RESEARCH PAPER

Efficacy and Safety of Rosuvastatin 5 mg Versus 10 mg in Treatment-Naïve Patients with Dyslipidemia: A Prospective Randomized Open-Label Study

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ABSTRACT

Background:
Elevated low-density lipoprotein cholesterol (LDL-C) is a major modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD). Rosuvastatin is an effective statin for dyslipidemia management, and lower starting doses are recommended in Asian populations.

Objective:
To compare the efficacy and safety of rosuvastatin 5 mg and 10 mg once daily in treatment-naïve patients with dyslipidemia.

Methods:
This prospective, randomized, open-label study enrolled 60 treatment-naïve adults with dyslipidemia. Participants were randomized equally to receive rosuvastatin 5 mg (n=30) or 10 mg (n=30) once daily for 6 weeks. Lipid profiles were assessed at baseline and week 6. The primary outcome was percentage reduction in LDL-C. Secondary outcomes included changes in total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), triglycerides (TG), and adverse drug reactions.

Results:
Baseline characteristics were comparable between groups. At 6 weeks, LDL-C decreased by 17.83% in the 5 mg group and 20.33% in the 10 mg group. Mean changes in the 5 mg and 10 mg groups were −45.23 and −58.00 mg/dL for TC, −30.10 and −34.43 mg/dL for LDL-C, +4.43 and +4.87 mg/dL for HDL-C, and −25.20 and −26.13 mg/dL for TG, respectively. Both groups showed significant improvement from baseline; however, no statistically significant between-group differences were observed for lipid parameters or adverse events (all $p>0.05$). Myalgia was the most common adverse drug reaction.

Conclusion:
Both rosuvastatin 5 mg and 10 mg improved lipid parameters over 6 weeks in treatment-naïve patients with dyslipidemia. No statistically significant differences were observed between groups for efficacy or safety outcomes. Larger, longer-duration studies are needed to confirm these findings.

Keywords: Dyslipidemia; Rosuvastatin; LDL-C; Statins; ASCVD

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INTRODUCTION

Dyslipidemia is a major modifiable risk factor for Athero Sclerotic CardioVascular Diseases (ASCVD). Worldwide 17.7 million people died from ASCVDs in 2015, representing 31% of all global deaths. Studies from India reported 46.9 million patients with ASCVD which lead to death of 1.2 million people.

India is expected to contribute for more than half the cases of ASCVD globally within the next 15 years [1].

Guidelines recommend Statins as first choice hypolipidemic drug for prevention of ASCVD.[2,3] Statins are HMG-CoA reductase inhibitors, which are the most effective and best tolerated drugs. Among them, Rosuvastatin is one of the most potent long acting statin and is currently widely prescribed. Rosuvastatin has distinct advantages in terms of potency to reduce lipid parameters, high hydrophilicity, low potential for drug-drug interactions, cost-effectiveness, pleiotropic effects and less dosage requirement for Asians when compared to Caucasians.[4,5]

Inspite of many beneficial effects of statin, patients discontinue long term statin therapy due to side effects and cost. Though statins are well tolerated, few adverse effects like myalgia, muscle cramps and weakness were witnessed in 10% of the patients and it is dose related[4]. It is therefore important to know the dose-related magnitude of effect of Rosuvastatin on blood lipids. The Food and Drug Administration (FDA) advises low starting dose of Rosuvastatin at 5 mg/day in Asians[6]. Few studies have proved that Rosuvastatin 5 mg is as effective as Rosuvastatin 10 mg in improving the lipid profile with few side effects.[7,8,9] Several studies have suggested that lower doses of rosuvastatin may provide lipid-lowering efficacy comparable to higher doses while minimizing the incidence of adverse effects. However, evidence from Indian treatment-naïve patients remains limited. Hence, the present study was undertaken to compare the efficacy & safety of Rosuvastatin 5mg versus Rosuvastatin 10 mg in patients with dyslipidemia.

