



Accuracy of Dexcom G6 Continuous Glucose Monitoring in Non–Critically Ill Hospitalized Patients With Diabetes

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OBJECTIVE

Advances in continuous glucose monitoring (CGM) have transformed ambulatory diabetes management. Until recently, inpatient use of CGM has remained investigational, with limited data on its accuracy in the hospital setting.

RESEARCH DESIGN AND METHODS

To analyze the accuracy of Dexcom G6, we compared retrospective matched-pair CGM and capillary point-of-care (POC) glucose data from three inpatient CGM studies (two interventional and one observational) in general medicine and surgery patients with diabetes treated with insulin. Analysis of accuracy metrics included mean absolute relative difference (MARD), median absolute relative difference (ARD), and proportion of CGM values within 15, 20, and 30% or 15, 20, and 30 mg/dL of POC reference values for blood glucose >100 mg/dL or ≤100 mg/dL, respectively (% 15/15, % 20/20, % 30/30). Clinical reliability was assessed with Clarke error grid (CEG) analyses.

RESULTS

A total of 218 patients were included (96% with type 2 diabetes) with a mean age of 60.6 ± 12 years. The overall MARD ($n = 4,067$ matched glucose pairs) was 12.8%, and median ARD was 10.1% (interquartile range 4.6, 17.6]. The proportions of readings meeting % 15/15, % 20/20, and % 30/30 criteria were 68.7, 81.7, and 93.8%, respectively. CEG analysis showed 98.7% of all values in zones A and B. MARD and median ARD were higher in the case of hypoglycemia (<70 mg/dL) and severe anemia (hemoglobin <7 g/dL).

CONCLUSIONS

Our results indicate that CGM technology is a reliable tool for hospital use and may help improve glucose monitoring in non–critically ill hospitalized patients with diabetes.

Continuous glucose monitoring (CGM) technology in the outpatient setting has transformed glucose monitoring for diabetes self-management, providing more comprehensive glycemic control data than intermittent point-of-care (POC) blood glucose (BG) monitoring and hemoglobin A_{1c}. Ambulatory use of CGM continues to expand as devices improve in accuracy, accessibility, ease of use, and standardization of metrics for CGM data reporting (1). Approved

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devices for nonadjunctive use in outpatient diabetes management now include two factory-calibrated CGM systems that no longer rely on intermittent calibrations with capillary glucose values to ensure accuracy (Dexcom G6 and Abbott FreeStyle Libre/Libre 2). These advances in CGM technology have increased the interest in using CGM in the hospital setting; however, until recently inpatient use of CGM has only been investigational, with limited data regarding its accuracy in hospitalized patients (2,3).

During the coronavirus disease 2019 (COVID-19) pandemic, critical shortages of personal protective equipment led many health care professionals to explore the use of CGM to replace capillary POC BG testing in order to minimize infectious exposures without sacrificing glycemic control and monitoring (4,5). Despite limited experience with CMG use in hospital, the U.S. Food and Drug Administration (FDA) has not objected to the implementation of inpatient CGM during this public health crisis (6,7). The implementation of CGM in the hospital during the COVID-19 era has highlighted the importance of understanding its accuracy compared with that of the current standard of care (POC glucose testing) in a broad patient population. Two recent small pilot studies showed feasibility of CGM in patients during COVID-19, but additional information on CGM accuracy in hospitalized populations is greatly needed (8–10).

The close monitoring of glucose values afforded by CGM provides an attractive option for inpatient glucose monitoring. Previous observational studies have shown increased detection of hypoglycemic events with use of CGM in the hospital (11,12). Additionally, a recent randomized trial by Singh et al. (13) showed the ability of CGM to prevent and reduce hypoglycemia in high-risk hospitalized patients with diabetes through the use of remote CGM alarms. Given the rapid increase in inpatient CGM use and the urgent need for data on its accuracy in this population, we analyzed CGM and POC glucose data from a large and diverse population of non-critically ill hospitalized patients with diabetes.

