Accuracy of Four Blood Glucose Monitoring Systems

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Objective: To compare the accuracy of four latest models of blood glucose monitoring systems.

Method: Accuracy of the four blood glucose monitoring systems for fingertip capillary blood testing was assessed at three diabetes clinics. A total of 142 diabetic subjects were included in the study. At each study site, the trained operator tested the subject's fingertip blood with the four systems and a YSI glucose analyzer, which served as the reference. Accuracy was evaluated according to ISO 15197 by calculating the percentage of meter results falling within ±5%, ±10%, ±15% and ±20% of the reference value for glucose concentrations 75 mg/dL (4.2 mmol/L) or higher, and within ±5, ±10, ±15 mg/dL (±0.28, ±0.56 and ±0.83 mmol/L) of the reference value for glucose concentrations below 75 mg/dL (4.2 mmol/L).

Results: Based on the percentage of meter results falling within ±20% of the reference value as the criterion, the four systems performed comparably. However, when based on the percentage of meter results falling within ±15% (or ±15 mg/dL; 0.83 mmol/L) of the reference value, the FreeStyle® Lite Blood Glucose Monitoring System had significantly ($p < 0.05$) more results meeting the criterion than Ascensia Contour. When based on the percentage of meter results falling within ±10% (or ±10 mg/dL; 0.56 mmol/L) of the reference value, the FreeStyle Lite system had significantly ($p < 0.05$) more results meeting the criterion than Ascensia Contour and OneTouch Ultra2. When based on the percentage of meter results falling within ±5% (or ±5 mg/dL; 0.28 mmol/L) of the reference value, the FreeStyle Lite system had significantly ($p < 0.05$) more results meeting the criterion than Ascensia Contour, OneTouch Ultra2 and Accu-Chek Aviva.

Conclusions: Of the four latest models of blood glucose monitoring systems evaluated, the FreeStyle Lite system showed the highest level of accuracy. More accurate glucose results may help reduce errors in deciding the amount of carbohydrate intake and insulin dosage.

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Devices for self-monitoring of blood glucose play an important role in diabetes management. In addition to convenience and ease of use, the monitoring systems should provide accurate results to aid the patients in their glycemic control. Manufacturers continue to introduce newer, modified products. We evaluated the accuracy of four latest models of these monitoring systems.

Materials and Methods

GLUCOSE MONITORING SYSTEMS

The technologies and features of the four systems evaluated in this study are shown in Table 1. Accu-Chek Aviva and OneTouch Ultra2 meters require coding by the user, and they were properly coded by the trained operators at the study sites before use. Control solution testing was performed on all four systems at each study site to verify proper functioning before the start of the study. All systems and supplies were stored, handled and operated according to the manufacturer's instructions.

Table 1. Technologies and features of the four monitoring systems

	FreeStyle® Lite	Accu-Chek® Aviva	OneTouch® Ultra®2	Ascensia® Contour®
Manufacturer	Abbott Diabetes Care	Roche Diagnostics	LifeScan	Bayer Diabetes Care
Methodology	Coulometry	Amperometery	Amperometery	Amperometery
Sample Size, µL	0.3	0.6	1.0	0.6
May apply second blood drop	Yes, within 60 sec.	Yes, within 5 sec.	No	No
Test Time, sec	5	5	5	5
Referenced to plasma glucose values	Yes	Yes	Yes	Yes

Information excerpted from current labeling.

REFERENCE GLUCOSE MEASUREMENT

The YSI 2300 Stat Plus Glucose Analyzer (YSI Inc., Yellow Springs, OH) was used as the reference. The calibration accuracy of the YSI analyzer at each study site was validated by testing National Institute of Standards and Technology (NIST)[1] secondary reference material SRM 965a, which consists of four levels of glucose concentrations. The YSI whole blood glucose results were multiplied by 1.12 to yield plasma equivalent values.

ACCURACY EVALUATION

The accuracy of the four monitoring systems for fingertip capillary blood testing was evaluated at three diabetes clinics, each using a different lot of test strips. The order of testing the four systems was rotated after each subject. With each subject, immediately after applying blood to the four systems, additional blood was collected from the finger into a heparin tube for testing in duplicate on the YSI analyzer. The protocol specifies that the first YSI test must be completed within 15 minutes of the first meter test, and the duplicate YSI results must agree within ±4 mg/dL (±0.2 mmol/L) at glucose concentrations up to 100 mg/dL (5.5 mmol/L) or within ±4% at glucose concentrations above 100 mg/dL (5.5 mmol/L). Before testing the blood sample of each subject on the YSI, the YSI standard (180 mg/dL; 10.0 mmol/L) was tested and the result must be within the range of 177-183 mg/dL (9.8-10.2 mmol/L). A total of 163 diabetic subjects were enrolled at the three sites. Twenty-one subjects were excluded due to protocol deviations, yielding 142 subjects. Fingertip capillary blood glucose results obtained with the FreeStyle Lite system were compared to results obtained on the YSI.

