Continuous Glucose Monitoring in Non-Insulin-Using Individuals with Type 2 Diabetes: Acceptability, Feasibility, and Teaching Opportunities

Nancy A. Allen, Ph.D.,¹ James A. Fain, Ph.D.,² Barry Braun, Ph.D.,³ and Stuart R. Chipkin, M.D.³

Abstract

Background: Continuous glucose monitoring (CGM) has the potential to provide useful data for behavioral interventions targeting non-insulin-using, sedentary individuals with type 2 diabetes mellitus (T2DM). The aims of this study were to describe CGM in terms of (1) feasibility and acceptability and (2) dietary- and exercise-teaching events.

Methods: Cross-sectional data were analyzed from 27 non-insulin-using adults with T2DM who wore CGM for 72 h as part of a larger study on using CGM for exercise counseling in this population. Feasibility data included accuracy of entering daily self-monitored blood glucose (SMBG) readings and events (e.g., meals, exercise), sensor failures, alarms, optimal accuracy of glucose data, and download failures. Acceptability data included CGM satisfaction and wearing difficulties. Dietary- and exercise-teaching events were identified from CGM and activity monitor data.

Results: CGM graphs showed 141 dietary- and 71 exercise-teaching events. About half the participants (52%) reported difficulty remembering to enter events into CGM monitors, but most (82%) kept an accurate paper log of events. Insufficient SMBG entries resulted in 32 CGM graphs with “use clinical judgment” warnings. Eighty-three percent of missed SMBG entries were from 18 participants 55–77 years old. Missing correlation coefficients resulted from glucose concentrations varying <100 mg/dL. A majority of participants ($n = 19$) were willing to wear CGM again despite reporting minor discomfort at sensor site and with wearing the monitor.

Conclusions: CGM data provided several teaching opportunities in non-insulin-using adults with T2DM. Overall, CGM was acceptable and feasible. Some identified problems may be eliminated by newer technology.

Introduction

CONTINUOUS GLUCOSE MONITORING (CGM) technology has the potential to change approaches to educating individuals with diabetes. Since the first CGM device was approved by the U.S. Food and Drug Administration in 1999,¹ other models have been developed and distributed,^{2,3} with improved accuracy of glucose sensors.⁴ These devices provide different types of CGM data, retrospective and real-time, for counseling individuals with diabetes.^{5–9} The increasing importance of CGM technology in diabetes health care is reflected by the term “continuous glucose monitoring” as the topic of 26 research presentations and three symposia at the 2007 American Diabetes Association’s 67th Scientific Session and by this search term in Medline retrieving an increasing number of articles (10 articles in 1998–1999, 146

articles in 2006–2007). However, few studies have addressed how clinicians can use this technology to counsel non-insulin-using individuals with type 2 diabetes mellitus (T2DM) to change behaviors and to improve diabetes self-management skills.

Although technology-related interventions might change behaviors and improve health-related outcomes, feasibility studies are necessary before advancing to costly clinical trials. To determine the feasibility of using CGM in a larger, randomized control pilot study to change lifestyle behaviors in individuals with T2DM,¹⁰ we first conducted a preliminary focus group study with nine non-insulin-using individuals with T2DM who wore CGM.¹¹ The results of that study were used to develop the feasibility and acceptability measures for this cross-sectional pilot study with 27 sedentary, non-insulin-using individuals with T2DM.¹⁰ Data from

¹Yale University, New Haven, Connecticut.

²University of Massachusetts Dartmouth, Dartmouth, Massachusetts.

³University of Massachusetts Amherst, Amherst, Massachusetts.

those 27 individuals were examined in the present study to determine (1) feasibility and acceptability of CGM and (2) uses of CGM data to provide dietary and exercise education to non-insulin-using individuals with T2DM.

Research Design and Methods

This study examined cross-sectional data from non-insulin-using individuals with T2DM who wore CGM (Medtronic MiniMed, Northridge, CA) for 72 h as part of a larger pilot study ($n = 52$).¹⁰ Twenty-five participants in the larger study were part of a control group that did not wear CGM. There were no significant differences between the groups at baseline.

