

Accuracy of Roche Accu-Chek Inform Whole Blood Capillary, Arterial, and Venous Glucose Values in Patients Receiving Intensive Intravenous Insulin Therapy After Cardiac Surgery

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Key Words: Glucometer; Intensive insulin; Intravenous insulin

DOI: 10.1309/6RFQCKAAJGKWB8M4

Abstract

Intravenous insulin protocols are increasingly common in the intensive care unit to maintain normoglycemia. Little is known about the accuracy of point-of-care glucometers for measuring glucose in this patient population or the impact of sample source (capillary, arterial, or venous whole blood) on the accuracy of glucometer results. We compared capillary, arterial, and venous whole blood glucose values with laboratory plasma glucose values in 20 patients after cardiac surgery. All 4 samples (capillary, arterial, and venous whole blood and laboratory plasma glucose) were analyzed hourly for the first 5 hours during intravenous insulin therapy in the intensive care unit. There were no significant differences between median capillary whole blood (149 mg/dL [8.3 mmol/L]) and laboratory plasma (151 mg/dL [8.4 mmol/L]) glucose levels. The median arterial (161 mg/dL [8.9 mmol/L]) and venous (162 mg/dL [9.0 mmol/L]) whole blood glucose levels were significantly higher than the median laboratory plasma glucose level. Capillary whole blood glucose levels correlate most closely with laboratory plasma glucose levels in patients receiving intensive intravenous insulin therapy after cardiac surgery.

In 2001, a landmark article was published by Van den Berghe et al¹ demonstrating that tight glucose control (maintenance of the blood glucose level between 80 and 110 mg/dL [4.4-6.1 mmol/L]), accomplished via intensive intravenous (IV) insulin therapy, decreased mortality in critically ill patients in a surgical intensive care unit (ICU). Since that time, more studies have suggested that intensive insulin protocols may benefit critically ill patients, although frequent glucose monitoring is necessary to prevent hypoglycemia.² Several protocols have been developed that use bedside glucometers as part of an insulin dosing protocol to decrease the amount of time to achieve normoglycemia and the incidence of hypoglycemia in patients undergoing intensive IV insulin therapy.³⁻⁶ These studies have used capillary, arterial, and venous whole blood measurement via glucometer and plasma glucose measured in a central laboratory interchangeably to measure glucose levels in patients receiving IV insulin. Differences between glucose values drawn via different sample sites (arterial, capillary, and venous) have not been addressed in any of the protocols describing the management of critically ill patients receiving intensive insulin therapy.

It is well known that differences exist between glucose levels in whole blood and plasma and in capillary and venous blood. In general, fasting glucose concentrations are approximately 15% lower in whole blood than in plasma.⁷ To account for this difference and ensure comparability of results between the glucometer (whole blood) and laboratory (plasma) measurement of glucose, the Roche Accu-Chek Comfort Curve test (Roche Diagnostics, Indianapolis, IN), similar to other hospital glucometers, is calibrated to deliver plasma-like values.⁸ The Accu-Chek strip is calibrated to correlate very well with standard laboratory hexokinase

measurement of glucose regardless of whether capillary, venous, or arterial whole blood is used.⁸ Thus, in healthy adults (in a fasting state), little difference should be seen between whole blood glucometer and laboratory plasma measurements of glucose concentrations.

The issue of comparability between capillary and venous whole blood glucose measurement has been more controversial. The mean capillary whole blood glucose level is greater than the mean venous whole blood level after glucose challenge testing,^{9,10} although the difference is diminished in patients with gestational diabetes.¹⁰ In contrast to outpatients undergoing an oral glucose challenge, one study found that non-critically ill patients admitted to the emergency department had higher venous whole blood glucose values than capillary whole blood values. The same study found that capillary and venous whole blood glucose levels were significantly higher than the laboratory plasma glucose level.¹¹ The capillary glucose level is significantly lower than the venous glucose level in patients in shock, such that some investigators have recommended that capillary glucose measurements not be used for this patient population.^{12,13}

The purpose of the present study was to examine differences in arterial, capillary, and venous whole blood glucometer measurements in patients receiving intensive IV insulin therapy after cardiac surgery and the accuracy of glucometer whole blood measurements relative to laboratory plasma glucose measurements used as a reference method in the same population.

