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ORIGINAL RESEARCH

Detection accuracy of three glucose meters estimated by capillary blood glucose measurements compared with venous blood evaluated by the diabetes unit of the Hospital Evangélico de Curitiba, Brazil

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Objective: To compare capillary blood glucose measurements between three different glucose meters and with the serum glucose values of inpatients at the diabetes unit of Hospital Universitário Evangélico de Curitiba, Brazil.

Materials and methods: A total of 132 non-intensive care unit patients admitted for medical and surgical pathologies were evaluated. All patients reported a previous diagnosis of diabetes mellitus, were under 60 years of age, had no hematocrit alterations, remained hemodynamically stable during the time of data collection, and were given no ascorbic acid, acetaminophen, dopamine, or mannitol during follow-up. Capillary and serum blood glucose samples were collected simultaneously by finger-stick and venipuncture 2 hours after lunch, by the same observer, who was blinded to the serum glucose results. First, between July and November 2009, capillary glucose levels were measured using the blood glucose meters OneTouch SureStep® and MediSense Optium®. Between November 2009 and February 2010, capillary blood glucose levels were measured on the glucose meters OneTouch SureStep and Optium Xceed®. The capillary glucose readings were analyzed between meters and also in relation to the serum blood glucose values by the *t*-test for paired samples and the Mood two-sample test.

Results: The patients' mean age was 50.45 years. The blood glucose means obtained using the meters OneTouch SureStep, MediSense Optium, and Optium Xceed were, respectively, 183.87 mg/dL, 178.49 mg/dL, and 192.73 mg/dL, and the mean for the serum glucose values was 174.58 mg/dL. A significant difference was found between the capillary measurements taken by the glucose meters and the serum glucose measurements ($P < 0.05$), and no significant interdevice difference was found. After stratification of the serum blood glucose values into two groups, below and above 180 mg/dL, the variance found for the glucose meter OneTouch SureStep was statistically greater ($P = 0.03$) in relation to the serum glucose levels above 180 mg/dL, which was not the case with the glucose meters MediSense Optium ($P = 0.06$) and Optium Xceed ($P = 0.12$). The percentage of capillary blood glucose values showing a variation of less than 20% compared with serum values was 64.94% for OneTouch SureStep, 47.83% for Medisense Optium, and 51.61% for Optium Xceed, when serum glucose was greater than 75 mg/dL.

Conclusion: The glucose meters tested showed an adequate interdevice correlation in their capillary glucose readings, in addition to correlating with the serum glucose values (ie, if a blood glucose reading is high or low in one test, it is likely to be respectively high or low in another). The means for the capillary blood glucose readings, however, were significantly different from the mean serum glucose. When serum glucose was above 180 mg/dL, there was a greater variance

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in the capillary measurements on the glucose meter OneTouch SureStep, with less correlation with the serum blood glucose ($P < 0.05$), which did not occur significantly with the two other glucose meters. On the other hand, OneTouch SureStep had the highest accuracy in relation to serum glucose when the whole sample of serum glucose values above 75 mg/dL was analyzed, considering a variation of less than 20% in the measurements. The three glucose meters provide readings that correlate with the serum glucose values of hospitalized patients. However, one should bear in mind that capillary measurements quite often show more than a 20% variation in relation to serum glucose values, and caution should be exercised in interpreting the readings when serum glucose levels are elevated.

Keywords: capillary blood glucose, serum glucose, glucose meters, hospitalized patients

Introduction

Self-monitoring of blood glucose through capillary blood glucose has already been recognized as an important tool in the control of blood glucose levels of patients with diabetes.[1,2] In type 1 diabetes, it is recommended that the monitoring be performed through at least four daily measurements of capillary blood glucose for correction of hyperglycemia or hypoglycemia. Type 2 diabetes patients should also be monitored through determinations of fasting and postprandial blood glucose.[1] Several studies have shown that tight glycemic control through capillary blood glucose testing correlates with a decline in glycated hemoglobin even in type 2 diabetes patients.[3,4] Since the publication of the DCCT (Diabetes Control Complication Trial), home glucose monitoring with capillary blood glucose measurements using glucose meters has reduced the incidence of the chronic complications of diabetes.[2,4,5] Studies have demonstrated that the accuracy of glucose meters relies as much on the person handling them as on the devices themselves.[6] In the hospital setting, laboratory blood glucose determinations are obtained from venous or arterial blood; however, capillary blood glucose measurements on glucose meters are more often used on account of their low cost and prompt results. Few studies have been published describing the reliability of blood glucose levels of hospitalized patients obtained with glucose meters. Variations of less than, or equal to, 20% as compared with serum blood glucose are recognized by the National Committee for Clinical Laboratory Standards as accuracy criteria.[7,8] The American Diabetes Association proposes a reference value with a deviation of up to 5%.[5,7] Studies assessing the accuracy of glucose meters have used the requirements of the International Organization for Standardization as standards; these recommend a deviation of less than 10% from laboratory reference values.[9]

