Patient Satisfaction with Professional Continuous Glucose Monitoring in a Diverse Family Medicine Clinic: A Pilot Study

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Abstract
Primary care providers (PCPs) manage a large portion of patients with diabetes. Continuous glucose monitoring (CGM) can give detailed information about glucose trends to improve treatment and safety. We conducted a prospective cohort pilot study to understand patient experience with the use of professional CGM in a primary care practice with a high volume of diverse, non-English speakers. Eligible patients were on an insulin regimen and either had an A1c above goal or whose PCPs had concerns for hypoglycemia. Surveys were collected prior to the intervention to assess the acceptability of the patient's self-monitoring blood glucose efforts and after the intervention to assess their experience of using the CGM. Participants at baseline had a mean A1c of 10.6% and a high amount of emotional distress as measured on the Problem Areas in Diabetes (PAID) scale. Post-intervention, patients reported their experience with professional CGM was positive and, overall, as acceptable of an intervention as their previous self-monitoring blood glucose practice. Professional CGM can serve as an additional, acceptable tool for PCPs to better understand how to help patients achieve diabetes blood glucose goals. Ambulatory care pharmacists are well positioned to lead this effort in clinics.

Keywords: continuous glucose monitoring; primary care; non-English speaking

Introduction

Continuous glucose monitoring (CGM) serves as a useful tool to provide additional information, where A1c and patient reported self-monitoring blood glucose results lack.[1] The use of CGM can assist providers in further clarifying the problem of blood glucose results not meeting goals when it is not otherwise apparent from available data, especially to identify the frequency, severity, and timing of hypo- and hyperglycemic shifts. Two categories of CGM devices are available on the market, personal and professional. Personal CGM devices represent technology owned by the patient, including those that provide real-time blood glucose data and others that provide blood glucose data when the patient interacts with the sensor, known as "intermittently scanned CGM." Professional CGM devices represent technology owned by the clinic and can provide real-time blood glucose data or blood glucose data can be blinded to the patient, i.e., not accessible until downloaded by clinic staff. These devices are recommended for multiple scenarios including for short term use to provide additional diagnostic information, when personal CGM is not available. Situations where blinded professional CGM may be valuable is when there is a discrepancy between A1c and self-monitoring blood glucose values or when patients are having hypoglycemia or there is concern for hypoglycemia unawareness. Primary care providers (PCPs) care for the large majority of patients with type 2 diabetes and this increasingly complex care is in competition with all of the other responsibilities of primary care.[2] Especially in settings of complex patients and medication regimens, professional CGM has been shown to be increasingly useful to providers in making clinical decisions as it has the potential to identify necessary interventions to decrease A1c and frequency of hypoglycemia.[3,4,5] While the patient experience is thought to be generally positive and patients recognize professional CGM as a useful tool to help make behavior changes, more data is needed to understand the patient experience with the implementation of professional CGM into a diverse, primarily non-English speaking, primary care population.[3,6]

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Materials and Methods

This pilot study was designed as a prospective cohort study set to determine the patient experience after a single use of professional, blinded CGM with the iPro2 (Medtronic; Dublin, Ireland) in their primary care clinic. This CGM device was chosen because it was the less expensive of the two options on the market at the time the study was completed. Patients were recruited from a single, urban, family medicine residency training clinic serving a diverse, predominantly underserved population (60% Medicaid, 20% Medicare, 20% Commercial; 25% with a primary language other than English). Eighteen family medicine physician residents and six family medicine physician faculty provide care in the clinic. Goal recruitment was defined as 30 patients. This was determined based on funds available to purchase professional CGM equipment.

