Evaluating the Impact of Pharmacist-Led Continuous Glucose Monitoring Educational Interventions on Markers of Quality of Life and Device Utilization in a Large Community Pharmacy Chain

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Background

Throughout the years, there have been several technological advancements related to diabetes care. Self-monitoring blood glucose (SMBG) devices, among other advancements, have led to improvements in accuracy as well as the amount of blood required for one blood glucose reading. However, one of the biggest breakthroughs is the emergence of continuous glucose monitoring (CGM) devices. Several CGM device options exist, such as Freestyle Libre and Dexcom®, both demonstrating a positive impact on patients' diabetes control.[1,2,3]

CGMs include a small sensor that is inserted under the skin. The sensor tests the interstitial blood glucose levels every few minutes and wirelessly transmits readings to a secondary device that records the readings.[4] CGMs have been primarily used by patients with type 1 diabetes mellitus (T1DM) and more recently have increased use in patients with type 2 diabetes mellitus (T2DM). As the use of CGM devices continues to grow, the American Diabetes Association (ADA) released guidelines detailing CGM device recommendations for use and goals related to blood glucose readings, designated as the time in range (TIR). TIR is defined as the duration of patients' blood glucose levels within the optimal ranges (70 to 130 mg/dL fasting blood glucose and <180 mg/dL for post-prandial). The frequency at which patients should measure their blood glucose levels is dependent on diabetes type, disease control, age, and risk for hypoglycemic events. The ADA guidelines recommend that patients with T1DM and T2DM maintain 70% TIR per day and limit hypoglycemic events (blood glucose < 70 mg/dL) to less than 4% of the time in a day.[5,8]

Multiple studies have investigated the impact of CGM devices on patients' health outcomes, such as A1c, hypoglycemic frequency, and trend of blood glucose levels pertaining to CGM usage. Furthermore, several publications addressed markers on quality of life (QOL) in multiple different settings, such as hospitals and outpatient facilities.[1,3,6,9,10,12] QOL markers were evaluated to investigate the impact of CGM devices on other areas of patients' health and lifestyle including, overall comfortability with the device, ease of use, effects of the device on daily life and diet, patients sense of empowerment, awareness of the significance of information received from the device, and overall maintenance of health with feedback from the CGM device.[1,3]

Many studies evaluating markers of QOL, such as the DIaMonD trial and the I HART CGM trial, focused solely on patients with T1DM and included these markers as secondary objectives. While they did not include patients with T2DM, these studies found positive changes in patients' feelings who use CGM devices and identified positive effects on patients' health and lifestyle as a result of CGM device utilization.[9,10,11,12]

Though CGM device studies demonstrated a positive impact on clinical and humanistic outcomes, patients continue to struggle with CGM device initiation and usage. As the most

accessible healthcare professionals, pharmacists are uniquely positioned to serve as a resource for patients initiating CGM devices. When patients begin using CGM devices, pharmacists can provide education on how to properly use these devices in addition to what to expect, recommendations for frequency of use, and therapeutic goals.

Community pharmacists work to provide patients with the information and education needed to optimize CGM device utilization. However, even though pharmacists are highly accessible and equipped to provide education, many patients continue to struggle to initiate CGM devices and interpreting their results. Improving CGM device utilization is imperative to improving health outcomes for patients. The purpose of this study was to assess the effects pharmacist education on markers of QOL and CGM device utilization by incorporating a pharmacist follow-up after CGM device initiation.

Objectives

This study evaluated the impact of a community pharmacist-led CGM device educational intervention program on patient markers of QOL and CGM device utilization in patients with diabetes who fill prescriptions at a large community pharmacy chain. The primary objective was to determine the impact of pharmacist-led educational interventions on patients' markers of QOL post CGM initiation. The secondary objectives were to assess patients' TIR, episodes of hypoglycemia, and CGM device fill history and device utilization.

