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Original article

Relative accuracy of arterial and capillary glucose meter measurements in critically ill patients

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Abstract

Aim. – As optimizing glucose control in critically ill patients remains a challenge for intensive-care physicians, this study aimed to determine the accuracy of glucose measurements.

Methods. – The accuracy of capillary and arterial blood glucose meter measurements was compared with central laboratory arterial glucose measurements; the factors associated with inaccurate measures were also determined.

Results. – Altogether, 302 samples from 75 patients were assessed. Mean glucose levels were 126 ± 52 mg/dL for capillary measurements, 133 ± 50 mg/dL for arterial measurements and 143 ± 54 mg/dL for serum glucose laboratory measurements. Compliance with the ISO 15197 guidelines was observed in 74.8% of the capillary samples and 88.7% of the arterial samples. However, all measurements by glucose meter (with either capillary or arterial samples) led to underestimations of serum glucose.

Conclusion. – In critically ill patients, glucose measurements from capillary and arterial blood by glucose meter are inaccurate, and can potentially lead to inappropriate use of insulin-infusion protocols and failure to achieve glycaemic targets.

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Keywords: Glycaemia; Insulin; Glucose meter analysis; Intensive care unit

Résumé

Précision de la valeur de glycémie mesurée chez les patients de réanimation.

Objectif. – Le contrôle de la glycémie est essentiel chez les patients de réanimation.

Méthode. – Nous avons comparé la fiabilité de la mesure de glycémie capillaire et artérielle par lecteur glycémique (CONTOUR® TS) avec la mesure de la glycémie sérique, sur prélèvement artériel, du laboratoire de biochimie et déterminé les facteurs expliquant le manque de fiabilité des mesures.

Résultats. – Trois cent-deux échantillons furent prélevés chez 75 patients. La valeur moyenne de glycémie obtenue était respectivement de 126 ± 52 mg/dL, 133 ± 50 mg/dL et 143 ± 54 mg/dL pour les prélèvements capillaires, artériels et du laboratoire. Les prélèvements capillaires et artériels respectent la norme ISO 15197 dans 74,8 % et 88,7 % des cas respectivement. Les mesures par lecteur glycémique capillaire ou artériel conduisent à une sous-estimation de la glycémie sérique.

Conclusion. – Chez les patients de réanimation, la mesure de glycémie par lecteur glycémique sur échantillon capillaire ou artériel n'est pas fiable. Cela conduit à un mauvais usage de l'algorithme d'infusion d'insuline et à un échec dans l'obtention des valeurs de glycémie dans la cible désirée.

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Mots clés : Glycémie ; Insuline ; Lecteur glycémique ; Unité de réanimation

Abbreviations: ISO, International Organization for Standardization; CLSI, Clinical and Laboratory Standards Institute; ICU, Intensive Care Unit; BMI, Body Mass Index; SAPS II, Simplified Acute Physiology Score II; GDH, Glucose Dehydrogenase; FAD, Flavin–Adenine Dinucleotide; SD, Standard Deviation; ICC, Intraclass Correlation Coefficient; CI, Confidence Interval; SOFA, Sequential Organ Failure Assessment; IQR, Interquartile Range.

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1. Introduction

Optimizing glucose control in critically ill patients remains a challenge for intensive-care physicians. Hyperglycaemia can be found in various settings, such as myocardial infarction [1], stroke [2] and sepsis [3]. In the ICU, hyperglycaemia is associated with increased mortality [4–6] as is also wide variability in blood glucose concentrations [7,8]. Also, how to control glucose is still a matter of debate, as is whether to aim for a tight or conventional target [9,10]. Intensive insulin therapy increases the risk of hypoglycaemia [11,12], especially in diabetic patients. Although the impact of hypoglycaemia on patients' outcomes is still not clearly understood [13], it has been associated with higher mortality rates [14,15]. In fact, the optimal target is difficult to define, as it depends on multiple factors such as the accuracy of glucose measurements. Glucose-monitoring techniques differ across studies and may significantly affect results [16].

The accuracy of glucose measurement by glucose meter analysis (using capillary and/or arterial samples) has already been tested in ICU patients, and a high level of accuracy has rarely been found [17–20]. Studies have shown overestimation of glycaemia by fingerstick analysis and, because of the risk of such poor accuracy, fingerstick blood glucose measurement using capillary blood is not recommended in the ICU [21]. Arterial blood samples appear to be more accurate for measuring glucose blood levels [17,22], but there is a lack of data comparing in ICU patients, simultaneous measurements of glucose from capillary and arterial blood with laboratory blood glucose measurements, considered to be the reference value.

