Lipid Treatment Assessment Project 2
A Multinational Survey to Evaluate the Proportion of Patients Achieving Low-Density Lipoprotein Cholesterol Goals

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Background—Information about physicians’ adherence to cholesterol management guidelines remains scant. The present survey updates our knowledge of lipid management worldwide.

Methods and Results—Lipid levels were determined at enrollment in dyslipidemic adult patients on stable lipid-lowering therapy in 9 countries. The primary end point was the success rate, defined as the proportion of patients achieving appropriate low-density lipoprotein cholesterol (LDL-C) goals for their given risk. The mean age of the 9955 evaluable patients was 62±12 years; 54% were male. Coronary disease and diabetes mellitus had been diagnosed in 30% and 31%, respectively, and 14% were current smokers. Current treatment consisted of a statin in 75%. The proportion of patients achieving LDL-C goals according to relevant national guidelines ranged from 47% to 84% across countries. In low-, moderate-, and high-risk groups, mean LDL-C was 119, 109, and 91 mg/dL and mean high-density lipoprotein cholesterol was 62, 49, and 50 mg/dL, respectively. The success rate for LDL-C goal achievement was 86% in low-, 74% in moderate-, and 67% in high-risk patients (73% overall). However, among coronary heart disease patients with ≥2 risk factors, only 30% attained the optional LDL-C goal of <70 mg/dL. In the entire cohort, high-density lipoprotein cholesterol was <40 mg/dL in 19%, 40 to 60 mg/dL in 55%, and >60 mg/dL in 26% of patients.

Conclusions—Although there is room for improvement, particularly in very-high-risk patients, these results indicate that lipid-lowering therapy is being applied much more successfully than it was a decade ago. (Circulation. 2009;120:28-34.)

Key Words: hypercholesterolemia ■ lipids ■ prevention ■ statins

Many clinical trials have demonstrated that low-density lipoprotein cholesterol (LDL-C) lowering, predominantly with statins, reduces the incidence of coronary and cerebrovascular events across a broad spectrum of patients at risk.1,2 Guidelines for the management of patients at risk have been established in Europe and North America.3–5 As clinical trial evidence has accumulated, the guidelines have advocated progressively lower LDL-C targets and more aggressive use of statin therapy.3–6

Clinical Perspective on p 3

Data from older studies revealed that most patients did not reach their LDL-C goal.7–9 For example, the original Lipid Treatment Assessment Project (L-TAP), conducted in the United States among 4888 patients in 1996 and 1997, found that LDL-C goal attainment in a primary care setting was only 38% overall and 18% among patients with established coronary heart disease (CHD).10 In a survey undertaken in 15 European countries between 1999 and 2000, only 42% of 5226 patients with established CHD reached a total cholesterol goal of <193 mg/dL (5.0 mmol/L).7 More recent surveys show an improvement in attaining previous LDL-C goals but low rates of reaching the new target of <70 mg/dL (1.8 mmol/L) for high-risk CHD patients.10,11

L-TAP 2 is a survey performed in >10 000 patients in 9 countries (United States, Canada, Mexico, Brazil, Spain, the

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Netherlands, France, Taiwan, and Korea) between September 2006 and April 2007. The primary end point was defined as the success rate in achieving appropriate LDL-C goals for the patient's level of risk. The National Cholesterol Education Program Adult Treatment Panel (NCEP ATP) III, the 2003 Joint European Societies, or the 2003 Canadian Working Group guidelines were used for each corresponding geographic area. In addition to LDL-C, high-density lipoprotein cholesterol (HDL-C) and triglyceride levels were measured in patients in the fasting state.

Methods

Patient Selection
Patients were eligible if they were ≥20 years of age and if they had been treated with the same lipid-lowering therapy for at least 3 months. Diet and exercise were counted as permissible lipid-lowering therapies. Patients were excluded if ≥1 of the following conditions were present: major trauma, surgery requiring anesthesia, or hospitalization within 12 weeks; acute infection requiring antibiotic therapy; change in usual diet within 1 month; pregnancy, breast-feeding, or postpartum within 6 months; myocardial infarction within 12 weeks; any unstable medical condition; life expectancy <6 months; or treatment with an investigational lipid-altering drug or device within 30 days of the study visit. All patients gave written informed consent, and the study was approved by an institutional review board when required.

The goal for enrollment was 3000 patients in the United States; 1000 patients each in Canada, Spain, the Netherlands, France, Taiwan, and Korea; 400 patients in Brazil; and 600 patients in Mexico. Cluster sampling was used, with a cluster defined as each practicing physician-investigator. Each investigator was expected to enroll ~20 patients.

