

Clinical accuracy and user acceptance of the OneTouch® UltraSmart™ Blood Glucose Monitoring System

Abstract

The clinical accuracy and ease of use of the OneTouch® UltraSmart™ Blood Glucose Monitoring System when used by 105 patients with diabetes were determined at three clinical sites. At each site, patients performed self-monitoring tests using capillary blood samples and results were compared to those obtained by a healthcare professional (HCP). Clinical accuracy was assessed for patients and HCPs by comparing meter values to plasma glucose results obtained from the same sample using a Yellow Springs Instruments Blood Glucose Analyzer (YSI). Patient results were equivalent to those obtained by the HCP. Using Clarke Error Grid Analysis, the results for clinical accuracy of the patient tests gave 96% of the results within Zone A (clinically accurate) and 4% in Zone B (benign or no treatment). System equivalence testing demonstrated that the OneTouch® UltraSmart™ and OneTouch® Ultra® Systems give equivalent glucose results on fingerstick capillary blood obtained from patients with diabetes. All patients were asked to evaluate the OneTouch® UltraSmart™ System by completing a user acceptance questionnaire regarding the ease of use and value of system features. The average ratings ranged from 3.6 to 4.9 out of a possible 5.0. Patients gave the system high ratings for ease of blood application, ease of detecting adequate blood volume, blood volume required, and test time.

Objective

The purposes of this clinical study were: 1) to assess the clinical accuracy of the new system and its equivalence to an existing meter system; 2) to estimate the user error of a new blood glucose monitoring system; and 3) to obtain patient feedback on the ease of use of the new system.

Methods

Study design

- During a single visit to one of three clinical trial sites, patients with diabetes and healthcare professionals evaluated the performance and ease of use of the OneTouch® UltraSmart™ System.

Clinical sites

- Henry Ford Health System, Detroit, Michigan
- Barbara Davis Center for Childhood Diseases, Denver, Colorado
- New England Diabetes and Endocrinology Center, Waltham, Massachusetts

Materials

- Three lots of OneTouch® Ultra® Test Strips were used for the study.
- Seven OneTouch® UltraSmart™ Meters and two OneTouch® Ultra® Meters were used in this study. The same meters were used at each clinical site.

Participants

- All study participants (patients) had experience performing routine self-monitoring of blood glucose (SMBG).
- The patients represented a wide range of age, education, and frequency of SMBG (Table 1).

Procedure

- Each patient performed a fingerstick and self-test of his or her blood glucose using only the product labeling as a guide. All self-tests were performed independently by the patient.
- An additional fingerstick was performed by the HCP, and the patient performed another self-test using the OneTouch® UltraSmart™ System.
- Using blood from the same fingerstick, the HCP tested the blood in duplicate on the OneTouch® UltraSmart™ System and the OneTouch® Ultra® System.
- Additional blood from the same fingerstick was collected into a heparinized tube for further analysis by the HCP.
- Analysis of whole blood included a single hematocrit measurement. The remaining specimen was then centrifuged and the resulting plasma was analyzed in duplicate using the YSI.
- All patients who participated in the clinical study were asked to complete a questionnaire about their experience with the OneTouch® UltraSmart™ System.

Table 1. Demographic summary of study participants

| | Site 1 | Site 2 | Site 3 |
|---------------------------------|--------|--------|--------|
| N | 35 | 35 | 35 |
| Gender | | | |
| Females (%) | 71 | 49 | 37 |
| Males (%) | 29 | 51 | 63 |
| Age (%) | | | |
| ≤ 10 years | 0 | 0 | 11 |
| 11–20 | 0 | 6 | 46 |
| 21–30 | 20 | 31 | 23 |
| 31–40 | 17 | 26 | 14 |
| 41–50 | 37 | 14 | 3 |
| 51–60 | 11 | 14 | 3 |
| 61–70 | 9 | 3 | 0 |
| 71–80 | 6 | 6 | 0 |
| > 80 | 0 | 0 | 0 |
| Median (years) | 43 | 34 | 17 |
| Range (years) | 22–71 | 19–79 | 9–57 |
| Education level (%) | | | |
| ≤ Elementary | 0 | 0 | 37 |
| Some high school | 0 | 3 | 17 |
| High school graduate | 23 | 14 | 9 |
| Some college | 43 | 29 | 20 |
| College degree | 20 | 37 | 11 |
| Graduate school/degree | 14 | 17 | 6 |
| Diabetes (years) | | | |
| Median | 11 | 20 | 9 |
| Range | 0.8–19 | 3–49 | 2–26 |
| Type of diabetes (%) | | | |
| Type 1 | 40 | 91 | 97 |
| Type 2 | 54 | 9 | 3 |
| Gestational/other | 6 | 0 | 0 |
| SMBG (years) | | | |
| Median | 15 | 20 | 9 |
| Range | 0.8–19 | 3–25 | 2–21 |
| Daily frequency SMBG (%) | | | |
| < 1 × | 17 | 3 | 0 |
| 1–2 × | 26 | 23 | 9 |
| 3–4 × | 29 | 43 | 31 |
| 5–6 × | 17 | 23 | 46 |
| ≥ 7 × | 11 | 8 | 14 |
| Other | 0 | 0 | 0 |

