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Demonstrating the Clinical Impact of Continuous Glucose Monitoring Within an Integrated Healthcare Delivery System

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Abstract

Background: Approximately 30 million Americans currently suffer from diabetes, and nearly 55 million people will be impacted by 2030. Continuous glucose monitoring (CGM) systems help patients manage their care with real-time data. Although approximately 95% of those with diabetes suffer from type 2, few studies have measured CGM's clinical impact for this segment within an integrated healthcare system.

Methods: A parallel randomized, multisite prospective trial was conducted using a new CGM device (Dexcom G6) compared to a standard of care finger stick glucometer (FSG) (Contour Next One). All participants received usual care in primary care clinics for six consecutive months while using these devices. Data were collected via electronic medical records, device outputs, exit surveys, and insurance company (SelectHealth) claims in accordance with institutional review board approval.

Results: Ninety-nine patients were randomized for analysis ($n = 50$ CGM and $n = 49$ FSG). CGM patients significantly decreased hemoglobin A1c ($p = .001$), total visits ($p = .009$), emergency department encounters ($p = .018$), and labs ordered ($p = .001$). Among SelectHealth non-Medicare Advantage patients, per member per month savings were $417 for CGM compared to FSG, but $9 more for Medicare Advantage. Seventy percent of CGM users reported that the technology helped them better understand daily activity and diet compared to only 16% for FSG.

Discussion: Participants using CGM devices had meaningful improvements in clinical outcomes, costs, and self-reported measures compared to the FSG group. Although a larger study is necessary to confirm these results, CGM devices appear to improve patient outcomes while making treatment more affordable.

Keywords

diabetes, continuous glucose monitoring, CGM, healthcare

Introduction

Approximately 30 million Americans, or 9% of the population suffers from diabetes mellitus, a condition in which a person does not make enough insulin, or their body cannot use its own insulin to effectively control blood glucose levels.[1] Without proper management, diabetes can lead to a myriad of health issues, which include: heart disease, blindness, stroke, kidney disease, limb loss, nerve damage, death, etc..[1-3] Diabetes, often referred to as the "silent epidemic," has tripled in incidence in the United States between 1990 and 2010,[4] likely caused by increased rates of obesity, an aging population who is living longer, and growth in minority groups who have higher risk for developing diabetes.[5] Especially concerning is that diabetes prevalence is expected to increase by 54% to nearly 55 million Americans, with annual mortality growing by 38% to nearly 385 000, and total medical and societal cost attributed to this disease expected to swell by 53% to over $622 billion by 2030.[4] Diagnosis and treatment of diabetes comprises $1 in every $7 of U.S. healthcare expenditures[6] and spending is more than double for those with this disease.[7] New tools and technologies are needed to address the societal, economic, and quality-of-life hardships caused by diabetes.

Traditional mechanisms for assessing glycemic variation have relied on self-monitoring of blood glucose (SMBG) capillary testing, but these assessments (seldom >4 measurements daily) have insufficient temporal resolution for understanding the pattern of glucose levels in the context of daily living (eg,

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diet, physical activity, sedentary time, medication dosing, etc.).[8] Continuous glucose monitoring (CGM) devices have been commercialized since 1999,[3] but have not become a standard of care for noninsulin-dependent diabetes. Significant improvements have been made in the technology since its introduction including: (1) devices no longer require recalibration, (2) electrical components (eg, transmitters, sensors, etc.) last for longer than a week, (3) glucose concentrations are measured interstitially every five minutes, (4) accuracy has improved with mean absolute relative difference less than 10%, and (5) CGM data are available in real time to patients via smart devices.[3,9-11] Several recent CGM-based studies have used these next-generation sensors and shown modest reductions in hemoglobin A1c (HbA1c) levels, improved patient outcomes, enhanced quality of life,[8,10-13] and a relationship between the number of data points surfaced to participants with type I diabetes and their HbA1c levels (eg, frequency of SMBG testing led were associated to lower A1c).[14]

Although promising, validation of a CGM-based approach in diabetes care has remained limited because: (1) previous research has focused predominately on those with type I diabetes although only representing 5% of the diabetes population[7]; (2) rarely have clinical studies been performed within an integrated healthcare system that can assess the true impact on care, utilization, and cost; and (3) the technology has not been focused on the diabetes care in patients ≥65 years old who account for 61% of all diabetes care expenditures.[6] Addressing these limitations, our team conducted a parallel randomized, multisite prospective trial to assess the ability of patients to self-manage their glucose levels using CGM or FSG devices in the ambulatory setting and home.

