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Appropriateness of Cholesterol Management in Primary Care by Sex and Level of Cardiovascular Risk

Ann Hiott Barham, MD[1], **David C. Goff Jr, MD, PhD**[2,3], **Haiying Chen, PhD**[2], **Aarthi Balasubramanyam, MS**[2], **Erica Rosenberger, MS**[2], **Denise E. Bonds, MD, MPH**[2,3], and **Alain G. Bertoni, MD, MPH**[2,3]

[1]Department of Family and Community Medicine, Wake Forest University, School of Medicine, Winston-Salem, NC

[2]Division of Public Health Sciences, Wake Forest University, School of Medicine, Winston-Salem, NC

[3]Department of Internal Medicine, Wake Forest University, School of Medicine, Winston-Salem, NC

Abstract

A study was undertaken to ascertain the appropriateness of lipid screening and management per the Third Report of the Adult Treatment Panel National Cholesterol Education Program (ATP III) guideline in a sample of North Carolina primary care practices. Demographics, cholesterol values, and comorbid conditions were abstracted from the medical records from 60 community practices participating in a randomized practice-based trial (Guideline Adherence for Heart Health). Eligible patients were aged 21 to 84 years, seen during the baseline period of June 1, 2001, through May 31, 2003, and who were not taking lipid-lowering therapy. Multivariable logistic regression was utilized to assess whether age, sex, race/ethnicity, diabetes, cardiovascular disease, ATP III risk category, or pretreatment low-density lipoprotein (LDL) influenced treatment. Among 5031 eligible patients, 1711 (34.5%) received screening lipid profiles. Screening rates were higher with older age, diabetes, and cardiovascular disease. No large differences were seen by sex. Among patients screened (mean age, 51.6 years; 57.9% female), 76.6% were appropriately managed within 4 months. In adjusted analyses, older age was associated with less appropriate treatment (odds ratio [OR] per 5 years, 0.91; P=.01), and patients with LDL cholesterol ≤130 mg/dL (OR, 18.8; P<.001) and the low-risk group (OR, 27.5; P<.001) were more likely to be managed appropriately compared with patients with LDL ≥190 mg/dL and those at high risk. Among 375 patients eligible for drug treatment, those with LDL levels between 131 and 159 mg/dL were much less likely to be treated (OR, 0.15; P<.001) compared with those with LDL >190 mg/dL, whereas risk category did not influence treatment. The challenge facing implementation of ATP III guidelines is much greater for intermediate- and high-risk patients than for low-risk patients.

Dyslipidemia is a major risk factor for coronary heart disease (CHD), the leading cause of death in the United States.1 In addition, CHD accounts for the majority of cardiovascular disease (CVD) deaths in women and disproportionately affects racial and ethnic minorities.2 Treatment of dyslipidemia can reduce the risk of heart disease by about 30% during a 5-year period. Although the benefits of lipid-lowering therapy have been demonstrated most conclusively in persons with CVD, lipid-lowering therapy is effective even in persons without clinically apparent CVD.3 The National Cholesterol Education Program's series of Adult

Address for correspondence: Ann Hiott Barham, MD, Department of Family and Community Medicine, Wake Forest University, School of Medicine, Winston-Salem, NC 27157-1084, annhiott@hotmail.com.

Treatment Panel (ATP) reports have been developed to provide health care professionals with recommendations pertinent to detecting and managing dyslipidemia. The third report, ATP III, was released in May 2001.4 Previous studies have documented the challenges involved in implementing earlier versions of these guidelines in practice settings.5–21 Although some prior papers have demonstrated sex, race, and ethnic disparities in cholesterol management,22,23 inconsistent results have been reported.24 In addition, less information on potential disparities in treatment is available for ATP III.

We previously investigated whether lipid screening and management was consistent with ATP III in a sample of North Carolina primary care practices participating in the Guideline Adherence for a Healthy Heart (GLAD Heart) trial,25,26 a practice-based randomized controlled trial. The lipid profile screening rate at half of the practices met or exceeded recommendations; however, practices varied substantially in the appropriate management of initial lipid profile results. In one fifth of the practices, the quality gap exceeded 30%. In this analysis we aimed to determine whether patient-level characteristics such as sex, ethnicity, and CVD risk are associated with disparities in lipid screening and management at the primary care level. These data are preintervention.

