Retrospective, Longitudinal, One Group Study about the Implementation of Continuous Glucose Monitoring in Improving Quality of Care for Patients with Type I Or II DM in Internal Medicine Residency Continuity Community Clinic

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Received: 08-Sep-2022, Manuscript No. jdm-22-19257; **Editor assigned:** 10-Sep-2022, PreQC No: jdm-22-19257(PQ); **Reviewed:** 24-Sep-2022, QC No. jdm-22-19257; **Revised:** 28-Sep-2022, Manuscript No. jdm-22-19257(R); **Published:** 05-Oct-2022, DOI: 10.35248/2155-6156.1000956

Abstract

Diabetes mellitus affects more than 34 million and pre- diabetes mellitus affects 88-million Americans and the prevalence is rising. The disease leads to micro and macro vascular complications if uncontrolled. Diabetes Mellitus is the number one cause of blindness, non-traumatic amputation and ESRD in the USA. 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 11-patients with type- I and type- II diabetes mellitus uncontrolled on 3-4 injections of Insulin per day who were self- monitoring their blood glucose 4- times a day (SMBG). The CGM was initiated by internal medicine residents through a remote portal, and the subsequent titration of the insulin dose was done by the residents under the supervision of a board-certified endocrinologist who was also a member of the clinic. The goal of the present study was to demonstrate improvement of patients' HbA1c measured by a glucose management indicator, a decrement of mild, defined as less than 70 mg/dl hypoglycemia and severe- defined as less than 54 mg/dl hypoglycemia to less than 4% and 1% respectively, achievement of time in range between 70- 180 mg/dl blood sugar in 24-hour period of 50-70% of the time based on the patient's age and have glucose variability less than 36%. The HbA1c was reduced in 3- months after introduction of the CGM from 10.5% to 7.47%, the mild hypoglycemia with blood sugar less than 70 mg/dl happened on average 7- minutes a day (less than 4%) from 27- minutes and severe hypoglycemia happened 3- min a day (less than 1%) from 7 minutes while the patients were using SMBG. These were the goals with the use of CGM. Time in range we achieved was 62% which was between 50 and 70%. Based on the average age of the patient of 53-years this is compatible with the goals using CGM. The glucose variability was 29% below the goal of 36% which is excellent. The patient satisfaction with the device measured by the CGM Quality of life questionnaire was very good. The unique feature of this study is that it demonstrates the successful introduction of the CGM was done by Internal Medicine Residents under the supervision of a Board-Certified Endocrinologist who was also a member of the clinic which we are not aware that it was done before.

Keywords: Diabetes mellitus Type- I and type- II; Continuous glucose monitoring (CGM); HbA1C; Glucose management indicator (GMI); Glucose variability; hypoglycemia.

Introduction

Professional continuous glucose monitoring (CGM) systems that allow health care provider assessment or retrospective analysis of captured interstitial glucose levels have been an important diabetes management technology since early clinical application [1]. Data from these systems have allowed quantitative analysis of glycemic metrics that include the percentages of time spent below, within, and above target glucose range; areas under the curve during hypoglycemic and hyperglycemic excursions; and within-period glucose variability on which ongoing therapy decisions can be made [2].

Hypoglycemia and hyperglycemia are known to be linked to micro vascular and macro vascular complications observed in individuals living with diabetes. Intensive glucose-lowering treatments used to reach or maintain glycemic objectives can increase the risk of hypoglycemia [3]. Ongoing hypoglycemia exposure has been shown to cause future exposure and to increase the incidence of severe hypoglycemic events, as well as impaired hypoglycemia awareness [3]. Both randomized and observational studies of early and more recent real-time CGM (RT-CGM) systems have demonstrated improved glycemic control (ie, reduced glucose variability, hypoglycemia, severe hypoglycemia, fear of hypoglycemia, and even impaired hypoglycemia awareness) compared to conventional self-monitoring of blood glucose (SMBG) measurements alone or blinded CGM use with multiple daily injections (MDIs) therapy [4-7]. Improved quality of life and psychological wellbeing, as well as cost-effectiveness, have been reported with standalone RT-CGM system use [5-7].