Study Protocol
Data on history of smoking, alcohol use, past coronary disease or other atherosclerotic events, hypertension, diabetes mellitus, family history of coronary or atherosclerotic disease, hypothyroidism, nephrotic syndrome, liver disease, and any other significant medical condition were obtained from each patient at the study visit. Current cholesterol medications, if any, and duration of therapy and any nonpharmacological interventions for dyslipidemia (diet, exercise) were recorded. Height, weight, waist circumference, and blood pressure were measured. A venous blood sample was drawn in patients after fasting for at least 8 hours. All samples were analyzed in a central laboratory (MDS Pharma Services Central Laboratory, Mississauga, Ontario, Canada) for total cholesterol, HDL-C, triglycerides, blood glucose, and high-sensitivity C-reactive protein with a Roche Modular Analyzer; LDL-C was calculated by the Friedewald formula. Framingham 10-year risk of developing a coronary event was calculated for each patient.

Statistical Analyses

Sample Size Determination
The primary end point of success rate would have a 2% margin of error at a 0.05 level of significance, assuming a success rate of 50%, if the sample size were 2401. The enrollment goal was set at 3000 patients in the United States. 3000 patients in Europe (1000 each in Spain, the Netherlands, and France); 2000 patients in Asia (1000 each in Taiwan and Korea), and 1000 in South America (400 in Brazil and 600 in Mexico). The margin of error for the primary end point was thus <2% in the United States and >2% in the geographic groups with smaller numbers of participants.

Study End Points
The primary end point was success rate, defined as the proportion of patients achieving LDL-C treatment goals. NCEP ATP III guidelines were used for the United States, Latin America, and Asia; Joint European guidelines were used for patients in European countries; and Canadian guidelines were used for patients in Canada. For LDL-C, the primary end point was defined as the proportion of patients within categories of HDL-C (<40, 40 to 60, and >60 mg/dL). Secondary efficacy parameters were levels of LDL-C, HDL-C, total cholesterol, triglycerides, and high-sensitivity C-reactive protein.

LDL-C success rates were compared among risk groups with the \( \chi^2 \) test. Multivariate predictors of LDL-C success rates and HDL-C levels were determined from logistic regression models. Normally distributed data are expressed as mean±SD; nonnormally distributed data such as high-sensitivity C-reactive protein levels are expressed as median values with interquartile ranges.

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

A total of 10 174 patients were enrolled, but 219 (2.2%) were excluded because of missing LDL-C values, leaving a study population of 9955. The clinical characteristics of the patients enrolled in each country are listed in Table 1. Overall, the average age of the patients was 62±12 years, and 54% were male. Coronary disease had been diagnosed in 30%, diabetes in 31%, hypertension in 64%, a family history of premature coronary disease in 29%, and current smoking in 14%. Current treatment consisted of a statin in 75% of patients, a fibrate in 7%, ezetimibe in 5%, simvastatin/ezetimibe in 5%, and nonpharmacological therapy only in 16%. Niacin, omega-3/ fish oil, and bile acid sequestrants each were used by <2% of the study population. The most commonly used statins were atorvastatin in 33% of patients, simvastatin in 17%, rosvastatin in 12%, and pravastatin in 7%. The median duration of statin therapy was 2.0 years (interquartile range, 0.8 to 3.6 years).

Patients were classified into low-, moderate-, and high-risk groups, with low-risk patients being those with ≤1 risk factor, moderate-risk patients being those with ≥2 risk factors, and high-risk patients being those with coronary or other atherosclerotic vascular disease or diabetes mellitus. The characteristics of the patients in each group are listed in Table 2.

LDL-C Success Rate

Overall, 7239 of the 9955 patients attained their LDL-C goal, for a success rate of 73%. The rate was 86% (1782 of 2066) in low-risk patients, 74% (1459 of 1959) in moderate-risk patients, and 67% (3998 of 5930) in high-risk patients (P<0.0001). Among low-risk patients, mean LDL-C was 108±27 mg/dL (2.8±0.7 mmol/L) among those who successfully reached goal and 185±24 mg/dL (4.8±0.6 mmol/L) among those who did not. In moderate-risk patients, mean LDL-C was 92±22 mg/dL (2.4±0.6 mmol/L) in those who reached goal and 158±23 mg/dL (4.1±0.6 mmol/L) in those who did not. In the high-risk group, mean LDL-C was 73±17 mg/dL (1.9±0.4 mmol/L) in those who reached goal and 127±28 mg/dL (3.3±0.7 mmol/L) in those who did not.