Sample and setting

Participants were recruited from two health systems in Western Massachusetts. Inclusion criteria were (1) known history of T2DM, (2) >18 years old, (3) not exercising more than 2 days per week, (4) hemoglobin A1c >7.5%, (5) not receiving insulin, and (6) able to read and speak English. Exclusion criteria were (1) inability to walk 0.25 miles in 10 min, (2) taking glucocorticoids, and (3) failing prescreening evaluation (e.g., ischemic heart disease, systolic blood pressure >200 mm Hg, diastolic blood pressure >110 mm Hg, dyspnea on exertion).

Written informed consent was obtained from participants in accordance with study protocols and institutional review boards at study sites.¹⁰ Study data were obtained from 27 participants who wore CGM in the intervention group of a larger study ($n = 52$).¹⁰

Demographic information

Demographic data included gender, race, ethnicity, marital status, education, age, and duration of diabetes. Participants also provided information on current diabetes medications and smoking history.

Glucose levels

Glucose levels were monitored two ways: (1) continuously for 72 h by the Medtronic CGM device and (2) at least three times per day by self-monitored blood glucose (SMBG) readings. The CGM device has four components: pager-sized glucose monitor, disposable subcutaneous glucose-sensing device with an external electrical connector, connecting cable, and communication device to download data from the monitor to a personal computer.¹² Signals from the sensor are sent every 10 s to a glucose monitor, where they are averaged and stored every 5 min. The monitor calibrates sensor readings against the wearer's three or four daily required SMBG readings entered into the CGM device. Information from the CGM device is not available to the wearer but must be downloaded at the end of 72 h by a clinician to a personal computer. CGM software produces daily glucose trend plots, a summary table of average glucose levels, glucose ranges, and standard deviations. Daily and modal color graphs are also produced with glucose values and markers for meals, exercise, and medication events, visually showing the interaction among these parameters. Participants were instructed to keep a written log of events (e.g., SMBG, meals, exercise)

on a standardized worksheet. Glucose values obtained with CGM correlate with plasma glucose concentrations measured in the laboratory¹³ and at home.¹²

Physical activity

The amount and intensity of physical activity were objectively measured by an ActiGraph (Pensacola, FL) accelerometer. This small ($5.1 \times 3.8 \times 1.5$ -cm) device was secured by an elastic strap at each participant's right waist. Monitors were programmed to collect data every minute over 7 days. These data were downloaded into ActiGraph software (DOS RIU256K.EXE, version 2.27) for analysis. The cut points of Freedson et al.¹⁴ were used to determine sedentary (<499 counts), light activity (500–1,951 counts), moderate activity (1,952–5,724 counts), and vigorous activity ($\geq 5,725$ counts).

Feasibility measures

The variables used to assess CGM feasibility, as developed in a preliminary focus group study,¹¹ were (1) accuracy of participant's CGM input, (2) sensor failures (i.e., signal <10 or >200; initialization signal varies randomly), (3) alarm data, (4) optimal accuracy of glucose data, and (5) data download failures (e.g., lost data, gaps in graphs). Accuracy of CGM input refers to participant-entered meals, exercise, and medication. Missed meal entries were identified by a rise in glucose levels without an event marked on the CGM graph and were recognized by participants as a meal on the paper log or during review of CGM data with the researcher. Missed exercise entries were identified by a decrease in glucose level without an event marker following increased activity measured by activity monitors or acknowledged by participants during review with the researcher. Missed medication entries were identified by reviewing CGM graphs for medication entries and comparing to participants' medication list.

Acceptability measures

Acceptability was assessed by six questions developed from a preliminary focus group study.¹¹ Four of these questions addressed issues related to wearing the CGM sensor and monitor, one addressed participant satisfaction with the CGM, and one addressed understandability of the CGM graphs (Table 1).

Dietary- and exercise-teaching events

A dietary-teaching event was defined as a glucose excursion (a peak change in glucose level of >20 mg/dL) in response to a meal and/or two meals with glucose excursions of differing magnitudes (in mg/dL). Similarly, an exercise-teaching event was defined as a decline in glucose levels following a bout of self-reported exercise or an exercise event marked on the CGM graph. An exercise-teaching event also included increases in glucose levels following sedentary behavior. CGM graphs were reviewed for teachable dietary and exercise events based on participants' meals and exercise from entered CGM meter events, written log, participants' report during counseling, and/or comparison to activity monitor data. For each participant, the number of

