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ORIGINAL RESEARCH

Head-to-head comparison of two continuous glucose monitoring systems on a cardio-surgical ICU

M. A. Punke[1] · C. Decker[3] · M. Petzoldt[1] · D. A. Reuter[1] · K. H. Wodack[1] · H. Reichenspurner[2] · M. Kubik[3] · S. Kluge[3]

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Abstract

In critical illness hypo-and hyperglycemia have a negative influence on patient outcome. Continuous glucose monitoring (CGM) could help in early detection of hypo-and hyperglycemia. A requirement for these new methods is an acceptable accuracy and precision in clinical practice. In this pilot study we prospectively evaluated the accuracy and precision of two CGM sensors (subcutaneous sensor: Sentrino®, Medtronic and intravasal sensor: Glucoclear®, Edwards) in 20 patients on a cardio-surgical ICU in a head to head comparison. CGM data were recorded for up to 48 h and values were compared with blood-gas-analysis (BGA) values, analysed with Bland–Altman-plots and color-coded surveillance error-grids. Shown are means ± standard deviations. In total 270/255 intravasal/subcutaneous pairs with BGA-values were analysed. The average runtime of the sensors was 28.4 ± 6.4 h. Correlation with BGA values yielded a correlation coefficient of 0.76 (subcutaneous sensor) and 0.92 (intravasal sensor). The Bland Altman Plots revealed an accuracy of 2.5 mg/dl, and a precision of + 43.0 mg/dl to − 38.0 mg/dl (subcutaneous sensor) and an accuracy of − 6.0 mg/dl, and a precision of + 12.4 mg/dl to − 24.4 mg/dl (intravasal sensor). No severe hypoglycemic event, defined as BG level below 40 mg/dl, occurred during treatment. Both sensors showed good accuracy in comparison to the BGA values, however they differ regarding precision, which in case of the subcutaneous sensor is considerable high.

Keywords Continuous glucose monitoring · Sensors · Blood glucose · Cardio-surgical patients

1 Introduction

Hypoglycemia and hyperglycemia as well as blood glucose (BG) variability have negative influence on the outcome of critically ill patients [1–4]. Furthermore, optimal glucose adjustment is often difficult to achieve for the caregiving team in critical care patients [5, 6]. The main disadvantages are multiple blood samples, which may lead to increased nurse workload and also to discomfort for the patient. Therefore continuous monitoring of BG with the ability to immediately identify changes may lead to enhanced glycemic control and should improve the management of dysglycemia.

The issue of glucose monitoring becomes more complex as there are different type of sensors available with different methods of glucose measuring, regarding compartment and technique. Measuring techniques for CGM are based on glucose oxidase, mid infrared spectroscopy or fluorescence [7–12]. The monitoring sites include whole blood, plasma, interstitial and microdialysis fluid [7–13].

In this study we tested two different sensors in a head to head comparison in the same patient. We compared a sensor for subcutaneous (Sentrino®, Medtronic) and a sensor for intravasal application (Glucoclear®, Edwards) both with a glucose oxidase based technique. The subcutaneous sensor was placed in the subcutaneous fat tissue of the upper thigh, where it measures the glucose levels in the interstitial tissue. The intravasal sensor was placed via a catheter in a peripheral vein, where it measures the glucose levels in the venous blood stream. We compared the BG values obtained

✉ M. A. Punke
punke@uke.de

[1] Department of Anesthesiology, Center of Anesthesiology and Intensive Care Medicine, Hamburg-Eppendorf University Medical Center, Martinistraße 52, 20246 Hamburg, Germany

[2] Department of Cardiovascular Surgery, University Heart Center, Hamburg-Eppendorf University Medical Center, Hamburg, Germany

[3] Department of Intensive Care Medicine, Center of Anesthesiology and Intensive Care Medicine, Hamburg-Eppendorf University Medical Center, Hamburg, Germany

by the different systems against arterial BG values obtained by blood gas analysis, a measurement with recognized high accuracy [14] in critically ill patients in a cardio-surgical ICU.

