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Short Communication

Point-of-care testing to promote cardiovascular disease risk assessment: A proof of concept study

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ABSTRACT

Updated cholesterol guidelines emphasize multivariable cardiovascular disease (CVD) risk estimation to guide treatment decision-making in primary prevention. This study tested the preliminary feasibility, acceptability and efficacy of point-of-care testing (POCT) and quantitative CVD risk assessment in high-risk adults to increase guideline-recommended statin use in primary prevention. Participants were aged 40–75 years, without CVD or diabetes mellitus, and potentially-eligible for consideration of statins based on estimated 10-year CVD risk from last-measured risk factor levels in the electronic health record. We performed POCT to facilitate quantitative CVD risk assessment with the Pooled Cohort Equations immediately before a scheduled primary care provider (PCP) visit. Outcomes were: physician documentation of a CVD risk discussion and statin prescription on the study date. We also assessed acceptability of the intervention through structured questionnaire. We recruited 18 participants (8 from an academic practice and 10 from a federally-qualified health clinic). After the intervention, 83% of participants discussed CVD risk with their PCP, 47% received a statin recommendation from their PCP, and 29% received a new statin prescription during the PCP visit. Participants reported high levels of satisfaction with the intervention. This study demonstrates that in initial testing pre-visit POCT and quantitative CVD risk assessment appears to be a feasible and acceptable intervention that may promote guideline-recommended statin initiation in primary prevention. Future research with an adequately powered trial is warranted to determine the effectiveness of this approach in clinical practice.

1. Introduction

In 2013 the American College of Cardiology (ACC) and American Heart Association (AHA) released updated cholesterol guidelines for the prevention of atherosclerotic cardiovascular disease (CVD) (Stone et al., 2014). These guidelines eliminated cholesterol goals and instead identified evidence-based CVD risk thresholds to guide clinician-patient decision-making for statin initiation in primary prevention, a shift that has been recognized as the next paradigm in "personalized" CVD prevention (Robinson and Ray, 2016). This approach requires estimating 10-year CVD risk from multiple traditional risk factors including laboratory values like total cholesterol and high-density lipoprotein cholesterol to guide risk assessment and treatment discussions. However, there are many practical barriers to risk-based prevention such as availability of blood test results at the time of consultation, time required for risk factor measurement and absolute risk estimation, and poor integration of these steps into clinic workflow (van Steenkiste et al., 2004). These barriers contribute to missed opportunities for optimal primary prevention, especially among adults at increased CVD risk (Pokharel et al., 2017).

Point-of-care testing (POCT) is a promising technology to promote personalized CVD prevention (King et al., 2016). POCT provides rapid blood test results at the time of physician consultation to facilitate integration of these results into clinical decision-making (Gialamas et al., 2010). Traditionally, studies evaluating POCT have focused on diagnostic test accuracy or acute care decision-making in emergency settings, but there is growing interest in their application to primary care (St John, 2010). Systematic reviews of the literature, however, identify limited high quality evidence to guide its application in primary care (Gialamas et al., 2010), and a recent Cochrane systematic review of strategies for implementing CVD risk scores in clinical practice identified no studies that utilized POCT for this purpose (Karmali et al., 2017).

Abbreviations: CVD, cardiovascular disease; POCT, point-of-care testing; FQHC, federally-qualified health center; PCP, primary care provider; ACC, American College of Cardiology; AHA, American Heart Association; EHR, electronic health record.

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In light of this limited evidence, we performed a study to determine the preliminary feasibility, acceptability, and efficacy of pre-visit POCT and quantitative CVD risk assessment immediately before a routinely scheduled primary care provider (PCP) visit among high-risk adults.

2. Methods

2.1. Study design

This was an uncontrolled study in which participants received pre-visit, quantitative CVD risk assessment facilitated by POCT between July–October 2014. Outcomes were assessed by manual chart review after the study visit. The Institutional Review Board of Northwestern University and the participating federally qualified health center's (FQHC) research committee approved the study.

