Technical Brief

Accuracy of Two Rapid, Fingerstick Methods for Measuring LDL Cholesterol

Abstract

The CardioChek P.A™ and the Cholestech LDX® System are rapid, point-of-care testing methods that measure total cholesterol, HDL cholesterol, and triglycerides, and both will automatically calculate LDL cholesterol (LDL-C). In the present study, accuracy of both methods was assessed and compared with a clinical diagnostic laboratory reference method. Fingerstick samples and venous whole blood specimens were obtained from 22 random patients. The mean bias of the calculated LDL-C value with the Cholestech LDX was a -4.0%; it was 50.4% for the CardioChek P.A. 17 (out of 22) of the LDL-C values obtained with the CardioChek P.A exceeded NCEP total error guidelines with 16 patients' results being clinically misclassified. The Cholestech LDX System appears to provide lipid profile results that are more accurate than those obtained with the CardioChek P.A.

Introduction

The National Cholesterol Education Program's Adult Treatment Panel III (NCEP ATP III) Guidelines have identified LDL cholesterol (LDL-C) as the primary target of cholesterol-lowering therapy. A basic principle of prevention is that the intensity of risk-reduction therapy should be adjusted to a person's absolute risk. Risk assessment requires accurate measurement of LDL-C as part of lipoprotein analysis and identification of accompanying risk determinants.[1] Accurate LDL-C measurements are essential for managing patients requiring lifestyle or drug therapy.

The CardioChek P.A (Polymer Technology Systems, Inc.) is a hand held, battery operated analyzer that measures total cholesterol (TC), HDL cholesterol (HDL-C), and triglycerides (TRG) and calculates LDL-C values. A whole blood sample is applied to a disposable reagent test strip. The CardioChek P.A uses reflectance photometry to measure the analyte concentration.

The Cholestech LDX (Cholestech Corp.) is a small, lightweight analyzer designed for POCT lipid profile analysis. A whole blood sample is dispensed into a single, disposable cassette. The Cholestech LDX uses reflectance photometry to measure the analyte concentration. The analyzer automatically calculates LDL-C values.

The objective of the present study was to compare the accuracy of the Cholestech LDX System and the CardioChek P.A to clinical diagnostic laboratory reference methods (Synchron CX®4CE, Beckman Coulter, Inc.). 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.

Method

Fingerstick samples and venous whole blood samples were collected from 22 random volunteers at Phoebe Putney Memorial Hospital (Albany, GA). The fingerstick samples were analyzed on both the Cholestech LDX and the CardioChek P.A analyzers. The venous whole blood samples were centrifuged and the serum isolated for analysis on the Synchron CX4CE. All samples were analyzed for TC, HDL-C, and TRG. The LDL-C was calculated for all methods based on the Friedewald equation.

Results were evaluated for conformance to NCEP guidelines for total error (TE) that take into account both the accuracy bias and precision of a method.[2,3] These TE guidelines are ≤ 8.9% for TC, ≤ 13% for HDL-C, ≤ 15% for TRG, and ≤ 12% for LDL-C.

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 whole blood results were compared to venous serum results in this study, 15% was added to the TE guidelines to account for increased variability due to the difference in sample type.

Bias calculations for the difference between the reference and rapid 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.[1] 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 100, 130, 160, and 190 mg/dL for LDL-C.

Table. Accuracy of Point-of-care Methods for a Lipid Profile Compared to Reference Methods

Analyte	Comparison of Reference vs.	R	Mean Bias (%)	> NCEP TE (N)	> NCEP TE +15% (N)	Clinical Misclassification (N)
TC	CardioChek P.A.	0.49	20.6	19	18	10
	Cholestech LDX	0.97	-3.8	1	1	0
HDL-C	CardioChek P.A.	0.91	-4.5	5	5	0
	Cholestech LDX	0.98	-4.7	3	1	0
TRG	CardioChek P.A.	0.98	-10.8	7	6	1
	Cholestech LDX	0.96	-0.6	1	1	0
LDL-C	CardioChek P.A.	0.85	50.4	18	18	16
	Cholestech LDX	0.95	-4.0	5	2	0

Results

Analyte values ranged from 126–272 mg/dL for TC, 30–122 mg/dL for HDL-C, and 64–409 mg/dL for TRG. Correlation coefficients and bias assessments for comparisons between the reference methods and the Cholestech LDX were in excellent agreement, but were in weaker agreement for the CardioChek P.A (Table).

Cholestech LDX LDL-C values had a mean bias of -4.0% versus the reference method. The CardioChek P.A had a mean bias of 50.4%. CardioChek P.A results exceeded NCEP total error guidelines for one or more tests in all of the samples overall. 18 (out of 22) of the calculated LDL-C values from the CardioChek P.A exceeded total error guidelines relaxed to allow for differences between fingerstick and serum. These biases led to 16 patients' results being clinically misclassified.

Discussion

The NCEP ATP III Guidelines have identified elevated LDL-C as the primary target of cholesterol-lowering therapy. As a result, the primary goals of therapy and the cut-points for initiating treatments are stated in terms of LDL-C.[1] Accurate measurement of LDL-C is essential for risk assessment and patient management.

Significant bias in the LDL-C values obtained using the CardioChek P.A led to clinical misclassification in almost three-fourths of the individuals tested if the reference methods were considered the gold standard. This bias appears to be largely due to errors in TC measurement. By contrast, the modest bias of Cholestech LDX values for all analytes did not result in any clinical misclassifications.

In summary, the Cholestech LDX System appears to provide lipid profile results that can be used for risk assessment and patient management. The CardioChek P.A appears to be clinically inaccurate.

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References

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