Methods

Study Operations

Participants were recruited from Intermountain Healthcare (Salt Lake City, Utah, United States) in four Reimagined Primary Care (RPC) clinics in Utah (The Avenues Internal Medicine, Salt Lake City; Cottonwood Family Practice, Murray; Cottonwood Senior Clinic, Murray; and Holladay Internal Medicine, Murray) in accordance with institutional review board (IRB) approval. Patients were selected based on documented HbA1c ≥6.5%, if between the ages of 18 and 80, having been diagnosed with type I or II diabetes, not currently using a CGM device, not pregnant or planning to become pregnant for the duration of the study, and upon recommendation from their respective primary care provider (PCP). We planned to enroll 120 patients for randomization, anticipating 10% attrition at six months. Patients were selected without consideration of their current dietary, oral medication or injectable therapeutic regimens.

Upon completion of each patient's PCP visit, interested parties met with a Clinical Research Coordinator (CRC) who verified the patient inclusion criteria, explained CGM technology, ensured that the participant had a compatible smart phone device to download required applications (app), electronically consented subjects using an iPad and REDCap interface, and shared their contact information to minimize the burden on physicians. Envelopes were filled using block randomization to assign patient's their respective study group and individuals were asked to open and reveal whether they received the Contour Next One (standard of care FSG) or Dexcom G6 (CGM) for the duration of the study. Patients were given their assigned device at the time of randomization by the CRC and instructed on how to use them. FSG and CGM data were captured using the apps from each product, imported into Intermountain's enterprise data warehouse (EDW), and then displayed in a Tableau report for safety and monitoring for the attending physicians and in-house endocrinology subject-matter expert who assessed trends weekly. Electronic medical data of healthcare utilization were uploaded to Intermountain's EDW every 24 hours. All patient identifiers were removed from any public facing report and replaced with unique study codes to protect confidentiality.

Patients were initially provided with a one-month supply of Contour Next One or Dexcom G6 and a new shipment delivered monthly to their home or picked up at their respective clinic by the CRC as to adhere to study participation. Participants agreed to use the device for six consecutive months, provided baseline body mass index (BMI) and HbA1c measurements at the time of recruitment (using one of Intermountain Healthcare's laboratories and listed in the EDW) and again at six months follow-up. Participants answered Likert-based and qualitative-based questions at study exit to assess how the devices impacted their lifestyle behaviors and care. The investigative team did not ask the attending physicians in the RPC clinics to change their traditional practice—the study's sole intervention was the introduction of a Dexcom G6 or Contour Next One device for glucose measurement.

Statistics Analyses

Inferential statistical analyses focused on three broad study aims: (1) to understand the effect of CGM on clinical data (eg, HbA1c and glucose); (2) to assess the impact of CGM on healthcare utilization, and cost; and (3) to qualitatively understand patient perspectives of CGM. All analyses were prespecified, with clear delineation of primary, secondary, and qualitative analyses.

The primary analysis compared the distributions of patient-level, six-month change in HbA1c between randomized groups using the two-sided Wilcoxon rank-sum test. Five prespecified secondary analyses were conducted related to this aim: (1) longitudinal change in mean amplitude of glycemic excursions (MAGE) in CGM patients, (2) longitudinal change in daily coefficient of variation of blood glucose levels (BGL), (3) longitudinal change in daily BGL range, (4) longitudinal change in daily proportion of time that BGL

readings were between 70 and 180 mg/dl, and (5) change in BMI for each cohort. Secondary analyses (1)-(4) were conducted on CGM patients only, as those analyses cannot be compared between groups with different BGL sampling frequencies (ie, continuous vs daily).

Each CGM patient's daily MAGE was calculated using the "gluvarpro" R package (https://rdrr.io/cran/gluvarpro/man/) and then had its location and scale modeled as a zero-adjusted gamma distribution with respect to time using a hierarchical model with patient-level random intercepts and slopes.[15] This measured how the probability of having a glycemic excursion event changed over time, as well as how the amplitude of glycemic excursion events changed over time. Analyses of longitudinal changes in daily coefficient of variation, change in daily BGL range, and proportion of time that BGL readings were between 70 and 180 mg/dl, were performed using Bayesian multilevel models (with weekly informative priors, patient-level random intercepts, and slopes among CGM patients only).[16,17]