2.2. Settings and participants

We performed this study at the Northwestern Medicine faculty general medicine practice and a federally-qualified health clinic (FQHC) in Chicago, IL. Both sites had electronic health records (EHR) that could be used to calculate 10-year predicted CVD risk. We included men and women with: (1) age 40 to 75 years, (2) ≥2 clinic visits in the past 2 years, and (3) a scheduled PCP visit during the recruitment period, and (4) 10-year CVD risk ≥ 10% based on last measured risk factor levels in the EHR. For patients with measured lipid values in the past 2 years, we used the Pooled Cohort Equations (Goff et al., 2014) and for those with no measured lipid values during this period, we used the non-laboratory Framingham risk score (D'Agostino et al., 2008). We used this strategy to identify adults who were likely to meet current ACC/AHA risk thresholds for statin consideration when evaluated in clinic. Patients were excluded if they had an active statin prescription; were non-English speaking; had a history of stroke, congestive heart failure, coronary heart disease, angina, heart attack, or diabetes mellitus; were pregnant; or were marked as inappropriate for study by their PCP.

2.3. Participant recruitment

Study staff reviewed patient records at regular intervals to identify potentially-eligible adults with appointments 10–20 days in the future and obtained approval to contact them from their PCPs. Participants were recruited by mail and screened for eligibility by telephone call. A study visit was scheduled immediately prior to the patients' PCP appointment. Study staff obtained written informed consent at the beginning of the study visit.

2.4. Study visit and CVD risk assessment

Participants were surveyed about medical history, lifestyle behaviors, and family history. A research assistant measured weight and blood pressure using standardized procedures (Pickering et al., 2005). Three blood pressures were measured, and the average of the last 2 was used for the study visit blood pressure. Finger sticks were used to obtain capillary blood for POCT. We used the Cholestech LDX (Alere, Hayward, CA) to measure total and high-density lipoprotein cholesterol and the Siemens DCA Vantage Analyzer (Siemens Healthcare Diagnostics, Deerfield, IL) to measure glycosylated hemoglobin (HbA1c) to detect undiagnosed diabetes mellitus. The research assistant then prepared and reviewed a "CVD Risk Assessment" form with the participant. This form listed the participant's 10-year predicted atherosclerotic CVD risk as estimated by the Pooled Cohort Equations and provided personalized treatment recommendations and lifestyle modifications per current ACC/AHA prevention guidelines (Stone et al., 2014; Eckel et al., 2014). The research assistant then provided the completed form to the participant and his or her PCP prior to the office visit.

2.5. Measures and analysis

The primary efficacy outcomes were: physician documentation of CVD risk discussion and statin prescription at the time of the PCP visit. Both outcomes were assessed by manual chart review. We administered a questionnaire to assess acceptability of the intervention measured on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). We used descriptive statistics to characterize results.

3. Results

3.1. Characteristics

We identified 77 patients who met study eligibility criteria during the 4 month study period. From this group, we recruited and consented 18 participants (8 from Northwestern Medicine clinics and 10 from the local FQHC) for this study. All recruited participants completed the pre-visit POCT and quantitative CVD risk assessment. Participants' characteristics at the time of the study visit are listed in Table 1.

3.2. Preliminary efficacy-testing

Outcomes are summarized in Table 2. After the intervention, 83% of participants discussed CVD risk with their PCP. Moreover, 47% of participants were recommended a moderate-intensity statin for primary prevention by their PCP; one participant discussed statins with their PCP but was not recommended treatment due to a potential drug-drug interaction. In total, 29% of all participants meeting ACC/AHA risk thresholds for consideration of statin therapy received a new statin prescription during their PCP visit after the POCT intervention.

3.3. Preliminary acceptability of the intervention

Participants who were surveyed after the intervention deemed it highly acceptable (Table 2).

