Lipid-lowering therapy using statins in patients with cardiovascular risk in clinical practice in Thailand

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ABSTRACT

Background Since the release in Thailand in 2001 of the Third Guidelines by the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults or the Adult Treatment Panel (ATP III), there have been no nationwide studies on the proportion of dyslipidaemic patients who have achieved the low-density lipoprotein cholesterol (LDL-C) goals. The authors therefore aimed to estimate the percentage achievement of LDL-C goals based on the modified NCEP ATP III guidelines in intermediate- to high-risk patients.

Methods The authors conducted a hospital-based, cross-sectional, epidemiological survey. Patients (1240) were selected consecutively from 50 hospitals across Thailand. Patients were included if they had been treated with statins for at least 3 months.

Results Two-thirds were female, and the mean age was 61.7 ± 9.5 years. The median duration of statin treatment was 21 months. Half (633/1240) of the patients achieved the LDL-C goal levels as defined by the NCEP guidelines (51.1%, 95% CI 48.3% to 53.8%). The very-high-risk group had the lowest percentage achievement (11.6%; 95% CI 5.6% to 21.6%), compared with 54.2% (95% CI 50.9% to 57.4%) for the high-risk group and 47.0% (95% CI 41.1% to 52.8%) for the moderate-risk group. More males achieved the LDL-C goals than females (55.6% vs 48.9%; p = 0.029).

Conclusions Overall, 51.1% of the patients with cardiovascular risk, on statins treatment, achieved the NCEP ATP III LDL-C goal levels.

INTRODUCTION

Elevated, low-density, lipoprotein cholesterol (LDL-C) is a major risk factor of coronary heart disease (CHD): it is possible, however, to reduce it. Since 1993, the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel or ATP) has periodically updated the treatment guidelines which identify LDL-C as a cause of CHD and the primary aim for diagnosis and treatment of hypercholesterolaemia.1–2

In 2001, the latest recommendations were released in the Third ATP Report (NCEP ATP III),3 which reaffirmed the risk of CHD from increased LDL-C, the benefit of LDL-C-lowering therapy and maintaining intensive treatment of patients with CHD. The report also added a call for more intensive LDL-C-lowering therapy as the primary aim for patients with a CHD risk equivalent. Although the guidelines have been widely available, achieving the lower LDL-C goals in practice has been suboptimal. In a US study, only 58% of 4888 patients under primary care in five regions achieved the LDL-C target levels.4 The respective success rates were 68% and 37% in the low- and high-risk groups. Only 18% of the patients with established CHD with the highest risk of future CHD events achieved the lower LDL-C targets. Another study, based on the records of 461 patients in rural areas, covering all risk levels from four practices, found that only 54% of dyslipidaemic patients achieved the NCEP ATP III goals.5 In 1998, a survey in Thailand assessing the achievement of LDL-C goals in high-risk patients indicated an unsatisfactorily low percentage of 59.2%.6 The most recent nationwide survey was conducted between December 2002 and June 2003.7 The study involved 1921 patients from 48 hospitals across Thailand. Percentage achievements of LDL-C targets in the CHD and CHD equivalents, high-, and low-risk group were 34.6%, 56.4% and 76.8%, respectively.8

In 2004, several changes were made to the guideline, released as the Modified NCEP ATP III in that year.9 There has, however, been no recent nationwide study in Thailand investigating the proportion of dyslipidaemic patients who have achieved the updated LDL-C goals.

Our study aimed to estimate the percentage of LDL-C goals achievement based on the NCEP ATP III guidelines in intermediate- to high-risk patients receiving statins for at least 3 months in clinical practice in Thailand.

METHODS

This was a hospital-based, cross-sectional, epidemiological survey and retrospective chart review, in both secondary and tertiary care across Thailand (http://ClinicalTrials.gov Identifier: NCT00684151). The hospitals studied were randomly selected using a simple random scheme generated by Stata V.10 Statistical Software (StataCorp). Each hospital selected was evaluated as to whether it had diabetes or any other types of outpatient clinics that involved lipid-lowering drug prescriptions. If not, it was replaced by another hospital based on the stated sampling method. This process was repeated until a total of 50 hospitals were selected, which represents approximately half of the total number of secondary- and tertiary-care hospitals in Thailand. The investigators, who were not attending physicians, were confidentially scheduled to do the data collection, and the selected hospitals were informed that the physicians would be attending 1 week prior to the date of data collection.
collection. Lipid levels were based on an analysis conducted by local laboratories on the day of the data collection, if not available on the most recent visit.