Eligible patients were defined as those 18-90 years old, with a diagnosis of diabetes for at least 1 year, currently treated with insulin (either basal or basal-bolus regimens) +/- oral therapies, most recent A1c greater than 9% or any A1c if concern for hypoglycemia, established clinic patient for at least 1 year, history of adherence and ability to follow up (defined by two or

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fewer no show appointments in the past year), ability and willingness to check point-of-care blood glucoses at least four times a day (as required for calibration by the chosen CGM device), current coverage for billing for CGM services (defined as covered service by patient's insurance plan, verified by study staff), patient or caregiver willing to log required data points (point-of-care blood glucose, food and activity log), and not currently using a personal CGM device. The food and activity logs were included to help the interpretability of the CGM data and to create opportunities for education and counseling. Physicians identified eligible patients and referred them to study staff for participation. Study staff then contacted the patient and scheduled study visits. Participation was not incentivized. Patients were excluded if their diabetes was managed by an outside specialist (endocrinology), were pregnant, on dialysis, or were unable to provide consent. Before study roll-out, two 1-hour education sessions were available for physicians. The sessions reviewed CGM recommendations available at the time and how to use and interpret data reports provided by the CGM device manufacturer.[12]

This study consisted of three visits. The first two study visits were carried out by the clinic pharmacist and the third visit was completed with the referring physician. During the first study visit, after obtaining written informed consent, patients completed the baseline surveys, received education on wearing the CGM sensor and data collection requested of them (point-of-care blood glucose, diet, and activity log), and the CGM sensor was applied. Patients returned for the second study visit after wearing the sensor for 4-7 days. This interval was chosen based on CGM billing requirements and because of the memory and battery limits of the chosen device. At this visit the sensor was removed and data was downloaded. The clinic pharmacist interpreted the data and provided recommendations for the patient's medication regimen to the referring physician via documentation in the electronic medical record. For the final study visit, patients returned within 1 week of completion of CGM or as able based on patient and physician availability. At this visit, CGM results were reviewed, and a plan was developed to improve blood glucose control. Patients completed the follow up survey at the end of the study visit. A certified, in-person, interpreter was used for all visits where the patient's preferred language was not English.

Baseline surveys completed at the first study visit included the Problem Areas in Diabetes (PAID) questionnaire to understand patients' current level of diabetes related emotional distress and a modified version of the CGM Satisfaction Scale (CGM-SAT) tool, originally designed to provide feedback on patient satisfaction and perceived impact of CGM on diabetes management and therapy.[7,8,9] As eligible patients were not using personal CGM at time of study enrollment, the tool was modified to inquire about their current home glucose monitoring (HGM) system, thus subsequently referred to here as the HGM-SAT tool. Modifications to the original CGM-SAT to create the HGM-SAT tool included substituting the original question header, "Using the continuous glucose monitor" with "Using your current home glucose monitor" as well as removing questions not applicable to use of HGM. After completion of the intervention at the final study visit, patients completed a follow up survey, which was a modified version of the original CGM-SAT tool, subsequently referred to here as the mCGM-SAT tool. The original tool was modified only to remove questions not applicable to the use of a blinded, professional CGM device (i.e., questions related to real time CGM). To assess the acceptability and usability of both their HGM and professional CGM devices, new questions were added to the baseline and follow up surveys (Table 1).

All questions on the baseline (HGM-SAT) and follow-up (mCGM-SAT) surveys were crafted using a five-point Likert scale (Agree Strongly, Agree, Neutral, Disagree, Disagree Strongly). The surveys included both positive and negatively worded questions. In data analysis and calculation of the mean, responses from negatively worded questions were reverse coded so a higher value would always equate with higher satisfaction. Mean scores on the baseline HGM-SAT were compared to mCGM-SAT after intervention. All surveys were completed on paper and subsequent deidentified data was entered into a REDCap database.[10, 11] The most recent A1c available and demographic data was collected from the electronic health record at the time of enrollment and included patient-identified race, ethnicity, sex assigned at birth, date of birth, preferred language, and diabetes classification. Microsoft Excel was used for data evaluation. The Institutional Review Board of the University of Minnesota reviewed and approved this study.

Results

A total of 12 patients were recruited for this study; all completed the baseline surveys, and 11 patients completed the follow up survey. 19 of the sensors expired before patient enrollment could be completed. The majority of the patient participants were female (66.7%). The mean age of participants was 58 years (range: 49-67 years). A total of 58.5% (n=7) of participants were Asian, 16.7% (n=2) Black or African American, 16.7% (n=2) White, and 8.3% (n=1) Hispanic/Latino. The majority of the patients were Hmong speaking (58.3%, n=7), other languages included English (33.3%, n=4) and Oromo (8.3%, n=1). A total of 83.3% (n=10) of participants had type 2 diabetes mellitus, 16.7% (n=2) with type 1 diabetes mellitus. Average A1c at time of enrollment was 10.6% (range: 7.7-14).

