Accuracy of the One Touch II Whole Blood Glucose Analyzer When Used by Analysts with Diverse Technical Backgrounds

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Background. The accuracy of hand-held analytical systems is dependent on the complexity of the instrument and the technical skills of the tester. We evaluated the analytical performance of the LifeScan One Touch II glucose analyzer when used by persons with various levels of technical skill and experience.

Methods. A medical technologist conducted tests on three One Touch II systems to ensure that the units were functioning properly. The technologist then trained six analysts (a physician, a registered nurse, a licensed practical nurse, a physician assistant, and two patients) in the proper use of the glucose analyzer.

Results. In the hands of a medical technologist, the precision of the three glucose analyzers tested was from 1.0% to 1.9% coefficient of variation (CV) and from 2.3% to 4.2% CV for the low- and high-quality control materials, respectively. The day-to-day precision (5-day period) was from 2.1% to 3.6% CV, and from 3.5% to 4.1% CV for the low- and high-quality control materials, respectively. Comparisons of the glucose values (n = 40 fresh patient serum samples) with a reference method yielded a correlation coefficient of 0.992 to 0.993, and an overall bias of −7%. Although the values obtained by the six operators were statistically different, the differences were not clinically relevant.

Conclusions. Our data suggest that the One Touch II glucose analyzer is a reliable system, and that its function is not dependent on the technical skills of the operator.

Key words. Blood glucose; blood glucose self-monitoring; technology, medical; reproducibility of results.
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Blood glucose monitoring has steadily increased over the last three decades as new technology has made it possible for testing to be done at the hospital bedside, the outpatient clinic, the physician's office, and even in the patient's own home. The ease of operation of these new-generation glucose analyzers and the increased reliability of the data obtained have resulted in more effective monitoring of patient blood glucose levels and enhanced patient motivation for compliance with therapy. Research has shown that most of the hand-held glucose analyzers are reliable and accurate.[1–5] However, closer inspection of these published studies reveals that these data were usually based on values obtained by trained technologists or chemists rather than actual end-users (ie, physicians, nurses, physician assistants, patients). Studies have shown that for many analytical systems, the quality of the data generated depends on the technical skills and background of the analyst.[6–9]

LifeScan Inc (Milpitas, Calif) has introduced a new-generation glucose analyzer that eliminates the need for the removal of excess specimen from the dry-reagent pad (the "wipe step"), which may reduce interindividual variation of results. According to the manufacturer, the glucose analyzer has an analytical range of 0 to 600 mg/dL (0 to 33.33 mmol/L) and is not affected by the hematocrit level if it is within 30% to 60%. Currently there are no analytical reports on the performance characteristics

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of this model. This study was conducted to examine the performance of the current One Touch II glucose analyzer in the hands of both trained laboratorians and typical users.

Methods

This study was done in three stages: (1) technologist familiarization phase, (2) instrument evaluation, and (3) field trials. The familiarization phase included in-service training of a medical technologist by a certified instructor from LifeScan Inc. Essentially, the One Touch II procedure is simple: (1) turn power switch to ON, (2) match the code numbers on the meter to the code number (lot number) on the test strip package, (3) insert the test strip into the meter, (4) add one rounded drop of specimen, (5) wait for the digital result to appear (45 seconds). The testing procedure was repeated until the technologist was able to obtain consistent results from two pools of control fluid, supplied by the manufacturer.

For the instrument evaluation stage, the medical technologist first evaluated the performance characteristics of each of three One Touch II glucose analyzers by following the protocol from the National Committee for Clinical Laboratory Standards (NCCLS).[10,11] To determine within-day and day-to-day precision, the One Touch low and high glucose control solutions were analyzed in duplicate four times per day over a 5-day period on each of the three glucometers. For accuracy studies, 40 fresh whole blood specimens (EDTA treated) were analyzed in duplicate on each of the One Touch II systems. The same 40 specimens were immediately centrifuged (2500 rpm for 10 minutes) to collect the plasma samples. Duplicate specimens were analyzed by the glucose oxidase reference method of the Cleveland Veterans Affairs Medical Center, using the Beckman Synchron CX7 system (Beckman Instruments, Inc, Brea, Calif). The plasma glucose values were divided by a factor of 1.12 to convert them to whole-blood glucose values to compensate for the 10% to 12% difference between the two sources of specimens.[12] The mean glucose values obtained by the One Touch II method were compared with the mean glucose values obtained by the glucose oxidase method, using the linear regression model.

