Effectiveness of Glucose Monitoring Systems Modified for the Visually Impaired

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OBJECTIVE — To compare three glucose meters modified for use by individuals with diabetes and visual impairment regarding accuracy, precision, and clinical reliability.

RESEARCH DESIGN AND METHODS — Ten subjects with diabetes and visual impairment performed self-monitoring of blood glucose using each of the three commercially available blood glucose meters modified for visually impaired users (the AccuChek Freedom [Boehringer Mannheim, Indianapolis, IN], the Diascan SVM [Home Diagnostics, Eatontown, NJ], and the One Touch [Lifescan, Milpitas, CA]). The meters were independently evaluated by a laboratory technologist for precision and accuracy determinations.

RESULTS — Only two meters were acceptable with regard to laboratory precision (coefficient of variation <10%)—the Accuchek and the One Touch. The Accuchek and the One Touch did not differ significantly with regard to laboratory estimates of accuracy. A great discrepancy of the clinical reliability results was observed between these two meters. The Accuchek maintained a high degree of reliability ($y = 0.99X + 0.44$, $r = 0.97$, $P = 0.001$). The visually impaired subjects were unable to perform reliable testing using the One Touch system because of a lack of appropriate tactile landmarks and auditory signals.

CONCLUSIONS — In addition to laboratory assessments of glucose meters, monitoring systems designed for the visually impaired must include adequate tactile and audible feedback features to allow for the acquisition and placement of appropriate blood samples.

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Type I diabetes, insulin-dependent diabetes mellitus; type II diabetes, non-insulin-dependent diabetes mellitus; SMBG, self-monitoring of blood glucose; CV, coefficient of variation; ANOVA, analysis of variance; ANCOVA, analysis of covariance.

Increasing numbers of individuals with blindness caused by diabetes are participating in the work force, family life, and many other aspects of society. Acquiring adaptive techniques for diabetes self-management is essential for maintaining independence, a good quality of life, and stable glycemic control. Manufacturers of glucose monitoring systems have modified existing glucose meters with speech synthesizers and tactile mechanisms for use by the visually impaired (1–4). These meters should allow individuals with diabetes to become active participants in their own health care, improve glycemic control, and reduce fear of unanticipated hypoglycemia. Systems for the visually impaired must be designed so that accurate results can be obtained by a user who is unable to depend on visual feedback.

This study compares three glucose monitoring systems modified for the visually impaired, available for purchase in December 1991. The AccuChek Freedom (Boehringer Mannheim, Indianapolis, IN), the Diascan SVM (Home Diagnostics, Eatontown, NJ), and the One Touch (Lifescan, Milpitas, CA) were evaluated with respect to accuracy, precision, and clinical reliability.

RESEARCH DESIGN AND METHODS

— Ten subjects with diabetes mellitus and visual impairment participated in this trial. The protocol was approved by the St. Louis University Institutional Review Board. All subjects, including 4 men and 6 women—8 with type I diabetes and 2 with type II diabetes—ranging from 35 to 55 yr of age, were followed at St. Louis University in a specialized clinic for patients with diabetes and visual impairment. Of all the subjects, 3 were totally blind, 7 subjects were legally blind (visual acuity <20/200), and 0 were capable of using conventional glucose monitoring systems. They were unable to see the digital display and could not visually identify the correct placement of the blood sample.

Table 1—*Precision or percentage CV of the various glucose meters tested*

Glucose concentration (mM)	Glucose meters			Overall significance*
	Diascan	AccuCheck	One Touch	
4.5	18†	4	5	$P = 0.001$
9.6	9‡	2	2	$P = 0.0001$
24.0	5	2	2	NS

*P value obtained by one-way ANOVA.
†$P = 0.005$ compared with AccuChek and One Touch.
‡$P = 0.001$ compared with AccuChek and One Touch.