RESULTS

Of the 142 diabetic subjects included in this study, their blood glucose concentrations, based on the YSI results, ranged from 46 to 432 mg/dL (2.5-24.0 mmol/L), with a mean value of 170 mg/dL (9.4 mmol/L) and a median of 159 mg/dL (8.8 mmol/L).

Based on the percentage of meter results falling within ±20% of the reference value as the criterion, the four systems performed comparably (Table 2). However, when based on the percentage of meter results falling within ±15% of the reference value, or ±15 mg/dL (±0.83 mmol/L) at glucose concentrations below 75 mg/dL (4.2 mmol/L), the FreeStyle® Lite system had significantly ($p = 0.0007$) more results meeting the criterion than Ascensia Contour. When based on the percentage of meter results falling within ±10% of the reference value, or within ±10 mg/dL (±0.56 mmol/L) at glucose concentrations below 75 mg/dL (4.2 mmol/L), the FreeStyle Lite system had significantly more results meeting the criterion than Ascensia Contour ($p=0.0002$) and OneTouch Ultra2 ($p=0.0021$). When based on the percentage of meter results falling within ±5% of the reference value, or ±5 mg/dL (±0.28 mmol/L) at glucose concentrations below 75 mg/dL (4.2 mmol/L), the FreeStyle Lite system had significantly more results meeting the criterion than Ascensia Contour ($p = 0.0007$), OneTouch Ultra2 ($p < 0.0001$) and Accu-Chek Aviva ($p = 0.0478$).

Table 2. Percentage of meter results falling within various intervals of the reference glucose value

System	Within ±5 mg/dL (±0.28 mmol/L) or ±5%	Within ±10 mg/dL (±0.55 mmol/L) or ±10%	Within ±15 mg/dL (±0.83 mmol/L) or ±15%	Within ±20%
FreeStyle Lite	69.7%	92.3%	98.6%	99.3%
Accu-Chek Aviva	58.5%*	94.4%	98.6%	99.3%
One Touch Ultra2	43.7%*	79.6%*	95.8%	99.3%
Ascensia Contour	50.0%*	76.1%*	88.7%*	95.8%

N = 142 patients tested using each blood glucose monitoring system

**Shaded areas indicate significant difference from the FreeStyle Lite system: $p < 0.05$.*

DISCUSSION

According to ISO 15197[1], the minimum acceptable accuracy for results produced by a glucose monitoring system shall be as follows: Ninety-five percent (95 %) of the individual glucose results shall fall within ± 15 mg/dL (0.83 mmol/L) of the results of the manufacturer's measurement procedure at glucose concentrations < 75 mg/dL (< 4.2 mmol/L) and within ± 20 % at glucose concentrations ≥ 75 mg/dL (≥ 4.2 mmol/L). In this study, all four monitoring systems met the minimum acceptable accuracy of the ISO Standard. The accuracy criterion of ± 20 % may not be adequate in some situations. Error in the preprandial glucose measurement can lead to errors in adjustment of carbohydrate intake and insulin dosage by people with diabetes. Consequently, the postprandial glucose value may fall outside of the target range. Based on a Diabetes Test Error Model, it has been estimated that a preprandial error of +20% may result in occasional hypoglycemia if preprandial glucose values are between 131 and 259 mg/dL; a preprandial error of –20% may result in postprandial hyperglycemia if preprandial glucose values are above 240 mg/dL.[2]

The 1986 consensus conference,[3] organized by the American Diabetes Association (ADA), led to the following recommendations: (1) With current systems, SMBG (self-monitoring of blood glucose) measurements should be within 15% of the results of the reference measurement; (2) The goal of all future SMBG systems should be to achieve variability (system plus user) of < 10% at glucose concentrations of 30 – 400 mg/dL (1.7 – 22.2 mmol/L) 100% of the time. In this study, the FreeStyle Lite system had 98.6% of its results agreeing within ±15% of the reference, significantly better than Ascensia Contour. The FreeStyle Lite system also had 92.3% of the results agreeing with ±10% of the reference,

significantly better than OneTouch Ultra2 and Ascensia Contour.

The 1993 ADA consensus conference[4] provided the following recommendation: The goal of SMBG device manufacturers should be to make future SMBG systems with an analytical error of ±5%. It has been suggested that reducing the total analytical error of the glucose monitoring system from 10 – 15% toward 5% may significantly reduce the frequency and magnitude of insulin dosage errors.[5] The FreeStyle® Lite system had 69.7% of its results agreeing within ±5% of the reference, significantly better than Ascensia Contour, OneTouch Ultra2 and Accu-Chek Aviva.

In conclusion, of the four latest models of blood glucose monitoring systems evaluated, the FreeStyle Lite system showed the highest level of accuracy. More accurate glucose results may help reduce errors in deciding the amount of carbohydrate intake and insulin dosage.

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