



Comparison of High Intensity Statin Therapy Tolerance in Patients with Newly Diagnosed Coronary Artery Diseases

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Vol 4, No 3. Pp. 241-251.

Submission: 11 January 2025 | Acceptance: 15 June 2025 | Publication: 30 July 2025

Abstract

Objectives: To determine and compare frequency of high-intensity statin therapy and moderate-intensity statin therapy in newly diagnosed coronary artery disease patients in a real-world clinical setting. **Study design: longitudinal Study: Place and duration of study:** Department of Cardiology, DALIAN Medical University china from 1st March 2024 to August 2024. **Methods:** A total of 1200 newly diagnosed CAD patients aged ≥ 18 years were included through consecutive sampling. Patients were allocated to group MIS (those who were recommended moderate intensity statin therapy) or group HIS (those who were recommended high intensity statin) based on clinical judgment of the treating cardiologists, in accordance with the institutional guidelines. Follow-up was arranged at 1, 3, and 6 months to find the adherence of patients to the statin treatment, dose adjustments, discontinuation, and adverse effects. Primary outcome was set as the tolerance to the prescribed statin therapy defined as continuation without dose reduction or discontinuation within the study period. **Results:** Mean age in this study was 51.69 ± 9.36 years with higher number of males (54.42%) compared to females 547 (45.58%). The results of primary outcomes showed significantly better tolerance in Group MIS compared to Group HIS (93.3% vs 87.0%, RR 1.07, 95% CI 1.03-1.11, $p < 0.001$) with lower rates of dose reduction and discontinuation in the MIS group (5% vs 8.5%, RR 0.59, 95% CI 0.38-0.91, $p = 0.02$) and (1.7% vs 4.5%, RR 0.37, 95% CI 0.18-0.76, $p = 0.01$), respectively. **Conclusion:** MIS therapy offers significantly better tolerance compared to the HIS therapy in newly diagnosed CAD patients, with lower rates of dose modification and discontinuation. **Keywords:** Coronary artery disease, Dyslipidemia, High intensity statin therapy, Moderate intensity statin therapy, Statin intolerance.



Introduction:

Preventive Coronary artery disease (CAD) has consistently ranked as a leading cause of death for decades, accounting for almost one-third of global mortality in adults over 35 years. The approximate annual number is 17.8 million deaths which creates a significant health and economic burden, underscoring a need for effective measures and management plans.^{1,2} Both primary and secondary prevention strategies have been proposed to reduce the cardiovascular (CV) risk and address this major public health challenge. The management paradigm for CAD includes lipid lowering therapy as a fundamental part of all these preventive measures.^{2,3}

Statins, also known as HMG-CoA reductase inhibitors, are now established as the first-line intervention for managing dyslipidemia. Both the European and American guidelines recommend statins to lower the low-density lipoprotein (LDL) cholesterol, which is a primary therapeutic target in CV prevention. In addition to this principal effect, statins are also reported to reduce vascular inflammation and restore endothelial functions by minimizing the oxidative stress thereby stabilizing the atherosclerotic lesions.^{4,5}

The above mentioned guidelines also recommend the High Intensity Statin (HIS) therapy, comprising of atorvastatin 40–80 mg or rosuvastatin 20–40 mg, for secondary prevention in established CAD patients. This HIS therapy is defined by its capacity to effectively lower LDL cholesterol by $\geq 50\%$. This is in comparison to the Moderate-intensity statin (MIS) therapy, including atorvastatin 10–20 mg or rosuvastatin 5–10 mg, which typically reduces LDL-C by 30-50%. The superiority of HIS over MIS is also supported by number of clinical evidence from randomized controlled trials (RCTs) which demonstrate that HIS provides significant improved CV outcomes in CAD patients compared to MIS.^{6,7}

