IJPSR (2025), Volume 16, Issue 7 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 06 February 2025; received in revised form, 19 February 2025; accepted, 21 February 2025; published 01 July 2025

A COMPARATIVE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ROSUVASTATIN 5MG VERSUS ATORVASTATIN 20MG IN PATIENTS WITH DYSLIPIDAEMIA

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Keywords:

Dyslipidaemia, ASCVD, Rosuvastatin, Atorvastatin

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ABSTRACT: Dyslipidemia is a known risk factor for Atherosclerotic Cardiovascular Diseases (ASCVD). Statins are first choice drug for the treatment of dyslipidemia. The FDA advises a low starting dose of rosuvastatin at 5 mg/day in Asians. The present study is a randomized, open labelled study done at Victoria Hospital, Bangalore to compare the efficacy and safety of rosuvastatin 5mg versus atorvastatin 20mg in patients with dyslipidemia. A total of 60 treatment naïve adult patients with dyslipidemia were randomized into two arms of 30 each in 1:1 ratio to receive either rosuvastatin 5mg or atorvastatin 20mg. Lipid profiles at baseline and at 6th week follow-up visit was recorded. Efficacy was assessed by mean change in lipid parameters at the end of 6 weeks and safety by recording the number and severity of adverse events reported by the patient at any time during the study. Among the 60 patients the mean difference at 6th week from baseline for Total cholesterol, LDL, HDL and Triglyceride for the rosuvastatin and atorvastatin group were (mg/dl) -48.7, -38.6, +4.7, -20.1 and -56.6, -46.6, +4.8, -19 respectively. In both the arms, the mean differences were significant. However, no significant difference ($p>0.05$) was seen in any lipid parameter between the two arms at the 6th week. Five patients reported myalgia in the atorvastatin arm and one patient reported myalgia in the rosuvastatin arm. Hence, this study concludes that rosuvastatin at a dose of 5mg OD was found to be as efficacious as atorvastatin 20mg OD with relatively less side effects in patients with dyslipidemia.

INTRODUCTION: Elevated LDL-C level is a major modifiable risk factor and an important point of intervention in the prevention of Atherosclerotic Cardiovascular Diseases. Worldwide an estimated 19.9 million people died from ASCVDs in 2021, representing 31% of all global deaths.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.16(7).1978-84

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(7).1978-84

Prevalence of dyslipidemia in Indian urban population is 25–30% and 15–20% in rural subjects [1, 2]. Studies from India reported approximately 46.9 million patients with ASCVD which led to death of an estimated 1.2 million people per year.

India is expected to contribute more than half the cases of ASCVD globally within the next 15 years [3]. Elevated plasma LDL-C levels being a major modifiable risk factor for atherosclerosis, presents an important point of intervention in the primary prevention of CVD. National Cholesterol Education Programme (NCEP) adult treatment panel III guidelines and American Association of

Cardiology/American Heart Association (AAC/AHA) both recommend statins as the first choice hypolipidemic drug which are the most effective and best tolerated agents for treating dyslipidemia [4]. Statins are HMG-CoA reductase inhibitors, which are the most effective and best tolerated agents. Among the statins, atorvastatin and rosuvastatin are commonly used worldwide. When compared to atorvastatin, rosuvastatin has distinct advantages in terms of potency to reduce lipid parameters, hepatic specificity, high hydrophilicity, low potential for drug-drug interactions, cost-effectiveness, pleiotropic effects and less dosage requirement for Asians when compared to Caucasians [5, 6].

There is no consensus with available scientific literature about dose equivalence of atorvastatin versus rosuvastatin. Majority of the studies have proved that rosuvastatin 10mg is superior to atorvastatin 20mg, whereas there are limited studies concluded that rosuvastatin 5mg is equivalent to atorvastatin 20mg [7, 8, 9]. The Food and Drug Administration (FDA) advises a low starting dose of rosuvastatin at5 mg/day in Asians. So, to further strengthen the existing scientific knowledge about rosuvastatin, the present study is undertaken.

Aim and Objectives:

1. To compare the efficacy of Rosuvastatin 5mg on markers of dyslipidemia with Atorvastatin 20mg.
2. To compare the safety of Rosuvastatin 5mg versus Atorvastatin 20mg in patients with dyslipidemia.