RESEARCH DESIGN AND METHODS

Study Design

In this study is a pooled analysis with combination of data from three ongoing inpatient clinical studies conducted at four urban hospitals (Emory University Hospital Midtown, Grady Memorial Hospital, University of Maryland Medical Center, and the Baltimore VA Medical Center) using the factory-calibrated Dexcom G6 CGM system (Dexcom, San Diego, CA). Two of the included studies are interventional trials with assessment of real-time CGM in the inpatient setting (NCT03877068, NCT03508934, ClinicalTrials.gov), while the other is an observational trial (NCT03832907). The purpose of this analysis was to analyze matched pairs of CGM and capillary POC glucose values for assessment of CGM accuracy in the hospital setting. All studies received institutional review board approval by participating institutions.

Data from non-critically ill medical or surgical patients ($n = 218$) with type 1 (T1) or type 2 diabetes treated with basal and/or rapid-acting insulin and with admission BG <400 mg/dL were included. All studies included patients without evidence of diabetic ketoacidosis and with an expected length of stay >3 days. We excluded patients admitted or transferred to the intensive care unit or those expected to require intensive care unit-level care, as well as patients who were pregnant or breastfeeding at the time of enrollment.

Patients were recruited from general medical and surgical units. Basic demographic and inpatient clinical data were obtained from the electronic health record, and all analyzed CGM sensors had been placed on the abdomen. POC BG values were obtained by hospital-calibrated Nova StatStrip (14) (Grady Memorial Hospital), ACCU-CHEK Inform II glucose meters (15) (Emory University Midtown Hospital and University of Maryland Medical Center), and Abbott Precision Xceed Pro (16) (Baltimore VA Medical Center). POC glucose values were checked as per hospital protocol, as clinically indicated if there was a concern for hypoglycemia or if the clinical team deemed that this was necessary for patient care. A total of 4,067 matched pairs of CGM and capillary POC glucose values were analyzed. We matched CGM-POC glucose pairs by time, using the sensor glucose value within the following 5-min window of

the POC glucose measurement to account for CGM lag time (17,18). Matched pairs with POC glucose values outside of the CGM reading range (BG <40 mg/dL or >400 mg/dL) were excluded. For assessment of accuracy during the first 12 and 24 h of sensor life, patients requiring any sensor change ($n = 61$) were excluded. Patients were also stratified according to renal function based on estimated glomerular filtration rate (eGFR) and severity of anemia based on hemoglobin level on admission.

Study End Points

Mean absolute relative difference (MARD) was used as the main accuracy measure. Secondary measures included median absolute relative difference (ARD) and the percentage of CGM readings within 15 mg/dL of POC reference values ≤ 100 mg/dL or 15% of POC values >100 mg/dL (% 15/15). Analogous measurements for % 20/20 and % 30/30 were also calculated, consistent with the FDA accuracy requirements for approval of nonadjunctive factory-calibrated CGM systems (19,20). MARD and median ARD were analyzed during the first 12 and 24 h of wear and during the entire hospital stay, as well as by glucose ranges (<70 , 70–180, 180–250, and >250 mg/dL), renal function (eGFR <30 , 30–59, 60–90, and >90 mL/min/1.73 m²), and hemoglobin level (<7 , 7–10, 10–14, and >14 g/dL) on admission. An exploratory analysis of accuracy within different BMI categories was also performed. The overall % 15/15, % 20/20, and % 30/30 was also analyzed across different glucose ranges. Clinical reliability was assessed with Clarke error grid (CEG) analyses.

Statistical Analysis

MARD and median ARD were determined as the average relative difference between the CGM and POC glucose matched pairs and expressed as a percentage. Statistical methods for CGM performance analysis were based on recommendations by Clarke and Kovatchev (21). To determine the accuracy of sensor values compared with POC testing in population subgroups, analyses were based on glucose ranges, renal function, and hemoglobin categories. We also calculated the accuracy according to sensor life (first 12 h and first 24 h). Data are

presented as mean (\pm SD) for continuous and count (%) for categorical variables. Error grid analyses were determined with the R package *ega*, which is designed for Clarke or Parkes error grid analysis (<https://cran.r-project.org/web/packages/ega/ega.pdf>). Additional analyses were conducted with SAS.