Methods

Practice Description

Kroger Health is a large community pharmacy chain that operates over 2,300 pharmacies in 37 states and 215 convenience care clinics in nine states. Each location is employed with a healthcare team committed to helping people live healthier lives. Recently, Kroger Health became the first national chain pharmacy to obtain Community Pharmacy Practice Accreditation through the National Association Boards of Pharmacy. This project was implemented within one regional division of the chain, which consists of 103 pharmacies. Pharmacists in this division routinely provide a wide variety of direct patient care services, including biometric healthcare screenings, vaccine services, medication therapy management services, chronic disease state management, and appointment-based medication synchronization services. In addition, many Kroger Health pharmacies across the country offer advanced clinical services.

Training

The pharmacy resident completed training to interpret new therapy fill reports to identify and target potential study patients. Additionally, the pharmacy resident completed CGM manufacturer-specific training to be proficient in providing CGM device utilization education, identify episodes of hypoglycemia, provide education on management, and troubleshoot CGM device questions. The pharmacy resident designed a standardized script to guide patient encounters.

Patient Eligibility

As part of an existing diabetes care program, patients were targeted for CGM device initiation based on SMBG testing frequency and insulin utilization. Organization leadership generated new therapy fill reports in the pharmacy management system to identify eligible patients. The report

identified patients who recently initiated CGM devices, such as the Freestyle Libre Reader and Dexcom® Receiver. Pharmacies were randomized into control or intervention groups based on a comparison of their average weekly prescription fill count. Patients associated with each pharmacy were then placed into the control and intervention groups, respectively. This study included patients with T1DM and T2DM. Patients who were pregnant, did not speak English as a first language, or under the age of 18 were excluded from study participation. Patients who filled a CGM device for greater than three months were also excluded.

Intervention

For the intervention and control group, the pharmacy resident outreached patients telephonically at the 14-day and 45-60 day mark from the first fill of the CGM device. Upon the initial encounter with both the control and intervention group, the resident administered the markers of QOL survey and collected clinical data from the patients. If a patient in the control group required counseling at the initial encounter, they were excluded from the study since they no longer met the inclusion criteria of the control group. At the initial encounter with the intervention group, the resident discussed device usage, provided education, troubleshot any technical issues, and discussed diabetes care goals, such as TIR, episodes of hypoglycemia, and frequency of device utilization. Then the resident administered the 45-60 day follow-up encounter and provided patient education, as appropriate, to all patients in the control and intervention groups. All results were confidential as patient identifiers were not be collected.

Evaluation

This study was a retrospective and prospective, multisite study under review by the University of Cincinnati Institutional Review Board. The training period occurred in December 2020, with longitudinal project support provided following the training. The implementation period and data collection began in February 2021 and was completed in June 2021. For the primary outcome A paired t-test was used to analyze pre- and post-survey data from the intervention and control group. Descriptive statistics were used to analyze secondary objectives.

Measurement of Primary Objective

The primary objective, determining the impact of pharmacist-led educational interventions on patients' markers of QOL, was measured by evaluating changes in patient QOL survey responses at 14-days and 45-60 days post-CGM initiation. Patients' responses were evaluated using a five-point Likert scale. The pharmacy resident entered the responses while engaging with the patients telephonically. The survey responses were collected and stored in the Research Electronic Data Capture (REDCap) platform. REDCap is a HIPAA compliant, secure web application used for building and managing online surveys and databases.

