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Relative Accuracy of the BD Logic® and FreeStyle® Blood Glucose Meters

The Diabetes Research in Children Network (DirecNet) Study Group

Abstract

Background—The BD Logic® (Becton, Dickinson and Co.; Franklin Lakes, NJ) and FreeStyle® (Abbott Diabetes Care; Alameda, CA) meters are used to transmit data directly to insulin pumps for calculation of insulin doses and to calibrate continuous glucose sensors as well as to monitor blood glucose levels.

Methods—The accuracy of the two meters was evaluated in two inpatient studies conducted by the Diabetes Research in Children Network (DirecNet). In both studies, meter glucose measurements made with either venous or capillary blood were compared with reference glucose measurements made by the DirecNet Central Laboratory at the University of Minnesota using a hexokinase enzymatic method.

Results—The BD Logic tended to read lower than the laboratory reference regardless of whether venous (median difference = −9 mg/dL) or capillary blood (median difference = −7 mg/dL) was used. This resulted in lower accuracy of the BD Logic compared with the FreeStyle meter based on the median relative absolute difference (RAD) for both venous blood (median RAD 9% versus 5%, $P < 0.001$) and capillary blood (median RAD 11% versus 6%, $P = 0.008$). The greatest discrepancy in the performance of the two meters was at higher reference glucose values. Accuracy was not significantly different when the reference was =70 mg/dL.

Conclusions—The BD Logic meter is less accurate than the FreeStyle meter.

Introduction

Blood glucose meters are used extensively to monitor blood glucose levels in individuals with diabetes mellitus. In addition, the BD Logic® (Becton, Dickinson and Co.; Franklin Lakes, NJ) and FreeStyle® (Abbott Diabetes Care; Alameda, CA) meters are used to transmit data directly to insulin pumps for calculation of insulin doses and to calibrate continuous glucose sensors. Thus, the accuracy of these meters is especially important. In this study, we examined the accuracy of both meters compared with reference laboratory values using venous samples obtained from indwelling catheters in children with T1D. Previously, we reported results with the FreeStyle meter.(1) Because it has been suggested that the accuracy of the BD Logic may be adversely affected by low oxygen tension in venous samples, a second study was done to evaluate the accuracy of the BD Logic and the FreeStyle meters using capillary blood samples.

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Research Design and Methods

The BD Logic and FreeStyle meters were evaluated in two inpatient studies conducted at the five DirecNet clinical sites. In both studies, glucose measurements were made at the bedside using a BD Logic and a FreeStyle meter at the same time that a blood sample was drawn for reference glucose that was measured by the DirecNet Central Laboratory at the University of Minnesota using a hexokinase enzymatic method.(2,3) The study was approved by the institutional review boards at each center and informed consent and assent were obtained.

In the first study, 50 subjects with type 1 diabetes mellitus (T1D) (mean age $\pm$ SD 14.8 ± 1.7 years, 44% female, 90% Caucasian, mean duration of diabetes 7.0 ± 3.7 years, mean HbA1c $7.8 \pm 0.8\%$) were hospitalized for approximately 24 hours on two occasions, one of which included a 75-minute exercise session in the late afternoon.(4,5) Meter and central lab glucose measurements were made prior to each meal and bedtime, before and during the exercise session, hourly overnight, and at the time of symptoms of hypoglycemia. In this study, meter testing was performed using a drop of venous blood after obtaining the sample to be used for reference blood glucose from an indwelling intravenous catheter.(1)

In the second study, 27 subjects with T1D (mean age $\pm$ SD 11.2 ± 4.2 years, 37% female, 93% Caucasian, mean duration of diabetes 5.4 ± 2.8 years, mean HbA1c $7.1 \pm 0.6\%$) were also hospitalized for approximately 24 hours. During these admissions, fingerstick samples were obtained for BD Logic and FreeStyle glucose measurements, as well as a simultaneous venous sample for glucose determinations by the central laboratory.

