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The Effectiveness of Atorvastatin, Rosuvastatin, and Simvastatin among Coronary Heart Disease/Coronary Heart Disease Risk Equivalent Patients in Usual Clinical Practice

ประสิทธิผลของยาอะทอร์วาสทาทิน, โรซูวาสทาทิน, และ ซิมวาสทาทิน ในผู้ป่วยที่มีประวัติโรคหัวใจขาดเลือดและผู้ป่วยที่มีความเสี่ยงเทียบเท่าโรคหัวใจขาดเลือด ในเวชปฏิบัติทั่วไป

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The objectives of this study were to compare the effectiveness of atorvastatin, rosuvastatin, and simvastatin among coronary heart disease (CHD)/CHD risk equivalent patients in usual clinical practice. A cross-sectional retrospective study was conducted by using electronic database among patients who were newly prescribed statin therapy during October 2004 to September 2007 and did not receive dyslipidemic drugs in the preceding 6 months. Patients aged 35 years or older with CHD/CHD risk equivalent and low-density lipoprotein cholesterol (LDL-C) baseline >100 mg/dL were included. Patients must receive statins not less than 90 days. Outcome measurements were the percentage of patients who achieved LDL-C goal according to NCEP ATP III guidelines and mean of percent change in LDL-C reduction. Economic assessment included only drug costs. Chi-square test and ANOVA were used for statistic analysis. Of the 1,024 patients who met the study criteria, 794 taking simvastatin, 109 taking atorvastatin, and 121 taking rosuvastatin. Patients had average age of 62 years and 47.9 percent were male. Results showed that lipid goal achievement, LDL-C <100 mg/dL, of rosuvastatin (78 percent), simvastatin (68 percent), and atorvastatin (62.4 percent) were not statistically different (p=0.078). The mean percentage change in LDL-C reduction of rosuvastatin was greatest compared with simvastatin and atorvastatin (46.1, 38.5, and 38.2 percent, p<0.05). Simvastatin was the most cost-effectiveness drug compared with rosuvastatin and atorvastatin (376; 16,670; and 29,417 Baht per patient at goal per year). In conclusion, simvastatin is the most cost-effectiveness drug in achieving LDL-C goals according to NCEP ATP III guideline among CHD/CHD-risk equivalent patients compared with rosuvastatin and atorvastatin. Therefore, simvastatin should be the first choice for CHD/CHD-risk equivalent patients except the patients who has contra-indication with simvastatin.

Key words : Effectiveness of statins, Lipid Goal Achievement, Atorvastatin, Rosuvastatin, Simvastatin, coronary Heart Disease