TABLE 1. CGM ACCEPTABILITY DATA

<i>CGM evaluation question</i>	<i>Frequency (%) (n = 21)</i>
1. What issues, if any, did you have with the CGM?	
a. Skin irritation	4 (19)
b. Pain at sensor site day 1	1 (4.8)
c. Pain at sensor site continuously	0
d. Discomfort at sensor site day 1	2 (9.5)
e. Discomfort at sensor site continuously	2 (9.5)
f. Discomfort with sensor location	0
g. Discomfort due to monitor location	0
h. Infection at sensor site	0
i. Limited my activities	2 (9.5)
j. Remembering to enter blood sugars, meals, exercise into the monitor	11 (52.4)
l. Alarms	6 (28.6)
m. Difficulty understanding direction	2 (9.5)
2. How much difficulty did you experience when showering with the CGM?	
a. None	11 (55)
b. Small	4 (20)
c. Moderate	3 (15)
d. Large	2 (10)
3. How much difficulty did you experience when sleeping with the CGM?	
a. None	17 (81)
b. Small	2 (9.5)
c. Moderate	2 (9.5)
d. Large	0
4. How much difficulty did you experience while wearing the CGM during the daytime?	
a. None	20 (95.2)
b. Small	1 (4.8)
c. Moderate	0
d. Large	0
5. Would you wear the CGM again?	
a. Yes	18 (85.7)
b. No	2 (9.5)
c. Don't know	1 (4.8)
6. Did you experience difficulty in understanding the CGM graph?	
a. Yes	0
b. No	21 (100)
c. Don't know	0

teaching events was counted for each day the CGM device was worn.

Body mass index

Body mass index was calculated as weight (kg)/height (m²). Weight was measured to the nearest 0.1 kg using a designated standing scale in each clinic. Participants were asked to wear light indoor clothing and to remove shoes before being weighed. Height was measured to the nearest 0.5 cm.

Hemoglobin A1c levels

Hemoglobin A1c levels were drawn and assayed by high-pressure liquid chromatography (Variant instrument, Bio-Rad, Hercules, CA) according to standard clinical methods.

Procedures

After participants provided consent, they were assessed at baseline for (1) demographic data, (2) medication history, (3) hemoglobin A1c, and (4) body mass index. Participants were next instructed on wearing the CGM device, entering data, entering events, and using a log to record SMBG data, meals, exercise, and other events. The CGM device was inserted and worn for 72 h. Participants removed the CGM device at home and brought it to the clinic the following week. Data were downloaded at that appointment and reviewed individually with each participant. The activity monitor was simultaneously worn during the same 72 h and for an additional 4 days after removing the CGM. Data from activity monitors were not reviewed with participants but were used

TABLE 2. PARTICIPANT DEMOGRAPHICS ($N = 27$)

Characteristic	n = 27
Age (years) mean $\pm$ SD	57.0 $\pm$ 15
Diabetes' duration (years) (mean $\pm$ SD)	8.3 $\pm$ 6
Body mass index (kg/m ²) (mean $\pm$ SD)	36.05 $\pm$ 7
Hemoglobin A1c (mean $\pm$ SD)	8.3 $\pm$ 1
Activity (min/day)	
Light/sedentary	1,427 $\pm$ 12
Moderate activity	13 $\pm$ 11
Gender (n [%])	
Female	15 (56)
Male	12 (44)
Race (n [%])	
White	25 (93)
African American	2 (7)
Ethnicity (n [%])	
Not Hispanic or Latino	25 (93)
Hispanic or Latino	2 (7)
Marital status (n [%])	
Single	8 (30)
Married	14 (52)
Divorced	4 (15)
Widowed	1 (4)
Education (n [%])	
Graduate or professional training	5 (19)
College or university graduate	4 (15)
Partial college education	10 (37)
High school graduate	7 (26)
Partial high school education	1 (4)

to identify amounts and duration of exercise in relation to glucose excursions.

Statistical analysis

Frequency distributions and appropriate summary statistics for central tendency and variability were used to describe demographic and clinical data using SPSS version 15 (SPSS, Chicago, IL). Descriptive statistics were used to analyze CGM feasibility data, acceptability data, and teachable events (dietary- and exercise-related glucose changes).

Results

Participants

Most participants were female, white, and obese, with a mean age of 57 years, and spent the majority of their time engaging in light-intensity activity (Table 2). On average, participants had an 8-year history of diabetes, partial college education, and suboptimal glycemic control. The majority of participants were taking a sulfonylurea ($n = 18$) and metformin ($n = 17$), while only six participants were taking a glitazone. No participants were taking an alpha-glucosidase inhibitor or meglitinide analog.

