Frequency of High-Risk Patients Not Receiving High-Potency Statin (from a Large Managed Care Database)

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We examined trends in low-density lipoprotein cholesterol (LDL-C) goal attainment in high-risk patients and use of high-potency statins (HPS) in a large, managed-care database from 2004 to 2012. The 2013 American Heart Association/American College of Cardiology prevention guidelines recommend that subjects with atherosclerotic cardiovascular disease (ASCVD) should be prescribed HPS therapy, irrespective of LDL-C levels. Previous guidelines recommend an LDL-C target <70 mg/dl. Patients diagnosed with ASCVD based on *International Classification of Diseases, Ninth Revision* codes with ≥1 LDL-C test from January 2004 to December 2012 were identified in the Optum Insight database. Patients were identified as treated if they received lipid-lowering therapy (LLT) within 90 days of the LDL-C measurement and untreated if they did not receive LLT treatment. LLT treated patients were stratified into HPS users or non-HPS LLT users. There were 45,101 eligible patients in 2004 and 40,846 in 2012. The proportion of high-risk patients who were treated with LLT increased from 61.4% (2004) to 70.5% (2008) then remained relatively constant until 2012 (67.9%). Mean LDL-C values in treated patients decreased from 103.7 ± 32.1 (2004) to 90.8 ± 31.4 mg/dl (2012). The proportion of patients treated with HPS increased from 13% in 2004 to 26% in 2012. Although the proportion of treated high-risk patients who achieve LDL-C <70 mg/dl levels has increased sharply from 2004, approximately 3 of 4 patients still did not meet this target. Only 1/4 of ASCVD patients are on HPS. In conclusion, our findings highlight the need for renewed efforts to support guideline-based LDL-C treatment for high-risk patients. **(Am J Cardiol 2015;115:190−195)**

Using a large, contemporary database of managed care claims, our study sought to explore trends in low-density lipoprotein cholesterol (LDL-C) goal achievement from 2004 to 2012 as a function of treatment status. Additionally, we examined the percentage of high-risk, eligible patients being treated with high-potency statin (HPS) therapy over the study period.

Methods

The objectives of this study were threefold, namely: (1) to examine trends in average LDL-C levels as a function of whether the patient is being treated with lipid-lowering therapy (LLT); (2) to examine trends in attainment rates of the LDL-C goal of <70 mg/dl among high-risk and very high-risk patients; and (3) to determine the trends in the percentage of high-risk patients being treated with HPS as recommended by the current guidelines.

This study used the Optum Insight database consisting of patients' longitudinal records of enrollment, inpatient and outpatient medical claims, pharmaceutical claims, and laboratory results for over 45 million unique managed care members across the United States. This database consists of de-identified Health Insurance Portability and Accountability Act compliant patient records of United Healthcare managed care enrollees in the United States.

This was a retrospective study of high-risk and very high-risk patients with atherosclerotic cardiovascular disease (ASCVD) that met the study inclusion and/or exclusion criteria from January 2004 to December 2012. The study examined the proportion of high-risk and very high-risk patients treated for high LDL-C levels, their average LDL-C levels and attainment rates of the optional LDL-C goal of <70 mg/dl by initial treatment status. Outpatient laboratory test results were available for subpopulations of the research database. Laboratory data are available for approximately 30% of the study sample.

The study period included available data from January 2004 to December 2012. Eligible subjects had ASCVD based on *International Classification of Diseases, Ninth*

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Funding for this research was provided by Merck Sharp & Dohme Corp.

See page 194 for disclosure information.

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0002-9149/14/$ - see front matter
http://dx.doi.org/10.1016/j.amjcard.2014.10.021

Table 1
Demographics and select comorbidities of patients meeting enrollment criteria (select years)

