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Clinical Utility of a Fingerstick Technology to Identify Individuals With Abnormal Blood Lipids and High-Sensitivity C-Reactive Protein Levels

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Abstract

Purpose—The purpose of this study was to determine the ability of a commonly used fingerstick technology to identify individuals with abnormal blood levels of total cholesterol (TC), calculated low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides (TG), and high-sensitivity C-reactive protein (hsCRP) compared with a standardized laboratory.

Methods—Participants (n = 250; mean age, 48.0 ± 13.5 years; 66% female; 36% nonwhite) were eligible for primary prevention of cardiovascular disease (CVD). Blood lipids and hsCRP were measured simultaneously by (1) fingerstick analyzed by Cholestech LDX analyzers and (2) fresh venous blood that was analyzed by Columbia University General Clinical Research Center (GCRC) Core Laboratory. Pearson correlation coefficients, kappa, sensitivity, and specificity were calculated for fingerstick versus GCRC laboratory values for lipids and hsCRP.

Results—The correlations between fingerstick and core laboratory for TC, LDL-C, HDL-C, TG, and hsCRP were .91, .88, .77, .93, and .81, respectively (all $p < .01$). Sensitivity and specificity of the fingerstick to identify those with abnormal lipids and hsCRP ≥ 1 mg/L were all ≥75%.

Conclusion—Fingerstick screening is accurate and has good clinical utility to identify persons with abnormal blood lipids and hsCRP at the point of care in a diverse population that is eligible for primary prevention of CVD. These results may not be generalizable to patients at high risk for CVD or who have known hyperlipidemia.

Keywords

CVD Prevention; CVD Screening; Fingerstick Technology; Hypercholesterolemia; C-Reactive Protein; Lipid Measurement. Manuscript format: research; Research purpose: instrument development; Study design: cross-sectional analysis; Outcome measure: correlation coefficient; sensitivity/specificity; Setting: clinical/health care; Health focus: screening and education; Strategy: education; Target population age: adults; Target population circumstances: race/ethnicity

Purpose

The National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP III) guidelines[1] stress the importance of cholesterol screening to identify and manage patients with hypercholesterolemia. It is recommended that all adults older than 20 years have a full blood lipid profile, including total cholesterol (TC), triglycerides (TG), high-density lipoprotein

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cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C), assessed every 5 years, or more frequently if an abnormal value is detected. In addition, high-sensitivity C-reactive protein (hsCRP) assessment has been recommended for patients who fall into an intermediate-risk category in which the result might be used to guide further evaluation and therapy.[2]

Point-of-care screening for abnormal blood lipid and hsCRP values provides immediate patient education, could facilitate communication of risk, and may increase adherence to national guidelines. Fingerstick measurement is a point-of-service assessment tool commonly used in clinical, community, and other health promotion settings. Accuracy and precision of fingerstick measurements by using Cholestech LDX to assess blood lipids have been examined in previous studies.[3–7] However, the clinical utility of using fingerstick technology to screen individuals as adherent or nonadherent to ATP III lipid guidelines has not been established in diverse community or clinical settings, nor has its use for classifying patients as having abnormal vs. normal hsCRP concentrations been assessed. The purpose of this study was to evaluate the ability of a commonly used point-of-care fingerstick assessment tool to identify abnormal blood lipid and hsCRP values in a diverse group of individuals who were eligible for primary prevention of cardiovascular disease (CVD).

Methods

Design

This study is a cross-sectional analysis of baseline data of 250 participants who were randomized to the screening/educational intervention arm of the National Heart, Lung, and Blood Institute-sponsored Family Intervention Trial for Heart Health. This research study was reviewed and approved by the Columbia University Medical Center Institutional Review Board. Cholestech Corporation (Hayward, CA) provided in-kind donations of fingerstick technology.

Sample

Participants were family members or cohabitants of patients hospitalized with CVD and were eligible to participate if they were between 20 and 79 years of age, did not have established CVD or diabetes themselves, and spoke either English or Spanish. Potential participants were excluded if they had end-stage renal disease, liver disease, or known or suspected malignancy with a life expectancy less than 5 years. Baseline data collection was conducted between January 2005 and June 2007. All participants signed written informed consent.

Measures

At the baseline study visit, all participants underwent concurrent fasting capillary blood sampling obtained by fingerstick and venous blood draw. Fresh venous blood was analyzed by the Columbia University General Clinical Research Center (GCRC) core laboratory by using standard methods for serum lipids[8] and ultrasensitive enzyme-linked immunoassay (ELISA) for hsCRP. Capillary samples were analyzed for blood lipid and hsCRP concentrations by Cholestech LDX (Hayward, Calif) technology. Point-of-care values were available within 5 minutes, and participants were informed of their results by trained health educators at the same visit. Additionally, each participant's results were forwarded to his or her primary care provider.