METHODOLOGY

Study Design and Setting

This Prospective, comparative, open labelled, randomized study was conducted on out-patient basis in the Department of Medicine in the hospitals affiliated to Bangalore Medical College and Research Institute, Bengaluru between November 2018 to May 2020. Prior Institutional Ethics Committee approval was obtained (BMC/PG/124/2018-19) before initiating the study.

Study Participants

Treatment-naïve adult patients with dyslipidemia who satisfied the predefined inclusion and exclusion criteria and provided written informed consent were enrolled. A total of 60 participants were included in the study

Insert Figure 1

Randomization and Intervention

Participants randomized in 1:1 ratio using computer-generated random sequence were allocated into one of two treatment groups.

Group 1(n = 30): Received Rosuvastatin 5mg tablet orally once daily at night for 6 weeks.

Group 2(n = 30): Received Rosuvastatin 10mg tablet orally once daily at night for 6 weeks.

Participants in both groups received counselling regarding dietary modifications and regular physical activity.

Study Assessments

Demographic data, medical history, co-morbid conditions, physical examination, laboratory investigations and details of drug prescription by the treating physician were recorded at baseline. Lipid profile testing was done at day-1 and at 6 weeks. Medication adherence was assessed using pill counts during follow-up visits, and adverse events were recorded as reported during the study period.

Outcome Measures

The primary efficacy endpoint was percentage reduction in LDL-C from baseline to six weeks. Secondary efficacy endpoints were changes in Total cholesterol (TC), High-density lipoprotein cholesterol (HDL-C) and Triglycerides (TG). Safety assessment was based on the number and severity of adverse events reported by the patient at any time of the study.

Statistical analysis:

Results were analysed using Vassar Stats and social science statistics. All continuous variables were presented as mean ± standard deviation (SD), when normally distributed. Categorical variables were described as frequencies and percentages. Comparisons between groups were performed using the independent-samples t-test or Mann–Whitney U test as appropriate. Categorical variables were analysed using the Chi-square test or Fisher's exact test. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant

Sample size:

The sample size calculation reported by the original manuscript yielded a required sample sizeof 26 participants per group.The investigators enrolled 30 participants per group to allow better evaluation. Sample size was calculated using the formula given below

$$N=\frac{(r+1)\,(Z_{\alpha/2}+Z_{1-\beta})^2\delta^2}{rd^2}$$

n1 and n2 = sample size for Group 1 and Group 2

such that, N = n1 = n2 and ratio r = n1/n2 = 1/1 = 1

Zα/2 = normal deviate at a level of significance

= 1.96 for 5% level of significance

Z1-β= normal deviate at 1-β % power

= 0.84 at 80% power

δ = Standard deviation of 2 groups = 13.76., d = difference between two means = 10.80

$$N = \frac{(1+1)\,(1.96+0.84)^2\,(13.76)^2}{1(10.8)^2} = 25.46$$

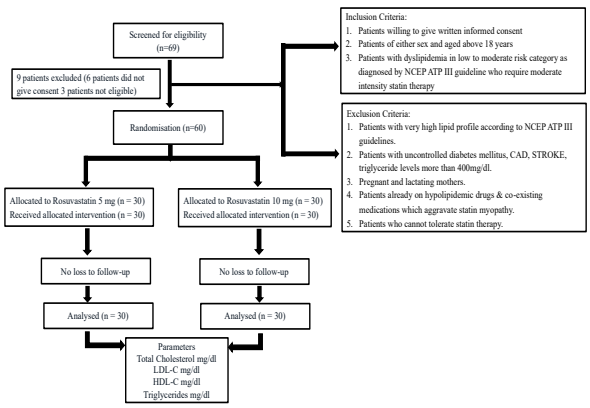


Figure 1: Study flow diagram

RESULTS

Participant flow and baseline characteristics

Sixty participants were randomized equally into the two treatment groups, and all randomized participants were analyzed. No loss to follow-up was reported. The groups were also comparable with respect to sex distribution and reported comorbidities.