For the final stage of the study, the medical technologist trained (for 15 minutes) six people (a physician, a registered nurse, a licensed practical nurse, a physician assistant, and two patients) using the same information and protocol provided by the manufacturer's instructor. None of the six operators had ever used the One Touch II system before. However, with the exception of the physician, all of the operators had used other glucose analyzers. All operators were monitored by the medical technologist for about 1 hour to allow the six operators to achieve proficiency before data for this study were collected. Each operator was then given the same two lots of control fluids and was told to analyze the specimens eight times each day for 5 days.

The mean values, standard deviation (SD), and coefficient of variation (CV) were calculated for each operator. The Student's *t* test and analysis of variance were used to compare the mean values.

Table 1. Accuracy Study with 40 Analyses Performed on Each of Three LifeScan One Touch II Glucose Analyzers

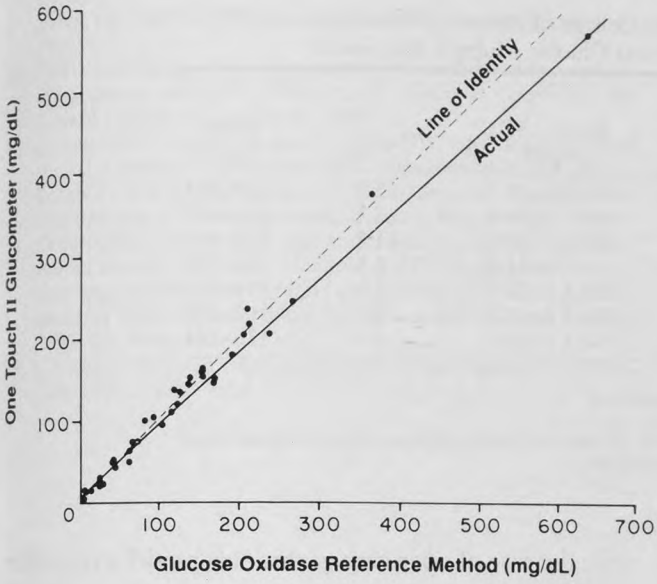
Unit	Linear Regression Equation	Range, mg/dL	Correlation Coefficient*
Analyzer 1	Y = 6.253 + 0.867X	4–582	.993
Analyzer 2	Y = 8.890 + 0.862X	5–573	.992
Analyzer 3	Y = 7.214 + 0.853X	4–574	.993

**Comparison of the One Touch II glucose analyzer with results from the oxidase reference method using the Synchron CX7 (Beckman Instruments, Inc, Brea, Calif).*

Results

The within-day precision for the three glucose analyzers was from 1.0% to 1.9% CV for the low-control pool (50.2 ± 0.7 mg/dL [2.79 ± 0.04 mmol/L]) and from 2.3% to 4.2% CV for the high-control pool (327.3 ± 10.7 mg/dL [18.17 ± 0.59 mmol/L]). The day-to-day precision for the three glucose analyzers was from 2.1% to 3.6% CV for the low-control pool and from 3.5% to 4.1% CV for the high-control pool. The Student's *t* test indicated that the mean glucose values for each glucose analyzer for both the high and low pools were not significantly different.