Analysis

Means and proportions were used to describe participant characteristics. ATP III guidelines[1] were used to define abnormal serum cholesterol values: (1) TC ≥ 200 mg/dL, (2) TG ≥ 150 mg/dL, (3) HDL-C < 40 mg/dL, (4) LDL-C ≥ 130 mg/dL (borderline high), and (5) LDL-C ≥

100 mg/dL (above optimal). American Heart Association and Centers for Disease Control and Prevention standardized cut-points were used to define above optimal (≥1 mg/L but <10 mg/L) and high (≥3 mg/L but <10 mg/L) serum hsCRP concentrations.[2]

Blood lipid and hsCRP values were assessed for normality, and Pearson correlation coefficients were calculated to assess reliability of continuous TC, TG, HDL-C, LDL-C, and hsCRP values obtained by Cholestech LDX against the core laboratory. The hsCRP values ≥ 10 mg/L were excluded from correlation analysis, because hsCRP levels elevated greater than this number may not reflect a CVD risk factor but rather an underlying process, such as chronic disease or inflammation.[2] Kappa statistics were calculated to assess categorical agreement between the core laboratory and the Cholestech LDX analyzer in classifying participants as having abnormal blood lipid or hsCRP results. A good or strong positive correlation coefficient was defined as ≥.7. Kappa values between .4 and .75 were defined as fair to good agreement, and values >.75 were defined as excellent agreement.

Sensitivity of the fingerstick measurements to categorize a participant as having an abnormal blood lipid or hsCRP result was calculated separately for each variable by taking the total number of participants who were assessed as having an abnormal value for that variable by both the core laboratory and fingerstick analysis and dividing by the total number assessed as abnormal by the core laboratory. Similarly, specificity of fingerstick technology to categorize participants as having an abnormal blood lipid or hsCRP result was calculated by taking the total number of participants assessed as having an abnormal value for that variable by both the core laboratory and fingerstick analysis and dividing by the total number identified as abnormal by the core laboratory. Statistical analysis was performed using SAS statistical software version 9.1 (SAS Institute, Inc., Cary, NC).[9]

Results

Participants had a mean [standard deviation] age of 48.0 [±13.5]; 66% were female; and 36% were nonwhite (Table 1). Pearson correlation coefficients between core laboratory and fingerstick measurements were good with all correlations ≥ .77 and were statistically significant ($p < .01$; Table 2). The Pearson correlation coefficient for hsCRP was .81 ($p < .0001$).

Categorical agreement between fingerstick analysis and the core laboratory was good to excellent for most lipids (Table 2): TC ≥ 200 mg/dL ($k = .75$), TG ≥ 150 mg/dL ($k = .78$), LDL-C ≥ 100 mg/dL ($k = .69$), and LDL-C ≥ 130 mg/dL ($k = .69$). Categorical agreement was fair for HDL-C at <40 mg/dL ($k = .40$). Agreement for hsCRP was fair and was the same ($k = .58$) for both the high and above-optimal cutoffs.

At a clinical cut-point of TC ≥ 200 mg/dL, the fingerstick measurement had 79% sensitivity to categorize participants as having abnormal cholesterol and 95% specificity to categorize participants as having normal cholesterol levels. Sensitivity to identify abnormal values was ≥ 76% for all categories of lipids, 75% for hsCRP ≥ 1 mg/L, and 56% for hsCRP ≥ 3 mg/L but <10 mg/L. Specificity to classify participants as meeting clinical guidelines was ≥ 78% for all categories of lipids, 95% for hsCRP ≥ 1 mg/L, and 99% for hsCRP ≥ 3 mg/L but <10 mg/L (Table 2).

Conclusion

Summary

Our data show that there is good agreement between a point-of-care fingerstick technology commonly used in health promotion settings compared with a university core laboratory in categorizing individuals as adherent or nonadherent to ATP III lipid cut-points and as having

abnormal hsCRP values. The sensitivity of fingerstick screening to categorize patients as adherent to ATP III lipid cut-points was ≥76% for TC, HDL-C, LDL-C, and TG. The sensitivity of categorizing patients with hsCRP ≥ 1 mg/L was 75% but was less sensitive for hsCRP ≥ 3 mg/L but <10 mg/L. There have been few, if any, studies of the validity of fingerstick technology for assessing hsCRP concentrations.