Feasibility

Events were most accurately entered on the first and last days of wearing the CGM device (Table 3). On these days, the events most accurately entered, in decreasing order, were exercise (70–82%), medications (56–68%), and meals (42–58%). The CGM device was worn for the shortest times

on the first and last days. Of all events entered on days 2 and 3, meals were entered with the lowest accuracy (26–33%), with exercise (52–59%) and medications (46–58%) generally entered with moderate accuracy. These data support those from the acceptability follow-up questionnaire showing that 52% of participants had difficulty remembering to enter CGM events. Despite many participants using the event monitor with only moderate accuracy, most (81.5%) kept an accurate paper log of events. No sensors failed, but one CGM cable failed.

The CGM has five possible alarms: (1) disconnect, (2) ISIG (initialization signal) out of range, (3) memory full, (4) calibration error, and (5) noise. Of the 27 CGM files reviewed, three had CGM-disconnect alarms. Of these three, two sensors had been disconnected. One sensor was disconnected because of a CGM cable caught on a door, and another for an unknown reason. The third monitor was turned off for an unknown reason. No ISIG out-of-range or memory-full alarms occurred. The five calibration-error alarms were caused by meter glucose readings falling outside the acceptable limits used to calibrate sensor glucose values. For example, one participant entered three values (245, 229, 209 mg/dL) that rapidly decreased over 15 min, causing a calibration alarm. Lastly, two participants had sensor-noise alarms related to rapidly rising glucose levels (>400 mg/dL).

Optimal accuracy of CGM glucose data was calculated by CGM software from two sources, glucose sensor and glucose meter data, for each day the sensor was worn.¹⁵ Optimal accuracy depended on two criteria: (1) correlation between sensor and meter readings of at least 0.79 and (2) mean absolute difference $\leq 28\%$.¹⁵ When data from the CGM device were downloaded, correlation coefficients were calculated between glucose meter readings and sensor glucose values (paired data) for each day. These paired data were used to

TABLE 3. ACCURACY OF PARTICIPANT-ENTERED EVENTS ON THE CGM DEVICE

Number of missed events identified on CGM tracings ^a	n (%) on day wearing CGM device			
	1	2	3	4
Meals				
0	15 (57.7)	7 (25.9)	9 (33.3)	11 (42.3)
1	6 (23.1)	6 (22.2)	5 (18.5)	8 (30.8)
≥ 2	5 (19.2)	14 (51.8)	13 (48.1)	7 (26.8)
Exercise				
0	22 (81.5)	16 (59.3)	14 (51.9)	18 (69.2)
1	4 (14.8)	9 (33.3)	10 (37)	8 (30.8)
2	1 (3.7)	2 (7.4)	3 (11.1)	
Medications				
0	18 (67.7)	15 (57.7)	12 (46.2)	14 (56)
1	8 (29.6)	5 (19.2)	7 (26.9)	8 (32)
≥ 2	1 (3.7)	6 (23)	7 (26.9)	3 (12)

^aMissed meal entries were identified by a rise in glucose levels without an event marked on the CGM graph and were recognized as a meal by participants as a meal on the paper log or during review of CGM data. Missed exercise entries were identified by a decrease in glucose level without an event marker following increased activity measured by activity monitors or acknowledged by participants during a review. Missed medication entries were identified by reviewing CGM graphs for medication entries and comparing to participants' medication list.

TABLE 4. OPTIMAL ACCURACY OF CGM SENSOR DATA

Optimal accuracy criterion ^a	n (%) on day wearing CGM device			
	1	2	3	4
Paired sensor-meter readings				
≤2	14 (51.8)	4 (14.8)	4 (19.1)	14 (51.9)
3	9 (33.3)	6 (22.2)	10 (38.5)	6 (22.2)
≥4	4 (14.8)	17 (63)	11 (42.2)	7 (25.9)
Missing			1	
Correlation coefficient				
<0.79	2 (50)	1 (11.1)	0	0
≥0.79	2 (50)	8 (88.9)	6 (100)	2 (100)
Missing	23	18	21	25
Mean absolute difference				
≤28	24 (96)	24 (96)	25 (100)	20 (100)
≥29	1 (4)	1 (4)		
Missing	2	2	2	7
Use clinical judgment	19 (70.4)	5 (18.5)	6 (22.2)	13 (48.1)

^aThe CGM software calculates the paired sensor-meter readings, correlation coefficient, and mean absolute difference data. The above categories are displayed on the CGM sensor report for each day the sensor is worn.

calculate the mean absolute difference, i.e., the difference between the meter and sensor glucose values, divided by the meter value, and averaged across meter-sensor pairs/day. When optimal accuracy criteria were not met or if fewer than three meter-sensor pairs were available (required to calculate correlation coefficients), a message appeared (“use clinical judgment”) (Table 4).