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การศึกษานี้ มีวัตถุประสงค์เพื่อเปรียบเทียบประสิทธิผลของยาอะทอร์วาสทาทิน โรซูวาสทาทิน และซิมวาสทาทินของผู้ป่วยที่มีประวัติโรคหัวใจขาดเลือด และผู้ป่วยที่มีความเสี่ยงเทียบเท่าโรคหัวใจขาดเลือดในเวชปฏิบัติ โดยใช้วิธีการศึกษาแบบตัดขวางและเก็บข้อมูลย้อนหลังจากฐานข้อมูลในกลุ่มผู้ป่วยที่ได้รับยาสทาทินครั้งแรกระหว่างเดือนตุลาคม พ.ศ. 2547 ถึง เดือนกันยายน พ.ศ. 2550 และไม่เคยได้รับยาลดไขมัน 6 เดือนก่อนรับยาที่ศึกษา กลุ่มผู้ป่วยที่ศึกษามีอายุ ≥35 ปี มีประวัติโรคหัวใจขาดเลือดหรือมีความเสี่ยงเทียบเท่าโรคหัวใจขาดเลือด และมีระดับ LDL-C แรกเริ่ม >100 มิลลิกรัม/เดซิลิตร ระยะเวลาได้รับยาสทาทินต้องไม่น้อยกว่า 90 วัน วัดผลจากร้อยละของผู้ป่วยที่บรรลุเกณฑ์เป้าหมายของระดับ LDL-C ตามแนวทางของ NCEP ATP III และค่าเฉลี่ยของร้อยละการเปลี่ยนแปลงของการลดระดับ LDL-C รวมทั้งประเมินผลทางเศรษฐศาสตร์โดยคิดต้นทุนเฉพาะค่ายาเท่านั้น สถิติที่ใช้ คือ chi-square test และ ANOVA ผู้ป่วยที่มีคุณสมบัติตรงตามเงื่อนไขที่ศึกษา 1,024 ราย เป็นผู้ป่วยที่ได้รับยาซิมวาสทาทิน 794 ราย ยาอะทอร์วาสทาทิน 109 ราย และยาโรซูวาสทาทิน 121 ราย มีอายุเฉลี่ย 62 ปี เพศชายร้อยละ 47.9 ผลการศึกษาพบว่า การบรรลุเป้าหมายระดับ LDL-C<100 มิลลิกรัม/เดซิลิตร ตามแนวทางของ NCEP ATP III ของยาโรซูวาสทาทิน (ร้อยละ 78) ยาซิมวาสทาทิน (ร้อยละ 68) และยาอะทอร์วาสทาทิน (ร้อยละ 62.4) แตกต่างกันอย่างไม่มีนัยสำคัญทางสถิติ (p=0.078) ค่าเฉลี่ยของร้อยละการเปลี่ยนแปลงของการลดระดับ LDL-C ของยาโรซูวาสทาทินดีที่สุดเมื่อเปรียบเทียบกับยาซิมวาสทาทินและยาอะทอร์-วาสทาทินอย่างมีนัยสำคัญทางสถิติ (ร้อยละ 46.1, 38.5, และ 38.2, p<0.05) ยาซิมวาสทาทินมีความคุ้มค่าทางเศรษฐศาสตร์มากที่สุดเมื่อเปรียบเทียบกับยาโรซูวาสทาทินและยาอะทอร์วาสทาทิน (376; 16, 670; และ 29,417 บาท ต่อผู้ป่วย 1 รายที่บรรลุเป้าหมายระดับไขมันในเลือดต่อปี) โดยสรุปยาซิมวาสทาทินให้ผลบรรลุเป้าหมายระดับไขมันในเลือดตามแนวทางของ NCEP ATP III ที่มีความคุ้มค่าด้านเศรษฐศาสตร์มากที่สุดเมื่อเปรียบเทียบกับยาโรซูวาสทาทินและยาอะทอร์วาสทาทิน จึงควรเลือกใช้เป็นยาลำดับแรกสำหรับผู้ป่วยโรคหัวใจขาดเลือดและผู้ป่วยที่มีความเสี่ยงเทียบเท่าโรคหัวใจขาดเลือด ยกเว้นผู้ป่วยที่มีข้อห้ามใช้กับยาซิมวาสทาทิน

คำสำคัญ : ประสิทธิผลของยาสทาทิน การบรรลุเป้าหมายระดับไขมันในเลือด อะทอร์วาสทาทิน โรซูวาสทาทิน ซิมวาสทาทิน โรคหัวใจขาดเลือด

Introduction

Cardiovascular disease (CVD) is the most common cause of death in many countries including Thailand.[1] Data from the Ministry of Public Health reported that heart disease was the third cause of death for many years. Death from hypertension and stroke increased from 18.9:100,000 population in 2000 to 34.8:100,000 population in 2004.[2] Hypercholesterolemia is a crucial risk factor to cause CVD.[1, 3] Evidence-based guidelines issued by the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) underline the importance of hyperlipidemia treatment with an aggressive low density lipoprotein cholesterol (LDL-C) goal of <100 mg/dL for high-risk

patients. Moreover, updated optional recommendations to the ATP III guidelines, published in July 2004, now recommend an optional LDL-C goal of <70 mg/dL in very high-risk patients.[3]

ATP III identified persons according to cardiovascular risk into three groups: high, moderate, and low. Patients with established coronary heart disease (CHD) and CHD risk equivalent (patients who have type 2 diabetes without CHD; non-coronary forms of clinical atherosclerotic disease; and patients who have multiple risk factors with 10-year risk of CHD >20 percent) are classified as high risk. If the patients have established CHD with diabetes mellitus, acute coronary syndrome, or metabolic syndrome, they are classified as very high risk.[3]