Hospital capillary blood glucose is the analysis of whole blood drawn from the patient's fingertip and, according to some studies, yields results 5%–10% lower than those obtained with plasma glucose. Capillary measurements, when compared with laboratory determinations using venous or arterial blood, are controversial.[7,9,10]

The objective of the current study was to compare the capillary blood glucose values obtained by three different glucose meters and to determine the accuracy of those measurements relative to serum blood glucose values of inpatients at the Hospital Universitário Evangélico de Curitiba, Brazil.

Materials and methods

The study included 132 nonintensive care unit patients at the Hospital Universitário Evangélico de Curitiba who had been admitted for a variety of medical and surgical pathologies. All the patients had previously been diagnosed with diabetes mellitus, were under 60 years of age, and were hemodynamically stable during sample collection. Patients under 18 years of age or with gestational diabetes were excluded from the study.

Patient enrollment was conducted at the beginning of their hospital stay. Data were collected concerning the reason for admission, the presence of comorbidities, time since diagnosis of diabetes, and previous treatments. None of the patients was given ascorbic acid, acetaminophen, dopamine, levodopa, or mannitol during or before data collection over the length of their hospital stay. All the patients had hematocrit values within the normal range and presented with no hyperuricemia, severe dyslipidemia, or increased unconjugated bilirubin.[11] Patients with a hematocrit of more than 55% or less than 35% were excluded from the study. The same observer, who was blinded to the venous blood glucose values, conducted the capillary blood glucose measurements.

Serum blood glucose values were obtained through an enzymatic process that uses the enzymes hexokinase and glucose-6-phosphate dehydrogenase.

Glucose meters

Following contact with capillary blood, the test strip of the OneTouch SureStep® glucose meter (LifeScan Inc, Milpitas, CA) filters out the red blood cells and allows plasma to be in contact with the reagents. Glucose is oxidized by the enzyme glucose oxidase in the presence of atmospheric oxygen, thus producing hydrogen peroxide (H_2O_2). This compound reacts with a specific dye and produces a chromophore,

a light-absorbing dye. Subsequently, a light-emitting diode emits a specific light on the dye, and the reflected light is absorbed by a sensor that converts it into electronic signals. The intensity of the color generated at the end of the reaction is proportional to the glucose concentration in the sample.

The glucose meters Medisense Optium® (Abbott Diabetes Care, São Paulo, Brazil) and Optium Xceed® (MediSense UK, Abingdon, UK), on the other hand, use the enzyme glucose dehydrogenase, the coenzyme nicotinamide adenine dinucleotide, and the electrochemical mediator phenanthroline quinone. The emission of electrons at the end of the chemical reactions is measured and converted into electronic signals.

The capillary blood was collected in the amount recommended by the manufacturer using disposable 0.45 mm × 0.13 mm needles. The glucose meters and the test strips for capillary blood glucose were provided by the laboratories that were informed of the current study. The test strips were handled and stored in compliance with laboratory instructions.

The capillary and serum blood glucose samples were collected simultaneously from the fingertips ipsilateral to the arm from which the venous blood was collected, always 2 hours after the patients' lunch, and immediately taken to the laboratory in order to prevent glycolysis.[10]

Procedure

In the first phase, between July and November 2009, 81 patients were enrolled for analysis of their capillary blood glucose levels using the glucose meters OneTouch SureStep and Medisense Optium. The first 21 participants of the study had only capillary blood glucose levels tested. All except six patients had serum and capillary samples collected and analyzed at a later time, thus totaling 54 complete samples and another 21 samples used only for comparisons between the glucose meters.