MATERIALS AND METHODS:

Study Design: This prospective, randomized, open labelled and comparative study was conducted in the Department of Medicine, Bangalore Medical College and Research Institute. Eligible 60 patients entered a 6-week treatment period. Sample size was calculated with 5% level of significance at 80% power considering difference between the two means as 10.67 and standard deviation of the two groups as 13.85. By substituting the above values, the sample size was 26 for each group, but it was decided to include 30 per group considering dropouts and for better evaluation. Patients were randomized (1:1) to receive either rosuvastatin 5mg/day orally at night or atorvastatin 20 mg/day orally at night, for 6 weeks. Both the groups were advised to follow low fat diet. The study was conducted in accordance with ICH-GCP and the study protocol was approved by the Institutional Ethics Committee (No BMC/PGs/289/2017-18 dated 03/11/2017).

Study Population: We screened 72 patients for eligibility and enrolled 60 treatment naïve patients (≥18 years of age) of dyslipidemia in low to moderate risk group (LDL <160mg/dL) according to NCEP ATP III (National Cholesterol Education Program Adult Treatment Panel III) guidelines who satisfied the inclusion and exclusion criteria.

Inclusion Criteria: Patients with dyslipidemia who met following criteria were included:

1. Patients who gave written informed consent.
2. Patient of either sex aged above 18 years.
3. Patients with dyslipidemia in low to moderate risk category as diagnosed by NCEP ATP III guideline who require moderate intensity statin therapy.

Exclusion Criteria:

1. Patients with very high lipid profile according to NCEP ATP III guidelines.
2. Patients with uncontrolled diabetes mellitus.
3. Patients with a documented history of acute coronary syndrome, cerebrovascular accident or on-going angina.
4. Patients with triglyceride levels more than 400mg/dl.
5. Pregnant and lactating mothers.
6. Patients already on hypolipidemic drugs.
7. Patients on co-existing medications which aggravate statin myopathy.
8. Patients who cannot tolerate statin therapy.

Study Assessments: Before starting the study, all patients underwent an initial screening assessment that included demographic characteristics, medical

history, concomitant medications and detailed physical/clinical evaluation. At the baseline and at week 6, we evaluated the following parameters: LDL-C and other lipid markers such as High-density of Lipoprotein (HDL-C), triglycerides, and total cholesterol (TC). Safety assessments included incidence and severity of adverse events were reported.

Statistical Analyses: Results were analyzed using SPSS version 20. All continuous variables were presented as mean±SD, if they were normally distributed. Categorical variables were described with absolute and relative (percentage) frequencies. Comparisons between the 2 individual groups were performed using the Mann Whitney U test, unpaired‘t’ test and Pearson Chi-square test for continuous and categorical variables, respectively. Wilcoxon sign rank test was used to compare before and after comparison. All tests were two-sided and a probability value of $p<0.05$ was considered statistically significant.

RESULTS AND DISCUSSION: We screened 72 patients for eligibility and recruited 60 drug naïve patients with dyslipidemia. Thus, 30 patients were randomized to receive rosuvastatin 5mg/day orally at night and the remaining 30 patients received atorvastatin 20mg/day orally at night.

The baseline demographic characteristics and various lipid parameters such as TC, LDL, HDL and triglycerides in both rosuvastatin and atorvastatin group were shown in **Table 1** and **Table 2.** Effect of rosuvastatin 5mg and atorvastatin 20mg on reduction of various lipid parameters from baseline to 6th week was shown in **Table 3** and **Table 4.**

TABLE 1: BASELINE SOCIO-DEMOGRAPHIC CHARACTERISTICS

Variable		R 5mg Arm (n=30)	A 20mg Arm (n=30)	Significance*
Age	Mean (SD)	59.6 (6.9)	62.7 (7.1)	0.1141
Sex (Male)	Frequency (%)	16 (53.3%)	16 (53.3%)	1.0
Diabetes	Frequency (%)	11 (13.7%)	8 (23.7%)	0.406
Hypertension	Frequency (%)	6 (20%)	2 (1.7%)	0.254

*Significance value is based on unpaired ‘t’ test for continuous variables and Pearson’s Chi square test for categorical variables across both groups.