About half the participants (51.8%) did not enter more than two glucose meter readings on days 1 and 4 (Table 4). This omission may be partly attributable to the shorter wear times on those days. In contrast, most participants entered three or more glucose meter readings on days 2 (85.2%) and 3 (80.7%). Of the 59 missed glucose meter readings, 49 (83%) were from 18 participants 55–77 years old, and only 17% were from nine participants 19–54 years old.

Of the 21 CGM reports with calculated correlation coefficients, three failed to meet the criterion of ≥ 0.79 (two on day 1 and one on day 2) (Table 4). Most participants had missing correlation coefficients because their daily glucose levels varied <100 mg/dL, below the range needed to calculate these coefficients (Table 3). The mean absolute difference could not be calculated for two participants on days 1–3 and for seven participants on day 4 because of insufficient paired glucose readings. Several CGM graphs ($n = 32$) had “use clinical judgment” messages on days 1 ($n = 19$) and 4 ($n = 13$) because participants did not enter at least three SMBG readings. Overall, optimal accuracy criteria were not met by a majority of participants on days 1–4 because their glucose levels varied ≤ 100 mg/dL, and they did not enter enough glucose meter readings on days 1 and 3 (Table 4). Five CGM daily graphs had gaps due to participants failing to correctly enter SMBG data or having unpaired meter readings (meter and sensor readings disagreed or monitor was turned off).

Acceptability

Participants reported minor CGM difficulties: skin irritation ($n = 4$), pain ($n = 1$), or discomfort at sensor site ($n = 2$) and activity limitations ($n = 2$). No infections were observed

or reported at CGM sensor sites. Participants reported small ($n = 5$), moderate ($n = 3$), and large ($n = 2$) amounts of difficulty with the CGM device while showering. Similarly, participants reported small ($n = 3$) and moderate ($n = 2$) difficulty sleeping with the monitor. However, the majority reported no difficulty wearing the CGM ($n = 20$) and answered “yes” when asked if they would wear the monitor again ($n = 19$). Only two participants reported difficulty understanding CGM directions, but 11 participants reported difficulty entering events such as meals, exercise, and SMBG data. No participants reported difficulty understanding the CGM graphs.

TABLE 5. CGM TEACHING EVENTS

Number of teaching events on CGM graphs per day ^a	n (%) on day wearing CGM device			
	1	2	3	4
Exercise				
0	18 (66.7)	8 (29.6)	9 (33.3)	14 (51.9)
1	7 (25.9)	13 (48.1)	13 (48.1)	12 (44.4)
2	2 (7.4)	4 (14.8)	4 (14.8)	1 (3.7)
3		1 (3.7)	1 (3.7)	
4		1 (3.7)		
Diet				
0	10 (37)	2 (7.4)	5 (18.5)	8 (29.6)
1	15 (55.6)	6 (22.2)	6 (22.2)	12 (44.4)
2	1 (3.7)	14 (51.9)	10 (37)	6 (22.2)
3	1 (3.7)	5 (18.5)	6 (22.2)	
4				1 (3.7)

^aA dietary-teaching event was defined as a glucose excursion (a peak change in glucose level of > 20 mg/dL) in response to a meal and/or two meals with glucose excursions of differing magnitudes (in mg/dL). An exercise-teaching event was defined as (1) a decline in glucose levels following a bout of self-reported exercise or an exercise event marked on the CGM graph or (2) increases in glucose levels following sedentary behavior.

FIG. 1. CGM teaching events. Day 2 of CGM depicts glucose level decrease following physical activity in a 58-year-old white man: physical activity/exercise (✕), meal (◆), long-acting medication (△), and SMBG (✦).