Thus, the purpose of the present study was to determine the accuracy of bedside glucose measurements by comparing a fingerstick capillary blood glucose meter and an arterial blood glucose meter (CONTOUR[®] TS, Bayer HealthCare, Tarrytown, NY, USA) with laboratory arterial blood glucose measurements as defined by the ISO guidelines of the CLSI [23], and to determine the factors associated with inaccuracy.

2. Patients and methods

2.1. Study participants

The present study was approved by our local institutional ethics committee, and an information handout was given to each family to obtain their consent to participate. In our institution's 16-bed mixed ICU, 75 consecutive patients were enrolled in the study from November 2009 to May 2010. Patients were included on admission if the duration of their ICU stay was considered likely to be more than or equal to 3 days and if placement of an arterial catheter was required. Contraindication criteria were: age under 18 years; no arterial line; anticipated length of stay less than 72 hours; diabetic ketoacidosis; and severe hepatic failure. Patients were enrolled on admission for a maximum of 3 days. A nurse-driven insulin algorithm was used to control glucose levels (Supplementary data, Table S1). Glucose measurements were taken every 2 hours by fingerstick,

with additional tests performed when necessary. The glycaemic target was 80–180 mg/dL. Insulin was initiated when glycaemia increased to more than 180 mg/dL and interrupted when glycaemia was less than 120 mg/dL. Glycaemia less than 80 mg/dL was corrected by glucose infusion.

2.2. Glucose measurement

Three simultaneous blood glucose measurements were performed as described in the study by Kanji et al. [17], comprising glucose meter analysis of capillary blood (fingerstick), glucose meter analysis of arterial blood and central laboratory blood glucose measurement (from an arterial sample). Capillary blood samples were obtained from the patient's fingerstick sample by instillation of a drop of blood onto a test strip for glucose detection and analyzed by a glucose meter (CONTOUR[®] TS, Bayer HealthCare). Arterial blood glucose measurements were obtained from the patient's arterial catheter: 3 mL of waste blood was first discarded, then a drop of blood was analyzed by the same glucose meter and 5 mL of blood sent to the central laboratory for biochemical analysis (glucose oxidase method) after centrifugation (Olympus AU 2007/Beckman Coulter, Brea, CA, USA). Arterial samples were sent as an emergency to the laboratory, as is the standard procedure in our ICU, and were immediately analyzed. The intra- and interassay coefficients of variation for the test are less than 5%. Every day, a maximum of three sets of samples were obtained and analyzed (more if a hypoglycaemic event occurred).

2.3. Data collection

Age, gender, BMI, SAPS II and SOFA score at admission, history of diabetes, corticosteroid used and admitting diagnosis were recorded. Norepinephrine, epinephrine or dobutamine levels, insulin perfusion rates, arterial pH, PaO₂, PaCO₂ and lactate range were also recorded. In addition, the route and amount of nutritional support, and the need for insulin-infusion were noted during the first 72 hours.

2.4. Statistical analysis

Statistical analyses were performed using Stata statistical software (release 11.0). Patients' characteristics on admission to the ICU were reported using descriptive statistics (median and IQR for quantitative data, and frequency tabulations for qualitative data). Capillary and arterial blood glucose meter measurements and central laboratory blood glucose values were expressed as means \pm SD.

Accuracy was first assessed using the ICC, then according to the ISO 15197 guidelines [23] and the modified error-grid analysis proposed by Kanji et al. [17]. Also, as a series of glucose pairs from a single patient might not be considered independent, the same analyses were also conducted in a sub sample comprising only the first paired measurements for each patient.

The sensitivity and specificity of the capillary and arterial measurements to detect hypoglycaemia (less than 80 mg/dL) and hyperglycaemia (more than 180 mg/dL) were also

calculated with their 95% CI. Comparisons of the characteristics of accurate and inaccurate measurements (as defined by the ISO 15197 guidelines) were based on the χ^2 test (or bilateral Fisher's exact test when necessary) for qualitative variables and on Mann–Whitney's test for quantitative data.

3. Results

In the 75 critically ill patients, 304 glucose measurements were performed, of which 302 (99%) were analyzed (two sets were incomplete). The median number of glucose measurements per patient was four. The demographic characteristics of the patients are presented in Table 1. All patients were mechanically ventilated. Four (5.3%) patients had diabetes and five (6.7%) were receiving corticosteroids.