The success rate varied considerably by country, from a low of 47% to a high of 84% (Figure 1A). As shown in Figure 1B, success rates were higher in moderate/high-risk patients in the 3 European countries but higher in low-risk patients in the other countries. The success rate was higher in men than in women, 74% compared with 72% (P<0.0001). Multivariate predictors of successful LDL-C goal achievement were lipid-lowering therapy (P<0.0001), lower-risk group (P<0.0001), geographic
region ($P<0.0001$), male gender ($P<0.0001$), older age ($P<0.0001$), race (Asian>$white>$black; $P<0.0001$), absence of dietary counseling ($P<0.0001$), diabetes ($P=0.0028$), and hypertension ($P=0.0105$).

The success rate for non–HDL-C goals ranged from a low of 60% to a high of 84%, as illustrated in Figure 1C. Non–HDL-C goals are not part of the European or Canadian guidelines.

In patients with CHD and ≥2 risk factors, an optional LDL-C treatment target of <70 mg/dL (1.8 mmol/L) has been recommended by the NCEP since 2004.6 Among the 2334 L-TAP 2 patients in this very-high-risk category, 704 (30%) attained this goal. In the United States, 274 (35%) of 751 very-high-risk patients achieved this goal. The success rate in other countries (where this goal was not part of national guidelines) ranged from 16% to 37%.

### HDL-C Levels

HDL-C levels for low-, moderate-, and high-risk patients are listed in Table 2. Overall, 19% of patients had an HDL-C level <40 mg/dL (1.0 mmol/L), and 26% had a level >60 mg/dL (1.6 mmol/L). Low-risk patients had substantially higher HDL-C levels than moderate- or high-risk patients did. (At least part of the reason for this was that a high HDL-C level counted as a negative risk factor.) Among low-risk patients, only 7% had an HDL-C of $40 \text{mg/dL} \ (1.0 \text{mmol/L})$ compared with 55% who had an HDL-C of $60 \text{mg/dL} \ (1.6 \text{mmol/L})$. In moderate- and high-risk patients, 20% and 33%, respectively, had an HDL-C level <40 mg/dL (1.0 mmol/L).

If low HDL-C is defined as $<40 \text{mg/dL} \ (1.0 \text{mmol/L})$ in men and $<50 \text{mg/dL} \ (1.3 \text{mmol/L})$ in women, 27% of men (1453 of 5413) and 32% of women (1453 of 4512) had low HDL-C levels. With this definition, in the high-risk group, 30% of men (1067 of 3576) and 38% of women (900 of 2353) had low HDL-C levels.

Predictors of low HDL-C levels in men were higher body mass index, lower LDL-C, geographic region, smoking, nonstatin lipid therapy, younger age (all $P<0.0001$), and diabetes ($P=0.0001$). Predictors of low HDL-C levels in females were larger waist circumference, geographic region, diabetes, younger age, lower LDL-C (all $P<0.0001$), smoking ($P=0.0006$), hypertension ($P=0.007$), and nonstatin lipid therapy ($P=0.019$).

The distribution of low, intermediate, and high HDL-C levels by country is shown in Figure 2. The proportion of patients with low HDL-C was $>20\%$ in Canada and the United States and $<12\%$ in France, Spain, and Brazil.
Spain, and Brazil had the highest proportion of patients with an HDL-C level >60 mg/dL (1.6 mmol/L).

**Discussion**

The results of this survey indicate that the proportion of patients attaining LDL-C treatment goals is much higher than it was a decade ago. Overall, 73% of patients reached their LDL-C goal; in high-risk patients, the rate was 67%. The comparative rates in the original L-TAP survey done 10 years earlier (in 1996 to 1997) were 38% and 18%. Despite this improvement, one third of high-risk patients remain inadequately treated. Using the more recently recommended optional goal of <70 mg/dL (1.8 mmol/L) for very-high-risk patients (CHD plus ≥2 major risk factors), we find that the success rate was only 30%. More aggressive treatment of patients not meeting goals and improving success rates in underperforming countries have the potential to further reduce cardiovascular risk.