Dietary- and exercise-teaching events

Over the 72-h CGM period, 77 exercise- and 141 dietary-teaching events occurred (Table 5 and Figs. 1 and 2). Most exercise-teaching opportunities (66–70%) occurred on days 2 and 3, but the majority of participants had dietary-teachable opportunities on all 4 days.

Discussion

Overall, the CGM was reliable, acceptable, and provided many teaching opportunities. CGM has most frequently been used to adjust insulin levels in people with type 1 diabetes,^{16–18} T2DM,¹⁹ and during pregnancy.²⁰ However, this study identified many opportunities for teaching non-insulin-using individuals with T2DM about the influence of diet and exercise on glucose levels. Although these participants were generally sedentary, several CGM graphs showed decreased glucose levels after exercise. These observations are consistent with reports that moderate exercise significantly reduces blood glucose concentration in individuals with T2DM.^{21,22} One study showed that a single bout of moderate exercise improved glycemic levels for at least 24 h in obese individuals with T2DM.²² These data further support using CGM to detect changes in glucose levels in response to exercise, thus providing opportunities for counseling.

Participants' CGM graphs also showed glucose level changes in response to meals, particularly after breakfast or supper. Similarly, in another study dietary glycemic excursions were observed after meals on CGM graphs of individuals with T2DM.²³ Glucose levels in that study were examined 4 h after meals (postprandial) and at all other times (interprandial) before and after an 18-day calorie-restricted diet. Caloric restriction significantly improved interprandial

hyperglycemia but did not affect postprandial glucose excursions after breakfast.²³ CGM data may provide opportunities for developing individualized treatment plans, including the content and timing of meals and exercise. Future studies are needed to determine if behavior change following counseling is evident on a repeat CGM study. Moreover, CGM tracings may reveal that behavior changes are insufficient to control glucose levels, and further research is needed to determine whether CGM studies might be used to counsel individuals with T2DM on the necessity of initiating insulin therapy. Lastly, CGM devices with non-blinded, real-time displays might be more effective in changing diet and exercise behavior because individuals can immediately see the results of their behaviors and make instantaneous changes. To date, it is unknown whether individual real-time decision-making versus retrospective counseling is more effective at changing diet and exercise behaviors in non-insulin-using individuals with T2DM.

Using CGM in older individuals with T2DM raised a technology-related consideration not found in younger individuals with T2DM. Older participants had difficulty remembering to enter events such as meals and exercise into the CGM device. However, most participants kept an accurate paper log of these events, which were easily transferred to the CGM graphs for teaching purposes. To date, the accuracy of paper logs versus the accuracy of entering events into the CGM device has not been reported in this population. Most importantly, however, all participants reported understanding the CGM graphs regardless of their age.

The optimal accuracy of glucose data on CGM reports revealed two common problems in participants with T2DM: narrow range of glucose concentrations and insufficient SMBG values entered. Non-insulin-using individuals with

FIG. 2. CGM teaching events: dietary. Day 3 of CGM depicts glucose level increases with high carbohydrate meals and some lowering of glucose levels following physical activity in a 47-year-old African American woman: physical activity/exercise (⊗), meal (◆), long-acting medication (▲), and SMBG (◇).

T2DM, unlike those with type 1 diabetes, may not have glucose levels that vary more than 100 mg/dL, as needed to calculate correlation coefficients between interstitial and blood glucose concentrations. Therefore, researchers and clinicians can expect to see a majority of CGM reports with "N/A" next to correlation coefficients. Another problem was participants entering fewer than three SMBG readings into CGM devices, which occurred most frequently on the first and last wear days, resulting in a "use clinical judgment" warning. Older individuals with T2DM entered fewer SMBG readings than younger participants. A similar problem was reported in another study of individuals with type 1 and type 2 diabetes but was resolved by educating participants to enter more daily glucose values.²⁴ However, older participants were not reported to have more difficulty using the CGM device.²⁴ Similarly, older adults (66 ± 6 years) with T2DM experience more technological difficulties learning continuous insulin infusion therapy²⁵ than middle-age adults (55 ± 10 years).²⁶ Interpretability of CGM graphs in the present study was not compromised, but future studies might consider follow-up phone calls on day 1 to reinforce written instructions and decrease the number of "use clinical judgment" warnings on the CGM accuracy report.

