CGM placement and the medication changes made by an interprofessional team based on the CGM results affected HbA1c levels for patients who received at least one CGM. This study was conducted at a single ambulatory care family medicine resident run clinic where the residents provide care for their longitudinal patients throughout their three year program. The clinic is also staffed by family medicine attending physicians, a clinical pharmacist from a nearby College of Pharmacy, a nurse who is a certified diabetes care and education specialist (CDCES), medical students, and pharmacy students. Initially the 72 hour CGMs were mainly utilized in the clinic in patients with T2DM that were on long acting and/or short acting insulin to better optimize their glycemic control and insulin doses. With the addition of the CDCES in 2018, the use of CGMs in the clinic became more widespread. CGMs were utilized in patients with or without insulin as part of their diabetes medication regimen to optimize their glucose control. Additional evidence in CGM effectiveness in lowering HbA1c in T2DM could allow for more widespread use of this strategy and ultimately lead to better patient outcomes.

Objectives

The primary objective of the study was to determine the impact of short-term CGM use on the change in baseline HbA1c levels three to six months after CGM placement in T2DM patients. Secondary objectives were to assess whether management by the healthcare team after CGM results were obtained led to an intensification of medication therapy, an addition of diabetes medications, or a change in weight for the study participants.

Methods

A retrospective analysis of patient data was performed for patients who received a 72 hour CGM at an ambulatory care family medicine clinic between June 2017 and May 2020. Institutional Review Board approval for the study was obtained from the parent teaching hospital of the clinic and the lead author's primary institution prior to conducting the study. To be included in the study patients had to have a diagnosis of T2DM, be enrolled as a patient at the family medicine clinic, receive at least one short-term CGM during the specified dates, be 18 years of age or older, and have a HbA1c 6.5% or greater. Patient data was excluded from being collected if the patient had a diagnosis of T1DM, was pregnant, had a history of long-term CGM use, or had current chronic glucocorticoid use. Patients were identified by a family medicine resident, the pharmacy team, or the CDCES as candidates for CGMs mainly due to their uncontrolled T2DM or their inability to consistently perform self-monitoring of their blood glucose or both. Two appointments were made for these patients once they agreed to have the CGM placed, one for placement of the CGM and one for removal approximately 72 hours later. An iPro2 from Medtronic was utilized as the CGM for the vast majority of study participants and usually placed by the CDCES or a trained nurse in the clinic. Data from the CGM was analyzed either at the date of CGM removal or their next follow-up appointment with their assigned family medicine resident. Medication changes, which consisted of adjustment of doses, addition of diabetic medications, and/or discontinuation of diabetic medications, were done as a collaborative agreement among the family medicine resident, the CDCES, and the clinical pharmacist and pharmacy. In most cases the CDCES and pharmacy team collaborated to give verbal recommendations to the family medicine resident who then accepted or modified the medication plan and received final approval form the attending physician. Medication recommendations and changes were made based on CGM results, followed guideline recommendations when

appropriate, included input and buy in from the patient, and considered insurance formulary coverage of medications.

The retrospective data collected for the study participants consisted of date of birth, gender, race, weight, blood pressure, heart rate, baseline HbA1c, and the number and type of diabetes medications when the CGM was placed. Data was then collected three to six months after CGM placement and medication changes were made and consisted of blood pressure, heart rate, weight, HbA1c, and number and type of diabetes medications. Descriptive statistics were used for the patient demographics that were collected. A paired t-test was used for the primary and secondary outcomes and a p-value of ≤ 0.05 was considered statically significant.

Results

Baseline Characteristics

This study identified 115 participants who had a CGM placed for 72 hours between June 2017 and May 2020 and met the inclusion criteria. Mean age of participants was 59 years (range 25 to 81 years), with 72 (62.6%) being women. Mean baseline HbA1c was 9.9% (range 7% to 15.2%) and mean diabetes baseline medication count was 2.33 (range 1 to 5). Participants baseline and follow-up characteristics are outlined in **Table 1**.

