ORIGINAL ARTICLE

The Comparative Effectiveness between Branded Generic Atorvastatin (Lipostat®) and Authorized Generic Atorvastatin (Xarator®): A Prospective Cohort Study

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Background: An authorized generic drug has identical ingredients as the brand-name drug but marketed as a generic version by the innovator company with a lower cost. A branded generic drug is an imitation of the brand-name medication whose patent has expired. The active elements of a branded generic medicine are the same as those of the original drug, however the inactive ingredients may differ.

Objective: To assess the effectiveness of the branded generic atorvastatin (Lipostat®), compared to the authorized generic atorvastatin (Xarator®) in decreasing low density lipoprotein cholesterol (LDL-C) levels.

Materials and Methods: The present study was a prospective cohort study that included patients who had been taking the authorized generic atorvastatin (Xarator®) 40 mg once daily for at least three months. The authorized generic atorvastatin (Xarator®) was switched to branded generic atorvastatin (Lipostat®) 40 mg once daily for the next three months. Blood chemistry including lipid profile were evaluated before and three months after the transition from Xarator® to Lipostat®.

Results: Of the 61 patients, mean age was 67.0±9.9 years, and 45 (73.7%) were male. The two most common comorbidities included coronary artery disease in 80.3% and hypertension in 60.7%. At three months after switching to branded generic atorvastatin, the mean total cholesterol changed from 133.6±28.8 to 130.0±25.8 mg/dL, the triglyceride changed from 123.3±78.3 to 115.6±70.1 mg/dL, and the LDL-C changed from 68.8±24.1 to 65.5±20.3 mg/dL, thus, they were not significantly different compared to the baseline. There were also no significant differences in adverse events between Lipostat® and Xarator®.

Conclusion: Branded generic atorvastatin (Lipostat®) is as effective as the authorized generic atorvastatin (Xarator®) in lowering LDL-C levels.

Keywords: Atorvastatin; Authorized generic drug; Branded generic atorvastatin; Low-density lipoprotein cholesterol; High-density lipoprotein cholesterol; Statin

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Atherosclerotic cardiovascular disease (ASCVD) is an important health problem worldwide[1]. It is well-established that dyslipidemia is a strong risk factor of ASCVD[2]. International guidelines recommend lowering the low-density lipoprotein cholesterol (LDL-C) as a primary target[3-6]. In high-risk patients including established ASCVD, familial hypercholesterolemia, diabetes mellitus with target organ damage, the aim is to reduce LDL-C by at least 50% from baseline levels and to the level below 70 mg/dL in those at high risk[6]. The high-potency statin is recommended as the first-line therapy in those with high-risk ASCVD. However, a large cohort of Thai patients with high-risk ASCVD (CORE-Thailand registry) demonstrated a significantly low rate of LDL-C goal attainment in Thai population[7]. The reason may be due to the limited access to standard of care due to the high cost of medications.

Atorvastatin is a high-potency statin that is commonly used worldwide in patients with dyslipidemia and those with ASCVD[8,9]. During the current era of cost-concern in health economics, the comptroller general's department, which is a Thai government agency under the Ministry of Finance,

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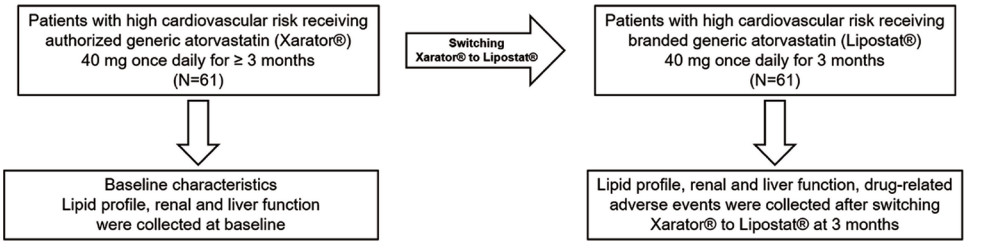

Figure 1. Consort diagram.

has set the middle price for atorvastatin. As a result, the original, brand-name, atorvastatin (Lipitor®) is no longer in the national drug list in Thailand due to its high cost.

An authorized generic drug refers to a medication that is identical to its branded counterpart, manufactured by the same company, but marketed under a different name. It is authorized or approved by the original manufacturer and typically enters the market after the patent expiration or exclusivity period of the branded drug. On the other hand, a branded generic drug is a medication that is produced by a company other than the one that initially developed and marketed the brand-name drug. However, the branded generic drug carries the same active ingredients, dosage form, strength, and intended use as the original branded drug. The difference lies in the branding and marketing, as the generic drug is sold under a different trade name. Both authorized generic drugs and branded generic drugs are intended to provide cost-effective alternatives to the brand-name drugs while maintaining comparable quality and therapeutic efficacy[10].