Glucose measurements are shown in Table 2. The mean absolute difference between laboratory and capillary values was 16 ± 22 mg/dL, with an ICC of 0.91 (95% CI: 0.89–0.93). The mean absolute difference between laboratory and arterial values was 10 ± 21 mg/dL, with an ICC of 0.92 (95% CI: 0.90–0.93). In the sub sample comprising only the first paired measurements from each patient, the results were similar; suggesting that data clustering within patients had no effect on our interpretation of the results.

Using the ISO criteria, 76 (25.2%) of the capillary and 34 (11.3%) of the arterial values were inaccurate. Modified error-grid analyses as proposed by Kanji et al. [17] are graphically shown in Supplementary data, Figs. S1 and S2 and detailed in Table 3.

Inaccurate samples were found over the entire range of blood glucose values, with a higher level of inaccuracy among the lowest values of glycaemia. Glucose values were often underestimated by glucose meter analysis (whether by capillary or arterial method) compared with laboratory testing. The sensitivity of both capillary and arterial sampling to detect hypo- or hyperglycaemic events was poor (Supplementary data, Table S2).

Table 1
Patients' characteristics on admission to the intensive care unit (ICU).

Number of patients (n)	75
Male, n (%)	43 (57)
Age (years), median (IQR)	59 (46–69)
BMI (kg/m ²), median (IQR)	25 (22–28)
SAPS II, median (IQR)	56 (43–69)
SOFA, median (IQR)	8 (6–11)
Diagnosis at admission	
Respiratory failure, n (%)	22 (29)
Sepsis, n (%)	21 (28)
Trauma, n (%)	14 (19)
Other, n (%)	18 (24)
Diabetes mellitus, n (%)	4 (5.3)
Steroid use, n (%)	5 (6.7)
Parenteral nutrition, n (%)	32 (43)
Enteral feeding, n (%)	40 (53)
Insulin, n (%)	17 (23)

IQR: interquartile range; BMI: body mass index; SAPS II: Simplified Acute Physiology Score II; SOFA: Sequential Organ Failure Assessment.

Comparison of accurate and inaccurate measurements was performed to analyze those factors contributing to inaccuracy (Tables 4 and 5). However, the only statistically significant factor linked with inaccuracy in both types of measurements was the absence of insulin-infusion. Norepinephrine was a predictive factor for inaccuracy for arterial samples, but not for capillary samples. Gender, BMI, SAPS II, pH less than 7.35 and lactate level more than 2 mmol/L also had no influence on any differences between methods.

4. Discussion

Our present study has demonstrated that glucose measurements using capillary and arterial glucose meter analysis can be inaccurate in ICU patients. Biases with arterial laboratory values (glucose oxidase method) were, on average, 16 mg/dL and 10 mg/dL for capillary and arterial samples, respectively. Arterial samples were more accurate than capillary samples (11.3% vs. 25.2%, respectively, of values were outside the desired ISO range; $P < 0.001$). Nevertheless, both bedside methods failed to fulfill ISO criteria (95% of values were within the ISO desired range) [23]. Thus, capillary measurements should not be used in critically ill patients.

The mechanisms underlying the differences between these methods are still unknown. Inaccuracy may be related to the point-of-care device itself because of confounders interacting with enzymes on the test strips [20]. Some potential confounders have already been recognized, such as biological (haematocrit, extremes of oxygen tension, acidosis) and pharmacological (paracetamol or acetaminophen use) factors. However, the glucose meter used in our study is thought to be independent of all these factors. The (CONTOUR[®] TS, Bayer HealthCare) reader used in the present study is based on the chemistry of GDH and FAD, and does not interfere with maltose or galactose [24]. Moreover, GDH–FAD is not sensitive to oxygen and can be used with all types of blood (arterial, venous and capillary). The analyzer device is also not biased by haematocrit values, or the presence of endogenous (bilirubin, cholesterol, triglyceride) or exogenous (paracetamol, salicylic acid) substances. The CONTOUR[®] TS system corrects for haematocrit levels within a range of 0–70% [25]. Haematocrit compensation eliminates the effect of glucose underestimation at high haematocrit values [24]. Interestingly, however, inaccuracy in our present study was observed over the entire range of blood glucose values, even including low glucose values. In fact, the glucose meter produced the same type of error (the absolute difference between reference and glucose meter values was similar) across the entire range of blood glucose measurements, thereby strongly suggesting that the error is related to the method itself and not glucose levels.