Despite these recommendations by international guideline, implementation of HIS therapy in real-world practice remains challenging, where patient's tolerability and adherence to treatment are the primary concerns. This poor tolerability is related to some potential side effects reported with HIS therapy which includes musculoskeletal complaints like myalgia and myopathy. While the data shared by research trials show a 5-10% rate of statin-associated muscle symptoms (SAMS), some observational studies report substantially higher incidences from 15-29% in real world clinical practice which ultimately compromises the CV protection that might be expected by adhering to the HIS therapy. Moreover, hepatotoxicity and, less commonly, glucose metabolism disturbances and neurological symptoms also lead to reduce the statin dose, intermittent dosing, or even a cession of the treatment.^{8,9} These observational data suggest that patients prescribed HIS discontinue or downgrade therapy within six months at a notably higher rate than those on MIS. Consequently, a combination of MIS with ezetimibe is being explored as an alternative to HIS.¹⁰



The data on comparative tolerance rates between HIS and MIS remain inconsistently reported, particularly in South Asian populations. Moreover, statin metabolism may be affected by genetic, dietary, and pharmacogenomics differences and create differences in the tolerability of statins in our population.

This longitudinal study therefore planned to compare the tolerance of HIS and MIS therapies in patients newly diagnosed with CAD over a 6-month follow-up. These findings provide a real-world clinical practice scenario and will help our clinicians to offer evidence-based management of dyslipidemia in these patients.

Methodology:

This prospective longitudinal study was conducted in the Department of DALIAN Medical University china Cardiology, from 1st march 2024 August 2024 over period of 6 months after getting prior approval from ethical committee of the hospital with ref. number 9/2/R& D/2024/25

WHO calculator was used to calculate the sample size, with a two-sided significance level (α) =5%, power =80% and anticipated proportions of discontinuation/dose reduction in the MIS group of 4.5% while 8.6% in the HIS group.¹¹ The calculated sample size was (n) = 1,142 with 571 patients in each group. However, to account for potential dropouts, a total of 1200 patients (600 in each group) were enrolled in this study.

A total of 1200 newly diagnosed CAD patients (confirmed within 30 days) aged ≥ 18 years reporting at the outpatient department were included through consecutive sampling. Patients were allocated to group MIS or HIS as per the recommended dose of statin, based on clinical judgment of the treating cardiologists, in accordance with the institutional guidelines.

Presence of CAD was confirmed by one or more of the criteria including, coronary angiographic evidence of significant CAD ($\geq 50\%$ stenosis in a major epicardial artery), myocardial infarction (MI) diagnosed on the basis of elevated cardiac enzymes (and corresponding ECG changes), or a +ve stress test with imaging, confirming myocardial ischemia.

Patients with prior use of statins, significant renal impairment (defined as an eGFR of less than 30 mL/min/1.73 m²) or baseline creatine kinase exceeding five times the upper limit of normal levels were excluded. Those with active hepatic disease or liver enzyme levels $>3\times$ the normal upper threshold (for both alanine aminotransferase and aspartate aminotransferase) were also excluded. Moreover, patients with a history of intolerance to the study drugs, myopathy, rhabdomyolysis, untreated hypothyroidism, concurrent use of strong CYP3A4 inhibitors or excessive alcohol intake (>14 units per week) were also not eligible for inclusion.

An informed written consent was taken from eligible participants before their inclusion in this study.

All the baseline demographics, comorbid conditions, and laboratory investigations (such as lipid profile, liver function tests, CK levels, and renal functions) were recorded at the time of enrollment.



In Group MIS, patients received atorvastatin 10–20 mg, rosuvastatin 5–10 mg, or simvastatin 20–40 mg daily, while in Group HIS they received atorvastatin 40–80 mg or rosuvastatin 20–40 mg daily. Participants were asked for the follow-up at 1, 3, and 6 months of initiating their statin therapy. The data was collected regarding adherence to treatment, any dose adjustment, discontinuation, and any adverse effects reported during that period.

The primary outcome was set as tolerance of statin therapy, defined as continuation of the prescribed statin regimen without any discontinuation or dose reduction within the study period of six months. The secondary outcomes were the incidence of adverse effects such as SAMS (recorded as any new or worsened muscle pain, aching, stiffness, tenderness, or weakness temporally related to statin therapy), elevations in liver function tests or rise in CK levels.