Participants wore the CGM sensor for an average of 7 days (range: 4-14) and produced an average of 5.75 days (range: 2-8) of CGM data. The presence of outliers from the planned sensor wear time (4-7 days) was largely due to patient availability for study visits and producing fewer than 4 days of CGM data, the minimum wear time, was due to lack of calibration point-of-care blood glucose values. Half of patients did not complete the food and activity log as requested, 25%

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completed independently, and 25% completed with assistance from family or friends. Results from the PAID questionnaire showed 10 of the 12 participants had a high amount of emotional distress from their diabetes (score > 40).

See Table 1 for baseline and follow up survey results. Before intervention, the HGM-SAT scores were lower than neutral (3 on a 5-point scale) with a mean + SD score of 2.53 + 0.23. After the short intervention, the mean mCGM-SAT scores were 2.93 + 0.52. 18 out of 24 questions asked on both the HGM-SAT and mCGM-SAT had improvement in satisfaction (positive delta mean) after intervention. In six questions the mean changed towards decreased satisfaction after the intervention. Specifically, when compared to the previous HGM, fewer patients agreed with the blinded CGM helping to keep low blood sugars from happening, teaching them how eating affected their blood sugar, helping them learn how exercise affected their blood sugar, helping them learn how to treat low blood sugars better, giving them more freedom in their daily life, and helping them worry less about having low blood sugars. The three questions included only on the follow-up survey (mCGM-SAT) had above neutral responses for all. Patients expressed CGM made it easier to accept doing blood sugar tests, improved the control of their diabetes even when not wearing it, and it did not make it harder to sleep.

Discussion

The data suggests, to this group of diverse patients, a professional, blinded CGM is at least as acceptable as compared to their previous self-monitoring blood glucose practices. To date, while professional CGM has been shown to be a helpful tool to aid in decreasing A1c or frequency of hypoglycemia, the experience with diverse communities using professional CGM devices has not been assessed. While the sample size was limited, the most notable results were observed in improving testing comfort (question 13), despite the requirement of calibration point-of-care blood glucose testing, decreasing patient hassle (question 7), and decreased embarrassment from feeling different than others (question 23). These three questions all had a greater than one point improvement in the 5-point scale. Patients also noticed improvement in how much their results made sense (question 24). The questions which showed decreased satisfaction (questions 5, 8, 9, 14, 17, and 27) referred to patient reactions to the values the CGM could give them as they wore it. Since the CGM used in the intervention was blinded, patients were unable to react to the information in real time. The use of an unblinded CGM device could overcome this, especially considering the positive results the patients gave to the rest of the questions.

Limitations include using a professional CGM device that required calibration point-of-care blood glucose checks. This may have represented an increase in the number of times patients were performing self-monitoring of blood glucose prior to study enrollment. The availability of this data could have influenced survey results. An additional limitation included the use of modified versions of the CGM-SAT, a validated tool. The use of certified interpreters also could have introduced bias into survey completion as translation of survey questions was left to the discretion of the assigned interpreter, rather than a standardized script. An additional limitation is the small sample size defined not by statistical needs but by funding available and further restricted by expiration dates of supplies. Professional CGM devices are all subject to expiration dating, a notable learning for future studies would be to purchase equipment in a rolling fashion as enrollment occurs to prevent waste of unused, expired supplies. An additional learning is the reimbursement for CGM services and can help to cover overhead costs of the CGM supplies. The described intervention was designed for partnership with ambulatory care pharmacists, this could be a rate limiting step for other sites, however other care team members like Certified Diabetes Care and Education Specialists or registered nurses could serve as additional collaborators for providing education on the use of professional CGM devices and application of the sensors.

The use of a “history of adherence and ability to follow up” as a part of the inclusion criteria was chosen to help decrease the likelihood of the reusable, costly technology being lost and/or not returned, however this limited the pool of eligible patients and the applicability of the results. The eligible patient population could also have been limited given patients were identified by clinic physicians and due to the frequency of office visits that was required. In comparison to personal CGM devices, the nature of the use of professional CGM devices requires more visits to clinic. This can be burdensome to patients in many ways including the need for transportation and possibly copayments for office visits. However, for patients who are not interested in having personal CGM devices due to technology barriers, professional CGM devices put the burden of learning and using a “new” technology on the clinic and could increase access.

