Improvement of glucose control after successful introduction of Continuous Glucose Monitoring (CGM) in internal medicine residency continuity community clinic-retrospective, longitudinal one group study

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World Journal of Advanced Research and Reviews, 2022, 14(02), 115–120

Publication history: Received on 26 March 2022; revised on 06 May 2022; accepted on 08 May 2022

Article DOI: https://doi.org/10.30574/wjarr.2022.14.2.0381

Abstract

In our study we retrospectively looked at patients in which as a standard of care Continuous Glucose Monitoring (CGM) with Dexcom G6 Device was started in Internal Medicine Residency Continuity Community clinic in Mountain View Hospital, Las Vegas, Nevada in 10-patients with Type- II diabetes mellitus uncontrolled on 3-4 injections of Insulin per day-Multiple Injections of Insulin per day (MDI) who were Self- monitoring their blood glucose 4- times a day (SMBG). The CGM was initiated by Internal Medicine Residents, adjustment of the Insulin dose was done by them under the supervision of Board-Certified Endocrinologist. The goal was to show improvement of patients HbA1c measured by glucose management Indicator. The HbA1c was reduced in 3- months after introduction of the CGM from 10.0% to 7.87%. Time in range we achieved was 65% with the goal based on patient's age and comorbid conditions between 50 and 70%. Based on the average age of the patient of 51- years this is compatible with the goals using CGM.

The main objective of our study was that it was possible to show improvement of glucose control measured by changes in HbA1c after introduction of CGM in most difficult to treat patients with Type -II Diabetes Mellitus by Internal Medicine Residents under the supervision of Endocrine specialist. This can be adopted by other Internal Medicine Residency Programs in USA.

Keywords: Diabetes Mellitus Type- II; Continuous Glucose Monitoring (CGM); Hba1c; Glucose Management Indicator (GMI); Internal Medicine Residents; Board Certified Endocrinologist

1. Introduction

The number of patients suffering from type 2 diabetes mellitus is increasing worldwide, with estimates suggesting that approximately 300 million individuals could develop the disease by 2050 [1]. Previous studies have revealed that strict blood glucose control is extremely important for preventing microangiopathy and macrovascular disorders [2, 3]. Primary treatment for type 2 diabetes mellitus includes diet/exercise therapy, whereas pharmacotherapy is administered only when diet therapy/exercise therapy is insufficient. However, in many cases, favorable blood glucose control cannot be achieved through the aforementioned therapeutic interventions alone [4, 5]. With the time some patients with DM Type-2 progress and require Insulin. Some of them have difficulties controlling their blood sugar with 3-4 injections of basal and bolus Insulin per day by self-monitoring their blood glucose (SMBG).

Self-monitoring blood glucose (SMBG) has been proven to be useful for long-term glycemic control in patients with type 2 diabetes mellitus [6]. However, this method places considerable burden on the patient given that performing finger
pricking several times per day is not only troublesome but also painful [7]. Furthermore, understanding detailed blood sugar fluctuations, such as elevated blood glucose after meals or asymptomatic hypoglycemia, may be difficult [8].

Continuous glucose monitoring (CGM) allows for continuous measurement of interstitial glucose levels in subcutaneous tissues and evaluation of the detailed blood glucose profile of the patient. CGM includes retrospective CGM (r-CGM), which is used for retrospective examination of lifestyle problems and pharmacotherapy adjustment after understanding the blood glucose profile over several days, and real-time CGM (RT-CGM), which confirms the blood glucose profile in real-time. Studies have shown that utilization of such CGM approaches promotes favorable blood glucose control by changing patient behaviors or pharmacotherapy adjustment [9, 10].

A 2013 meta-analysis that examined the influence of CGM on blood glucose levels in patients with type 2 diabetes mellitus indicated significant improvements in HbA1c levels [8, 11].

Majority of the studies with CGM were conducted in the specialized clinics- Endocrinology clinics and Internal Medicine clinics by Board Certified Endocrinologist or Internist. In the present study our goal was to show that in Internal Medicine Residency Continuity Community Clinic the CGM can be introduced by Internal medicine Residents under the supervision of Endocrine Specialist successfully. We were looking for decrement of HbA1c before and after the switch to CGM and the time in range achieved using CGM. That way other Internal Medicine Residency Programs in USA can start introducing the device by their Residents and improve the care of most difficult to treat patients with Type-2 DM on 3-4 injections of Insulin per day who were self-monitoring their blood Glucose before the switch to CGM. As far as we know this is the first study in that nature.

As a reference we were using ADA recommendations for time in range in 24- hour period- Fig. 1

As we know time in range is related to development of micro-vascular complications- Fig. 2

![Figure 1 ADA recommendations for the blood sugar goals using CGM](image)

**Objectives**

The goal of the study was to show that improving the care of patients with DM type -2 on 3, or 4 - injections of insulin per day - multiple injections of Insulin per day (MDI) can be done by switching them from SMBG to CGM.