Accuracy studies on the three glucose analyzers indicated that the glucose values obtained for fresh patient specimens were very close to those obtained by the reference method (Table 1). Based on the linear regression equations, the glucose analyzers 1, 2, and 3 gave glucose values of 40.9, 43.4, and 41.3 mg/dL (2.27, 2.41, and 2.29 mmol/L), respectively, at a medical decision point of 40 mg/dL (2.22 mmol/L); at a medical decision point of 200 mg/dL (11.10 mmol/L), glucose analyzers 1, 2, and 3 gave glucose values of 179.7, 181.3, and 177.8 mg/dL (9.98, 10.06, and 9.87 mmol/L), respectively; at a normal glucose concentration (ie, 100 mg/dL [5.6 mmol/L]), glucose analyzers 1, 2, and 3 gave glucose values of 93.0, 95.1, and 92.5 mg/dL (5.16, 5.28, and 5.13 mmol/L), respectively. Thus, the overall bias at 40 mg/dL is about −4.75%; at 100 mg/dL, −6.6%; and at 200 mg/dL, −10.05%. A comparison of values obtained for 40 patients' fresh whole blood using



Linear regression curve comparing the whole blood glucose results for 40 patient specimens obtained using the One Touch II (LifeScan Inc, Milpitas, Calif) glucose analyzer (*y* axis) with glucose results obtained using the Beckman Synchron CX7 (Beckman Instruments, Inc, Brea, Calif) chemistry analyzer (*x* axis). The *line of identity* illustrates perfect correlation (r = 1.0) between the two methods; the *actual* line illustrates a correlation of r = .993.

the One Touch II analyzer and sera using the glucose oxidase method is shown in the Figure.

The results obtained by the six different operators are shown in Table 2. The day-to-day precision (5 days, n = 40) with the six operators ranged from 2.0% to 5.6% CV. According to the analysis of variance data, most of the mean values obtained by each operator were significantly different from the values obtained by the other operators for both levels of controls ($P < .05$). However, from a clinical standpoint, the mean values of each operator were very similar to each other. The means were statistically significant because the CVs were very small and a large number of replicate measurements (n = 40) were done.

Table 2. Comparison of Results Obtained by Six Operators with Limited Technical Backgrounds, Each Performing 40 Analyses Using the LifeScan One Touch II Glucose Analyzer

Analyst	Mean ± SD, mg/dL	CV, %
Low pool*		
Patient A	47.2 ± 1.1	2.3
Patient B	48.8 ± 1.0	2.0
Licensed practical nurse	49.9 ± 2.4	4.8
Registered nurse	48.4 ± 1.2	2.4
Physician assistant	52.1 ± 1.2	2.3
Physician	52.3 ± 1.3	2.5
High pool†		
Patient A	308.6 ± 8.4	2.7
Patient B	308.5 ± 13.4	4.3
Licensed practical nurse	323.3 ± 13.3	4.1
Registered nurse	322.2 ± 0.6	3.4
Physician assistant	328.5 ± 7.8	2.4
Physician	333.9 ± 18.8	5.6

**A medical decision point of 50 mg/dL (an extremely low blood glucose level) was used.*
†A medical decision point of 300 mg/dL (an extremely high blood glucose level) was used.
SD denotes standard deviation; CV, coefficient of variation.

Discussion

Our data suggest that the One Touch II glucose analyzer is reliable, and that its accuracy is not dependent on the technical skills and background of the operator. The three analyzers gave comparable glucose results. Precision for same-day and day-to-day results averaged 2.4% and 3.3% CV, respectively. This is in agreement with Frishman et al[3] and Buritt et al.[5] According to the policy statement published in *Diabetic Medicine*,[13] a precision of less than 5% CV is an acceptable performance goal for alternate-site (outside the laboratory) testing.