TABLE 2: BASELINE LIPID PARAMETERS

Variable		R 5mg Arm (n=30)	A 20mg Arm (n=30)	Significance*
Total cholesterol	Mean (SD)	248.3 (25.8)	255.2 (25.6)	0.4295
LDL	Mean (SD)	168.3 (17.7)	173.8 (17.7)	0.3125
HDL	Mean (SD)	39.7 (5.3)	40.3 (5.21)	0.4902
Triglyceride	Mean (SD)	175.5 (27.7)	177.2 (10.5)	0.215

*Significance value is based on Mann Whitney U test across both groups.

TABLE 3: MEAN CHANGE IN LIPID PARAMETERS AFTER 6 WEEKS OF ROSUVASTATIN 5mg THERAPY FROM BASELINE

Lipid parameter	Baseline [mg/dl (mean)]	After 6 Weeks [mg/dl (mean)]	Mean change	Significance*
Total Cholesterol	248.3 (25.8)	199.6 (35.3)	-48.7	<0.001
LDL	168.3 (17.7)	134.6 (34.6)	-38.6	<0.001
HDL	39.7 (5.3)	45.1 (4.7)	+4.7	<0.001
Triglycerides	175.5 (27.7)	155.4 (15.7)	-20.1	<0.001

*Significance based on Wilcoxon signed ranks test.

TABLE 4: MEAN CHANGE IN LIPID PARAMETERS AFTER 6 WEEKS OF ATORVASTATIN 20mg THERAPY FROM BASELINE

Lipid parameter	Baseline [mg/dl (mean)]	After 6 Weeks [mg/dl (mean)]	Mean change	Significance*
Total Cholesterol	255.2 (25.6)	198.6 (28.5)	-56.6	<0.001
LDL	173.8 (17.7)	127.2 (17.7)	-46.6	<0.001
HDL	40.3 (5.21)	45.1 (4.7)	+4.8	<0.001
Triglycerides	177.2 (10.5)	158.2 (13.2)	-19	<0.001

* Significance based on Wilcoxon signed ranks test.

When comparing the values of lipid parameters at week 6 with the baseline, the percent change in total cholesterol was 19.9% in rosuvastatin 5mg group and it was 22.1% in the atorvastatin 20mg

group. With regard to the LDL cholesterol values, there was fall of 20% and 26.8% in the R arm and A arm, respectively. Similarly, the percentage fall of triglycerides in both the arms was 11.4% and 10.7% respectively, in R and A arms. The percent rise of HDL was 10.4% and 10.9% in R arm and in A arm respectively, as shown in **Fig. 1.**

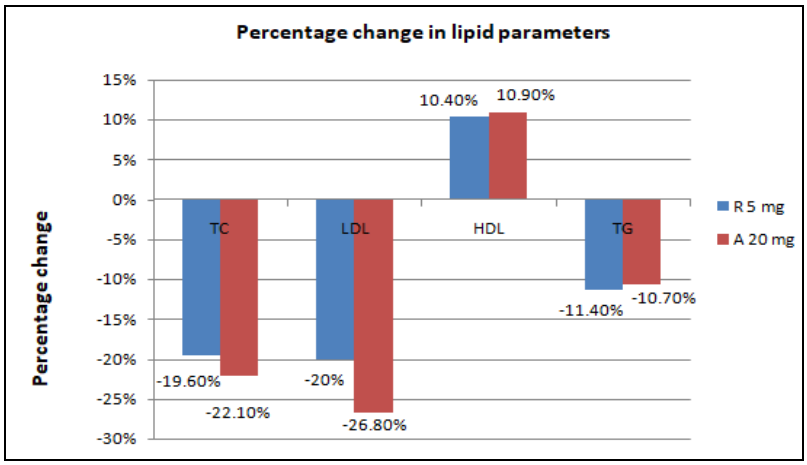

FIG. 1: PERCENTAGE CHANGE IN LIPID PARAMETERS FROM BASELINE TO 6TH WEEK

Mean difference of lipid parameters shown no difference in between the 2 groups at the end of 6th week with Mann Whitney – U test which is depicted in **Table 5.**

TABLE 5: EFFECT OF ROSUVASTATIN 5MG VERSUS ATORVASTATIN 20 MG ON VARIOUS LIPID PARAMETERS AFTER 6 WEEKS OF THERAPY

Lipid parameters	R 5mg Arm (mg/dl) Mean diff	A 20mg Arm (mg/dl) Mean diff	Significance*
Total Cholesterol	-48.7	-56.6	0.096
LDL	-38.6	-46.6	0.062
HDL	+4.7	+4.8	0.477
Triglycerides	-20.1	-19	0.509

* Significance based on Mann Whitney-U test.