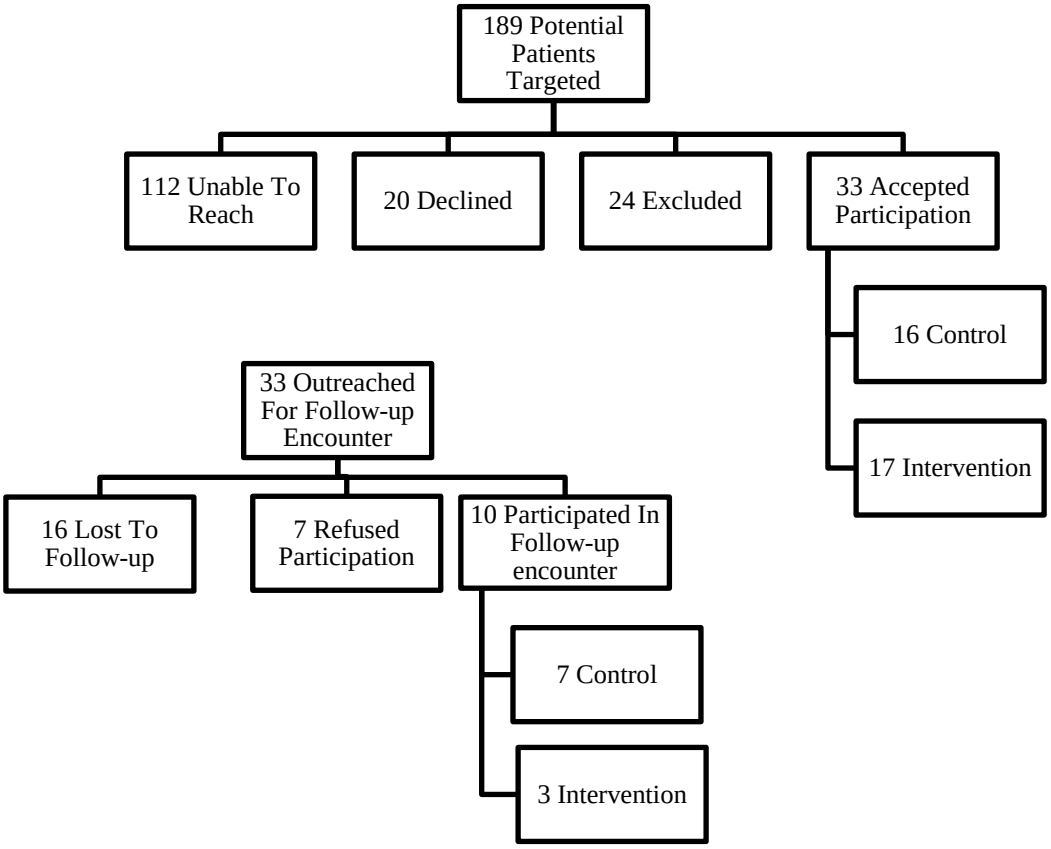
Measurement of Secondary Objective

The secondary objectives were to assess the impact on patients' TIR, episodes of hypoglycemia, CGM device fill history, and device utilization. The pharmacy resident assessed changes in TIR or episodes of hypoglycemia in the control and intervention groups at the initial and follow-up encounters. Additionally, patient CGM fill history in the pharmacy management system and patient-reported frequency of device utilization was evaluated. All data was stored in REDCap.

Results

Between February and June 2021, 189 patients were targeted as potential patients for this study (Figure 1). The pharmacy resident contracted each patient at least two occasions, with a non-descript voicemail recorded if the patient was unable to be reached. At the second attempt, if no response was received, the patient was marked as unable to reach. Patients who were successfully reached were informed before the initiation of the survey that if they would no longer like to participate in the survey, they were able to stop at any time. Patients were able to decline participation if they did not feel comfortable participating or did not want to participate. Of the 33 patients who participated in the survey-based study, 16 were in the control group, and 17 were in the intervention group. During the follow-up, ten of the original patients were successfully outreached and participated in the follow-up survey, seven from the control group and three from the intervention group

Figure 1: Patient Screening, Allocation, and Study Follow-up



Patients were equally distributed in terms of patient demographics, as shown in Table 1. Of note, most patients were diagnosed with T2DM, but two patients in each group were diagnosed with T1DM. Just over half of the intervention group was female, while just over half of the control group was male. Most of the patients in both groups initiated their CGM device in the past one to three weeks. A quarter of the control group had a TIR greater than 90%, six of the patients in the control group had a time below range (TBR) less than 1%, and five patients had

an A1c above 9.5%. Five patients in the intervention group were unable to retrieve their initial TIR and TBR data. Additionally, two patients could not recall their most recent A1c, restricting researchers' ability to compare data for the initial and follow-up encounter.

