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ORIGINAL ARTICLE

Perioperative Characteristics of the Accuracy of Subcutaneous Continuous Glucose Monitoring: Pilot Study in Neurosurgery and Cardiac Surgery

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Abstract

Background: The aim of this study was to elucidate the characteristics of accuracy of subcutaneous continuous glucose monitoring (SCGM) in the perioperative period for neurosurgical and cardiac surgery patients.
Methods: Forty-five subjects, including healthy volunteers ($n = 15$), neurosurgical patients ($n = 15$), and cardiac surgery patients ($n = 15$), were enrolled. A subcutaneous sensor of the MiniMed™ 620G SCGM system was inserted into the upper arm. On the day after sensor insertion, SCGM data and blood glucose data were collected simultaneously and compared. In cardiac surgery patients, data were continuously collected on postoperative day (POD) 1 and POD 3. Clarke error grid analysis and Bland–Altman analysis were performed to assess the accuracy of SCGM.
Results: Clarke error grid analysis showed clinical acceptance of the SCGM system with 82.7% and 86.8% of the data being within zone A for healthy volunteers and neurosurgical patients, respectively. Mean biases were −2.1 mg/dL in healthy volunteers and −8.3 mg/dL in neurosurgical patients. In cardiac surgery, although Clarke error grid analysis showed clinical acceptance, 65.3% of the data were within zone A and mean bias was −23.5 mg/dL. Changes in accuracy of SCGM in individuals occurred during cardiopulmonary bypass (CPB), and SCGM tended to show a lower glucose level. On POD 1 and POD 3, the accuracy improved, and 85.0% and 86.3% of the data were within zone A.
Conclusions: Although the accuracy of the SCGM system was clinically acceptable in the perioperative period, sensor accuracy was affected by CPB and showed lower glucose levels.

Keywords: Continuous glucose monitoring, Accuracy, Perioperative period, Neurosurgery, Cardiac surgery, Cardiopulmonary bypass.

Introduction

In the perioperative period, hyperglycemia is associated with increases in the incidence of various complications[1–3] and glycemic control is an important issue. Previous studies[4–9] showed that strict blood glucose control increased the risk of hypoglycemia and potentially induced life-threatening complications[7–9]; therefore, reducing the risk of hypoglycemia while treating hyperglycemia is essential for a glycemic control protocol. To achieve these requirements, both frequent and accurate measurements of glucose are required.

Subcutaneous continuous glucose monitoring (SCGM) systems that can monitor and record real-time interstitial glucose levels have been developed and they have been used for efficient treatment of diabetic patients.[10,11] Continuous recording provides trends and the peak of changes in interstitial glucose, and some SCGM systems have an alert for hyperglycemia and hypoglycemia. In addition, an SCGM system is wearable and does not restrict the patient's movement. If the system is applicable to perioperative glucose monitoring, glycemic control in the perioperative period may change; however, data on the accuracy of SCGM in the perioperative period are not sufficient.

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In this pilot study, we evaluated the accuracy of an SCGM system during different types of surgeries, including neurosurgery—in which many electrical devices are used in the operating room—and cardiac surgery with cardiopulmonary bypass (CPB)—in which the patient's condition can drastically change. In addition, we followed and evaluated the accuracy of the SCGM system in the postoperative period of cardiac surgery.

Materials and Methods

Patient selection

The study protocol was approved by the ethics committee of our institution (No. 3605) and the study was registered in the University Hospital Medical Information Network Clinical Trials Registry (No. 000025271). Written informed consent was obtained from each subject. Healthy volunteers were recruited from medical staff in our institution. Patients aged 20 years or older who were scheduled to undergo neurosurgery or cardiac surgery with CPB under general anesthesia and in whom arterial catheter placement was planned were enrolled in this study. Patients receiving anticoagulant therapy and patients with pre-existing coagulopathy (patients with platelet count $<10\times10^4/mm^3$, prothrombin time-international normarized ratio >1.5, activated partial thromboplastin time >40 s, and fibrinogen <150 mg/dL or patients receiving heparin) or a skin disorder were excluded from the study.