Data were entered and analyzed using SPSS version 26. Descriptive statistics were employed to present the baseline characteristics where quantitative variables were shown as mean $\pm$ standard deviation (SD) (or median and interquartile range), depending on the normality of data (assessed using the Shapiro–Wilk test). All continuous variables demonstrated normal distribution and were therefore presented as mean $\pm$ SD. Categorical variables were presented as frequencies and percentages were used to share the categorical variables. For comparing the categorical variables chi-square test or Fisher's exact test was used, while independent sample t-test or Mann–Whitney U test were applied for continuous variables taking a p-value ≤ 0.05 as statistically significant.

Results:

The mean age of patients was 51.69 ± 9.36 years which ranged from 32–71 years. The number of male patients was higher 653 (54.42%) compared to females 547 (45.58%) in overall study population. The group wise details of demographics, base line clinical characteristics and laboratory parameters are shown in Table-I.

Table-I: Demographics, base line clinical characteristics and laboratory parameters

n=1200

Demographics, base line clinical characteristics and laboratory parameters		Group MIS (n= 600)	Group HIS (n=600)
Age (Mean $\pm$ SD) years		51.38 $\pm$ 9.46	52.01 $\pm$ 9.26
Gender	Male n (%)	332 (55.33)	321 (53.5)
	Female n (%)	268 (44.67)	279 (46.5)
BMI (Mean $\pm$ SD) Kg/m ²		29.16 $\pm$ 4.03	28.8 $\pm$ 4.17
Hypertension n (%)		323 (53.83)	336 (56)
Diabetes n (%)		267 (44.5)	253 (42.17)



Smoking n (%)	117 (19.5)	141 (23.5)
Total cholesterol (Mean± SD) mg/dL	229.9 ± 31.2	232.58±30.05
LDL Cholesterol (Mean± SD) mg/dL	154.8 ± 27.3	158.5 ± 26.4
HDL Cholesterol (Mean± SD) mg/dL	42.8 ± 7.7	43.51±7.18
Triglycerides (Mean± SD) mg/dL	247.2 ± 73.9	248.9 ± 71.2
ALT (Mean± SD) U/L	38.08 ± 16.78	38.97 ± 16.74
CK (Mean± SD) U/L	167.14 ± 85.12	168.21 ± 80.75
eGFR (Mean± SD) mL/min/1.73m ²	71.11 ± 19.78	72.61 ± 19.95

Details of statins prescribed in each group show that rosuvastatin 10 mg was the most prescribed statin in Group MIS (32%) while rosuvastatin 40 mg was the most prescribed statin in Group HIS (34.67%). The details of statin prescribed to the study participants are shown in Table-II.

Table-II: Group wise details of lipid lowering drugs prescribed

n=1200

Details of lipid lowering drugs prescribed		
Group MIS (n= 600)	Rosuvastatin 5 mg n (%)	84 (14)
	Rosuvastatin 10 mg n (%)	192 (32)
	Atorvastatin 10 mg n (%)	108 (18)
	Atorvastatin 20 mg n (%)	144 (24)
	Simvastatin 20 mg n (%)	65 (10.83)
	Simvastatin 40 mg n (%)	7 (1.17)
	Ezetimibe 10 mg n (%)	262 (43.67)
Group HIS (n=600)	Rosuvastatin 20 mg n (%)	178 (29.67)
	Rosuvastatin 40 mg n (%)	208 (34.67)
	Atorvastatin 40 mg n (%)	180 (30)
	Atorvastatin 80 mg n (%)	34 (5.67)

Results of primary outcomes of the study showed that statin tolerance (continued without modification) at six months were significantly higher in the MIS group compared to the HIS group (93.3% vs 87.0%, RR 1.07, 95% CI 1.03-1.11, $p < 0.001$). For those who were intolerant to the statins, dose reduction and discontinuation of therapy



was required in significantly lesser number of patients in MIS group compared to the HIS group (5% vs 8.5%, RR 0.59, 95% CI 0.38-0.91, $p=0.02$) and (1.7% vs 4.5%, RR 0.37, 95% CI 0.18-0.76, $p=0.01$) respectively, as shown in Table-III.

