



Glucose as the Fifth Vital Sign: A Randomized Controlled Trial of Continuous Glucose Monitoring in a Non-ICU Hospital Setting

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OBJECTIVE

The current standard for hospital glucose management is point-of-care (POC) testing. We conducted a randomized controlled trial of real-time continuous glucose monitoring (RT-CGM) compared with POC in a non-intensive care unit (ICU) hospital setting.

RESEARCH DESIGN AND METHODS

A total of 110 adults with type 2 diabetes on a non-ICU floor received RT-CGM with Dexcom G6 versus usual care (UC). RT-CGM data were wirelessly transmitted from the bedside. Hospital telemetry monitored RT-CGM data and notified bedside nursing of glucose alerts and trends. Standardized protocols were used for interventions.

RESULTS

The RT-CGM group demonstrated significantly lower mean glucose ($M\Delta = -18.5$ mg/dL) and percentage of time in hyperglycemia >250 mg/dL (-11.41%) and higher time in range 70 – 250 mg/dL ($+11.26\%$) compared with UC (P values <0.05). Percentage of time in hypoglycemia was very low.

CONCLUSIONS

RT-CGM can be used successfully in community-based hospital non-ICU settings to improve glucose management. Continuously streaming glucose readings may truly be the fifth vital sign.

In the hospital, uncontrolled blood glucose is common and contributes to higher morbidity, mortality, and health care costs (1–7). The causes of poor inpatient glycemic control are multifactorial and include the effects of acute illness on glucose (“stress hyperglycemia”), fluctuating appetite and/or nutritional status, steroid use and/or other medication changes, unpredictable timing of tests and procedures, concerns about hypoglycemia and varying familiarity with newer medications and insulin formulations among providers and staff, and a focus on primary admission diagnosis, not diabetes.

The current standard for hospital glucose management is point-of-care (POC) testing; however, blinded continuous glucose monitoring (CGM) has retrospectively shown POC testing to miss $\sim 33\%$ of hyperglycemic (8) and up to 90% of hypoglycemic events (8,9). A 2016 U.S. expert panel asserted that CGM has the potential to detect hyper- and hypoglycemia in the hospital that would otherwise be missed by POC (10). However, expansion of CGM into U.S. hospitals has been limited due to numerous factors. First, institutional challenges can act as a significant barrier. For example, there may be insufficient numbers of hospital staff to assume the increased workload required to initiate and monitor new devices; lack of knowledge on device function, including “app”

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functions for sharing and monitoring; need for additional equipment (mobile phones), Bluetooth transmission capability, and information services support for glucose data transmission; and, possibly most importantly, a lack of consensus, training, and protocols on how to best use the enormous amount of streaming glucose data that will now be available for glycemic management. Additionally, a number of significant potential confounders exist in the hospital setting (i.e., medications, procedures, renal function, hepatic function, and acute illness), all of which can potentially impact the validity of CGM.

Finally, there is a lack of randomized controlled trials (RCTs) of real-time CGM (RT-CGM) compared with POC in hospital settings that might provide guidance on CGM implementation in this environment. This report is a subset of a larger, statistically powered ($N = 404$) RCT (NCT03068273) being conducted at two large hospitals in San Diego (Scripps Health). However, due to the current coronavirus disease 2019 (COVID-19) pandemic, we felt compelled to analyze this subset of Dexcom G6 CGM (San Diego, CA) users to provide data to hospital systems that are implementing Dexcom G6.

RESEARCH DESIGN AND METHODS

A total of 110 adults ≥ 18 years old, Spanish or English speaking, with type 2 diabetes (T2D) and three POC or serum values >200 mg/dL in the last 24 h, requiring subcutaneous insulin, were admitted to a non-intensive care unit (ICU) floor at Scripps Mercy Hospital (San Diego, CA) and enrolled in an RCT for ≥ 18 h. Pregnancy, intravenous insulin, adhesive allergy, anticipated computed tomography/MRI/diathermy procedures in next 24 h, or any condition deemed contraindicated were reasons for exclusion. The Scripps Health Institutional Review Board (San Diego, CA) approved the study.