Most participants were willing to wear the CGM device again and overall tolerated the procedure well. However, some reported minor skin irritation and discomfort, and one reported pain at the sensor site. This finding echoes a report that eight of 70 patients experienced discomfort at CGM sensor sites.²⁵ Although participants should be prepared for possible discomfort at sensor sites, they can be reassured that such discomfort has generally been transitory and insufficient to deter individuals' willingness to wear the CGM device again.

Some problems identified in this study will be eliminated by newer technology, such as the CGMS[®] iPro (Medtronic). This newer technology uses the same sensor, which is attached to a quarter-sized recorder instead of the cumbersome cable and monitor of the original CGM. Therefore, many wearing issues identified in this study (i.e., showering and sleeping with the monitor) will be eliminated. Furthermore, there are no alarms for wearers to manage. At least three or four SMBG readings per day must still be obtained, but this information is entered into software by clinicians/researchers along with events on the log sheet when the unit is downloaded. Although this new technology eliminates some problems associated with the older CGM device, our findings suggest emphasizing to wearers that they must enter at least three SMBG values every day the sensor is worn and to avoid entering SMBG values when glucose levels are rapidly changing. Furthermore, individuals with T2DM and/or a limited range of glucose concentration will likely show "N/A" correlation coefficients, which will not affect interpretability of data.

CGM technology offers many opportunities to counsel individuals with T2DM on strategies to lower glucose levels and improve self-management behaviors. Such technology offers T2DM patients personalized visual data that may be effective at communicating the need to change life-style behaviors.

Acknowledgments

This study was supported by grants F31 NR008818-01A1 and T32NR008346-05 from the National Institutes of Health. Medtronic Minimed provided a small equipment grant, and Bio-Rad Laboratories provided all A1c assays. We are grateful to Claire Baldwin for her editorial assistance.

Author Disclosure Statement

No competing financial interests exist.