Table 1: Baseline and Follow-Up Characteristics

Variable	Observed Value
Age (years)	
Median	56 [25-81]
Mean	59.06 (10.64)

Gender	
Male	43 (37.4%)
Female	72 (62.6%)
Race/Ethnicity	
White	34 (29.6%)
African American	78 (67.8%)
Hispanic	2 (1.7%)
Other	1 (0.9%)
Pre-Weight (kg)	97.32 (28.15)
Post-Weight (kg)	96.43 (27.35)
Pre-Systolic BP (mmHg)	137.92 (17.03)
Post-Systolic BP (mmHg)	135.77 (16.04)
Pre-Diastolic BP (mmHg)	77.15 (12.78)
Post-Diastolic BP (mmHg)	76.53 (11.49)
Pre-Pulse Rate (bpm)	82.62 (13.18)
Post-Pulse Rate (bpm)	81.62 (15.40)
Total Diabetic Pre-Medications	2.34 [1-5]
Total Diabetic Post-Medications	2.68 [1-5]

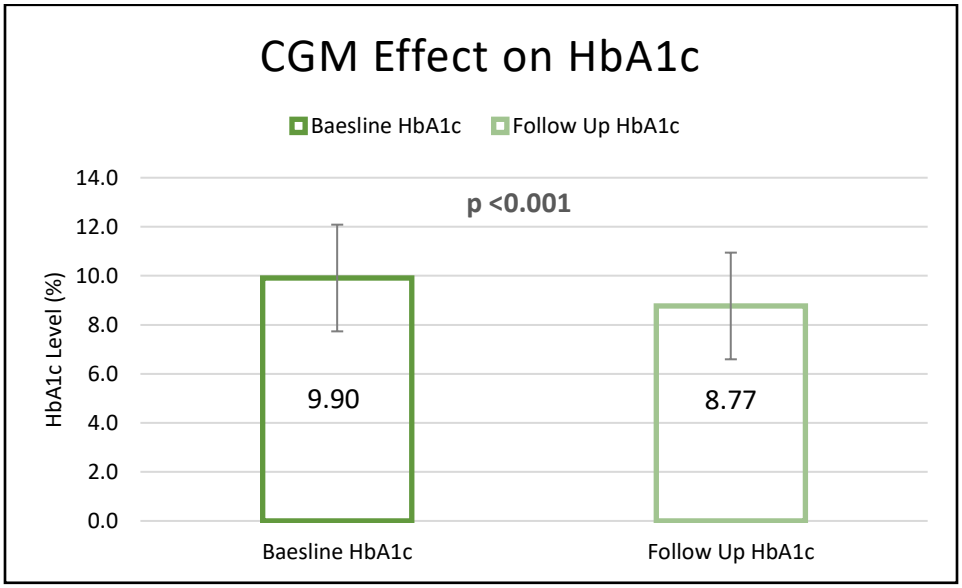
Table 1: Baseline and follow up characteristics of the treatment group. Values are mean (SD), N (%), or mean [range]. 'Pre-' refers to before continuous glucose monitoring. 'Post-' refers to after continuous glucose monitoring. Total number (*n*) = 115. SD = Standard Deviation.

Changes in HbA_{1c} and Medication Therapy

Patients received continuous glucose monitoring for approximately 72 hours and medications were adjusted based on results. Mean HbA1c at baseline was 9.9% and decreased to 8.8% three to six months after the CGM results were obtained and medications were adjusted. **Graph 1** depicts the significant decrease in HbA_{1c} levels by -1.1% (p = <0.001) from baseline. At baseline 9 (7.8%) patients had an HbA1c of <7% and following CGM placement 17 (14.8%) patients achieved that goal.

Medication alterations from baseline to follow up are shown in **Table 2**. The most common medication modification seen was dose adjustment which occurred in 93 (80.9%) patients. Dose adjustments consisted of increasing or decreasing the patient's baseline medication dosage. Long acting and short acting insulin were the most often (50.4%) adjusted medications followed by metformin (13.9%) and then GLP-1 receptor agonists (8.7%). 39 (33.9%) patients had a medication added to their current regimen to obtain stricter glucose control. GLP-1 receptor agonists, long and short acting insulins, and SGLT-2 inhibitors were the most common medications added, as visualized in **Graph 2**. Additionally, 10 (8.7%) of the patients had medication discontinued from their current medication regimen. The alteration in medication regimens led to a significant increase of medications from an average of 2.3 at baseline to 2.7 following CGM placement (p< 0.001) in total medications taken by patients from baseline to follow-up, as shown in **Graph 3**. Other criteria relating to diabetes such as weight change were recorded but not found to be significant.