Table-III: Primary outcomes- tolerance to statin therapy

n=1200

Outcomes	Group MIS (n= 600)	Group HIS (n=600)	p-value	Relative Risk (95% CI)
Overall tolerance				
Tolerant n (%)	560 (93.3)	522 (87)	< 0.001	1.07 (1.03-1.11)
Intolerant n (%)	40 (6.66)	78 (13)		
Type of Intolerance				
Dose reduction n (%)	30 (5)	51 (8.5)	0.02	0.59 (0.38-0.91)
Discontinuation n (%)	10 (1.7)	27 (4.5)	0.01	0.37 (0.18-0.76)

Incidence of SAMS occurred in significantly lesser patients in MIS group compared to HIS group (6% vs 11.33%, RR 0.53, 95% CI 0.36-0.78, $p<0.01$). Number of patients with elevated liver enzymes ($>3\times$ ULN) and elevated CK levels ($>5\times$ ULN) were numerically lower in MIS group but did not reach statistical significance, (1.5% vs 3%, RR 0.50, 95% CI 0.23-1.1, $p=0.09$) and (0.7% vs 1.7%, RR 0.40, 95% CI 0.13-1.27, $p=0.12$) respectively, as shown in Table-IV.

Table-IV: Secondary outcomes-adverse events

n = 1200

Adverse events	Group MIS (n= 600)	Group HIS (n=600)	p-value	Relative Risk (95% CI)
SAMS (myalgia or muscle symptoms) n (%)	36 (6)	68 (11.33)	< 0.01	0.53 (0.36-0.78)
Elevated liver enzymes ($>3\times$ ULN), n (%)	9 (1.5)	18 (3)	0.09	0.50 (0.23-1.1)
Elevated CK ($>5\times$ ULN), n (%)	4 (0.7)	10 (1.7)	0.12	0.40 (0.13-1.27)

Discussion:

The results of primary outcomes showed significantly better tolerance in Group MIS compared to Group HIS (93.3% vs 87.0%, RR 1.07, 95% CI 1.03–1.11, $p < 0.001$) with lower rates of dose reduction and discontinuation in the MIS group (5% vs 8.5%, RR 0.59, 95% CI 0.38–0.91, $p = 0.02$) and (1.7% vs 4.5%, RR 0.37, 95% CI 0.18–0.76, $p =$



0.01), respectively. Adverse events like SAMS occurred less frequently in the MIS group (6% vs 11.33%, RR 0.53, 95% CI 0.36–0.78, $p < 0.01$); however, no significant difference was observed regarding the incidences of elevated liver enzymes and elevated CK levels.

While international guidelines recommend HIS therapy for secondary prevention in CAD, significant challenges are faced in implementation in real-world practices related to tolerability and adherence. Our study addresses this gap by comparing the tolerance profiles of MIS versus HIS therapy in our local population over a six-month follow-up period.

Kim BG et al. compared MIS therapy with HIS therapy in atherosclerotic CV disease patients. Drug intolerance-related discontinuation was lower with MIS therapy for both males and females (men 4.8% vs 8.0%, $p < 0.001$; women 4.5% vs 8.6%, $p = 0.014$). Moreover, the target set for LDL-C < 70 mg/dL was achieved more frequently with MIS therapy, showing superiority both in terms of lipid lowering and tolerance irrespective of gender.¹¹

With these limitations related to tolerance, the concept of combining MIS with ezetimibe has gained particular attention as an alternative strategy. Watson KE et al. compared 3,780 ASCVD patients on MIS plus ezetimibe therapy (rosuvastatin 10 mg + ezetimibe 10 mg) with patients receiving HIS monotherapy (rosuvastatin 20 mg) over a three-year period. The MIS group achieved the primary composite outcome compared to HIS (9.1% vs 9.9% respectively) with fewer discontinuations (4.8% vs 8.2%), demonstrating that MIS combination therapy was equally effective and better tolerated than HIS therapy.¹²

The issue of tolerability profile is more relevant to clinical practice in elderly patients, a population that is often underrepresented in clinical trials, yet commonly affected by statin-related adverse effects. Cha JJ et al. aimed to compare the incidence of SAMS and LDL-C reduction between elderly patients with ASCVD receiving MIS therapy plus ezetimibe or HIS therapy. In a six-month study with 561 patients, SAMS occurred in 0.7% of the MIS group versus 5.7% of the HIS group. There was no statistically significant difference regarding achievement of target LDL-C < 70 mg/dL, concluding that with similar LDL-C lowering, MIS therapy provides significantly better tolerance.¹³

