Clinical Outcomes of High-Intensity Doses of Atorvastatin in Patients with Acute Coronary Syndrome: A Retrospective Cohort Study Using Real-World Data

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Abstract

Abstract Aim: To compare the effectiveness and safety of two high-intensity atorvastatin doses (40mg vs. 80mg) among acute coronary syndrome (ACS) patients. Methods: This retrospective observational cohort study using real-world data included patients admitted with ACS to the Heart Hospital in Qatar between January 1, 2017 and December 31, 2018. The primary endpoint was a composite of cardiovascular disease (CVD)-associated death, non-fatal ACS, and non-fatal stroke. Cox proportional hazard regression analysis was used to determine the association between the two high-intensity atorvastatin dosing regimens and the primary outcome at 1 month and 12 months post-discharge. Results: Of the 626 patients included in the analyses, 475 (75.9%) received atorvastatin 40mg, while 151 (24.1%) received atorvastatin 80mg following ACS. Most of the patients were Asian (73%), male (97%) with a mean age of 50 years, and presented with ST-elevation myocardial infarction (60%). The incidence of the primary effectiveness outcome did not differ between the atorvastatin 40mg and 80mg groups at 1 month (0.8% vs. 1.3%; aHR= 0.59, 95% CI 0.04-8.13, p= 0.690) and at 12 months (3.2% vs. 4%; aHR= 0.57, 95% CI 0.18-1.80, p= 0.340). Similarly, the use of the two doses of atorvastatin resulted in comparable safety outcomes, including liver toxicity, myopathy, and rhabdomyolysis with an event rate of $< 1\%$ in both groups. Conclusion: The use of atorvastatin 40mg in comparison to atorvastatin 80mg in patients with ACS resulted in similar cardiovascular effectiveness and safety outcomes.

Introduction

A high-intensity statin, defined as atorvastatin 40mg or 80mg and rosuvastatin 20mg or 40mg orally, which lowers low-density lipoprotein cholesterol (LDL-C) by [?]50%, is recommended by clinical practice guidelines for secondary prevention of cardiovascular events among patients who have an atherosclerotic cardiovascular disease (CVD) (Class 1A).[1,2] Several clinical trials have demonstrated that statin use reduces major cardiovascular events.[3–10]Specifically, large randomized controlled clinical trials have established the efficacy and safety of statins for secondary prevention of CVDs.[8–10] The Intensive versus Moderate Lipid Lowering with Statins after Acute Coronary Syndromes (PROVE IT) trial that compared atorvastatin 80mg to pravastatin 40mg demonstrated a risk reduction of 16% over two years in the composite endpoint of all-cause mortality, myocardial infarction, documented unstable angina requiring re-hospitalization, revascularization (performed at least 30 days after randomization), and stroke among patients with the acute coronary syndrome (ACS).[8]

Additionally, the Intensive Lipid Lowering with Atorvastatin in Patients with Stable Coronary Disease (TNT) trial that compared atorvastatin 80mg to 10mg showed a risk reduction of 22% over 4.9 years in a major adverse cardiovascular event (MACE), defined as cardiovascular death, non-fatal myocardial infarction, resuscitation after cardiac arrest, and fatal or non-fatal stroke.[9] Similarly, in the Effects of Atorvastatin on Early Recurrent Ischemic Events in Acute Coronary Syndrome (MIRACL) trial, the early use of atorvastatin 80mg after ACS compared to placebo had resulted in a 16% significant reduction in a primary composite outcome of mortality, non-fatal myocardial infarction, and cardiac arrest with resuscitation over a follow-up period of 16 weeks.[10]

Therefore, the use of atorvastatin 80mg among patients with coronary artery disease (CAD) had resulted in a risk reduction of 16-22% in MACE. However, to the best of our knowledge, the secondary prevention cardiovascular benefit of atorvastatin 40mg compared to 80mg in the setting of ACS has not yet been well-established. Although the CURE-ACS trial compared both doses among ACS patients in terms of LDL-C reduction[11], there is no head-to-head comparison between atorvastatin 40mg and 80mg to assess the cardiovascular secondary prevention effect of the two regimens. Therefore, this retrospective, observational cohort study aimed to compare using real-world data the effectiveness and safety of two high-intensity statin doses (atorvastatin 40mg vs. 80mg) in patients with ACS at 1 month and 12 months post-discharge, and to determine the predictors of prescribing 80mg upon discharge.

