CLINICAL RESEARCH STUDY

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Cholesterol Treatment and Changes in Guidelines in an Academic Medical Practice

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ABSTRACT

BACKGROUND: National guidelines are intended to influence physician cholesterol treatment practices, yet few studies have documented the effect of new guidelines on actual prescribing behaviors and impacts on patient eligibility for treatment. We describe current cholesterol treatment in an academic practice of Family and Internal Medicine physicians as well the effect of a change in cholesterol treatment guidelines from 2001 Adult Treatment Panel III (ATPIII) to 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines.

METHODS: Medical records were extracted from primary care patients aged 40-75 years with at least one outpatient visit from January 1, 2012 to July 31, 2013; patients were included if they had records of cholesterol testing, blood pressure measurement, sex, race, and smoking status. Patients were classified into ATPIII and ACC/AHA categories based on clinical variables (eg, diabetes, hypertension, atherosclerotic cardiovascular disease), Framingham Risk Score, and 10-year atherosclerotic cardiovascular disease risk.

RESULTS: There were 4536 patients included in the analysis. Of these, 71% met ATPIII goals and 56% met ACC/AHA guidelines, a 15% decrease. Forty-three percent of high-risk patients met their low-density lipoprotein goals and 46% were on statins. Overall, 32% of patients would need to be started on a statin, 12% require an increased dose, and 6% could stop statins. Of patients considered low risk by ATPIII guidelines, 271 would be eligible for treatment by ACC/AHA guidelines, whereas 129 patients were shifted from intermediate risk to low risk with the change in guidelines.

CONCLUSIONS: The ACC/AHA guidelines expand the number of patients recommended to receive statins, particularly among patients who were previously thought to be at moderate risk, and would increase the intensity of treatment for many patients at high risk. Significant numbers of patients at risk for cardiovascular events were not receiving guideline-based treatment. New cholesterol guidelines may make treatment decisions easier.

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KEYWORDS: Atherosclerotic disease reduction; Cholesterol guidelines; Cholesterol treatment; Statin

Cardiovascular disease is the leading cause of mortality in the US, leading to almost 600,000 deaths annually.[1] On November 12, 2013, the American College of Cardiology/American Heart Association (ACC/AHA) guidelines[2] for treatment of cholesterol and atherosclerotic cardiovascular risk were released, supplanting the Adult Treatment Panel III (ATPIII) guidelines that were originally published in 2001[3] and revised in 2004.[4] In ATPIII, low-density lipoprotein (LDL) levels were the target of therapy based on the correlation between higher levels of LDL cholesterol and risk of atherosclerotic cardiovascular disease, resulting in various LDL treatment goals of LDL based on atherosclerotic cardiovascular disease risk. The new guidelines

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abandoned treatment based solely on cholesterol levels and favored an approach based on calculation of atherosclerotic cardiovascular disease (ASCVD) risk with pool-cohort equations.[5] The recent ACC/AHA guidelines endorsed the use of various intensities of statin medications to reduce overall atherosclerotic cardiovascular disease risk, because the efficacy of statins in cardiovascular disease risk reduction exists even in patients with normal levels of LDL.[6] Therefore, the new guidelines proscribe specific statins and the corresponding dose intensity as the primary pharmacologic treatment of elevated cholesterol in individuals at risk for atherosclerotic cardiovascular disease, which represents a significant change to prescribing patterns.

CLINICAL SIGNIFICANCE

- Seventy-one percent of primary care patients in an academic practice met Adult Treatment Panel III goals.
- New cholesterol guidelines increase the number of patients receiving statins.
- Many patients previously thought to be at low risk now require treatment.
- These guidelines may be easier to follow because they are based on disease risk.

Several criticisms of the guidelines stem from the movement away from the use of LDL targets and the development and use of the ASCVD risk estimator that creates the potential to have large numbers of patients newly classified as in need of risk reduction utilizing a statin medication.[7] Subsequent validation of the ASCVD risk estimation from pooled cohort equations in complementary populations showed moderate to good risk prediction, especially in patients without diabetes with LDL between 70 and 189 mg/dL, the population in whom there are significant questions about statin initiation.[8] Similarly, there may be a subset of the general population previously on a statin or other lipid-lowering agent that may no longer (or never did) require a lipid-lowering medication.

Prior studies have shown that despite changes in treatment guidelines, not all patients are prescribed indicated therapy,[9] and it may take years after a new guideline is published for providers to improve compliance.[10] This may be due in part to poor patient adherence to statin therapy,[11] although provider factors,[12] patient's race, and follow-up rate impact prescribing patterns.[13] Although estimates can be made from national health databases,[14] data from large medical record databases captures the real world of treatment-seeking patients engaged with primary care providers. Using real-world data also overcomes exclusion criteria and nonresponse, allowing for potentially more accurate measures of prescribing and a more generalizable sample. The present study analyzed patient data of a large clinical practice to provide an assessment of current cholesterol-lowering therapy prescribing patterns, and how a change in treatment recommendations might affect patient care.

METHODS

SLUCare is the academic clinical practice of the School of Medicine at Saint Louis University, based in Saint Louis, Missouri. The Division of General Internal Medicine and Department of Family Medicine include approximately 115 physicians, resident trainees, and associated staff at 3 ambulatory care clinics that see an average of approximately 13,000 unique patients per year. A Primary Care Patient Data registry was created by extracting records from 27,225 patients (Family Medicine = 10,994, General Internal Medicine = 16,231) who had at least one encounter (eg, office visit, procedure visit, or clinical support) between July 1, 2008 and July 31, 2013. The Primary Care Patient Data registry contains International Classification of Diseases, 9th Revision−Clinical Modification (ICD-9-CM) codes, prescription orders, Current Procedural Terminology codes, social and family history, demographics, laboratory orders, referrals, and vital signs. Our institutions' Institutional Review Board approved the development of the registry and subsequent analysis.

All patients aged 40-75 years whose last status was "alive" with at least one visit from January 1, 2012 to July 31, 2013 were eligible for the study (n = 9808, **Figure 1**). Patients were included if biometric variables of sex, race, blood pressure, and smoking status in addition to laboratory data of high-density lipoprotein (HDL), LDL, total cholesterol values, and statin dose were available in the registry (n = 4535). Clinical atherosclerotic cardiovascular disease was obtained based on collection of ICD-9 codes for coronary artery disease, peripheral vascular disease, and cerebrovascular disease. Patients diagnosed with type II diabetes and patients with diagnosed hypertension were also identified by ICD-9-CM codes.

Patients in the cohort were defined as statin users if there was a prescription written for a statin from January 1, 2011 through the end of the study period. We included medications from the year prior because most statins are prescribed for a year and patients may not require a new prescription at every visit and may not have repeat visits in the study period. Dose and type of statin was determined from the last available statin prescription or from historical prescription data entered by medical staff, as reported by the patient. Statin dose intensity was classified as low, moderate, or high based on 2013 ACC/AHA guidelines.[2] The use of other lipid-lowering agents was defined as any prescription from 1 year prior (January 1, 2011) to the end of the study time period. The last available data point was used to define biometric and laboratory data (LDL, HDL, total cholesterol, body mass index, blood pressure, hemoglobin A1c, and smoking status). Demographic characteristics included age, sex, and reported race.

Patients were stratified to treatment groups based on the ATPIII treatment recommendations. Their 10-year risk for cardiovascular disease was calculated based on the 10-year