Primary outcome
The primary outcome of this study was the percentage of dyslipidaemic patients on lipid-lowering therapy who had achieved their respective LDL-C target levels as defined by the NCEP ATP III guidelines (table 1).

Criteria for study subject selection
The data collection was conducted at the selected hospitals between March and July 2008, where patients were selected consecutively as they attended hypertension or diabetes clinics. The maximum number of patients per site was 40.

Patients enrolled in the study were outpatients seen in the hypertension or diabetes clinics, between 20 and 80 years of age, having at least one established risk factor, viz., coronary artery disease, postmyocardial infarction, acute coronary syndrome, peripheral artery disease, poststroke, CHD risk equivalent (ie, abdominal aortic aneurysm, diabetes mellitus, and peripheral vascular disease) or type 2 diabetes mellitus, and had been on the same type of statin as treatment of dyslipidaemia for at least 5 months.

Study procedures
The study was conducted in full conformity with Good Clinical Practice, and the investigators obtained Institutional Review Board approval prior to conducting the study. All subjects were informed about the study’s purpose and thereafter signed an informed consent form.

Each subject was screened for eligibility for the study. The data-collection process involved a face-to-face interview with each subject and a review of medical records. Laboratory results were transcribed from the medical records.

Statistical analysis
The results of two previous studies in Thailand, conducted in 1998 and 2003, suggest that the respective rates of achieving the lower LDL-C targets among the high-risk group were 39% and 35%. Our sample size calculation was based on achieving the lower LDL-C targets among the high-risk group depending on case availability on the date the survey was conducted.

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Statistical analysis
The results of two previous studies in Thailand, conducted in 1998 and 2003, suggest that the respective rates of achieving the lower LDL-C targets among the high-risk group were 39% and 35%. Our sample size calculation was based on the latter using methods suggested by Kish. A sample size of 1260 was therefore planned. The study was conducted in 50 hospitals, each of which enrolled between 10 and 40 patients depending on case availability on the date the survey was conducted.

The percentage achievement of LDL-C goals and 95% CIs (95% CI) were estimated based on normal approximation to binomial distribution. We estimated the effect of selected factors on the LDL-C goals achievement using multiple logistic regres-

**Table 1 Treatment goal definitions**

| Risk categories | Definitions                                                                 | Low-density lipoprotein cholesterol goals (mg/dl) |
|-----------------|-----------------------------------------------------------------------------|--------------------------------------------------|
| Very high risk  | Postmyocardial infarction with diabetes mellitus, poststroke with diabetes mellitus, peripheral arterial disease and postmyocardial infarction with peripheral arterial disease | ≤70                                               |
| High risk       | Coronary artery disease, cardiovascular diseases, poststroke and diabetes mellitus | ≤100                                              |
| Moderate risk   | ≥2 risk+ (hypertension or dyslipidaemia)                                     | ≤130                                              |
| Low risk        | 0–1 risk+ (hypertension)                                                    | ≤160                                              |

RESULTS

Number of patients and participating hospitals
There are 95 secondary- and tertiary-care hospitals across Thailand, 50 (52.6%) of which were selected for the study. The number of selected hospitals in each region was proportional to the total number of eligible hospitals in each region (ie, the North, the Northeast, the South and Central). A total of 1750 patients attending OPD clinics were screened by interviews, and 167 (9.6%) were excluded: 161 not currently treated with statin, five not consented and one not within 20–80 years of age (figure 1). After the chart review was conducted, a further 525 (20.7%) cases were excluded: 216 treated <3 months before lipid profile became available, 52 lipid profile not available and 75 having not received the same statin before lipid profile became available. The final number of subjects included in the analysis was 1240.

Time from the most recent lipid profile to data collection
The duration between the date of data collection and the most recent lipid profile ranged between 0 and 41 months (median 5.5 months). The treatment outcome was measured at a mean of 5.5 months prior to the study date.

Duration of statin treatment prior to the most recent lipid profile
The duration of statin treatment prior to the most recent lipid profile ranged between 3 and 191 months (median 6.5 years). Almost all of the attending physicians (94%) were 45 years of age or higher. A similar percentage was seen in each risk group. For females at risk, about three-quarters received the same statin before lipid profile became available.