Table 1: DEMOGRAPHIC CHARACTERISTICS

Variable		Group 1 (R 5mg Arm)	Group 2(R	*p value*
Age	Mean	60.07 (7.35)	57.33	0.25*
Gender	Male [n	16 (53.3%)	21 (70%)	0.28**
	Female	14(46%)	9 (30%)	
Co-morbidities	DM [n (%)]	5 (16.7%)	7 (23.3%)	0.85**
	HTN [n (%)]	4 (13.3%)	3 (10%)	
	HT [n	5 (16.7%)	7 (23.3%)	
		2 (6.7%)	2 (6.7%)	

*Data analysed using unpaired t test **Data analysed Chi-square test, *p value* <0.05 is considered statistically significant, R5- Rosuvastatin 5 mg , R10- Rosuvastatin 10 mg ,DM-Diabetes Mellitus, HTN-Hypertension, HT- Hypothyroidism.

EFFICACY PARAMETERS

Efficacy outcomes

At 6 weeks, both treatment groups showed improvement in lipid parameters and was statistically significant. However, between-group comparisons revealed no statistical significance.

Insert Table 2

Table 2: Effect of Rosuvastatin 5mg and Rosuvastatin 10mg on lipid parameters between baseline and 6th week

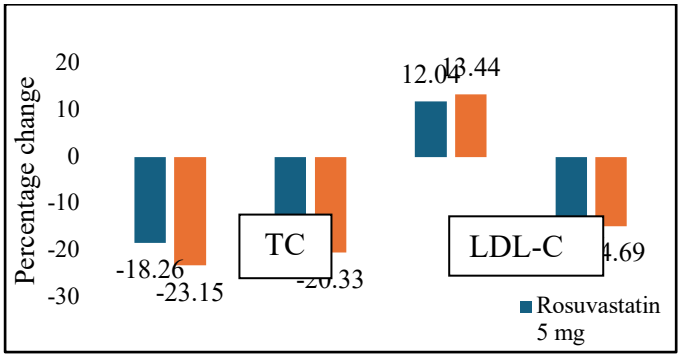
Parameters	Group-1				Group-2			
	Baseline [mg/dl mean(SD)]	After 6 Weeks [mg/dl mean(SD)]	Mean difference	* *p value*	Baseline [mg/dl mean (SD)]	After 6 Weeks [mg/dl (mean)]	Mean diffeR Ence	P value *
Total Cholesterol	248 - 25.83	202.77 -31.7	-45.23	<0.001	249.2 - 27.33	191.2 - 20.87	-58	<0.001
LDL-C	169.07 - 17.13	138.96 - 21.83	-30.1	<0.001	169.47 - 17.01	135.03 - 16.65	-34.43	<0.001
HDL-C	39.9 -5.27	44.33 -4.54	4.43	<0.001	40.07 - 6.12	44.93 - 3.95	4.87	<0.001
Triglycerides	178.87 - 26.47	153.67 - 20.15	-25.2	<0.001	182 -32	155.8 - 33.39	-26.13	<0.001

* Data analysed by using paired t test, *p* value <0.05 is considered as statistically significant

Table 3: Mean Difference Of Rosuvastatin 5mg Versus Rosuvastatin 10mg On Various Lipid Parameters From Baseline To 6 Weeks Of Therapy

Lipid	Group 1	Group	*p
Total	-45.23	-58.0	0.06
LDL-C	-30.10	-34.43	0.12
HDL-C	+4.43	+4.87	0.28
Triglycerides	-25.2	-26.13	0.32
* Significance based on Mann Whitney-U test			

Figure 2: Percentage Change In Various Lipid Parameters From Baseline To 6th Week:



Safety outcomes

The adverse effects encountered were mild to moderate in nature. A total of 13% adverse reactions were encounterd in the Rosuvastatin 5mg group and 26% in Rosuvastatin 10mg group. There was no statistically significant difference seen between the groups (*p value* = 0.82). Myalgia was the most commonly reported adverse drug reaction, occurring in 2 participants in the rosuvastatin 5 mg group and 3 participants in the rosuvastatin 10 mg group. Other reported adverse events included dizziness, headache, and gastritis.

