Clinical Performance of the BioScanner 2000™ and the Cholestech L•D•X® System Compared to a Clinical Diagnostic Laboratory Reference Method for the Determination of Lipid Profiles

Abstract

BioScanner 2000 and Cholestech L•D•X System are rapid, point-of-care methods that measure total cholesterol (TC), HDL cholesterol (HDL-C), triglycerides (TRG), and glucose (GLU) in fingerstick samples. In the present study, precision and accuracy of both methods were assessed and compared with a clinical diagnostic laboratory reference method. Fingerstick specimens were obtained from healthy donors. Precision coefficients of variation (CVs) ranged between 6.9% and 9.1% for the BioScanner 2000 and between 2.1% and 6.5% for the Cholestech L•D•X Analyzer. TC, HDL-C, TRG, and LDL-C values obtained with the Cholestech L•D•X Analyzer were in complete clinical agreement with the reference method. The Cholestech L•D•X System appears to provide lipid profile results that are more reproducible and accurate than those obtained with the BioScanner 2000.

Introduction

A fasting lipid profile consisting of total cholesterol, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, and triglycerides should be measured every five years in all adults aged 20 years or older.1 Individuals with diabetes have as high a risk for a major coronary event as individuals diagnosed with coronary heart disease (CHD).1 Rapid, point-of-care methods are available for obtaining lipid profile and glucose results from a fingerstick sample.

The BioScanner 2000 (Polymer Technology Systems) is a hand held, battery operated instrument that measures total cholesterol (TC), HDL cholesterol (HDL-C), triglycerides (TRG), and glucose (GLU). It is CLIA-waived for these tests. A fingerstick sample of blood is applied to a disposable, analyte-specific reagent test strip. The BioScanner 2000 uses reflectance photometry to measure the analyte concentration. To obtain a full lipid profile, test strips specific for each test must be assayed sequentially. Alternatively, four BioScanner 2000 instruments could be used, one for each analyte. Calculation of LDL cholesterol (LDL-C) must be done manually using the TC, HDL-C, and TRG values.

The Cholestech L•D•X is a small, lightweight analyzer designed for point-of-care lipid profile and glucose analysis. A fingerstick sample of blood is dispensed into a single, disposable cassette and the results are available in 5 minutes. The Cholestech L•D•X uses reflectance photometry to measure the analyte concentration. The TC, HDL-C, TRG and GLU tests are CLIA-waived for professional use. The analyzer automatically calculates LDL-C values.

The objective of the present study was to compare the precision and accuracy of the Cholestech L•D•X System and the BioScanner 2000 to clinical diagnostic laboratory reference methods (Synchron CX4CE, Beckman Coulter). The calibration of the Synchron CX4CE methods for TC, HDL-C, and TRG is traceable to the Centers for Disease Control and Prevention (CDC) reference methods for these analytes.

Methods

Four donors were recruited for the precision study. One donor was used for each analyte: TC, HDL-C, TRG, and GLU. Five sequential 35 µL capillary tubes were drawn by fingerstick from each donor and run on the Cholestech L•D•X Analyzer. At the same time, five sequential fingerstick samples were obtained from each donor for testing on the BioScanner 2000. Calculation of LDL-C precision was precluded since different donors were used for each analyte’s precision study. Because of the length of time necessary to run each test, more than one fingerstick was performed on each donor to complete the precision study on both analyzers.

Twenty donors were recruited for the accuracy study. Most (18 of 20) donors were nonfasting. Because GLU levels can vary significantly between capillary and venous blood after eating, comparisons with the reference method were not made. One or more fingersticks were performed on each donor. One sample was run on the Cholestech L•D•X Analyzer. At the same time samples were collected for TC, HDL-C and TRG on the BioScanner 2000. Because only one test can be run at a time on one BioScanner 2000, more than one fingerstick was performed on some donors. A venous sample was also drawn into a serum separator tube and TC, HDL-C and TRG were run on the Synchron CX4CE using the serum sample.