Sample collection

In each of the healthy volunteers, an Enlite™ sensor of MiniMed™ 620G (MiniMed; Medtronic Diabetes, Northridge, CA) was inserted into the upper arm, which is the site recommended by the manufacturer, on the day before the measurement day. Capillary blood samples were obtained by finger prick and the SCGM system was calibrated as recommended by the manufacturer. Blood glucose measured by using a HemoCue™ Glucose 201 DM RT analyzer[12] (HemoCue AB, Ängelholm, Sweden) was considered as the reference value, and SCGM levels displayed on the SCGM system at the time of blood sampling were recorded. Blood sampling was performed 10 times within 12 h at intervals of more than 20 min on the measurement day, and blood sampling just after a meal was avoided.

In neurosurgery and cardiac surgery patients, Enlite sensor insertion, SCGM calibration, and glucose measurement were performed in the same way as that in healthy volunteers on the day before surgery. In neurosurgery patients, data for blood glucose and SCGM were collected on the day of surgery. In patients undergoing cardiac surgery with CPB, data were collected on the day of surgery and on postoperative day (POD) 1 and POD 3. When patients were in the operating room or intensive care unit (ICU), blood samples were obtained from an arterial line. After discharge from the ICU, capillary blood samples were obtained by finger prick. Glucose levels were measured by the same HemoCue Glucose 201 DM RT analyzer in both arterial and capillary blood samples during the study period. Blood sampling was performed 9 or 10 times during surgery and 5 or 6 times within 12 h in the postoperative period at intervals of more than 20 min. Sampling just after administration of glucose or insulin and just after a meal was avoided. Blood sampling during cardiac surgery was performed two or three times before CPB, three to five times during CPB, and three to five times after CPB. The SCGM system was calibrated every 12 h until POD 3 in cardiac surgery patients. The target glucose range in the perioperative period was set at 70–200 mg/dL.

Glucose analysis

Clarke error grid analysis[13,14] was performed to quantify the clinical accuracy of the SCGM system. The reference blood glucose levels were plotted on the x-axis and SCGM levels were plotted on the y-axis. The error grid was divided into five zones. Zone A represents points that are within 20% of the blood glucose value; zone B represents points that differ by more than 20% from the blood glucose values, but would not lead to inappropriate treatment; zone C represents points that would lead to an overcorrection of blood glucose values; zone D represents points for which SCGM values would cause failure to detect hypoglycemia or hyperglycemia; and zone E represents points that would bring about an inverse treatment. A Bland–Altman plot was used to visualize the deviation of SCGM values from blood glucose values. Mean bias and limits of agreement (mean bias $\pm1.96\times$ standard deviation of the differences between the paired measurements) were marked. To investigate the change of dissociation between SCGM and blood glucose ([SCGM − blood glucose]/blood glucose [%]) during cardiac surgery, the average of the difference by the timing of surgery in each patient was calculated.

Statistical analysis

All data are expressed as numbers, means ± standard deviations, or medians [interquartile range] unless otherwise specified. To investigate the change of dissociation between blood glucose and SCGM by timing during cardiac surgery (before CPB, during CPB, and after CPB), the average dissociation at each timing was calculated. The Mann–Whitney test was used to analyze differences in patients' characteristics. $P<0.05$ was considered as statistically significant. Considering previous studies in which the accuracy of SCGM in the operating room was tested,[15,16] the number of subjects in each group was set at 15. Statistical analysis was performed using GraphPad Prism 6 (GraphPad Software, La Jolla, CA).

Results

First, we confirmed the accuracy of the SCGM system in healthy volunteers. During the study period from January to October in 2017, we included 15 healthy volunteers. The number of comparative samples per subject was 10 and the total number of samples was 150. Characteristics of healthy volunteers are shown in Table 1. Results of Clarke error grid analysis of blood glucose levels and SCGM levels in healthy volunteers are shown in Figure 1A. All of the data were included in clinically acceptable zones (zone A and zone B) and the ratios of points included in zone A and zone B were 82.7% and 17.3%, respectively. Bland–Altman analysis in healthy volunteers (Fig. 1B) revealed that the mean bias was only −2.1 mg/dL and the upper and lower limits of agreement were 33.7 mg/dL and −37.8 mg/dL, respectively. These results in healthy volunteers are comparable with results of previous studies[17,18] and showed that the SCGM system has