The authorized generic atorvastatin and branded generic atorvastatin are two variations of the generic drug atorvastatin, with slight differences in their marketing and branding. However, it is noteworthy that in Thailand, authorized generic atorvastatin is associated with higher costs compared to branded generic atorvastatin. Consequently, investigating the comparative effectiveness of these two variants, specifically focusing on the more affordable branded generic atorvastatin, becomes imperative to mitigate healthcare expenses.

Lipostat® is one of branded generic atorvastatin, marketed by Siam Pharmaceutical, Thailand. A bioequivalence study has demonstrated similar pharmacokinetic and pharmacodynamic (PK/PD) parameters between Lipostat® and the original atorvastatin. The present study aimed to assess the effectiveness of branded generic atorvastatin (Lipostat®), compared to the authorized generic atorvastatin (Xarator®) in decreasing LDL-C levels.

Materials and Methods

The present study was a prospective cohort study of patients presenting to the out-patient cardiology clinic at Maharaj Nakorn Chiang Mai Hospital between July 2021 and May 2022. The inclusion criteria for the study were participants aged 18 years or older who had been on a once-daily dose of Xarator® 40 mg for a minimum of three months and had successfully reached the specified LDL-C goal according to the lipid guideline. All participants required a baseline LDL-C level measured while they were receiving Xarator® 40 mg once daily for at least three months. Patients who met the inclusion requirements and agreed to participate in the study were enrolled. Baseline characteristics including age, gender, body mass index, comorbidities, socio-economic status, and concomitant medications, and laboratory data including lipid profile, renal function, and liver function were collected.

The authorized generic atorvastatin (Xarator®) 40 mg once daily was switched to the branded generic atorvastatin (Lipostat®) 40 mg once daily for three months. At 3-month follow-up, the lipid profile, renal function, and liver function were measured. The adverse events, including myalgia, myositis, and rhabdomyolysis, were collected over the 3-month period. The change of other lipid-lowering agent was discouraged during the study period. Methods of measuring medication adherence included the use of pill counts (Figure 1).

Statistical analysis

The authors calculated the sample size by comparing a mean to a known value (pair t-test). Previous study demonstrated the mean level of LDL-C after taking the high-potency statin was 100 mg/dL[11]. The standard deviation of the sampled population was estimated as 13 mg/dL. The authors proposed the acceptable difference of LDL-C lowering between the two generic atorvastatin was

6%. The estimated total sample size was 54 patients. The authors anticipated that 10% of the patients may be lost to follow-up or will have drug compliance issue. Therefore, a total sample size of 60 patients was required.

Continuous variables were reported as mean ± standard deviation (SD), while categorical variables were presented as counts with corresponding percentages. Baseline demographic and clinical information were summarized using descriptive statistics. Within-group comparisons of numerical variables were performed using paired t-tests. Statistical software package IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA, https://www.ibm.com/products/spss-statistics) was used for analysis.

The present study was carried out following the Declaration of Helsinki and approved by the Research Ethics Committee of the Faculty of Medicine, Chiang Mai University, Approval No. 308/2564.

Results

Sixty-one patients switched treatment from authorized generic atorvastatin (Xarator®) to the branded generic atorvastatin (Lipostat®). Baseline characteristics of dyslipidemia patients are shown in Table 1. The mean age was 67.0±9.9 years, and 45 patients (73.7%) were male. The mean body mass index was 24.6±4.8 kg/m². The three most common comorbidities included coronary artery disease in 80.3% (49 patients), hypertension in 60.7% (37 patients), and diabetes mellitus in 37.7% (23 patients). There was no chronic liver disease or familial hypercholesterolemia in the present study population. Anti-platelet therapy was used in 53 patients (86.9%) of the patients. Of the 61 patients, 51 patients (83.6%) used beta blocker, and 81.9% of them used angiotensin converting enzyme inhibitor/angiotensin receptor blocker/angiotensin receptor neprilysin inhibitor. Regarding lipid lowering agents, 41.0% used ezetimibe and 1.6% used fibrate in combination with statin. No bile acid sequestrants or PCSK9 inhibiting drug were used in the present studied population.