In the second phase, between November 2009 and February 2010, 55 patients were enrolled for analysis of their capillary blood glucose levels on the glucose meters OneTouch SureStep and Optium Xceed. From those patients, 22 were excluded due to lack of data; consequently, the data of 33 patients were considered in the study.

The study sample comprised 132 patients. The measurements were compared between meters and with the serum blood glucose collected concurrently.

The study variables were mean age of the subjects, mean blood glucose values as determined by each glucose meter and mean serum blood glucose values, range of blood glucose across which the measurements on each glucose meter predominated, correlations between the glucose meters and with serum blood glucose values, and a comparison of the mean blood glucose levels found by each method. The patients were then allocated into two groups, the first one comprising the patients whose serum glucose values were lower than 180 mg/dL, and in the second those who had serum glucose levels higher than 180 mg/dL. The variance of the glucose meter readings in each group was analyzed and a comparison between the devices was conducted. The analysis also included the percentage of capillary blood glucose values with less than 20% variation compared with serum values, either upward or downward, when those values were greater than 75 mg/dL. The sample of serum blood glucose values below 75 mg/dL was small, which discouraged further analysis.

Statistical analysis

The correlations between the blood glucose values were calculated through Pearson's correlation coefficient, and the means for the blood glucose values measured on the three devices were compared using the paired-sample *t*-test. In order to validate the variance in the measurements between the glucose meters and the two groups of serum glucose, above and below 180 mg/dL, the Mood two-sample test was used.

Results

The mean age of the study patients was 50.45 years (±8.1 years). A total of 104 patients were tested for capillary blood glucose levels with the glucose meter OneTouch SureStep, with mean blood glucose of 183.87 mg/dL (±92.99 mg/dL); 71 patients with Medisense Optium, with mean blood glucose of 178.49 mg/dL (±82.51 mg/dL); and 33 patients with Optium Xceed, with mean blood glucose of 192.73 mg/dL (±76.47 mg/dL). For the comparative analysis, the serum blood glucose of 88 patients was determined, with mean blood glucose of 174.58 mg/dL (±89.20 mg/dL). The distribution of the measurements obtained on each glucose meter and from the serum dosing across different ranges of blood glucose is shown in Figure 1.

The correlation between the capillary blood glucose values obtained simultaneously on the glucose meters OneTouch SureStep and Medisense Optium was 95.31%, and between the blood glucose values determined by OneTouch SureStep and Optium Xceed was 91.31%. Regarding the serum glucose values, their correlation with