Variable	2004 n= 45,101			2006 N= 52,283			2008 N= 49,990			2010 N= 49,923			2012 N= 40,846		
	Treated	Untreated	p-value	Treated	Untreated	p-value	Treated	Untreated	p-value	Treated	Untreated	p-value	Treated	Untreated	p-value
n	27,710	17,391		35,507	16,776		35,225	14,765		34,218	15,705		27,736	13,110	
Treated	61.4%	-		67.9%	-		70.5%	-		68.5%	-		67.9%	-	
Female	32.3%	50.3%	<0.0001	30.2%	53.0%	<0.0001	30.5%	53.8%	<0.0001	30.2%	52.4	<0.0001	29.6%	51.8%	<0.0001
Age, Mean (Years)	59.0%	57.3%	<0.0001	57.3%	51.9%	<0.0001	57.9%	52.5%	<0.0001	58.2%	53.0	<0.0001	58.8%	53.5%	<0.0001
Comorbidities															
Acute MI	7.04%	3.57%	<0.0001	7.25%	2.78%	<0.0001	7.47%	2.59%	<0.0001	7.56%	3.00%	<0.0001	7.86%	3.07%	<0.0001
Acute IHD	10.67%	6.97%	<0.0001	9.96%	6.32%	<0.0001	8.67%	6.54%	<0.0001	8.39%	6.07%	<0.0001	8.09%	5.51%	<0.0001
Previous MI	9.03%	3.97%	<0.0001	8.46%	2.84%	<0.0001	8.65%	3.33%	<0.0001	8.26%	3.51%	<0.0001	8.85%	3.49%	<0.0001
Stable Angina	18.96%	18.75%	0.5734	17.88%	21.20%	<0.0001	15.25%	19.13%	<0.0001	13.63%	16.00%	<0.0001	12.91%	16.22%	<0.0001
Chronic IHD	76.62%	55.43%	<0.0001	74.64%	46.45%	<0.0001	73.80%	45.56%	<0.0001	72.74%	44.83%	<0.0001	71.94%	42.33%	<0.0001
Revascularization	15.30%	10.48%	<0.0001	15.25%	10.05%	<0.0001	14.20%	9.04%	<0.0001	13.88%	9.49%	<0.0001	13.08%	8.09%	<0.0001
Atherosclerosis	20.78%	18.47%	<0.0001	20.36%	18.22%	<0.0001	19.81%	17.68%	<0.0001	19.81%	19.61%	0.6135	19.50%	18.80%	0.0961
Ischemic Cerebrovascular	1.70%	2.08%	0.0039	1.80%	2.37%	<0.0001	2.02%	2.56%	0.0001	2.09%	2.77%	<0.0001	2.13%	2.97%	<0.0001
Ischemic Stroke	7.49%	9.92%	<0.0001	7.56%	10.40%	<0.0001	8.10%	11.89%	<0.0001	8.35%	12.23%	<0.0001	8.78%	13.42%	<0.0001
Diabetes	31.98%	23.47%	<0.0001	31.21%	20.70%	<0.0001	32.07%	21.37%	<0.0001	31.22%	20.99%	<0.0001	31.48%	20.75%	<0.0001

Revision, Clinical Modification (ICD-9-CM) and *Current Procedure Terminology-4* administrative codes. The earliest date of a valid LDL-C value was defined as the "Index Date." Patients were followed until the end of enrollment in their health plan or up to December 31, 2012, whichever came first. Participants were included in the study if they had at least 1 valid LDL-C value during the study period, were >18 at the index date, and had documented ASCVD as defined by ICD-9-CM codes including acute coronary syndrome, clinical coronary heart disease history (stable angina and coronary artery procedures), or coronary heart disease equivalents including symptomatic or significant carotid artery disease, peripheral arterial disease, cerebrovascular disease, abdominal aortic aneurysm, and diabetes mellitus (Supplementary Table 1). Patients with LDL-C levels <50 mg/dl or >600 mg/dl were excluded from the analyses. Because of effects on hepatic LDL-C production, patients with liver disease were excluded from the analyses.

Study eligible treated patients were defined as patients who received at least 1 prescription for any of the lipid-lowering agents including statins, niacin, fibrates, ezetimibe, bile acid sequestrants, prescription strength omega-3, or any combinations of the previously mentioned, which contained a lipid-lowering drug in the formulation. HPSs were defined as atorvastatin 40 mg or 80 mg, rosuvastatin 20 mg or 40 mg, and simvastatin 80 mg.

To be considered treated for a given month, the LLT prescription must have been filled at some time during the 90 days before the LDL-C test for that month. Patients who did not receive any LLTs in the 90-day period preceding the date of the LDL-C test for a specific month were considered untreated for that month. For annual reporting, to be considered treated for a given year, the LLT prescription must have been filled at any time during the 90 days before 1 January of that year to 31 December of that year. Patients who did not receive any LLTs in that period were considered untreated that year.

Key information extracted from the database included demographics (age, gender, and index year), pharmacy claims to determine if patient was treated or untreated (National Drug Code, fill date), medical claims to determine if patient had ASCVD as well as clinically relevant co-morbidities (ICD-9-CM diagnoses codes, *Current Procedure Terminology-4* codes, and date of service), enrollment records to determine if the patient met age and enrollment requirements (date of enrollment, date of disenrollment, and year of birth), and laboratory results (laboratory test type, date of lab test, test value, and test unit). Additionally, adjacent enrollment records with enrollment gaps ≤45 days were combined into a single enrollment period record of continuous enrollment. Missing LDL-C values were calculated using Friedewald equation as long as the value for triglycerides was ≤400 mg/dl.

Primary outcomes were monthly and annual assessment of the average LDL-C measure, the percent of patients with LDL-C measures at or below the optional LDL-C goal of 70 mg/dl, and the proportion of high-risk patients treated with HPSs. This assessment was also replicated where the LDL-C goal was at or below 100 mg/dl. All outcome measures were stratified by treatment status (treated vs untreated).

Descriptive statistics were generated for the demographic variables (age and gender) and cardiovascular