The lipid profile, renal function and liver function are demonstrated in Table 2. At baseline, total cholesterol was 133.6± 28.8 mg/dL, high-density lipoprotein cholesterol (HDL-C) was 47.9±11.8 mg/dL, LDL-C was 68.8±24.1 mg/dL, and triglyceride was 123.3±78.3 mg/dL. Three months after switching from Xarator® to Lipostat®, total cholesterol was 130.0±25.8 mg/dL, HDL-C was 47.9±11.8 mg/dL, LDL-C was 65.5±20.3 mg/dL, and triglyceride was 115.6±70.1 mg/dL. There were no statistically significant differences in terms of efficacy between Xarator® and Lipostat®.

Table 1. Baseline characteristic of dyslipidemia patients who switched treatment from the authorized generic atorvastatin (Xarator®) to the branded generic atorvastatin (Lipostat®)

Baseline characteristics	Total patients (n=61)
Age (years); mean±SD	67.0±9.9
Male; n (%)	45 (73.7)
Body mass index (kg/m^2); mean±SD	24.6±4.8
Health care payment scheme; n (%)	
Civil servant medical benefit scheme	35 (57.4)
Universal health-care coverage scheme	18 (29.5)
Social security	7 (11.5)
Self-pay	1 (1.6)
Comorbid diseases; n (%)	
Diabetes mellitus	23 (37.7)
Chronic kidney disease	19 (31.2)
Hypertension	37 (60.7)
Coronary artery disease	49 (80.3)
Cerebrovascular disease	3 (5.0)
Current medications; n (%)	
Antiplatelet	53 (86.9)
Betablocker	51 (83.6)
ACEI/ARB/ARNI	50 (81.9)
Anti-diabetic drug	20 (32.8)
Proton pump inhibitor	19 (31.2)
Ezetimibe	25 (41.0)
Fibrate	1 (1.6)

ACEI=angiotensin converting enzyme inhibitor; ARB=angiotensin receptor blocker; ARNI=angiotensin receptor neprilysin inhibitor; SD=standard deviation

The medication adherence was reported as 100% in 59 of 61 patients (97%) of the patients. There were no reports of drug-related adverse events, including myalgia, myositis, and rhabdomyolysis, after switching from Xarator® to Lipostat®. In the present study, the authors successfully maintained complete patient follow-up throughout the duration of the research, with no loss to follow-up.

Discussion

In the era of economic concerns in the healthcare community, the cost-effectiveness of therapy has emerged as a crucial issue. The cost-effectiveness of dyslipidemia therapy depends on several factors, including baseline CVD risk and LDL-C levels, cost of treatment, and uptake of preventive strategies[12]. The use of less expensive generic medications has developed as a substitute strategy[13].

Table 2. Biochemical parameters before and 3 months after switching treatment from the authorized generic atorvastatin (Xarator®) to the branded generic atorvastatin (Lipostat®)

Biochemical parameters	Baseline; mean±SD	At 3 months follow-up; mean±SD	Mean differences (95% CI)	p-value
Total cholesterol (mg/dL)	133.6±28.8	130.0±25.8	–3.6 (–2.4 to 9.6)	0.235
HDL (mg/dL)	47.9±11.8	48.4±11.7	0.6 (–2.6 to 1.4)	0.566
LDL (mg/dL)	68.8±24.1	65.5±20.3	–3.3 (–1.3 to 7.9)	0.156
Triglyceride(mg/dL)	123.3±78.3	115.6±70.1	–7.7 (–1.5 to 16.8)	0.101
Creatinine (mg/dL)	1.3±0.9	1.3±1.0	0.1 (–0.1 to 0.1)	0.516
AST (U/L)	25.7±7.7	26.6±11.3	0.9 (–3.3 to 1.6)	0.478
ALT (U/L)	24.2±12.3	26.4±15.7	2.2 (–5.1 to 0.7)	0.130
ALP (U/L)	92.9±83.7	96.3±100.2	3.4 (–10.1 to 3.4)	0.321
Total bilirubin (mg/dL)	0.67±0.3	0.68±0.3	0.1 (–0.1 to 0.0)	0.440
Direct bilirubin (mg/dL)	0.3±0.1	0.3±0.1	0.0 (–0.0 to 0.0)	0.716

HDL=high-density lipoprotein; LDL=low-density lipoprotein; AST=aspartate aminotransferase; ALT=alanine transaminase; ALP=alkaline phosphatase; SD=standard deviation; CI=confidence interval

Generic medicine is an equivalent of an originator pharmaceutical product because it contains the same active substance as the originator product. Three categories of generic drugs have been described, authorized generic drugs, branded generic drugs, and unbranded generic drugs[10]. The key difference between authorized generic drug and branded generic drug is that the former was manufactured by the innovator company and the latter was manufactured by a different company. As a result, the authorized generic drug has identical active and inactive compounds as an original drug. On the other hand, the branded generic drug had similar active ingredients, but the inactive compounds may be dissimilar. The unbranded generic drugs are usually known by their chemical name. Although the unbranded generic drugs are the cheapest among generic drugs, they are not widely available in the market.