Table 1. Characteristics of Study Participants

	Healthy volunteers	*Neurosurgery patients*	*Cardiac surgery patients*
Number of patients	15	15	15
Male/female	9/6	7/8	10/5
Age (year)	31 [29–33]	60 [41–73]	69 [52–78]
Height (cm)	168.0 ± 7.8	163.4 ± 9.0	161.4 ± 9.9
Weight (kg)	62.1 ± 8.8	62.4 ± 13.6	60.1 ± 12.4
Body–mass index (kg/m^2)	22.0 ± 2.2	23.2 ± 3.6	23.0 ± 3.3
ASA-PS (1/2/3/4) (*n*)	15/0/0/0	4/11/0/0	0/15/0/0/
Type 1 diabetes	0	1	0
Type 2 diabetes	0	0	0
Type of operation (*n*)	—	Transsphenoidal pituitary surgery (2) Craniotomy for tumor (6) Aneurysm clipping (5) Spine surgery (2)	Valve surgery (12) Thoracic aortic surgery (3)
Anesthesia time (min)	—	406 [306–544]	470 [433–696]
Operation time (min)	—	289 [239–450]	370 [300–559]
Blood loss (mL)	—	100 [10–200]	996 [630–1600][a]
Fluid balance (mL)	—	947 ± 438	1818 ± 1789
CPB time (min)	—	—	195 [139–375]
Minimum rectal temperature	—	36°C–37°C (10) 35°C–36°C (5)	33°C–34°C (13) 24°C–28°C (2)
Timing of extubation (*n*)		After the surgery at OR (15)	POD 0 at ICU (4) POD 1 at ICU (8) POD 2 at ICU (2) POD 3 at ICU (1)

Data are expressed as numbers (*n*), means ± standard deviations, or median [interquartile range].
[a]$P < 0.05$ compared with neurosurgery patients.
ASA-PS, American Society of Anesthesiologists–physical status; CPB, cardiopulmonary bypass; ICU, intensive care unit; OR, operating room; POD, postoperative day.

clinically acceptable accuracy,[19] meaning that use of the SCGM system would not lead to inappropriate glycemic treatment in a nonsurgical setting.

To investigate whether the SCGM system can be used in an operating room where many electrical devices that may affect the performance of the SCGM system are used, we assessed the SCGM accuracy in neurosurgical patients. Fifteen neurosurgical patients were screened and enrolled in this study. The number of comparative samples per subject was 9 or 10 and the total number of samples was 144. Characteristics of neurosurgical patients are shown in Table 1. Results of Clarke error grid analysis in neurosurgical patients (Fig. 1C) showed that all of the data were included in zone A (86.8%) and zone B (13.2%). Bland–Altman analysis in neurosurgical patients (Fig. 1D) showed that the mean bias was −8.3 mg/dL and the upper and lower limits of agreement were 20.6 and −37.1 mg/dL, respectively. These results were almost the same as the results for healthy volunteers in a nonsurgical setting, suggesting that this SCGM system can be used in an operating room without leading to inappropriate glycemic treatment.

Cardiac surgery with CPB is one of the most invasive types of surgeries and induces hyperglycemia in the intraoperative and postoperative periods. If continuous glucose monitoring can be used in cardiac surgery in the perioperative period, the benefit would be great. We therefore investigated the accuracy of SCGM in the intraoperative and postoperative periods. In cardiac surgery, we screened 40 patients and enrolled 17 patients. Only two patients were excluded during the surgery: one for loosening of sensor fixture and the other due to a worn-out battery. The number of comparative samples per subject was 10 and the total number of samples was 147. Characteristics of cardiac surgery patients are shown in Table 1. Lowest rectal temperature during CPB was more than 33°C in 80% of the cases and the amount of blood loss was 996 [630–1600] mL (Table 1). Extubation was performed within POD 3 in all cases and postoperative courses were uneventful. Results of Clarke error grid analysis in cardiac surgery patients (Fig. 2A) showed that the ratios of data included in zone A, zone B, and zone D were 65.3%, 34.0%, and 0.7%, respectively. Although 99% of the data were included in a clinically acceptable zone, the ratio of data in zone A was low and the ratio of data in zone B was high. These results indicated that the accuracy of SCGM was different from that in healthy volunteers and in a neurosurgical setting. Bland–Altman analysis in cardiac surgery patients (Fig. 2B) also showed that the mean bias was considerably low (−23.5 mg/dL) and the range of limits of agreement was considerably large, as indicated by the upper limit of agreement of 30.3 mg/dL and the lower limit of −77.3 mg/dL.