Graph 1: Change in HbA1c from baseline to follow up



Graph 1: HbA1c average at baseline was 9.90% and decreased to 8.77% at follow up after monitoring

with a continuous glucose meter. Error bars represent SD. The difference in HbA1c was statistically significant

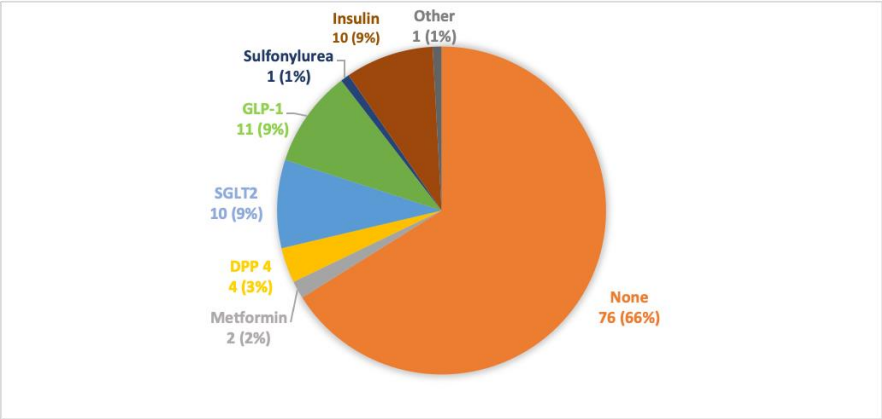
from baseline.

Table 2: Medication modifications after CGM

Drug Class	Medication before CGM	Dosage change	Drug added	Drug Stopped
Metformin	74 (64.3)	16 (13.9)	2 (1.7)	0
Sulfonylurea	34 (29.6)	8 (7)	1 (0.9)	4 (3.5)
GLP1	26 (22.6)	10 (8.7)	11 (9.6)	0
SGLT2	8 (7.0)	1 (0.9)	10 (8.7)	0
DPP4	13 (11.3)	0	4 (3.5)	3 (2.6)
Insulin (LA and SA)	106 (92.2)	58 (50.4)	10 (8.7)	3 (2.6)
Other Insulin	9 (7.8)	0	1 (0.9)	0

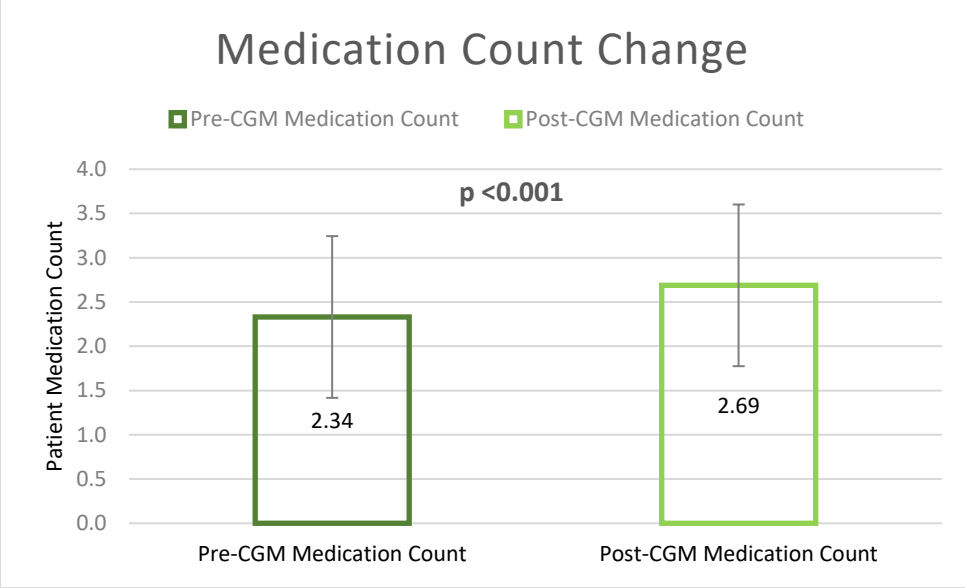
Table 2: Medication adjustments made while on CGM. CGM = Continuous Glucose Monitoring. Values are N (%). Drug added refers to the listed medication class being added to the patient's baseline drug regimen. Drug stopped refers to the listed medication class being removed from the patient's baseline drug regimen

