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Predictors of cholesterol treatment discussions and statin prescribing for primary cardiovascular disease prevention in community health centers

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ABSTRACT

Background. Although cholesterol guidelines emphasize cardiovascular disease (CVD) risk to guide primary prevention, predictors of statin use in practice are unknown. We aimed to identify factors associated with a cholesterol treatment discussion and statin prescribing in a high-risk population.

Methods. We used data from a trial conducted among participants in community health centers without CVD or diabetes and a 10-year coronary heart disease (CHD) risk ≥ 10%. Cholesterol treatment discussion was assessed at 6 months and statin prescription at 1 year. We used logistic regressions to identify factors associated with each outcome.

Results. We analyzed 646 participants (89% male, mean age 60 ± 9.5 years). Cholesterol treatment discussion occurred in 19% and statin prescription in 12% of participants. Ten-year CHD risk was not associated with treatment discussion (OR 1.11 per 1 SD increase, 95% CI 0.91–1.33) but was associated with statin prescription (OR 1.41 per 1 SD increase, 95% CI 1.13–1.75) in unadjusted models. After adjusting for traditional CVD risk factors that contribute to CHD risk, low-density lipoprotein cholesterol (LDL-C) was independently associated with statin prescription (OR 1.82 per 1 SD increase, 95% CI 1.66–1.99). Antihypertensive medication use was independently associated with both cholesterol treatment discussion (OR 3.68, 95% CI 2.35–5.75) and statin prescription (OR 3.98, 95% CI 3.30–4.81). Other drivers of CVD risk (age, smoking, and systolic blood pressure) were not associated with statin use.

Conclusions. Single risk factor management strongly influences cholesterol treatment discussions and statin prescribing patterns. Interventions that promote risk-based statin utilization are needed.

Trial registration. Clinicaltrials.gov.: NCT01610609

1. Introduction

Cardiovascular disease (CVD) remains the leading cause of mortality in the US, yet effective preventive medications exist (Mozaffarian et al., 2015). Clinical trials and meta-analyses have demonstrated that statins safely and effectively reduce the risk of CVD regardless of the presence of clinically manifested disease, baseline low-density lipoprotein-cholesterol (LDL-C) level, or baseline CVD risk (Cholesterol Treatment Trialists et al., 2012; Taylor et al., 2013). Consequently, cholesterol treatment guidelines emphasize the importance of absolute CVD risk assessment in guiding the intensity of prevention efforts, thereby directing the most intensive prevention efforts to those at highest risk (Third Report of the National Cholesterol Education Program (NCEP), 2002; Stone et al., 2014).

Prior cholesterol guidelines released by the National Cholesterol Education Program Adult Treatment Panel III recommended drug therapy for individuals with 10-year coronary heart disease (CHD) risk of 10–20% and an LDL-C ≥ 130 mg/dL with an option to begin therapy for LDL-C ≥ 100–129 mg/dL (Third Report of the National Cholesterol Education Program (NCEP), 2002; Grundy et al., 2004). The 2013 updates to these guidelines released by the American College of Cardiology and American Heart Association (ACC/AHA) continue the principle of risk-stratified treatment but remove LDL-C goals altogether and instead recommend absolute multivariable CVD risk assessment along with a shared clinician–patient discussion to guide eligibility for statin therapy in primary prevention in most patients (Stone et al., 2014).

The increasing shift toward absolute risk assessment to guide statin use in primary prevention means that treatment eligibility can often be the result of the co-occurrence of multiple traditional risk factors like age, sex, smoking, and blood pressure rather than cholesterol level alone (Karmali et al., 2014; Marma and Lloyd-Jones, 2009). Prior analyses identifying predictors of statin therapy have been performed in

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retrospective cohorts and among individuals with high-risk conditions such as diabetes mellitus and prevalent CVD, where absolute risk assessment is not used to guide therapy (Berthold et al., 2009; Canavero et al., 2014; Kulik et al., 2007). These studies have shown that statin use is associated with secondary prevention status, disease-specific severity, cholesterol level, albuminuria and smoking. However, little is known about the influence of CVD risk information in guiding cholesterol treatment discussions or statin prescribing in primary prevention among individuals who are at "high-risk" due to risk factors alone.

We recently completed a pragmatic randomized controlled trial to determine whether lay outreach and an individualized CVD risk message would improve primary CVD preventive care delivery in community health centers (Persell et al., 2015). We demonstrated that individualized CVD risk communication with patients increased discussions about cholesterol treatment with primary care clinicians but these discussions infrequently led to a statin prescription. In this post-hoc secondary analysis, we aimed to identify factors associated with cholesterol treatment discussion and statin prescription.