Methods

Study Setting

This study was conducted at the Heart Hospital in Qatar. The hospital is a 116-bed tertiary cardiology center under the Hamad Medical Corporation (HMC), and it is the only national center for CVDs in the country.[12]

Study Design and Population

We conducted a retrospective, observational, cohort study using real-world data from Heart Hospital. The study was approved by HMC Medical Research Centre and Institutional Review Board in Qatar. The study comprised four stages: (1) determining the time to a primary composite outcome of CVD-associated death, non-fatal ACS, and non-fatal stroke within 1 month and 12 months of discharge among high-intensity statin naïve patients admitted with ACS, along with determining the time to secondary effectiveness outcomes within 1 month and 12 months of discharge; (2) determining the effect of the two high-intensity statin dosing regimens (atorvastatin 40mg vs. 80mg) in achieving a goal of reducing LDL-C by [?] 50% from baseline or LDLC $<$ 70mg/dL; (3) assessing the safety outcomes, including the occurrence of myopathy, rhabdomyolysis, and elevation of liver enzymes to three times the upper limit of normal (ULN) and; (4) conducting a retrospective analysis of the demographic and clinical characteristics of the atorvastatin 80mg vs. 40mg users to identify the predictors of prescribing atorvastatin 80mg among the ACS patients in our facility.

All patients admitted to the Heart Hospital with the diagnosis of ACS, which includes ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI), or unstable angina (UA) during 1 January 2017 and 31 December 2018 were screened for inclusion in the study. Patients who met the inclusion criteria and discharged on high intensity atorvastatin dosing (either atorvastatin 40mg or 80mg oral once daily) were identified. All patients who met the inclusion criteria and discharged on atorvastatin 40mg were included in the atorvastatin 40mg group (atorvastatin 40mg users), while those discharged on atorvastatin 80mg were included in the atorvastatin 80mg group (atorvastatin 80mg users).

Eligibility Criteria

Patients were included in the study if they fulfilled all of the following eligibility criteria: (1) adult patients aged [?]18 years, but [?] 75 years; (2) diagnosed with ACS (STEMI, NSTEMI, or UA); (3) were either statin-naive or on a low-to-moderate intensity statin therapy prior to admission and; (4) were discharged on either atorvastatin 40mg or atorvastatin 80mg. Patients were excluded if they had one of the following: (1)

a known hypersensitivity to any statin; (2) active liver disease or hepatic dysfunction defined as a level of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) of > three times ULN; (3) pregnancy or breast-feeding; (4) receiving proprotein convertase subtilisin/kexin Type 9 (PCSK9) inhibitor; (5) receiving ezetimibe; (6) or already on a high-intensity statin prior to ACS diagnosis and hospitalization.

Outcome Measures and Follow-Up

The effectiveness outcome measures in this study included: (1) a primary composite outcome of CVD-associated death, non-fatal ACS, and non-fatal stroke within 1 month and within 12 months of discharge among high-intensity statin naive patients who were discharged on either atorvastatin 40mg or 80mg; (2) secondary effectiveness outcomes, including, all-cause mortality, CV mortality, fatal or non-fatal stroke, fatal or non-fatal ACS, coronary revascularization, stent thrombosis, and stent restenosis within 1 month and 12 months post-discharge and; (3) lowering LDL-C by [?] 50% from baseline or LDL-C < 70mg/dL. On the other hand, the safety outcome measures of the study included**:** (1) myopathy; (2) rhabdomyolysis; (3) elevation of ALT or AST > three upper limits of normal and; (4) any adverse drug event requiring statin discontinuation. Predictors of prescribing atorvastatin 80mg among ACS patients, including several patient-related, disease-related, and medication-related factors, such as demographics, comorbid diseases, and concomitant prescription drugs during hospitalization were also measured. Patients were followed-up for 1 year post-discharge date, or until the occurrence of the primary endpoint, or until censoring if they were lost to follow-up.

Covariates

The results of the effectiveness outcomes were adjusted for clinically relevant patient-, disease-, and medication-related variables that were associated with ACS, including: gender, age, geographical region of origin, smoking status, family history of CVD, hypertension, diabetes, chronic kidney disease (CKD), peripheral artery disease (PAD), CAD, index event of STEMI, index event of NSTEMI, index event of UA, primary percutaneous coronary intervention (PCI), number of deployed stents, type of stent, level of baseline LDL-C, and use of aspirin, P2Y12 inhibitors, and beta-blockers.

Data Collection Procedures

Data were collected from the HMC electronic medical records system (Cerner$^{(r)}$). Relevant data were manually extracted using a pretested data collection form. The outcomes of interest, including the primary and secondary outcomes as well as patient-, disease-, and medication-related factors were extracted accordingly.

Statistical Analyses

Data analyses were performed using the Statistical Package for Social Sciences program version 24.0 (IBM SPSS Statistics for Windows; IBM Corp, Armonk, NY). Descriptive statistics in the form of frequencies and percentages were reported for categorical variables and mean +- standard deviation (SD) for continuous variables. The chi-square test was used to compare categorical variables between the two groups (atorvastatin 80mg users vs. atorvastatin 40mg users), and Student's t-test was used to compare continuous variables between the two groups.

