Longitudinal Study on the Effects of Implementing Continuous Glucose Monitoring for the Management of Patients with Type-I and Type-II Diabetes Mellitus on Multiple Insulin Injections in an Internal Medicine Residency Clinic

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Background

The number of patients suffering from diabetes mellitus (DM), types 1 and 2, 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).

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].

Diabetes mellitus is the leading cause of blindness, non-traumatic amputation, and end-stage renal disease in the US. Continuous Glucose Monitoring (CGM) is an advancement in diabetes technology that continuously and automatically tracks blood glucose throughout the day and night. When combined with proper education, follow-up, and support, CGM has proven to be effective at improving management for insulin-dependent diabetics. The aim of our study is to implement GCM in a resident run internal medicine clinic, not specialized in endocrinology, to improve the quality of care for diabetic patients using 3-4 insulin injections daily.

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].

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 and Transitional Year Residency Continuity Community Clinic the CGM can be introduced by Transitional Year and 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 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.

Objective

- The standard of care in the Internal Medicine and Transitional Year Residency Continuity Community Clinic before this project was for 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.
- To try to decrease the number of Injections of Insulin in Patients with DM without compromising their blood sugar control after switching from SMBG to CGM.
- To show that this can safely be done in the community clinic under the supervision and guidance of an endocrinologist to assure patient safety and benefit.
- To decrease utilization of insulin following blood sugar control and improvement of HbA1C/GMI with combination/utilization of oral medications, diet, and exercise.

Methods

A longitudinal retrospective study was conducted for twenty-five (n = 25) patients between 42 and 75 years of age with uncontrolled diabetes recruited by a team of internal medicine residents, transitional year residents, and a board-certified endocrinologist at the internal medicine resident clinic at MountainView Hospital in Las Vegas, Nevada. The patients had either Type 1 DM (15% of patients) or Type 2 DM (85% of patients). At the time of recruitment, all of the patients were using 3-4 injections of insulin a day, in addition to antidiabetic oral medications or GLP1-RAG. Patients were self-monitoring their blood glucose at least four times a day. The average HbA1c of these patients prior to the implementation of CGM was 11.21%. All subjects were current patients at the resident clinic and were given information regarding CGM if they met inclusion criteria for the study. Patients who expressed an interest in CGM instead of SMBG signed a consent form for implementation of CGM and which gave an explanation regarding the usage of CGM and the possible risks and benefits of participation in our study. No coercion or forceful behavior was used to convince patients to sign the form. The decision to use CGM and participate in the study was completely voluntary and patients were permitted to leave the study at any point.

In the clinic, diabetic patients were given pamphlets describing how to adjust their insulin at home if needed. They were also counseled about diet and exercise and provided a pamphlet with carbohydrate and caloric content of different foods and meals. Patients needed to show understanding of the procedure and teach back this understanding before implementation of CGM. The CGM Dexcom G6 device was used in our study due to the availability of the device, the availability of technical team support, and the device not requiring calibration. The data was collected from the CGM Dexcom database through the Dexcom G6 Clarity database and the clinic EHR. Patients with device compatible iPhones or Android phones were given a share code by the CGM team so that the research team could monitor their blood glucose data on a continuous basis. Patients who did not have compatible phones were given a receiver and were seen at the clinic at least once a month. Patients' data were downloaded at the clinic visit so that their insulin regimen could be adjusted appropriately and additional data could be collected for the study. All patients were seen at least once a month at the internal medicine residency clinic. They were also contacted by a member of the CGM team biweekly and their insulin regimens were adjusted based on their blood glucose readings with the help of our board-certified endocrinologist.

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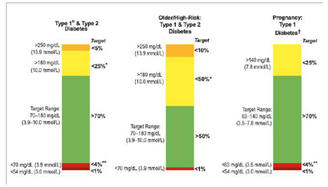
Results

	Prior to CGM Device insertion	After CGM Device insertion
Patients' Average HbA1c/GMI	11.21%	7.04%

	SMBG	CGM
Time In Range*	18%	74%
Coefficient of Variation*	39%	29%

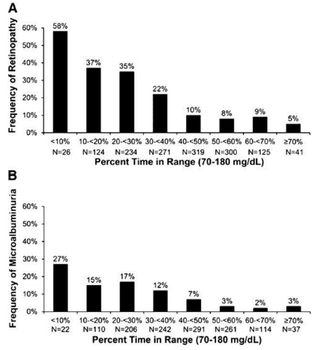
* *indicates areas which have met objective goals*