Statins are the most effective drugs for lowering LDL-C levels and known as 3-hydroxy -3-methylglutaryl coenzyme A (HMG-coA) reductase inhibitors. Statins can reduce LDL-C by 18-55 percent, triglycerides (TG) by 7-30 percent, but increase HDL-C by 5-15 percent.[3] Evidences from large clinical trials showed that statins can decrease the risk for CHD, total mortality by 24-37 percent and all causes of mortality by 22 percent.[3] Statins are well-tolerated by most of the persons because of less adverse events.

Three statins mostly used in many hospital of Thailand, including Sappasittiprasong hospital, are atorvastatin (ATV), simvastatin (SVT), and rosuvastatin (RSV). Several evidences showed that these statins are class effects. In three clinical trials studies including STELLAR trial (2003)[4], DISCOERY trial (2006),[5] and SOLAR trial (2007),[6] the results showed that RSV significantly reduced LDL-C levels (50 vs 42 percent for ATV and 40 percent for SVT) and achieved NCEP goal greater than ATV and SVT (76 vs 58 and 53 percent, respectively) in high-risk patients with LDL-C baseline>130 mg/dL and length of statin therapy was 12 weeks.

Recent observational studies demonstrated that in usual care setting number of patients who were prescribed statin therapy and achieved the NCEP goal, were less than in clinical trial. The results from Lipid Treatment Assessment Project (L-TAP),[7] Achievement in Singapore of Cholesterol Targets (A-SACT),[8] and REALITY -PHARMO study[9] showed that the patients achieved LDL-C goals range from 30 to 38 percent. Similar to the first L-TAP study in Thailand, only 41.2 percent of patients who were treated with statins achieved cholesterol therapy.[10] Five years after the first L-TAP study, the L-TAP II study reported that 34.6 percent of patients with CHD/CHD risk equivalent achieved LDL-C goal<100 mg/dL.[11]

However, some studies in usual clinical practice showed the results that were the same as in clinical trials. RSV reduced LDL-C and had the achievement of LDL-C goal more than ATV and SVT. Ohsfeldt et al.[12] and Fox et al.[13] compared the effectiveness of RSV, ATV, and

SVT in usual care setting using data from medical records and electronic database, the results showed that RSV had the percentage of LDL-C reduction (37 vs 28 percent for ATV and 37 vs 27 percent for SVT). RSV achieved NCEP ATP III goal higher than ATV and SVT (69.7 vs 54.8 percent for ATV and 69.7 vs 51.2 Spercentfor SVT).

Sappasittiprasong hospital, a 1000-beds hospital, is a regional hospital in North-East Thailand. Three statins are included in the hospital formulary: simvastatin, atorvastatin, and rosuvastatin. These statins were prescribed in the highest top ten drug expenditures for several years. Overall drug expenditures of three statins were about 30 million baht in 2007 and the expenditures increased rapidly. Drug prices are different; 50.29 Baht for ATV, 34.71 Baht for RSV, and 0.70 Baht for SVT. Because of the difference of drug prices, the rapid increase of drug expenditures, and conflicting results in effectiveness of statins between clinical trials and usual clinical practices, it is difficult to decide which statins are the most cost-effectiveness to be selected in hospital formulary. In addition, the study in Thailand which compared the effectiveness of the three statins was not found. Therefore, this study was conducted to compare the effectiveness of RSV, ATV, and SVT in achieving LDL-C goal according to NCEP ATP III guidelines and reducing serum LDL-C levels among CHD/CHD-risk equivalent patients in usual clinical practice of Sappasittiprasong hospital. The economic evaluation of statin therapies in CHD and CHD risk equivalent patients were also conducted.