2 Methods

2.1 Study design

We conducted a single center, prospective study to validate the accuracy and precision of an intravasal and a subcutaneous sensor for continuous glucose monitoring. The study was designed as a method comparison study. The basic assumption (null hypothesis) was that the new continuous measurement methods (GlucoClear® CGM, Edwards Lifesciences, Sentrino® CGM, Medtronic) are able to validate the blood glucose in comparison to the gold standard (Glucose measurement via BGA). Preliminary studies indicated that a systematic measurement error of 10 mg/dl is relevant with a standard deviation of 20 mg/dl. To dispel the null hypothesis, we performed a power analysis, with a beta error of 0.8 and an alpha error of 0.05, that yielded 100 measurement points. Sensor accuracy was measured as the mean absolute relative differnce (MARD) and anaylzed with Bland–Altman plots [15].

The study was approved by the ethics committee of the Medical Board of the city of Hamburg, Germany (Ref. Nr. PV4613) and written informed consent was obtained from all participants. All 20 patients were undergoing major cardiac surgery e.g. coronary artery bypass grafting (CABG) and/or valve replacement reconstruction or ascending aortic replacement surgery.

2.2 Study group

20 patients scheduled for elective cardiac surgery were enrolled in the study between 16th of April 2014 and 8th of august 2014. All enrolled patients successfully completed the study. Patients were excluded from the study, if they were under 18 years of age, or if patients had a premedical history of steroid therapy.

2.3 BG monitoring

The Sentrino® sCGM System (Medtronic) combines a monitor with a minimally invasive, subcutaneous sensor, which is inserted subcutaneously with a needle sensor into the upper thigh. The sensor has a novel drug interference rejection technology that ensures minimal interference with a wide array of pharmaceuticals used in the critical care unit. The monitor continuously determines a value for BG values, and displays a sensor glucose value every minute as well as a graph over time with the option to set levels of alarms for hypo- and hyperglycemia.

The GlucoClear® iCGM System (Edwards) combines a monitor with an intravasal sensor, which is placed via a catheter in a peripheral vein and then connected with a flush infusion. Blood is intermittently allowed to cover the sensor to measure BG and then cleared with flush solution of a known glucose concentration to calibrate the system. A new glucose value is obtained every 5 min by the system. Both systems work with the glucose oxidation technique.

Following the recommendations of the both manufacturers, sensors were only used for 72 h. All nurses were familiar with the two sensors after instruction provided by the manufacturers.

BG values between 100 and 180 mg/dl were regarded as normal. A glucose value below 70 mg/dl was defined as a hypoglycemic event, and a value below 40 mg/dl was a severe hypoglycemic event. Measurements of BG with blood gas analysis were performed during the ICU stay every hour within the first 6 h after placement, and then every 2 h. All BG measurements via blood gas analysis were performed with a cassette-based blood gas analyser (Radiometer Copenhagen ABL 90 FLEX, Radiometer Copenhagen, Denmark). The blood samples were collected in heparinized blood gas syringes (PICO50, Radiometer Copenhagen, Denmark), and measured at 37 °C. The blood gas analyser was regularly maintained and equilibrated according to national laws (Guidelines of the German Federal Board of Medicine) and to the recommendations of the manufacturer.

2.4 Statistical analysis

Statistical analyses were performed by using linear correlations, Bland–Altman-plots, color-coded-surveillance-error-grids, MARD and glucose variability. Glucose variability was calculated as the mean of the standard deviations of the different glucose measurements in each patient. Accuracy in the Bland Altman Plot was considered acceptable when the maximum bias was ± 10 mg/dl. Precision in the Bland Altman Plot was considered acceptable when the upper and lower limits were in the range ± 20 mg/dl. All statistical comparisons were calculated with IBM SPSS (Version 20, IBM Deutschland GmbH, Ehningen, Germany) and Microsoft Excel (Version 14.7.1 for Macintosh, Microsoft Cooperation, Redmond, USA). Color-Coded Surveillance Error-Grids were performed with an excel macro [16]. Data was visualized graphically for normality distribution. Shown are mean ± standard deviation, n = number of patients.