Cox proportional hazard regression analysis was used to assess the association between atorvastatin doses and time-to-primary composite outcome and secondary effectiveness outcomes at 1 month and 12 months following discharge. The 1-month and 12-month Cox proportional hazard models were adjusted for clinically relevant variables. The results were presented as unadjusted hazard ratio and adjusted hazard ratio (aHR) with 95% confidence intervals (CIs). A P-value of <0.05 was used to indicate statistical significance. Furthermore, multivariate logistic regression was used to determine the predictors of prescribing atorvastatin 80mg among ACS patients. Sixteen clinically relevant variables were included in the logistic regression model, using the backward stepwise likelihood ratio with the probability of entry of 0.05 and removal of 0.10 at each step. The results are presented as adjusted odds ratio (aOR) with corresponding 95% CI. A P-value of <0.05 was used for statistical significance.

Results

Subjects' Selection

We identified 7,372 patients who were dispensed either atorvastatin 40mg (n=7,009) or 80mg (n=363) through the Heart Hospital electronic pharmacy record system during the study period (i.e. 1 January 2017 to 31 December 2018), suggesting that atorvastatin 40mg is more commonly prescribed than atorvastatin 80mg at our facility. Upon screening the potentially eligible patients above, 626 fulfilled the study's eligibility criteria and classified into two: 475 (75.9%) in the atorvastatin 40mg group and 151 (24.1%) in the atorvastatin 80mg group.

Baseline Characteristics

The baseline characteristics comparisons between the atorvastatin 40mg group (n=475) and the atorvastatin 80mg group (n=151) are presented in**Table 1** . About 97% of the patients included in the analyses were male with a mean age of 50 +- 9 years. Most of the patients originate from Asia (72.7%) and the Middle East (24.3%) (**Table 1**). In addition, diabetes, hypertension, history of smoking, and family history of CAD were highly prevalent in the studied population with the following proportions: 47.3%, 40.6%, 46.8%, and 15.5%, respectively. These characteristics were balanced between the two study groups. However, history of a previous CAD was significantly more prevalent in the atorvastatin 40mg group compared to the 80mg group (13.5% vs. 6%; P = 0.012).

The mean LDL-C level in the atorvastatin 80mg group was 130 +- 44.7 mg/dL compared to 110 +- 41.9 mg/dL in the atorvastatin 40mg group (P<0.001), while the baseline levels of liver enzymes were significantly lower in the atorvastatin 80mg group (**Table 1**).

Sixty percent of the patients were admitted with the diagnosis of STEMI, while 33.5% had NSTEMI. Around 80% of the patients underwent PCI with the proximal left anterior descending artery (LAD) as the most common identified culprit lesion (36.3%). The atorvastatin 80mg group had a higher prevalence of STEMI events compared to the atorvastatin 40mg group (76.8% vs. 54.9%; P<0.001). Similarly, more patients in the atorvastatin 80mg group underwent PCI compared to the 40mg group (87.4% vs. 75.4%; P=0.002). The implantation of drug-eluting stents (DES) was more frequent in the atorvastatin 80mg arm compared to the 40mg arm (74.2% vs. 62.9%; P=0.035).

The use of other medications for ACS was similar in both groups, as shown in **Table 2** . Almost 100% of the patients in both groups were prescribed aspirin and $P2Y_{12}$ inhibitors, while 71.4% of the patients in the atorvastatin 40mg group compared to 66.9% of those in the atorvastatin 80mg group were prescribed an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB), and more than 90% of the patients in both groups received a beta-blocker.

Effectiveness Outcomes

There was no statistically significant difference between the atorvastatin 40mg and 80mg groups in the primary composite outcome of CVD-associated death, non-fatal ACS and non-fatal stroke at 1 month (0.8% vs. 1.3%, HR= 0.60, 95% CI 0.10-3.30; P=0.551). After adjusting for variables that are associated with ACS, including gender, age, geographical region of origin, smoking status, family history of CVD, hypertension, diabetes, CKD, PAD, CAD, index event of STEMI, index event of NSTEMI, index event of UA, primary PCI, number of deployed stents, type of stent, baseline LDL-C value, and concomitant medications for ACS, the primary composite outcome did not differ between the two groups (aHR= 0.59, 95% CI 0.04-8.13; P= 0.690). Similarly, within 1 year of discharge, the primary composite outcome did not significantly differ between the atorvastatin 40mg and 80mg groups (3.2% vs. 4.0%, HR= 0.58, 95% CI 0.22-1.50; P=0.243, aHR= 0.57, 95% CI 0.18-1.80; P=0.340) as shown in **Table 3** .