Objectives

1. To compare the effectiveness of atorvastatin, rosuvastatin, and simvastatin among CHD and CHD risk equivalent patients in usual clinical practice at Sappasittiprasong Hospital in terms of:

1.1 The percentage of patients who achieved their LDL-C goal (LDL-C<100 mg/dL) according to NCEP ATP III guidelines.

1.2 The mean of percent change in LDL-C reduction.

2. To assess economic values among atorvastatin, rosuvastatin and simvastatin therapies in CHD and CHD risk equivalent patients at Sappasittiprasong hospital.

Methods

Study population were patients who firstly prescribed ATV, RSV, or SVT during October 2004 to September 2007, had no prior use of dyslipidaemic medications (bile acid sequestrants, fibrate, nicotinic acid, ezetimibe or statins) within the 6 months before starting statin therapy, and met the following criteria.

Inclusion criteria:

1. Patients aged 35 years or older.

2. Patients who were diagnosed CHD or CHD risk equivalents according to NCEP ATP III guidelines.

3. Patients who had serum LDL-C level at baseline>100 mg/dL.

Exclusion criteria:

1. Patients who were switched to another statins or received other dyslipidemic medications (bile acid sequestrants, fibrate, nicotinic acid and ezetimibe) after using statins. However, the titration of the statins dosage is permitted, if LDL-C level target did not achieve.

2. Patients who discontinued statin therapy.

3. Patients who didn't have the final lipid measurement.

Cross-sectional retrospective study was designed using data from electronic database (Hom C system) of Sappasittiprasong hospital.

The patient's data were extracted from electronic database of medical record, pharmacy records, and laboratory results into excel file before analysis.

Pharmacy dispensing database was used to estimate the first dispensed prescription for considering the starting date of statin therapy, statin types, co-administrated drugs, dosage, frequency, quantity, date of received drugs, age of patients, sex, and medical benefit schemes. CHD and CHD risk equivalents were extracted from medical record database by using ICD-9 and ICD-10 codes for diabetes mellitus, ischemic heart disease, myocardial infarction, angina pectoris, abdominal aortic aneurysm, peripheral vascular disease, carotid stenosis, cerebral infarction, coronary angioplasty, and coronary artery surgery. Identification number (HN and AN), sex, age, and medical benefit scheme of the patients were also used to extract the data related to diseases.

Lipid results and test dates obtained from clinical laboratory database for total cholesterol (TC), LDL-C, HDL-C, and triglyceride (TG). The LDL-C baseline was defined as the lipid value closest to the start date of statin therapy. If lipid panel results were not available within 3 months before initiating statin therapy, the patient was excluded from the study. The final lipid value was defined as the lipid measurements obtained closest to the end of the study period. The final lipid value had to be obtained at least 30 days after initiating statin therapy and not more than 90 days after the end of study.

Duration of statin therapy was at least 3 months. The patient who discontinued statin therapy was defined as the lack of a prescription or refill order within 15 days after the period of the prescription supply. The outcome measures were computed for each individual statin. Changes in TC, HDL-C, and TG were also computed.

Chi-square test was used to assess the difference in proportion of patients who achieved LDL-C goals according to NCEP ATP III guideline.

ANOVA was used to assess the difference in the mean percent change of LDL-C reduction in patients among statin groups.

An economic value assessment was calculated based on the provider perspective. Costs included only drug costs within a time horizon of 1 year. Drug costs were based on the retail price at Sappasittiprasong hospital in 2007.

Results and Discussions

Of the 1,024 patients who met the study criteria; 794 taking SVT, 109 taking ATV, and 121 taking RSV. Patient's characteristics (Table 1) showed that the mean age was 62 years and 47.9 percent were male. RSV and ATV were mostly prescribed for out of pocket and CSMBS patients, while SVT was mostly prescribed for UC scheme patients. This result clearly indicated the effect from the difference of statin prices. The patients with CHD-risk equivalent were more likely to be in every statin groups (60.2 percent) and 10.6 percent were very high-risk patients. The mean of statin daily dose was 17.7 milligram. Patients taking RSV had baseline LDL-C, HDL-C, TG, and TC higher than patients taking SVT and ATV.