ADA Goals for Various Patient Groups: "Time-In-Range" now important



Glycemic variability calculation is: Standard deviation of glucose/ average glucose
Goal for GV: <36%

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



Discussion

Over the last twenty years CGM has become increasingly used for real-time monitoring of blood glucose in a variety of diabetes treatment settings and applications (2,3,14). The CGM devices have become easier to use, smaller and more accessible through a wider range of insurance plans (16). As the convenience and software support have continued to improve, the clinical evidence base has continued to evolve as well (15,17). The earliest application of the CGM devices were in patients with type- 1 diabetes on intensive insulin therapy with the goal to reduce hypoglycemia and improve glucose control (10). However, the early studies of efficacy in type-1 diabetes were largely proof of concept . Initial studies of CGM were in patients with type- 1 diabetes, but the majority of studies were using Insulin Pumps rather than Multiple daily Injections of Insulin (MDI).

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 Diabetic patients treated with MDI (10,11). CGM clinical research in type- 2 diabetes lagged behind type- 1 diabetes, particularly with regard to patients treated with MDI, but the trials with usage of CGM confirms benefit in type- 2 diabetes treated with MDI as three quarters of the patients had an HbA1c improvement of at least 0.5% (3,4,5,6,7,8,9,13,15,16,17). The Glucose management indicator (GMI) measured by the CGM provides an estimation of HbA1c levels and is less prone to inferences from conditions like anemia, chronic kidney disease, liver cirrhosis etc. (1,2). The American Diabetic Association and International Consensus provides recommendations for blood glucose control using CGM as shown in Figure 1(20,21). The most important goal to be achieved with the usage of CGM is the blood sugar between 70-180 mg/dl. We call this Time in range. The goal is the blood glucose to be in the range between 70-180 mg/dl 70% of the time, except in older patients with high risk of hypoglycemia and pregnant patients as you can see from Figure 1(20). There is a correlation between time in range and the microvascular complication of patients with type -I and type -II DM as described in figure 2(20,21). The CGM device led to improvement in the majority of the studies of HbA1c by 0.3-0.6%. Also, it decreased the risk of hypoglycemia on patients who were using Insulin (3).

In our study for the first time as far as we know we introduced CGM in the General Internal Medicine Residency Clinic with the active participation of our Transitional Year and Internal Medicine Residents. The effectiveness of our efforts by using CGM compare to SMBG in patient with DM type- 1 and type-2 on multiple injections of Insulin per day was measured by improving the GMI reflecting HbA1C to equal or less than 7%, decreasing the average Blood Glucose, increasing time in range to 70% or above, decreasing mild hypoglycemia less than- 70- mg/dl to less than- 4%- a day , and decreasing pronounced hypoglycemia less than – 54- mg/dl to less than- 1% a day, improving the patient's satisfaction measured by CGM Quality of life questionnaire, decreasing the number of Insulin Injections if possible in patients with DM type-2 or switching their treatment to oral antidiabetic medications plus/minus injectable GLP1-RAG without compromising the diabetes control.
Four of our patients after overcoming their glucotoxicity with Insulin were able to reduce and eliminate their Insulin Injections and be compensated only on oral antidiabetic medications and or GLP1-RAG.

The reported average improvement of HbA1c in our patient's population was- 4.17%, while on average HbA1c improves based on other studies was between 0.3-0.6% (4,5,6). The Coefficient of Variation decreased from 39% to 29% after the switch.

We hypothesized that the more significant drop in our population of patients of HbA1c 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 realizing 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 amount of time spent by our members of the CGM team in explaining the patients the carbohydrates needed to be consumed per meal and their type, the number of calories per day, the exercise programs and frequently following the patients by phone and in the clinic was decisive for the success of our CGM team. Also, having an on Board Endocrinologist as a part of the CGM team was critical for our success.

The main barriers we encountered was to assure that the patient understood how to use the CGM data in adjusting their Insulin dosages, the problems with the insurance coverage of the CGM device and the lack of Diabetic educator and dietitian in the clinic to help in educating the patients.
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.

Conclusion

This study shows that the utilization of the CGM device with proper patient education and follow-up can be successfully utilized in a residency continuity clinic run by Transitional year and Internal Medicine residents to the benefit of diabetic patients. Traditionally, the CGM system was only used in specialized endocrine centers. Given such positive results witnessed in our clinic, we are confident that our success can be replicated by other Internal Medicine Residency Programs across the country to improve the quality of care of patients with DM on MDI and improve the quality of education of Transitional year and Internal Medicine Residents.

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