Table 1 Patient characteristics

Age (years)	65.1 ± 13.7
Gender (male/female)	13/7
BMI (kg/m^2)	26.0 ± 4.2
Operative procedure	10—CABG (4 of 10 + valve replacement) 7—valve replacement 3—ascending aortic repair
Diagnosis of diabetes (yes/no)	0/20
SAPS score	26.7 ± 6.4
Administration of vasopressors (yes/no)	10/10
Sensor running time (h)	28.4 ± 6.4

3 Results

20 patients (13 male and 7 female) were included in the study. 10 patients had coronary artery bypass grafting and four of them combined with valve replacement. 7 Patients had valve replacements and 3 had ascending aortic repair. The clinical characteristics of patients are shown in Table 1. All patients were on mechanical ventilation during the observation period on the ICU for 7.3 ± 5.0 h. 10 patients received catecholamine therapy for 3.3 ± 2.6 h and were mainly treated with norepinephrine. Three out of ten where simultaneously treated with norepinephrine and epinephrine. The average runtime of the sensors was 28.4 ± 6.4 h. No complications, such as bleeding or infection at the insertion site could be detected.

Accuracy expressed as the mean absolute relative difference yielded 12.3% in case of the subcutaneous sensor and 7.2% in case of the intravasal sensor. The Bland Altman Plots revealed an accuracy of 2.5 mg/dl, and a precision of + 43.0 mg/dl to − 38.0 mg/dl for the subcutaneous sensor and an accuracy of − 6.0 mg/dl, and a precision of + 12.4 mg/dl to − 24.4 mg/dl for the intravasal sensor (Figs. 1, 2). Correlation with BGA values yielded in case of the subcutaneous sensor the correlation coefficient of 0.76 and 0.92 in case of the intravasal sensor and an R^2 of 0.58 and 0.85, respectively (Figs. 3, 4).

In comparison of the mean blood glucose values ploted against the ascending number of samples, the line of the subcutaneous sensor lies above the lines of intravasal sensor and BGA, which show a good accordance (Fig. 5).

The surveillance error grid (SEG) is a tool for analysis and visualization of blood glucose errors. The SEG uses the current BGM standard accuracy ISO 15197:2013. In the color-coded surveillance grids 95.4% of the values of the intravasal sensor were in the area without risk, whereas in case of the subcutaneous 83.9% were in this area (Fig. 6). In case of the intravasal sensor 4.6% of the BG pairs were in