Materials and Methods

Study Population

Patients undergoing cardiopulmonary bypass surgery with 1 of 2 participating surgeons were recruited the morning of surgery for the study (study period, May-September 2005). A total of 50 patients were recruited to obtain the 20 patients enrolled in the study (30 patients gave consent but did not receive IV insulin in the ICU and/or had an initial glucose level of ≤ 130 mg/dL [7.2 mmol/L]). Patients arriving from the operating room who were receiving IV insulin were included in the study only if they met the criteria (initial ICU arterial whole blood glucose level of >130 mg/dL [7.2 mmol/L]) commonly used for initiation of insulin infusion in the ICU. Initiation of IV insulin in the operating room and/or ICU was at the discretion of the surgical services. Nothing by mouth status was maintained during the time glucose samples were obtained. Patients were selectively recruited to give an approximately equal number of diabetic and nondiabetic patients. Recruitment of patients was not consecutive, and consent from a maximum of 4 patients was obtained on any

given day to allow for sufficient resources to obtain glucose samples from each patient enrolled in the study. A total of 100 sample sets were obtained; 4 sample sets could not be analyzed owing to failure to obtain the laboratory sample or a delay in transport of the laboratory sample. The study was approved by the Mayo Clinic Institutional Review Board (Rochester, MN).

Glucose Measurements

If patients qualified for the study, the first 5 hourly glucose measurements after initiation of insulin infusion in the ICU were used to compare arterial, capillary, and venous blood glucose levels. For these 5 measurements, fresh (no anticoagulant used) arterial whole blood (arterial catheter collection), capillary finger-stick whole blood, and fresh (no anticoagulant used) venous (venipuncture or venous catheter collection) whole blood glucose levels were measured nearly simultaneously on an Accu-Chek Inform blood glucose monitoring system (glucometer) (Roche Diagnostics). Interassay precision for the glucose meters across the institution averages a coefficient of variation of 4% to 6% for the range of glucose values typically encountered.

Nearly simultaneously, a plasma sample (from an arterial catheter or by venipuncture) was obtained in a 4-mL gray-top potassium oxalate/sodium fluoride tube and sent to the central laboratory for glucose analysis by the hexokinase method on a Double P Modular System (Roche Diagnostics) using standard laboratory techniques. Glucometer measurement and collection of blood samples for laboratory glucose measurement was accomplished within 5 minutes to ensure comparability of results. The laboratory plasma sample was used to evaluate glucometer accuracy because hexokinase methods have been found to be suitable for use as reference methods for glucose determination with close correlation to definitive methods that use mass spectrometry.¹⁴ Precision on the laboratory hexokinase method was previously evaluated, with a coefficient of variation of less than 2% across the range of glucose values typically encountered. Plasma was separated (centrifuged) within 1 hour of collection, such that degradation of glucose was less than 5% (data not shown). Systolic and diastolic blood pressure values were recorded at the time of each glucose measurement. Catheter collections were performed following standard laboratory procedure, with a minimum 5-mL discard volume and all medications and IV solutions discontinued for a minimum of 2 minutes before collection.

Statistical Analyses

Because of the repeated measures design used in this study, generalized estimating equations (GEEs), which adjust variances for clustering within patients, were used to perform statistical analyses. GEEs were used because there was little variation within patients but a large amount of variation

between patients. Bias was assessed by testing the hypothesis that the slope of the regression of the plasma glucose measurement on each of the arterial, capillary, and venipuncture glucose measurements, adjusting the variance for multiple measurements per patient, was equal to 1 (indicating that the values were identical). A significant *P* value would mean that there was significant bias. Bland-Altman plots were created to assess the degree of agreement between each whole blood measurement and the plasma glucose measurement. Recursive partitioning was used to determine if there was any level of glucose at which the bias significantly increased among the 3 comparisons. Once this breakpoint was determined, the bias values above and below that point were assessed using GEEs with bias between laboratory and whole blood glucose as the dependent variable and glucose group (defined as 0 if the average of the laboratory glucose and the whole blood values is less than the breakpoint and 1 if that average is greater than the breakpoint value) as the independent variable, with appropriate adjustments for multiple measurements per patient.

GEEs were also used to assess the effects of systolic and diastolic blood pressure and diabetes status (yes or no) on the bias between whole blood and laboratory glucose values. All continuous data are summarized as median (interquartile range [IQR]). Significance of any bias was defined as a *P* value of .02 or less to allow for multiple comparisons.