Patients characteristics
The high-risk group accounted for the largest number of patients, followed by moderate- and high-risk patient types. The mean age was 61.7 ± 9.5 years, and approximately two-thirds were female (table 2). The mean age of each risk group was similar. For each sex, the percentage distribution was similar across all risk groups. Overall, the majority of males at risk (94%) were 45 years of age or higher. A similar percentage was seen in each risk group. For females at risk, about three-quarters were aged 55 years or older. Most common cardiovascular risks were diabetes mellitus (66.1%) and hypertension (57.6%).

Treatments at the most current visit
More than 90% of the patients received statins without any other lipid-lowering drugs (table 3). Simvastatin was used by 85.4% of the patients attending OPD clinics were screened by interviews, and 167 (9.6%) were excluded: 161 not currently treated with statin, five not consented and one not within 20–80 years of age (figure 1). After the chart review was conducted, a further 525 (20.7%) cases were excluded: 216 treated <3 months before lipid profile became available, 52 lipid profile not available and 75 having not received the same statin before lipid profile became available. The final number of subjects included in the analysis was 1240.

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Achievement of LDL-C treatment goals
Percentage achievement of LDL-C goals for all patients
Among the 1240 patients, 633 achieved the lower LDL-C goals as defined by the NCEP ATP III guidelines (51.1%; 95% CI 48.3% to 53.8%) (table 4). The very-high-risk group had the lowest achievement level at about one tenth. The achievement rate varies among regions where the highest achievement rate was 57.4% in the central area, and the lowest achievement rate was 42.6% in the eastern part of the country. On average, the very-high-risk patients were about half, 49.7%, to reach the LDL-C target goal.

Percentage LDL-C goals achievement by selected factors
Males had a statistically higher percentage achievement of the lower LDL-C goals than females (p=0.024) (table 5). The duration of statin treatment and the statin use, either alone or combined with other regimens, had a similar percentage achievement of lower LDL-C goals.

DISCUSSION
The efficacy of statins in atherosclerotic conditions, particularly in the treatment and prevention of CHD, has been well established. Large-scale, randomised, prospective trials involving patients with CHD have shown that statins reduce the clinical consequences of atherosclerosis, including cardiovascular-related deaths, non-fatal MI and stroke, hospitalisation for acute coronary syndrome and heart failure, as well as the need for coronary revascularisation.11–13

The Heart Protection Study demonstrated that LDL-C reduction to levels as low as 1.7 mmol/l was associated with significant clinical benefits in a wide range of high-risk individuals, including patients with type 2 diabetes mellitus, or

Table 2  Patient characteristics by patient group, shown as number (%) unless specified otherwise

| Characteristics                                      | Very high | High    | Moderate | Total     |
|------------------------------------------------------|-----------|---------|----------|-----------|
| Mean (SD) age, years                                 | n=43      | n=914   | n=283    | n=1240    |
|                                                      | 61.0 (10.3)| 61.5 (9.5)| 62.7 (9.3)| 61.7 (9.5) |
| Sex, total                                           | n=43      | n=914   | n=283    | n=1240    |
| Male                                                 | 17 (39.5) | 303 (33.2)| 97 (34.3) | 417 (33.6) |
| Female                                               | 26 (60.5) | 611 (66.8)| 186 (65.7)| 823 (66.4) |
| Male at risk by age (years), total                   | n=17      | n=303   | n=97     | n=417     |
| ≥45                                                  | 16 (94.1) | 286 (94.4)| 92 (94.8) | 394 (94.5) |
| <45                                                  | 1 (5.9)   | 17 (5.6) | 5 (5.2)  | 23 (5.5)  |
| Female at risk by age (years), total                 | n=26      | n=611   | n=186    | n=823     |
| ≥55                                                  | 22 (84.6) | 462 (75.6)| 139 (74.7)| 623 (75.7) |
| <55                                                  | 4 (15.4)  | 149 (24.4)| 47 (25.3) | 200 (24.3) |
| Cardiovascular risks                                 | n=43      | n=914   | n=283    | n=1240    |
| Coronary artery disease, myocardial infarction and   |           |         |          |           |
| acute coronary heart syndrome                        | 22 (51.2) | 190 (20.8)| 0 (0)    | 212 (17.1) |
| Stroke                                               | 14 (32.6) | 13 (1.4) | 0 (0)    | 27 (2.2)  |
| Peripheral artery disease                            | 11 (25.6) | 2 (0.2)  | 0 (0)    | 13 (1.1)  |
| DM                                                   | 42 (97.7) | 774 (85.2)| 818 (66.1)|           |
| Hypertension                                         | 28 (65.1) | 514 (56.2)| 172 (60.8)| 714 (57.6) |