2. Methods

2.1. Study participants and trial design

Details of the methods, patient eligibility, and primary results of this clinical trial have been previously described (Persell et al., 2015). Briefly, the trial recruited participants from 11 federally qualified community health centers in Illinois and Arizona from August 2012 to March 2013. Participants were eligible for the study if they: were men ≥ 35 years old and women ≥ 45 years old, visited a study site for ≥1 face to face visit in the 6 months prior to randomization, had an LDL-C checked within the preceding 5 years, did not have a lipid lowering medication on their active medication list, had a calculated 10-year CHD risk ≥ 10% based on the ATP-III risk calculator, had an LDL-C of ≥100 mg/dL and did not have diabetes. Each community health center is part of a larger network of health centers. In this trial, the 11 community health centers were part of 3 health networks (2 in Chicago, 1 in Arizona). In order to balance the number of participants in each treatment group for each of the networks, we stratified eligible participants by network and then performed a 1:1 randomization at the patient-level to allocate treatment within each stratum. Randomization was performed using a random number generator in SAS 9.3 statistical software (SAS Institute, Cary, NC).

2.2. Risk message intervention

The risk message intervention tested in the trial consisted of: 1) telephone outreach; 2) personalized patient education and risk messaging delivered by telephone and mail; and 3) a preventive care visit dedicated to CVD prevention. For the telephone outreach, care managers called eligible participants and informed them of their higher than average heart disease risk, described the importance of cholesterol management, and encouraged participants to schedule an appointment with their primary care clinician. Care managers facilitated appointment scheduling if desired by the participant. After the telephone outreach, care managers mailed participants personalized patient education materials, which included: 1) a summary of their individualized heart disease risk and 2) educational material explaining the role of cholesterol in heart disease and statins in the prevention of heart disease. Participants who were not reached by the care manager after 3 phone call attempts were mailed a letter providing the same educational and personalized risk information. Care managers then forwarded a note in the electronic health record (EHR) to the participants' primary care clinician that included a summary of the participants' CVD risk factors, their CVD risk level, treatment targets, and that the participant may be coming for a CVD prevention visit.

2.3. Outcomes

The primary outcomes were obtained from data collected during routine clinical care and entered into the EHR. The primary process outcome was cholesterol treatment discussion documented in the patient's medical record by a physician, advanced practice nurse or physician assistant within 6 months. This outcome was assessed by blinded chart review and consisted of: 1) statin prescription during the visit, 2) documentation of drug treatment recommendation but no prescription, 3) documentation of patient refusal of drug treatment for cholesterol, and 4) documentation of cholesterol treatment discussion but no recommendation for cholesterol treatment. The other process outcome was statin prescription at 12 months assessed through review of the medication list within the EHR. Complete details of outcome ascertainment have been described previously (Persell et al., 2015).

2.4. Statistical analyses

We used simple logistic regression to identify unadjusted characteristics associated with cholesterol treatment discussion and statin prescription with generalized estimating equations to account for the stratified randomization by health center network (PROC GENMOD). We also performed a pre-specified, multivariable logistic regression that adjusted for: intervention group, demographic variables (age, sex, and race), and traditional Framingham risk factors (LDL cholesterol, HDL cholesterol, current smoking, systolic blood pressure, and antihypertensive medication use) that are used to estimate 10-year CHD risk (Third Report of the National Cholesterol Education Program (NCEP), 2002; Goff et al., 2014; Wilson et al., 1998) We substituted LDL-C for total cholesterol after identifying collinearity between total cholesterol and HDL cholesterol in our data. Results were unchanged with this substitution. We tested for interactions between 10-year CHD risk, intervention group, and number of clinic visits during the study period with cholesterol treatment discussions and statin prescriptions by incorporating corresponding interaction terms in the analyses. We calculated 95% confidence intervals and used a p value of <0.05 to determine statistical significance. Intent-to-treat method was applied to all the analyses. Analyses used SAS version 9.3 statistical software (SAS Institute, Cary, NC).

2.5. Ethics

This study was approved by the Northwestern University Institutional Review Board with a waiver of informed consent.

2.6. Funding

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3. Results

3.1. Baseline characteristics

646 participants were randomized in the trial (328 intervention, 318 controls). Baseline characteristics of participants are shown in Table 1, by cholesterol treatment discussion status, and Table 2, by statin prescription status. Most participants were male and English speaking. Mean age was 60 ± 9.5 years. In total, 19% of participants (125/646) discussed cholesterol treatment during an office visit within 6 months and 12% (78/646) received a statin prescription within 1 year.

Mean 10-year CHD risk was similar in participants who had a cholesterol treatment discussion compared to those who did not have one documented (14.4% versus 13.9%, $p = 0.33$). However, total and LDL cholesterol levels were greater among participants who had a