References

- Food and Drug Administration: Food and Drug Administration Summary of Safety and Effectiveness Data for Continuous Glucose Monitoring System (CGMS). <http://fda.gov/cdc> (accessed January 11, 2003).
- Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L: Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care* 2006;29:44–50.
- Weinstein RL, Schwartz SL, Brazg RL, Bugler JR, Peyser TA, McGarraugh GV: Accuracy of the 5-day FreeStyle Navigator continuous glucose monitoring system: comparison with frequent laboratory reference measurements. *Diabetes Care* 2007;30:1125–1130.
- Weinzimer SA, DeLucia MC, Boland EA, Steffen A, Tamborlane WV: Analysis of continuous glucose monitoring data from non-diabetic and diabetic children: a tale of two algorithms. *Diabetes Technol Ther* 2003;5:375–380.
- Bode B, Gross K, Rikalo N, Schwartz S, Wahl T, Page C, Gross T, Mastrototaro J: Alarms based on real-time sensor glucose values alert patients to hypo- and hyperglycemia: the Guardian continuous monitoring system. *Diabetes Technol Ther* 2004;6:105–113.
- Feldman B, Brazg R, Schwartz S, Weinstein R: A continuous glucose sensor based on wired enzyme technology—results from a 3-day trial in patients with type 1 diabetes. *Diabetes Technol Ther* 2003;5:769–779.
- Gross TM, Bode BW, Einhorn D, Kayne DM, Reed JH, White NH, Mastrototaro JJ: Performance evaluation of the MiniMed continuous glucose monitoring system during patient home use. *Diabetes Technol Ther* 2000;2:49–56.
- Maran A, Crepaldi C, Tiengo A, Grassi G, Vitali E, Pagano G, Bistoni S, Calabrese G, Santeusano F, Leonetti F, Ribaudo M, Di Mario U, Annuzzi G, Genovese S, Riccardi G, Previti M, Cucinotta D, Giorgino F, Bellomo A, Giorgino R, Poscia A, Varalli M: Continuous subcutaneous glucose monitoring in diabetic patients: a multicenter analysis. *Diabetes Care* 2002;25:347–352.
- Potts RO, Tamada JA, Tierney MJ: Glucose monitoring by reverse iontophoresis. *Diabetes Metab Res Rev* 2002;18(Suppl 1):S49–S53.
- Allen NA, Fain JA, Braun B, Chipkin SR: Continuous glucose monitoring improves physical activity behaviors of individuals with type 2 diabetes: a randomized clinical trial. *Diabetes Res Clin Pract* 2008;80:371–379.
- Allen NA, Fain JA, Braun B, Chipkin SR: Feasibility and acceptability of continuous glucose monitoring and accelerometer technology in exercising individuals with type 2 diabetes. *J Clin Nurs* 2009;18:373–383.
- Gross TM, Mastrototaro JJ: Efficacy and reliability of the Continuous Glucose Monitoring System. *Diabetes Technol Ther* 2000;2(Suppl 1):S19–S26.
- Rebrin K, Steil GM, Van Antwerp WP, Mastrototaro JJ: Subcutaneous glucose predicts plasma glucose independent of insulin: implications for continuous monitoring. *Am J Physiol* 1999;277:E561–E571.
- Freedson PS, Melanson E, Sirard J: Calibration of the Computer Science and Applications, Inc. accelerometer. *Med Sci Sports Exerc* 1998;30:777–781.
- Mastrototaro JJ: The MiniMed Continuous Glucose Monitoring System. *Diabetes Technol Ther* 2000;2(Suppl 1):S13–S18.
- Bode BW, Gross TM, Thornton KR, Mastrototaro JM: Continuous glucose monitoring used to adjust diabetes therapy improves glycosylated hemoglobin: a pilot study. *Diabetes Res Clin Pract* 1999;46:183–190.
- Deiss D, Kordonouri O, Hartmann R, Hopfenmuller W, Lupke K, Danne T: Treatment with insulin glargine reduces asymptomatic hypoglycemia detected by continuous subcutaneous glucose monitoring in children and adolescents with type 1 diabetes. *Pediatr Diabetes* 2007;8:157–162.
- Kaufman FR, Gibson LC, Halvorson M, Carpenter S, Fisher LK, Pitukcheewanont P: A pilot study of the continuous glucose monitoring system: clinical decisions and glycemic control after its use in pediatric type 1 diabetic subjects. *Diabetes Care* 2001;24:2030–2034.
- Zick R, Petersen B, Richter M, Haug C, Group SS: Comparison of continuous blood glucose measurement with conventional documentation of hypoglycemia in patients with type 2 diabetes on multiple daily insulin injection therapy. *Diabetes Technol Ther* 2007;9:483–492.
- Murphy HR, Rayman G, Duffield K, Lewis KS, Kelly S, Johal B, Fowler D, Temple RC: Changes in the glycemic profiles of women with type 1 and type 2 diabetes during pregnancy. *Diabetes Care* 2007;30:2785–2791.
- Kang J, Kelley DE, Robertson RJ, Goss FL, Suminski RR, Utter AC, Dasilva SG: Substrate utilization and glucose turnover during exercise of varying intensities in individuals with NIDDM. *Med Sci Sports Exerc* 1999;31:82–89.
- MacDonald AL, Philp A, Harrison M, Bone AJ, Watt PW: Monitoring exercise-induced changes in glycemic control in type 2 diabetes. *Med Sci Sports Exerc* 2006;38:201–207.
- Colette C, Ginet C, Boegner C, Benichou M, Pham TC, Cristol JP, Monnier L: Dichotomous responses of inter and postprandial hyperglycaemia to short-term calorie restriction in patients with type 2 diabetes. *Eur J Clin Invest* 2005;35:259–264.
- Chico A, Vidal-Rios P, Subira M, Novials A: The Continuous Glucose Monitoring System is useful for detecting unrecognized hypoglycemia in patients with type 1 and type 2 diabetes but is not better than frequent capillary glucose measurements for improving metabolic control. *Diabetes Care* 2003;26:1153–1157.
- Raskin P, Bode BW, Marks JB, Hirsch IB, Weinstein RL, McGill JB, Peterson GE, Mudaliar SR, Reinhardt RR: Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes: a randomized, parallel-group, 24-week study. *Diabetes Care* 2003;26:2598–2603.
- Herman WH, Ilag LL, Johnson SL, Martin CL, Sinding J, Al Harthi A, Plunkett CD, LaPorte FB, Burke R, Brown MB, Halter JB, Raskin P: A clinical trial of continuous subcutaneous insulin infusion versus multiple daily injections in older adults with type 2 diabetes. *Diabetes Care* 2005;28:1568–1573.

Address reprint requests to:
 Nancy A. Allen, Ph.D.
 Yale University
 100 Church Street South
 P.O. Box 9740
 New Haven, CT 06536-0740

E-mail: nancy.a.allen@yale.edu