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Original Article

Trends in high-intensity statin use and low-density lipoprotein cholesterol control among patients enrolled in a clinical pharmacy cardiac risk service

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BACKGROUND: Although high-intensity statin therapy (HIST) is recommended for most patients between 21 and 75 years of age with atherosclerotic cardiovascular disease (ASCVD), several recent analyses examining contemporary statin use trends have identified a clinical care gap in the utilization of HIST.

OBJECTIVE: The objective of this study was to assess secular trends in lipid management for patients with ASCVD enrolled in a clinical pharmacy program within an integrated health care delivery system.

METHODS: We performed serial cross-sectional studies over time, comprising 18,006 adults with both acute and chronic ASCVD, to assess trends in statin use and low-density lipoprotein cholesterol (LDL-C) levels from 2007 to 2016.

RESULTS: Although the use of statin therapy (any intensity) remained relatively consistent throughout the 10-year study period (89% in 2007, 87% in 2016), the proportion of patients receiving HIST increased over time (44% in 2007, 67% in 2016; $P < .001$ for trend). Population mean LDL-C levels ranged from 73 to 83 mg/dL with a downward trend over the 10-year study period ($P < .001$ for trend). By 2016, the proportion of patients attaining an LDL-C <100 mg/dL and <70 mg/dL was 85% and 54%, respectively. Nonstatin lipid-lowering therapy use decreased over the study period, which was primarily driven by decreased use of ezetimibe (24% in 2007, 2% in 2016; $P < .001$ for trend).

CONCLUSIONS: Among adults with ASCVD enrolled in a clinical pharmacy cardiac risk reduction service, guideline-directed use of HIST significantly increased over the past 10 years and coincided with decreased population LDL-C levels.

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Introduction

Cardiovascular disease is the leading cause of death and medical costs in the United States with annual direct and indirect costs estimated at more than $316 billion.[1] Low-density lipoprotein cholesterol (LDL-C) is one of the most important modifiable risk factors for the development and progression of atherosclerotic cardiovascular disease (ASCVD).[2–4] Statins effectively lower LDL-C levels, reduce morbidity, and mortality associated with ASCVD, and as such, are the cornerstone of medical therapy for both prevention and treatment of ASCVD.[2,3,5]

In 2013, the American College of Cardiology/American Heart Association (ACC/AHA) published an updated cholesterol treatment guideline focused on reducing the risk of ASCVD.[2] The guideline highlighted the importance of high-intensity statin therapy (HIST), particularly in individuals with ASCVD, which confers an incremental lowering of cardiovascular events as compared to treatment with lower intensity statin therapy. This approach was not without controversy as it represented a marked departure from years of clinical practice focused on targeting specific LDL-C and non-HDL-C treatment goals. Since the publication of these guidelines, estimates of individuals with ASCVD receiving guideline-recommended HIST have varied widely with some studies reporting rates as low as 20%.[6–11] The primary objective of this study was to assess secular trends in lipid management for patients with ASCVD enrolled in a clinical pharmacy program within an integrated health care delivery system.

Methods

Study design and setting

Serial cross-sectional studies over time, with each calendar period being a separate cross-sectional study, were used to examine secular trends in the use of statin therapy (including statin intensity), nonstatin lipid-lowering therapy, and population LDL-C levels in patients with ASCVD. Patients were included if they were enrolled in the clinical pharmacy cardiac risk service (CPCRS) at Kaiser Permanente Colorado (KPCO). KPCO is a nonprofit integrated health care delivery system, which provides services to over 675,000 members throughout Colorado. The CPCRS is a population-management service focused on the long-term care of more than 16,000 patients with ASCVD. All patients with ASCVD at KPCO are enrolled into the service with the exception of a small number who have short life expectancy or actively choose to opt out of enrollment. Most patients (>90%) have diagnosed coronary artery disease (CAD), whereas most have a history of noncardioembolic ischemic stroke (~10%) or peripheral artery disease (~5%), either with or without comorbid CAD. Detailed descriptions of the CPCRS have been previously published.[12,13] Using a systems-based approach, the CPCRS works closely with primary care providers, cardiologists, and nurses to implement evidence-based, secondary prevention strategies for the management of dyslipidemia, hypertension, diabetes, antiplatelet therapy, and smoking cessation. Under a collaborative practice agreement, the CPCRS clinical pharmacists initiate and modify guideline-directed therapies for ASCVD, order laboratory tests, and follow-up with patients as clinically indicated. Optimization of statin therapy and LDL-C goal attainment have long been core functions of the CPCRS, which follows patients longitudinally to ensure that these therapies are effective, affordable, adhered to, and well tolerated.

Procedures and data collection

The study was approved by the KPCO institutional review board with waiver of informed consent. Administrative queries of integrated laboratory and pharmacy databases at KPCO were used to collect study-related data. The study period was January 1, 2007 to December 31, 2016, which was divided into 6-month time intervals ("calendar halves") defined as January 1 to June 30 (first half) and July 1 to December 31 (second half). All patients enrolled in the CPCRS were evaluated for potential study eligibility in each calendar half. The look-back period to determine patient eligibility was defined as the 6 months immediately preceding the start of each calendar half. Eligible patients were 21 to 75 years of age at the start of the calendar half, continuously enrolled as a KPCO member during the entire look-back period (allowing for gaps in KPCO membership of ≤30 days), and enrolled in the CPCRS before the start of the calendar half. Patients were excluded if they died or were disenrolled from KPCO and/or the CPCRS during the calendar half under study (Fig. 1). Patients were eligible to be included in multiple calendar halves if they met all eligibility criteria.

Statin and nonstatin lipid-lowering therapy use

Lipid-lowering therapy use was categorized by outpatient pharmacy dispensing records of statin and nonstatin medications and was limited to prescription medications only. Among patients who met eligibility criteria, lipid-lowering therapy use was defined as at least 1 outpatient pharmacy fill that occurred during the calendar half under study. Daily statin dose was calculated as milligrams (mg) per day and assigned an intensity level consistent with those defined by the 2013 ACC/AHA blood cholesterol guidelines.[2] This method of assigning statin intensity was also applied to patients receiving alternative dosing strategies (eg, every other day, once a week, etc.). For patients with more than 1 statin filled during a calendar half, we selected the earliest fill to define the intensity of statin therapy. The same approach was used to define nonstatin lipid-lowering therapy, which included fibrates, bile acid sequestrants, prescription niacin, ezetimibe (alone or as a component of a combination product), and proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.