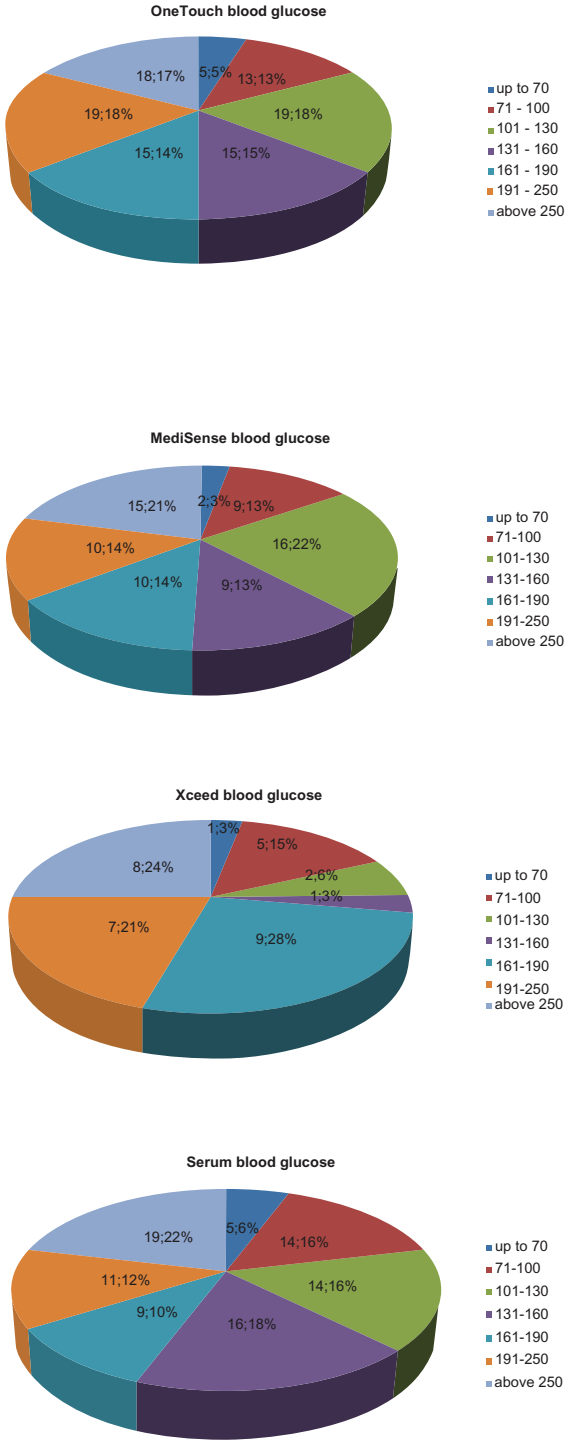

Figure 1 Distribution in blood glucose ranges of the measurements obtained on each glucose meter and by serum level determination.

the measurements of each glucose meter was 93.07% with OneTouch SureStep, 92.40% with Medisense Optium, and 92.31% with Optium Xceed (Figure 2). The mean of the glucose levels determined by the three glucose meters showed a significant difference in relation to the mean serum glucose, with $P = 0.01$ (paired t-test) for the glucose meters OneTouch

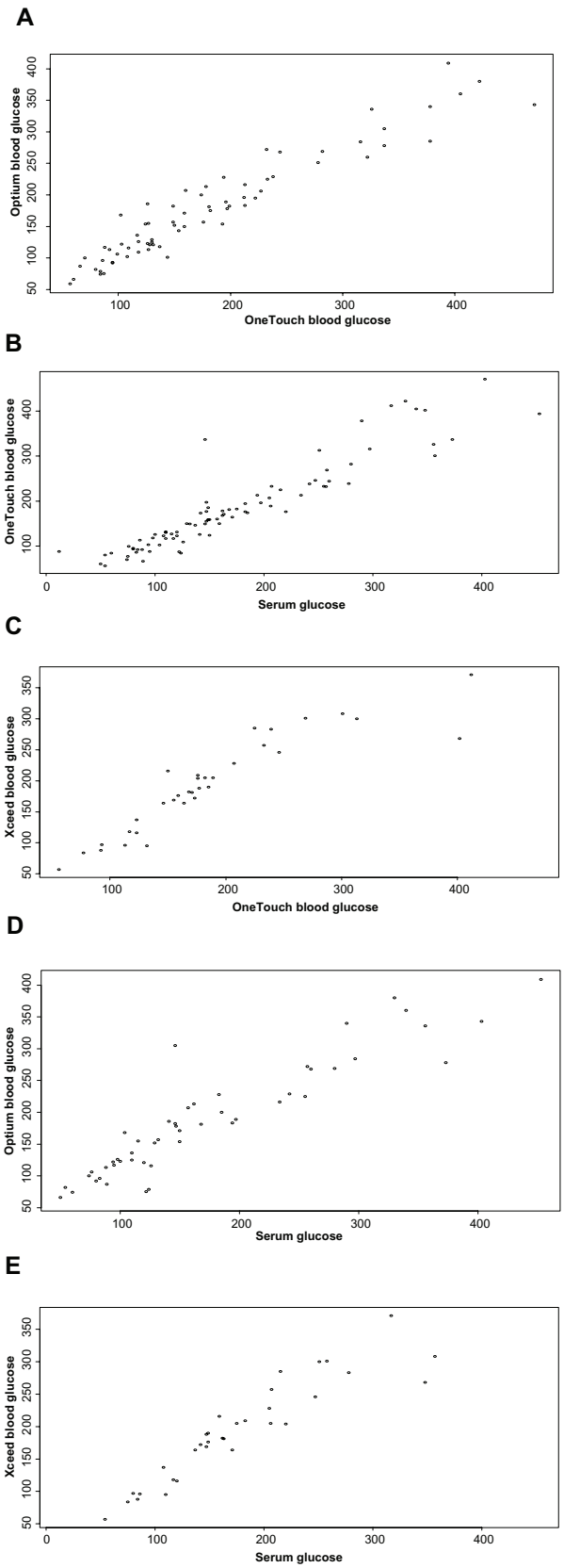

Figure 2 Correlations between capillary blood glucose values on the glucose meters and individual correlation with serum glucose. (**A**) Glucose meters Optium versus OneTouch. (**B**) Glucose meters OneTouch versus serum glucose. (**C**) Blood glucose: Optium Xceed versus OneTouch. (**D**) Blood glucose: Optium versus serum glucose. (**E**) Blood glucose: Optium Xceed versus serum glucose.

