

Analysis Article on the Performance Analysis of the OneTouch® UltraVue™ Blood Glucose Monitoring System

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Abstract

In this issue of *Journal of Diabetes Science and Technology*, Chang and colleagues present the analytical performance evaluation of the OneTouch® UltraVue™ blood glucose meter. This device is an advanced construction with a color display, used-strip ejector, no-button interface, and short assay time. Accuracy studies were performed using a YSI 2300 analyzer, considered the reference. Altogether, 349 pairs of results covering a wide range of blood glucose concentrations were analyzed. Patients with diabetes performed a significant part of the tests. Obtained results indicate good accuracy of OneTouch UltraVue blood glucose monitoring system, satisfying the International Organization for Standardization recommendations and thereby locating >95% of tests within zone A of the error grid. Results of the precision studies indicate good reproducibility of measurements. In conclusion, the evaluation of the OneTouch UltraVue meter revealed good analytical performance together with convenient handling useful for self-monitoring of blood glucose performed by elderly diabetes patients.

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The results reported by Chang and colleagues¹ in this issue of *Journal of Diabetes Science and Technology* characterize the analytical performance of the OneTouch® UltraVue™ blood glucose meter. This device, recently marketed by LifeScan, Inc., represents an advanced construction with a color display, used-strip ejector, no-button interface, and short 5 s assay time. The OneTouch UltraVue uses a well-known electrochemical measurement technique with a glucose oxidase method. Because of its convenient handling and simplicity of use, this glucose meter is designed for self-monitoring of blood glucose (SMBG) performed by elderly people with diabetes and possibly impaired eyesight or neurological problems. Chang and coworkers, in a very well-designed study, evaluated the meter's analytical performance on the

basic level, including assessment of accuracy and imprecision. The obtained results indicate good accuracy of glucose concentrations measurements performed by the OneTouch UltraVue meter as compared to the YSI 2300 analyzer, considered the reference. It is noteworthy that accuracy was evaluated using two series of samples amounting to 113 and 236 specimens of fresh capillary blood, respectively. Analysis included altogether 349 pairs of results covering a wide range of blood glucose concentrations. It is also important that health care professionals and patients with diabetes performed measurements of glucose concentrations using an evaluated glucose meter. Data obtained using linear regression analysis, correlation coefficients, difference plots, and error grid analysis indicate good accuracy

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Abbreviations: (CV) coefficient of variation, (SMBG) self-monitoring of blood glucose

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of the OneTouch UltraVue blood glucose system (meter and test strips), satisfying the International Organization for Standardization recommendations and thereby locating >95% of tests within zone A of the error grid, indicating accuracy bias below 20% without any clinical consequences.

Two aspects of accuracy studies have to be stressed. First, good accuracy of results obtained by patients with diabetes indicates reliability and robustness of the electrochemical measuring system and the glucose monitoring system as the whole, thus avoiding user-dependent errors. The next reason can be education of patients participating in the study. Poorer accuracy of results obtained by patient-operated glucose meters has been reported in several studies.²⁻⁴ Second, the good accuracy of results in the low glucose concentration range, below 75 mg/dL, accurate measuring of low glucose levels, and thereby reliable detection of hypoglycemia has been a problem for many glucose meters for many years.⁵ Furthermore, difference plots also clearly demonstrate the acceptable bias level for higher glucose concentrations.

For accuracy studies, the authors used several glucose meters and three lots of test strips for each series of samples. However, this evaluation could be supplemented by direct comparison of the results obtained in the same sample material using test strips from different lots to assess lot-to-lot variability. Such variability has been demonstrated for glucose meters and test strips.^{3,6}

Blood samples selected for the studies were within the OneTouch UltraVue specific hematocrit range of 30% to 55%. This should be properly understood, however. It means that, across this hematocrit range, the accuracy of tests is not significantly affected. In fact, there is a linear relationship between hematocrit value and the accuracy bias.⁷ In the case of the OneTouch UltraVue meter, it could be evaluated in further studies.

Results of the imprecision studies indicate good reproducibility of measurements. The within-day imprecision assessment yielded, for samples with glucose concentrations <100 mg/dL, standard deviation values below 1.5 mg/dL and, for samples with glucose levels >100 mg/dL, coefficient of variation (CV) values below 2.0%. The between-day imprecision studies, although performed using aqueous glucose solutions, yielded similar results. Altogether, observed reproducibility of measurements performed using the OneTouch UltraVue meets some of the analytical quality recommendations requiring imprecision CV less than 5%.

In conclusion, evaluation of the OneTouch UltraVue revealed good analytical performance of this blood glucose monitoring system operated both by health care professionals and the diabetes patients. Accuracy and imprecision characteristics of the evaluated meter meets current recommendations for analytical quality. It should be stressed that such a high level of analytical quality was maintained in a blood glucose monitoring system that provided comfort and simplicity of handling and use. Such a glucose meter can increase availability and reliability of SMBG among elderly patients, including those with diabetes complications.

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