In addition, no strong effect of the patient's condition on glucose measurement bias was observed. The need for vasopressor agents and the presence of upper-extremity oedema have both been recognized as potential sources of error in bedside blood glucose measurements [17,19]. In critically ill patients, peripheral hypoperfusion may explain the differences between arterial and capillary glucose concentrations. However, in our present study, vasopressor use was associated with inaccuracy

Table 2
Results of 302 glucose samples taken from 75 patients in the intensive care unit.

Glucose measurements (<i>n</i> = 302)	Capillary value (mg/dL)	Arterial value (mg/dL)	Laboratory value (mg/dL)	Difference between capillary and reference values (mg/dL) ^a	Difference between arterial and reference values (mg/dL) ^b
Mean ± SD	126 ± 52	133 ± 50	143 ± 54	16 ± 22	10 ± 21
Range	28–449	16–406	31–419		
ICC				0.91 (95% CI: 0.89–0.93)	0.92 (95% CI: 0.90–0.94)

ICC: intraclass correlation coefficient.

^a laboratory minus capillary values.

^b laboratory minus arterial values.

Table 3
Comparison of laboratory, capillary and arterial values from 302 glucose samples using modified error-grid analysis.

Predefined zones of analysis	Number of measurements	Comparison with laboratory value	Capillary value (<i>n</i> [%])	Arterial value (<i>n</i> [%])
Hypoglycaemia (< 80 mg/dL)	25	Target zone	17 (68)	20 (80)
		Overestimation	3 (12)	1 (4)
		Underestimation	5 (20)	4 (16)
Tolerable glycaemia (80–120 mg/dL)	79	Target zone	53 (67)	67 (85)
		Overestimation	5 (6)	4 (5)
		Underestimation	21 (27)	8 (10)
Normoglycaemia (120–180 mg/dL)	149	Target zone	117 (79)	135 (91)
		Overestimation	0 (0)	2 (1)
		Underestimation	32 (22)	12 (8)
Hyperglycaemia (> 180 mg/dL)	49	Target zone	40 (82)	45 (92)
		Overestimation	0 (0)	0 (0)
		Underestimation	9 (18)	4 (8)
Total	302	Target zone	227 (75)	267 (88)
		Outside of target zone	75 (25)	354 (121.3)
		Overestimation	8 (3)	7 (2)
		Underestimation	67 (22)	28 (10)

As proposed by Kanji et al. [17].

compared with the reference method only for arterial, but not for capillary, samples; also, neither a pH less than 7.35 nor lactate level more than 2 mmol/L had any influence. Insulin-infusion to correct raised glucose values was associated with better measurement accuracy, which is in line with the smaller discrepancy observed for glycaemic values more than 120 mg/dL.

Inaccurate glucose measurements lead to the inappropriate use of insulin-infusion protocols. In the present study, even when the selected glycaemic target was high, 24% of laboratory

values were outside the target. Hypoglycaemia was a rare event (8% of measurements were less than 80 mg/dL), whereas hyperglycaemia may not have been corrected enough (16% of measurements were more than 180 mg/dL). There was also an unacceptable risk of failure to detect and treat hyperglycaemia particularly with the use of fingersticks, and the sampling method may also explain the observed differences: glycaemia is known to be lower in whole blood compared with serum [26,27]. For this reason, manufacturers have already added a correction

Table 4
Clinical and pharmacological characteristics of patients with accurate and inaccurate capillary sample values according to International Organization for Standardization (ISO) criteria.

	Accurate (<i>n</i> = 226)	Inaccurate (<i>n</i> = 76)	<i>P</i> value
Male, <i>n</i> (%)	132 (58)	48 (63)	0.465
Age (years), median (IQR)	60 (47–69)	53 (39–63)	0.010
BMI (kg/m ²), median (IQR)	25 (22–28)	25 (22–28)	0.897
SAPS II, median (IQR)	57 (42–68)	58 (49–69)	0.095
Insulin, <i>n</i> (%)	33 (15)	2 (3)	0.005
pH < 7.35, <i>n</i> (%)	47 (21)	22 (29)	0.161
Lactate ≥ 2 mmol/L, <i>n</i> (%)	49 (22)	20 (26)	0.850
Norepinephrine, <i>n</i> (%)	131 (58)	39 (51)	0.312
Any vasoactive drugs (dobutamine, norepinephrine, epinephrine), <i>n</i> (%)	139 (62)	39 (51)	0.118

IQR: interquartile range; BMI: body mass index; SAPS II: Simplified Acute Physiology Score II.