The correlation between laboratory plasma glucose and capillary, arterial, and venous whole blood glucose values was examined by using the Shrout-Fleiss fixed set intraclass correlation coefficient (ICC).¹⁵ ICC is a measure of agreement with 1.0 indicating perfect agreement and is similar to the Pearson correlation coefficient. However, the Pearson correlation coefficient disregards systematic differences and assumes all observations are independent. The ICC accounts for systematic differences and multiple observations per patient and can be interpreted as a chance corrected index of agreement. We used the benchmarks for ICC set forth by Landis and Koch¹⁶ whereby 0.00 to 0.20, 0.21 to 0.40, 0.41 to 0.60, 0.61 to 0.80, and 0.81 to 1.00 indicate poor, fair, moderate, substantial, and almost perfect agreement, respectively. A power analysis performed before the study indicated that 20 patients would be needed to achieve 90% power to detect a difference of 10 mg/dL (0.6 mmol/L), assuming an overall type I error rate of 0.05 and a correlation of 0.8 among the glucose measurements.

Results

Of 20 patients, 9 had known diabetes mellitus and 11 did not have diabetes (Table 1). Most patients received inotropic agents, including epinephrine or norepinephrine, in the perioperative period. All patients with diabetes and 7 of

Table 1
Demographic and Clinical Data for 20 Patients Who Received Intravenous Insulin After Cardiac Surgery

	Diabetic Patients	Nondiabetic Patients
Total participants	9	11
Male	7	7
Female	2	4
Type 1 diabetes	0	—
Type 2 diabetes	9	—
Oral agent therapy	7	—
No therapy	2	—
Average (range) age, y	69.6 (55-81)	68.1 (40-87)
Average (range) blood pressure, mm Hg		
Systolic	110 (88-139)	111 (89-132)
Diastolic	56 (36-77)	56 (36-79)
No. who received		
Intraoperative insulin	9	7
Perioperative inotropic agent	9	8
Perioperative epinephrine or norepinephrine	7	7
Perioperative corticosteroid	1	0

11 without diabetes received IV insulin in the operating room before arrival in the ICU. Systolic and diastolic blood pressure values were not significantly different between diabetic and nondiabetic patients (Table 1).

The median laboratory plasma glucose level was 149 mg/dL (8.3 mmol/L), with an IQR (25th-75th percentile) of 134 to 169 mg/dL (7.4-9.4 mmol/L). The median capillary whole blood glucose level was 151 mg/dL (8.4 mmol/L; IQR, 132-172 mg/dL [7.3-9.5 mmol/L]). The median bias between capillary whole blood and laboratory plasma glucose levels was -1 mg/dL (-0.1 mmol/L; IQR, -4 to 5 mg/dL [-0.2 to 0.3 mmol/L]), which was not significantly different from 0 (*P* = .88). The bias in capillary minus laboratory values for patients with diabetes was 0 mg/dL (0.0 mmol/L; IQR, -2 to 15 mg/dL [-0.1 to 0.8 mmol/L]), which was not significantly different from the value of -1 mg/dL (-0.1 mmol/L; IQR, -5 to 5 mg/dL [-0.3 to 0.3 mmol/L]) obtained for patients without diabetes (*P* = .07). In contrast, the median arterial whole blood glucose level was 161 mg/dL (8.9 mmol/L; IQR, 149-185 mg/dL [8.3-10.3 mmol/L]); which was significantly positively biased by 14 mg/dL (0.8 mmol/L; IQR, 10-18 mg/dL [0.6-1.0 mmol/L]) compared with laboratory plasma glucose values (*P* = .02). The venous whole blood median glucose level was 162 mg/dL (9.0 mmol/L; IQR, 141-194 mg/dL [7.8-10.8 mmol/L]), which was also significantly positively biased by 12 mg/dL (0.7 mmol/L; IQR, 3-24 mg/dL [0.2-1.3 mmol/L]) compared with laboratory plasma glucose values (*P* = .001).

Correlation between laboratory plasma and capillary, arterial, or venous whole blood glucose levels was assessed by regression analysis of the mean glucose level for each of the 20 patients. The slope of the regression line for arterial vs laboratory glucose values was 1.16 with a negative intercept of

–10 mg/dL (–0.6 mmol/L). For capillary whole blood glucose vs plasma laboratory glucose levels, the slope of the regression line was 1.14 with a negative intercept of –20 mg/dL (–1.1 mmol/L). For venous whole blood glucose levels, the slope of the regression line was higher (1.37) and the intercept more negative (–41 mg/dL [–2.3 mmol/L]) than for arterial or capillary glucose levels. Goodness of fit of the regression line was assessed by the ICC. The ICC for arterial vs laboratory glucose levels and capillary vs laboratory glucose levels was 0.94, and the ICC for venous vs laboratory glucose levels was 0.92. These ICC values reflect almost perfect agreement according to Landis and Koch,¹⁶ indicating a very strong relationship between whole blood and laboratory plasma glucose values.