SureStep and Medisense Optium and $P = 0.004$ in relation to Optium Xceed (Appendix 1).

Comparing the variance in the readings of each glucose meter across different ranges of serum glucose, it was found that the variance in the measurements taken with the glucose meter OneTouch SureStep was significantly greater when serum glucose exceeded 180 mg/dL, with $P = 0.03$ (Mood two-sample test) (Figure 3). Regarding the glucose meters Medisense Optium and Optium Xceed, there was no significant difference in their variances across different ranges of serum glucose, with $P = 0.06$ and $P = 0.12$ (Mood two-sample test), respectively (Table 1).

The assessment of the variations in capillary blood glucose levels compared with serum values when these were greater than 75 mg/dL showed that 64.94% of the glucose values obtained on the glucose meter OneTouch SureStep, 47.83% of those determined by Medisense Optium, and 51.61% using Optium Xceed yielded less than a 20% variation in relation to serum glucose (Table 2 and Figure 4).

Discussion

The use of glucose meters in medical practice has encouraged patients to invest in the management of diabetes. The utilization of self-monitoring devices has already shown an improvement in the control of the disease and a reduction in the incidence of its chronic manifestations.[1,2] Today, glucose meters are more accurate, lighter, and easier to operate. Whole blood glucose as measured by glucose meters is known to be unstable, especially in hospitalized or critically ill patients, and consensus is lacking as to whether those devices provide good accuracy when used in the hospital setting.[4] Historically, the sensitivity and specificity of glucose meters have been evaluated through the determination of the serum glucose of venous blood collected concurrently with the capillary glucose.[7]

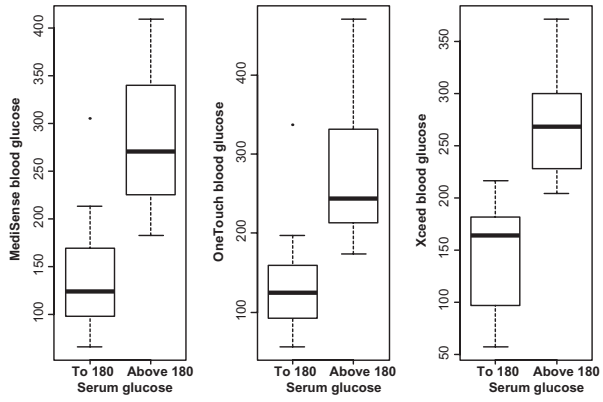

Figure 3 Box-plot of the glucose meter measurements.

Table 1 Standard deviation of the measurements on the glucose meters compared with serum glucose values

Serum glucose (mg/dL)	Standard deviation		
	OneTouch blood glucose	MediSense blood glucose	Xceed blood glucose
Up to 180	47.23	50.94	46.86
Greater than 180	85.83	68.84	48.78
Overall	97.01	89.34	76.47

The difference between whole blood and plasma blood glucose is due to the balance between the water and glucose in the analyzed blood. The concentration of water in plasma differs from its concentration in whole blood because of the presence of erythrocytes in the latter. These cells have both a lipid membrane and high levels of hemoglobin that repel water; thus, the amount of water in blood varies according to the hematocrit. Plasma has a high water content as well as a high glucose concentration – approximately 11%–12% more when compared with whole blood with a normal hematocrit of 45%.[12,13] Studies have shown that the concentration of glucose measured in capillary blood is inversely proportional to the hematocrit when compared with the laboratory method.[10,12]

Numerous factors can influence capillary blood glucose measurements performed by different methods. Arterial blood shows higher glucose values than venous blood.[14] Glucose levels also differ in the fasting and postprandial states. Postprandial variability can be minimized by rubbing the fingertip vigorously to increase local perfusion. In the post-meal state, blood glucose levels may be 20%–25% higher than those found in venous blood. Those differences become significant if the glucose meter accuracy is evaluated using capillary and serum samples of individuals simultaneously in the postprandial state.[15] Typically, conditions of poor blood perfusion are accompanied by divergent capillary and venous glucose values.[16] In the present study, the patients were hemodynamically stable.