4. Discussion

This study provides initial data to suggest that pre-visit POCT and quantitative CVD risk assessment appears to be a feasible intervention for increasing guideline-recommended statin use in primary prevention. The positive feedback from participants also supports the

Table 1
Characteristics of participants at the time of study visit.

Characteristic	N (%)
Mean age, y	64.7 (8.5)
Female sex	13 (72.3%)
Race/ethnicity	
Non-Hispanic white	5 (27.8%)
Black	8 (44.4%)
Hispanic	1 (5.6%)
Other, unknown	4 (22.2%)
Drug-treated hypertension	10 (55.6%)
Current smoker	7 (38.9%)
Characteristic	**Mean (SD)**
Ten-year cardiovascular disease risk[a]	14.7 (7.2)
Total cholesterol, mg/dL	201 (40)
HDL-cholesterol, mg/dL	56 (20)
Systolic blood pressure, mm Hg	132 (12)
Diastolic blood pressure, mm Hg	79 (10)

[a] Risk is estimated by the ACC/AHA Pooled cohort risk equation that predicts 10-year risk of an atherosclerotic cardiovascular disease event (defined as nonfatal myocardial infarction, nonfatal stroke, or cardiovascular disease death). Risk is calculated from age, sex, race/ethnic group, total cholesterol level, high-density lipoprotein (HDL) cholesterol level, systolic blood pressure level, diabetes mellitus status, smoking status, and presence or absence of blood pressure medications (Goff et al., 2014).

Table 2
Preliminary efficacy-testing and acceptability outcomes.

Chart review outcomes	N (%)
Documented discussion of CVD risk	15 (83.3%)
Drug treatment for cholesterol recommended at office visit[a]	8 (47.1%)
Statin prescribed at office visit[a]	5 (29.4%)
Acceptability statement (5-point Likert scale, 1 = strongly disagree and 5 = strongly agree)	**Mean (SD)**
The Cardiovascular risk factor review session strengthened my relationship with my doctor.	4.3 (0.8)
I felt more motivated to look after my cardiovascular health after the risk factor review session.	4.5 (0.8)
The CVD Risk Assessment form was difficult to understand.	1.6 (1.0)
The CVD Risk Assessment form helped me talk with my doctor about things I could do to prevent heart attacks and strokes.	4.8 (0.6)
My doctor used the CVD Risk Assessment form during the visit.	4.5 (0.8)
My doctor did not follow the recommendations outlined on the CVD Risk Assessment form	1.9 (1.1)
The finger-stick required to get blood tests during the risk factor review session was bothersome.	1.3 (0.9)
I have confidence in the accuracy of the blood test obtained by finger prick.	4.5 (0.8)
It was helpful to know my numbers before I met with the doctor.	4.8 (0.6)

[a] Out of 17 participants because 1 participant had a potential drug-drug interaction.
CVD = cardiovascular disease.

intervention's acceptability in both an academic medical center and FQHC.

Among the participants who met absolute CVD risk thresholds for consideration of statin therapy based on ACC/AHA cholesterol guidelines, the finding that 83% discussed CVD risk reduction with their PCP and that 29% received a new statin prescription during their PCP visit is noteworthy. The magnitude of these rates compares favorably with a recent randomized controlled trial conducted by our group that also leveraged EHR data to deliver individualized CVD risk messages to high-risk adults who were not treated with statins (Persell et al., 2015). In this study, participants randomized to the intervention group discussed CVD risk reduction with their PCP only 26.8% of the time and received a statin prescription during a PCP visit only 10.1% of the time. Therefore, pre-visit POCT appears to be quite promising for promotion of CVD risk discussions and statin initiation in adults at increased CVD risk.