The other more important objective was to show that this can safely be done in Internal medicine Residency Continuity Community Clinic by internal Medicine. Another objective was to try to decrease the number of Injections of Insulin in Patients with type -2 DM without compromising their blood sugar control after switching from SMBG to CGM.

The standard of care in our Internal Medicine Residency Continuity clinic until this project was the patients with Diabetes mellitus on multiple injections of Insulin per day to self-monitor 3-4 times a day their blood glucose/SMBG/ by performing finger sticks which was painful, cumbersome and frequently missed low/high blood sugars.
Figure 2 Relationship between microvascular complications of patients with diabetes mellitus and the CGM Time in range

2. Methods and Procedures

Ten Patients were recruited by Internal Medicine and Transitional Year residents during their rotation in Internal medicine Residency Continuity Community clinic in Mountain View Hospital, Las Vegas, Nevada.

The patients were with type-II Diabetes mellitus with average HbA1c 10.0% and were using 3-4 injections of Insulin per day plus minus antidiabetic oral medications and or GLP1-RAG.

The patients were between 41-71 years of age. After the treating physician in the clinic was notified by the patients about their interest in having CGM – Dexcom- G6- Device and their eligibility, a consent form was signed by the treating physician and the patient and the study team was notified. No force or coercion methods were implemented. The participation was strictly voluntary.

Data were collected using Dexcom- G6- CGM database and the clinic EMR. The eligible patients were given share code by the treating team to share their CGM Data with the clinical team constantly. The patients were given Instructions in the clinic about their diet, exercise, and also given pamphlet how to adjust their Insulin dose based on their CGM data. The patient needed to show understanding and teach back their understanding of the CGM. Also, UN application with the carbohydrate content and calorie content was given with appropriate recommendations by the CGM team.

Twice a week a representative from the CGM team was contacting the patients and adjusting their Insulin dose based on their CGM data and giving them advises about their diet and exercise. On a monthly bases there was additional appointment of the patients in the clinic with representative of the CGM team. On these appointments with the CGM team in the clinic additional adjustments of the patient’s Insulin Regimen were done by the treating team under the supervision of the Board-Certified Endocrinologist.

The following criteria were used for the selection of the patients:

2.1. Inclusion Criteria

Age 18-80 Having type-II Diabetes Mellitus Having HbA1c above 7% uncontrolled while using SMBS four times a day To be seen only in Internal Medicine Residency continuity clinic for 6-months Patients to have compatible I-Phone or Android phone with the CGM- device Dexcom- G6 to be able to look and share with the clinic their CGM data Patients to
be on 3 or 4 injections of insulin +/- oral medications or injectable GLP1-RAG before enrollment to the study with switching from SMBG to CGM. To self-monitor their blood sugar 4x a day before the switch to CGM. Patients after the switch to CGM to be on 3-4 injection of insulin +/- oral medications or injectable GLP1-Receptor agonists (GLP1-RAG) Patient to be able to understand and adjust their insulin based on the CGM data To qualify for CGM Dexcom- G6- based on patient’s insurance information Biweekly the management of the Diabetes Mellitus type- II was adjusted based on CGM data Collection by the Internal medicine Residents under the supervision of the Endocrinologist by calling the patients and or by patients themselves after the written instructions were given to them by residents in the clinic.

2.2. Exclusion Criteria

Patients who were not on insulin 3-4 injections per day Patients with type-I DM Patients who do not have compatible phone for the Dexcom-G-6 CGM device Patients who are non-compliant with dietary recommendations Patients who cannot understand the titration of insulin instructions Patients who were wearing the CGM less than 70% of the time Patients with impaired decision-making capacity Patients who miss >2 scheduled visits Pregnant patients Incarcerated patients If the patient’s insurance does not cover the CGM device - Dexcom- G6 If the patient does not respond to their calls from the clinic with the advices how to adjust their Insulin given to them by the residents.

3. Results

At 3- months the 10- patients with type -II DM on 3-4 injections of Insulin per day who were switched followed by us from SMBG – 4 times a day to continuous Glucose monitoring -CGM by us showed statistically significant improvement of their HbA1c from 10.0% to 7.87% -P<=0.005%. The Internal Medicine and Transitional Year Residents in the Internal medicine Continuity Clinic under the supervision of Board-certified Endocrinologist were contacting each patient on average twice weekly and adjusting the patients Insulin based on the CGM data shared with the clinic by the patients. Also, the patients were visiting the Internal Medicine Residency clinic – the CGM Residency Team on average once a month.