Icodextrin, commonly used as an osmotic agent in peritoneal dialysis, may be metabolized to maltose, which reacts similarly to glucose on the meter, thus falsely

Table 2 Serum blood glucose values above 75 mg/dL and variation in capillary measurements of up to 20% (accurate) and above 20% (errors)

Above 75 mg/dL	OneTouch		MediSense		Xceed	
Accuracy	50	64.94%	22	47.83%	16	51.61%
Error	27	35.06%	24	52.17%	15	48.39%
Total	77	100.00%	46	100.00%	31	100.00%

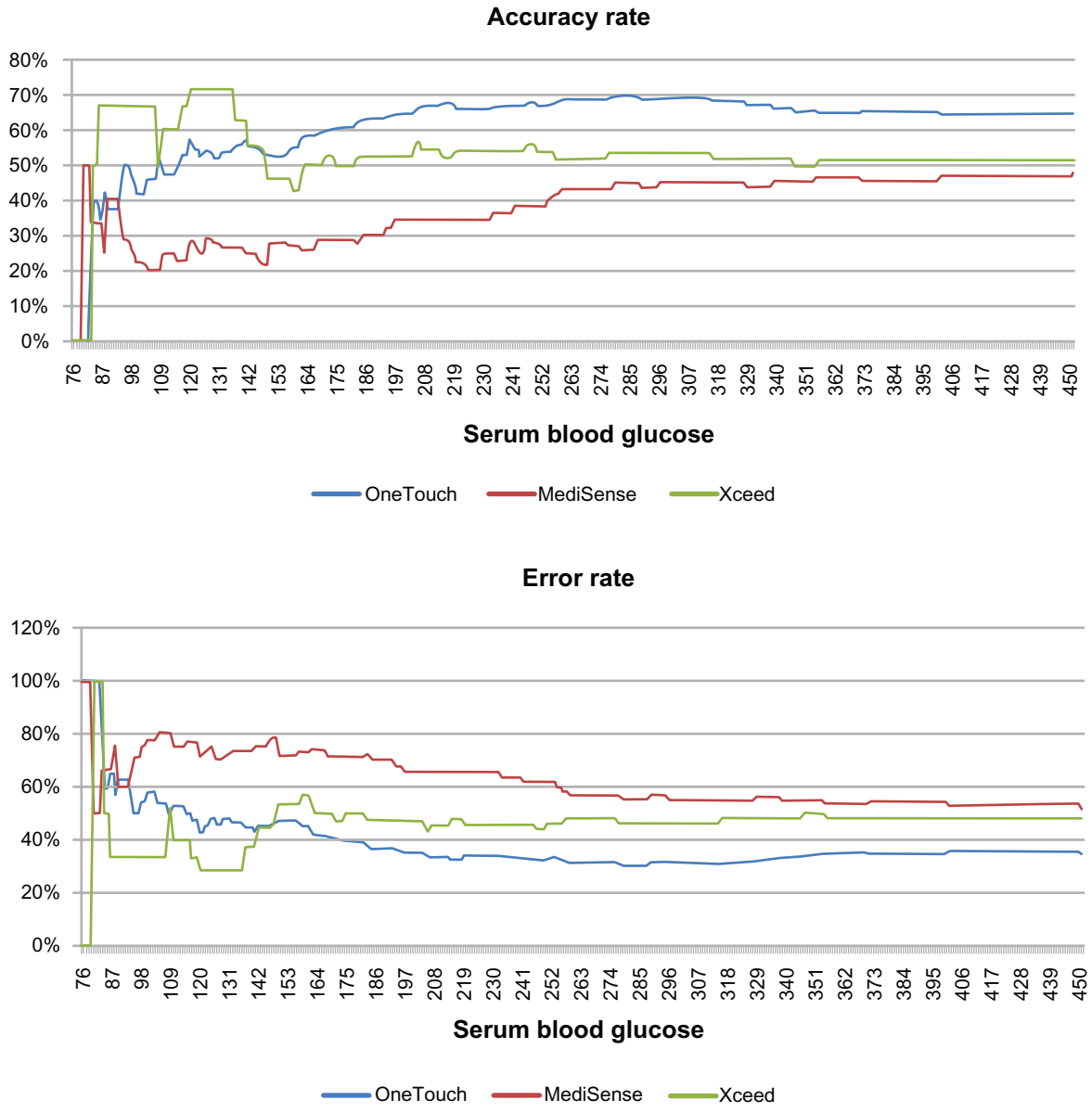

Figure 4 Values with a variation of less than 20% in relation to serum blood glucose (accurate) and with a variation of more than 20% (errors).