Bland-Altman plots of capillary vs laboratory **Figure 1A**, arterial vs laboratory **Figure 1B**, and venous vs laboratory **Figure 1C** glucose values are shown. There was a visible trend toward increasing bias, as a function of glucose concentration, for whole blood vs laboratory plasma glucose values.

Recursive partitioning was used to determine whether there was an optimal breakpoint in the glucose data to perform mean bias analysis on subsets of data (ie, median bias above or below some glucose level). Recursive partitioning of the glucose data identified breakpoints at 154, 160, and 164 mg/dL (8.5, 8.9, and 9.1 mmol/L) for capillary, arterial, and venous glucose values, respectively. For ease of comparison, the median bias above and below 160 mg/dL (8.9 mmol/L) was calculated for all 3 sample types.

For capillary whole blood glucose values, the median bias was –3 mg/dL (0.2 mmol/L; IQR, –7 to 3 mg/dL [–0.4 to 0.2 mmol/L]) at glucose values less than 160 mg/dL (8.9 mmol/L) and 10 mg/dL (0.6 mmol/L; IQR, 1–16 mg/dL [0.1–0.9 mmol/L]) for glucose values of 160 mg/dL (8.9 mmol/L) or more. This represented a significant difference ($P = .02$) in capillary whole blood–plasma laboratory bias for glucose values more and less than 160 mg/dL (8.9 mmol/L). For arterial blood samples, the median bias was 10 mg/dL (0.6 mmol/L; IQR, 7–13 mg/dL [0.4–0.7