To assess the impact on healthcare utilization and costs, six prespecified secondary analyses were evaluated between the randomized groups: (1) counts of overall healthcare visits, (2) PCP visits, (3) specialty visits, (4) emergency department (ED) encounters, (5) laboratory tests ordered, and (6) total variable costs.[18] The five encounter-based analyses used a two-sample, normal approximated Poisson test, whereas costs of care were compared using a two-sample Wilcoxon rank-sum test. The cost was computed during the study period (December 2018 to May 2019) on a per member per month (PMPM) basis for those that used Intermountain Healthcare's insurer, SelectHealth. If members had 2+ SelectHealth plans, only member months for the primary policy were included. All policies were for Utah-based patients. Further, all hypothesis testing was two-tailed with significance set at the putative threshold ($\alpha = .05$). Bayesian analyses reported highest posterior density intervals (HPDI) in place of frequentist p values.[19] Statistical data analysis was conducted in R v3.6.3 (R Foundation for Statistical Computing, Vienna, Austria. https://www.R-project.org/) and Python v3.7.4 (Python Software Foundation, Wilmington, DE, USA. https://python.org/).

Patient-reported survey data were used to identify key themes replanted to: (1) a participant's self-reported willingness to participate in a CGM pilot, (2) individual satisfaction with CGM or FSG, and (3) perceptions of how devices changed their lifestyle behaviors, medication adherence, and so forth. To measure willingness, the number of potential candidates who the study approached, consented, and participated were recorded. To measure satisfaction, exit surveys were used for all patients, focusing on their satisfaction with the devices.

Results

One hundred and thirteen patients consented between the period of December 2018 and May 2019, and 99 remained engaged for the full study duration (50 CGM and 49 FSG users). Of the 14 lost to attrition, 79% of these occurred after the patients opened their sealed envelope and revealed that they would be receiving the standard of care device (Contour Next One) by randomization and they asked to be excused. Of the 99 patients who completed six months of CGM or FSG usage, 93 persons had type 2 diabetes and six had type 1. Fifty-six identified as female and 43 as male. Forty-seven enrollees were commercially insured. Intermountain Healthcare was at financial risk for the remaining 52 participants (eg, SelectHealth, Medicare, etc.) that include capitation, bundled payments, and shared savings arrangements. The median number of captured BGL readings among CGM patients was 45,250 (interquartile interval [IQI] 40,599 to 48,359) with a minimum and maximum of 17,480 and 53,781 respectively. In FSG patients, the median number captured BGL readings among FSG patients was 189 (IQI 135 to 326) with a minimum and maximum of 20 and 1448 respectively. Exit interviews were completed by 89 participants and a complete breakdown of the patient's age is listed in Table 1 and comorbidities in Table 2.

Table 1. Ages of Participants (Years).

18-24	0
25-34	6
35-44	6
45-54	13
55-64	26
65-74	38
75-80	10
Total	99

Table 2. Comorbidities of the Participants.

	CGM	FSG
Chronic pulmonary disease	28	23
Mild liver disease	12	21
Renal disease	8	15
Congestive heart failure	9	8
Peripheral vascular disease	10	11
Cerebrovascular disease	6	9
Cancer	7	10
Connective tissue—Rheumatic disease	4	3
Peptic ulcer disease	4	2
Myocardial infarction	3	2

Note. CGM, Continuous glucose monitoring; FSG, finger stick glucometer.

The primary analysis found that the six-month change in HbA1c (%) of CGM patients (median –0.6, IQI –1.4 to 0.1) significantly decreased compared with FSG users (median –0.1, IQI –0.7 to 0.1) ($p = .001$). When evaluating BGL in CGM patients, the odds of experiencing a glycemic excursion event decreased by 5.15% every 30 days (95% CI 4.92-5.39%, $p < .001$), but when glycemic excursion events

Table 3. Utilization Data Showing the Mean and Standard Deviation.

Utilization type	CGM mean (SD)	FSG	*p* value
Any visit	5.6 (3.6)	7.0 (5.1)	.009
PCP visit	1.8 (1.9)	3.3 (2.0)	.28
Specialty visit	2.6 (2.3)	3.2 (4.0)	.066
ED visit	0.2 (0.5)	0.5 (1.1)	.018
Labs ordered	7.7 (7.9)	11.9 (14.1)	<.001

Note. CGM, Continuous glucose monitoring; ED, emergency department; FSG, finger stick glucometer; PCP, primary care provider.

occurred (eg, an outlier), their MAGE tended to increase by 3.46% every 30 days (95% CI 3.35-3.57%, $p < .001$). The daily coefficient of variation of BGL remained stable on average, with 0.1% mean increase every 30 days (95% HPDI –0.03 to 0.2%). The daily range of BGL also tended to remain stable over time, with a mean change of –0.48 mg/dL every 30 days (95% HPDI –1.5 to 0.54 mg/dL). Finally, the daily proportion of time that BGL was between 70 and 180 mg/dL also remained stable over time, with a 0.72% mean increase every 30 days (95% HPDI –0.51 to 1.7%).