Likewise, as shown in **Table 4** , there was no difference in the secondary outcomes of all-cause mortality, cardiovascular mortality, fatal or non-fatal stroke, fatal or non-fatal ACS, coronary revascularization, stent thrombosis, and stent restenosis at 1 month and at 12 months post-discharge. Although atorvastatin 40mg

and 80mg appeared similar in reducing LDL-C to less than 70 mg/dL (24% vs. 22.5%), atorvastatin 80mg compared to the 40mg significantly reduced the LDL-C by more than 50% from baseline (21.2% vs. 15.2%; P=0.022). However, we were able to obtain the LDL-C levels after discharge for around 40% of the patients in both groups.

Safety Outcomes

The frequency of adverse events related to the statin therapy was very low in both groups, with myopathy occurring in around 0.8% and increased ALT > three ULN in around 0.7% in both groups as presented in **Table 4** . Only three patients (0.3%) in the atorvastatin 40mg group and no patient in the 80mg group discontinued the statin therapy secondary to adverse events.

Predictors of Prescribing Atorvastatin 80mg in ACS

As shown in **Table 5** , the likelihood of physicians prescribing atorvastatin 80mg increased by around four folds in patients diagnosed with STEMI (aOR= 3.8, 95% CI 2.2-6.5; P<0.001). The increase in tendency to prescribe atorvastatin 80mg was also observed in ACS patients who underwent PCI (aOR of 2.8, 95% CI 1.5-5.2; P=0.001). Similarly, the use of BMS was associated with around 2-fold increase in atorvastatin 80mg prescription (aOR= 2.2, 95% CI 1.1-4.3; P=0.024).

Discussion

In this retrospective observational cohort study, we found that the use of two high-intensity doses of atorvastatin (40mg vs. 80mg) post-ACS was associated with similar cardiovascular outcomes, including CVD-related death, non-fatal ACS, and non-fatal stroke at 1 month and 12 months post-discharge. In addition, the two high-intensity doses of atorvastatin resulted in similar safety outcomes. Since a high-intensity statin therapy, such as atorvastatin 40mg or 80mg, is recommended by clinical practice guidelines for secondary prevention post atherosclerotic CVD based on landmark trials that mainly evaluated the efficacy and safety of atorvastatin 80mg,[1,2] it was hypothesized that atorvastatin 40mg would result in comparable CV benefit post-ACS when compared to the atorvastatin 80mg.

The cardiovascular benefit of high-intensity statin therapy was demonstrated in a meta-analysis of five randomized controlled trials evaluating more vs. less intensive statin therapy among a total of 39,612 individuals.[13] The meta-analysis showed a significant reduction in the major adverse vascular events of 15% (95% CI 11–18; p <0.0001), non-fatal myocardial infarction (MI) of 13% (95% CI 7–19; p <0.0001), coronary revascularization of 19% (95% CI 15–24; p <0.0001), and ischemic stroke of 16% (95% CI 5–26; p=0.005) with the use of high-intensity statin. The benefit of atorvastatin 80mg post-ACS specifically was well established in the PROVE-IT and IDEAL trials.[8,14] In the PROVE-IT trial, the use of atorvastatin 80mg compared to pravastatin 40mg over 2 years had resulted in a significant reduction in a composite endpoint of all-cause mortality, MI, UA requiring hospitalization, revascularization, and stroke (22.4% vs. 26.3, 95% CI 5-26; p=0.005).[8] In the IDEAL trial, atorvastatin 80mg compared to simvastatin 20mg reduced non-fatal MI significantly (6% vs. 7.2%, HR = 0.83; 95% CI, 0.71-0.98; p=0.02) over a follow-up period of 4.8 years among patients with previous history of MI.[14] Compared to the PROVE-IT and IDEAL trials, the present study reported a lower event rate of the CV outcomes, which might be explained by the shorter follow-up period of 12 months. Nevertheless, the current study demonstrated a novel and reassuring observation, that atorvastatin 40mg has similar CV benefits post-ACS in comparison to atorvastatin 80mg.