To investigate the involvement of CPB in the change in accuracy of SCGM, we divided the intraoperative data by the different timing of surgery, that is, before CPB, during CPB, and after CPB. Changes in the accuracy of SCGM in individuals (Fig. 2C) revealed that the SCGM system showed a lower glucose level during CPB in all patients except for one outlier (Fig. 2C, arrow). After CPB, the degrees of dissociation were within 20% difference (within zone A in Clarke error grid analysis) in some patients (Fig. 2C, Group A) and more than 20% difference (outside of zone A in Clarke error grid analysis) in other patients (Fig. 2C, Group B). We performed subgroup analysis and found that there was no

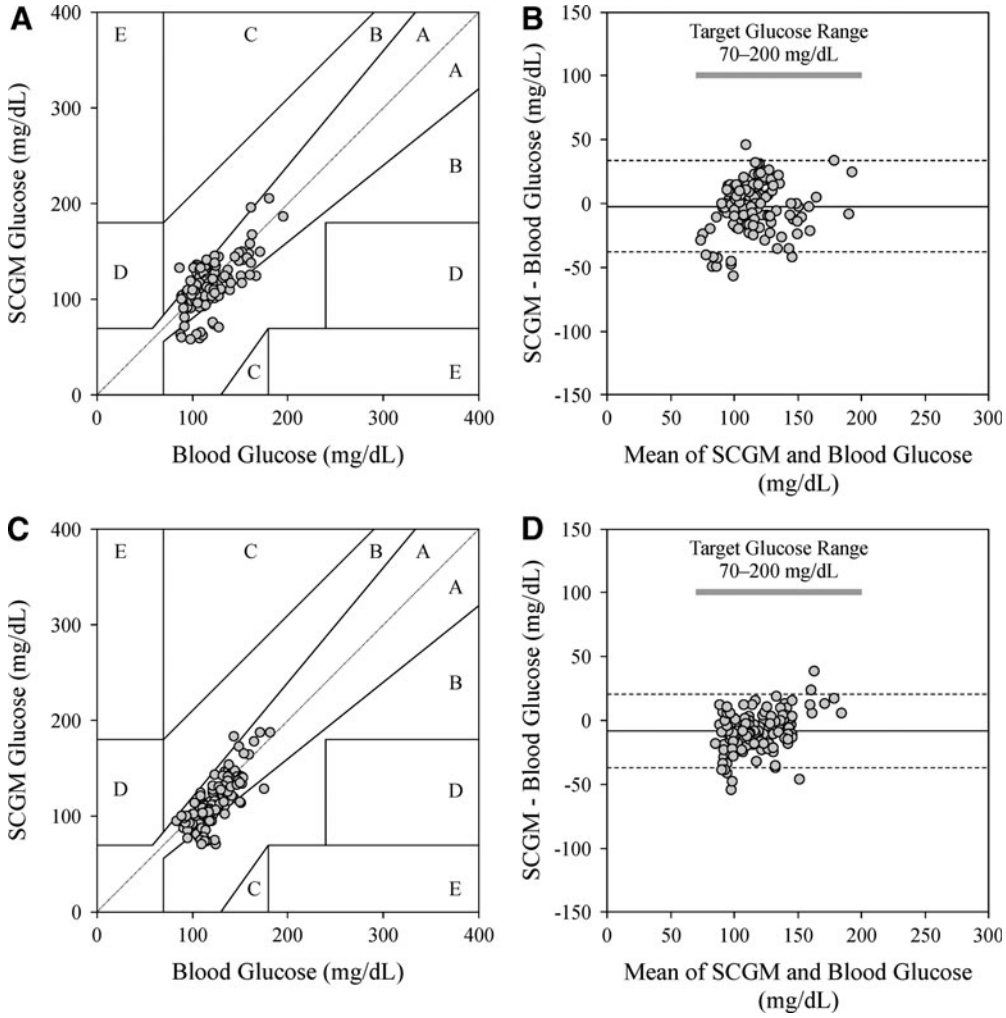

FIG. 1. Clarke error grid analysis **(A, C)** and Bland–Altman plot **(B, D)** of SCGM and blood glucose bias (SCGM minus blood glucose) versus mean of SCGM and blood glucose in healthy volunteers **(A, B)** and in neurosurgical patients **(C, D)**. In Clarke error grid analysis, zones are labeled from A to E. In Bland-Altman plots, black lines represent mean bias and dashed lines represent limits of agreement. SCGM, subcutaneous continuous glucose monitoring.

significant difference between the characteristics of patients in Group A and Group B (Table 2).

