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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)

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CONFLICT OF INTEREST STATEMENT

The other authors report no conflicts.

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.

Keywords

cardiovascular disease prevention; cholesterol; risk assessment

Introduction

Cardiovascular disease (CVD) remains the leading cause of mortality in the US, yet effective preventive medications exist.(1) Clinical trials and meta-analyses have demonstrated that statins safely and effectively reduce the risk of CVD regardless of the presence of clinically manifest disease, baseline low-density lipoprotein-cholesterol (LDL-C) level, or baseline CVD risk.(2, 3) 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.(4, 5)

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.(4, 6) The 2013 update 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.(5)

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.(7, 8) Prior analyses identifying predictors of statin therapy have been performed in 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.(9-11) 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.(12) 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.

Methods

Study participants and trial design

Details of the methods, patient eligibility, and primary results of this clinical trial have been previously described.⁽¹²⁾ 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 $\geq 10\%$ 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).

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.

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.(12)

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.(4, 13, 14) 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).

Ethics

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

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Results

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 cholesterol treatment discussion (220 mg/dL versus 210 mg/dL, p=0.001 and 138 mg/dL versus 131 mg/dL, p=0.01, respectively). Mean 10-year CHD risk was greater in participants who received a statin prescription at 1 year (10-year CHD risk 15.6% versus 10-year CHD risk 13.7%, p=0.002) as was total and LDL cholesterol levels (230 mg/dL versus 209 mg/dL, p<0.001 and 147 mg/dL versus 130 mg/dL, p<0.001, respectively). The Figure displays unadjusted rates of statin prescription by LDL-C category and 10-year CHD risk group.

Univariable predictors

Unadjusted factors associated with cholesterol treatment discussion and statin prescription are shown in Tables 1 and 2. Characteristics associated with cholesterol treatment discussion included: total cholesterol level, LDL-C level, antihypertensive medication use, and intervention group assignment. The strength of the association was strongest for antihypertensive medication use (OR 3.10, 95% CI 2.06-4.68) and intervention group assignment (OR 2.79, 95% CI 1.83-4.24). Of note, although communication of CHD risk was the primary intervention in the trial, 10-year CHD risk was not associated with cholesterol treatment discussion in unadjusted analyses (OR 1.11 per 1 SD increase, 95% CI 0.91-1.33).

Unadjusted factors associated with statin prescription at 1 year included: total cholesterol level, LDL-C level, antihypertensive medication use, number of clinic visits during the study period, and 10-year CHD risk. The strength of the association was strongest for antihypertensive medication use (OR 3.54, 95% CI 2.18-5.76). The intervention group was not found to be associated with statin prescription (OR 1.29, 95% CI 0.80-2.09). Only total cholesterol level, LDL-C level, and anti-hypertensive medication use were significantly associated with both cholesterol treatment discussion and statin prescription in unadjusted analyses (Table 2).

Multivariable predictors

Adjusted odds ratios predicting cholesterol treatment discussion and statin prescription are shown in Table 3. After multivariable adjustment, the association between LDL cholesterol level cholesterol treatment discussion was of similar magnitude but was not statistically significant (OR 1.27 per 1 SD increase, 95% CI 0.96-1.68, p=0.09), and LDL cholesterol was associated with statin prescription (OR 1.82, 95% CI 1.66-1.99, p<0.001).

Antihypertensive medication use was associated with both cholesterol treatment discussion (OR 3.68, 95% CI 2.35-5.75, p<0.001) and statin prescription (OR 3.98, 95% CI 3.30-4.81, p<0.001). Age, the strongest driver of 10-year CHD risk in the ATP-III risk calculator, was not associated with either cholesterol treatment discussion or statin prescription. In adjusted analyses, the odds of cholesterol treatment discussion were lower among current smokers than nonsmokers (OR 0.59, 95% CI 0.46-0.77, p<0.001) and among those with higher systolic blood pressure (OR 0.80 per 1 SD increase, 95% CI 0.65-0.99, p=0.04). However, these results should be interpreted with caution since the association was not demonstrated in unadjusted analyses or for the statin prescription outcome. We did not find evidence of

significant modification of the intervention effect by 10-year CHD risk or number of clinic visits for either outcome.