Our data are consistent with prior research, which investigated point-of-care Cholestech LDX evaluation of blood lipids for accuracy and precision in smaller and select patient populations but were not designed as real-world screening studies. Of five studies,[3–7] the largest one included 100 patients; in all of these studies, the correlation coefficient, percent bias, and coefficient of variation showed that Cholestech fingerstick measurements met accuracy and precision definitions set by the NCEP[8] for TC, TG, and HDL-C. Prior instruments have analyzed fingerstick measurements of lipids but have not been shown to meet NCEP guidelines of precision and accuracy for lipid measurement[10]; comparisons, therefore, were not drawn with our results. Our study demonstrates the validity of using Cholestech LDX fingerstick analysis to identify abnormal blood lipids and hsCRP in a heterogeneous clinical population.

More than one hundred million Americans older than 20 years have total blood cholesterol levels > 200 mg/dL, and one third of American adults have LDL-C > 130 mg/dL.[11] Given the large percentage of the population with abnormal risk factors for CVD and the potential barriers to screening, point-of-care technology can provide immediate and accurate results at a teachable moment for patients who have an increased risk for CVD.

Limitations

Although the results of this study are encouraging for the use of point-of-care technology for screening, there are some limitations of using this clinical screening tool. Previous work has examined the role of using fingerstick technology to assess CVD risk in a high-risk population of patients ≥ 70 years with known hyperlipidemia[12] and has found significant variability of fingerstick analysis in blood lipid determination for LDL-C and HDL-C. Because individuals who have known CVD or who are at high-risk for CVD were excluded from our study, our results may not be generalizable to this population. However, the participants in our study had a broad range of blood lipids, and more than 70% had an LDL ≥ 100 mg/dL, which suggests that our findings may be robust with respect to populations likely to have dyslipidemia. Our goal was to evaluate this technology as a screening tool; we therefore evaluated accuracy with respect to specific clinical endpoints. We cannot draw conclusions regarding the clinical utility for use in ongoing management and treatment decisions.

Future investigations for the role of fingerstick analysis include how well screening improves serum lipid control and the use and accuracy of this technology in following patients with hyperlipidemia in a clinical setting. Fingerstick analysis of blood lipids and hsCRP can help identify and screen a diverse group of patients at risk for CVD, can promote patient education, and can assist in their management at the point of care.

Significance

Our study illustrates that point-of-care fingerstick technology accurately identifies patients with abnormal blood lipid and hsCRP concentrations and is appropriate to use in health promotion and screening programs. Point-of-care testing can be conducted in diverse clinical and outreach settings, and it provides immediate cardiovascular risk stratification as well as concurrent patient feedback and education.

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Table 1

Participant Characteristics (N = 250)

Characteristic	%
Age ≥ 65 y*	12.0
Female	66.0
Race/ethnicity	
White	64.4
Black	5.6
Hispanic	25.6
Other	4.4
Core Laboratory	
Total cholesterol ≥ 200 mg/dL	49.2
Calculated LDL-C ≥ 100 mg/dL†	73.4
Calculated LDL-C ≥ 130 mg/dL†	38.0
HDL-C < 40 mg/dL†	10.8
Triglycerides ≥ 150 mg/dL	20.8
High Sensitivity C-Reactive Protein ≥ 1 mg/L‡	65.2
High Sensitivity C-Reactive Protein ≥ 3 mg/L‡	34.8
Age, y, Mean (SD)	48.0 (13.5)

*Mean age was 48.0 y (standard deviation, 13.5).

†LDL-C indicates low-density lipoprotein cholesterol; and HDL-C, high-density lipoprotein cholesterol.

‡Values ≥ 10 mg/L were excluded.

Table 2

Comparison of Lipid and hsCRP Measures Using Fingerstick Screening vs. Venous Samples Analyzed in Core Laboratory

Risk Factor	Correlation (*r*)	Clinical Cut-Point[†]	Sensitivity (%)	Specificity (%)	Kappa (κ)
Total cholesterol	0.91[*]	≥ 200 mg/dL	79	95	.75
LDL-C[‡]	0.88[*]	≥ 100 mg/dL	93	82	.75
		≥ 130 mg/dL	76	92	.69
HDL-C[‡]	0.77[*]	< 40 mg/dL	93	78	.40
Triglycerides[‡]	0.93[*]	≥ 150 mg/dL	88	93	.78
hsCRP[‡,§]	0.81[*]	≥ 1 mg/L	75	95	.58
		≥ 3 mg/L	56	99	.58

[†]Clinical cut-points were based on recommendations of the National Cholesterol Education Program Adult Treatment Panel III for blood lipids and the American Heart Association/Centers for Disease Control and Prevention for hsCRP.[1–2]

[‡]LDL-C indicates low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; hsCRP, high sensitivity C-reactive protein.

[§]hsCRP values ≥ 10 mg/L were excluded from analysis.

[*]$p < 0.01$.