RESULTS

Characteristics of the included study population are outlined in Table 1. The mean \pm SD age of patients was 60.6 \pm 12 years, with an average BMI of 33.4 \pm 9.0 kg/m². Most patients had type 2 diabetes (96%); among them, mean duration of diabetes was 15.9 \pm 10.3 years and admission hemoglobin A_{1c} 9.1 \pm 2.2%. The majority of patients were admitted to a primary medical service (88%). Mean enrollment BG was 203.6 \pm 69.8 mg/dL, with a median length of hospital stay of 5 days (interquartile range [IQR] 3, 8). Average daily mean glucose by POC testing was 178.7 \pm 39.6 mg/dL and by CGM 176.7 \pm 43.4 mg/dL.

The MARD was 12.8% and median ARD 10.1% [IQR 4.6, 17.6] during the hospital stay for all available matched

pairs ($n = 4,067$), with lower accuracy during the first 12 and 24 hours ($n = 263$, MARD 16.4% and median ARD 12.5% [5.6, 23.2], and $n = 627$, MARD 14.4% and median ARD 11.1% [5.3, 20.0], respectively) (Table 2). For further evaluation, CGM accuracy data were stratified by subgroups according to POC glucose categories, hemoglobin, and renal function ranges (Fig. 1). The assessment of MARD and median ARD according to POC glucose level strata showed similar accuracy for target range of 70–180 mg/dL ($n = 2,423$, MARD 13.0% and median ARD 10.2% [4.5, 18.1]); mild-moderate hyperglycemia, 181–250 mg/dL ($n = 1,103$, MARD 11.8% and median ARD 10.0% [4.7, 16.7]); and severe hyperglycemia, >250 mg/dL ($n = 475$, MARD 12.1% and median ARD 9.4% [4.4, 16.1]). A higher MARD and median ARD were observed in the case of hypoglycemia, 50–70 mg/dL ($n = 52$, MARD 18.8% and median ARD 14.5% [IQR 6.9, 27.3]). Additionally, CGM showed consistent accuracy according to different admission hemoglobin ranges (7–10 g/dL, $n = 1,024$, MARD 12.9% and median ARD 10.2% [4.5, 18.0]; 10.1–14 g/dL, $n = 2,543$, MARD

12.8% and median ARD 10.2% [4.7, 17.6]; >14 g/dL, $n = 428$, MARD 11.7% and median ARD 9.3% [4.1, 15.6]), down to a hemoglobin value <7 g/dL, where a higher MARD and median ARD were observed ($n = 72$, MARD 17.8% and median ARD 15.8% [IQR 8.9, 23.5]).

Comparable accuracy metrics were also observed across admission renal function categories based on eGFR, including eGFR values <30 mL/min/1.73 m² (>90 mL/min/1.73 m², $n = 950$, MARD 13.2% and median ARD 10.8% [IQR 4.7, 18.8]; 60–90 mL/min/1.73 m², $n = 1,134$, MARD 12.2% and median ARD 10.1% [5.1, 16.5]; eGFR 30–59 mL/min/1.73 m², $n = 1,079$, MARD 13.3% and median ARD 10.1% [4.4, 18.1]; and eGFR <30 mL/min/1.73 m², $n = 904$, MARD 12.5% and median ARD 9.8% [4.3, 17.4]).