We continuously used the SCGM system until POD 3 with calibration every 12 h and evaluated the accuracy. The number of comparative samples per subject was five or six and the total number of samples was 80 on both POD 1 and POD 3. Results of Clarke error grid analysis for POD 1 and POD 3 in the cardiac surgery patients (Fig. 3A, C) showed that the ratios of data included in zone A, zone B, and zone D were 85.0%, 13.8%, and 1.3%, respectively, on POD 1 and 86.3%, 12.5%, and 1.3%, respectively, on POD 3. Since these ratios were better than those during cardiac surgery and almost the same as those in healthy volunteers, the accuracy of SCGM was considered to be improved in the postoperative period. Bland–Altman analysis for POD 1 and POD 3 (Fig. 3B, D) showed that the mean biases were −5.34 mg/dL on POD 1 and −10.9 mg/dL on POD 3. The upper and lower limits of agreements were 45.5 mg/dL and −56.1 mg/dL, respectively, on POD1 and 35.9 mg/dL and −57.8 mg/dL, respectively, on POD 3. The results of glucose analysis are summarized in Table 3. The results showing that the mean biases in both the intraoperative and postoperative periods were negative revealed that the SCGM system tended to show lower glucose levels in the perioperative period.

Discussion

In acute medical care, SCGM can provide real-time data for glucose trends. This is a great advantage compared with intermittent glucose monitoring; however, characteristics of the accuracy of SCGM in the perioperative period have remained unclear. Although some studies, in which the accuracy of SCGM during cardiac surgery was evaluated,[16,20–23] showed that correlation between blood glucose and SCGM was relatively weak, the applicability of an SCGM system in the operating room itself was not examined and data for SCGM in the postoperative period were insufficient.

In this pilot study, we examined the accuracy of SCGM under different perioperative conditions. After confirming that the SCGM system used in this study has clinically acceptable accuracy in healthy volunteers, we examined the accuracy of SCGM in the operating room by assessing the