increasing the readings on devices using the reagent glucose dehydrogenase.[17]

A simulation modeling study showed that the glucose meters yielding a coefficient of variation ≤5%–6% (total <14%) presented minimal errors in the prescription of insulin doses.[18]

The International Organization for Standardization and the US Food and Drug Administration have established as an accuracy criterion a variation of ±20 mg/dL for glucose levels lower than 100 mg/dL or ±20% for levels of more than 100 mg/dL for at least 95% of the results.[16] In the present study, the means for the blood glucose readings on the three glucose meters evaluated showed adequate correlation. A correlation of 95.31% was found between OneTouch SureStep and Medisense Optium, whereas 91.31% was the correlation between OneTouch SureStep and Optium Xceed.

Clarke et al[7] observed bias greater than 10% in more than one-third of the glucose determinations by three new capillary glucose meters calibrated to plasma. In the present study, the discrepancy was even greater, with only 47.83%–64.94% of the results achieving variability under 20%. Such imprecision leads to changes in the clinical course of action in face of the blood glucose levels provided.

A recent study has shown that with variability of only 5% between the glucose meter readings and the serum glucose values, the doses of insulin diverged in 8%–23% of the cases.

With variability exceeding 10%–15%, the discrepancy in insulin dosing was at least two-fold.[9] Clinically acceptable values for variability are usually defined by a 15% difference from the reference value. The difference of ±20% used to detect significant errors in capillary measurements is arbitrary; however, no consensus exists as yet as to whether those inaccurate measurements lead to inadequate insulin dosing.[20,21]

Variability below 1%–2% would be necessary to ensure, with precision of at least 95%, an insulin dose similar to that which would be prescribed based on laboratory glucose measurements;[19] such a variability rate was not found in the present study.

Conclusion

To date, no consensus has been achieved by standardizing organizations to define the most acceptable performance criterion.

Multiple factors can influence the accuracy of glucose meter readings, including the technique employed by the operator, environment exposure, and adverse effects of medications the patient may be taking. Therefore, one must consider this wide array of influences on results and interpret these with caution, challenging the values whenever the results are not consistent with the clinical picture.

Blood samples analyzed with miscoded glucose meters pose great potential for insulin dose errors, with ensuing clinically significant hypo- or hyperglycemia.

Patients should always be instructed and periodically re-educated on the correct use of their glucose meters, especially for those devices that require coding.

Disclosure

Each author certifies that there are no commercial associations that might pose a conflict of interest in connection with the submitted article.

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Appendix 1 Relationship between the means of the blood glucose values obtained on the glucose meters and the mean of serum glucose values

Test for paired samples	Paired differences					*t*-value	Degrees of freedom[a]	*P*-value[b]	Conclusion
	Mean	Standard deviation	Standard error	95% confidence Interval					
				Minimum	Maximum				
OneTouch glucose MediSense glucose	4.30	31.60	3.75	−3.18	11.77	1.146	70	0.25587396	With a *P*-value = 0.25 we cannot conclude that there is a significant difference between the OneTouch and MediSense blood glucose means
OneTouch glucose Serum glucose	9.88	35.49	3.90	2.13	17.63	2.536	82	0.01309733	With a *P*-value = 0.01 we can conclude that there is a significant difference between the OneTouch and serum blood glucose means
OneTouch glucose Xceed glucose	−6.55	33.67	5.86	−18.48	5.39	−1.117	32	0.27237217	With a *P*-value = 0.27 we cannot conclude that there is a significant difference between the OneTouch and Xceed blood glucose means
MediSense glucose Serum glucose	12.90	37.84	5.35	2.15	23.65	2.411	49	0.01972121	With a *P*-value = 0.01 we can conclude that there is a significant difference between the MediSense and serum blood glucose means
Serum glucose Xceed glucose	−16.15	30.08	5.24	−26.82	−5.49	−3.085	32	0.00417892	With a *P*-value = 0.004 we can conclude that there is a significant difference between the Xceed and serum blood glucose means

Notes: [a]Degrees of freedom = N − 1; [b]Significant value (two-tailed) = *P*-value.