Graph 2: Medication classes added to pre-CGM therapy



Graph 2: Medication classes added to pre-CGM or baseline therapy. Values are N (%).

Graph 3: Change in medication count from baseline to follow up using CGM



Graph 3: Mean number of medications patients were on at baseline was 2.33. After follow up using CGM, mean medication count was 2.69. Error bars represent S. The difference in medication count was statistically significant from baseline.

Discussion

The findings of our study suggest that the utilization of short-term CGM placement was effective in lowering HbA1c levels from baseline by greater than 1%. The results mimic, on a much smaller scale, those seen in previous randomized controlled trials and studies evaluating the effects of CGM use on HbA1c levels in patients with T1DM. In addition, the CGM values in this population were used to adjust patients' diabetes medication therapies and optimize their care. From baseline, patients with controlled T2DM, defined as having a HbA1c level less than 7%, nearly doubled after optimization of medication therapy through one or more medication dose adjustments and/or one or more medication class changes.

In this clinic setting, all patients received detailed verbal and written instructions regarding CGM placement and follow up; there were no reported complications or required therapeutic interventions from CGM use. Socioeconomic factors and lack of insurance coverage are major concerns related to more widespread and continued use of CGMs within this population. Based on the outcomes of this study, greater utilization of CGMs in T2DM patients with or without insulin would serve to enhance medication therapy management and guide therapeutic decision making by providers. One benefit of our study is the collaborative practice among medical residents, clinical pharmacists, diabetes care nurse, attending physicians, and students to assess the GGM results of each patient to provide optimal therapeutic interventions and medication management. We believe the interprofessional review of outcomes, patient history, current medications, and medication accessibility led to enhanced study results, as the therapeutic interventions were made in real time without lags in access to patient records or communication among the varied healthcare providers. Based on the positive results of this retrospective review, larger prospective studies across multiple sites could allow for increased use of CGMs in T2DM patients with similar outcomes, and the incorporation of multiple healthcare disciplines may lead to more optimal, individualized therapy choices.

Despite significantly lower HbA1c levels and improvements in medication therapy management, this study has several limitations. First, it was a retrospective review and not all eligible patients were included due to an inability to collect all necessary data for the primary and secondary objectives. Second, due to the retrospective nature of this study, there was not a true control as there would be in a prospective trial. This makes the study prone to selection and/or misclassification bias by investigators. Third, data was collected from a single center family medicine clinic, potentially limiting its external validity. Fourth, most patients were African-American females, which could limit the overall generalizability of the results. Finally, the follow-up period was relatively short at three to six months post CGM placement. Expanded studies could evaluate the long term effects of CGM utilization and medication therapy changes based on CGM results on overall diabetes care and management.

Conclusion

This study demonstrated that short-term CGM utilization and medication therapy optimization led to significant reductions in HbA1c levels from baseline in T2DM patients with or without insulin use within a resident-led family medicine clinic. Following CGM interpretation by the health care team, most patients experienced a change to their medication regimen in this setting. Additionally, CGM use may help to narrow and guide therapeutic decision making and optimize selection of medication classes. As CGM use increases, providers will need to determine those patients who are most likely to benefit from the additional intervention. Based on the results of this study, CGM placement may be most useful for those T2DM patients unwilling or unable to adequately monitor blood glucose multiple times per day or in those who experience an inadequate response to their currently prescribed diabetes medications.

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