Adverse Events: No serious adverse events were reported during treatment in both groups. Out of 30 patients, 9 patients experienced adverse events in the group receiving atorvastatin 20 mg and 4 patients experienced adverse events in the group receiving rosuvastatin 5 mg therapy **Table 6**. Myalgia, headache, gastritis, dizziness etc., were the reported adverse events. These adverse events were mild in intensity.

TABLE 6: INCIDENCE OF ADVERSE EVENTS

Incidence of adverse events	Rosuvastatin 5mg	Atorvastatin 20mg
Total (%)	4 (13.3)	9 (30)
	Musculoskeletal system	
Myalgia	1	5
	Central nervous system	
Dizziness	-	1
Headache	1	1
	Gastrointestinal system	
Nausea/ vomiting	1	-
Gastritis	1	2

In the present study, Rosuvastatin 5mg dosing provided percentage reduction of LDL-C by 20% which was comparable to 26.8% reduction with Atorvastatin 20mg. Similar studies by Kendrach MG *et al* and Schneck DW *et al*, for effect of Rosuvastatin and Atorvastatin across their dose ranges found that there was 41.5% reduction in LDL-C in Rosuvastatin 5mg whereas in Atorvastatin 20mg it was 43.3% [10, 11]. However a study done by Glueck C J *et al*, found out that after a median treatment duration of 16 weeks with Rosuvastatin 5mg/day there was a mean reduction

in LDL-C by 34mg/dl [12]. Higher reductions in LDL-C in the above study could be attributed to long duration of the study period. So, Rosuvastatin with low starting dose of 5mg/day effectively reduces LDL-C levels which is a major modifiable risk factor for atherosclerosis. In the present study, percentage reduction in total cholesterol (TC) was 19.60% and 22.10% with rosuvaststin 5mg and atorvastatin 20mg therapy respectively, Prakash C. Deedwania *et al* and Michael G Kendrach *et al* conducted studies which showed similar reductions in TC [9, 10]. A study done by Abdul Rehman Arshad showed a 19.84% reduction in TC in the rosuvastatin 5mg group at the end of the 6th week, which was in congruence with our study [13]. However, Choel Whan Lee *et al*, found that there was a 29% reduction in TC inpatients on atorvastatin 20 mg group at the end of 6 months [14].

In the present study High density cholesterol (HDL-C) increased from 39.7 (5.3) mg/dl to 44.3 (4.7) mg/dl in rosuvastatin 5mg group and in atorvastatin 20mg group from 40.3 (5.21) mg/dl to 45.4 (4.7) at the 6th week. A review article done by Ahmed Abbas *et al* found that a dose dependent increase in HDL-C (5.5%–7.9%) was seen with rosuvastatin (5 mg–40 mg) and an inverse increase in HDL-C was seen with higher doses of atorvastatin (4.5% at 10 mg and 2.3% at 80 mg) [15].

A study done by Yasushi Saito *et al* on Japanese patients found that there was a+14.5 (16.9) percentage increase in HDL-C with rosuvastatin 5mg which was similar to our study [16]. Strong epidemiological evidence links low levels of serum HDL cholesterol to increased CHD morbidity and mortality. Clinical trials provide suggestive evidence that raising HDL-C cholesterol levels will reduce risk for CHD [4]. However, it remains uncertain whether raising HDL-cholesterol levels per se, independent of other changes in lipid and/or non-lipid risk factors will reduce risk for CHD.