Discussion

In this study, we report a secondary analysis of a pragmatic clinical trial that tested the effect of an individualized CVD risk message intervention to identify factors associated with cholesterol treatment discussion and statin prescription in higher risk individuals (10-year CHD risk 10%) without prevalent CVD. We identified that cholesterol levels (total cholesterol and LDL-C) were associated with statin prescription and that antihypertensive medication use was associated with both cholesterol treatment discussion and statin prescription. Although the intervention for the trial consisted of an individualized CVD risk message and promotion of a dedicated CVD preventive health visit, cholesterol treatment discussions was not associated with 10-year predicted CHD risk, and statin prescriptions were only weakly associated with 10-year predicted CHD risk.

In multivariable analyses that adjusted for the traditional Framingham CVD risk factors that are used to calculate 10-year CHD risk, the association between CVD risk and statin prescribing appeared to be driven by cholesterol level (total cholesterol and LDL-C) and antihypertensive medication use. Other traditional cardiovascular risk factors that are potent drivers of estimated 10-year risk (age, sex, current smoking, and systolic blood pressure) were not positively associated with statin prescribing. Smoking and systolic blood pressure, in particular, were even negatively associated with cholesterol treatment discussions. These data suggest that clinicians and patients continue to view statins primarily as *cholesterol-lowering* agents rather than as *overall CVD risk-lowering* agents as clinical practice guidelines advocate.(5)

Our results are consistent with prior analyses that provided absolute risk assessments to clinicians but found that single risk factor levels rather than multivariable risk influenced prescribing practices.(15-19) In one study that used clinical decision-support software to recommend statin treatment in high-risk individuals, odds of cholesterol-lowering treatment in treatment-eligible patients were higher in those with elevated LDL-C rather than high risk categories.(18) Systematic reviews have also shown that cardiovascular risk assessment can be a useful tool for patient education but that evidence for clinical effectiveness on health outcomes is lacking.(20-22)

More recently, an analysis of the nationally representative Medical Expenditure Panel Survey demonstrated that the presence of hyperlipidemia had a stronger association with statin use than high-risk conditions like prevalent CHD or diabetes.(16) For example, participants with a diagnosis of hyperlipidemia, but without diabetes or CHD, were more likely to be prescribed a statin than those with diabetes or CHD, but without hyperlipidemia, in spite of the established higher risk status of those in the latter group (probability 0.59, 95% CI 0.54-0.64 versus 0.04, 95% CI 0.02-0.06).

The magnitude of the associations between antihypertensive medication use and cholesterol treatment discussion and antihypertensive medication use and statin prescription are novel

findings from our analysis. They suggest that clinicians may be reluctant to engage patients in drug therapy for primary prevention if patients are not already taking a chronic, daily medication. These findings have been suggested previously in a trial among general practitioners from Australia where hypothetical cases were systematically varied and demonstrated that clinicians were five times more likely to prescribe a statin in individuals who were already prescribed antihypertensive medication.(15) Our results confirm these findings in a population of patients who received personalized risk information as part of a clinical trial. Although antihypertensive medication use contributes to calculated 10-year CHD risk, the strength of the association relative to age or current smoking (two stronger markers of CVD risk) and the independence of this effect from cholesterol, suggest that the presence of another daily preventive medication has a prominent influence on the clinician-patient discussion and resultant treatment decision-making. Although it is well-known that patients may have a broad range of disutility ascribed to daily preventive medication use, (23) the low rates of treatment discussion and prescription seen in our trial, particularly among individuals who were not already taking a chronic cardiovascular medication, suggest that clinicians may also have a strong bias against initiating a chronic medication for prevention. Conversely, clinicians may find it easier to discuss and prescribe a statin in someone who has already shown a willingness to take a daily medication for CVD prevention.

These findings contrast with a prior study from our group that tested a similar individualized CVD risk message intervention in high-risk individuals from an academic medical center. (24) In that trial, randomization to an individualized mailed CVD risk message intervention led to greater odds of receiving a lipid-lowering medication (OR 2.13, 95%CI 1.05-4.32). However, there are key differences between the two trials. The present study was performed in community health centers and tested the intervention in a population with a much higher rate of smoking and lower LDL-C levels. In both trials, however, the effect on statin prescription patterns were similarly small in absolute terms.