Future directions to consider include understanding the patient experience in populations previously underrepresented in previous research, namely non-English speaking, with the use of alternative professional CGM devices. In addition, future studies should evaluate the impact of professional CGM use in this patient population, which could include assessing change in A1c, time in range, and/or prescribed medicines over time. There is a need in the literature to define the ideal frequency and clinical patient characteristics that represent an opportunity for professional CGM use. While the baseline data showed patients had high levels of emotional distress per the PAID questionnaire, future studies should evaluate the change in levels of distress to assess the impact of a professional CGM intervention.[13]

Conclusions

In this primary care, diverse, largely non-English speaking population, with a high amount of emotional distress related to diabetes, the use of a professional, blinded CGM was reported

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by patients to be as acceptable of an intervention as the patient's previous self-monitoring blood glucose efforts. Professional CGM represents an additional tool that can be implemented by ambulatory care pharmacists, or other healthcare team members, during office visits to provide PCPs and their teams with more powerful data to help patients achieve diabetes blood glucose control.

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Conflicts of Interest: None.

The opinions expressed in this paper are those of the authors.

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Table 1

			HGM-SAT USING YOUR CURRENT HOME GLUCOSE MONITOR (n=12)							mCGM-SAT USING THE CONTINUOUS GLUCOSE MONITOR (n=11)						
Question number			Mean Score	Agree Strongly	Agree	Neutral	Disagree	Disagree Strongly		Mean Score	Agree Strongly	Agree	Neutral	Disagree	Disagree Strongly	Delta Mean
1		Causes me to be more worried about controlling blood sugars	2.17	16.7%	58.3%	16.7%	8.3%	0.0%		2.45	9.1%	54.5%	18.2%	18.2%	0.0%	0.29
2	*	Helps me to be sure about making diabetes decisions	3.67	8.3%	50.0%	41.7%	0.0%	0.0%		3.91	18.2%	54.5%	27.3%	0.0%	0.0%	0.24
3		Causes others to ask too many questions about diabetes	2.75	8.3%	25.0%	58.3%	0.0%	8.3%		2.82	18.2%	18.2%	36.4%	18.2%	9.1%	0.07
4		Makes me think about diabetes too much	2.42	16.7%	41.7%	33.3%	0.0%	8.3%		2.64	18.2%	27.3%	27.3%	27.3%	0.0%	0.22
5	*	Helps to keep low blood sugars from happening	3.50	0.0%	66.7%	16.7%	16.7%	0.0%		3.09	0.0%	27.3%	54.5%	18.2%	0.0%	-0.41
6	*	Has taught me new things about diabetes that I didn't know before	3.50	0.0%	58.3%	33.3%	8.3%	0.0%		3.64	9.1%	45.5%	45.5%	0.0%	0.0%	0.14
7		Causes too many hassles in daily life	2.33	16.7%	50.0%	25.0%	0.0%	8.3%		3.55	9.1%	0.0%	27.3%	54.5%	9.1%	1.21
8	*	Teaches me how eating affects blood sugar	3.82	8.3%	58.3%	25.0%	0.0%	0.0%		3.55	9.1%	36.4%	54.5%	0.0%	0.0%	-0.27
9	*	Has helped me to learn how exercise affects blood sugar	3.67	8.3%	50.0%	41.7%	0.0%	0.0%		3.45	0.0%	54.5%	36.4%	9.1%	0.0%	-0.21
10	*	Has shown me that blood sugar is predictable and orderly	3.33	0.0%	58.3%	25.0%	8.3%	8.3%		3.36	0.0%	54.5%	27.3%	18.2%	0.0%	0.03