METHODS

The design, recruitment experience, and primary baseline results of the GLAD Heart trial have been described previously.25,26 Briefly, 61 primary care practices, not at academic medical centers, were recruited from within a 3-hour drive of Winston-Salem, NC. Physician and nonphysician providers consented to participate and to have chart abstraction performed at baseline and at follow-up. As this project involved quality improvement, individual patient-level consent for chart review was not deemed to be required by the institutional review board. We complied with Health Insurance Portability and Accountability Act privacy directives.

Cholesterol Management Data Collection

Chart abstraction was performed by the Carolinas Center for Medical Excellence (CCME), the state's quality improvement organization. From December 2003 to October 2004 trained nurse abstractors visited practices for on-site review of medical records during the baseline 2-year period, using a standardized data collection tool on a laptop computer. Intraobserver and interobserver agreement was assessed in 858 records and was 95.2% and 89.9%, respectively. Eligible patients were aged 21 to 84 years, seen in the primary care practices during the baseline period (June 1, 2001–May 31, 2003). The chart abstraction period ended 4 months later to allow for management decisions to be documented for patients screened at the end of the window. We a priori expected 3 categories of patients: (1) patients taking lipid-lowering therapy prior to June 2001 (for whom no further data abstraction was performed because any lipid testing would be for management purposes rather than initial decision-making); (2) patients not taking lipid-lowering therapy prior to and without lipid screening data during the data collection period; and (3) patients not taking therapy prior to June 1, 2001, with lipid testing during the data collection period (ie, patients screened). Data elements collected for group 2 and 3 included demographics (age, sex, race/ethnicity) and major comorbidities (CHD and diabetes) in order to examine screening patterns. Race/ethnicity was taken from the chart, either self-reported or provider's impression. For patients screened, additional variables abstracted included the initial lipid profile values, additional CVD diagnoses (stroke, peripheral vascular disease), CVD risk factors (smoking, blood pressure, diagnosed hypertension, antihypertensive medicine prescription, family history of heart disease), date of follow-up lipid profile and lipid values, and date of prescription of lipid-lowering medication. Evidence of documentation of therapeutic lifestyle changes (TLC) recommendations was recorded. Based on estimates of the frequency of lipid screening, it was planned to randomly select independent

samples of 140 patients for abstraction in order to yield 30 full abstractions. When 30 valid charts were abstracted, no further charts were retrieved. At some practices, additional samples of 140 patient charts were prepared in order to reach abstraction goals.

Definitions

A person was considered to have been screened if (1) they were not previously taking a lipid-lowering medication, and (2) a complete lipid profile was documented in the chart as having been performed during the data collection period. We did not consider assessment of total and high-density lipoprotein cholesterol to qualify as adequate screening because it would not be possible to determine whether subsequent management of low-density lipoprotein cholesterol (LDL-C) was appropriate in such patients. Screened patients were categorized into ATP III risk categories based on the documented history and, if required, the 10-year risk of CHD calculated using the Framingham risk score (FRS).[27] Patients were assigned to 1 of 4 ATP III risk categories: (1) low risk (0 or 1 risk factors for CHD), (2) intermediate low risk (≥2 risk factors and FRS <10%), (3) intermediate high risk (≥2 risk factors and FRS 10%–20%), and (4) high risk (CHD risk equivalent [diabetes or CVD] and/or ≥2 risk factors and FRS >20%). Patients were classified as having dyslipidemia if their LDL-C level exceeded the risk group–specific ATP III goal (160, 130, or 100 mg/dL). Patients were considered eligible for drug therapy if their LDL-C concentration exceeded the risk-specific drug-initiation thresholds (190, 160, or 130 mg/dL). Patients were classified as being treated appropriately with respect to their LDL-C if any of the following criteria were met:

- LDL-C was < LDL goal, and drug therapy was not initiated during the 4 months following initial testing.
- LDL-C was ≥ the drug initiation cutpoint and drug therapy was prescribed within 120 days.
- LDL-C was ≥ the drug initiation cutpoint, a follow-up lipid profile confirmed this within 120 days, and drug therapy was prescribed within 150 days of the original lipid profile.
- LDL-C was ≥ the drug initiation cutpoint, was documented during the following 120 days to have decreased below the LDL goal, and drug therapy was not initiated.
- LDL-C was ≥ the drug initiation cutpoint, was documented during the following 120 days to have decreased below the drug initiation point, but still > LDL goal, and TLC advice was documented.
- LDL-C was ≥ LDL goal but below the risk stratum–specific drug treatment initiation threshold and TLC advice was documented.
- LDL-C was in a “grey zone” where ATP III indicated that drug therapy was optional, and drug therapy (initiated within 120 days) and/or TLC advice was documented.

Otherwise, patients were classified as being inappropriately treated with respect to their dyslipidemia.

Patients were at risk for being inappropriately prescribed lipid-lowering therapy if the initial LDL-C level was below the medication initiation or drug optional threshold and if prescribed drug therapy within 120 days was considered to be inappropriately treated. Patients were inappropriately treated if the initial LDL-C level was below the medication initiation or drug optional threshold yet were prescribed drug therapy within 120 days. Patients were also inappropriately treated if their initial LDL-C level was above the medication initiation threshold yet did not receive treatment within 120 days.

Statistical Analysis

Descriptive statistics are used to summarize the practice and patient characteristics. The characteristics and management of patients within a practice are expected to be correlated with each other. This intraclass correlation (ICC) is accounted for when obtaining the overall patient characteristics across all practices (eg, patient age). The estimated ICC for the patient age is around 0.09. In addition, sampling weights are used in all the analyses involving patient outcomes to adjust for the different sampling proportions in the practices. Appropriateness of management was assessed for the overall population and by sex, ethnicity, ATP III risk category, and pretreatment LDL-C using logistic regression models and included the sampling weights and accounted for clustering. To draw valid statistical inferences that properly reflected the uncertainty due to missing values of ethnicity (403 patients), a multiple imputation method was applied to impute ethnicity in the analyses of both screening and lipid management outcomes. For each model, a complete case analysis was also performed to compare the results from the multiple imputations. Since there were no substantial differences in the inferences based on the 2 sets of results, we present only results from the multiple imputation models. All significance tests were 2-tailed, with a significance level of .05. Analyses were performed using SAS (version 9.0; SAS Institute Inc, Cary, NC) and SUDAAN (version 8.0; Research Triangle Institute, Research Triangle Park, NC).

RESULTS

GLAD Heart recruited 61 primary care practices. Of the 60 practices with available chart data, a total of 5742 charts were examined. Of these, 669 patients were taking a lipid-lowering medication prior to ATP III's release so were excluded in an effort to assess compliance with ATP III. In addition, 42 patients were on treatment when the first lipid profile in the chart was documented, leaving 5031 patients eligible to be abstracted by CCME. Of these, 1737 (34.5%) were screened but 17 had high triglycerides (>400 mg/dL), 1 record was deleted as an outlier (total cholesterol 1751 mg/dL), and 8 were missing data needed to determine Framingham risk, leaving 1711 patients for the evaluation of cholesterol management. Characteristics of patients eligible for screening and for the screened population are shown in Table I. Our sample was predominantly female and white, although race/ethnicity was missing for a substantial proportion. Diabetes and CVD were common diagnoses. Among screened patients, more than half had a pretreatment LDL-C ≤130 mg/dL and only 5% had an LDL-C of at least 190 mg/dL. About one third of screened patients were classified into the low-risk categories and about one quarter were classified into the high-risk category.