In an exploratory analysis of this retrospective matched-pair data, accuracy metrics were analyzed by BMI categories (≤ 30 kg/m², between 30–40 kg/m² and >40 kg/m²). Overall accuracy metrics between BMI categories were comparable, though the MARD and median ARD trended slightly lower as BMI increased (BMI ≤ 30 kg/m², $n = 1,459$, MARD 13.3% and median ARD 10.0% [IQR 4.7, 17.9]; 30 < BMI ≤ 40 kg/m², $n = 1,662$, MARD 12.6% and median ARD 10.4% [4.8, 17.7]; and BMI >40 kg/m², $n = 946$, MARD 12.4% and median ARD 9.8% [4.3, 17.0]) (Supplementary Table 1).

The % 15/15, % 20/20, and % 30/30 increased between the first 12 h (57.0, 69.2, and 85.9%, respectively) and 24 h (63, 75.6, and 89.2%) of sensor life. The overall % 15/15, % 20/20, and % 30/30 criteria were 68.7, 81.7, and 93.8%, respectively (Table 2).

A CEG analysis of all matched pair data showed good clinical reliability, with 98.7% of values falling in CEG zones A and B (zone A, 80.9%; zone B, 17.8%; zone C, 0.1%; zone D, 1.1%; and zone E, 0.0%). CEG analysis during the first 12 h of sensor life revealed 98.8% of values in zones A and B (zone A, 81.8%; zone B, 17.0%; zone C, 0.1%; zone D, 1.1%; and zone E, 0.0%) and during the first 24 h showed 98.7% values in zones A and B (zone A, 82.0%; zone B, 16.7%; zone C, 0.1%; zone D, 1.2%, and zone E, 0.0%) (Fig. 2).

Table 1—Patient characteristics

Age, years	60.6 \pm 12.0
Sex, n (%)	
Male	147 (67)
Female	71 (33)
BMI, kg/m ²	33.4 \pm 9.0
Race, n (%)	
Black	159 (73)
White	52 (24)
Hispanic	6 (2.8)
Other	1 (0.5)
Type 2 diabetes, n (%)	209 (96)
Duration of diabetes, years	15.9 \pm 10.3
Admission service, n (%)	
Medicine	192 (88)
Surgery	26 (12)
Admission hemoglobin A _{1c} , %	9.1 \pm 2.2
Enrollment BG, mg/dL	203.6 \pm 69.8
LOS (postenrollment), days, median (IQR)	5 (3, 8)
Grouped admission diagnosis, n (%)	
Cardiovascular	76 (35)
Infectious	66 (30)
Neurologic	21 (9.6)
Pulmonary	17 (7.8)
Other (DM related, GI, surgical, gynecologic, renal)	52 (24.3)

Data are means \pm SD unless otherwise indicated. DM, diabetes mellitus; GI, gastrointestinal; LOS, length of stay.

Table 2—CGM reliability by sensor age

	CGM vs. capillary POC (first 12 h)	CGM vs. capillary POC (first 24 h)	CGM vs. capillary POC (entire hospitalization)
Paired readings, <i>n</i>	258	614	4,067
MARD, %	16.4	14.4	12.8
ARD, %, median (IQR)	12.8 (5.6, 23.2)	11.1 (5.3, 20.4)	10.1 (4.6, 17.6)
% 15/15, 20/20, 30/30	57.0, 69.0, 86.0	63.0, 75.2, 89.1	68.7, 81.7, 93.8