After informed consent, enrollment, and randomization, a Dexcom G6 was placed by a research assistant or nurse. Blinded CGM data were used for evaluation only in usual care (UC) (standard POC testing protocol; $n = 53$). Data in the RT-CGM group ($n = 57$) were wirelessly transmitted from a bedside smartphone to secure Health Insurance Portability and Accountability Act-compliant, monitoring platforms: Dexcom FOLLOW and CLARITY (Supplementary Fig. 1A). To target a hospital time in range (TIR) of 70–250 mg/dL, hospital telemetry monitored RT-CGM

data in FOLLOW on an iPad and notified nursing of hyperglycemia (>250 mg/dL, 9:00 P.M.–4:00 A.M.) and trends toward hypoglycemia (<90 mg/dL, 24 h/day) for rapid treatment per protocol (Real-Time Adjustments, Supplementary Fig. 1Ba). Of note, because CGM was not U.S. Food and Drug Administration-approved for hospital use, confirmatory POC testing was conducted before treatment, and RT-CGM participants were still monitored via the hospital's standard POC protocol (~ 4 times/day). All previous anti-hyperglycemic agents were discontinued, and participants were placed on the hospital subcutaneous insulin protocol to standardize glucose management across groups. A diabetes advanced practice nurse conducted the POC review for all participants and remotely monitored CGM trends in CLARITY and collaborated with hospitalists to make standardized algorithm-based insulin adjustments using trends noted to optimize therapy in the RT-CGM only (Daily Adjustments, Supplementary Fig. 1Bb).

Baseline characteristics were examined to evaluate randomization using χ^2 , t , and Mann-Whitney tests. Restricted maximum likelihood was used in a linear effects model (11) to evaluate concordance between CGM and POC values. Participant-level CGM metrics included CGM duration, glucose mean, SD, and coefficient of variation, and percentage of TIR (70–180, 70–200, 70–250 mg/dL) and time in hyperglycemia (>250 , 300 mg/dL) and hypoglycemia (<70 , 54 mg/dL). Outcomes were tested in unadjusted linear regression models with group as a fixed effect, unless otherwise specified. Results reported in the text are regression coefficients (β) for the group effect and represent expected mean differences between RT-CGM (coded 1) and UC (coded 0). Hypoglycemic events (≥ 20 min <54 or 70 mg/dL) were descriptively analyzed to document the number of participants with one or more event and the number/participant and event duration. All analyses were conducted in R 3.5.3 software.

RESULTS

Participants ranged from 30 to 89 years old (mean 61.94 [SD 13.22]); most were women (54.5%) and Hispanic (74.3%). No significant between-group differences were observed in baseline characteristics, CGM duration, use of glucose-affecting medications during the hospitalization, or length of stay (P

values >0.31). CGM values obtained within 5 min of POC were highly predictive of the POC value ($P < 0.001$). Respectively, marginal and conditional $R^2 = 0.76$ and 0.83 for the entire course of CGM data, and $R^2 = 0.77$ and 0.84 with removal of the initial 6 h of CGM data postsensor insertion. There were no qualifying adverse events.

Analysis of CGM outcomes showed the RT-CGM group demonstrated significantly lower mean glucose ($\beta = -18.5$) and percentage of time in hyperglycemia >250 mg/dL ($\beta = -11.41$) and higher TIR 70–250 mg/dL ($\beta = 11.26$) compared with UC (P values <0.05). Percentage of time in hyperglycemia >250 mg/dL was inversely correlated with TIR 70–250 mg/dL ($r = -0.99$, $P < 0.0001$). The RT-CGM group also exhibited trends toward a lower percentage of time in hyperglycemia >300 mg/dL ($\beta = -7.05$) and higher TIR 70–200 mg/dL ($\beta = 9.14$) compared with UC (P values <0.07). There were no between-group differences in TIR 70–180 mg/dL or glucose variability (P values >0.14).