All of the subjects were performing SMBG at home. Five were using the Diascan SVM, 1 was using the AccuChek Freedom, 2 were using the One Touch, 1 was using the AccuChek II, and 1 was using the Glucometer II.

Patient SMBG trials

Subjects were assigned to use each of three glucose meters according to a random block design. Subjects received individual instruction in the use of each meter from a diabetes nurse educator. The subjects then demonstrated understanding and practiced the technique under supervision. Each subject performed 1 test/meter under observation and obtained capillary glucose samples according to the recommended guidelines for each meter. Serum glucose was obtained by simultaneous venipuncture and analyzed using the Beckman CX-3 clinical chemistry analyzer (Beckman, Brea, CA).

Laboratory evaluation of glucose meters

Accuracy determinations. Laboratory control solutions were prepared by adding stock glucose solution to glycolyzed whole blood to yield standard glucose concentrations of 2.1, 4.5, 9.6, 17.2, 24.0, and 32.8 mM. Samples of control solutions were pipetted onto the appropriate reagent strips for each glucose meter according to the manufacturers instructions. Each meter was evaluated 4 times using the complete set of standards, and the results were compared with those obtained on the Beckman CX-3 System. Accuracy for each meter was represented by the slope and the intercept of the linear regression line, comparing the reference values with those obtained using the meter.

Precision determinations. Precision of each meter was evaluated by applying the 4.5, 9.6, and 24.0 mM glucose control solutions 20 times for each meter. Precision was represented by the intra-assay CV.

Clinical reliability. Clinical reliability was determined by comparing subject SMBG results to reference serum glucose. SMBG results that were within 15% of the reference glucose values were considered clinically reliable.

Statistical analysis

Parametric data were analyzed by one-way ANOVA for overall effects, and comparisons between groups were then determined by the Bonferroni correction. Correlation and regression analysis were performed by the method of least square. ANOVA, Student's t tests, and the correlation analysis were performed using the statistical program RS/1 (BBN Software, Cambridge, MA). Comparison between regression lines was performed by ANCOVA using the statistical package SAS (SAS Institute, Cary, NC) within the GLM program. All data were analyzed by two-tailed tests, and $P < 0.05$ was considered significant.

RESULTS — The precision determinations for each of the three glucose meters tested are listed in Table 1. Precision, expressed as intra-assay CV, was in the acceptable 10% range for two meters over the entire range of blood glucose levels tested. The One Touch (CV = 2–5%) and the AccuChek Freedom (CV = 2–4%) were not statistically different from each other. The precision of the Diascan SVM was unacceptable at a glucose concentration of 4.5 mM (CV = 18%). Although it was acceptable at 9.6 mM (CV = 9%), it was statistically different from the other two meters, as indicated in Table 1.

Accuracy estimations using laboratory control solutions are shown in Fig. 1. Of these three meters, only the AccuChek Freedom had accuracy determinations in the acceptable range of 10% throughout the range of glucose values. A consistent 34% depression of the meter results below the mean reference values was found using the Diascan SVM. The One Touch deviated from the reference values by 13 and 7% at lower glucose values (2.1 and 4.5 mM) but results were depressed by 18% at higher values (17.2 and 24.0 mM). Comparison of the slopes between the regression lines for the accuracy of the meter results versus the laboratory reference values showed that the Accuchek was not significantly different from the One Touch.

Considerable divergence among the three meters with respect to clinical reliability was observed (Fig. 2). The accuracy ($y = 0.99X + 0.44$) and the correlation ($r = 0.97$, $P = 0.001$) of SMBG tests with laboratory reference values using the AccuChek Freedom were very good. The Diascan SVM showed SMBG values that were consistently below the reference range. Comparison of the slopes of the regression lines for clinical reliability testing demonstrated that the Accuchek differed significantly from the Diascan SVM ($F_{1,16} = 10.0$, $P = 0.01$). No correlation of SMBG results with reference values using the One Touch was detected. Most subjects had difficulty