Screening rates and appropriate treatment rates are shown in Table II by age, sex, ethnicity, presence of diabetes mellitus, CVD, pretreatment LDL-C, and ATP III risk category. The screening rate was 34.5%, which is close to the ATP III goal of 40% for the 2-year baseline period. Overall, 1310 of the 1711 patients were appropriately managed (76.6%). Of the 401 patients with inappropriate management, 61.4% (n=246) did not have a drug prescribed when it should have been, 7.0% (n=28) had a drug inappropriately prescribed, and 31.7% (n=127) did not have documentation of TLC. The vast majority of inappropriate treatment constituted undertreatment; overtreatment was uncommon, occurring in only 28 of 998 persons for whom drugs were not indicated. Screening rates were higher at older ages; however, the appropriateness of treatment was lower at older ages. No large differences were seen by sex, despite 95% power to detect a difference of 7.7%. Post hoc analysis revealed insufficient power to detect a difference of 4.1% in ethnicity. Patients with diabetes or CVD were more likely to be screened but less likely to be treated appropriately than patients without these conditions. Receipt of appropriate treatment was more common in the low LDL-C (≤130 mg/dL) and the low-risk groups than in the higher LDL-C or risk groups.

Adjusted odds ratios for receipt of screening are shown in Table III. Older age and presence of diabetes were associated with increased likelihood of screening. CVD was not significantly associated with screening in the adjusted model. Adjusted odds ratios for receipt of appropriate treatment are shown separately in Table IV. In the screened population, after adjustment for covariates, older patients were less likely and patients with lower LDL-C and at lower risk were more likely to be appropriately treated. Because a minority of patients qualified for lipid-lowering drug treatment, no treatment was appropriate for most of the patients. Hence, we examined treatment in the subgroup (375) that qualified for lipid-lowering drug treatment separately (Table V). Prior to adjustments, undertreatment of drug-eligible patients was observed to vary from 19.4% of low-risk patients to 70.1% of intermediate-risk patients and 65.1% of high-risk patients when requiring that treatment with lipid-lowering drugs be initiated within 4 months of the qualifying lipid profile. In the adjusted model (Table V), lower pretreatment LDL-C level was associated with a lower likelihood of receiving drug treatment when indicated. Age and risk group were not associated with receipt of drug treatment when indicated. Data regarding appropriate treatment in this subset for sex and race are also presented in Table V; however, post hoc analysis revealed insufficient power (<15%) to comment on sex and ethnicity in this subset.

DISCUSSION

The major finding of this report is that persons at higher risk for CVD, including >20% and 10% to 19% in the 10-year risk groups, are at greatest risk of being undertreated for their dyslipidemia per ATP III recommendations. In these higher-risk groups, 30% to 40% of patients were undertreated with respect to starting medicine. Another 10% to 20% of high-risk patients did not receive TLC counseling. Our data show that appropriate treatment is more strongly related to the pretreatment LDL-C value than to the level of risk, suggesting that providers may not be fully appreciating the level of risk. We additionally demonstrate that older persons are more likely to be screened but less likely to be appropriately treated, independent of their risk status.

Our results demonstrating substantial undertreatment are consistent with previous studies conducted with earlier versions of the ATP guidelines.5[-21] Our finding that higher-risk persons were more likely to be undertreated is consistent with an analysis of the Multi-Ethnic Study of Atherosclerosis (MESA),[22] in which it was reported that 46% of persons with drug-eligible dyslipidemia were not treated, and undertreatment varied from 17% of low-risk persons to 50% of intermediate-risk and 52% of high-risk persons with drug-eligible dyslipidemia. However, the timeliness of treatment initiation was not examined in MESA. In the present study, undertreatment of drug-eligible patients varied from 19.4% of low-risk patients to 70.1% of intermediate-risk patients and 65.1% of high-risk patients when requiring that treatment with lipid-lowering drugs is initiated within 4 months of the qualifying lipid profile.

