

Loss of early gains in low-density lipoprotein cholesterol goal attainment among high-risk patients

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BACKGROUND: Guidelines recommend a low-density lipoprotein cholesterol (LDL-C) measurement of <70 mg/dL as a reasonable goal in high-risk patients with coronary heart disease (CHD) or atherosclerotic vascular disease (AVD).

METHODS: This retrospective, cross-sectional study examined LDL-C goal attainment monthly trends from January 1, 2004, to August 31, 2008, in a large, managed-care claims database in the United States. High-risk CHD or AVD patients who had at least one LDL-C test during that time period were included (N = 284,915). Average LDL-C values and percent of patients not achieving LDL-C goal (LDL-C \geq 70 mg/dL) were obtained by averaging patient level LDL-C values for each month. A linear trend analysis with first-order autocorrelated errors was conducted.

RESULTS: The proportion of patients treated with lipid-lowering therapy gradually increased from 58.5% in 2004 to 70.5% in 2008. Mean LDL-C values in patients treated with lipid-lowering therapy decreased from 100.4 to 96.4 mg/dL, whereas LDL-C remained relatively constant in untreated patients (114.3 mg/dL). In treated patients, the percentage with LDL-C \geq 70 mg/dL decreased from 87.5% in January 2004 to 73.8% in December 2006 ($P < .0001$), then gradually declined between January 2007 (79.6%) and August 2008 (76.2%; $P < .0001$). Among untreated patients, 92.9% had LDL-C levels \geq 70 mg/dL in January 2004 and 93.0% in August 2008.

CONCLUSION: In conclusion, the percentage of high-risk patients with CHD or AVD treated with lipid-lowering therapy who achieve LDL-C <70 mg/dL levels has increased since 2004, although a large proportion of these patients still do not meet this goal. Additionally, 1 of 4 high-risk patients otherwise eligible for lipid-lowering therapy remains untreated. These data suggest the need for renewed efforts to support guideline-based LDL-C lowering in high-risk patients.

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Current guidelines suggest the attainment of low-density-lipoprotein cholesterol (LDL-C) levels of <70 mg/dL as an optional goal for high-risk patients with

established coronary heart disease (CHD) or atherosclerotic vascular disease (AVD), including peripheral artery disease, aortic abdominal aneurysm, and carotid artery disease.^{1,2} Recent trends in managed-care databases indicate that switches from patient use of high-potency lipid-lowering therapies to lower-potency generic statins with reduced LDL-C lowering efficacy are occurring.^{3–5} The impact of these recent treatment patterns on LDL-C goal attainment

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are unknown. Although recent surveys have shown an overall improvement in LDL-C goal attainment,^{6,7} only about one third of high-risk patients with CHD or AVD attain levels of LDL-C <70 mg/dL.^{8,9} There is a need not only for more intensive treatment of high-risk patients who are not at goal but also treatment of those with LDL-C levels ≥ 70 mg/dL who are currently not receiving lipid-lowering therapy.⁶⁻⁹ In this analysis, we examined trends in the average LDL-C levels and attainment of LDL-C <70 mg/dL among high-risk patients with CHD and/or AVD who were treated with lipid-lowering therapy and those who were untreated during January 2004 to August 2008 by using data from a large, managed-care claims database in the United States.

Methods

The data used in this analysis were obtained from an extensive, computerized database in the United States for an employed, commercially insured population with dependents that is widely used for research purposes. This database contains the following information: administrative medical claims for outpatient, inpatient, and emergency room visits; associated diagnoses and procedure codes; prescription dispensing; automated laboratory data for a subset of patients; and health plan membership (enrollment) file. The database is updated multiple times a year, and the current analysis included patient level data updated through August 2008.

Eligible patients were those 18 years of age and older with CHD and/or AVD identified by diagnosis (Ninth revision of International Classification of Diseases) and/or procedure codes (Table 1) that were recorded up to a maximum of 12 months before the date of the first available LDL-C test between January 2004 and August 2008. Patients had to be continuously enrolled for 2 months before and during the month tested. All measures were calculated monthly from January 2004 until August 2008. Individuals who were not tested in the current month are not included in that month.

In this analysis, the treated population was defined as those patients who had at least one prescription for a lipid-lowering therapy, including statins (atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin, ezetimibe/simvastatin), niacin, fibrates (clofibrate, fenofibrate, micronized fenofibrate, gemfibrozil), bile acid sequestrants (cholestyramine, colesvelam, colestipol), and ezetimibe. The treated population included patients with at least one lipid-lowering therapy prescription at any time during the study period, regardless of the duration before the LDL-C test. The untreated population consisted of those who did not receive lipid-lowering therapy before the LDL-C test for the month. If any untreated patients received a lipid-lowering therapy prescription later, they were placed in the treated group starting from the date lipid-lowering therapy was initiated. Also included were patients newly enrolled in

the database. Patients on lipid-lowering therapy and/or who had LDL-C measurements were included up to the time of disenrollment. The average LDL-C and percent of patients not at LDL-C goal <70 mg/dL were assessed for patients with CHD and/or AVD from January 2004 until August 2008 for each month. A linear trend analysis with first-order autocorrelated errors was conducted for treated and untreated patients separately for before and after December 2006.

Results

A total of 284,915 patients met the inclusion criteria and were included in this analysis. The overall mean age of the patients was 59 ± 11.8 years in 2004 and decreased slightly over time to 56 ± 9.3 years in 2008 (Table 2). There were slightly more male than female patients. A majority (61.6%–73.6%) of patients had chronic ischemic heart disease, about one third of the patients were diabetic (33.4%–38.4%) or atherosclerotic (33.8%–36.4%), and 21.7%–25.3% had angina.

From January 2004 to August 2008, the proportion of patients treated with lipid-lowering therapy increased gradually from 58.5% to 70.5%, and the proportion of untreated patients decreased from 41.5% to 29.5% (Table 3). The mean age of both treated and untreated groups was similar during 2004 and 2005 and was greater in the treated compared with untreated groups during 2006 to 2008. Average age decreased over time in both groups. There were more men than women in the treated groups compared with untreated patients, and more patients had diabetes in the treated than untreated population. The numbers of patients who had cardiovascular disease (acute myocardial infarction, previous myocardial infarction, acute and chronic ischemic heart disease, and revascularization) was greater in the treated groups compared with the untreated groups for all years. The number of patients with peripheral vascular disease, ischemic stroke, angina, acute carotid artery procedures, and atherosclerosis was initially similar in the 2 groups and then became greater in the treated than untreated group by 2008. The average LDL-C levels were 114.3 ± 33.1 mg/dL for untreated patients and 97.5 ± 34.3 mg/dL for treated patients during this time period.

The average patient LDL-C values declined over time in the treated group, from 104.7 ± 34.8 mg/dL in January 2004 to 96.2 ± 37.0 mg/dL in August 2008 (Fig. 1). In the untreated group, LDL-C values remained generally constant over the period, with a slight decrease from 116.7 ± 35.6 mg/dL in January 2004 to 113.7 ± 32.1 in August 2008. The percentage of treated patients with LDL-C levels ≥ 70 mg/dL decreased from 87.5% in January 2004 to 73.8% in December 2006 (range, 71.8%–87.5%; linear trend, $P < .0001$). This downward trend reversed with an increase to 79.6% in January 2007, followed by a more gradual decline to 76.2% in August 2008 (range, 76.2%–79.6%; linear trend, $P < .0001$; Fig. 2). The percentage of untreated patients with LDL-C ≥ 70 mg/dL

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