Percentage of time in hypoglycemia <70 and <54 mg/dL was very low and did not differ significantly between groups (all medians = 0; P values >0.26). An examination of hypoglycemic events <70 and <54 mg/dL revealed a slightly greater number experiencing one or more hypoglycemic event(s) in the RT-CGM group. However, descriptive analyses conducted among those who experienced one or more hypoglycemic event(s) showed that the median number of events per person was lower in the RT-CGM versus the UC group for hypoglycemia <70 mg/dL (1.0 vs. 2.0) and <54 mg/dL (1.0 vs. 3.5). Further, the median duration of these events was 50.00 and 7.41 min shorter in the RT-CGM group for hypoglycemia <70 and <54 mg/dL, respectively.

The RT-CGM group also exhibited significantly lower mean POC glucose ($P = 0.01$); however, there were no statistically significant differences in average daily insulin dosing by group (P values >0.90). All findings are further detailed in Table 1.

CONCLUSIONS

This was the first RCT to compare the effectiveness of RT-CGM versus standard hospital glucose management in a non-ICU hospital setting. Our data demonstrate that RT-CGM and standardized protocols for the RT management of acute hyper-/hypoglycemia improved mean glucose and TIR without increasing

Table 1—Demographics and results

	UC (n = 53)	RT-CGM (n = 57)	P value
Baseline demographics^a			
Age, mean (SD)	60.94 (12.37)	62.88 (14.01)	0.5946
Male, n (%)	23 (43.4)	27 (47.4)	0.6759
Hispanic, n (%)	42 (80.8)	39 (68.4)	0.5620
T2D duration, years, mean (SD)	18.51 (12.04)	16.23 (9.74)	0.5653
Clinical characteristics at admission^a			
HbA _{1c} , %	8.65 (7.68–10.53)	9.5 (7.6–11.1)	0.7957
POC, mg/dL	245.5 (196.5–298.25)	261 (213–315)	0.7957
Serum creatinine, mg/dL	1.00 (0.70–1.90)	1.00 (0.60–2.10)	0.7956
Hematocrit, %, mean (SD)	36.42 (6.08)	36.11 (7.02)	0.8012
eGFR, mL/min/1.73 m ² , n (%)			0.8012
<30	15 (28.3)	17 (29.8)	
30–45	6 (11.3)	5 (8.8)	
46–60	3 (5.7)	1 (1.8)	
>60	29 (54.7)	34 (59.7)	
BMI, kg/m ²	30.65 (25.27–36.20)	29.9 (25.02–33.40)	0.7957
Primary admission diagnosis, n (%)			
Infection	27 (50.9)	23 (40.4)	0.3199
Cardiac	4 (7.6)	11 (19.3)	
Diabetes, glucose-related	6 (11.3)	10 (17.5)	
Pulmonary, noninfection	4 (7.6)	9 (15.8)	
Orthopedic	3 (5.7)	0 (0.0)	
Other	9 (17.0)	4 (7.0)	
Hospitalization statistics			
Length of stay, days	5.0 (3.0–9.0)	5.0 (3.0–8.0)	0.9880
Glucose-affecting medications, n (%)^b			
Steroids	14 (26.4)	16 (28.1)	0.9490
Psychotropics	11 (20.8)	5 (8.8)	0.6545
Quinolones	6 (11.3)	3 (5.3)	0.8360
Dextrose-containing fluids	19 (35.9)	24 (42.1)	0.8360
Other	2 (3.8)	1 (1.8)	0.9490
Insulin dosing, units/kg/day			
Long-acting	0.25 (0.16–0.34)	0.26 (0.19–0.32)	0.9094
Rapid-acting	0.31 (0.20–0.40)	0.26 (0.18–0.36)	0.9094
Total	0.50 (0.31–0.70)	0.53 (0.33–0.64)	0.9094
Glucose outcomes^c			
POC, mg/dL, mean (SD)	212.40 (45.91)	191.50 (38.89)	0.0115
CGM			
CGM duration, in h	47.75 (25.92–80.42)	51.00 (25.33–96.25)	0.8091
Mean glucose, mg/dL, mean (SD)	238.05 (45.26)	219.51 (43.75)	0.0311
SD glucose, mg/dL, mean (SD)	57.16 (19.44)	54.58 (16.94)	0.7041
CV glucose, mg/dL, mean (SD)	24.78 (9.20)	25.41 (8.07)	0.7041
% TIR			
70–180 mg/dL	19.89 (3.34–40.09)	25.31 (11.78–42.97)	0.1460
70–200 mg/dL	33.38 (10.90–55.74)	42.82 (25.66–58.53)	0.0615
70–250 mg/dL	63.95 (31.25–77.95)	72.83 (59.03–83.57)	0.0404
% Hyperglycemia			
>250 mg/dL	32.96 (20.40–68.75)	27.00 (16.01–40.97)	0.0403
>300 mg/dL	13.10 (2.90–39.40)	7.33 (2.03–18.54)	0.0512
% Hypoglycemia			
<70 mg/dL	0.00 (0.00–0.00)	0.00 (0.00–0.00)	0.2680
<54 mg/dL	0.00 (0.00–0.00)	0.00 (0.00–0.00)	0.8093
Hypoglycemic events^d			
N (%) with ≥1 event(s)			
<70 mg/dL	5 (9.43)	11 (19.3)	
<54 mg/dL	2 (3.77)	4 (7.02)	

