Drug Use Evaluation of Statins at Siriraj Hospital, 2008

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Statins are commonly used for lipid reduction. There is no significant difference in the efficiency of each type of statins. The study of statins' efficacy shows that only generic simvastatin is cost-effective in coronary heart disease prevention.

Objective: *To determine the use and appropriateness of usage of statins in out-patients attending Siriraj Hospital in 2008.*

Material and Method: *Medical records of all patients in Siriraj Hospital who received statins from January 1st to December 31st, 2008 were reviewed. The appropriateness of statins used was analyzed in 247 medical records based on number of risks and 10-year risk.*

Results: *There were 105,950 patients who received statins with total value of 308 million baht in 2008. The major usages of statins were simvastatin (65%), atorvastatin (12%) and rosuvastatin (6%). However, the costs of statins were 9%, 42%, and 20% for simvastatin, atorvastatin and rosuvastatin, respectively. Analysis of 247 medical records of the patients who received statins showed that statins were appropriately used in 19.4% of cases. Inappropriate use of statins was due to not starting drugs treatment with simvastatin, or shifting from simvastatin to other statins inappropriately.*

Conclusion: *Inappropriate use of statins at Siriraj Hospital is very common. Interventions for promoting more appropriate use of statins should be implemented.*

Keywords: *Drug Use Evaluation, Statins*

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Dyslipidemia, one of the major risk factors of atherosclerosis, coronary artery disease (CAD) and other peripheral vascular diseases, is highly prevalent in Thailand. Management of dyslipidemia should start with lifestyle modification including diet control. However, a certain number of patients cannot achieve the treatment goal with lifestyle modification alone. Therefore, lipid lowering drugs are recommended for such individuals to reduce the risk of coronary heart disease, both as primary and secondary prevention.

Nowadays, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors or statins are considered the best and most popular drugs for serum lipid reduction. The National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) Guidelines[1] and the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD) 2007 Guidelines[2] recommend that initiation of these drugs should be based on both the level of low-density lipoprotein cholesterol (LDL-C) and the number of other CAD risk factors. Usually, lifestyle modification may be sufficiently effective in patients with no or low CAD risks and primary prevention of CAD. In the individuals with CAD or CAD equivalent, which goal of treatment is low, lipid lowering drugs may be indicated. In addition, certain groups of patients such as diabetics with stroke, type 1 diabetics who are older than 40 years or having more than 1 CAD risk factor, statins are indicated regardless of LDL-C levels.

The statins that are available in Thailand and in Siriraj Hospital include simvastatin, atorvastatin, rosuvastatin, pravastatin and fluvastatin[3]. The efficacy of each statin was shown to be equivalent in most studies[4] but the prices of each statin are quite different. The study on cost-benefit of statins in USA[5] and Thailand[6] indicated that only generic simvastatin is

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cost-beneficial in prevention of CAD. Thus, according to the Thailand National Drug Committee, simvastatin is the only member of the statin family listed in the National List of Essential Medicines 2008, and is recommend as the first line drug for treatment of hypercholesterolemia[7]. However, some physicians inexplicably still use other statins as a primary drug resulting in very high burden to the hospital budgets and to the patients.

The objective of the study was to determine the use and appropriateness of usage of statins in out-patients attending Siriraj Hospital in 2008.

Methods

The study was approved by Siriraj Ethical Committee on Human Research. It was a retrospective descriptive study in out-patients attending Siriaj Hospital in 2008 who received simvastatin, atorvastatin, fluvastatin, pravastatin or rosuvastatin for at least 3 months. The sample size was calculated based on the assumption that the prevalence of inappropriate use of statins was 50 $\pm$ 5% with 2-tailed type I error of 5%. Thus, the calculated sample size is 400 cases. Four-hundred seventy-seven medical records of the patients who received statins were randomly selected. The appropriateness of statins used was analyzed based on indications to initiate statins or to change type of statins. Information extracted from the medical records included demographic data such as age, gender, underlying diseases; drug information such as type and dose of firstly prescribed drug(s), timing of ingestion, date of prescription; CAD risk factors; 10-year risk calculated by Electronic 10-year risk calculator from http://www.nhlbi.nih.gov/guidelines/cholesterol; indication for prescribing cholesterol lowering drugs; lifestyle modification recommended prior to initiation of the drug(s) and duration; results of drug treatment (at least 3 months) follow-up including information about LDL-C and highest dose of medication; type and doses of modified cholesterol lowering drug(s) and indication for changes. The main outcome measured is appropriateness of initiated statins based on demographic information, indication for drug(s) usage, result of treatment, highest doses of medication and reason for changes of medication. The data was analyzed by descriptive statistics.