Analysis

- Clinical accuracy for HCP and patient testing was assessed using linear regression analysis and error grid analysis.¹
- User error was evaluated using partitioned bias analysis.²
- Equivalence of OneTouch® UltraSmart™ and OneTouch® Ultra® Systems was tested using Deming Regression Analysis.

Results

Clinical accuracy

- Linear regression analysis indicates good agreement between the OneTouch® UltraSmart™ System and YSI reference in both patient-performed tests and HCP-performed tests (Table 2).
- For patient testing, 101 (96%) of the 105 OneTouch® UltraSmart™ System results fell within Zone A, and the remaining 4 results fell within Zone B of the error grid (Figure 1).
- For HCP testing, 102 (97%) of the 105 OneTouch® UltraSmart™ System results fell within Zone A, and the remaining 3 results fell within Zone B of the error grid (Figure 1).

User error

- All 95% confidence intervals (CI) of bias estimated using the partitioned bias calculations include 0.0, indicating that the mean bias between patient tests and HCP tests is not significantly different from zero throughout the range of glucose concentrations tested (Table 3).

System equivalence

- The 95% confidence intervals of systematic difference at each medical decision level bracket 0.0, thus indicating a lack of statistically significant systematic differences at each glucose concentration (Table 4).

Patient acceptance evaluation

- Each patient answered a questionnaire about the experience with the OneTouch® UltraSmart™ System. Questions were selected to highlight key areas such as the blood testing procedure, handling, and overall ease of use. Patients were asked to rate each area on a scale of 1 to 5 (Figure 2).

Table 2. Linear regression analysis

| | Patient | HCP |
|---|------------------------|------------------------|
| <i>N</i> | 105 | 105 |
| Range (mg/dL) (mmol/L) | 47.9–445.0 2.7–24.7 | 47.8–445.0 2.6–24.7 |
| Slope | 0.881 | 0.906 |
| Intercept (mg/dL) (mmol/L) | 5.12 0.28 | 2.65 0.15 |
| <i>S</i> _{y,x} (mg/dL) (mmol/L) | 13.1 0.73 | 13.2 0.73 |
| <i>r</i> | 0.985 | 0.985 |

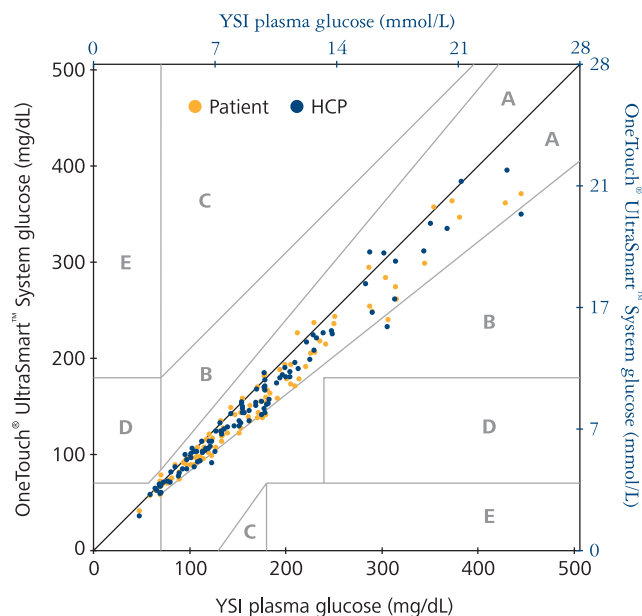
Table 3. Summary of partitioned bias results