The overall bias of the three glucometers averaged −7% from the reference method values. If the one glucose value with a large negative bias (574 mg/dL) was removed and the data were recalculated, the linear regression equation for the rest of the 39 patient values would be $y = 2.234 + 0.991\ x$, $r = 0.991$ with an average overall bias of only 2.0%. Thus, up to about 375 mg/dL, glucose testing is very accurate with the One Touch II. According to the guidelines of the 1988 Clinical Laboratory Improvement Amendments (CLIA) for accuracy of glucose testing in the clinical laboratory, a target value (TV) ± 10% or TV ± 6 mg/dL (0.33 mmol/L), whichever is greater, is considered acceptable performance.[14] The 1986 Self-Monitoring of Blood Glucose Consensus Conference[15] recommended ±15% of the reference measurements as an acceptable performance range. According to our data, the One Touch II, currently a waived test, has met both the Consensus Conference guidelines and CLIA accuracy standards for the clinical laboratories.

We believe that the elimination of the "wipe step" makes this system more dependable and reproducible, and less dependent on the training and technical skills of the operator. The training time required is minimal (usually less than 15 minutes). This does not imply that training is not critical—quite the contrary. Proper specimen collection (ie, not milking the finger for sufficient whole blood), vigorously mixing the quality-control materials before analysis, making sure that the test strip lot number matches the meter code number, having adequate specimen placed on the test strip, and proper and regular maintenance and cleaning of the meter are five

Table 3. Whole Blood Glucose Results from the College of American Pathologists (CAP) Proficiency TestingSurveys: the 1992 Whole Blood Glucose Multiple Site Survey

Analyzer	No. of Laboratories Participating	Mean (±SD), mg/dL	CV, %	Range, mg/dL
Ames Glucometer II†	267	222.2 (±28.7)	12.9	132–313
Ames Glucometer 3†	263	245.7 (±32.5)	13.2	164–353
Ames Glucometer QA (film)†	2080	248.6 (±28.6)	11.5	159–342
BMD Accu-Chek II‡	4532	236.5 (±14.3)	6.0	194–273
BMD Accu-Chek III‡	1631	231.8 (±13.5)	5.8	194–273
LifeScan One Touch	1159	156.3 (±17.3)	11.1	108–208
LifeScan One Touch II	1298	146.1 (±12.6)	8.6	110–184

†Manufactured by Ames, Inc, Elkhart, Ind.
‡Manufactured by Boehringer-Mannheim Corporation, Indianapolis, Ind.
CV denotes coefficient of variation.
Adapted with permission from the College of American Pathologists.[16] All conclusions and interpretations in this article with respect to the CAP data base are those of the authors and not those of the College.

important requirements that, if neglected, can lead to inaccurate test results.

One way to illustrate the potential inaccuracy of glucose testing is to examine the results obtained from the College of American Pathologists (CAP) Proficiency Testing Survey (Table 3). CAP sends five unknown specimens three times a year to about 1800 laboratories and alternate-testing sites that do whole blood glucose measurements. The data indicate great variations within each peer group.[16] For example, at a glucose concentration level of about 220 mg/dL (12.21 mmol/L), the range of reported results from the Ames Glucometer II group was 132 to 313 mg/dL (7.33 to 17.37 mmol/L), the range from the BMD Accu-Chek II was 194 to 279 mg/dL (10.77 to 15.49 mmol/L), and the range from Lifescan One Touch II was 110 to 184 mg/dL (6.11 to 10.22 mmol/L). It should be emphasized that the reported ranges are established *after* removing outlier values (reported values greater than ±3 SD on two consecutive passes). Thus, many of these seemingly simple glucose devices require further technological improvements before reliable and accurate results can be achieved by typical operators. Some office laboratory testing has been shown to be sufficiently simple that school children were able to teach themselves how to perform the test and to obtain results as accurate as those obtained by clinical laboratory personnel.[17]

Conclusions

Our data suggest that the wipeless technology of the One Touch II places it among the new generation of glucose analyzers that can be considered more accurate and reliable than previous systems. This type of system is ideal for alternate-site testing where there are multiple operators with different technical backgrounds. However, despite the ease of operation of this new model, every effort must be made to ensure accurate measurement, maximal use of the data, and implementation of an effective quality assurance program.[18–21] There are numerous factors that must be considered in the purchase of an instrument system.[22] A system that allows the operator to obtain reliable results without having to undergo extensive training is a major step forward.

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