A similar trend of glycemic improvement with RT-CGM has been observed for individuals with type-2 diabetes (T2D) treated with MDI therapy compared to Self-Monitoring of the blood Glucose (SMBG) [8-11]. Also, the Self- Monitoring Blood Glucose gives the patient and the physician values at one point only while the CGM gives the Blood sugar values throughout the day and night and allows it to be made which leads to improvement of the blood sugar control [12].

Current recommendations by American Diabetic Association/ADA/ about control of blood sugar using CGM are described in Figure 1. (Figure 1)

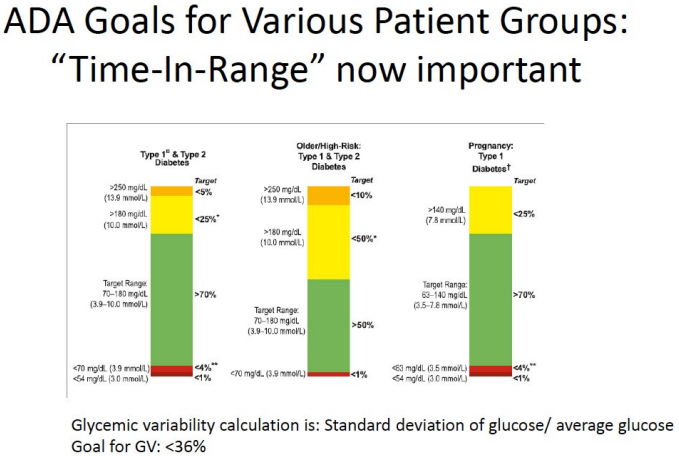

Figure 1.

The most important goal to be achieved with the usage of CGM is the blood sugar between 70-180 mg/dl mg /dl- so called time in range. The relationship between Percent of time the Blood sugar is in range and the micro vascular complications of Diabetes mellitus Type- I and Type- II are described in figure 2. (Figure 2)

Frequency of development of microvascular complication according to level of TIR (70–180 mg/dL) computed from quarterly seven-point blood glucose testing.

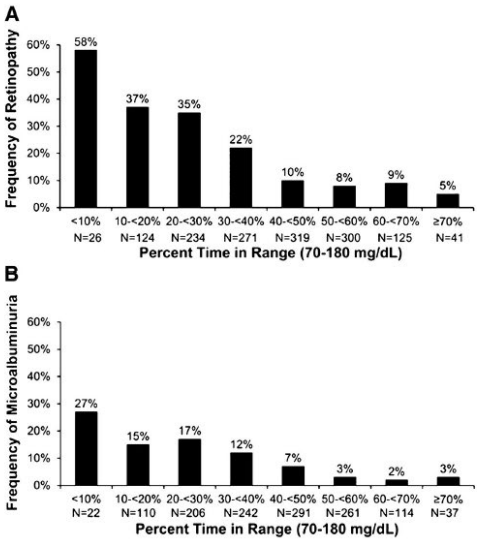

Figure 2: Time in range and relationship to microalbuminuria.

Objectives

To improve the quality of care of patients with DM type-I and type-II on 3 or more injections of insulin per day in internal medicine continuity community residency clinic in Mountain view Hospital, Las Vegas, Nevada by switching from Self-Monitoring Blood Glucose (SMBG) 3-4 times a day to Continuous Glucose Monitoring (CGM) as measured by improving patient's glucose management indicator (GMI) which approximates HbA1c, but is a more accurate indicator of glucose control. GMI is not affected by the factors which can influence the accuracy of HbA1c measurement like anemia, chronic kidney or liver disease.

Another goal of this project is to improve the quality of care of patients with DM type- I and type-II on three or more injections of insulin per day in the internal medicine residency clinic was by switching from SMBG to CGM to decrease mild – less than 70 mg/dl and severe – less than 54 mg/dl hypoglycemia per day.