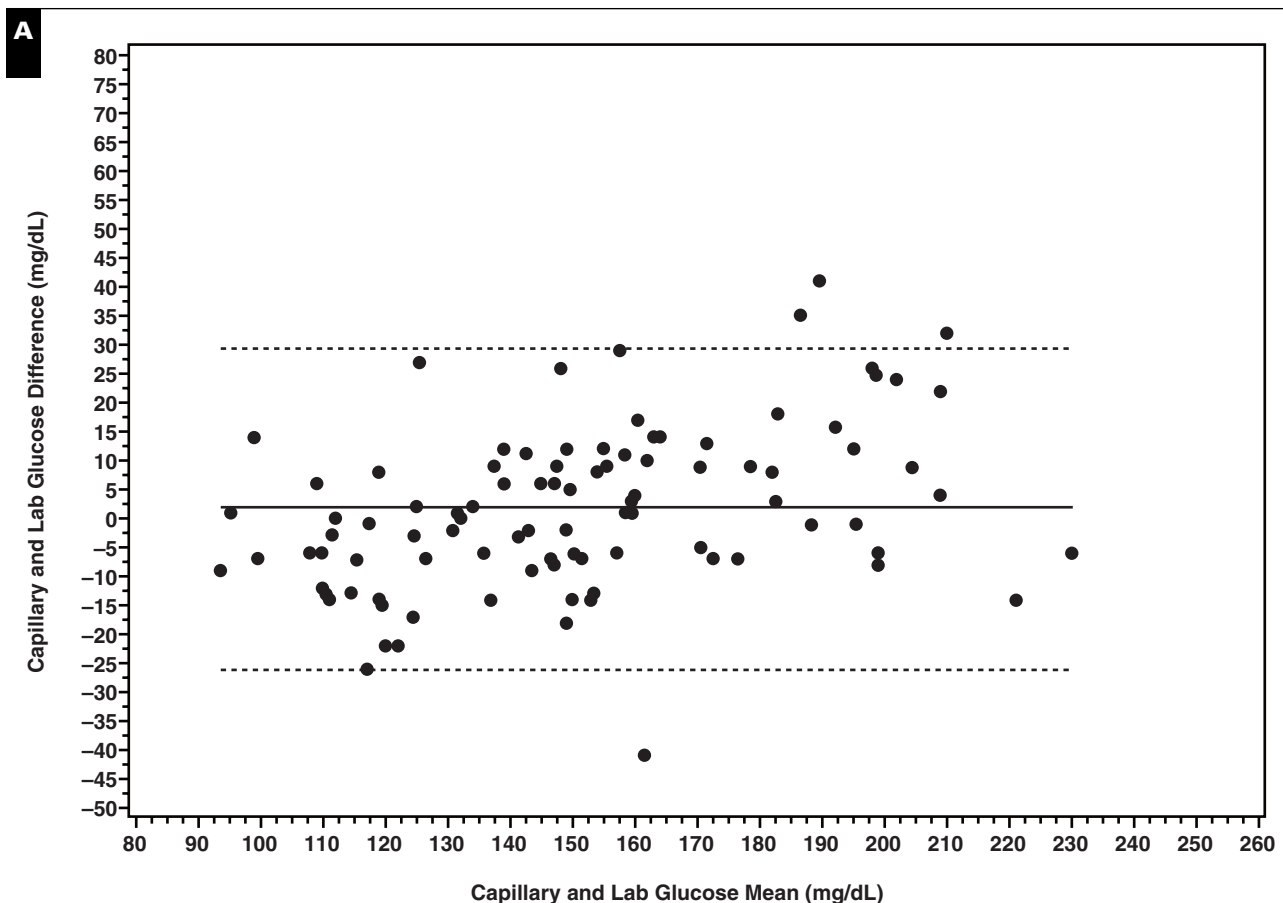
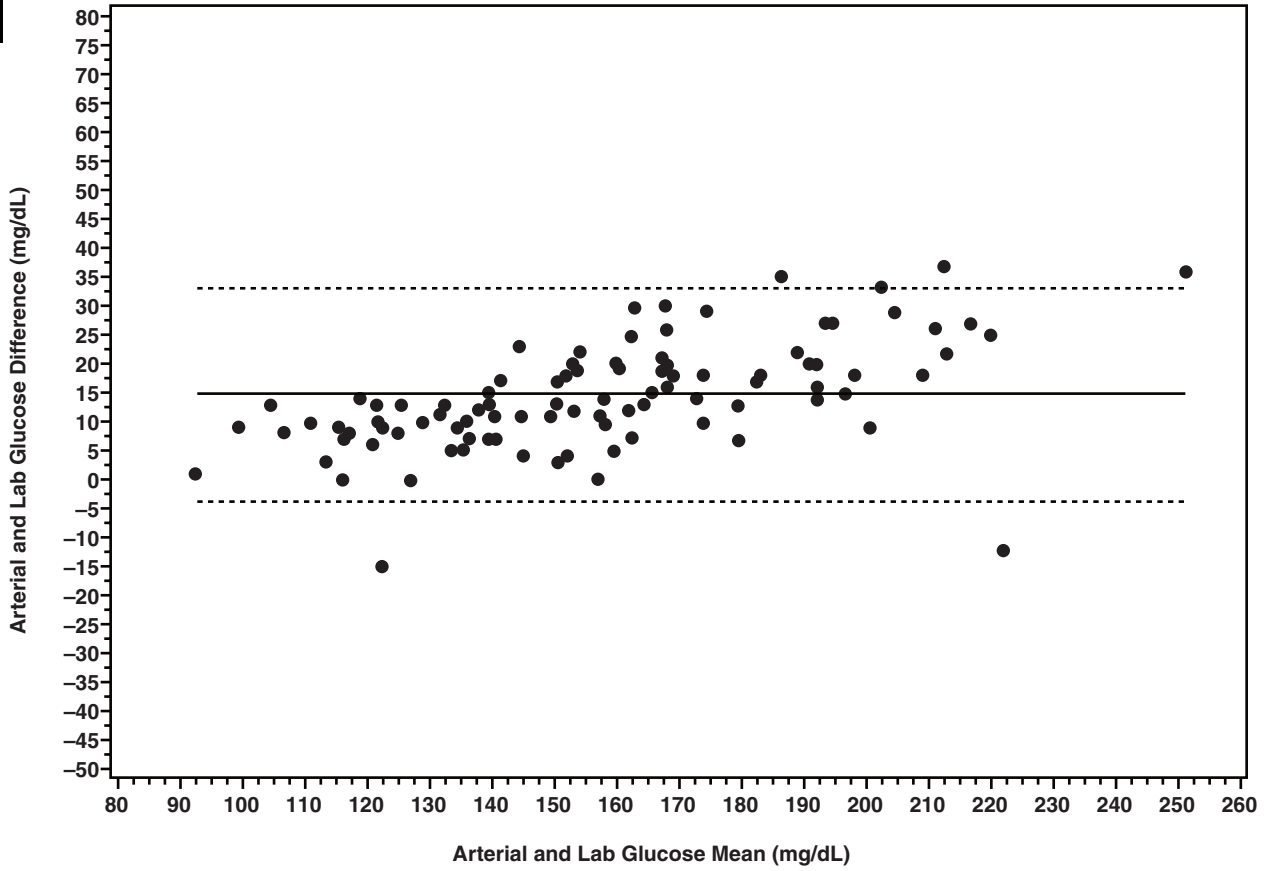
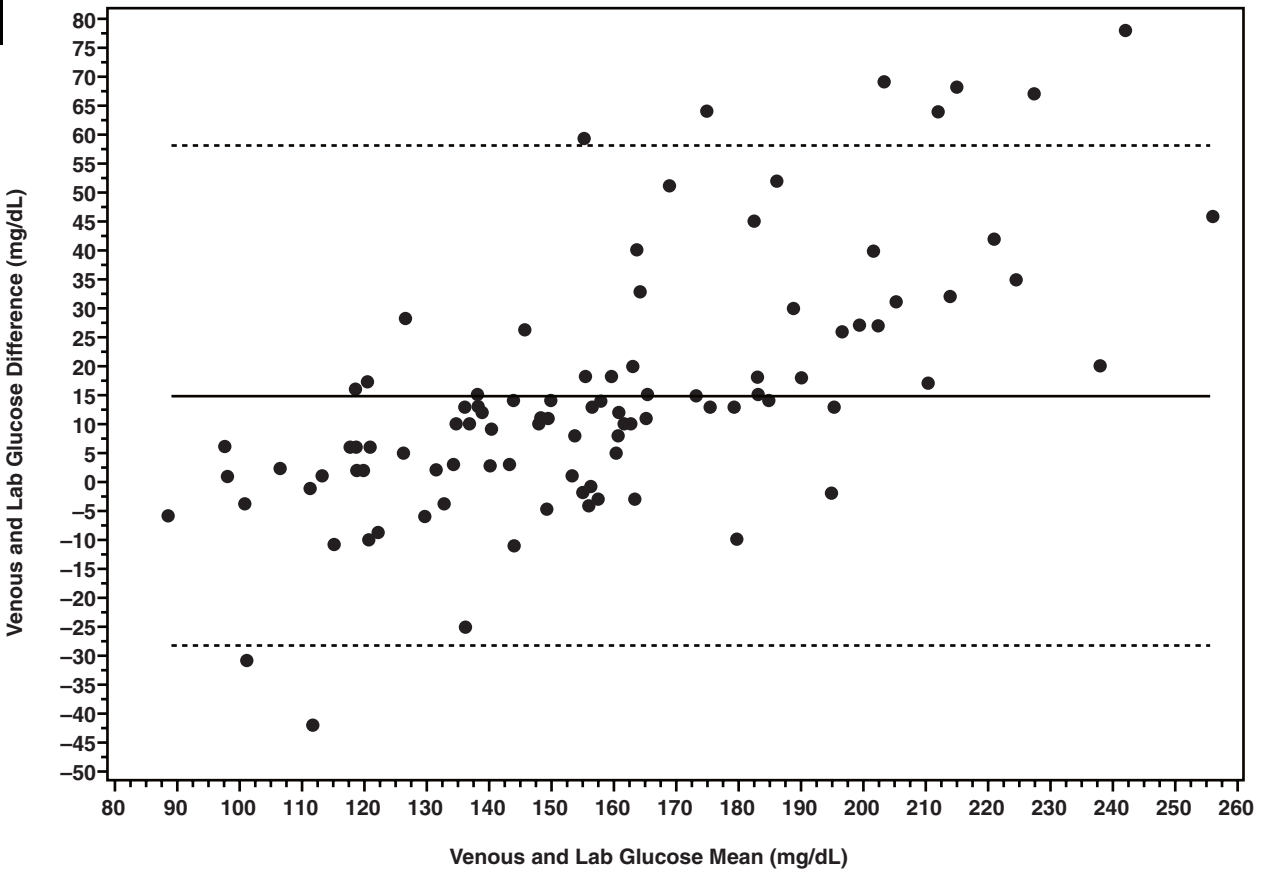