Very-high-risk patients had postmyocardial infarction with diabetes mellitus (DM), poststroke with DM or peripheral artery disease with DM. High-risk patients had coronary artery disease, cardiovascular disease, poststroke or DM. Moderate-risk patients had two or more risks plus either hypertension or dyslipidaemia.
Epidemiology

Table 3  Treatment pattern by patient group shown as number (%)

| Treatments                          | Very high (n = 43) | High (n = 914) | Moderate (n = 283) | Total (n = 1240) |
|-------------------------------------|--------------------|----------------|-------------------|------------------|
| Statin prescriptions                |                    |                |                   |                  |
| Statins only                        | 39 (90.7)          | 847 (92.7)     | 270 (95.4)        | 1156 (93.2)      |
| Statins with other lipid-lowering drugs | 4 (9.3)           | 67 (7.3)       | 13 (4.6)          | 84 (6.8)         |
| Type of statins                     |                    |                |                   |                  |
| Pravastatin                         | 0 (0.0)            | 3 (0.3)        | 0 (0.0)           | 3 (0.2)          |
| Simvastatin                         | 38 (88.4)          | 798 (87.3)     | 223 (78.8)        | 1059 (85.4)      |
| Atorvastatin                        | 1 (2.3)            | 66 (7.2)       | 32 (11.3)         | 99 (8.0)         |
| Rosuvastatin                        | 4 (9.3)            | 47 (5.1)       | 28 (9.9)          | 79 (6.4)         |
| Duration (months) of statin treatment|                    |                |                   |                  |
| 3–6                                 | 4 (9.3)            | 93 (10.2)      | 39 (13.8)         | 136 (11.0)       |
| 7–12                                | 10 (23.3)          | 174 (19.0)     | 61 (21.6)         | 245 (19.8)       |
| 13–24                               | 13 (30.2)          | 254 (27.8)     | 82 (29.0)         | 349 (28.1)       |
| 25–36                               | 11 (25.6)          | 170 (18.6)     | 54 (19.1)         | 235 (19.0)       |
| ≥37                                 | 5 (11.6)           | 223 (24.4)     | 47 (16.6)         | 275 (22.2)       |
| Field of expertise of the attending physicians |     |                |                   |                  |
| Internal medicine                   | 41 (95.3)          | 905 (99.0)     | 281 (99.3)        | 1227 (99.0)      |
| General                             | 26                 | 755            | 248               | 1029             |
| Cardiologist                        | 13                 | 90             | 25                | 128              |
| Endocrinologist, nephrologists or neurologist | 2               | 58             | 7                 | 67               |
| Unspecified                         | 0                  | 2              | 1                 | 3                |
| Non-internal medicine               | 2 (4.7)            | 9 (1.0)        | 2 (0.7)           | 13 (1.0)         |

Very-high-risk patients had postmyocardial infarction with diabetes mellitus (DM), poststroke with DM or peripheral artery disease with DM. High-risk patients had coronary artery disease, cardiovascular disease, poststroke or DM. Moderate-risk patients had two or more risks plus either hypertension or dyslipidaemia.

We, thus, included only patients who had been treated for at least 3 months with no maximum limit of treatment duration. The results in table 5 indeed suggest that the duration of statin treatment had no effect on the percentage achievement of LDL-C goals among the NCEP ATP III guidelines in patients receiving statins for at least 3 months in clinical practice in Thailand.

Initially, the calculated sample size was 1260, of which 20 (1.8%) patients had a statin treatment of <3 months. These were identified after enrolment and excluded from the analysis. This elimination did not, however, affect the study findings, that is, the percentage achievement of LDL-C goals was 52.5% when they were included, compared with 51.1% when they were excluded.

We thus, included only patients who had been treated for at least 3 months with no maximum limit of treatment duration. Our study was based on the availability of lipid profiles of patients measured on request, as per real-life clinical practice; however, there were no significant differences between the percentage achievement of LDL-C goals among patients whose lipid profile was assessed before or after the median of 5.5 months prior to the survey date. This result might indicate that LDL-C levels were underutilised to adjust the treatment.