Another goal to improve the care of patients with DM type- I and type-II on 3- or more injections of insulin per day in an internal medicine residency clinic by switching from SMBG to CGM was to improve the patient's satisfaction assessed by using the CGM Quality of life questionnaire.

One of our main objectives was to show that not only in specialized endocrine or internal medicine clinics but in internal medicine residency continuity community clinic under the supervision of Board-Certified Endocrinologist who was a member of the clinic in Mountain View Hospital, Las Vegas, Nevada switching from SMBG to CGM is possible and successful.

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 by performing finger sticks which was painful, cumbersome and frequently missed both episodes of both high and low blood sugars.

Methods and Procedures

Eleven 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- I or type- II diabetes mellitus with average HbA1c 10.7% and were using 3-4 injections of insulin per day and for patients with type II diabetes mellitus +/- anti-diabetic 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 acquiring a 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 the Dexcom- G6- CGM database and the clinic EMR. The eligible patients were given a share code by the treating team to share their CGM. Data was shared with the clinical team continuously. The patients were given instructions in the clinic about their diet, exercise, and also given a pamphlet on how to adjust their Insulin dose based on their CGM data. The patient needed to show understanding and teach back of the procedures. Also, an application with the carbohydrate content and calorie content of the food was given with appropriate recommendations by the CGM team.

Twice a week a representative from the clinical team contacted the participating patients and adjusted their insulin dose based on their CGM data. At that time, advice on diet, eating habits, and exercise was provided as well. On a monthly basis, there was an additional appointment scheduled for the patients in the clinic with representatives of the CGM team. During these appointments with the CGM team, additional adjustments of the patient's insulin regimen were performed under the supervision of a board-certified endocrinologist.

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

Inclusion Criteria:

• Age 18-80

• Having type- I or 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 iPhone or Android phone with the CGM-device Dexcom- G6 to be able to look and share with the clinic their CGM data

• Patients had to be on 3 or 4 injections of insulin and for patients with diabetes mellitus type -II +/- oral medications or injectable GLP1-RAG before enrollment to the study with switching from SMBS to CGM.

• To self-monitor their blood sugar 4x a day before the switch to CGM.

• Patients, after the switch to CGM, have to be on 3-4 injection of insulin and for patients with diabetes mellitus type -II +/- oral medications or injectable GLP1-Receptor agonists (GLP1-RAG)

• Patient has 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 I or 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.

Exclusion Criteria:

• Patients who were not on insulin 3-4 injections per day

• 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 advice on how to adjust their Insulin given to them by the residents

Results

At 3- months the 11- patients with type- I and type -II DM on 3-4 injections of Insulin per day who were followed by us and switched from SMBG – 4 times a day to continuous Glucose monitoring -CGM showed statistically significant improvement of their HbA1c from 10.5% to 7.47%- P=<0.005% (fig.3). The Internal Medicine and Transitional Year Residents in the Internal Medicine Continuity Clinic under the supervision of board-certified Endocrinologist member of the clinic 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.

There was also statistically significant reduction of the incidence of mild hypoglycemia < 70 mg/dl blood sugar on average 1- per day lasting around 7- minutes on CGM compare to 1-4 episodes of mild hypoglycemia while SMBG on average lasting 27- minutes per day- P<0.005%. Also, the severe hypoglycemia <54 mg/dl blood sugar was reduced while using CGM to less than 1 episode per day lasting on average 3- minutes compare to the 1-episode of severe hypoglycemia while SMBG lasting on average -7 minutes-P<0.005% (fig. 4). (Figure 3, 4)

Time in range of blood sugar between- 70-180 mg/dl was 62% which was excellent given the mean age of the patients of 53.2 years. 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).