There are important limitations to acknowledge in our analysis. First, the primary outcome of cholesterol treatment discussion was determined by chart review. Thus, there is a possibility that some outcomes were misclassified due to poor documentation of risk discussions or cholesterol treatment recommendations. Second, the trial was completed before the 2013 ACC/AHA guidelines that provide more explicit support for prescribing statins based on absolute risk.(5) At the time of the trial, ATP-III guidelines recommended drug therapy in individuals with 10-year CHD risk 10-20% with an LDL-C goal of 130 mg/dL.(4) Although the 2004 guideline update recommended considering statin therapy as a therapeutic option in high-risk individuals with LDL-C 100-129 mg/dL, many clinicians may have chosen to avoid drug therapy in individuals with LDL-C 100-129 mg/dL.(6) This does not, however, explain the low rates of cholesterol treatment discussion and statin prescription among individuals with LDL-C 130-159 mg/dL (Figure). Third, the associations that we report are limited to the clinical variables that were measured within our pragmatic clinical trial. Thus, we are unable to comment on the relationship of other clinical variables that have been shown to be associated with statin prescribing in retrospective analyses, like body mass index, albuminuria, socioeconomic status, and insurance status.(9, 25-27) These factors, however, are not incorporated in risk prediction algorithms used in the US to guide

statin eligibility. Lastly, this analysis is a post-hoc secondary analysis of a trial originally powered for the primary outcome of cholesterol treatment discussion at 6 months. Thus, these findings are hypothesis generating and should be interpreted with caution.

Conclusion

In conclusion, we identified that single risk factor management, rather than multivariable CVD risk, strongly influences cholesterol treatment discussions and statin prescribing patterns. These results suggest that clinicians did not incorporate absolute risk into their clinical decision-making. Further studies are needed to support risk-based frameworks to guide statin utilization.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure.
Percent of participants with statin prescription by LDL-C category and 10-year CHD risk category

Table 1
Univariable association between baseline characteristics and cholesterol treatment discussion at 6 months

	Cholesterol treatment discussion (n=125)	No cholesterol treatment discussion (n=521)	OR (95% CI)	p value
Age in yr, mean (SD)	59.4 (8.2)	59.9 (9.8)	0.95 (0.78-1.16)	0.61
Female, n (%)	13 (10%)	60 (12%)	0.89 (0.47-1.68)	0.72
Race, n (%)				0.27
Black	55 (44%)	267 (51%)	0.78 (0.51-1.19)	
White	54 (43%)	205 (39%)	REF	
Other	16 (13%)	49 (9%)	1.24 (0.65-2.35)	
Primary language, n (%)				0.66
English	115 (92%)	475 (90%)	REF	
Spanish	10 (8%)	35 (7%)	1.18 (0.57-2.45)	
Other/missing	0	11 (2%)	N/A	
Number of clinic visits, mean (SD)	4.2 (3.6)	3.6 (3.0)	1.17 (0.97-1.40)	0.10
10-yr coronary heart disease risk, mean (SD)	14.4% (5.3)	13.9% (4.9)	1.11 (0.91-1.33)	0.33
Total cholesterol in mg/dL, mean (SD)	220.4 (34.0)	209.6 (30.7)	1.38 (1.14-1.66)	0.001
LDL cholesterol in mg/dL, mean (SD)	137.5 (27.2)	131.1 (24.6)	1.27 (1.06-1.53)	0.01
HDL cholesterol in mg/dL, mean (SD)	50.9 (14.6)	49.9 (14.3)	1.07 (0.89-1.30)	0.48
Systolic blood pressure in mmHg, mean (SD)	134.9 (17.6)	136.6 (19.5)	0.92 (0.75-1.12)	0.38
Diastolic blood pressure in mmHg, mean (SD)	84.1 (10.7)	83.9 (12.0)	1.01 (0.83-1.23)	0.91
Antihypertensive medication use, n (%)	56 (45%)	108 (21%)	3.10 (2.06-4.68)	<0.001
Current smoking, n (%)	62 (50%)	296 (56%)	0.74 (0.50-1.11)	0.15
CVD risk message intervention, n (%)	88 (70%)	240 (46%)	2.79 (1.83-4.24)	<0.001

Odds ratios for age, systolic blood pressure, diastolic blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, and 10-year coronary heart disease risk are per 1 standard deviation increase. Odds ratios for antihypertensive medication use and current smoking are for presence compared to absence. Odds ratio for clinic visits is per visit. P values listed are for unadjusted logistic regressions.