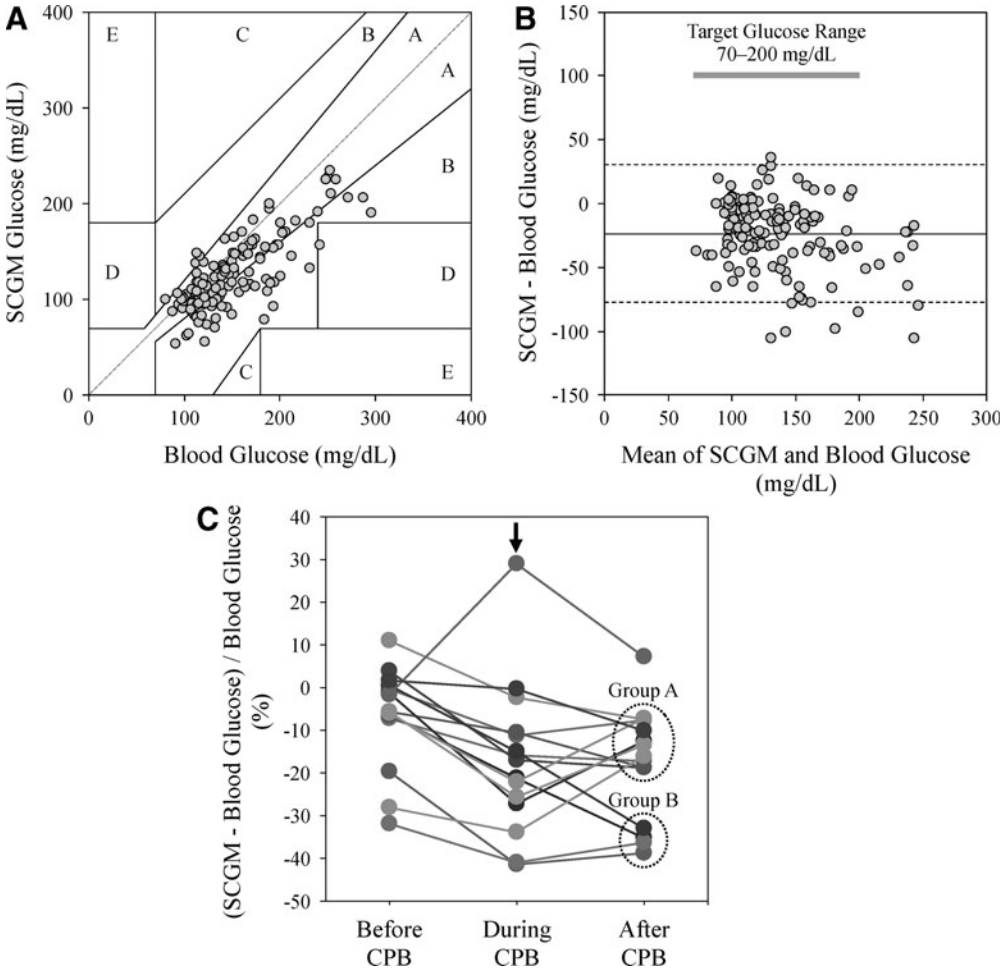

FIG. 2. Clarke error grid analysis **(A)** and Bland–Altman plot **(B)** of SCGM and blood glucose bias (SCGM minus blood glucose) versus mean of SCGM and blood glucose during cardiac surgery. In Clarke error grid analysis, zones are labeled from A to E. In Bland-Altman plots, black lines represent mean bias and dashed lines represent limits of agreement. Change of dissociation between SCGM and blood glucose by the different timing of surgery in each patient **(C)**. Black arrow indicates one outlier. Group A indicates moderate (within 20%) dissociation after CPB, and Group B indicates large (more than 20%) dissociation after CPB. CPB, cardiopulmonary bypass.

Table 2. Subgroup Analysis of Patients' Characteristics in Cardiac Surgery

	Group A	*Group B*	P
Number of patients	10	5	
Male/female	7/3	3/2	0.99
Age (year)	72 [50–78]	67 [56–73]	0.53
Height (cm)	158 [157–168]	164 [152–174]	0.71
Weight (kg)	62.5 [51.1–70.0]	55.5 [44.7–80.0]	0.99
Body–mass index (kg/m^2)	22.9 [20.5–25.2]	21.4 [19.2–26.5]	0.99
Type of operation (*n*)	Valve surgery (8)	Valve surgery (4)	
	Thoracic aortic surgery (2)	Thoracic aortic surgery (1)	
Anesthesia time (min)	463 [422–733]	495 [392–692]	0.95
Operation time (min)	356 [292–735]	370 [275–537]	0.86
CPB time (min)	188 [139–393]	195 [151–342]	0.93
Blood loss (mL)	988 [583–1939]	1022 [790–1786]	0.69
Fluid balance (mL)	1851 [634–3212]	1812 [516–2840]	0.69
Minimum rectal temperature	33°C–34°C (9)	33°C–34°C (4)	0.99
	24°C–28°C (1)	24°C–28°C (1)	

Data are expressed as numbers (*n*) or median [interquartile range].