Insert Table 4:

Table 4: Adverse Drug Reactions Between Two Study Groups

Adverse Drug	Group 1	Group 2	*p*
Myalgia	2	3	0.82*
Dizziness	1	1	
Headache	0	2	
Gastritis	1	2	

*Data analysed using Fisher exact test, *p value* <0.05 is considered statistically significant

DISCUSSION

This prospective, randomized, open-label study compared the efficacy and safety of rosuvastatin 5 mg versus 10 mg in treatment-naïve patients with dyslipidemia over six weeks.

Rosuvastatin 5 mg reduced LDL-C by 17.83% (mean difference 30.10), comparable to the 20.33% reduction (mean difference 34.43) with rosuvastatin 10 mg, without statistical significance (p = 0.12). This aligns with Ullah et al., who similarly found no significant difference between the two doses

in 82 patients with type 2 diabetes and hypercholesterolemia (p = 0.116).[8] Tuomilehto and Teramoto et al. reported even greater LDL-C reductions (42–52%) with low-dose rosuvastatin in Asian cohorts, attributable to heightened statin sensitivity in this population.[23],[24],[25]

Total cholesterol fell by 18.26% and 23.15% in the 5 mg and 10 mg groups, respectively — broadly consistent with the 19.84% reduction reported by Arshad et al. for rosuvastatin 5 mg.[26] Larger reductions reported by Lee et al. (31% at 6 months)[27] and Blasetto et al. (29.6–33% at 12 weeks)[22] likely reflect their longer follow-up durations relative to the present six-week study.

HDL-C rose by 12.04% and 13.44% in the 5 mg and 10 mg groups, respectively, closely matching the 12–13% increases reported by Davidson et al.[21] and consistent with the STELLAR trial finding that rosuvastatin raises HDL-C more effectively (8–10%) than atorvastatin (2–6%) or simvastatin (5–7%).[28] While higher HDL-C is generally associated with reduced coronary heart disease risk, whether raising HDL-C independently reduces risk remains uncertain. Triglycerides decreased by 13.36% and 14.69% in the two groups, consistent with reductions reported by Blasetto et al. (16.4–19.2%)[22] and Olsson et al. (15–19%).[29]

Adverse events were mild to moderate, occurring in 13% of the rosuvastatin 5 mg group versus 26% of the rosuvastatin 10 mg group (p = 0.82). Myalgia and gastrointestinal disturbances were the most common reactions, with headache and gastritis more frequent in the 10 mg group — a pattern consistent with Tuomilehto et al.[23] Since myalgia is a well-recognized driver of statin discontinuation, the numerically lower adverse event rate with rosuvastatin 5 mg supports its use as a well-tolerated, comparably potent alternative for Asian patients, particularly those intolerant of higher doses.

LIMITATIONS

Patients were recruited from a single tertiary care hospital; a multicenter design with a larger sample would improve generalizability. Further long-term, double-blind, randomized controlled trials are needed to confirm these findings.

CONCLUSION

Rosuvastatin in a dose of 5mg/day was found to be as efficacious as that of Rosuvastatin 10mg/day therapy for treating mild to moderate dyslipidaemia. Also, the side effects are less reported with rosuvastatin 5mg/day therapy when compared to Rosuvastatin 10mg/day therapy. This will improve the compliance and lower doses will be cost effective with fewer side effects. So, rosuvastatin 5mg/day can be used for patients intolerant to Rosuvastatin 10mg/day, with equal efficacy. However further studies with larger number of subjects would help in confirming the same results and establish further findings.

Both rosuvastatin 5 mg and rosuvastatin 10 mg significantly improved lipid parameters in treatment-naïve patients with dyslipidemia over 6 weeks. No statistically significant differences were observed between the two treatment groups for LDL-C reduction or other lipid parameters. While adverse events were numerically less frequent with rosuvastatin 5 mg, this difference was not statistically significant. These findings suggest that rosuvastatin 5 mg may provide lipid-lowering efficacy comparable to rosuvastatin 10 mg in the short term; however, larger and longer-duration randomized studies are required to confirm these observations and assess comparative clinical outcomes

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