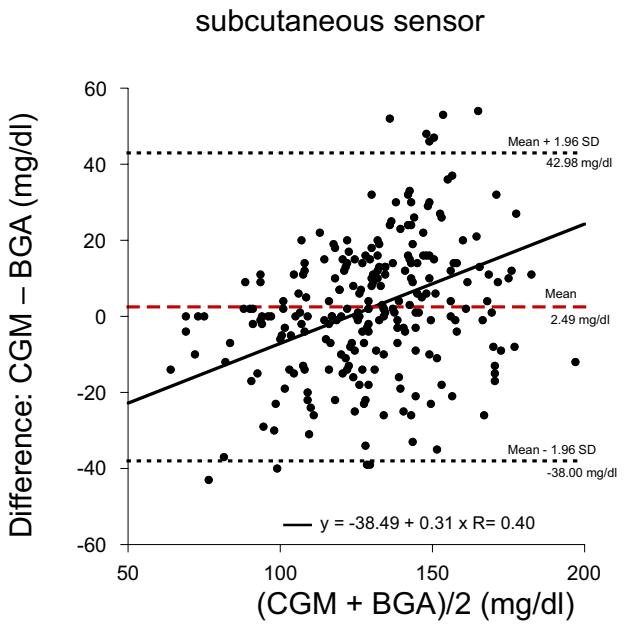


Fig. 1 Shows the Bland Altman plot of the subcutaneous sensor. The mean of the CGM-BG pairs is plotted on the x-axis and the difference between CGM and BG measurements is plotted on the y-axis. The dashed line represent the difference from the mean and the upper and lower dotted lines represent the upper and lower limit of agreement with the mean difference plus or minus 1.96 times the SD of the difference. It revealed a difference of the mean of 2.49 mg/dl, and an upper limit of agreement of + 42.98 mg/dl and a lower limit of agreement of − 38.00 mg/dl. To analyse trending effects we plotted a linear regression to the data, which yielded y = − 38.49 + 0.31 x; R = 0.40. N = 270 BG pairs of 20 patients

the slightly lower zone and none of the BG pairs were in the higher risk zones. The subcutaneous sensor had 13.3% of the BG pairs in the slight lower zone, 2.0% in the slight higher risk zone and 0.8 in the moderate risk zone.

The mean glucose levels were 128.0 ± 23.2 mg/dl, 131.8 ± 31.2 mg/dl and 128.4 ± 24.4 mg/dl for intravasal sensor, subcutaneous sensor and BGA respectively. Glucose variability per patient differed between the sensors and was 18.1 ± 7.3 mg/dl, 24.5 ± 10.3 mg/dl and 19.7 ± 7.7 mg/dl for intravasal sensor, subcutaneous sensor and BGA respectively. No severe hypoglycemic event, defined as BG level below 40 mg/dl, occurred during the study period. However, moderate hypoglycemic events defined as BG values below 70 mg/dl occurred in the arterial BGA measurements once, twice in the intravasal sensor measurements and eight times in the subcutaneous sensor measurements.

Severe hyperglycemic events defined as BG level above 180 mg/dl occurred arterial BGA measurements nine times, four times in the intravasal sensor measurements and 13 times in the subcutaneous sensor measurements (for details see Table 2). Overall 83.1% of the measurements were in the target range (100–180 mg/dl). We had 12.3% and 7.5%

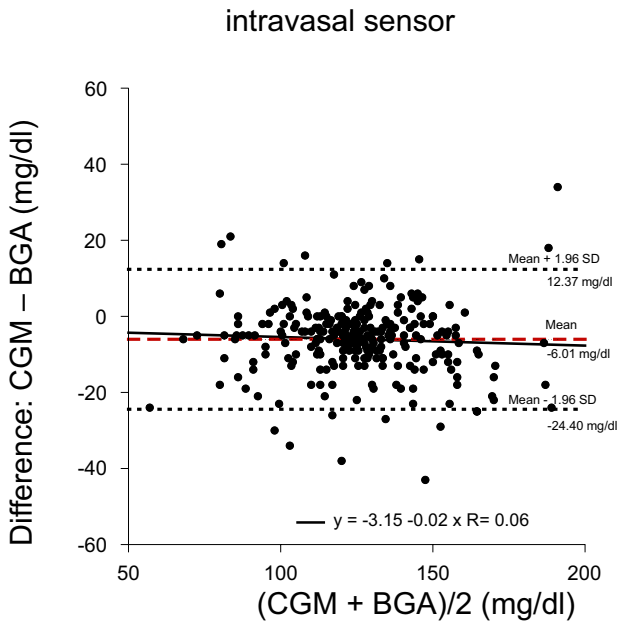


Fig. 2 Shows the Bland Altman plot of the intravasal sensor. The mean of the CGM-BG pairs is plotted on the x-axis and the difference between CGM and BG measurements is plotted on the y-axis. The dashed line represent the difference from the mean and the upper and lower dotted lines represent the upper and lower limit of agreement with the mean difference plus or minus 1.96 times the SD of the difference. It revealed a difference of the mean of -6.01 mg/dl, and an upper limit of agreement of + 12.37 mg/dl and a lower limit of agreement of − 24.40 mg/dl. To analyse trending effects we plotted a linear regression to the data, which yielded y = − 3.15 − 0.02 x; R = 0.06. N = 255 BG pairs of 20 patients