However, triglycerides (TG) in the present study reduced by 11.40% vs 10.70% with rosuvastatin 5mg and atorvastatin 20mg therapy respectively. A study done by Blasetto JW *et al*, found that rosuvastatin 5mg reduced TG levels by 14.9% from baseline at the end of 12th week [17]. Also a study done by Yamazaki T *et al*, comparing rosuvastatin 5mg and atorvastatin 10mg found that there was 14.6% reduction in rosuvastatin 5mg group and 13.6% reduction in atorvastatin 10mg group respectively at the end of 8th week [18]. However, a study done by Arshad AR showed that there was 3.52% reduction in rosuvastatin 5mg group and a 5.92% reduction in atorvastatin 10mg group at the end of the 6th week [13]. Early multivariate analyses generally did not identify serum triglycerides as an independent risk factor for CHD. Lipoprotein metabolism is integrally linked, and elevations of serum triglycerides can be confounded by significant correlations with total, LDL, and HDL cholesterol levels [4].

In the present study we encountered mild adverse effects such as myalgia and gastrointestinal disturbances in both the groups [rosuvastatin 5mg (13.3%) versus atorvastatin 20mg (30%)]. However minor adverse effects like myalgia, dyspepsia, nausea & vomiting, headache were more commonly encountered with atorvastatin 20 mg. Previous similar studies showed that side effects in rosuvastatin 5mg were less when compared to that of atorvastatin 20mg [17, 19, 20].

A significant percentage of patients taking statins discontinue their therapy because of side effects, particularly myalgia [21]. Rosuvastatin at a dose of 5mg/day particularly for Asians is very well tolerated and is as potent as atorvastatin 20mg/day with less side effects. So, rosuvastatin 5mg/day therapy is safe when compared to atorvastatin 20mg/day therapy.

The affinity of rosuvastatin for the active site of the HMG-CoA reductase enzyme is four times greater than the affinity of atorvastatin for the enzyme. It has the highest affinity for HMG-CoA reductase among the statins marketed [8]. Rosuvastatin also has distinct advantages in terms of potency to reduce lipid parameters, hepatic specificity, high hydrophilicity, low potential for drug-drug interactions, cost-effectiveness and pleiotropic effects.

The present study confirms that rosuvastatin should be started at 5mg/day in patients of Asian origin. These properties would, reasonably make rosuvastatin 5mg a better choice than atorvastatin 20mg to get effective results. Robust statistical tests employed enabled us to generate valuable

information & our study could provide reliable baseline information for future research. However, our study had some limitations. Patients were recruited from a single tertiary care hospital but a multicentre study with a larger sample size would be the ideal. We didn't follow up the subjects after 6 weeks as it could deprive patients from standard of care as per treatment guidelines. Further long term, double blind, randomized control trials are required to accurately evaluate these effects.

CONCLUSION: Rosuvastatin at a dose of 5mg/day was found to be as efficacious as that of atorvastatin 20mg/day therapy for treating Asian patients with mild to moderate dyslipidemia. Also, the side effects were less reported with rosuvastatin 5mg/day therapy when compared to atorvastatin 20mg/day therapy.

ACKNOWLEDGEMENT: The authors thank all the study participants, research assistants and the faculty from the Department of Medicine, Bangalore Medical College and Research Institute, Bengaluru, for their immense support in conducting the project work. All authors have made a substantial contribution to drafting the article or reviewing it. All authors have given final approval of this version of the article to be published.

Funding: None

CONFLICT OF INTEREST: None

REFERENCES:

1. Guptha S, Gupta R, Deedwania P, Bhansali A, Maheshwari A and Gupta A: Cholesterol lipoproteins and prevalence of dyslipidemias in urban Asian Indians: A cross sectional study. Indian Heart J 2014; 66(3): 280–8.
2. Joshi SR, Anjana RM, Deepa M, Pradeepa R, Bhansali A and Dhandania VK: Prevalence of Dyslipidemia in Urban and Rural India: The ICMR–INDIAB Study. Goel K, editor. PLoS ONE 2014; 9(5): 96808.
3. Park K: Epidemiology of chronic non-communicable diseases and conditions. In: Park K, editor. Park's Textbook of Preventive and Social Medicine. 23rd Ed. Jabalpur: Bhanot 2009; 365-372.
4. National Cholesterol Education Program (NCEP) Expert Panel on Detection, evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002; 106: 3143-421
5. Bersot TP: Drug therapy for hypercholesterolemia and dyslipidemia. In: Brunton LL, Chabner BA, Knollmann BC, editors. Goodman and Gilman's, The Pharmacological Basis of Therapeutics. 12th Ed. New York: McGraw-Hill: 2011; 877-908.
6. Tuomilehto J: Rosuvastatin: The most efficient treatment option for patients with dyslipidemia. Future Lipidology 2007; 2(2): 127-41.
7. Wlodarczyk J, Sullivan D and Smith M: Comparison of benefits and risks of Rosuvastatin versus Atorvastatin from a meta-analysis of head-to-head randomized controlled trials. Am J Cardiol 2008; 15; 102(12): 1654-62.
8. Luvai A, Mbagaya W, Hall AS and Barth JH: Rosuvastatin: A review of the pharmacology and clinical effectiveness in cardiovascular disease. Clin Med Insights Cardiol 2012; 6: 17–33.
9. Deedwania PC, Gupta M, Stein M, Yčas J and Gold A: Comparison of Rosuvastatin versus Atorvastatin in South-Asian Patients at Risk of Coronary Heart Disease (from the IRIS Trial). Am J Cardiol 2007; 99(11): 1538–43.
10. Kendrach MG and Kelly-Freeman M: Approximate equivalent rosuvastatin doses for temporary statin interchange programs. Ann Pharmacother 2004; 38(7–8): 1286–92.
11. Schneck DW, Knopp RH, Ballantyne CM, McPherson R, Chitra RR and Simonson SG: Comparative effects of rosuvastatin and atorvastatin across their dose ranges in patients with hypercholesterolemia and without active arterial disease. Am J Cardiol 2003; 91(1): 33–41.
12. Glueck CJ, Aregawi D, Agloria M, Khalil Q, Winiarska M and Munjal J: Rosuvastatin 5 and 10 mg/d: A pilot study of the effects in hypercholesterolemic adults unable to tolerate other statins and reach ldl cholesterol goals with nonstatin lipid-lowering therapies. Clin Ther 2006; 28(6): 933–42.
13. Arshad AR: Comparison of Low-Dose Rosuvastatin with Atorvastatin in Lipid-Lowering Efficacy and Safety in a High-Risk Pakistani Cohort: An Open-Label Randomized Trial. J Lipids 2014; 2014: 1–5.
14. Lee CW, Kang S, Ahn J, Song HG, Lee J and Kim W: Comparison of Effects of Atorvastatin (20 mg) Versus Rosuvastatin (10 mg) Therapy on Mild Coronary Atherosclerotic Plaques (from the ARTMAP Trial). AJC [Internet] 2012; 109(12): 1700.
15. Abbas A, Milles J and Ramachandran S: Rosuvastatin and atorvastatin: Comparative effects on glucose metabolism in non-diabetic patients with dyslipidaemia. Clin Med Insights Endocrinol Diabetes 2012; 5: 13–30.
16. Saito Y, Yamada N, Shirai K, Sasaki J, Ebihara Y and Yanase T: Effect of rosuvastatin 5-20 mg on triglycerides and other lipid parameters in Japanese patients with hypertriglyceridemia. Atherosclerosis 2007; 194(2): 505–11
17. Blasetto JW, Stein EA, Brown WV, Chitra R, Raza A and McKenney JM: Efficacy of rosuvastatin compared with other statins at selected starting doses in hypercholesterolemic patients and in special population groups. Am J Cardiol 2003; 91(5-1): 3–10.
18. Yamazaki T and Kurabayashi M: Rosuvastatin 5 mg and Atorvastatin 10 mg on the Plasma. Ann Vasc Dis 2009 2010; 2(3): 159–73.
19. Armitage J: The safety of statins in clinical practice. Lancet 2007; 370(9601): 1781–90.
20. Toth PP and Dayspring TD: Drug safety evaluation of rosuvastatin. Expert Opin Drug Saf 2011; 10(6): 969–86.
21. Luvai A, Mbagaya W, Hall AS and Barth JH: Rosuvastatin: A review of the pharmacology and clinical effectiveness in cardiovascular disease. Clin Med Insights Cardiol 2012; 6: 17–33.

How to cite this article:
Venkataraman AP, Sushma P, Kamath L and Raveendra KR: A comparative study to evaluate the efficacy and safety of rosuvastatin 5mg versus atorvastatin 20mg in patients with dyslipidaemia. Int J Pharm Sci & Res 2025; 16(7): 1978-84. doi: 10.13040/IJPSR.0975-8232.16(7).1978-84.