Several other investigators have examined treatment of dyslipidemia in the ATP III era. Patel and colleagues[28] examined ATP III compliance among a small number of internal medicine and cardiology practices and found that, overall, 70% of patients eligible for drug treatment were prescribed a cholesterol-lowering medication, consistent with a 30% rate of undertreatment. Ma and colleagues[29] reported 50% undertreatment of intermediate- and high-risk patient visits using data from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Care Survey; however, they applied a modified version of the ATP III algorithm due to data constraints and they were limited to single-patient encounters. Our results provide evidence that the timeliness of treatment initiation is an additional challenge beyond treatment initiation. Our results provide evidence of greater undertreatment when a 4-month window for treatment initiation following the qualifying lipid profile was employed

than has been reported from studies not incorporating that feature of the ATP III guideline in the assessment of implementation.

The screening difference observed by age category might reflect providers' beliefs that screening is less important in younger persons who are typically at much lower risk for CVD. The basis for the lower likelihood of appropriate treatment at older ages, which was seen even after adjusting for risk and pretreatment LDL-C is less clear but could relate to prioritization of treatment decisions related to comorbid conditions. These speculations should be the subject of future research. There were no large sex differences in screening. In addition, while we saw little evidence for sex or race differences in cholesterol management in this study, our sample size and power was insufficient to draw conclusions about management.

This study has several strengths. Our primary care sample was diverse with respect to specialty, size, location, and provider sex and ethnicity. Medical records were reviewed, and the abstracted records were randomly selected. Our abstraction template included many clinical variables, which enabled us to characterize an individual patient's risk level and the appropriateness of the subsequent management. The reliability of the nurse-abstractors was excellent. A limitation is that these practices agreed to participate in a quality improvement trial. The most likely effect of this bias is more optimistic results compared with the quality of cholesterol management in a truly random sample of community primary care practices. Some patients may have been screened or treated elsewhere during the abstraction window. We may have underestimated screening due to our decision not to credit measurement of total and high-density lipoprotein cholesterol in the absence of a full lipid panel; however, it would not have been possible to assess the appropriateness of subsequent decision making with respect to LDL-C management. While we present data on TLC documentation, this may not always be recorded despite the physician discussing it, due to time constraints and the reality that reimbursement is not generally dependent on TLC documentation. The treatment sample of 375 patients is small; however, it likely reflects the relatively younger and healthier patients screened for dyslipidemia by these primary care practices. Limitations of this analysis include the large number of records missing data for ethnicity. In addition, since the chart abstraction, cholesterol guidelines were updated in 2004 and now include the optional recommendation of an LDL-C goal <70 mg/dL for the highest-risk patients. Although the modifications to the ATP III treatment algorithm use terminology that may enhance the important first step of risk assessment, these modifications are presented as "a reasonable clinical strategy" and require increased participation by the provider and patient.[30] Adherence to this stricter goal was not assessed. Finally, the true scope of the problem of undertreatment may be worse than portrayed, because initiation of drug treatment is not equivalent to control of LDL-C.

In summary, the challenge facing implementation of ATP III is much greater for intermediate- and high-risk patients than for low-risk patients. Providers appear to respond more to the LDL-C number than to the ATP III risk category. Efforts should be directed at improving the appropriateness of management for intermediate- and high-risk patients, particularly with amended guidelines that suggest an even stricter goal.

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Table I

Characteristics of Screening Eligible and Screened Patients

Characteristic	Population Eligible for Screening, No. (%)	Screened Population, No. (%)
Sample size	5031	1711
Age, y		
21–44	2584 (49.4)	607 (32.6)
45–64	1725 (37.4)	766 (49.5)
65–84	722 (13.2)	338 (17.9)
Sex		
Male	2126 (40.7)	746 (42.3)
Female	2889 (59.3)	965 (57.7)
Missing	16	0
Ethnicity		
White	3071 (55.1)	1099 (60.8)
African American	455 (10.2)	171 (11.1)
Other	145 (2.4)	38 (1.5)
Missing	1360 (32.3)	403 (26.6)
Diabetes		
Yes	466 (9.4)	261 (14.7)
No	4565 (90.6)	1450 (85.3)
Cardiovascular disease		
Yes	368 (6.1)	192 (9.1)
No	4663 (93.9)	1519 (90.9)
Pretreatment LDL-C, mg/dL		
≤130	NA	963 (55.7)
131–159	NA	472 (28.2)
160–189	NA	186 (11.0)
≥190	NA	90 (5.0)
ATP III risk category		
Low	NA	661 (38.6)
Intermediate	NA	600 (35.1)
High	NA	450 (26.3)

Abbreviations: ATP III, Third Report of the Adult Treatment Panel National Cholesterol Education Program; LDL-C, low-density lipoprotein cholesterol.