Precision was assessed by calculating coefficients of variation (CVs) from the mean and SD of results. Methods were compared using least squares linear regression and critical t-test values at 95% confidence limits. Results were evaluated for conformance to the National Cholesterol Education Program (NCEP)
guidelines for total error that take into account both the accuracy bias and precision of a method (Table 1). It is expected that 95% of all results will be within the total error guidelines when comparing methods that both meet NCEP total error guidelines. The NCEP guidelines apply to comparisons of the same sample by different methods, e.g. serum to serum comparisons. There will be additional variability when different sample types are compared, e.g. fingerstick to serum comparisons, even when the samples are drawn at the same time. Because fingerstick results were compared to serum results in this study, 25% was added to the total error guidelines to account for the increased variability due to the differences in sample type (Table 1).

Bias calculations for the difference between the reference and fingerstick methods enabled determination of conformance to NCEP total error guidelines for individual samples. Results were also evaluated for clinical agreement at medical decision cut-points defined by NCEP. The cut-points were 200 and 240 mg/dL for TC, 40 mg/dL for HDL-C, 150 and 200 mg/dL for TRG, and 130 and 190 mg/dL for LDL-C.

**Results**

Precision CVs of the four tests ranged between 6.9% and 9.1% for the BioScanner 2000 and between 2.1% and 6.5% for the Cholestech L•D•X System (Table 2). For each analyte, the CV obtained using the Cholestech L•D•X System was lower than the CV obtained with the BioScanner 2000.

The range of values tested for each analyte is as follows: TC, 120–268 mg/dL, HDL-C, 33–82 mg/dL, TRG, 52–348 mg/dL. Correlation coefficients for comparisons between the fingerstick methods and the reference methods were generally in good agreement, except for LDL-C by BioScanner 2000 (Table 3). However, critical \( t \) values for BioScanner 2000 compared with the reference methods indicated that the results were statistically different (Table 3). BioScanner 2000 results exceeded NCEP total error guidelines two to eleven times more frequently than did Cholestech L•D•X results. None of the Cholestech L•D•X individual values resulted in clinical misclassification whereas 13 (out of 20) of the BioScanner 2000 values did (Table 3).
Discussion

In the present study, two rapid, point-of-care methods for measuring lipid profiles and glucose were compared. Both methods were reproducible when repeated measurements were made in individual subjects. However, the Cholestech L•D•X System was generally more reproducible than was the BioScanner 2000.

Some individual TC, HDL-C, TRG, and LDL-C values obtained with both methods exceeded the NCEP total error guidelines when comparisons were made with the reference method. Total error exceptions occurred two to eleven times more frequently with the BioScanner 2000 than occurred with the Cholestech L•D•X. Factoring in the difference in sample type (fingerstick vs. serum) reduced or eliminated the total error exceptions for the Cholestech L•D•X and slightly reduced them for the BioScanner 2000. Five percent of values, or one of the 20 samples in this study, are expected to exceed total error guidelines. For Cholestech L•D•X, one additional sample exceeded the total error for HDL-C and TRG. For the BioScanner 2000, 48% of all lipid values exceeded the total error. It should be noted that the total error of the reference method contributes to these analyses. Each serum sample was measured only once using the reference method. That method is subject to the same types of analytical errors that contribute to errors in the rapid, fingerstick methods.

A further analysis of accuracy between the methods indicated that lipid profile values obtained with the Cholestech L•D•X System were in complete clinical agreement with the reference method. 25% of the TC values, 20% of the HDL-C values, and 20% of the LDL-C values obtained with the BioScanner 2000 disagreed with the reference method. These results would be considered as clinical misclassifications if the reference methods were used as the gold standard.

Operators in this comparison study noted some additional differences between the two rapid, fingerstick methods. Once the capillary tube of blood is obtained and dispensed into the Cholestech L•D•X test cassette, pressing “run” is the last operator involvement until results for all four tests are completed. Test results are then printed on labels that can be applied to the patient’s medical record and given to the patient with educational materials. For the BioScanner 2000, a separate test strip and drop of blood is required for each test. The analyzer also requires a unique memory chip for each test. Thus, though each test takes approximately one minute, operator involvement is continuous for the entire period of obtaining results for all four tests. Operator involvement might be reduced somewhat if four BioScanner 2000s were employed, though at increased expense. In addition, the BioScanner 2000’s lack of both a printout and automatic calculation of LDL-C values could result in transcription and/or mathematical errors when patient values are transferred to their medical record.

In summary, the Cholestech L•D•X System appears to provide lipid profile results that are more reproducible and accurate than those obtained with the BioScanner 2000. In addition, the Cholestech L•D•X System offers rapid, walk-away convenience for healthcare professionals.

References