Figure 1 Bland-Altman plots (difference between whole blood glucose and laboratory plasma glucose values vs mean of whole blood and laboratory glucose values) of capillary whole blood vs laboratory plasma glucose (**A**), arterial whole blood vs laboratory plasma glucose (**B**), and venous whole blood vs laboratory plasma glucose (**C**) values. Dotted lines represent ± 2 SD of the mean bias. Data are given in conventional units; to convert to Système International units (mmol/L), multiply by 0.05551

B



C



mmol/L]) at glucose values less than 160 mg/dL (8.9 mmol/L) and 18 mg/dL (1.0 mmol/L; IQR, 13-26 mg/dL [0.7-1.4 mmol/L]) for glucose values of 160 mg/dL (8.9 mmol/L) or more. For venous samples, the median bias was 9 mg/dL (0.5 mmol/L; IQR, -1 to 12 mg/dL [-0.1 to 0.7 mmol/L] at glucose values less than 160 mg/dL (8.9 mmol/L) and 26 mg/dL (1.4 mmol/L; IQR, 15-41 mg/dL [0.8-2.3 mmol/L]) at values of 160 mg/dL (8.9 mmol/L) or more. Differences in median bias above and below 160 mg/dL (8.9 mmol/L) reached statistical significance ($P < .0001$) for arterial and venous samples.