Table 1: Initial Baseline Patient Demographics (n, %)		
Demographic	**Control (n=16)**	**Intervention (n=17)**
Mean Age	51.5 years	51.8 years
Gender	10 (63%) male, 6 (37%) female	8 (47%) male, 9 (53%) female
Diabetes Type		
Type 1 Diabetes Mellitus	2 (12%)	2 (12%)
Type 2 Diabetes Mellitus	14 (88%)	15 (88%)
Device Type		
Dexcom G6	6 (37%)	7 (41%)
Freestyle Libre 1 or 2	10 (63%)	10 (59%)
Device Duration		
Less than 1 week	1 (6%)	0 (0%)
1 to 3 weeks	8 (50%)	10 (59%)
One month	6 (37%)	7 (41%)
Other (i.e., not started)	1 (6%)	0 (0%)
14 Day Time in Range (TIR)		
Less than 70%	5 (31%)	9 (53%)
Between 70-90%	3 (19%)	1 (6%)
Greater than 90%	4 (25%)	2 (12%)
Not applicable	4 (25%)	5 (29%)
14 Day Time below Range (TBR)		
Greater than 5%	3 (19%)	3 (18%)
Between 1.5-5%	3 (19%)	6 (35%)
Less than 1%	6 (37%)	3 (18%)
Not applicable	4 (25%)	5 (29%)
Recent Provider HbA1c%		
Less than 7.0%	6 (37%)	3 (18%)
Between 7.0-9.5%	5 (31%)	5 (29%)
Greater than 9.5%	5 (31%)	7 (41%)
Other (i.e., no value)	0 (0%)	2 (12%)

With a limited follow-up sample, there was a positive shift in patients' sense of empowerment throughout their responses, device utilization related to daily activities, and sense of freedom regarding their CGM device and disease state (Table 2). The question which evaluated patients' worry about controlling their blood sugar realized a significant shift from

neutral upon initial assessments to patients agreeing with this statement on average for the intervention group and a minimal positive change for the control group.

Table 2. Patient Survey Responses Evaluating Markers of Quality of Life				
Survey "Using this device:"	**Initial Survey**		**Follow-up Survey**	
	Control (n=16)	**Intervention (n=17)**	**Control (n=7)**	**Intervention (n=3)**
Allows more freedom in daily life	4.75	4.41	4.85 (↑0.10)	4.67 (↑0.26)
It's easy to get a blood sugar reading	4.88	5.00	5.00 (↑0.12)	5.00 (no Δ)
Helps me to be sure about making diabetes decisions	4.75	4.35	4.85 (↑0.10)	4.33 (↑0.02)
Causes me to be more worried about controlling my blood sugar	3.13	3.00	3.29 (↑0.16)	4.33 (↑1.33)
Helps me understand how my daily activities impact my blood sugar	4.50	4.53	5.00 (↑0.50)	4.33 (↑0.20)
Helps to keep low blood sugars from happening	4.33	4.12	5.00 (↑0.12)	4.33 (↑0.21)

1= strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree

The response rate for the follow-up survey was small, with ten patients successfully completing the follow-up encounter. In addition, as patients continued to use their devices, their TIR fluctuated from initial and follow-up. Therefore, patients' responses were divided into control and intervention groups (Table 3). Patients in both groups consistently refilling their CGM sensors based off of the fill history from the pharmacy management system. None of the patients reported changes in their frequency of use throughout the duration of the project. Both groups shared trends with the exception of a few patients; the longer the patients had their CGM devices, the less they were within their TIR.

Table 3. Patient Survey Responses Evaluating Clinical Data								
Patient	**Group**	**Device**	**14 days**		**14 days**		**30 days**	
			Initial TIR %	**Initial TBR %**	**Follow-up TIR %**	**Follow-up TBR %**	**Follow-up TIR %**	**Follow-up TBR %**
1	Control	Dexcom G6	–	–	–	–	–	–
5	Control	Freestyle Libre	99	0	87	0	93	1
8	Control	Dexcom G6	99	<1	79	0	86	0
9	Control	Dexcom G6	70	4	–	–	–	–
10	Control	Freestyle Libre	99	0	99	1	98	1
11	Control	Freestyle Libre	38	27	32	20	35	25
14	Control	Freestyle Libre	71	13	61	34	65	31
2	Intervention	Freestyle Libre	–	–	11	7	25	4
6	Intervention	Freestyle Libre	14	1	10	0	20	1
7	Intervention	Dexcom G6	95	3	–	–	–	–