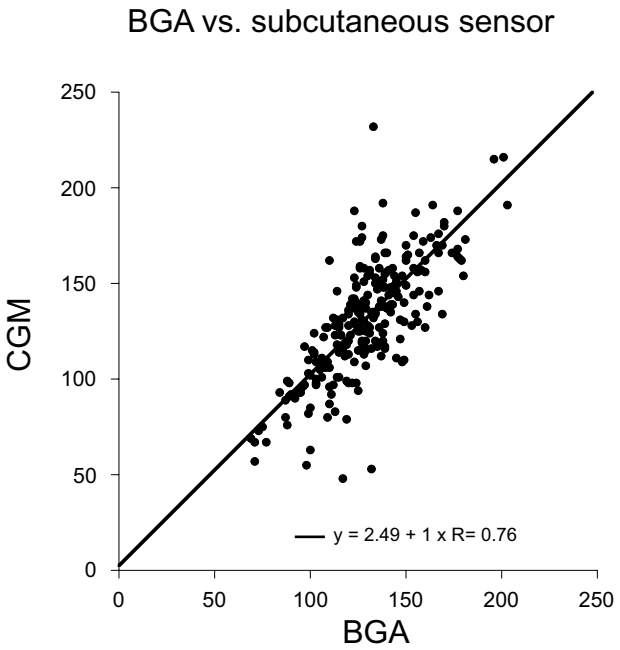


Fig. 3 Shows the linear regression of the subcutaneous sensor. BGA measurements are plotted on the x-axis and subcutaneous CGM values are plotted on the y-axis. The linear regression yielded: y = 2.49 + 1 x, with the correlation to BGA values of 0.76. N = 255 BG pairs of 20 patients

missing values in case of the subcutaneous and intravasal sensor, respectively.

4 Discussion

To have a better understanding of the clinical relevance of the different glucose monitor systems a round table meeting was arranged in 2014. The meeting recommended head to head comparison of the different sensor types to test for accuracy, reliability and feasibility in relevant patient populations [14]. Hence, we performed a head to head comparison. When compared with the clinical gold standard of blood analysis, both CGM sensors showed an acceptable accuracy with a slight overestimation of the mean BG level in case of the subcutaneous sensor, or rather underestimation in case of the intravasal sensor. However, in case of the subcutaneous sensor the precision was slightly over the clinically acceptable limits recently suggested by Critchley for comparison of monitoring techniques [17]. In case of the subcutaneous sensor linear regression showed an ascending trend with an underestimation of low blood glucose values and an