**Other Studies**

Previous studies have reported a wide range of success rates in attaining LDL-C goals. The differences appear to be related mainly to differences in patient populations and among treating physicians. In the NCEP Evaluation Project Utilizing Novel E-Technology (NEPTUNE) II survey conducted in 2003 among physicians who were high prescribers of cholesterol drugs, 67% of 4885 patients achieved their LDL-C goal according to NCEP ATP III. Among those at very high risk, only 18% attained the optional goal of <70 mg/dL (1.8 mmol/L). In a Canadian study of 8056 patients with CHD, diabetes, or both recruited between 2001 and 2004, 51% of patients reached their LDL-C goal. On the other hand, in a study of 110 primary care practices in Germany between 1998 and 2005, only 29% of 79 689 patients had attained their LDL-C goal at the last follow-up visit.

Data from 7399 individuals in the National Health and Nutrition Examination Survey (NHANES) in the United States between 1999 and 2002 were used to estimate the proportion of the adult population nationwide between 20 and 79 years of age who achieved NCEP ATP III goals. Overall, 66% of patients met their LDL-C goal, but among very-high-risk patients, only 4.6% had an LDL-C <70 mg/dL (1.8 mmol/L).

A limitation of our study, and other similar studies, is that we do not know to what extent the physicians and patients are representative. It may be that physicians involved in our study are more successful at achieving treatment goals than those who did not participate.

An advantage of L-TAP 2 compared with other studies is the presence of the original L-TAP as a reference. L-TAP enrolled patients in 1996 to 1997; L-TAP 2 enrolled patients in 2006 to 2007. Patient characteristics and LDL-C targets were roughly similar, so the difference in LDL-C goal

### Table 2. Clinical Features of the Patients According to Risk Category

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk/CHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, n</td>
<td>9955</td>
<td>2066</td>
<td>1959</td>
<td>5930</td>
</tr>
<tr>
<td>Age, y</td>
<td>62±12</td>
<td>57±14</td>
<td>61±11</td>
<td>64±11</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>4513 (46)</td>
<td>1254 (62)</td>
<td>905 (46)</td>
<td>2354 (40)</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>28.6±6.9</td>
<td>27.3±10.2</td>
<td>28.9±5.4</td>
<td>28.9±5.8</td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td>96.8±16.8</td>
<td>91.8±16.4</td>
<td>97.0±15.7</td>
<td>98.5±16.9</td>
</tr>
<tr>
<td>Risk factors, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt;45 y for men, &gt;55 y for women</td>
<td>8830 (89)</td>
<td>1434 (69)</td>
<td>1833 (94)</td>
<td>5563 (94)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>3088 (31)</td>
<td>0</td>
<td>0</td>
<td>3088 (52)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>6349 (64)</td>
<td>584 (28)</td>
<td>1541 (79)</td>
<td>4224 (71)</td>
</tr>
<tr>
<td>Current smokers</td>
<td>1358 (14)</td>
<td>134 (7)</td>
<td>411 (21)</td>
<td>813 (14)</td>
</tr>
<tr>
<td>Low HDL-C</td>
<td>790 (8)</td>
<td>18 (1)</td>
<td>201 (10)</td>
<td>571 (10)</td>
</tr>
<tr>
<td>No. of risk factors</td>
<td>2.1±1.2</td>
<td>0.6±0.6</td>
<td>2.4±0.6</td>
<td>2.5±1.1</td>
</tr>
<tr>
<td>Metabolic syndrome, n (%)</td>
<td>4274 (43)</td>
<td>492 (24)</td>
<td>917 (47)</td>
<td>2865 (48)</td>
</tr>
<tr>
<td>Lipid lowering therapy, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statin</td>
<td>7450 (75)</td>
<td>1225 (60)</td>
<td>1368 (70)</td>
<td>4857 (82)</td>
</tr>
<tr>
<td>Other</td>
<td>835 (8)</td>
<td>193 (10)</td>
<td>180 (9)</td>
<td>462 (8)</td>
</tr>
<tr>
<td>Dietary counseling, n (%)</td>
<td>6569 (68)</td>
<td>1535 (78)</td>
<td>1341 (70)</td>
<td>3693 (64)</td>
</tr>
<tr>
<td>Lipid measurements, mg/dL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL-C</td>
<td>100±37</td>
<td>119±37</td>
<td>109±37</td>
<td>91±33</td>
</tr>
<tr>
<td>HDL-C</td>
<td>53±15</td>
<td>62±16</td>
<td>49±12</td>
<td>50±14</td>
</tr>
<tr>
<td>Non-HDL-C</td>
<td>130±41</td>
<td>146±41</td>
<td>142±41</td>
<td>121±38</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>152±86</td>
<td>136±79</td>
<td>167±95</td>
<td>152±84</td>
</tr>
<tr>
<td>Triglycerides/HDL-C</td>
<td>3.3±2.8</td>
<td>2.5±2.0</td>
<td>3.8±3.3</td>
<td>3.4±2.7</td>
</tr>
<tr>
<td>hs-CRP, mg/L</td>
<td>1.5 (0.7–3.3)</td>
<td>1.3 (0.6–2.8)</td>
<td>1.6 (0.8–3.6)</td>
<td>1.6 (0.8–3.4)</td>
</tr>
<tr>
<td>Fasting blood glucose, mg/dL</td>
<td>115±39</td>
<td>99±22</td>
<td>103±19</td>
<td>125±45</td>
</tr>
</tbody>
</table>