Discussion

During the study period, patients demonstrated an improvement in markers of QOL. In addition, patients from the intervention group showed an increase in understanding how to access and interpret the available data from their respective devices. During the follow-up encounter, when discussing with patients' from the control group, they also demonstrated an understanding of how to pull up the data from their respective devices. However, only a few showed an understanding of the meaning of their data. Overall, in both groups, device utilization was consistent throughout the study. The pharmacy resident was able to properly educate patients on the current ADA guidelines and understanding of device placement and guided patients through application and technology-related issues.

There was an increase in patients' awareness of their disease state due to the initiation of a CGM device, helping them understand the effects of their lifestyle and activity levels. Multiple patients stated that they felt underprepared for using their CGM device due to a lack of guidance from their pharmacist and other healthcare professionals. Adherence to CGM devices and device fill history was not a barrier for these study patients, and device-related sensory component issues were appropriately addressed either by patients or by referral from the pharmacy resident. All CGM device manufacturers involved readily replaced components of the devices at patients' request.

Upon further discussion with intervention patients during the follow-up survey, patients indicated they became more worried about controlling their blood sugar meaning their disease state became something that was significant and important to them. Patients in the intervention group worried in a manner that helped them be mindful of their disease state, while patients in the control group were less worried about controlling their blood sugar. Overall, patients positively associated their sense of empowerment and control of their disease state with the use of their CGM device.

Of the 33 patients who initially engaged in the survey, ten were reached for the follow-up survey. Despite an existing patient relationship established with these patients, several patients were unwilling to provide clinical data such as TIR and TBR when prompted by the pharmacy resident, limiting the evaluation of secondary objectives. In addition, several patients in the intervention and control groups struggled to retrieve this data. These patients were prime candidates for pharmacists-led educational interventions with device utilization and data interpretation.

Overall, as patients continued to use their CGM devices their TIR began to decline, this was true for the majorty of both groups. This decline may have been due to a multitude of factors due to that patient’s lifestyle, environment, diet or any other number of factors. The follow-up encounter sample size was small and there were a few patients from each group that did not share their TIR and TBR information upon the follow-up encounter.

Almost all patients in both groups displayed a willingness to learn or at the very least listen to the information provided by the pharmacy resident during the follow-up encounter. Discussions included appropriate sensor placement and adhesion options as well as explaining the difference between their interstitial glucose levels compared to traditional finger stick glucose levels via SMBG.

An advanced program for CGM clinical and operational educational interventions may be a viable strategy for increasing patient understands and sense of empowerment with device utilization and data interpretation. Community pharmacists are conveniently positioned and able to improve CGM device utilization through pharmacist-led patient education with an emphasis on QOL markers and device utilization.

Limitations

Throughout the implementation of this research project, there were several study limitations. Primarily, the presence of a global pandemic that impacted researchers' ability to conduct interventions face-to-face. Of the 189 potential patients, 112 potential patients were unable to reached. This was most likely due to the telephonic nature of the research study, and follow-up was equally challenging due to this limitation. Adding to this concern, researchers had difficulty providing in-depth assistance to troubleshoot device and data-related issues telephonically and struggled to build rapport gaining patients' trust to disclose and discuss CGM-related data. While many patients gained a better understanding of their CGM devices, several

were unable or unwilling to participate in the clinical portion of the survey. Finally, several patients were excluded due to a history of filling an alternative CGM device within the previous three months.

Conclusion

Patients continued to experience challenges initiating CGM devices, understanding their diabetes-related care goals, and utilizing their devices to the utmost potential. Several studies have evaluated the impact of CGM devices combined with insulin and its effects on patient's health outcomes. Proactive pharmacist follow-up paired with pharmacist education has the potential to improve patients' markers of QOL and sense of empowerment with device utilization and data interpretation. However, future research is needed to determine the most effective way to incorporate pharmacist-led comprehensive CGM device training for patients new to therapy in the community pharmacy setting.

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