The patient's satisfaction measured by CGM Quality of life questionnaire

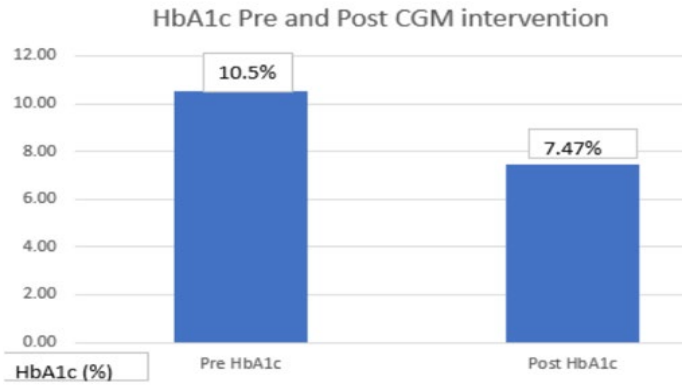

Figure 3: Reduction of HbA1C with the use of CGM.

	# of Hypoglycemic Episodes Pre and Post CGM	
	Mild (<70 mg/dl)	Severe (<54 mg/dl)
Pre	1-4	1
Post	<1	<1

Figure 4: Reduction of Hypoglycemia with the use of CGM.

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: Improvement of Quality of life after introduction of CGM.

after switching from SMBG to CGM improved significantly (fig.5). This was due to the improved control of their Diabetes mellitus and adopting healthier lifestyle. (Figure 5)

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 oral anti-diabetic medications and or injectable GLP1-RAG after the switch from SMBG to CGM.

Discussion

Over the last decade CGM has become an increasingly refined and valuable tool for real-time monitoring of blood glucose in a variety of diabetes treatment settings. As the accuracy, convenience, and software support have continued to improve, the clinical evidence base has continued to evolve as well [13, 14]. The obvious early application was in patients with type- 1 diabetes on intensive insulin therapy to reduce hypoglycemia and improve glucose control [2]. However, the early studies of efficacy in type -I diabetes were largely proof of concept with mixed diabetes types, exploratory study designs, and mixed insulin delivery methods. Even as studies became more specific for type- 1 diabetes, they often represented a disproportionate number of patients on insulin pump therapy and it was difficult to ascertain the specific value in type-I patients on MDI; the most common insulin delivery method. Recently, the GOLD Trial and the DIAMOND Trial, two randomized controlled trials, have confirmed the independent value of CGM in guiding intensive insulin therapy for type -I patients treated with MDI [6, 7]. The evidence is clear and allows for practical translation to everyday practice. Yet, the opportunity for further improvement in results will come from added research and experience as it relates to optimal, customized education, and follow-up.

Not surprisingly, the CGM clinical research in type- II diabetes lagged behind that for type- I diabetes, particularly with regard to patients treated with MDI, but the trials with usage of CGM confirms benefit in type- II diabetes treated with MDI as three quarters of the patients had an HbA1c improvement of at least 0.5% [9,11]. The benefit is now clear and expanded use and insurance coverage is warranted.

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 [13].

In our study, the majority of our patients were diagnosed with type II DM, 85%. They were on 3-4 injections of insulin daily. Previously published research shows the benefits of CGM not only in 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-3.03% in 3- months, while on average HbA1c improves based on other studies was between 0.3- 0.6 percent [14].

We believe that the more significant drop in our population of patients was due to the patients' characteristics. As this study was conducted in a community clinic that primarily serves patients with Medicare and Medicaid insurance, there were proportionally more patients of low socioeconomic status. Additionally, our community clinic is in Las Vegas, Nevada- a metro area with the second worst public schools in the United States according to a study published by the Fordham Institute in conjunction with the US Chamber of Commerce [15]. Given the sub-par public education accessible to our patients, it is unsurprising that baseline understanding of science and medicine amongst our patient population is low. Our patients' desire to learn more about their disease process and quick ascertainment of knowledge that led to our remarkable results speaks to their intelligence and resiliency. Ultimately, this study shows the tremendous effort our patients invested in acting upon the advice provided to them by clinic residents.