Continued on p. 2876

the percentage of time in hypoglycemia in patients with T2D. While slightly more participants in the RT-CGM group experienced one or more hypoglycemic event(s), the number of events per participant was lower and the duration of these events was shorter with RT-CGM. Prior studies demonstrate good correlation of CGM with POC, often identifying prolonged episodes of hyper- and hypoglycemia without any intervention (12). Two nonblinded, real-time studies examined the feasibility of using CGM to guide interventions to prevent impending hypo-/hyperglycemia in hospitalized patients with diabetes (13,14); however, both were small ($n = 1$ and 5) and used single-group designs, precluding conclusions about whether CGM facilitated better glycemic control than POC.

Our current hospital standardized protocols for subcutaneous insulin adjustment target a 100–180 mg/dL range. However, patients enrolled in this study were significantly dysglycemic at admission, and achieving a range of 70–250 mg/dL was a more realistic target. We speculate that meeting significance for the targets of 70–250 mg/dL rather than 70–180 mg/dL occurred because our interventions were tailored toward giving extra rapid-acting insulin overnight for blood glucose >200 mg/dL, a time when we otherwise would not be routinely using correction insulin. Furthermore, telemetry protocols were set for notifying nursing staff for overnight values >250 mg/dL in an effort to prevent alarm fatigue from very frequent notifications that might occur with alarms at >180 mg/dL. Daytime subcutaneous insulin protocol adjustments were made to meet the tighter targets, but 48 h of sensor wear may not have been long enough to see a full benefit of the daily changes that were made, and some of the hospital physicians did not always accept the recommendations. Hypoglycemia, however, needs more acute treatment if it occurs; therefore, 24-h monitoring and intervention was conducted for this parameter. Interestingly, we found no significant difference in the average daily dose of insulin delivered; however, it is possible that RT-CGM achieved improvements in TIR, mean glucose, and hyperglycemia by triggering earlier intervention in these patients to improve control.

American Diabetes Association *Standards of Medical Care in Diabetes* note insufficient

Table 1—Continued

	UC (n = 53)	RT-CGM (n = 57)	P value
Number of events ^e			
<70 mg/dL	2.00 (1.00–4.00)	1.00 (1.00–1.50)	
<54 mg/dL	3.50 (2.75–4.25)	1.00 (1.00–2.25)	
Duration of events ^e			
<70 mg/dL			
Number of readings	19.00 (15.00–20.25)	9.00 (7.50–11.00)	
Time, in min	95.00 (75.00–101.25)	45.00 (37.50–55.00)	
<54 mg/dL			
Number of readings	9.40 (7.20–11.60)	7.92 (7.38–12)	
Time, in min	47.00 (36.00–58.00)	39.59 (36.88–60)	