CONCLUSIONS

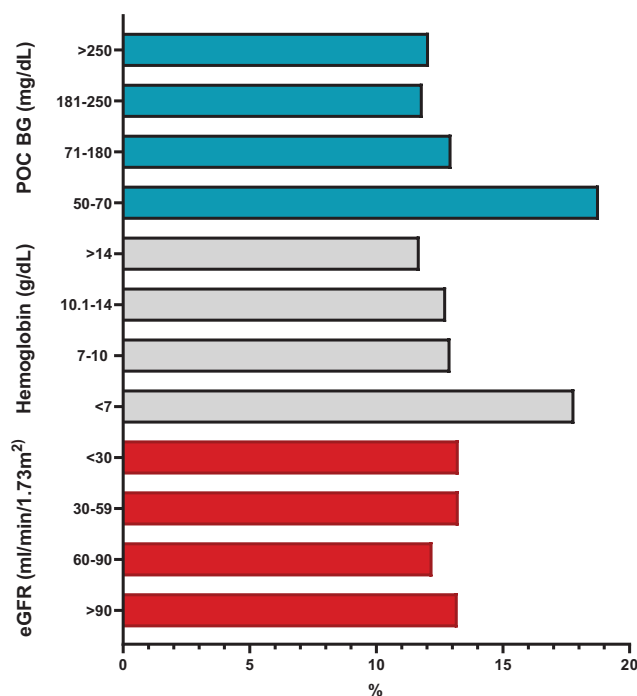
In a diverse population of non-critically ill hospitalized patients with diabetes receiving insulin therapy, our analysis shows very good overall accuracy of Dexcom G6 CGM, with a MARD of 12.8%, median ARD of 10.1%, and 98.7% of matched values within CEG on zones A and B compared with standard of care POC glucose monitoring. The Dexcom G6 CGM system performed well in medicine and surgery patients, including in those with cardiovascular and respiratory illnesses, impaired renal function, and mild-to-moderate anemia. Scenarios where CGM accuracy may be lower include hypoglycemia values with glucose <70 mg/dL and severe anemia with hemoglobin <7 g/dL, though sample sizes were small in these groups.

Close monitoring of glucose values in the hospital is necessary to achieve glycemic control and prevent adverse outcomes associated with dysglycemia. Recent clinical trial data suggest that CGM use may significantly improve hospital diabetes management. CGM devices provide an easier method for monitoring BG levels more frequently compared with labor-intensive capillary POC testing and other more cumbersome techniques (i.e., venous glucose sampling). Recently, the COVID-19 pandemic set into motion the rapid transition of CGM to the hospital setting to address these unmet needs in glucose monitoring during a time when minimizing bedside encounters became paramount. The CGM accuracy observed in this analysis is encouraging and indicates that

CGM provides an attractive option for inpatient glucose monitoring in general medicine and surgery patients with diabetes.

Previous studies have highlighted the utility of CGM in detecting and preventing hypoglycemia in the hospital. In a prospective study of 97 insulin-treated patients with type 2 diabetes, CGM (blinded FreeStyle Libre) showed overall lower mean glucose values than POC testing (176.1 ± 46.9 vs. 188.9 ± 37.3 mg/dL, respectively; $P < 0.001$) and detected significantly more hypoglycemia than POC testing alone (BG <70 mg/dL, 14 vs. 56%, $P < 0.001$, and <54 mg/dL, 4.1 vs. 36%, $P < 0.001$) (11). Another study investigated the use of CGM in hypoglycemia prevention, with use of a glucose telemetry alert system in

A Mean ARD



B Median ARD

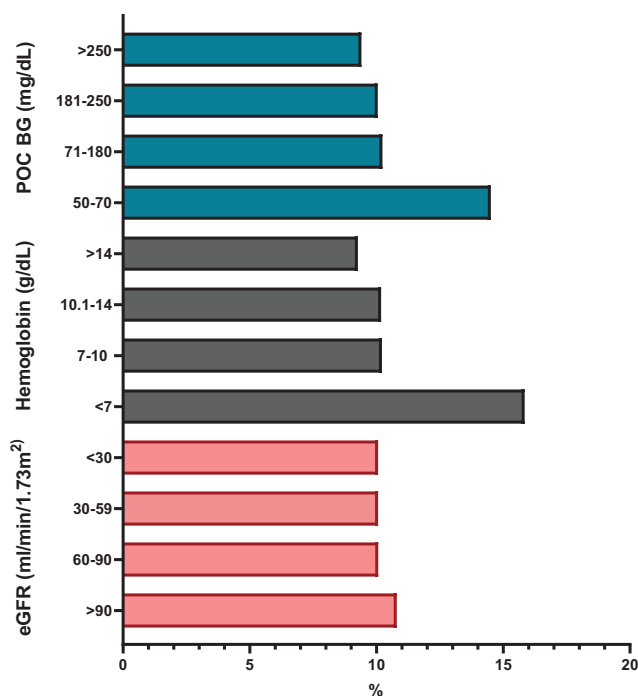


Figure 1—MARD (A) and median ARD (B) by glucose range, hemoglobin value, and eGFR category.