Results

From January to December 2008, there were 105,950 patients (93% were out-patients) who received statins with a total cost of 308 million baht. The distribution of the cases and costs of statins is shown in Fig. 1. Simvastatin was the most commonly used drug (65%) followed by atorvastatin (12%), rosuvastatin (6%), ezetimibe (3%) and fluvastatin (1%). The costs of the statins were 9%, 42%, 20%, 10% and 3% of total cost for simvastatin, atorvastatin, rosuvastatin, ezetimibe and fluvastatin, respectively.

From 477 randomly selected medical records, only 247 (51.8%) records had complete information and were eligible for analysis. Of 247 medical records, 91 cases (36.8%) were males and 156 cases (63.2%) were females. The mean age was 59.5 years (range 26 to 91 years). Most of the patients (94.7%) received the medication from the Department of Medicine. Most of the patients had one or more underlying diseases as shown

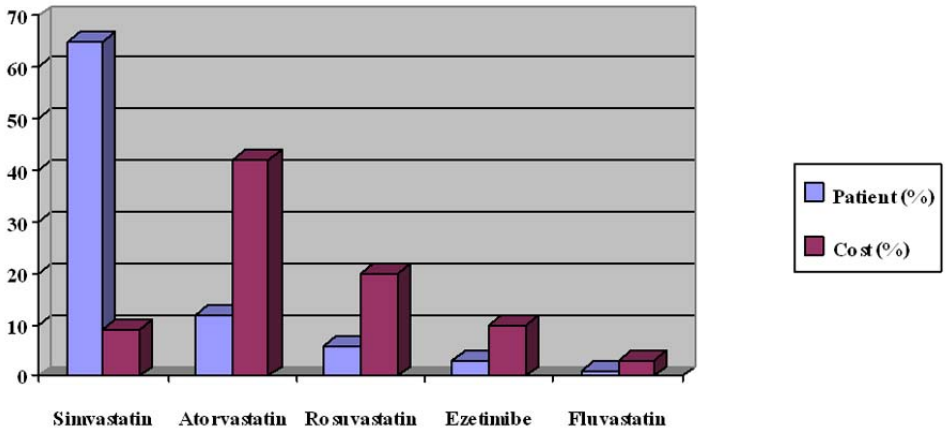

Fig. 1 Prescriptions of statins according to the distribution of the cases and costs of statins

in Table 1 and only 2.8% had no underlying diseases.

Choices of the initial cholesterol lowering drug(s) prescribed are shown in Table 2. Simvastatin was the initial drug for 100 patients (40.5%) followed by atorvastatin (40.1%), rosuvastatin (10.1%), pravastatin (8.1%) and fluvastatin (1.2%). Most of them were started at the dose of 5 to 40 mg/day except for rosuvastatin and fluvastatin. One hundred eighty-one patients (73.3%) were told to take medication in the evening.

Table 1. Underlying diseases of the patients

Underlying diseases	Number of cases (%)
Hypertension	175 (70.1)
Type 2 Diabetes Mellitus	74 (30)
CAD	46 (18.6)
Cerebrovascular disease	20 (8.1)
HIV/AIDS	2 (0.8)
Others (fatty liver, nephrotic syndrome, gout, obesity)	97 (39.3)
No underlying disease	7 (2.8)

The type and number of CAD risks (not include LDL-C level and 10-year risk) are shown in Table 3. Average number of CAD risk in the studied population was 1.6 ± 0.9 (range 0-4). By using the electronic 10-year risk calculator, the mean 10-year risk of the studied population is 8.9 ± 8.0 (range < 1 to > 30). The mean LDL-C before starting the medication was 166 ± 48 (range 56 to 372 mg/dL). From 175 cases (70.9%) who had hypertension, 66.8% were prescribed antihypertensive drugs and 4% were still smoke despite the smoking cessation was informed.

There were 5 indications for prescribing statins as shown in Table 4. The statins were prescribed to the patients for the indication I, II, III, IV and V in 47%, 10.5%, 7.7%, 9.7% and 0.4% respectively.