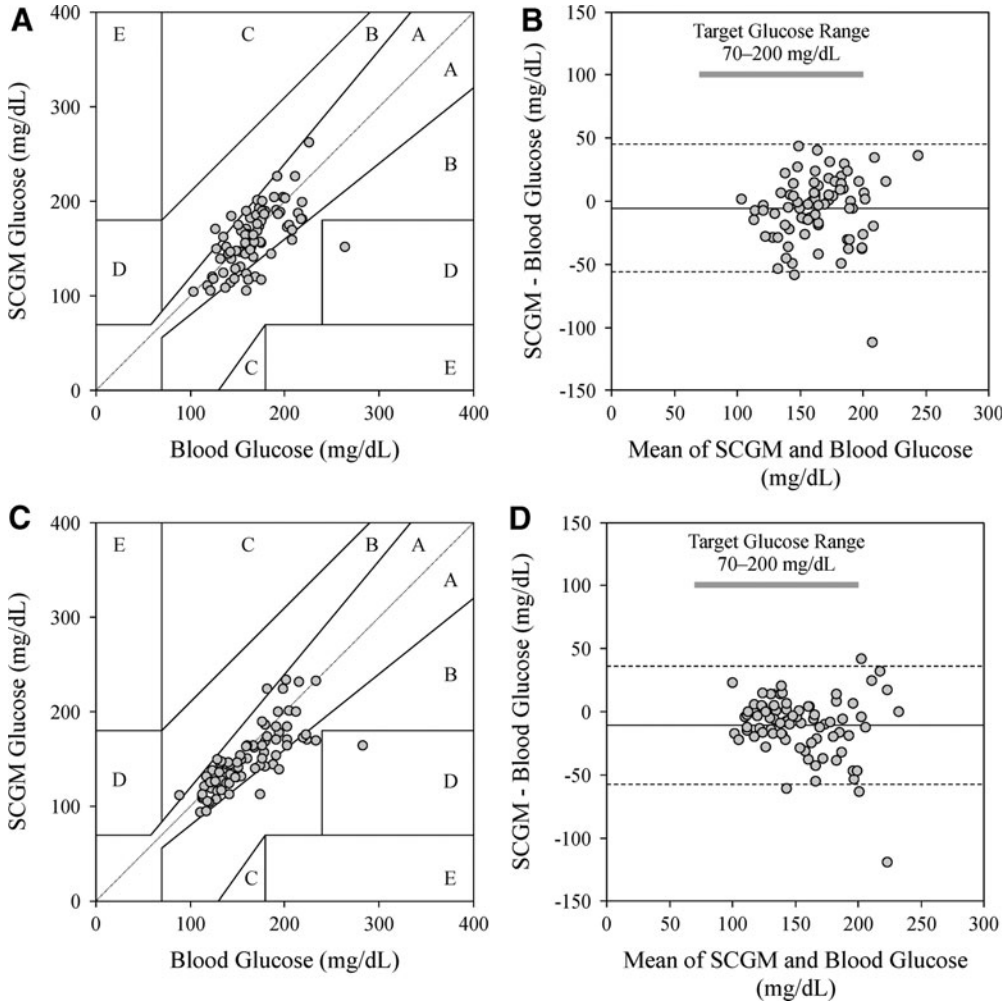

FIG. 3. Clarke error grid analysis **(A, C)** and Bland–Altman plot **(B, D)** of SCGM and blood glucose bias (SCGM minus blood glucose) versus mean of SCGM and blood glucose on POD 1 **(A, B)** and POD 3 **(C, D)** in cardiac surgery. In Clarke error grid analysis, zones are labeled from A to E. In Bland-Altman plots, black lines represents mean bias and dashed lines represent limits of agreement. POD, postoperative day.

accuracy of SCGM during neurosurgery. Our results clearly showed that the SCGM system can be used with the same accuracy as that in nonsurgical healthy people in the operating room without any influence from various electrical devices. If the surgery is similar to or less invasive than neurosurgery in this study and blood glucose levels of patients are not in diabetic states, the SCGM system will show good accuracy and can be used in the perioperative period.

On the other hand, although 98% of SCGM levels were within the clinically acceptable zone during cardiac surgery, dissociation between SCGM levels and blood glucose levels was large (limits of agreement; −77.3 to 30.3 mg/dL) and SCGM showed a lower glucose level than the blood glucose level (mean bias; −23.5 mg/dL). This tendency is in agreement with results of a previous study in which the accuracy of SCGM during cardiac surgery was investigated.[21,23] In addition to

TABLE 3. SUMMARY OF GLUCOSE ANALYSIS

		Bland–Altman analysis (mg/dL)		*Clark error grid analysis (%)*				
	BG range (mg/dL)	*Mean bias*	*Limits of agreement [lower, upper]*	*Zone A*	*Zone B*	*Zone C*	*Zone D*	*Zone E*
Healthy volunteers	87–195	−2.1	[−37.8, 33.7]	82.7	17.3	0.0	0.0	0.0
Neurosurgery	83–182	−8.3	[−37.1, 20.6]	86.8	13.2	0.0	0.0	0.0
Cardiac surgery	80–296	−23.5	[−77.3, 30.3]	65.3	34.0	0.0	0.7	0.0
Cardiac surgery POD 1	103–264	−5.3	[−56.1, 45.5]	85.0	13.8	0.0	1.3	0.0
Cardiac surgery POD 3	89–283	−10.9	[−57.8, 35.9]	86.3	12.5	0.0	1.3	0.0

BG, blood glucose.

these results, we also found that dissociation improved in the postoperative period, although the negative mean bias that increases the incidence of false hypoglycemia remained. These are the novel findings of our study and we need to pay attention to these characteristics of SCGM in the perioperative period.

Many factors such as time lag, peripheral perfusion, body temperature, and CPB itself have been discussed as causes of dissociation between SCGM and blood glucose. Since the time lag of SCGM level to blood glucose level has been reported to be 4 to 12 min,[24,25] we avoided blood sampling while blood glucose was changing, such as just after a meal and glucose intervention. In this study, we used both arterial blood and capillary blood for reference blood glucose values because it was difficult to obtain arterial blood frequently in the wards from the aspect of ethics and patient safety and because arterial blood and capillary blood are considered to be compatible in patients without shock[26,27]; therefore, we thought that the results of this study were not significantly influenced by the difference of reference blood.