For each meter-reference pair (matched within ± 5 minutes), the difference (meter minus reference value), and relative absolute difference (RAD; absolute value of the difference divided by reference value, expressed as a percentage) were computed. Accuracy measures were also stratified by reference glucose level. Confidence intervals and statistical comparisons were calculated using the bootstrap re-sampling technique to account for repeated measures from the same subject.(6)

Results

The BD Logic tended to read lower than the laboratory reference regardless of whether venous (median difference = -9 mg/dL) or capillary blood (median difference = -7 mg/dL) was used. This negative bias was observed when compared to reference glucose concentrations that were over 70 mg/dL, with the greatest median differences of -16 to -20 mg/dL when reference levels were over 180 mg/dL (table). In contrast, very little bias was observed with the FreeStyle meter in either study and across all reference glucose concentrations. As shown in the table, the accuracy of the BD Logic was lower than the FreeStyle meter based on the RAD for both venous blood (median RAD = 9% versus 5%, $P < 0.001$) and capillary blood (median RAD = 11% versus 6%, $P = 0.008$), due to differences in accuracy in measuring reference glucose levels that were > 70 mg/dL.

Discussion

As we have previously reported,(1) glucose measurements by the FreeStyle meter compare very favorably with reference glucose measurements. In contrast, the BD Logic meter was not as accurate, whether venous or capillary blood was used. While the two meters did not differ in their ability to measure reference glucose concentrations that were in the hypoglycemic range, there was an increasing divergence in the relative performance of the two meters with increasing reference glucose concentrations.

The first study was conducted using only venous blood obtained from an indwelling intravenous catheter in order to save the youngsters from the discomfort and inconvenience of extra fingersticks. However, it later came to our attention that the BD Logic is only FDA approved for capillary blood samples because the assay method used by this meter is thought to require the higher oxygen tension found in capillary as compared with venous blood. In order to validate the results of the first study and to examine the potential impact of using venous rather than capillary blood on the accuracy of the BD Logic, we performed a second study that only used capillary blood samples. Although the sample size of the second study was much smaller than the first because of the extra burden of multiple fingersticks to the subjects, the margin of error for the median RAD was only $\pm 2\%$ and the results indicate that using capillary blood did not improve the accuracy of the BD Logic meter. Indeed, the small differences in the accuracy of the Logic meter between the two studies favored the venous versus capillary blood measurements. The relative inaccuracy of the BD Logic meter in comparison to both the FreeStyle and One Touch Ultra meters (DirecNet reference), especially with high glucose concentrations, could adversely affect diabetes management, whether used independent of other technology, or when used in conjunction with insulin pump therapy or calibration of continuous glucose sensors.

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Table

Accuracy measures overall and stratified by reference glucose.

	N	Study 1: Venous Blood		P-value**	N	BD Logic	Study 2: Capillary Blood*		P-value**
		BD Logic	FreeStyle				N	Freestyle	
Difference***	1,096	-9 (-18, 0)	+3 (-2, +8)	<0.001	88	-7 (-21, +9)	64	+1 (-5, +12)	0.19
≤70 mg/dL	162	+2 (-2, +7)	+4 (+1, +7)		15	+5 (0, +13)	10	+3 (-1, +11)	
71-180 mg/dL	665	-9 (-17, -2)	+4 (-1, +9)		42	-8 (-15, +5)	36	+1 (-8, +12)	
>180 mg/dL	269	-16 (-28, -7)	-2 (-10, +4)		31	-20 (-38, +6)	18	+4 (-4, +16)	
RAD†	1,096	9% (4%, 14%)	5% (2%, 9%)	<0.001	88	11% (6%, 16%)	64	6% (2%, 14%)	0.008
≤70 mg/dL	162	8% (3%, 15%)	9% (3%, 12%)		15	11% (7%, 20%)	10	9% (2%, 18%)	
71-180 mg/dL	665	10% (5%, 15%)	5% (2%, 9%)		42	11% (7%, 17%)	36	6% (3%, 18%)	
>180 mg/dL	269	8% (4%, 13%)	3% (1%, 5%)		31	10% (5%, 15%)	18	4% (2%, 9%)	

* An analysis limited to 47 samples for which both BD Logic and FreeStyle measurements were available produced similar results.

** P-value (BD Logic vs. FreeStyle) calculated using the bootstrap re-sampling method(7) to account for repeated measures from the same subject.

*** Difference = Meter minus reference glucose value, median (25th, 75th percentiles).

† RAD = relative absolute difference (absolute value of the difference divided by reference value expressed as a percentage), median (25th, 75th percentiles).