Table 2

Univariable association between baseline characteristics and statin prescription at 1 year

	Statin prescription (n=78)	No statin prescription (n=568)	OR (95% CI)	p value
Age in yr, mean (SD)	58.7 (8.8)	60.0 (9.6)	0.88 (0.69-1.12)	0.29
Female, n (%)	9 (12%)	64 (11%)	1.03 (0.49-2.16)	0.94
Race, n (%)				0.37
Black	44 (56%)	278 (49%)	1.26 (0.76-2.07)	REF
White	5 (6%)	230 (40%)		
Other	29 (37%)	60 (11%)	0.66 (0.25-1.78)	
Primary language, n (%)				0.11
English	69 (88%)	521 (92%)	REF	1.89 (0.87-4.09)
Spanish	9 (12%)	36 (6%)		
Other/missing	0	11 (1.9%)	NA	
Number of clinic visits, mean (SD)	4.6 (4.0)	3.6 (3.0)	1.28 (1.05-1.56)	0.02
10-yr coronary heart disease risk, mean (SD)	15.6% (6.0)	13.7% (4.8)	1.41 (1.13-1.75)	0.002
Total cholesterol in mg/dL, mean (SD)	229.9 (37.4)	209.2 (30.0)	1.79 (1.44-2.22)	<0.001
LDL cholesterol in mg/dL, mean (SD)	146.6 (31.0)	130.4 (23.7)	1.73 (1.40-2.14)	<0.001
HDL cholesterol in mg/dL, mean (SD)	51.9 (16.2)	49.8 (14.0)	1.15 (0.92-1.43)	0.22
Systolic blood pressure in mmHg, mean (SD)	137.6 (19.2)	136.1 (19.1)	1.08 (0.86-1.36)	0.51
Diastolic blood pressure in mmHg, mean (SD)	85.1 (11.8)	83.8 (11.7)	1.11 (0.88-1.40)	0.38
Antihypertensive medication use, n (%)	39 (50%)	125 (22%)	3.54 (2.18-5.76)	<0.001
Current smoking, n (%)	43 (55%)	315 (55%)	0.99 (0.61-1.59)	0.96
CVD risk message intervention, n (%)	44 (56%)	284 (50%)	1.29 (0.80-2.09)	0.29

Odds ratios for age, systolic blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, and 10-year coronary heart disease risk are per 1 standard deviation increase. Odds ratio for female, antihypertensive medication use, and current smoking are for presence compared to absence. Odds ratio for clinic visits are per visit. P values are for unadjusted logistic regressions.

Multivariable-adjusted factors associated with cholesterol treatment discussion at 6 months and statin prescription at 1 year among Framingham CVD risk factors

Table 3

Framingham Risk Factor	Cholesterol treatment discussion	<i>p value</i>	Statin prescription	<i>p value</i>
Age	0.84 (0.67-1.06)	0.15	1.00 (0.79-1.27)	1.0
Female	0.93 (0.74-1.18)	0.56	0.73 (0.47-1.13)	0.16
Systolic blood pressure	0.80 (0.65-0.99)	0.04	0.98 (0.76-1.26)	0.88
Antihypertensive medication use	3.68 (2.35-5.75)	<0.001	3.98 (3.30-4.81)	<0.001
Current smoking	0.59 (0.46-0.77)	<0.001	0.87 (0.54-1.40)	0.56
LDL cholesterol	1.27 (0.96-1.68)	0.09	1.82 (1.66-1.99)	<0.001
HDL cholesterol	1.13 (0.86-1.49)	0.37	1.11 (0.82-1.49)	0.49
Intervention group	3.11 (2.27-4.28)	<0.001	1.31 (0.94-1.83)	0.11

Odds ratios for age, systolic blood pressure, LDL cholesterol, and HDL cholesterol are per 1 standard deviation increase. Odds ratio for female, antihypertensive medication use, current smoking, and intervention group are for presence compared to absence. Adjusted for all variables listed and race.