There has been the perception that branded and unbranded generic drugs are substandard than authorized generic drug among some physicians[14]. Nevertheless, the authorized generic drug is generally more expensive than the branded generic drug. These negative insights of branded generic drugs compared to authorized generic drug among health care workers represent a potential barrier to the use of lower cost medications[15,16].

Previous studies reported the generic atorvastatin is as effective as the original atorvastatin (Lipitor®) in lowering LDL-C levels, which could lead to substantial cost saving without diminishing clinical effectiveness[17-23]. Nevertheless, there has been no study comparing authorized generic atorvastatin and branded generic atorvastatin.

The present study is the first prospective cohort study in adult Thai patients demonstrating the similar effectiveness of authorized generic atorvastatin (Xarator®) and branded generic atorvastatin (Lipostat®) on LDL-C lowering in patients with high-risk ASCVD.

During the era of cost-concern in the medical community, high cost of medications is one of the barriers to medication adherence. The present study finding supports the usage of generic atorvastatin with lower cost in patients with high-risk ASCVD, which could lead to substantial cost saving for patients and health care plans without compromising clinical effectiveness[23,24]. The present study suggests that the outcomes obtained are applicable to a wider group of Thai patients in need of high-potency statin therapy to effectively manage their cardiovascular risk.

In the present study, the authors assessed lipid parameters three months after transitioning from authorized generic atorvastatin to branded generic atorvastatin. The authors acknowledge that the follow-up period for evaluating lipid reduction was short in relation to assessing the effectiveness of the drug. However, it is important to note that European guidelines for the management of dyslipidemias 2019 recommend assessing treatment response at six to eight weeks from the start of the therapy[6]. Despite the brief three-month follow-up period, the findings demonstrate that substituting the authorized generic atorvastatin (Xarator®) with the branded generic atorvastatin (Lipostat®) can effectively sustain the reduction of LDL-C levels.

Limitation

First, the sample size was small. Second, the present study was a non-randomized, non-blinded

clinical study aimed at comparing LDL-C levels in the same patient before and after switching from authorized generic atorvastatin to branded generic atorvastatin. Notably, the present study did not include a control group. Therefore, the observed effects of branded generic atorvastatin on LDL-C lowering could be influenced by the Hawthorne effect, a type of attention bias. The patients participating in the present study may have altered their behavior due to being observed, potentially impacting their LDL-C levels. However, the lifestyle modifications, such as reduced dietary saturated fat and exercise, typically lead to a modest 5% to 10% reduction in LDL-C levels[6]. Consequently, the potential confounding factors in the present study are unlikely to have had a significant impact on LDL-C levels. Finally, the cost-utility analysis was not performed. As a result, the cost-effectiveness of branded generic atorvastatin has yet to be proven. To support the present study findings, additional trials with cost-utility analysis and longer-term follow-up are required.

Conclusion

In the patients with dyslipidemia and high-risk ASCVD, the branded generic atorvastatin (Lipostat®) is as effective as the authorized generic atorvastatin (Xarator®) in lowering cholesterol levels without serious adverse effects.

What is already known on this topic?

Atorvastatin is a high-potency statin that is commonly used worldwide in patients with dyslipidemia and those with established ASCVDs.

What does this study add?

This study demonstrated that the branded generic atorvastatin (Lipostat®) 40 mg once daily has similar effectiveness in LDL-C reduction compared to authorized generic atorvastatin (Xarator®).

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Authors' contributions

NP performed statistical analysis, wrote the manuscript and tables. AP performed statistical analysis, data analysis and data interpretation. SG collected and re-checked the data prior to the analysis. WW designed the cohort, conception of the data analysis, data interpretation, and critically revised the manuscript. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Availability of data

The data that support the findings of the present study are available from the corresponding author upon reasonable request.

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Conflicts of interest

The authors declare no conflict of interest. The branded generic atorvastatin (Lipostat®) used in the present study was provided by Siam Pharmaceutical, Bangkok, Thailand. The investigators independently designed and conducted the study. The data was analyzed, and the manuscript was written by the investigators.

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