Table 1 Demographic of patient characteristics compared among statin groups

Characteristics	Simvastatin (n = 794)	Atorvastatin (n = 109)	Rosuvastatin (n = 121)	Total (n = 1,024)	P-Value
Sex: Male	366 (46.1%)	63 (57.8%)	61 (50.4%)	490 (47.9%)	0.060
Female	428 (53.9%)	46 (42.2%)	60 (49.6%)	534 (52.1%)	
Age: Mean ± SD (years)	61.9±10.6	63.1±10.6	61.4±10.0	62±10.5	0.456
Health benefit scheme[#]					
Out of pocket and CSMBS[a]	276 (34.8%)	99 (90.8%)	120 (99.2%)	495 (48.3%)	0.000*
SSS[b]	14 (1.8%)	3 (2.8%)	0 (0%)	17 (1.7%)	
UC[c]	504 (63.4%)	7 (6.4%)	1 (0.8%)	512 (50.0%)	
High risk patients					
CHD patients	237 (29.8%)	41 (37.6%)	21 (17.4%)	299 (29.2%)	0.001*
CHD risk equivalent	466 (58.7%)	57 (52.3%)	93 (76.9%)	616 (60.2%)	
Diabetes mellitus (DM)	354 (44.6%)	46 (42.2%)	78 (64.5%)	478 (46.7%)	
Others	112 (14.1%)	11 (10.1%)	15 (12.4%)	138 (13.5%)	
Very high risk patients					
(CHD+DM)	91 (11.5%)	11 (10.1%)	7 (5.8%)	109 (10.6%)	
Baseline lipid parameters					
LDL-C (mg/dL) mean±SD	153.7±34.4	162.5±36.2	167.3±45.7	156.2±36.4	0.001*
HDL-C (mg/dL)mean±SD	38.0±9.8	39.8±12.6	40.7±11.1	38.5±10.3	0.023*
TG (mg/dL) mean±SD	159.0±72.1	156.9±74.3	184.1±92.2	161.8±75.4	0.016*
TC (mg/dL) mean±SD	224.7±40.5	234.8±47.0	244.6±52.0	228.1±43.2	0.000*
Statin daily doses					
Mean±SD (mg)	19.0±7.4	17.0±7.8	10.0±2.6	17.7±7.6	0.000*

Remark: *Significant atp<0.05

using Fisher's extract test

[a]Civil Service Medical Benefit Scheme.

[b]Social Service Scheme,

[c]Universal Coverage Scheme

LDL-C = low density lipoprotein cholesterol, HDL-C = high density lipoprotein cholesterol, TG = triglyceride, TC = total cholesterol

1. **Achievement of LDL-C Goals** The result in Table 2 showed that patients taking RSV achieved LDL-C goals greater than patients taking ATV or SVT but the differences were not statistically significant. (76.0 vs 62.4 and 68.0 percent respectively, p=0.078). It should be noted that patients taking RSV or ATV had LDL-C baseline higher than SVT. For this reason, it may affect the probability of LDL-C goal achievement among statin groups.

Table 2. Comparisons of the number and percentage of patients achieving their LDL-C goal according to NCEP guideline (LDL-C level < 100 mg/dL) among statin groups

Statin Types	Number of Patients (%) Achieving NCEP Goals		Total
	Achieved	Did not Achieve	
Simvastatin	540 (68.0)	254 (32.0)	794
Atorvastatin	68 (62.4)	41 (37.6)	109
Rosuvastatin	92 (76.0)	29 (24.0)	121
Total	702 (68.6)	322 (31.4)	1024

P-value = 0.078

2. **Change in Lipid Parameters.** Results (Table 3) showed that patients taking RSV had the mean of percent change reduction in LDL-C, TG, and TC greater than patients taking ATV or SVT significantly (p<0.01). The result was not statistically different in the mean of percent change of HDL-C among statin groups.

Table 3 Mean of percent change in lipid parameters among CHD/CHD risk equivalent patients compared among statin groups.