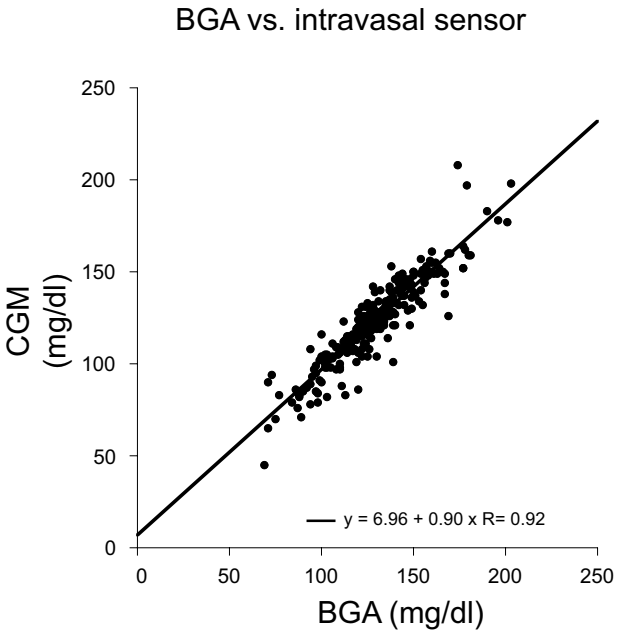


Fig. 4 Shows the linear regression of the intravasal sensor. BGA measurements are plotted on the x-axis and subcutaneous CGM values are plotted on the y-axis. The linear regression yielded: y = 6.96 + 0.90 x, with the correlation to BGA values of 0.92. N = 255 BG pairs of 20 patients

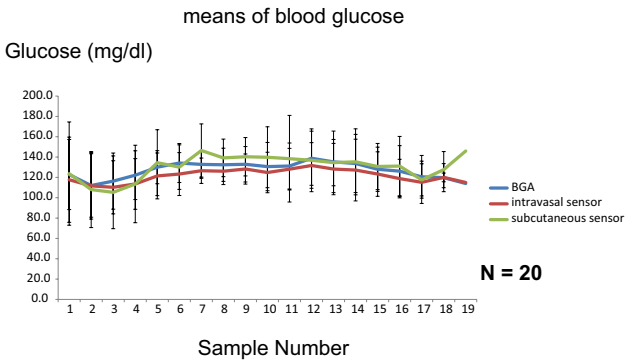
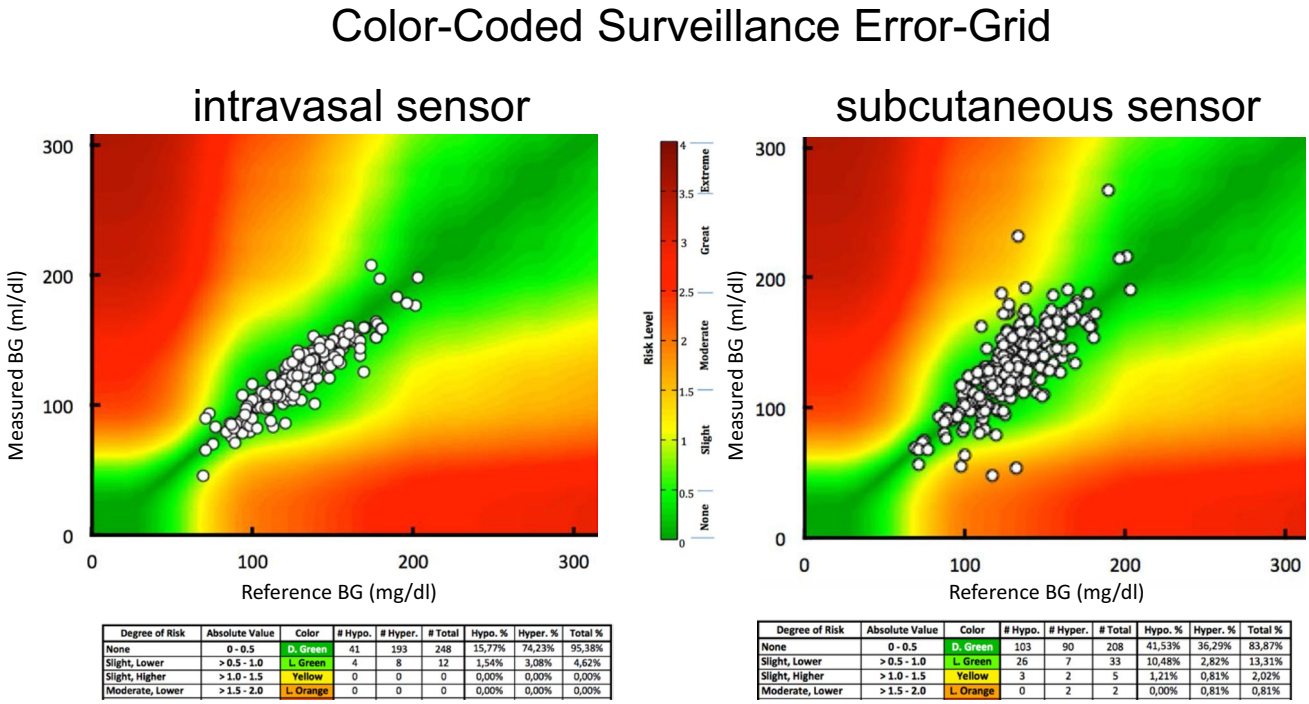