| | Data range (mg/dL, mmol/L) | | |
|--------------------|-----------------------------|----------------------------|----------------------------|
| | 43–106 2.4–5.9 | 107–165 5.9–9.2 | 166–418 9.2–23.2 |
| <i>N</i> | 36 | 33 | 36 |
| Avg. of HCP values | 82.6 4.6 | 135.8 7.5 | 236.4 13.1 |
| Mean bias | 0.33 0.0 | -0.94 -0.1 | -2.94 -0.2 |
| Standard deviation | 5.67 0.3 | 8.84 0.5 | 20.81 1.2 |
| 95% CI biases | -1.58, 2.25 -0.088, 0.12 | -4.07, 2.20 -0.23, 0.12 | -9.99, 4.10 -0.56, 0.23 |

Table 4: Estimated mean bias of OneTouch® UltraSmart™ versus OneTouch® Ultra® at medical decision levels

| | Medical decision level (mg/dL, mmol/L) | | |
|----------------|--|----------------------------|----------------------------|
| | 70 3.9 | 180 10.0 | 240 13.3 |
| Mean bias | -1.01 -0.06 | -1.67 -0.09 | -2.03 -0.11 |
| 95% CI of bias | -2.38, 0.37 -0.13, 0.02 | -3.93, 0.60 -0.22, 0.03 | -5.63, 1.58 -0.32, 0.09 |

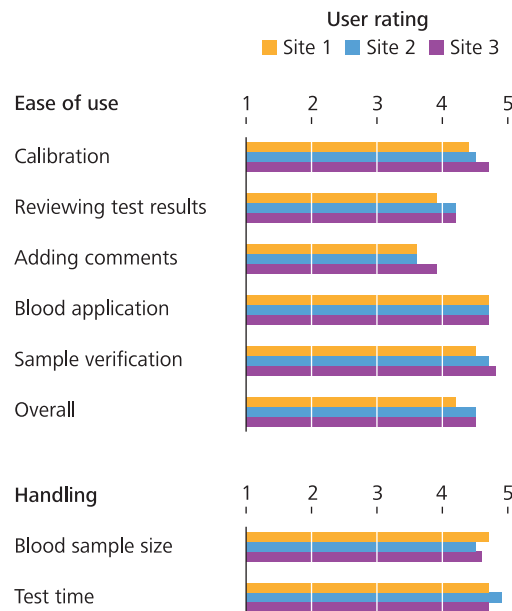
Figure 1. Error grid analysis of patient and HCP testing



Zone definitions

- Zone A: Clinically accurate.
- Zone B: Deviating from the reference method by more than 20% but would lead to benign or no treatment error.
- Zone C: Deviating from the reference method by more than 20% and would lead to unnecessary corrective treatment errors.
- Zone D: Potentially dangerous failure to detect and treat blood glucose levels outside of desired target range.
- Zone E: Would result in erroneous treatment.

Figure 2. Patient acceptance evaluation results



Conclusions

- The OneTouch® UltraSmart™ System produced clinically accurate results in the hands of patients with diabetes and healthcare professionals when compared to plasma glucose reference values.
- The results obtained using the OneTouch® UltraSmart™ System were equivalent to those obtained using the OneTouch® Ultra® System when used with the same lot of OneTouch® Ultra® Test Strips.
- Based on the questionnaire results, patients found the system easy to use and gave it high ratings for ease of blood application, ease of detecting adequate blood volume, blood volume required, and test time.

References

1. Clarke WL, Cox D, et al. Evaluating clinical accuracy of systems for self-monitoring of blood glucose. *Diabetes Care* 1987; 10:622–628.
2. National Committee for Clinical Laboratory Standards. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. NCCLS document EP9-A, 1995.

Acknowledgments

LifeScan acknowledges the major contributions of:

- Davida F. Kruger, MSN, APRN-BC, BC-ADM (Principal Investigator), at the Division of Endocrinology and Metabolism, Henry Ford Health System, Detroit, Michigan.
- Satish Garg, MD (Principal Investigator), at the Barbara Davis Center for Childhood Diseases, University of Colorado Health Sciences Center, Denver, Colorado.
- Stuart Brink, MD (Principal Investigator), at the New England Diabetes and Endocrinology Center, Waltham, Massachusetts.