Fifty-five patients (22.3%) were prescribed cholesterol lowering drug at an initial diagnosis of hypercholesterolemia without providing lifestyle modification interventions. Lifestyle modification was mentioned in the medical records in only 57 cases (23%). Average time of follow-up before starting drug(s) was 11.3 months (range 1 to 50 months).

The treatment goals were achieved in 200 cases (81%) after 3 months of cholesterol lowering drug

Table 2. Initial statins given to 247 patients

Doses (mg/day)	Number (%)				
	Simvastatin (n = 100)	Atorvastatin (n = 99)	Rosuvastatin (n = 25)	Pravastatin (n = 20)	Fluvastatin (n = 3)
5	13 (13)	19 (19.2)	7 (28)	7 (35)	0
10	58 (58)	70 (70.7)	18 (72)	5 (25)	0
20	26 (26)	9 (9.1)	0	6 (30)	1 (33.3)
40	3 (3)	1 (1.1)	0	2 (10)	0
80	0	0	0	0	2 (66.7)
Average dose (mg/day)	12.8	10.2	8.6	14.2	60
Mode (mg/day)	10	10	10	5	60

Table 3. CAD risks in studied population

	CAD risk	10-year risk	Chol (mg/dL)	HDL-C (mg/dL)	LDL-C (mg/dL)	SBP (mmHg)
Mean	1.6	8.9	247	54	166	135.2
SD	0.9	8.0	55	15	48	20.0
Minimum	0	1	102	20	56	90
Maximum	4	31	512	100	372	192

Table 4. Indications for prescribing statins

	I	II	III	IV	V	No clear Indication	Total
Patients	118 (47.8%)	26 (10.5%)	19 (7.7%)	24 (9.7%)	1 (0.4%)	59 (23.9%)	247

I = CAD, CAD equivalent, having 2 or more CAD risk with 10-year risk > 20%
II = 2 or more CAD risks and 10-year risk 10-20%
III = LDL-C ≥ 160 mg/dL with 2 or more CAD risks and 10-year risk < 10%
IV = LDL-C > 190 mg/dL with 0-1 CAD risk
V = diabetes with cerebrovascular disease or type 1 diabetes whose age > 40 years old or type 1 diabetes age 18-39 years with > 1 CAD risk regardless of LDL-C level

prescription as shown in Table 5. Eighty-five cases (72%) with CAD or CAD equivalent achieved the goal of LDL-C < 100 mg/dL (average LDL-C 78 mg/dL), but only 26 cases (22%) achieved the secondary goal of LDL-C < 70 mg/dL. Thirty-five cases of 45 cases (78%) who had > 2 CAD risk factors achieved the treatment goal of LDL-C < 130 mg/dL (average LDL-C 94 mg/dL) while 21 out of 24 cases (87.5%) who had 0-1 CAD risk achieved the goal of LDL-C < 160 mg/dL (average LDL-C 128 mg/dL).

The results of treatment according to type of lipid lowering drugs in patients who did not achieve the treatment goals are shown in Table 6. Average LDL-C in 41 cases (16.6%) who did not achieve the treatment goals was 152 mg/dL. Among 118 patients who had CAD or CAD equivalent, 31 cases (26.9%) did not achieve the LDL-C goal of < 100 mg/dL (LDL-C of 141 mg/dL) and 92 cases (78%) did not achieve the secondary LDL-C goal of < 70 mg/dL. For those with LDL-C goal of < 130 mg/dL, 8 out of 45 cases (17.8%) had average LDL-C of 181.3 mg/dL and those with LDL-C goal of < 160 mg/dL, 2 out of 24 cases (8.3%) had average LDL-C of 205.5 mg/dL.

Six patients (2.4%) did not receive re-evaluation of LDL-C level. The physicians suggested that 2 of them stop using the prescribed statin while the other 3 had their statins changed before re-evaluation of LDL-C level. One patient did not have LDL-C re-evaluation for 16 months. Among this group, 5 cases received simvastatin and 1 case received atorvastatin.