Some previous reports showing that the accuracy of SCGM in critical care patients was low pointed out the involvement of impaired peripheral perfusion.[20,28,29] On the other hand, another study in critical care patients showed that circulatory shock requiring norepinephrine therapy had no influence on the accuracy and reliability of the SCGM.[30] Another study in which the involvement of microcirculation in SCGM accuracy in cardiac surgery patients in the ICU was evaluated showed that although microcirculation was impaired to a limited extent in those patients, not impairment of microcirculation, but rather peripheral temperature less than 31°C and scores of Acute Physiology and Chronic Health Evaluation IV were related to sensor accuracy.[14] In our study, although the lowest rectal temperature during CPB was more than 33°C in 80% of the cases and the intra- and postoperative courses were favorable, sensor accuracy was impaired. This impaired sensor accuracy tended to recover after CPB in some patients (Fig. 2C, Group A), but not in others (Fig. 2D, Group B). We could not find a difference in patient characteristics between groups by subgroup analysis as shown in Table 2; however, skin temperature of the sensor site, which we did not monitor in this study, might have been different. Since the SCGM system uses an enzyme-based glucose oxidase method, low peripheral temperature may affect sensor accuracy. Recovery of skin temperature from hypothermia after CPB varies in each patient. It might therefore be interesting to monitor this temperature in a future study. Of course, CPB itself has potential to change sensor accuracy because altered fluid balance may affect the interstitial glucose concentration.[31] Therefore, when using SCGM during cardiac surgery, it should be kept in mind that the accuracy of SCGM might decrease.

There are some limitations of this study. First, patients were limited to ASA-PS 1 or 2 patients, and there was only one diabetic patient in the neurosurgical patient group and none in the cardiac surgery patient group. This might be due to the study protocol in which we excluded patients receiving anticoagulant therapy who were in highly complicated states with diabetes mellitus. Although previous studies showed that diabetes was not significantly associated with poor sensor accuracy in critically ill and cardiac surgery patients,[14,32,33] there remains the possibility in our study that exacerbation of sensor performance in cardiac surgery patients was caused by high-glucose variability and that SCGM would not perform well in patients with diabetic status in perioperative periods of other surgeries. Accumulation of data for patients in various situations, such as patients with a poor preoperative condition and patients with poor postoperative recovery, is needed.

Another limitation is that most of the blood glucose levels were within the normal range and the accuracy of SCGM in hyperglycemia was not examined in neurosurgery patients. We were interested in SCGM accuracy during surgery of patients with complicated diabetic states; however, it was difficult to include them in this pilot study. In scheduled surgery, high-glucose variability rarely occurs, other than in cardiac surgery, because the surgery is scheduled after glycemic control has been improved. For this reason, patients with a complicated diabetic state were not included in this study, although we did not set inclusion–exclusion criteria about a diabetic state. In emergency surgery, high-glucose variability sometimes occurs in patients with uncontrolled diabetes or patients with severe diseases that induce high insulin resistance such as sepsis and trauma; however, the SCGM system of this generation cannot be used for emergency surgery because preparation time (12 h in this study) is required. However, the SCGM system has a strong potential to improve glycemic control in emergency patients, and development of a new SCGM system that can be quickly used without preparation time is needed.

The SCGM system has been developed for glycemic control in diabetic patients during their daily life and not for glycemic control in perioperative patients. If collection of data for SCGM in the perioperative period increases, a measurement algorithm for perioperative use may be developed. In addition, SCGM has the great advantage of being able to intuitively show the trend and peak of change in the glucose level.[34] Recently, the World Health Organization recommended the use of protocols for intensive perioperative blood glucose control in surgical patients to reduce the risk of surgical site infection due to intraoperative hyperglycemia.[35] If the accuracy of SCGM in the perioperative period increases, SCGM may facilitate interpretation of glucose management in the perioperative period and contribute to reduction in complications.

Conclusions

In this pilot study, we showed that the SCGM system could be used in the operating room and that the accuracy of SCGM in neurosurgery patients without hyperglycemia was almost the same as that in healthy volunteers. We also showed that although the accuracy of the SCGM system was clinically acceptable during cardiac surgery, sensor accuracy was affected by CPB and SCGM tended to show a lower glucose level. From these findings, we conclude that although SCGM can be used in the perioperative period and has potential to improve glycemic control, further studies on SCGM in various perioperative conditions, including low skin temperature and surgery with insulin resistance, are necessary.

Author Disclosure Statement

No competing financial interests exist.

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