GEEs were used to univariately analyze the effects of systolic and diastolic blood pressure on the bias between laboratory and whole blood glucose values. Systolic and diastolic blood pressure were not univariately related to capillary whole blood-plasma laboratory glucose bias (systolic, $P = .40$; diastolic, $P = .95$) or arterial whole blood-plasma bias (systolic, $P = .71$; diastolic, $P = .27$); however, systolic blood pressure was marginally negatively associated with venous whole blood-plasma laboratory glucose bias ($P = .10$), and diastolic blood pressure was significantly negatively related to venous whole blood-plasma laboratory glucose bias ($P = .02$).

The clinical impact of glucometer bias has been assessed by error grid analysis and percentage of glucometer values within 10% of a reference method.¹⁷ Conventional error grid analysis does not take into account more intensive glucose treatment goals and, thus, is difficult to apply to patients receiving IV insulin. For capillary, arterial, and venous whole blood samples, there were 71 (74%), 54 (56%), and 60 (63%) of 96 samples within 10% of the reference laboratory values, respectively, corresponding to good or acceptable performance as defined previously.¹⁷

We also estimated the impact of glucometer whole blood glucose bias on patient care by determining the impact that glucometer bias had on insulin dose rate. Insulin dose rate is determined from a nomogram of dose rate vs glucose value, with incremental adjustments of the insulin infusion rate as glucose levels become higher or lower. By using the nomogram applied in our institution for this patient population, we calculated the insulin dose discrepancy for each of the 96 paired samples. Insulin dose discrepancy is defined as the difference between insulin dose based on glucometer glucose value and insulin dose based on the reference method (laboratory plasma glucose). Overall, the venous glucose samples resulted in more dosing discrepancies (55/96) than arterial (45/96) or capillary (40/96) samples. All arterial whole blood dosing discrepancies were within 1 U/h of the dose based on laboratory plasma glucose levels (Figure 2), and only 2 capillary dosing discrepancies exceeded this amount. In contrast, 15 of 96 venous whole blood dosing discrepancies exceeded 1 U/h (Figure 2).

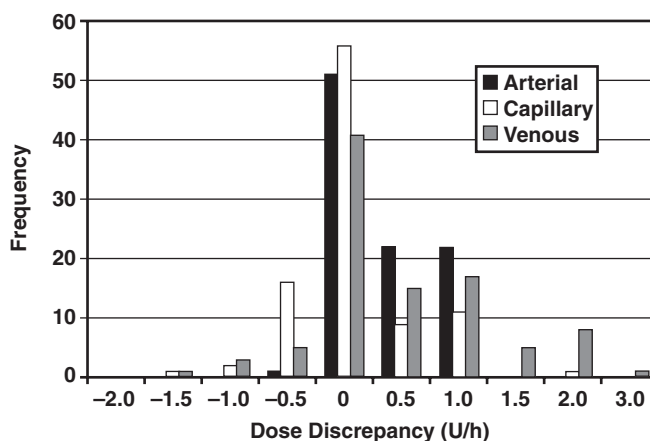


Figure 2 Insulin dose discrepancies calculated by determining the insulin dose based on the whole blood glucose level minus the insulin dose based on the laboratory plasma glucose level (using an institutional insulin dosing nomogram). An error of "0" indicates an insulin dose based on a whole blood glucose that was identical to the insulin dose based on the laboratory plasma level. Positive discrepancies indicate more insulin would have been given based on the whole blood glucose level than required based on the laboratory plasma glucose level, whereas negative discrepancies indicate less insulin would have been given based on whole blood glucose results.

Discussion

Median capillary whole blood glucose levels, measured on the Roche Accu-Chek Inform glucometer, were not significantly different from median laboratory plasma glucose levels as measured by a standard hexokinase method. Overall, more capillary whole blood glucose values (71/96) fell within 10% of the reference glucose value than did arterial or venous whole blood levels. In addition, insulin dose discrepancies occurred less often with capillary than with arterial or venous whole blood samples.