The dosages of initial lipid lowering drugs are shown in Table 7. Most of the patients had modification the dose or choices of statins used. Moreover, some received additional groups of lipid lowering drugs such as ezetimibe, gemfibrozil, fenofibrate and a combination of simvastatin 20 mg and Ezetimibe 10 mg. The choices of secondary or additional drug(s) are shown in Table 8. The reasons for changing the medications were: 6 cases (2.4%) had adverse drug reaction, 2 patients who received simvastatin had myalgia and dizziness, 3 patients who received atorvastatin had skin reaction and myalgia, 1 patient who received rosuvastatin had myalgia with elevated level of CPK. However, most of the medical records did not mention the cause for changing the medication.

Appropriateness of statins usage is shown in Table 9. Only 48 cases (19.4%) received statins appropriately. The main causes of inappropriateness were 1) not starting with simvastatin as recommended in 118 cases (47.7%), 2) no clear indications for starting the medications in 46 cases (18.6%).

Discussion

There were only 247 medical records available for analysis because many of the medical records of the chosen patients contained insufficient information to determine appropriateness of the usage of the statins they received, especially the information on CAD risk factors and indications for statin initiation. Moreover, some cases were excluded because the lipid lowering agents were initiated by healthcare personnel from other hospitals before they attended Siriraj Hospital. Therefore, our observations might not represent the data from a whole target population. The criteria we used to classify the inappropriate use of statins were 1) not using simvastatin as an initial drug, 2) unnecessary change of medication, 3) change of medication before maximum dose of the drug was achieved, 4) not changing medication when the treatment was unsuccessful, 5) change of medication without assessing the effect of prior treatment, and 6) increasing the dose of the drug even when the therapeutic goal had been achieved. When using these criteria, only 19% (95% CI 15.0 to 24.8%) of statins' prescriptions were consid-

Table 5. Results of treatment according to type of lipid lowering drugs in patients who achieved the treatment goals

	LDL Goal <100 mg/dL		LDL Goal <130 mg/dL		LDL Goal <160 mg/dL		Others*	Total cases who did achieve the treatment goals
Medication	Case	Mean LDL (mg/dL)	Case	Mean LDL (mg/dL)	Case	Mean LDL (mg/dL)	Case	Case (%)
Simvastatin	33	85	14	103	7	141	19	73 (73)
Atorvastatin	40	72	10	83	11	118	29	90 (91)
Rosuvastatin	7	72	7	84	1	103	7	22 (88)
Pravastatin	4	87	4	106	2	152	3	13 (65)
Fluvastatin	1	69	-	-	-	-	1	2 (67)
Total Case	85	78	35	94	21	128	59	200

* Others = patients who did not have clear indication for medication. LDL-C below target before initiation of medication or having other indications without target LDL-C mentioned

Table 6. Results of treatment according to type of lipid lowering medications in patients who did not achieve the treatment goals

	LDL Goal <100 mg/dL		LDL Goal <130 mg/dL		LDL Goal <160 mg/dL		Total cases who did not achieve the treatment goals
Medication	Case	Mean LDL (mg/dL)	Case	Mean LDL (mg/dL)	Case	Mean LDL (mg/dL)	Case (%)
Simvastatin	16	137	5	199	1	226	22 (22)
Atorvastatin	6	152	2	156	0	-	8 (8)
Rosuvastatin	3	127	0	-	0	-	3 (12)
Pravastatin	5	143	1	142	1	185	7 (35)
Fluvastatin	1	169	-	-	-	-	1 (33)
Total Case	31	141	8	181	2	206	41

Table 7. Dosage of initial lipid lowering drugs

	Patients (cases)	Average dose (mg/day)	Range (mg/day)
Simvastatin	124	21.5	5-80
Atorvastatin	134	15	5-80
Rosuvastatin	48	11.0	5-20
Pravastatin	29	21.9	5-40
Fluvastatin	8	72.5	20-80
Ezetimibe	18	9.7	5-10
Gemfibrozil	11	736.4	300-1200
Fenofibrate	10	140	100-200
Vytorin®	4	20/10	20/10-20/10