According to the 2018 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for dyslipidemia for secondary prevention of cardiovascular events among patients who have atherosclerotic CVD, a high-intensity statin is defined as a statin therapy that lowers LDL-C by [?]50%.[2] In the current study, atorvastatin 80mg was significantly better in lowering LDL-C by [?]50% compared to atorvastatin 40mg which is consistent with the CURE-ACS trial that mainly aimed at evaluating the LDL-C lowering effects of atorvastatin 40mg versus 80mg and showed a greater reduction of LDL-C in the atorvastatin 80mg group compared to the 40mg group (27.5% vs 19.04%).[11] Despite that the baseline LDL-C was significantly higher in the atorvastatin 80mg group (130 +- 44.7 vs. 110 +- 41.9 mg/dL ; p <0.001),

both doses were able to reduce LDL-C to less than 70mg/dL, which is the target LDL-C for patients with very high risk of atherosclerotic CVD as per the 2018 ACC/AHA guidelines for dyslipidemia.[2] However, the follow-up data of LDL-C was only available for 40% of the study patients, which might be explained by the fact that 2013 ACC/AHA guidelines for dyslipidemia for secondary prevention of cardiovascular events recommended using a high-intensity statin post-ACS regardless of LDL-C.[1]Therefore, this finding should be interpreted in the light of this limitation.

In addition to similar effectiveness between the two high-intensity doses of atorvastatin, this study demonstrated similar safety outcomes, including liver toxicity, myopathy, and rhabdomyolysis, with a very low event rate of $< 1\%$, which is consistent with high-intensity statin landmark trials.[8,10,14]

In the present study, we further investigated the predictors of prescribing atorvastatin 80mg compared to 40mg as the rate of prescribing 80mg at our facility is low, which resulted in unbalanced study groups in terms of the number of the study participants. Upon conducting the screening of patients who were prescribed high-intensity atorvastatin doses at our facility during the study period, we found that atorvastatin 80mg to 40mg prescribing ratio was 1:19. The factors that were significantly associated with prescribing atorvastatin 80mg were STEMI as an index event, PCI as the method of treatment of the index event, and BMS implantation. These findings demonstrate the prescribing pattern of atorvastatin high-intensity doses at our facility, but do not present causality.

This study was a retrospective observational cohort study using real-world data that is susceptible to potential limitations. First, data were collected from electronic medical records retrospectively with the expectation of missing some important clinical information. Second, the effectiveness outcomes were adjusted for clinically significant patient and disease variables; however, there is a potential for other measured or unmeasured variables to influence the results. Third, the number of atorvastatin 40mg and 80mg users was relatively small, and the groups had an unequal number of participants due to the prescribing pattern of atorvastatin high-intensity doses at our facility, which might have affected the robustness of the analyses. Nevertheless, this retrospective observational cohort study aimed to answer a clinically important question that is faced by cardiologists in daily practice, and it could serve as a preliminary indicator for future prospective studies to assess the impact of atorvastatin 40mg post-ACS on cardiovascular outcomes.

In conclusion, the use of atorvastatin 40mg in comparison to atorvastatin 80mg after ACS had resulted in comparable effectiveness and safety outcomes over a follow-up period of 1 year. Therefore, following ACS, clinicians may use either high-intensity atorvastatin dose. However, larger studies with a longer follow-up period are warranted to confirm the findings of the present study.

Conflict of interest

The authors declare that they have no conflict of interest.

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Data availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)
Characteristic	**All Patients (N=626) n (%)**	**All Patients (N=626) n (%)**	**Atorvastatin 40mg Users (N=475) n (%)**	**Atorvastatin 40mg Users (N=475) n (%)**	**Atorvastatin 80mg Users (N=151) n (%)**	**P-value**
Male gender	606 (96.8)	606 (96.8)	457 (96.2)	457 (96.2)	149 (98.7)	0.185*
Age[a]	50 ± 9.14	50 ± 9.14	50 ± 8.9	50 ± 8.9	48 ± 9.7	0.020
Weight[a]	77 ± 14.52	77 ± 14.52	77 ± 14.6	77 ± 14.6	77 ± 14.2	0.824
Region of origin						0.015*
Asia	455 (72.7)	455 (72.7)	358 (75.4)	358 (75.4)	97 (64.2)	
Middle East	152 (24.3)	152 (24.3)	104 (21.9)	104 (21.9)	48 (31.8)	
Africa	13 (2.1)	13 (2.1)	10 (2.1)	10 (2.1)	3 (2.0)	
Europe	2 (0.3)	2 (0.3)	2 (0.4)	2 (0.4)	0	
North America	3 (0.5)	3 (0.5)	1 (0.2)	1 (0.2)	2 (1.3)	
South America	1 (0.2)	1 (0.2)	0	0	1 (0.7)	
Smoking	293 (46.8)	293 (46.8)	214 (45.1)	214 (45.1)	79 (52.3)	0.376
Alcohol	46 (7.3)	46 (7.3)	27 (5.7)	27 (5.7)	19 (12.6)	0.005
Family history of CAD	97 (15.5)	97 (15.5)	67 (14.1)	67 (14.1)	30 (19.9)	0.091
Ejection fraction						1.0*
< 40%	102 (16.3)	102 (16.3)	77 (16.2)	77 (16.2)	25 (16.6)	
> 40%	522 (83.4)	522 (83.4)	396 (83.4)	396 (83.4)	126 (83.4)	
LDL-C (mg/dL) [a]	115 ± 43.4	115 ± 43.4	110 ± 41.9	110 ± 41.9	130 ± 44.7	<0.001
TC (mg/dL) [a]	185 ± 46.6	185 ± 46.6	181 ± 45.4	181 ± 45.4	196 ± 48.6	0.001
HDL (mg/dL) [a]	35 ± 9.9	35 ± 9.9	34 ± 9.9	34 ± 9.9	37 ± 9.7	0.010
HbA1c (%)[a]	7.2 ± 2.1	7.2 ± 2.1	7.2 ± 2.1	7.2 ± 2.1	7.3 ± 2.2	0.624
ALT[a]	33 ± 21.6	33 ± 21.6	34 ± 23.6	34 ± 23.6	30 ± 13.3	0.043
AST[a]	40 ± 42.3	40 ± 42.3	43 ± 47.4	43 ± 47.4	30 ± 14.9	0.001

Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**
Hypertension	**Hypertension**	254 (40.6)	198 (41.7)	56 (37.1)	56 (37.1)	0.316
Dyslipidemia	**Dyslipidemia**	78 (12.5)	61 (12.8)	17 (11.3)	17 (11.3)	0.830*
Diabetes mellitus	**Diabetes mellitus**	296 (47.3)	228 (48.0)	68 (45.0)	68 (45.0)	0.525
Chronic kidney disease	**Chronic kidney disease**	15 (2.4)	12 (2.5)	3 (2.0)	3 (2.0)	1.0*
Hyperthyroidism	**Hyperthyroidism**	1 (0.2)	1 (0.2)	0	0	1.0*
Hypothyroidism	**Hypothyroidism**	10 (1.6)	8 (1.7)	2 (1.3)	2 (1.3)	1.0*
Peripheral artery disease	**Peripheral artery disease**	2 (0.3)	2 (0.4)	0	0	1.0*
Coronary artery disease	**Coronary artery disease**	73 (11.7)	64 (13.5)	9 (6.0)	9 (6.0)	0.012
Index event	**Index event**					
STEMI	STEMI	377 (60.2)	261 (54.9)	116 (76.8)	116 (76.8)	<0.001
NSTEMI	NSTEMI	210 (33.5)	180 (37.9)	30 (19.9)	30 (19.9)	<0.001
Unstable Angina	Unstable Angina	35 (5.6)	30 (6.3)	5 (3.3)	5 (3.3)	0.162
PCI	**PCI**	490 (78.3)	358 (75.4)	132 (87.4)	132 (87.4)	0.002
Primary PCI	**Primary PCI**	252 (40.3)	186 (39.2)	66 (43.7)	66 (43.7)	0.501*
CABG	**CABG**	17 (2.7)	17 (3.6)	0	0	0.023*
Drug eluting stent	**Drug eluting stent**	411 (65.7)	299 (62.9)	112 (74.2)	112 (74.2)	0.035*
Bare metal stent	**Bare metal stent**	83 (13.3)	68 (14.3)	15 (9.9)	15 (9.9)	0.292*
Coronary angiography access	**Coronary angiography access**					0.347

Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)
Transradial	Transradial	540 (86.3)	413 (86.9)	127 (84.1)	127 (84.1)	
Transfemoral	Transfemoral	75 (12)	54 (11.4)	21 (13.9)	21 (13.9)	
Most common culprit lesions	**Most common culprit lesions**					
Proximal LAD	Proximal LAD	227 (36.3)	179 (37.7)	48 (31.8)	48 (31.8)	0.142
Middle LAD	Middle LAD	188 (30)	131 (27.6)	57 (37.7)	57 (37.7)	0.039
Proximal LCx	Proximal LCx	98 (15.7)	80 (16.8)	18 (11.9)	18 (11.9)	0.134
Number of stents	**Number of stents**					0.108
0	0	150 (24.0)	124 (26.1)	26 (17.2)	26 (17.2)	
1	1	328 (52.4)	248 (52.2)	80 (53.0)	80 (53.0)	
2	2	121 (19.3)	83 (17.5)	38 (25.2)	38 (25.2)	
3	3	21 (3.3)	16 (3.4)	5 (3.3)	5 (3.3)	
4	4	6 (1.0)	4 (0.8)	2 (1.3)	2 (1.3)	

Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**
[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary	[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary	[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary	[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary	[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary	[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary	[a]Values are expressed as mean ± SD; *P-value was calculated using Fisher's Exact test; **CAD:** coronary artery disease; **LDL:** low-density lipoproteins, **TC:** total cholesterol; **HDL:** high-density lipoproteins; **HbA1c:** glycated hemoglobin; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **STEMI:** ST-elevation myocardial infarction; **NSTEMI:** non-ST segment elevation myocardial infarction; **PCI:** percutaneous coronary

Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**	**Table 1: Baseline characteristics of acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N= 626)**

Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**
Medication Class	**All Patients (N=626) n (%)**	**Atorvastatin 40mg Users (N= 475) n (%)**	**Atorvastatin 40mg Users (N= 475) n (%)**	**Atorvastatin 80mg Users (N=151) n (%)**	**P-value**
Aspirin	626 (100.0)	475 (100.0)	475 (100.0)	151 (100.0)	–
$P2Y_{12}$ inhibitor	623 (99.5)	472 (99.4)	472 (99.4)	151 (100.0)	1.0*
List of $P2Y_{12}$ inhibitors					0.011*
Clopidogrel	565 (90.3)	437 (92.0)	437 (92.0)	128 (84.8)	
Ticagrelor	58 (9.3)	35 (7.4)	35 (7.4)	23 (15.2)	
ACE inhibitor or ARB	440 (70.3)	339 (71.4)	339 (71.4)	101 (66.9)	0.294
List of ACE inhibitors					0.916*

Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**	**Table 2: Concurrent medications prescribed among the acute coronary syndrome patients receiving two different high-intensity atorvastatin doses (N=626)**
Lisinopril	240 (38.3)	185 (38.9)	185 (38.9)	55 (36.4)	
Enalapril	12 (1.9)	9 (1.9)	9 (1.9)	3 (2.0)	
Ramipril	117 (18.7)	91 (19.2)	91 (19.2)	26 (17.2)	
Perindopril	37 (5.9)	27 (5.7)	27 (5.7)	10 (6.6)	
Fosinopril	1 (0.2)	1 (0.2)	1 (0.2)	0	
List of ARBs					0.435*
Valsartan	33 (5.3)	27 (5.7)	27 (5.7)	6 (4.0)	
Losartan	5 (0.8)	5 (1.1)	5 (1.1)	0	
Irbesartan	4 (0.6)	2 (0.4)	2 (0.4)	2 (1.3)	
Candesartan	1 (0.2)	1 (0.2)	1 (0.2)	0	
Beta-blocker	577 (92.2)	433 (91.2)	433 (91.2)	144 (95.4)	0.094
List of beta-blockers					0.660*
Bisoprolol	317 (50.6)	237 (49.9)	237 (49.9)	80 (53.0)	
Metoprolol	256 (40.9)	193 (40.6)	193 (40.6)	63 (41.7)	
Carvedilol	7 (1.1)	6 (1.3)	6 (1.3)	1 (0.7)	
Atenolol	1 (0.2)	1 (0.2)	1 (0.2)	0	
Ivabradine	11 (1.8)	7 (1.5)	7 (1.5)	4 (2.6)	0.504*
Nitrate	195 (31.2)	156 (32.8)	156 (32.8)	39 (25.8)	0.206*
*P-value was calculated using Fisher's Exact test; ACE: angiotensin converting enzyme; ARB: angiotensin II receptor blocker	*P-value was calculated using Fisher's Exact test; ACE: angiotensin converting enzyme; ARB: angiotensin II receptor blocker	*P-value was calculated using Fisher's Exact test; ACE: angiotensin converting enzyme; ARB: angiotensin II receptor blocker	*P-value was calculated using Fisher's Exact test; ACE: angiotensin converting enzyme; ARB: angiotensin II receptor blocker	*P-value was calculated using Fisher's Exact test; ACE: angiotensin converting enzyme; ARB: angiotensin II receptor blocker	*P-value was calculated using Fisher's Exact test; ACE: angiotensin converting enzyme; ARB: angiotensin II receptor blocker

Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)	**Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 3: Primary outcomes of two different high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**
Outcome	**Atorvastatin 40mg Users (N= 475) n (%)**	**Atorvastatin 80mg Users (N= 151) n (%)**	**Hazard Ratio 95% CI**	**P-value**	**Adjusted Hazard Ratio 95% CI**	**P-value**
Primary endpoint at 1 month CVD-associated death, non-fatal ACS, and non-fatal stroke	4 (0.8)	2 (1.3)	0.60 (0.10-3.30)	0.551	0.59 (0.04-8.13)	0.690
Primary endpoint at 12 months CVD-associated death, non-fatal ACS, and non-fatal stroke	15 (3.2)	6 (4.0)	0.58 (0.22-1.50)	0.243	0.57 (0.18-1.80)	0.340
CVD: cardiovascular disease; **ACS:** acute coronary syndrome	**CVD:** cardiovascular disease; **ACS:** acute coronary syndrome	**CVD:** cardiovascular disease; **ACS:** acute coronary syndrome	**CVD:** cardiovascular disease; **ACS:** acute coronary syndrome	**CVD:** cardiovascular disease; **ACS:** acute coronary syndrome	**CVD:** cardiovascular disease; **ACS:** acute coronary syndrome	**CVD:** cardiovascular disease; **ACS:** acute coronary syndrome

Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**
Outcome	**Atorvastatin 40mg Users (N= 475) n (%)**	**Atorvastatin 80mg Users (N= 151) n (%)**	**Adjusted Hazard Ratio 95% CI**	**P-value**
Secondary effectiveness endpoints at 1 month				
All-cause mortality	0	2 (1.3)	1 (0.03-35.2)	1.0
Cardiovascular mortality	0	2 (1.3)	1 (0.03-35.2)	1.0
Fatal or non-fatal stroke	0	0		
Fatal or non-fatal ACS	5 (1.1)	0	1 (0.10-9.60)	1.0
Coronary revascularization	2 (0.4)	0	1 (0.03-37.45)	1.0
Stent thrombosis	0	0		
Stent restenosis	0	0		
Secondary effectiveness endpoints at 12 months				
All-cause mortality	1 (0.2)	1 (0.7)	1 (0.02-41.29)	1.0
Cardiovascular mortality	1 (0.2)	1 (0.7)	1 (0.02-41.29)	1.0
Fatal or non-fatal stroke	4 (0.8)	0	–	0.577*
Fatal or non-fatal ACS	11 (2.3)	4 (2.6)	0.79 (0.18-3.41)	0.749
Coronary revascularization	5 (1.1)	3 (2.0)	0.62 (0.09-4.31)	0.632
Stent thrombosis	0	0		
Stent restenosis	2 (0.4)	1 (0.7)	1 (0.02-66.3)	1.0
Lipid lowering outcomes				
LDL-C < 70mg/dL[a]	114 (24.0)	34 (22.5)	–	0.812**
Reduction of LDL-C by 50%[a]	72 (15.2)	32 (21.2)	–	0.022**
Safety outcomes				

Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**	**Table 4: Secondary Outcomes of two high-intensity atorvastatin doses in patients with acute coronary syndrome (N= 626)**
Myopathy	4 (0.8)	1 (0.7)	–	1.0*
ALT > 3 ULN	4 (0.8)	1 (0.7)	–	1.0*
AST > 3 ULN	3 (0.6)	0	–	1.0*
Rhabdomyolysis	0	0		
Adverse drug event requiring statin discontinuation	3 (0.3)	0	–	1.0*
*P-value was obtained using Fisher's Exact test; **P-value was obtained using Chi-square test; [a]Missing data for ˜60% of study participants in both arms; **ACS:** acute coronary syndrome; **LDL-C:** low-density lipoproteins cholesterol; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase	*P-value was obtained using Fisher's Exact test; **P-value was obtained using Chi-square test; [a]Missing data for ˜60% of study participants in both arms; **ACS:** acute coronary syndrome; **LDL-C:** low-density lipoproteins cholesterol; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase	*P-value was obtained using Fisher's Exact test; **P-value was obtained using Chi-square test; [a]Missing data for ˜60% of study participants in both arms; **ACS:** acute coronary syndrome; **LDL-C:** low-density lipoproteins cholesterol; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase	*P-value was obtained using Fisher's Exact test; **P-value was obtained using Chi-square test; [a]Missing data for ˜60% of study participants in both arms; **ACS:** acute coronary syndrome; **LDL-C:** low-density lipoproteins cholesterol; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase	*P-value was obtained using Fisher's Exact test; **P-value was obtained using Chi-square test; [a]Missing data for ˜60% of study participants in both arms; **ACS:** acute coronary syndrome; **LDL-C:** low-density lipoproteins cholesterol; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase

Table 5: Predictors of atorvastatin 80mg use	**Table 5: Predictors of atorvastatin 80mg use**	**Table 5: Predictors of atorvastatin 80mg use**
Characteristic	**Adjusted Odds Ratio 95% CI**	**P-value**
STEMI	3.8 (2.2-6.5)	<0.001
PCI	2.8 (1.5-5.2)	0.001
Bare metal stent	2.2 (1.1-4.3)	0.024

Table 5: Predictors of atorvastatin 80mg use	**Table 5: Predictors of atorvastatin 80mg use**	**Table 5: Predictors of atorvastatin 80mg use**
STEMI: ST-elevation myocardial infarction; **PCI:** percutaneous coronary intervention	**STEMI:** ST-elevation myocardial infarction; **PCI:** percutaneous coronary intervention	**STEMI:** ST-elevation myocardial infarction; **PCI:** percutaneous coronary intervention