Our findings differ from those in a recent study that found that arterial whole blood was more accurate than capillary whole blood for selected ICU patients receiving IV insulin.¹⁸ Kanji et al¹⁸ used the Accu-Chek Inform for whole blood glucose measurements but selectively recruited patients with poor peripheral perfusion or significant peripheral edema and used a glucose oxidase/catalase reference method rather than a hexokinase reference method.¹⁸ Although it is clear that there are limitations that impact the ability to obtain good capillary samples from critically ill patients,^{12,13,18} previous studies have not determined whether (if a good sample can be obtained) whole blood glucose measurement is accurate in ICU patients receiving intensive insulin therapy. Our findings

demonstrate that capillary whole blood glucose values correlate well with values from a laboratory hexokinase reference method in patients receiving IV insulin therapy.

The median arterial whole blood glucose level was significantly higher than the median laboratory plasma glucose level, despite the fact that most of the laboratory samples analyzed were obtained via arterial access (ie, the same sample was dosed on a glucometer and sent to the laboratory for analysis). Positive bias in arterial whole blood glucose levels was more significant at higher glucose values (≥ 160 mg/dL [8.9 mmol/L]). To avoid hypoglycemia in patients receiving IV insulin infusions, correlation with the reference method at lower glucose values may be relatively more important than correlation at higher glucose values.

This can be demonstrated by examining the insulin dose discrepancies (Figure 2). Almost all dosing discrepancies (44/45) based on arterial whole blood were small positive changes (0.5 to 1 U/h insulin dose discrepancies). As glucose levels approached the normoglycemic range, arterial whole blood and laboratory plasma glucose values correlated better (Figure 1B). As a result, few insulin dosing discrepancies that are likely to result in hypoglycemic episodes occur. In fact, patients in this study received insulin doses based on arterial whole blood glucose levels, and no cases of hypoglycemia (defined as laboratory plasma glucose < 60 mg/dL [3.3 mmol/L]) were observed.

Venous whole blood glucose levels were also significantly higher than laboratory plasma glucose levels, and the positive bias was also a function of glucose concentration (Figure 1). Venous whole blood levels did not correlate as well (compared with capillary or arterial values) with laboratory plasma glucose levels at high or low glucose levels. There was a positive slope (1.37) and negative intercept (-41 mg/dL [-2.3 mmol/L]) observed when mean venous and laboratory glucose values were compared. More scatter in the Bland-Altman plot can also be noted visually (Figure 1). Insulin dosing discrepancies are also of a greater magnitude (Figure 2) when based on venous whole blood glucose values.

The cause of the positive bias in arterial and venous whole blood glucose levels remains to be elucidated. Preanalytic error may have contributed to bias for venous samples owing to the venous catheter draws (although lower rather than higher values would be expected owing to sample dilution). Hematocrit impacts multiple glucose meter technologies, with the combination of low hematocrit values (found in most patients after cardiac surgery) and high glucose values producing the greatest extent of positive bias.¹⁹ Further studies are necessary to determine whether hematocrit differences between capillary and arterial/venous blood and/or some other analytic interference are responsible for positive bias in venous and arterial whole blood glucose results in patients receiving IV insulin therapy.

We found no relationship between blood pressure and capillary whole blood–laboratory plasma glucose differences, although no patients in our study had systolic blood pressure less than 80 mm Hg (definition of shock used in previous studies).

Our study was subject to limitations that may impact the interpretation of our data. Many patients (16/20) received IV insulin in the operating room, and, as a result, few very high glucose results (> 200 mg/dL [11.1 mmol/L]) were observed during the study. Further studies are necessary to validate the accuracy of capillary and/or arterial whole blood glucose measurements at very high and very low values. We used only 1 glucometer technology in our study. If positive bias in venous and arterial whole blood measurement is due to an analytic interference on the glucometer used, we cannot predict how or whether this interference would affect other meters.

Conclusions

We found no significant difference between median capillary whole blood and laboratory plasma glucose values in 20 patients receiving IV insulin in the 5 hours after cardiac surgery. Thus, the whole blood glucose level, measured on the Roche Accu-Chek Inform glucometer, is appropriate for monitoring glucose levels in patients receiving IV insulin after cardiac surgery. The median arterial whole blood glucose level was significantly higher (14 mg/dL [0.8 mmol/L]) than the laboratory plasma glucose level, as was the median venous whole blood glucose value (12 mg/dL [0.7 mmol/L]). Differences between arterial and venous whole blood and laboratory plasma glucose levels increased as a function of glucose concentration.

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