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Lipid therapy utilization rates in a managed-care mixed dyslipidemia population

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BACKGROUND: National clinical treatment guidelines recommend pharmacologic treatment in addition to therapeutic lifestyle modifications in patients with mixed dyslipidemia and multiple risk factors for coronary heart disease (CHD).

OBJECTIVES: To evaluate real-world pharmacologic treatment of mixed dyslipidemia patients with cardiovascular disease (CVD) risk factors.

METHODS: Commercial health plan members in a large, United States managed-care database with complete lipid panel results (ie, high-density lipoprotein cholesterol [HDL-C], low-density lipoprotein cholesterol [LDL-C], total cholesterol [TC], triglycerides [TG]) between January 1, 2006 and December 31, 2006 were included. Mixed dyslipidemia was defined as any two nonoptimal lipid parameters (LDL-C, HDL-C, TG) according to National Cholesterol Education Program/Adult Treatment Panel III guidelines. Subjects were observed for 182 days pre-index to determine CVD risk factors (ie, male aged 45+ years, female 55+ years, CHD history, hypertension, diabetes mellitus). Lipid treatment status 6 months pre- and post-index dates was determined using pharmacy claims for any lipid monotherapy (statin, fibrate, niacin, "other"), or combination therapy (statin + fenofibrate; statin + niacin; statin + other).

RESULTS: Lipid treatment increased post-index for all mixed dyslipidemia groups and by total number of risk factors. The increased LDL-C and low HDL-C group had the lowest treatment rates; the group with low HDL-C and elevated TG had the highest. In the latter group, when treated, primarily statin monotherapy (51%) was used post-index; only 26% received niacin or fibrate therapy targeting HDL-C or TG abnormalities. Across all mixed dyslipidemia patients, >30% with three to four CVD risk factors were not treated ≥6 months post-index.

CONCLUSIONS: In real-world clinical practice, pharmacologic treatment rates increased upon assessment of multiple lipid abnormalities and by total risk factors for CHD. However, mixed dyslipidemia remained undertreated with low rates of niacin and fibrate usage.

Background

Mixed dyslipidemia is among the most important modifiable risk factors for coronary heart disease (CHD), which has been identified as the leading cause of death in the United States for both men and women.[1] Characterized by elevated low-density lipoprotein cholesterol (LDL-C) and triglyceride (TG) levels in conjunction with decreased levels of high-density lipoprotein cholesterol (HDL-C), mixed dyslipidemia is especially common in patients with diabetes mellitus, hypertension, and/or the metabolic syndrome, all of which have also been cited as risk factors for CHD.[2–5]

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Table 1 Abnormal lipid value criteria

	Nondiabetic/non-CHD population		
Lipid parameter	Males	Females	Diabetic/CHD population
LDL-C	LDL ≥130 mg/dL	LDL ≥130 mg/dL	LDL ≥100 mg/dL
HDL-C	HDL ≤40 mg/dL	HDL ≤50 mg/dL	HDL ≤50 mg/dL for females; HDL ≤40 mg/dL for males
TG	TG ≥200 mg/dL	TG ≥150 mg/dL	TG ≥150 mg/dL

CHD, coronary heart disease; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; TG, triglycerides.

The burgeoning prevalence of insulin resistance throughout the world is greatly increasing the incidence of mixed dyslipidemia. Insulin resistance is associated with hypertriglyceridemia, reduced production and increased catabolism of HDL particles, and increased serum concentrations of small, dense LDL particles.[6] Little data exist on the prevalence of mixed dyslipidemia in the United States, but the burden is considerable—as evidenced by the estimated expenditure of ~$400 billion attributable to cardiovascular disease (CVD) and stroke in the United States in 2008, a substantial proportion of which is related to dyslipidemia.[7]

Despite receiving statin therapy, patients with mixed dyslipidemia—or multiple lipid abnormalities—are at high risk for CHD. Elevated TG level remains an independent risk factor for CHD even after adjustment for HDL-C.[4] A subanalysis of the Helsinki Heart Study has provided additional detail on the relationship between other lipid changes and incidence of CHD, demonstrating that those at highest risk for initial CHD events were placebo-treated patients with TG levels >204 mg/dL and LDL-C/HDL-C ratio >5. This group experienced about three times as many events as those with more favorable LDL-C/HDL-C ratios.[1,8] In the Scandinavian Simvastatin Survival Study (a secondary prevention study with a mean LDL-C of 190 mg/dL), patients with mixed dyslipidemia experienced the greatest reductions in risk for cardiovascular morbidity and mortality during the follow-up period of the study when treated with statin therapy.[9] The results of these trials support the concept that patients at highest risk of CHD events (primary and recurrent) are those with mixed hyperlipidemia.[1]

Despite the abundance of data confirming the role of suboptimal lipoprotein levels as a risk factor for CHD and the availability of guidelines enumerating therapeutic lifestyle modifications and pharmaceutical treatment options for mixed dyslipidemia management, a substantial proportion of dyslipidemic patients remain untreated or inappropriately treated[10,11] or make a decision to discontinue treatment soon after it is initiated.[12]

The primary objective of the present study was to achieve greater understanding of treatment patterns in real-world patients by evaluating pharmacologic treatment of mixed dyslipidemia patients with CVD risk factors enrolled in a commercial health plan. Specifically, the purpose was to determine what proportion of patients with suboptimal LDL-C, HDL-C, and/or TG values are not being treated appropriately with lipid-modifying medications.

Methods

Data source

This was a retrospective claims data analysis using medical and pharmacy data, laboratory results, and enrollment information from a large managed health care plan in the United States. Claims for services provided to members of this health plan are submitted by physicians, facilities, and pharmacies for payment. The health plan comprises discounted fee-for-service independent practice association plans spanning the United States, with the largest concentration in the southern and midwestern regions. At the time the study was conducted, the administrative claims database included data for approximately 14 million health plan enrollees with both medical and pharmacy benefits. All study data were deidentified and accessed with protocols compliant with the Health Insurance Portability and Accountability Act. Institutional review board approval was therefore not required for this study.

Study subject identification

This study was conducted to determine treatment patterns among patients with mixed dyslipidemia. Study patients included commercial health plan enrollees with a laboratory value for LDL-C, HDL-C, and TG all drawn on the same day during the period from January 1, 2006 to December 31, 2006. An index date was set as of the date of the first suboptimal test result or first optimal test result. Patients were required to have been continuously enrolled for 182 days prior to and 182 days following the index date.

Two groups of patients were created; a subset with all lipid values (LDL-C, HDL-C, and TG) under control (categorized as the "Optimal Cohort") and another subset with at least one suboptimal lipid value ("Suboptimal Cohort"), as defined in Table 1. The criteria for the suboptimal cohort were developed based on the National Cholesterol Education Program (NCEP)–Adult Treatment Panel (ATP) III and American Heart Association guidelines.[13–15] The two