Data are median (interquartile range) unless otherwise specified. All reported *P* values are two-sided. Multiple comparisons within outcomes were accounted for using the false-discovery rate adjustment. CV, coefficient of variation. ^aAs a result of missing data at admission, the following represent the sample sizes for each: Hispanic (*n* = 52, 57), T2D duration (*n* = 51, 56), HbA_{1c} (*n* = 44, 49), POC (*n* = 52, 55), and BMI (*n* = 48, 56), in UC and RT-CGM, respectively. ^bStatistics reflect the *n* (%) of participants who were administered the glucose-affecting medication at any time during the hospitalization. ^cReported *P* values are derived from unadjusted linear regression models for each outcome with group as a fixed effect, except for both % hypoglycemia measures, which were derived from Mann-Whitney *U* tests due to skewed distribution. ^dDefined as four or more consecutive values below respective threshold. ^eAs a result of the low frequency of events in the overall sample, data are presented for participants with one or more hypoglycemic event. *P* values are not presented due to small *n* in these subanalyses.

data to recommend widespread use of CGM in hospitalized patients (15). The COVID-19 pandemic has accelerated the need to identify safe methods to monitor glucose in the hospital yet allow ongoing and effective interventions. Our RCT provides preliminary evidence of the value of CGM in a non-ICU environment and offers opportunities to share device implementation practices, standardized protocols, and team-based models that use existing staff (diabetes advanced practice nurse, bedside nurses, and telemetry) to manage glucose. Because hospitalists and bedside nurses were often unfamiliar with CGM, having our study team place devices, establish data transmission, and monitor/encourage adherence to alert protocols was valuable and alleviated burden for busy bedside nurses. We would like to emphasize the importance of having access to an inpatient diabetes team. CGM cannot be successfully deployed without dedicated diabetes-minded staff to help oversee the platform and educate frontline staff about its use.

Diabetes prevalence is higher in regions with high rates of ethnic/racial minority populations—groups that experience disproportionately higher rates of diabetes-related complications (16). This study, undertaken in a hospital near the U.S.-Mexico border, included 80% Hispanic patients and demonstrated successful outcomes for this high-risk population.

Patients tolerated the device well, without complaints of sleep interruption or discomfort. Sensor and/or transmitter issues, sensor detachment, and persistent sensor signal loss were extremely rare, and very few sensors were wasted. More common was (temporary) transmission loss when patients transferred out of the room for procedures. However, if the device remained in place during a procedure, data were captured retrospectively without gaps when the patients returned to their rooms and were within 20 feet of the study phone. Currently, there are restrictions to keeping the transmitter on during certain procedures such as MRI, computed tomography, and surgical procedures using diathermy (10). Although some early reports with devices not placed on patients indicated accuracy (17), more research is needed to indicate whether they can remain on during these procedures.

The low occurrence of hypoglycemia precluded statistical testing for differences in the number and duration of these events. However, descriptives clearly showed beneficial trends of RT-CGM. Future consideration might be given to intervening earlier—at higher thresholds than those used here for nurse notification (<90 mg/dL) and treatment (<80 mg/dL)—to further improve the prevention of hypoglycemic events. While this study selected participants based on observed

hyperglycemia, future studies should consider adding high risk for hypoglycemia as inclusion criteria. This study did not treat directly from CGM readings, although trends were used for adjustments, but it would be valuable to evaluate this approach.

Finally, the cost-to-benefit ratio must be considered because this could preclude use more broadly. Clearly, increased costs stem from having a CGM support team in place as well as the cost of the devices themselves. Although this may be offset by the fact that the cost of CGM is continuously declining, and despite average use of sensors in our study of 2 days, lengthening CGM placement time could ensue by allowing continued wear during currently restricted procedures (10). A final cost analysis will be conducted once the full study is completed, but further financial benefits could be accrued if improved glucose control lowers overall length of stay, infections, and other hospital costs. Additionally, we know that people with diabetes have higher rates of readmission (18,19), and if the CGM could be continued during the transition to the immediate postdischarge period, there may be further benefit in preventing readmissions.

In conclusion, RT-CGM can be used safely and successfully in community-based hospital settings to improve glucose management. The definition of a vital sign is a clinical measurement that indicates the state of a body's essential function. Maintaining metabolic and glucose equilibrium is part of that essential function, and now, with the ability to continuously stream glucose readings, this may truly be the fifth vital sign.

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