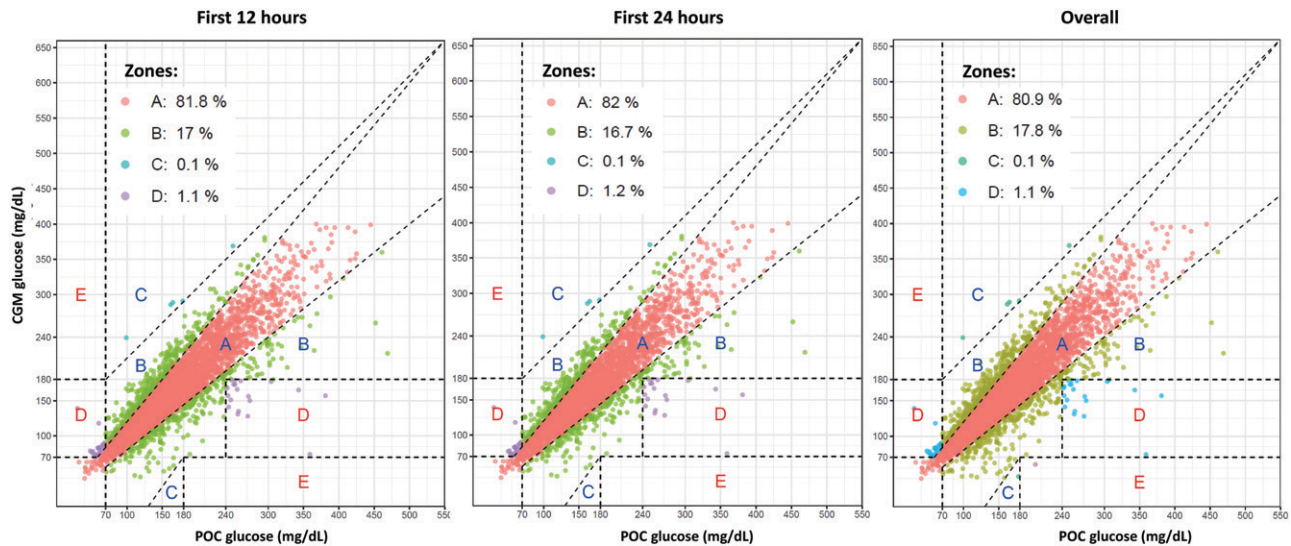


Figure 2—CEG analysis by sensor age.

insulin-treated patients with type 2 diabetes and high risk of hypoglycemia (13). Results showed that those randomized to real-time CGM with hypoglycemia alerts experienced fewer per-patient hypoglycemic events compared with those randomized to POC glucose monitoring (BG <70 mg/dL, 0.67 [95% CI 0.34–1.30] vs. 1.69 [1.11–2.58], $P = 0.024$, and <54 mg/dL, 0.08 [0.03–0.26] vs. 0.75 [0.51–1.09], $P = 0.003$), without a significant difference in time above range (13). While slightly lower accuracy was noted in the hypoglycemia range, these prior studies highlight the important safety role that CGM technology serves in the hospital in preventing hypoglycemia.

Studies evaluating other CGM systems have also reported reasonable accuracy of CGM compared with POC glucose values in the hospital. Two studies with use of the iPro2 CGM (Medtronic, Northridge, CA) in hospitalized patients with type 2 diabetes treated with basal-bolus insulin showed overall reliability of CGM, with >90% of values falling within CEG zones A and B. However, these CGM systems required frequent calibration with POC glucose values. Despite calibration, there were concerns regarding lower CGM accuracy for identification of hypoglycemia and the possibility of both persistent positive and negative biases for CGM glucose estimates compared with reference measurements.