Fig. 5 Shown are the means of blood glucose of all 20 patients measured by BGA and the comparative CGM readings of the intravasal and the subcutaneous sensor as well as the corresponding SD values. Plotted on the x- axis are the ascending numbers of samples and the blood glucose values are plotted on the y-axis. Sampling interval for BGA was 1–2 h

overestimation of high blood glucose values, whereas linear regression of the intravasal sensor did not show any trend.

To date, there are two studies published, which compare an intravasal and a subcutaneous sensors for accuracy [18, 19]. The study of Sechtersberger et al. was an observational study with 8 post-cardiac surgery patients and they were comparing an intraarterial sensor with a subcutaneous sensor. Both sensors had a comparable accuracy. The study of Munekage et al. was a direct comparison (without gold standard) of an intravasal and a subcutaneous sensor in 15 patients undergoing general surgery. Here we present in 20 patients a head to head comparison for accuracy and reliability of two glucose sensors sampling in different compartments (whole venous blood and interstitial fluid) in critically ill patients in comparison to conventional BG determination by a blood gas analyser as gold standard.

Different products using CGM with intravasal and subcutaneous sensor-techniques have been extensively studied in ICU patients, in particular the technical requirements for the sensors due to critical status of the patient and the complex environment are challenging. Two studies in ICU patients with the subcutaneous sensor device tested in our study (Sentrino® CGM, Medtronic) were recently published [20, 21]. In comparison of those two patient populations, to our study the severity of illness assessed by SAPS and the complexity of treatment regarding mechanical ventilation and catecholamine therapy were similar [20, 21]. A pilot study, which investigated the efficacy of perioperative CGM via peripheral intravenous sampling found



Degree of Risk	Absolute Value	Color	# Hypo.	# Hyper.	# Total	Hypo. %	Hyper. %	Total %
None	0 - 0.5	D. Green	41	193	248	15,77%	74,23%	95,38%
Slight, Lower	> 0.5 - 1.0	L. Green	4	8	12	1,54%	3,08%	4,62%
Slight, Higher	> 1.0 - 1.5	Yellow	0	0	0	0,00%	0,00%	0,00%
Moderate, Lower	> 1.5 - 2.0	L. Orange	0	0	0	0,00%	0,00%	0,00%

Degree of Risk	Absolute Value	Color	# Hypo.	# Hyper.	# Total	Hypo. %	Hyper. %	Total %
None	0 - 0.5	D. Green	103	90	208	41,53%	36,29%	83,87%
Slight, Lower	> 0.5 - 1.0	L. Green	26	7	33	10,48%	2,82%	13,31%
Slight, Higher	> 1.0 - 1.5	Yellow	3	2	5	1,21%	0,81%	2,02%
Moderate, Lower	> 1.5 - 2.0	L. Orange	0	2	2	0,00%	0,81%	0,81%

Fig. 6 Shown are the color-coded surveillance error-grids of the measured BG versus the reference BG of the intravasal and subcutaneous sensor, respectively. The surveillance error grid (SEG) is a tool for analysis and visualization of blood glucose errors. In the color-coded surveillance grids 95.4% of the values of the intravasal sensor were in the area without risk, whereas in case of the subcutaneous 83.9% were in this area. In case of the intravasal sensor 4.6% of the BG pairs were in the slightly lower zone and none of the BG pairs were in the higher risk zones. The subcutaneous sensor had 13.3% of the BG pairs in the slight lower zone, 2.0% in the slight higher risk zone and 0.8 in the moderate risk zone