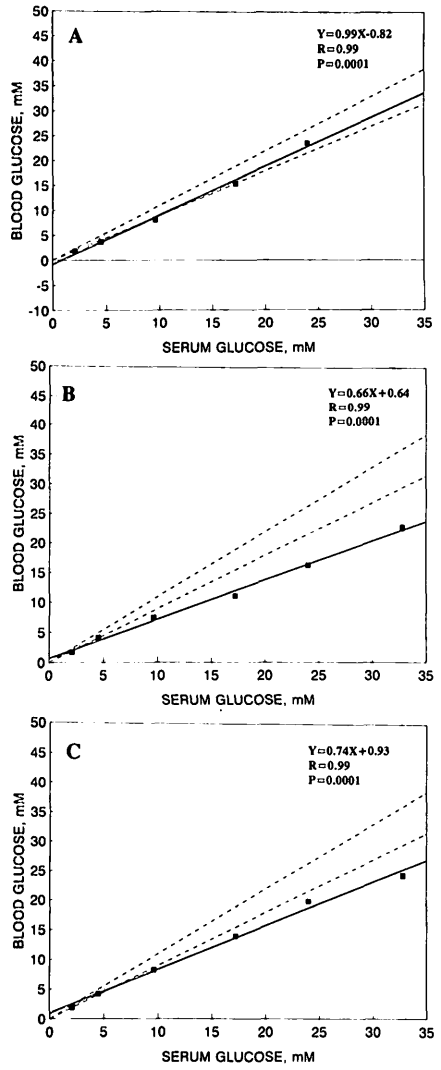

Figure 1—*Assessment of meter accuracy by comparison of laboratory determinations of meter determined blood glucose with serum glucose in the AccuChek Freedom (A), One Touch (B), and Diascan SVM (C). The individual determinations (■——■) are shown compared with the line of identity (· · ·) and ± 10% (– – –).*

finding appropriate landmarks on the reagent strip to place the blood drop, and 2 of 10 subjects were completely unable to perform testing on this meter even after repeated attempts. Although all subjects were performing SMBG at home, no difference in performance was observed when the subject had previous experience with a meter. Of those who were totally blind compared with those who were legally blind, no difference in the performance was observed.

When the data regarding clinical reliability of the meters were analyzed by the grid method of Clarke et al. (5), it was shown that there would have been no dangerous or inappropriate adjustment in the diabetes management based on the AccuChek SMBG results. Diabetes management based on Diascan SMBG results would have been inappropriate, because of a constant underestimation of glycemic control especially at high glucose levels (a type D error) (5). The SMBG results using the One Touch were found to be completely unreliable.

CONCLUSIONS— It is important to establish that modified glucose monitoring systems for the visually impaired can be managed by the intended users. Of the three systems evaluated, only the AccuChek Freedom demonstrated appropriate precision, accuracy, and clinical reliability. All participants were able to follow the steps necessary for operation and were able to independently obtain an accurate blood glucose result. This system, which includes tactile and audible feedback mechanisms to ensure the appropriate application of a droplet of blood, addresses the most difficult step in blood glucose monitoring for the visually impaired.

The poor clinical reliability of the Diascan SVM was caused by the lack of technical accuracy of the meter, rather than the ability of the user. Although most of the subjects could manage the blood application technique (which allows the user to apply the blood directly to the reagent pad without using a hanging drop) and could operate the system without difficulty, the Diascan SVM yielded glucose values consistently below the reference range. The One Touch, an appealing system because of its size and nonwipe technology, could not be used effectively. Subjects were unable to apply a sufficient blood sample to the reagent strip independently because the system lacked both landmarks for tactile feedback and an audio mechanism to assure adequate sample placement.