Abbreviations as in Table 1. Values are mean±SD when appropriate. hs-CRP is reported as median (interquartile range).
achievement, 38% in L-TAP and 73% in L-TAP 2, represents a definite and substantial improvement. More impressively, among patients with CHD in L-TAP, the success rate was only 18% compared with 67% in L-TAP 2 among high-risk patients (those with CHD, other atherosclerotic vascular disease, or diabetes). Longer exposure to more stringent guidelines and more potent statins likely accounts for this marked improvement.

Only 30% of L-TAP 2 patients at very high risk attained the optional LDL-C target of <70 mg/dL (1.8 mmol/L). Although this is superior to the 18% rate in NEPTUNE II\(^{10}\) and the 4.6% rate in NHANES,\(^{11}\) substantial room for improvement remains. Although very-high-risk patients make up only a small minority of the population, their very high event rate makes them a worthy focus of the most aggressive treatment.
Comparisons Among Countries
The success rate for attaining the LDL-C goal ranged from 47% to 84% across the 9 countries in L-TAP 2. The highest success rates were seen in Korea and the United States and the lowest in France and Spain. Differences in guidelines, patient characteristics, and healthcare systems among countries likely contribute to these outcome differences. Large differences in lipid levels and drug treatment were previously documented in CHD patients across 15 European countries in the European Action on Secondary Prevention by Intervention to Reduce Events (EUROASPIRE) II study.7

HDL-C Levels
The prevalence of low HDL-C in previous studies varies widely, depending on the features of the population and the cut point used to define low HDL-C. In an NHANES report of white Americans 20 to 90 years of age, 19.3% of men and 25.7% of women had low HDL-C, defined as <35 mg/dL (0.9 mmol/L) for men and <45 mg/dL (1.2 mmol/L) for women.14 In a Canadian health survey, 13% of men had a low HDL-C using the same criterion.15 In a survey of 8545 dyslipidemic patients treated by specialist physicians in 11 European countries, 33% of men had an HDL-C <40 mg/dL (1.0 mmol/L) and 40% of women had an HDL-C <50 mg/dL (1.3 mmol/L).16 Among patients with documented coronary disease, the prevalence is higher: In 1 study, 66% of patients with CHD or a CHD risk equivalent had low HDL-C (defined as <40 mg/dL [1.0 mmol/L] in men and <50 mg/dL [1.3 mmol/L] in women).17 In a study of male veterans in the United States, 64% of 8500 men with CHD had an HDL-C <40 mg/dL (1.0 mmol/L).18

The proportion of patients with low HDL-C in L-TAP 2 is closer to what has been seen in surveys of the general population than to what has been reported in CHD populations. Even in the high-risk group in L-TAP 2, the prevalence of low HDL-C was only 23% using the criterion of an HDL-C <40 mg/dL (1.0 mmol/L) for both men and women. Using the cut points of <40 mg/dL (1.0 mmol/L) in men and <50 mg/dL (1.3 mmol/L) in women, we find that 30% of high-risk men and 38% of high-risk women qualified as having low HDL-C levels.

Among the factors associated with low HDL-C levels in L-TAP 2 were smoking and components of the metabolic syndrome, specifically diabetes, a higher body mass index or waist circumference, and hypertension. A low prevalence of low HDL-C levels was seen in our study in France, Spain, and Brazil. In previous studies, a similar low prevalence has been reported for France19 but not for Spain20 or Brazil.21

Conclusions
L-TAP 2 documents considerable improvement in LDL-C goal attainment since the original L-TAP study performed about a decade ago. However, approximately one third of patients still do not attain their LDL-C goal, with wide variation among countries. Among patients in the very-high-risk group, with CHD and ≥2 risk factors, the success rate in reaching the more aggressive optional goal of <70 mg/dL (1.8 mmol/L) is only 30%. More aggressive treatment and higher success rates have the potential to reduce the incidence of new cardiovascular events significantly.

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for the Lipid Treatment Assessment Project 2 Investigators

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