Table 8. Alternative or additional lipid lowering drugs

Lipid lowering drugs		Patients (cases)	Average dose (mg/day)	Range of doses (mg/day)
Firstly prescribed	Alternative			
Simvastatin	Atorvastatin	28	19.1	5 – 40
	Rosuvastatin	10	12	10 – 20
	Pravastatin	8	18.8	10 – 40
	Fluvastatin	2	80	80 – 80
	Gemfibrozil	5	780	300 – 1200
	Fenofibrate	5	132	100 – 200
	Ezetimibe	7	10	10 – 10
	Vytorin	2	20/10	20/10 - 20/10
Atorvastatin	Simvastatin	12	20	10 – 60
	Rosuvastatin	9	10	10 – 10
	Fluvastatin	1	80	80 – 80
	Gemfibrozil	6	700	300 – 1200
	Fenofibrate	2	160	160 – 160
	Ezetimibe	5	10	10 -10
	Vytorin	1	20/10	20/10 - 20/10
Rosuvastatin	Simvastatin	2	20	20 -20
	Atorvastatin	2	10	10 – 10
	Pravastatin	1	20	20 – 20
	Fluvastatin	1	80	80 – 80
	Fenofibrate	2	130	100 – 160
	Ezetimibe	2	10	10 – 10
Pravastatin	Simvastatin	9	24.4	10 – 40
	Atorvastatin	5	24	10 – 40
	Rosuvastatin	3	10	10 – 10
	Fenofibrate	2	180	160 – 200
	Ezetimibe	2	7.5	5 – 10
	Vytorin	1	20/10	20/10 - 20/10
Fluvastatin	Simvastatin	1	40	40 - 40

Table 9. Appropriateness of statins usage in 247 patients

Appropriateness/causes	Patients (%)
Appropriate	48 (19.4)
Inappropriate	199 (80.6)
- No indication	46 (18.6)
- Start with Atorvastatin	79 (3)
- Start with Rosuvastatin	18 (7.3)
- Start with Pravastatin	18 (7.3)
- Start with Fluvastatin	3 (1.2)
- Unnecessary change to Atorvastatin	8 (3.2)
- Unnecessary change to Rosuvastatin	2 (0.8)
- Unnecessary change to Ezetimibe	1 (0.4)
- Change to alternative drugs before maximum dose of initial drug had been achieved	18 (7.3)
- Not change the dose or choice of medication when indicated	3 (1.2)
- Change the dose or choice of medication without checking prior treatment results	2 (0.8)
- Increase doses even when treatment results achieved the goal	1 (0.4)

ered appropriate. Foley also reported inappropriate use of statins even while implementing the clinical guideline[8].

In our study, CAD risks *i.e.* low HDL-C, hypertension, smoking, age, and familial history of premature CAD were assigned to have 1 point for each risk. The average risk score was 16 (range 0 to 4). However, since risk factors were not clearly mentioned in some medical records, they were counted as no risk and their true risks might be underestimated. In addition, calculation of 10-year risk by using a web-based equation might not be practical in daily practice. These factors might contribute to a high prevalence of inappropriate use of statins. Among the group that was classified as "no appropriate indication", there were 7 patients who were diagnosed of having "nonalcoholic fatty liver disease" and "non-alcoholic steatohepatitis" which were not indicators for using lipid lowering drugs according to the American Gastroenterological Association[9]. Also, our study did not consider alternative indication for medication such as LDL-C < 100 mg/dL in CAD or CAD equivalent cases, LDL-C 100-129 mg/dL in cases with ≥2 CAD risks with 10-year risk 10-20%, and LDL-C 160-189 mg/dL in those with 0-1 risk. If the alternative medical indications were taken into account, the prevalence of appropriateness of statins use might increase.

The average maximum doses of statin were 21.9, 21.5, 15, and 11mg/day for pravastatin, simvastatin, atorvastatin, and rosuvastatin respectively. Average dose of fluvastatin was 72.5 mg/day which was quite higher than other drugs because the recommended doses were 5-80 mg/day. All medications were used up to the maximum dose in some patients except for rosuvastatin for which the highest dose was only 20 mg/day.

Among 100 patients who were started with simvastatin, 28 cases were changed to atorvastatin, 10 cases to rosuvastatin, 8 cases to pravastatin and 7 cases to ezetimibe. The alternative drugs for the individuals who were started with atorvastatin (99 cases) were simvastatin (12 cases), and rosuvastatin (9 cases). The reason for such practices might be due to the fact that atorvastatin, one of the essential drugs in prior version, was not included in the new National List of Essential Medicines 2008. Regarding the rationale for changing the medication, the medications in some cases were changed without achieving the maximum doses of such drugs (23 cases). In addition, 15 cases received new medication even though the therapeutic goals had been achieved. The cholesterol levels could not be controlled in some patients despite of them receiving high doses of the medications (simvastatin, atorvastatin and rosuvastatin ≥ 40 mg/day or pravastatin ≥ 20 mg/day or fluvastatin ≥ 60 mg/day).