When comparing healthcare utilization between CGM and FSG users, significant differences were observed between the 50 CGM and 49 FSG patients for total visits ($p = .009$), ED encounters ($p = .018$), and labs ordered ($p = .001$). The individual assessments of PCP and Specialty Care visits were not significant between the CGM and FSG patients ($p = .28$ and $p = .066$, respectively) (Table 3). The differences in BMI for CGM patients (median –0.37 points, IQI –1.01 to 0.31) were not statistically significantly from the six-month change among FSG patients (median –0.12 points, IQI –0.64 to 1.3) ($p = .12$). Note that one CGM and two FSG patients were excluded for missing BMI data.

The median total cost among CGM users was $0.00 (IQI 0 to $935.87) and that among FSG users was $89.85 (IQI 0 to $1147.04), though the difference was not statistically significant ($p = .35$) because one CGM patient had very high costs ($175,387.80) while the high cost among FSG was much lower ($63,739.11). However, when evaluating just the fee-for-value participants, for those that had a SelectHealth product (36 people of which 18 were CGM users and 18 were FSG ones), actuary data demonstrated that the CGM user base had average savings amounting to $417 PMPM for SelectHealth non-Medicare Advantage and $9 more PMPM for SelectHealth Medicare Advantage members during the six months of usage. This included all costs for these participants.

Survey responses indicated that 56% of Contour Next One users believed that the device positively impacted their care compared to 90% for Dexcom subjects. When asked specifically about device helpfulness (on a 0-100 scale), the FSG group scored a 79.7 compared to a 92.9 for the CGM respondents. Ninety-seven percent of participants from both cohorts said they would participate in a future pilot with Intermountain Healthcare. Table 4 provides the patients' reports as to why they changed their health profiles during the study.

Discussion

Data from this study demonstrated that a CGM device improved patient health, decreased utilization, and reduced PMPM cost in a cohort of patients with diabetes. The principle self-reported measure for change in diabetes management was the CGM's impact on lifestyle behaviors (eg, physical activity, stress, and medication). The availability of real-time, continuous glucose information was educational and transformative for 70% of the CGM users, and this may have been because CGM users had approximately 240× the median number of glucose recordings during the six-month period. This presented additional opportunities to notice patterns and trends. Interestingly, data showed that while glycemic excursion events became less frequent over time for CGM users, when they occurred, their amplitude was larger. The authors postulate that while patients tended to be increasingly mindful of their daily caloric and carbohydrate intake—explaining the decrease in frequency of glycemic excursions—they also tended to indulge more during "cheat days"—explaining the increase in amplitude of glycemic excursions—though this conjecture has not been verified by ad hoc patient surveys. However, "cheat days" are common practice with dieting and literature has reported this could be beneficial for motivation and avoiding too much rigidity.[20]

The outcome measures reported herein for HbA1c and BMI are aligned with previous studies demonstrating the benefit of CGM. For example, Vigersky et al[10] who showed in a meta-analysis of five clinical trials that HbA1c levels decreased by 0.6%-2.3% in three to seven days of CGM usage, whereas Allen et al[21] found that after eight weeks, 26 patients reduced their HbA1C by 1.2%, lowered BMI by 0.5, and increased their exercise from 13 to 20 minutes a day compared to a nonsignificant 0.3% decrease for a control group with no change in BMI or exercise. While BMI change was not statistically significant in our study between groups, it is worth emphasizing that a threefold reduction was observed in the CGM users compared to FSG ones. Ehrardt et al[22] had the closest sample size to ours (approximately 100), used PCPs to manage care with intermittent CGM usage, but data showed minimal change in HbA1c despite being statistically equivalent.

Diabetes is one of several chronic conditions for which most health-related needs can be managed effectively in an ambulatory setting; despite this, over 11.5 million ED visits occurred in 2019 in the United Sates.[23] This problem is often exacerbated by patients who do not have a PCP managing their care and treatment.[24] In 2016, the Centers for Disease Control and Prevention reported that there were 235 000 cases of hypoglycemia (10.2 per 1000 persons with diabetes)

Table 4. Reasons for Changing Health Behaviors.