Table 5
Clinical and pharmacological characteristics of patients with accurate and inaccurate arterial sample values according to International Organization for Standardization (ISO) criteria.

	Accurate (n = 268)	Inaccurate (n = 34)	P values
Male, n (%)	162 (60)	18 (53)	0.401
Age (years), median (IQR)	59 (45–66)	55 (46–64)	0.620
BMI (kg/m ²), median (IQR)	25 (22–28)	25 (22–27)	0.643
SAPS II, median (IQR)	57 (45–69)	52 (41–66)	0.090
Insulin, n (%)	35 (13)	0 (0)	0.021
pH < 7.35, n (%)	64 (24)	5 (15)	0.140
Lactate ≥ 2 mmol/L, n (%)	62 (23)	7 (21)	0.147
Norepinephrine, n (%)	145 (54)	25 (74)	0.031
Any vasoactive drug (dobutamine, norepinephrine, epinephrine), n (%)	151 (56)	27 (79)	0.010

IQR: interquartile range; BMI: body mass index; SAPS II: Simplified Acute Physiology Score II.

factor in their point-of-care devices. The present results incorporated a correction factor between total whole blood and biochemical analysis of serum, and the device did not require calibration.

Nevertheless, our study showed that glucose meter measurements often lead to underestimation of blood glucose. This fact is not consistently found in the literature, as glycaemia has been found to be both overestimated [17,19,20,28–30] and underestimated [31,32] by glucose meter analysis (using either capillary or arterial samples). Accuracy of the point-of-care device can also be evaluated by the ISO 15197 guidelines. In at least 95% of measurements, the difference between fingerstick and laboratory (reference method) values should be less than 15 mg/dL when the reference value is less than 75 mg/dL, and more than 20% when the reference value is more than or equal to 75 mg/dL.

Whatever the chosen target, an error of 20% is unacceptable. Glycaemic control requires an accurate method of measurement. In the Leuven study [5], measurements were taken from whole blood by an accurate glucose analyzer. According to our insulin-infusion protocol, the glycaemic target was between 80 and 180 mg/dL. However, if fingerstick values are used to measure blood glucose and have an error of 20%, then the corrected target should have been between 96 and 144 mg/dL to reduce the risk to falling outside the target. Meynaar et al. [32] found that, even after applying a correction factor (to convert whole blood results to probable serum blood levels), only 70% of samples showed a difference of less than 10% between arterial fingerstick and laboratory values.

Nevertheless, there is an alternative option that was not evaluated by our present study: the use of a blood gas/chemistry analyzer. This is a more expensive method with good accuracy [21]. Bedside analysis leads to the real-time application of the insulin protocol and eliminates the metabolization of glucose by blood cells during the transit time before analysis of the sample (unless blood is drawn into a fluoride tube). However, this may not always be a feasible approach, and it is also associated with an increase in staff workload, costs and iatrogenic blood loss.

Our present study has a few limitations. First, this was a single-centre study, and the results might have been different with the use of, for example, a different glucose meter analyzer. Indeed, the CONTOUR[®] TS system was made for patient

self-testing; it was not designed for critically ill patients. Several studies have shown that glucose meters are not accurate for ICU applications [17,19,20,28–32]. In addition, the influence of the haematocrit was not studied although, for most measurements, the haematocrit was within the normal range and the bias established by the manufacturer was low (0.014) [24]. Furthermore, our results included several severe hypoglycaemic values (1.6% were less than 60 mg/dL and 0.66% were less than 40 mg/dL), and accuracy cannot be specifically evaluated for this specific range. Finally, there was no economic evaluation comparing all of the various methods of measurement.

5. Conclusion

The present study found that bedside point-of-care tests for blood glucose measurements in critically ill patients using a glucose meter analyzer are not accurate. Although accuracy appears to be slightly better for arterial than capillary blood samples, both methods failed to comply with the ISO guidelines, leading to a potential misuse of insulin-infusion protocols and a failure to achieve glycaemic targets.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Appendix A. Supplementary data

Supplementary material (Tables S1 and S2, Figs. S1 and S2) associated with this article can be found at <http://www.sciencedirect.com>, at doi:10.1016/j.diabet.2011.12.003.

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