LDL-C levels achieved the therapeutic goals after 3 months of treatment in 81% of the patients. The rate of favorable response was 90.9% for atorvastatin, 88% for rosuvastatin, 73% for simvastatin, 67% for fluvastatin and 65% for pravastatin. The difference in favorable responses was not statistically significant. However, if the patients who did not have indications to receive medication were excluded, the success rate were 61.6%, 60%, 54%, 50%, 50% for atorvastatin, rosuvastatin, simvastatin, fluvastatin and pravastatin, respectively. Thus, the effectiveness of each drug seemed to be closer in cases with specific indications because drugs that were given without indications were fluvastatin (33%), atorvastatin (29.3%), rosuvastatin (28%), simvastatin (19%) and pravastatin (15%). On the other hand, if we excluded individuals without indications for stains from 47 cases who did not achieve the treatment goals, the average unsuccessful rate would increase to 21.8% (35% for pravastatin, 33% for fluvastatin, 22% for simvastatin, 8% for atorvastatin and 3% for rosuvastatin. In addition, among 6 cases who did not receive re-revaluation of LDL-C level, 5 cases received simvastatin and 1 case received atorvastatin. This might result in changing the percentage of successful or unsuccessful rate of each drug. Adverse reactions of lipid lowering drugs leading to a change of medication were documented in 6 cases (2.4%). Most of them were minor reactions such as myalgia and skin reaction. Elevated CPK was reported in only one case and no rhabdomyolysis was found. This incidence of adverse events of the statins from our study was comparable to that of the previous reports[10,11].

In summary, the prevalence of inappropriate use of statins at Siriraj Hospital was high. The interventions for promoting more appropriate use of statins should be implemented.

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การประเมินความเหมาะสมของการใช้ยาลดไขมันในเลือดกลุ่ม statins ในโรงพยาบาลศิริราช พ.ศ. 2551

ณัฏฐกานต์ สุวรรณศักดิ์ศรี, วิษณุ ธรรมลิขิตกุล, ปรียานุช แย้มวงษ์

ภูมิหลัง: *ยา statins เป็นยาลดไขมันในเลือดที่ใช้มากที่สุด ประสิทธิภาพของยาในกลุ่มนี้ใกล้เคียงกัน การให้ยาสามัญ simvastatin เท่านั้นที่มีความคุ้มค่าในการป้องกันโรคหัวใจและหลอดเลือด*

วัตถุประสงค์: *เพื่อศึกษาการใช้และความเหมาะสมของการใช้ยากลุ่ม statins ในผู้ป่วยนอกที่รับการรักษาที่โรงพยาบาลศิริราช*

วัสดุและวิธีการ: *เก็บข้อมูลจากเวชระเบียนผู้ป่วยนอกที่ได้รับยากลุ่ม ตั้งแต่ มกราคม พ.ศ. 2551 ถึง ธันวาคม พ.ศ. 2551 ประเมินความเหมาะสมของการให้ยาตามจำนวนปัจจัยเสี่ยงและโอกาสเกิดโรคหลอดเลือดหัวใจใน 10 ปี*

ผลการศึกษา: *มีการใช้ยาลดไขมันในเลือดแก่ผู้ป่วย 105,950 ราย มูลค่า 308 ล้านบาท โดยเป็น Simvastatin 65%, Atorvastatin 12% และ Rosuvastatin 6% คิดเป็นมูลค่ายา 9%, 42% และ 20% ตามลำดับการวิเคราะห์รายงานผู้ป่วย 247 ราย พบว่าใช้ยาเหมาะสมเพียง 19.4% การใช้ยาอย่างไม่เหมาะสม เกิดจากการเริ่มการใช้ยาอื่นแทน Simvastatin การใช้ยาอย่างไม่มีข้อบ่งใช้ และการเปลี่ยนยาอื่นโดยยังไม่ได้ใช้ยาในขนาดที่เหมาะสม*

สรุป: *การใช้ยา statins ส่วนใหญ่ไม่เหมาะสม จำเป็นต้องได้รับการแก้ไขตามปัจจัยและสาเหตุที่เกี่ยวข้อง*