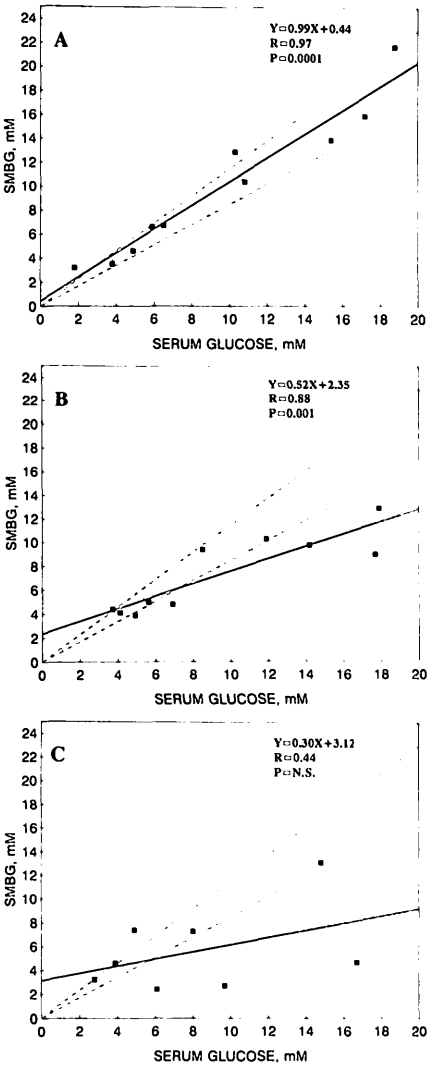

Figure 2—*Assessment of clinical reliability by comparison of patient determinations of SMBG with serum glucose in the AccuChek Freedom (A), One Touch (B),and Diascan SVM (C). The individual determinations (■——■) are shown compared with the line of identity (· · ·) and ± 15% (– – –).*

Modified glucose monitoring systems are substantially more expensive than standard glucose meters (~$400 for the adapted One Touch system and $600 for the Diascan SVM or the AccuChek

Freedom). Visually impaired users often purchase the systems through catalog distributors and receive no prior training in the use of the device. Visually impaired individuals should receive training from an experienced diabetes educator who can ensure proper technique and verify appropriate SMBG results before the system is purchased.

In conclusion, of the three blood glucose monitoring systems evaluated, only the AccuChek Freedom consistently provided clinically reliable results. In addition to meeting laboratory standards for accuracy and precision, glucose monitoring systems designed for the visually impaired must include adequate tactile and audible features to allow for the acquisition and placement of appropriate blood samples. Since these trials were conducted, the Lifescan One Touch system has been upgraded to include an audio indicator of adequate sample placement. Further trials should address the clinical reliability of this system.

References

1. Barger N, Bernbaum M, Cleary M, Luxton L, Petzinger RA, Ponchillia S: Recommendation for desirable feature of glucose monitoring systems for visually impaired customers. *Diabetes Care* 11:753–54, 1988
2. Prior JC, Alojado NC, Hunt JA, Begg IS: Use of tactile techniques for self-monitoring of blood glucose in visually impaired patients with diabetes mellitus. *Diabetes Care* 7:313–17, 1984
3. Ponchillia SV, LaGrow S: Independent glucose monitoring by functionally blind diabetics. *J Visual Impairment and Blind* 82:50–53, 1988
4. Fine N: Talking meters. *Diabetes Self Management* 8:33–37, 1991
5. American Diabetes Association: Consensus statement on self-monitoring of blood glucose. *Diabetes Care* 10:95–99, 1987
6. Havlin CE, Parvin CA, Cryer PE: The accuracy of blood glucose monitoring devices. *Clin Diabetes* 9:92–93, 1991
7. Tate PF, Clements CA, Walters JE: Accuracy of home blood glucose monitors. *Diabetes Care* 15:536–38, 1992
8. Koschinsky T, Dannehl K, Gries FA: New approaches to technical and clinical evaluation of devices for self-monitoring of blood glucose. *Diabetes Care* 11:619–29, 1988
9. Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL: Evaluating clinical accuracy systems for self-monitoring of blood glucose. *Diabetes Care* 10:622–28, 1987