There are several factors that may explain the preliminary efficacy of the intervention. First, the use of POCT enabled rapid estimation of blood cholesterol and HbA1c levels in clinic. This information could then be incorporated in the pre-visit CVD risk assessment. Second, POCT results and corresponding CVD risk estimates were paired with guideline-recommended pharmacologic and lifestyle behavior considerations to reduce CVD risk. Third, participants who were informed of their increased CVD risk had an immediate opportunity to discuss potential risk reduction options with their PCP. Fourth, this intervention provided PCP's with real-time risk factor levels and pre-calculated risk estimates at the time of consultation, which may have overcome therapeutic inertia that is common in primary prevention decision-making.

POCT has been used for decades to facilitate clinical decision-making in emergent settings and acute conditions where rapid diagnostic evaluation is essential, but there is growing recognition that these same attributes may apply to preventive healthcare (St John, 2010). Within primary care, POCT have been incorporated into chronic disease self-management programs to improve glycemic control in type-2 diabetes mellitus and therapeutic anticoagulation for those on warfarin (Heneghan et al., 2016; Zhu et al., 2016). However, its role in promoting guideline-recommended CVD preventive therapies among an asymptomatic, but at-risk, general population is still unclear. The most up to date systematic review of clinical trials evaluating POCT in primary care identified only 1 study evaluating POCT for CVD prevention (Gialamas et al., 2010). This study by Ruffin et al. reported an increase in confirmatory laboratory testing or physician documentation in the POCT group compared with usual care (68% versus 19%, $p = 0.0001$) but no difference in therapeutic considerations (38% in the POCT group versus 9% in the usual care group, $p = 0.183$) (Ruffin and McKenney, 1997). However, the relevance of this study to the contemporary era in primary CVD prevention is limited because this study: (a) included >50% of participants with known chronic conditions like diabetes mellitus and CVD, (b) did not use multivariable risk prediction equations to estimate CVD risk as advocated by CVD prevention guidelines since 2001, and (c) preceded the era of widespread statin use. Subsequent studies evaluating POCT interventions for CVD prevention have focused on pharmacy-based interventions that have used POCT for achievement of LDL cholesterol goals (Till et al., 2003; Peterson et al., 2004; Gerrald et al., 2010; Haggerty and Tran, 2016). However, most of these interventions occurred in adults with established CVD or high-risk chronic conditions like diabetes mellitus, were conducted outside of primary care settings, and did not include quantitative CVD risk assessment or risk discussions.

With the current shift in CVD prevention guidelines toward personalized treatment recommendations tailored to the unique benefit-harm assessment of a given patient, both quantitative CVD risk assessment and clinician-patient risk discussions are essential components of optimal CVD prevention (Robinson and Ray, 2016). However, we recently completed a systematic review that identified multiple evidence gaps pertaining to the best strategies for implementing these risk estimates in clinical practice (Karmali et al., 2017). One commonly cited limitation in prior studies was missing or incomplete risk factor data at the time of a clinical encounter. Pre-visit point-of-care testing (POCT) might be well-suited to address this limitation, but none of the 41 studies identified in the review utilized POCT for real-time CVD risk estimation. Therefore, POCT might provide an innovative strategy for promoting personalized and guideline-recommended care in primary prevention (King et al., 2016).

Although this study has promising results, there are important limitations. The study sample was small, limiting generalizability. Additionally, the lack of a control group hinders causal inference between the intervention and our outcomes. Further, due to limited funds, we did not measure patient-reported outcomes such as risk perception, patient activation, and decision-making quality. These are important limitations that could be addressed with an adequately powered randomized controlled clinical trial.

5. Conclusions

In conclusion, this study provides preliminary data about the effects of pre-visit POCT and quantitative CVD risk assessment in primary care. These findings suggest that use of POCT prior to primary care visits appears to be feasible, acceptable, and may promote guideline-recommended statin initiation in high-risk adults. Future research with an adequately powered clinical trial is warranted to determine the effectiveness of this approach in primary prevention.

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Conflicts of interest

Dr. Persell receives grant support from Pfizer, Inc. for research unrelated to this study. The other authors have no competing interests to report.

Transparency document

The Transparency document associated with this article can be found, in the online version.

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