In our study, the percentage of lowered LDL-C according to goal levels, as defined by NCEP ATP III guidelines, among the high-cardiovascular-risk group, was 51.1% compared with 59.2% in a 1997–1998 study6 and 54.6% in the 2002–2003 study.9 The higher percentage found in our study could be due to various reasons: (1) we included only patients who used statins and not any other lipid-lowering agent alone; (2) there has been an increasing focus on the benefits of intensive cholesterol reduction; (3) new and more efficacious statins have been developed; (4) 95% of the patients in our study were attended by specialists who might be more likely to adhere to the guidelines; and (5) two-thirds of the patients in our study were females, who might have had a greater rate of compliance to the treatment or might have had a greater response to therapy than males, although there are few data to support this. As with other studies, our study found that the lowest percentage of achieving the recommended LDL-C target was in the very-high-risk group.6 9 A number of aspects of our study can be considered strengths. First, the case selection was unbiased, as it was carried out

Table 4  Percentage and 95% CIs of low-density lipoprotein cholesterol (LDL-C) achievement goals by patient group

| Patient groups* | Total | Achieved goals | Percentage | 95% CI | Mean percentage† to target LDL-C |
|-----------------|-------|----------------|------------|--------|---------------------------------|
| Very high risk  | 43    | 5              | 11.6       | 1.6 to 21.6 | 49.7                           |
| High risk       | 914   | 495            | 54.2       | 50.9 to 57.4 | 51.8                           |
| Moderate risk   | 283   | 133            | 47.0       | 41.1 to 52.8 | 9.9                            |
| Overall         | 1240  | 633            | 51.1       | 48.3 to 53.8 | 27.5                           |

*Very high risk (LDL-C<70 mg/dl); high risk (LDL-C: 70 to 100 mg/dl); moderate risk (LDL-C: 100 to 130 mg/dl).
†Calculated based on the percentage difference between LDL-C level and the target goal among patients who did not achieve the LDL-C target.
Table 5 Percentage low-density lipoprotein cholesterol achievement goals by selected factors

| Selected factors                                      | No (%) | Percentage achievement | p Value |
|-------------------------------------------------------|--------|------------------------|---------|
| Sex                                                   |        |                        |         |
| Male                                                  | 417    | 55.4                   | 0.029   |
| Female                                                | 823    | 48.9                   |         |
| Male by age (years) at risk                           |        |                        |         |
| ≥45                                                   | 394    | 55.6                   | 0.750   |
| <45                                                   | 23     | 52.2                   |         |
| Female by age (years) at risk                         |        |                        |         |
| ≥55                                                   | 623    | 50.7                   | 0.057   |
| <55                                                   | 200    | 43.0                   |         |
| Duration (months) of statin treatment                 |        |                        | 0.997   |
| 3–6                                                   | 136    | 50.7                   |         |
| 7–12                                                  | 245    | 51.0                   |         |
| 13–24                                                 | 349    | 50.4                   |         |
| 25–36                                                 | 235    | 51.9                   |         |
| ≥37                                                   | 275    | 51.3                   |         |
| Statins received                                      |        |                        | 0.842   |
| Statins only                                          | 1156   | 51.1                   |         |
| Statins with other lipid-lowering drugs                | 84     | 50.0                   |         |
| Field of expertise of attending physicians            |        |                        | 0.360   |
| Internal medicine                                     | 1227   | 51.2                   |         |
| Non-internal medicine                                 | 13     | 38.5                   |         |
| Field of expertise of attending physicians who were in internal medicine |        |                        | 0.598   |
| General                                               | 1029   | 51.2                   |         |
| Cardiologist                                          | 128    | 53.9                   |         |
| Endocrinologist, nephrologists or neurologist         | 67     | 46.3                   |         |

consecutively and independent of the attending physicians. Second, we covered a large number (52.6%) of secondary- and tertiary-care hospitals across the country. Third, almost all of the studied patients (99.0%) were attended by an internal medicine specialist, particularly the very-high-risk and high-risk patients. Finally, our study represented real-life, clinical settings in Thailand, so the percentage achievement of LDL-C goals may represent clinical practice.

In summary, our study demonstrated that 51.1% of patients with cardiovascular risk on statin treatment achieved the LDL-C goal levels defined by the NCEP ATP III guidelines. We suggest that patients with a high CHD risk should be targeted for more aggressive lipid-lowering management. National campaigns to increase the awareness among both physicians and patients of the importance of achieving the LDL-C goals are needed to optimise the prevention of cardiovascular events and to further reduce the burden of cardiovascular diseases. Further investiga-

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