Table II

Screening Rates and Appropriate Treatment Rates

Characteristic	Screening Rate (N=5031)	Appropriate Treatment Rate (N=1711)
Age, y		
21–44	25.2	90.2
45–64	49.7	76.6
65–84	53.8	66.1
Sex		
Male	40.0	74.4
Female	36.9	82.6
Ethnicity		
White	42.4	77.7
African American	41.2	86.9
Other	23.8	63.2
Missing	30.9	80.1
Diabetes		
Yes	59.3	61.1
No	35.9	82.3
Cardiovascular disease		
Yes	59.9	52.6
No	36.7	81.8
Pretreatment LDL-C, mg/dL		
≤130	NA	94.0
131–159	NA	61.8
160–189	NA	54.9
≥190	NA	65.2
ATP III risk category		
Low	NA	96.3
Intermediate	NA	74.8
High	NA	56.0

Abbreviations: ATP III, Third Report of the Adult Treatment Panel National Cholesterol Education Program; LDL-C, low-density lipoprotein cholesterol; NA, not available. Values are expressed as percentages.

Table III

Adjusted Odds Ratios (and 95% Confidence Intervals) for Receipt of Screening by Age, Sex, Ethnicity, Diabetes, and Cardiovascular Disease

Characteristic	Odds ratio (95% Confidence Interval)	*P* Value
Age (per 5 y)	1.20 (1.14–1.27)	<.001
Sex (female vs male)	0.84 (0.68–1.03)	.10
Ethnicity (African American vs white)	1.02 (0.71–1.45)	.93
Diabetes	1.78 (1.31–2.44)	<.001
Cardiovascular disease	1.27 (0.75–2.15)	.38

Table IV

Adjusted Odds Ratios (and 95% Confidence Intervals) for Receipt of Appropriate Treatment Among All Screened Patients

	Screened population (N=1711)	
Characteristic	Odds ratio (95% Confidence Interval)	*P* Value
Age (per 5 y)	0.91 (0.85–0.98)	.01
Sex (female vs male)	1.22 (0.76–1.97)	.41
Ethnicity (African American vs white)	1.76 (0.72–4.31)	.21
Pretreatment LDL-C, mg/dL		
≤130	18.8 (6.87–51.3)	<.001
131–159	1.24 (0.58–2.69)	
160–189	1.00 (0.34–2.95)	
≥190	Reference	
ATP risk category		
Low vs high	27.45 (9.71–77.62)	<.001
Intermediate vs high	2.98 (1.61–5.51)	

Abbreviations: ATP, Report of the Adult Treatment Panel National Cholesterol Education Program; LDL-C, low-density lipoprotein cholesterol.

Table V

Adjusted Odds Ratios (and 95% Confidence Intervals) for Receipt of Appropriate Treatment Among the Subset (N=375) of Patients Screened Who Qualified for Lipid-Lowering Drug Treatment

Characteristic	Odds ratio (95% CI)	*P* Value
Age (per 5 y)	0.98 (0.85–1.13)	.81
Sex (female vs male)	0.69 (0.31–1.51)	.35
Ethnicity (African American vs white)	2.19 (1.03–4.64)	.04
Pretreatment LDL-C, mg/dL		
≤130	NA in this subset	<.001
131–159	0.15 (0.07–0.31)	
160–189	0.37 (0.13–1.06)	
≥190	Reference	
ATP risk category		
Low vs high	1.32 (0.27–6.41)	.22
Intermediate vs high	0.58 (0.28–1.22)	

Abbreviations: ATP, Report of the Adult Treatment Panel National Cholesterol Education Program; LDL-C, low-density lipoprotein cholesterol; NA, not available.