11		Sometimes gives too much information to work with	2.67	0.0%	50.0%	41.7%	0.0%	8.3%		2.82	9.1%	18.2%	54.5%	18.2%	0.0%	0.15
12	* +	Has made it easier to accept doing blood sugar tests								3.30	0.0%	45.5%	27.3%	18.2%	0.0%	N/A
13		Is uncomfortable or painful	2.42	8.3%	41.7%	50.0%	0.0%	0.0%		3.73	0.0%	9.1%	18.2%	63.6%	9.1%	1.31
14	*	Has helped me to learn how to treat low blood sugars better	3.58	8.3%	58.3%	16.7%	16.7%	0.0%		3.45	9.1%	45.5%	27.3%	18.2%	0.0%	-0.13
15		Is more trouble than it is worth	2.92	8.3%	25.0%	50.0%	0.0%	16.7%		3.45	0.0%	27.3%	9.1%	54.5%	9.1%	0.54
16	*	Shows patterns in blood sugars that we didn't see before	3.58	16.7%	33.3%	41.7%	8.3%	0.0%		3.91	18.2%	54.5%	27.3%	0.0%	0.0%	0.33
17	*	Allows more freedom in daily life	3.33	8.3%	33.3%	41.7%	16.7%	0.0%		3.18	9.1%	18.2%	54.5%	18.2%	0.0%	-0.15
18	*	Makes it clearer how some everyday habits affect blood sugar levels	3.75	8.3%	66.7%	16.7%	8.3%	0.0%		4.00	27.3%	45.5%	27.3%	0.0%	0.0%	0.25
19		Is too hard to get it to work right	2.67	0.0%	58.3%	25.0%	8.3%	8.3%		3.55	0.0%	9.1%	36.4%	45.5%	9.1%	0.88
20		Has been harder or more complicated than expected	3.00	0.0%	33.3%	41.7%	16.7%	8.3%		3.73	0.0%	9.1%	27.3%	45.5%	18.2%	0.73
21	* +	Has helped to control diabetes better even when not wearing it								3.18	0.0%	27.3%	63.6%	9.1%	0.0%	N/A
22	+	Makes it harder for me to sleep								3.73	0.0%	9.1%	18.2%	63.6%	9.1%	N/A
23		Causes more embarrassment about feeling different from others	2.50	0.0%	66.7%	25.0%	0.0%	8.3%		3.55	0.0%	0.0%	54.5%	36.4%	9.1%	1.05
24		Gives a lot of results that don't make sense	2.33	8.3%	58.3%	25.0%	8.3%	0.0%		3.27	0.0%	0.0%	72.7%	27.3%	0.0%	0.94
25		Causes too many interruptions during the day	2.75	8.3%	50.0%	16.7%	8.3%	16.7%		3.27	0.0%	9.1%	54.5%	36.4%	0.0%	0.52
26		The feedback from the device is not easy to understand or useful	2.92	0.0%	41.7%	33.3%	16.7%	8.3%		3.18	9.1%	0.0%	54.5%	36.4%	0.0%	0.27
27	*	Has made me worry less about having low blood sugars	3.33	8.3%	41.7%	33.3%	8.3%	8.3%		2.70	0.0%	0.0%	63.6%	27.3%	0.0%	-0.63
New Questions																
	* +	If possible, I want to use the device when the research study is over								3.09	0.0%	27.3%	54.5%	18.2%	0.0%	N/A
	*	Has encouraged me to make different choices about my diet, medications, exercise	3.50	8.3%	50.0%	33.3%	0.0%	8.3%		3.40	0.0%	45.5%	36.4%	9.1%	0.0%	-0.10
	*	Will improve my diabetes control moving forward	3.75	16.7%	41.7%	41.7%	0.0%	0.0%		3.45	0.0%	54.5%	36.4%	9.1%	0.0%	-0.30
	*	The results of the device were explained in a way that is useful to you	4.08	25.0%	58.3%	16.7%	0.0%	0.0%		3.73	0.0%	72.7%	27.3%	0.0%	0.0%	-0.36
	*	Teaches me how medicines affect my blood sugar	3.75	25.0%	41.7%	25.0%	0.0%	8.3%		3.18	0.0%	27.3%	63.6%	9.1%	0.0%	-0.57
	* +	The training I received at the previous visit adequately prepared me to wear the device								3.73	0.0%	72.7%	27.3%	0.0%	0.0%	N/A

Key:

* Negatively worded questions required reverse coding in data analysis. Likert score of 1 equates to “Agree Strongly”. Questions without “*”, Likert score of 5 equates to “Agree strongly”

+ Questions included only in follow up survey, mCGM-SAT

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