Clinical Accuracy of a Hospital Point-of-Care Glucose Meter

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Summary

Glucose meter performance was evaluated against the ISO 15197 guidelines in 221 time-matched venous and capillary blood samples. Accuracy decreased when the source of the reference and meter blood samples was not the same.

Background

Thomas Jefferson University Hospital (TJUH) is an academic medical center with 957 acute care beds serving patients in Philadelphia, Pennsylvania and the surrounding area. TJUH routinely uses point-of-care (POC) glucose meter and strip technology for glycemic management. In 2009, 361,443 POC glucose measurements were performed. Measurement accuracy of these meters was discussed at a recent public meeting sponsored by the US Food and Drug Administration to determine if the standards for accuracy should be made more stringent.

Materials and Methods

Data collected in an ongoing study to evaluate the Intravenous Blood Glucose Monitoring System (Edwards Lifesciences, Irvine, CA) were analyzed to assess the accuracy of the Accu-Chek Inform (Roche Diagnostics, Indianapolis, IN), the POC meter used at TJUH. Blood was sampled every 4 hours from a fingerstick (capillary) and a peripheral or central venous catheter (venous). Data consists of duplicate POC glucose measurements performed with two separate Accu-Chek meters on time-matched samples from the capillary and venous blood samples. In addition, a portion of the venous blood sample was centrifuged and the plasma glucose concentration was measured using the YSI 2300 STAT Plus analyzer (YSI Life Sciences, Yellow Springs, OH).

The results from each Accu-Chek meter (i.e., Meter A and Meter B) were analyzed separately for the purpose of assessing accuracy. Adherence to the ISO 15197 guideline is reported for each meter using the YSI as the reference device. The ISO 15197 guideline states that 95% of meter measurements should be within 15 mg/dL of reference for glucose <75 mg/dL and within 20% for glucose ≥75 mg/dL with measurements assessed separately for each range.

Results

A total of 225 venous blood samples were collected in 15 subjects undergoing major abdominal surgery at TJUH. Data from four samples was not included in the analysis. Descriptive statistics for the remaining 221 blood samples are given in Table 1. No reference values were below 75mg/dL. Per ISO guidelines, matched Accu-Chek results need to be with 20% of the reference. No Meter A results and nine Meter B results (4.1%) failed ISO guidelines when venous blood was tested. On the other hand, 24 Meter A results (10.9%) and 21 Meter B results (9.5%) failed ISO guidelines when capillary blood was tested. However, there were only 11 instances (5.0%) when both Meters A and B failed.

Conclusions

Repeat testing has the potential to identify aberrant glucose measurements which may need to be repeated a third time to determine the correct glucose concentration.

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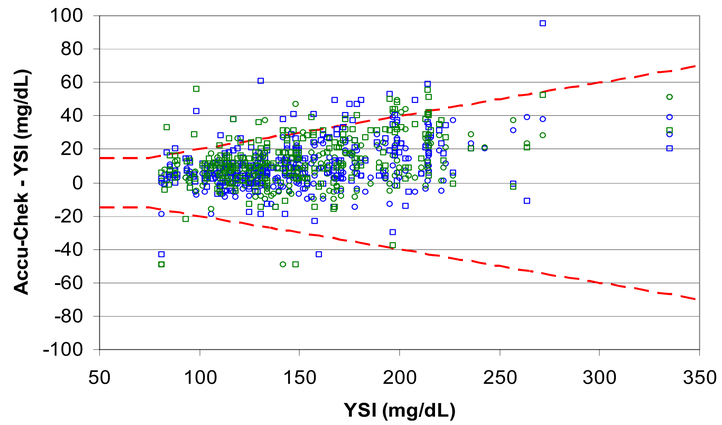
Table 1: Descriptive Statistics for YSI and Accu-Chek (Meters A and B) Results

	YSI	Meter A	Meter B	Meter A	Meter B
Blood Source	venous	venous	venous	capillary	capillary
Mean (SD)[a]	149 (42)	155 (48)	158 (49)	163 (52)	164 (51)
Minimum[a]	81	81	82	82	71
Maximum[a]	335	364	386	367	366
MARD[b]	-	5.5	7.0	10.4	11.2

[a]plasma glucose concentrations (mg/dL)

[b]Mean Absolute Relative Difference (%), MARD = |Accu-Chek – YSI|/YSI



Plot of the difference between the Accu-Chek Inform System and the YSI 2300 STAT Plus. Data points corresponding to plasma glucose measurements of time-matched venous (**O**/**O**) and capillary (□/□) blood samples are represented by circles and squares, respectively. All Accu-Chek measurements were performed in duplicate using two meters, **Meter A** and **Meter B**, and data points associated with these meters are represented by blue and green markers, respectively. The dashed red lines (---) represents the bounds of the ISO 15197 guidelines.