Under the supervision of a board-certified endocrinologist, internal medicine residents spent a significant amount of time counseling patients on the dietary changes necessary to successfully manage their diabetes. Dietary education efforts focused on the appropriate consumption of carbohydrates and caloric restrictions. Patients were also provided with education, both verbal and written, regarding insulin titration based on their real-time blood glucose measurement as monitored via CGM. The option to download specific smartphone applications designed to assist patients in monitoring their calorie and carbohydrate intake was provided as well. Patients' understanding of the above was assured using the teach-back technique.

Patients were closely monitored through bi-weekly phone calls from internal medicine residents and monthly clinic visits. Supervision of residents by a board-certified endocrinologist who was also a member of the clinic was integral to the success of our project as this ensured the provision of safe, quality, and cutting-edge medical care to participating patients as determined by expert opinion. The biggest barrier faced during this study was ascertaining the level of understanding from the patients on how to use the CGM data to adjust their insulin dose. This was a major safety concern as we initially thought patients would be highly prone to self-inducing iatrogenic hypoglycemia. However, through close follow-up and conservative insulin titration regimens, we did not encounter a single scenario where a patient becomes hypoglycemic to the point of requiring emergent medical attention. Another barrier to the success of our project was obtaining the appropriate insurance coverage so that our patients' CGM equipment and medications would be affordable. Additionally, to fully participate in our study, patients needed to have a phone compatible with the CGM software. Given the lower-than-average income of our patient population, this barrier unfortunately made some patients' participation not feasible.

Lastly, the lack of a diabetic educator and dietician in our clinic meant that all education on medication use, CGM reading and adjustment of the Insulin based on it and appropriate dietary habits was provided by the participating doctors. While study personnel were able to provide these services to patients in the course of the present study, if more patients were to be enrolled, more ancillary clinic staff would be necessary to provide safe and quality care. This is an important limitation for other programs considering the implementation of a similar program.The unique value of this study is the successful implementation of CGM in an internal medicine continuity community residency clinic in Mountain View hospital, Las Vegas, Nevada. The process was navigated by internal medicine residents under the supervision of a board-certified endocrinologist who was also a member of the clinic which was done for the first time in the USA as per our knowledge.

The CGM was not introduced in a specialized endocrinology or internal medicine clinic. This study shows that the CGM device can be introduced successfully in other Internal Medicine Residency Clinics in the country by Internal Medicine Residents under the supervision of Endocrinology specialist to improve the quality of care of the most difficult to treat Diabetic patients on Multiple Daily injections of Insulin (MDI). As far as we know this is the first study exploring this opportunity in the USA. The bias of the study was the small sample size, the short period of follow up and the type of the population studied.

Conclusion

In conclusion, we showed the successful implementation of CGM in patients with DM type- I and type- II in an Internal Medicine Residency Continuity Community Clinic in Mountain View Hospital, Las Vega, Nevada by Internal Medicine Residents under the supervision of a board-Certified Endocrinologist who was also a member of the clinic.

The HbA1c decreased compared to SMBG by 3.03% in the 3 months after the switch to CGM. Additionally, the mild and severe hypoglycemia was significantly reduced. The patient's satisfaction increased and the time in range of the blood sugar was at goal.

These results are encouraging as they robustly suggest that this device can be introduced in other internal medicine residency clinics in USA with the goal of improving the quality of care provided to patients with type 1 and type - II diabetes on multiple daily injections of insulin.

Funding

We did not receive any funding for this trial.

Disclaimer

This research was supported (in whole or in part) by HCA Healthcare and/or an HCA Healthcare affiliated entity. The views expressed in this publication represent those of the author(s) and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities.

Acknowledgement

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

Conflict of Interest

The above listed authors, Drs. Manov, Benge, Baig and Chauhan, have no conflict of interest to declare.

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Cite this article: Andre Manov, Elizabeth Benge, Samera Baig, Sukhjinder Chauhan. Retrospective, Longitudinal, One Group Study about the Implementation of Continuous Glucose Monitoring in Improving Quality of Care for Patients with Type I Or II DM in Internal Medicine Residency Continuity Community Clinic. J Diabetes Metab, 2022, 13(9): 956.