Table 2 Mean glucose level, glycemic variability and glycemic events

Number of glucose pairs	Intravasal sensor: 270 Subcutaneous sensor: 255 (BGA measurements: 292)
Mean glucose level ± SD	Intravasal sensor: 123.0 ± 23.2 Subcutaneous sensor: 131.8 ± 31,2 BGA: 128.4 ± 24.4
Glucose variability per patient (measured in SD mg/dl)	Intravasal sensor: 18.1 ± 7.3 Subcutaneous sensor: 24.5 ± 10,3 BGA: 19.7 ± 7.7
Glycemic events severe hypoglycaemia (≤ 40 mg/dl)	None
Glycemic events moderate hypoglycaemia (41–70 mg/dl)	Intravasal sensor: 2 Subcutaneous sensor: 8 BGA: 1
Glycemic events euglycemia (71–149 mg/dl)	Intravasal sensor: 232 Subcutaneous sensor: 176 BGA: 240
Glycemic events moderate hyperglacemia (150–180 mg/dl)	Intravasal sensor: 26 Subcutaneous sensor: 55 BGA: 38
Glycemic events severe hyperglycemia (> 180 mg/dl)	Intravasal sensor: 4 Subcutaneous sensor: 13 BGA: 9
Glucose minimum (mg/dl)	Intravasal sensor: 45 Subcutaneous sensor: 48 BGA: 69
Glucose maximum (mg/dl)	Intravasal sensor: 208 Subcutaneous sensor: 267 BGA: 214
Insulin treatment (yes/no)	5/20

MARD values that were similar to our MARD values of the intravasal sensor [22]. Regarding the reliability and robustness of this measurement technology it is stimulating that our results are comparable with those three afore mentioned studies.

The discussion about the best BG target range for the treatment of critically ill patients and the increasing evidence that hypo-, hyperglycaemia and finally glucose variability can negatively influence the outcome in these patients [1–4], were the cause that led to a broader recognition of the importance of glycemic control on the ICU. Also clear treatment recommendations have been implemented (Surviving Sepsis Campaign), therefore implicating the demand for optimal glucose monitoring on the ICU. And by nature, continuous monitoring of a clinical variable allows its closer regulation. Therefore, the ability to continuously measure BG by CGM can potentially help to intervene preemptively in glycemic dysregulation and thus to reduce dangerous hypo- and hyperglycemic events, both caused by the underlying disease and therapeutic interventions. So far, it is not routine practice, because studies with hard endpoints are missing. There are different sensor techniques, which are used at different monitor sites in different body compartments. Although termed continuous, current devices still sample intermittently with measurement intervals of seconds up to minutes.

In all 20 patients, placement of the needle sensor in the subcutaneous tissue of the upper thigh was successful and uneventful and did not lead to any complications, such as hemorrhage or infection. Due to volume status after cardio-surgical operation the placement of the needle to access the blood for the intravasal CGM system was sometimes difficult. A puncture of an adequate vein prior to the operation would be the better alternative. It is also obvious that the level of experience of the care giving team with such a new device will contribute to the run time of those sensors.

In conclusion both sensors showed an acceptable accuracy. In case of the subcutaneous sensor precision was slightly above the clinically acceptable limits. To date CGM systems are interesting devices for trend guidance, however for the interpretation of extreme values of hypo- and hyperglycemia the gold standard should be taken into account.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest, except MP, who is a member of the Medical Advisory Board of Radiometer Medical, Copenhagen, Denmark. No author or participant has any financial interest in the subject matter, materials or equipment discussed.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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