Real-time CGM technology has advanced to a degree that patients can now rely on CGM to make treatment decisions in the

outpatient setting without confirming glucose values by POC testing. In addition, factory-calibrated devices have integrated advanced remote monitoring technology and alert systems applicable to the inpatient setting, which has become very advantageous in the hospital setting during the COVID-19 pandemic (13). Two studies published recently with currently available factory-calibrated CGM devices suggest that newer devices may be more reliable in the hospital. For patients with diabetes undergoing elective general surgery ($n = 10$), with use of blinded Dexcom G6 CGM there was good correlation found between CGM and standard of care POC glucose values, with a reported MARD of 9.4%. The second study enrolling patients with COVID-19 receiving subcutaneous insulin therapy had similar results with regard to Dexcom G6 CGM reliability compared with POC glucose ($n = 105$ matched pairs), with a MARD of 9.77% and 84.8% of values falling within CEG zone A (8). Our study confirms these preliminary findings in a large heterogeneous population and expands the analysis to relevant subgroups of patients according to glucose level, renal function, and hemoglobin concentration. In addition, recent data indicate that continued CGM usage during radiology procedures (except for MRI) is reliable without interference in data transmission.

To our knowledge, this study includes the largest matched-pair sample size for assessment of inpatient CGM accuracy. There was also a high percentage of non-Hispanic Black patients included in

our analysis—an important advantage given that minority groups are frequently underrepresented in clinical trials (22). Limitations to our study include the use of POC glucose values as a comparator that may carry an inherent degree of variability and potential bias, with discrepancies between CGM and POC values potentially amplified by POC measurements made during times of rapid glucose fluctuation. We recognize the limitation that different glucometers were used across sites and acknowledge the need for large-scale analyses using laboratory or glucose analyzer techniques to confirm the accuracy of CGM in hospitalized patients. The higher MARD associated with very low hemoglobin levels may be impacted by the smaller sample size of matched pairs in this subgroup, with only 72 matched pairs. Similarly, the higher MARD for hypoglycemic range values may also stem from a limited number of observed matched pairs ($n = 52$), related to the observational and retrospective nature of this study. Additionally, only admission values for hemoglobin and renal function were assessed for this pooled analysis. Further evaluation of CGM accuracy during scenarios where these clinical parameters may experience frequent fluctuation is needed.

As diabetes technology continues to evolve in the inpatient setting, it is important to consider how accuracy criteria are used and interpreted in hospitalized patients. Although MARD is an accepted accuracy metric for CGM, it may

also be influenced by factors including the number, range, and distribution of paired glucose values, as well as the rate of change in glucose values. Accordingly, we chose also to report median ARD, as this real-life data set obtained from a less controlled environment may reflect a more skewed data distribution. Assessment of additional accuracy metrics, similar to those put forth by the FDA for integrated CGM use in automated insulin delivery, may be required or adapted for the inpatient setting, as protocols for hospital use of CGM continue to develop (5,20). These are important considerations for the management of hospitalized patients with dynamic clinical courses receiving diverse therapies and medications, especially with the interest in using diabetes technologies integrating CGM and insulin delivery in the inpatient setting. Larger studies should continue to address the potential for undiscovered clinical characteristics and elements of inpatient care that may impact CGM accuracy.

Conclusion

CGM is a promising tool for inpatient glucose monitoring, helping to reduce the care burden associated with bedside POC glucose monitoring. This analysis in a large and heterogeneous non-critically ill inpatient population with diabetes on insulin therapy suggests that Dexcom G6 CGM technology is reliable in the hospital compared with standard POC glucose monitoring. Subgroup analyses within this population of medicine and surgery patients show maintained CGM accuracy parameters in patients with impaired renal function and mild-to-moderate anemia. Future studies should confirm reduced CGM accuracy in patients with severe anemia, as well as the use of CGM to detect hyper- and hypoglycemia and guide inpatient insulin therapy.

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