	Dexcom G6 (CGM)		Contour next one (FSG)	
	Count (*N*)	%	Count (*N*)	%
General awareness	6	14%	15	33%
Investigators/Doctors were observing	0	0%	1	2%
Impact of Diet/Exercise/Stress/Medication	30	70%	7	16%
General/No response	1	2%	12	27%
Frequency of glucose checking and pattern recognition	6	14%	8	18%
Ability to load additional information in the application	0	0%	2	4%
Total	43	100%	45	100%

Note. CGM, Continuous glucose monitoring; FSG, finger stick glucometer.

and 224 000 incidents for hyperglycemic crisis (9.7 per 1000 persons with diabetes).[25] One unique insight from our data revealed that patients who used the CGM device experienced significantly fewer ED visits for all patients and total visits compared to FSG. We believe this reflects the added self-awareness and pattern recognition from alarms that go off on the Dexcom G6 prior to entering an emergent state. As noted by Gehlaut et al,[26] approximately half of the patients in his 108-patient study had at least one hypoglycemic episode after five days of CGM monitoring and 75% of those patients experienced at least one asymptomatic hypoglycemic episode. Proper detection of hypoglycemia is critical for preventing morbidity and mortality in this population.

Aside from the ED utilization, the highest cost drivers for diabetes have been reported to be medications, inpatient services, supplies to directly treat diabetes, and more office visits to physicians and other health providers.[6] Our study was able to address some of these cost drivers, as evidence by the PMPM savings ($417 in SelectHealth non-Medicare Advantage patients), and by decreasing primary and specialty care visits over a six-month duration. The authors caution too much emphasis on the cost piece as this could change with an increased sample size and longer study observation period. However, this study was intended to assess potential improvements in care and savings, while balancing the price of the devices (which cost several hundred to thousands of dollars a year, based on the model selected),[27] and resources required to consent patients/collect data, and so on.

To the authors' knowledge, data collected herein have shown the greatest change from HbA1c baseline using CGM technology. This may reflect duration of CGM usage, patient selection, and the setting within Intermountain Healthcare. In this study, intervention took place over a six-month observation period within Intermountain Healthcare's Reimagining Primary Care clinics—venues that treat patients with an average of four to five chronic conditions and where providers spend 30 to 60 minutes per appointment addressing their needs. Because this embraces a fee-for-value construct, patients have the time required to ask important questions, show their providers the pattern of their glucose results, and design care pathways that suit their individual needs. Intermountain Healthcare also primarily operates in Utah, which has the lowest economic cost of diabetes care per adult in the United States ($1103 in Utah compared to the highest being $2522 for West Virginia, and a median of $1875 across the United States).[28] This suggests that other healthcare systems may be able to make a more sizeable change in their PMPM savings with CGM given their difference in baseline cost.

This trial was also uniquely setup with CRCs having functioned as a teleservice to support clinical care. As CGMs have evolved, physicians are still learning how to analyze data, interpret artificial intelligence prompts, set alarms, evaluate trends, and use this information to drive meaningful patient care.[9] This study suggests that physicians, patients, and other members of the care team working together can enact positive healthy behaviors, improve quality health measures, reduce healthcare utilization and cost, and achieve an increase in patient satisfaction with their medical care.

Limitations

While this study showed significant improvements to patient health, there are several weaknesses worth noting. First, continuous glucose data were not obtained on patients randomized to the usual care FSG, preventing direct comparison of BGL statistics between groups. Second, though the trial was multicenter, all venues were from a single healthcare system with a relatively homogeneous population. Third, the questionnaire, while important for showing the rationale for patient change, was designed by the study team and has not been used in other studies. Validating this tool will help to better assess the qualitative impact of CGM.

Conclusion

The use of CGM (Dexcom G6) reduced healthcare utilization and decreased overall cost compared to a standard of care FSG tool (Contour Next One). Patients reported an overall positive satisfaction with CGM use, and they revealed

that real-time, continuous glucose data was helpful in modifying diet, physical activity, stress, and medication adherence as a combined set of behaviors as self-reported by the patients. HbA1c decreased markedly in the intervention group implying that CGM use in diabetes has advantages that should to be considered by patients, providers, and healthcare systems. These implications are increasingly relevant as the cost for CGM devices continue to decline, patients become more technologically savvy, and patients and providers partner together to improve the management of this disease globally.

Abbreviations

CGM, continuous glucose monitoring; FSG, finger stick glucometer; SMBG, self-monitoring of blood glucose; HbA1c, in hemoglobin A1c; RPC, Reimagined Primary Care; IRB, Institutional Review Board; PCP, Primary Care Provider; CRC, Clinical Research Coordinator; app, application; EDW, enterprise data warehouse; BMI, body mass index; MAGE, mean amplitude of glycemic excursions; BGL, blood glucose levels; ED, emergency department; PMPM, per member per month; HPDI, highest posterior density intervals; IQI, interquartile interval.

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