Lipid Values	Mean % change (SD) in Lipid Parameters (mg/dL)				P-Value
	Simvastatin [95% CI] n = 794	Atorvastatin [95% CI] n = 109	Rosuvastatin [95% CI] n = 121	Total [95% CI] N = 1024	
LDL-C	-38.5 (15.9) [-39.6, -37.4]	-38.2 (21.0) [-42.2, -34.2]	-46.1 (16.5) [-49.1, -43.2]	-39.4 (16.7) [-40.4, -38.3]	0.000*
HDL-C	2.6 (22.6) [1.0, 4.2]	6.4 (34.4) [-0.1, 12.9]	4.8 (20.4) [1.1, 8.4]	3.3 (23.9) [1.8, 4.7]	0.226
Triglyceride	7.1 (53.1)-0.0 [3.4,10.8]	1 (43.7) [-8.3, 8.3]	-14.9 (33.2) [-20.9, -9]	3.7 (50.7) [0.6, 6.8]	0.000*
Total cholesterol	-26.5 (14.4) [-27.5, -25.5]	-26.2 (18.7) [-29.7, -22.7]	-33.6 (14.2) [36.1, -31]	-27.3 (15.0) [-28.2, -26.4]	0.001*

Remark: *Significant at p<0.01

3. **Economic Value AssessmentResults** showed that SVT was the most cost-effective therapy among CHD/CHD risk equivalent patients with the lowest annual cost (376 Baht

per patient at goal and 7 Baht of 1 percent LDL-C reduction). The incremental cost-effectiveness of RSV was 155,163 Baht per patient at goal (LDL-C<100 mg/dL) and 1,633 Baht of 1 percent LDL-C reduction, compared with SVT (Table 4). ATV was least cost-effective with the lowest effectiveness and highest cost based upon the outcomes in this study.

Table 4 Comparisons of the cost-effectiveness in achievement of LDL-C goal according to NCEP guideline and LDL-C reduction among statin groups.

Statin Therapy	Effectiveness* (%)	Annual Costs** (Baht)	Cost-Effectiveness Ratio (Cost per Unit of Effectiveness)	Incremental Cost Effectiveness Ratio
NCEP LDL-C Goal (effectiveness as percent of patients at goal)				
Rosuvastatin 10 mg	76.0	12,669	16,670	155,163‡
Simvastatin 20 mg	68.0	256	376	dominated
Atorvastatin 20 mg	62.4	18,356	29,417	-
LDL-C reduction (effectiveness as percent LDL-C reduction)				
Rosuvastatin 10 mg	46.1	12,669	275	1,633‡‡
Simvastatin 20 mg	38.5	256	7	dominated
Atorvastatin 20 mg	38.2	18,356	481	-

Remark : * Effectiveness based on the effectiveness of statin daily dose in each statin: simvastatin 20 mg, rosuvastatin 10 mg, and atorvastatin 20 mg.

** Statin prices based on retail price at Sappasittiprasong Hhospital in 2007: simvastatin = 0.70 Baht, atorvastatin = 50.29 Baht, and rosuvastatin = 34.71 Baht. Thus, annual costs = price x 365

‡ Incremental cost-effectiveness ratio of patients atgoal = $\frac{\text{(cost of RSV-cost of SVT) X 100}}{\text{\% patients at goal of RSV-\% patients at goal of SVT}}$

‡‡ Incremental cost-effectiveness ratio of 1% LDL-C reduction = $\frac{\text{(cost of RSV-cost of SVT)}}{\text{\% LDL-C reduction of RTV-\%LDL-C reduction of SVT}}$

Conclusions

The findings indicated that patients with SVT are the most cost-effectiveness therapy compared with RSV and ATV (at current prices). Thus, in usual clinical practice, SVT should be the first choice for hyperlipidaemia treatment with CHD/CHD-risk equivalent patients except the patients who has contra-indication with SVT.

The findings should be proposed to the Pharmacy and Therapeutic Committee to improve the guidelines for appropriate and cost-effective use of statins in the hospital. The pattern of this study should be applied for evaluation of other drugs use in usual clinical practice.

Limitations of the study

Because this study collected retrospective data from electronic database, some data such as other risk of CHD, co-administered drug, drug

compliance, diet, and exercise were not available, generalizability of the results has to be concerned regarding this limitation.

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