Further work on these age-specific limitations was done by Khalid MU et al. who assessed the safety and efficacy of MIS (plus ezetimibe) therapy in elderly patients (≥ 60 years) with established ASCVD. In 221 patients followed for six months, target LDL-C < 70 mg/dL was achieved in 69.2% and < 100 mg/dL in 91.4% of patients. Adverse effects were reported as myalgia (3.2%), liver enzyme elevation (2.3%), and CK increase (1.8%), with only 1.4% discontinuing therapy. The MIS therapy therefore showed high efficacy, excellent tolerability, and strong adherence, and was suggested as an effective alternative to HIS monotherapy in elderly patients with ASCVD.¹⁴

Long-term adherence is a critical factor in determining real-world effectiveness of statin therapy. Virani SS et al. aimed to compare adherence between high- and low/moderate-intensity statin users. Among 629,005 patients



using statins, 36.5% received HIS therapy. The mean proportion of days covered was slightly lower in HIS compared to low/moderate-intensity (0.86 vs 0.87, $p < 0.0001$). Adherence ≥ 0.80 was recorded in 74.2% vs 76.3%, showing a statistically significant but modest reduction (OR 0.94, 95% CI 0.93–0.96).¹⁵

However, the literature is not entirely uniform and some studies do not support these observations of low tolerance with HIS in comparison to MIS therapy. Thongtang N et al. conducted an RCT with type-2 diabetic patients to evaluate whether switching from low-dose statin to HIS therapy improves lipid control from a baseline LDL-C < 100 mg/dL. HIS therapy significantly lowered LDL-C at both 6 and 12 weeks ($p < 0.001$) in this study of 150 participants. Intolerance was more frequent in the HIS group; however, no serious adverse events were reported, indicating overall safety of this treatment.¹⁶

Similarly, Hong SJ et al. prospectively compared, statin tolerance between MIS (treat-to-target) and HIS therapy including 1,200 CAD patients. After a 3-year follow-up, the study met its composite endpoints and non-inferiority for tolerance was demonstrated without a statistically significant difference in event rates (8.1% vs. 8.7%; $p < 0.001$ for non-inferiority).¹⁷

To synthesize this clinically important question, an important meta-analysis on this subject was conducted by Sydhom P et al. evaluating 15 studies (251,450 participants) comparing MIS plus ezetimibe with HIS therapy to assess CV outcomes, lipid reduction, and tolerance. MIS therapy achieved greater LDL-C reduction (MD = -7.95 mg/dL), higher LDL-C goal attainment (RR = 1.27), and fewer reports of SAMS (RR = 0.52) and liver enzyme elevations (RR = 0.51). Overall, MIS proved superior in lipid control, comparable in CV outcomes, and better tolerated than HIS therapy.¹⁸

The findings of our study and the studies discussed above indicate that MIS therapy provides comparable lipid-lowering efficacy with significantly improved tolerance and adherence compared to HIS, making it a safe choice and practical approach for patients newly diagnosed with CAD. This tolerance-guided approach may be particularly valuable in population where adherence to the medication present challenge and a personalized approach may yield better CV outcomes than directly opting for maximum-intensity regimens.

Limitations of this study include the non-randomized observational design and relatively short follow-up period, which may affect the generalizability of these findings especially for the assessment of long-term tolerance and outcomes.

Conclusion:

These findings on the pattern of real world practices show that MIS therapy offers significantly better tolerance compared to the HIS therapy in newly diagnosed CAD patients, with lower rates of dose modification and discontinuation. The incidence of common adverse events particularly SAMS was also significantly lower with MIS



therapy. Hence, the MIS therapy may be a more practical initial approach for dyslipidemia management in this patient segment, especially in our local population where adherence to the medication is already a challenge, potentially improving long-term adherence and CV protection.

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Clinical and Experimental
Health Sciences

Clinical and Experimental Health Sciences Journal (ISSN: 2459-1459)