Time in range of Blood sugar between - 70-180 mg/dl was 65% which was excellent given the mean age of the patients of 51.2 years and patients co- morbid conditions. The goal of the time in range was between 50-70% based on younger patients’ goal above 70% and older patients/high risk patients’ goal of above 50 % (fig. 1). This we expect to lead to less microvascular complications if sustained in a long run (fig.2).

Two of the patients with DM type- II stopped their Rapid Acting Insulin before meals and were able to control their DM type- II only with Basal Insulin and per oral antidiabetic medications and or injectable GLP1-RAG after the switch from SMBG to CGM.

4. Discussion

Continuous glucose monitoring (CGM) emerged in the past decade as an important tool to gain insight into patients’ glycemic patterns and trends. While self-monitoring of blood glucose with periodic finger sticks can capture glucose as a snapshot in time, CGM has the advantage of providing continuous measurements at 5 - to 15-minute intervals. This gives patients and their doctors much more data to work with as they tailor diets, lifestyle, and medications to manage diabetes.

Studies like GOLD trial and DIAMOND trial have confirmed the role of CGM in guiding therapy in patients with type- I Diabetes Mellitus on Intensive Insulin Therapy [12, 13].

Not surprisingly, the CGM clinical Research in type-II Diabetes Mellitus lagged behind, particularly with regard to patients treated with MDI, but the trials with the usage of CGM confirmed the benefit in type- II Diabetes Mellitus treated with MDI as three quarters of the patients had an HbA1c improvement of at least 0.5% [8, 11].

One 2013 meta-analysis involving four RCTs that collectively examined the effects of RT-CGM and r-CGM in patients with type 2 diabetes mellitus indicated that the CGM treatment group had significantly lower HbA1c levels than the SMBG group [11]. Similarly, another meta-analysis revealed that the CGM group had significantly lower HbA1c levels than the SMBG group [7].

A high percentage of adults who received multiple daily insulin injections for type- II diabetes used CGM on a daily or near-daily basis for- 24- weeks and had improved glycemic control. Because few insulin-treated patients with type- II
diabetes currently use CGM, these results support an additional management method that may benefit these patients [14].

In our study all of the patients had type DM type- II. They were on 3-4 injections of Insulin per day. We confirmed other studies that CGM benefits not only patients with DM type- I, but also patients with DM Type -II on multiple injections of Insulin per day.

The reported average improvement of HbA1c in our patient’s population was- 2.13% while on average HbA1c improves based on other studies was between 0.3-0.6percent [12]. Also, two of our patients were able to stop their Rapid Acting Insulin and be treated only with basal Insulin and per oral antidiabetic medications and or GLP1-RAG.

We think that the more significant drop of HbA1c in our population of patients was due to the patient’s characteristics- more indigent patients in Community settings, with poor understanding of their disease, with poor eating habits and not understanding how to adjust their Insulin dynamically at least twice a week based on the level of their blood sugar, before switching to CGM and counseled by our CGM clinic team.

Significant time spent by our Internal Medicine residents under the supervision of Board-Certified Endocrinologist in explaining to the patients the carbohydrates needed to be consumed per meal and their type, the number of calories per day helped the patients. Also, the residents were giving the patients special applications which the patients were installing on their phones to monitor their calorie and carbohydrate intake. Also, the patients were given pamphlets how to titrate their insulin dose based on their real time blood glucose using CGM. Patients understanding was assured by teaching back technique. Closely follow up of the patients by calling them twice a week by the Internal medicine Residents and seeing them at least once a month and adjusting their Insulin dose under the supervision of board-certified Endocrinologist based on the shared with the clinic CGM data helped tremendously in achieving these stellar results.

5. Conclusion

The unique value of the study was the successful implementation of CGM in Internal Medicine Continuity Community Residency Clinic in Mountain View hospital, Las Vegas, Nevada for patients on MDI insulin who had DM type-II. The process was navigated by Internal Medicine Residents under the supervision of Board-Certified Endocrinologist. We proved that in patients with type -II DM on Multiple daily injections of Insulin (MDI) the successful change from SMBG to CGM in terms of improving the glucose control measured by lowering HbA1c by 2.13% in 3- months, achieving time in range of 65% per day and reduction of daily injections of Insulin in 20% of the patients and switching them to the regimen of basal Insulin and per oral antidiabetic medications or GLP1-RAG.

Compliance with ethical standards

Acknowledgments

We want to express our gratitude to the research Department, Sunrise Health GME Consortium, Mountain View Hospital, Las Vegas, Nevada.

Disclosure of conflict of interest

There is no conflict of the interest of the authors.

Statement of informed consent

Informed consent was obtained from all participants in the study.

Funding

We did not receive any funding for this trial.

References


