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Original Research Article

A Prospective, Randomized, Open-Label Trial Comparing the Safety and Efficacy of Daily versus Alternate-Day Rosuvastatin Dosage for Patients with Dyslipidemia

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Conflict of interest: Nil

Abstract

Background: One significant risk factor for the onset of atherosclerotic cardiovascular disease (ASCVD) is dyslipidemia. HMG CoA reductase inhibitors, or statins, are thought to be the best lipid-lowering medications. This study evaluated the safety and efficacy of daily versus alternate-day rosuvastatin dosage schedules in patients with dyslipidemia.

Methods: This prospective, randomized, open-label study was conducted for a period of 3 months (from January 2026 to March 2026) at Department of Pharmacology with collaboration of Department of Medicine, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, and Bihar. A total of 180 participants who were randomly assigned to three groups—A (rosuvastatin 10 mg daily), B (rosuvastatin 10 mg on alternate days), and C (rosuvastatin 20 mg on alternate days)—completed the study. The participants were patients of either sex who were diagnosed with dyslipidemia and were between the ages of 18 and 65.

Results: In every group, rosuvastain significantly decreased triglycerides, total cholesterol, and low density lipoprotein cholesterol ($p<0.001$). The rise in high density lipoprotein cholesterol was not statistically significant ($p>0.05$). There was no statistically significant difference between the groups. Compared to groups B and C, group A reported somewhat more adverse events.

Conclusion: In patients who had dyslipidemia, alternate-day rosuvastatin medication demonstrated efficacy that was statistically comparable to daily dosage therapy. Additionally, it showed fewer adverse effects, indicating that it might be a practical method of controlling dyslipidemia, offering a more affordable and possibly safer substitute for daily administration.

Keywords: Dyslipidemia, Statins, Rosuvastatin, Lipid profile, cardiovascular risk.

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Introduction

A metabolic condition known as dyslipidemia is defined by excessively high or low blood levels of any or all lipids, such as fats, triglycerides, cholesterol, phospholipids, or lipoproteins.[1] The development of atherosclerotic cardiovascular diseases, such as peripheral artery disease, cerebrovascular disease, and coronary artery disease, is associated with dyslipidemia.[1]

Despite being a risk factor for cardiovascular disease, dyslipidemia may not always require the use of lipid-lowering medications.[2] A cardiovascular risk assessment takes into account not only dyslipidemia but also concomitant diseases and lifestyle.[3] 15–30% of Indians suffer from dyslipidemia, which is more common in cities and among men.One of the main risk factors for ASCVD is dyslipidemia [4]. A sedentary lifestyle, heavy alcohol use, smoking, a poor diet, and specific medical problems are additional risk factors.[5] There are two types of dyslipidemia: primary (genetic) and secondary (acquired). The discovery of statins, which are essential for controlling cholesterol levels, and the finding of the LDL receptor are examples of more recent advancements. Pharmacotherapy and lifestyle changes are examples of treatment strategies. The first-line medications for lowering LDL-C levels are statins, such as rosuvastatin.

Rosuvastatin has a long half-life of 18 to 24 hours and is very powerful and effective.[6] Patients with

high cholesterol are often administered it because there is evidence that it significantly reduces low-density lipoprotein levels and improves cardiovascular outcomes. In a dose-dependent manner, it can lower LDL-C levels by 18–55%.[7] Statins are typically used daily, which guarantees steady medication levels and steady cholesterol reduction. Alternate-day dosage is being investigated as a way to maintain therapeutic efficacy while minimizing side effects such muscle soreness and abnormal liver enzyme levels. Research indicates that rosuvastatin administered on alternate days may result in comparable LDL-C reductions and enhance adherence in people who encounter adverse effects when taking the medication every day. Despite their effectiveness, statins can have adverse consequences such central nervous system issues, diabetes mellitus, and muscle soreness. In rare instances, rosuvastatin may produce more serious side effects like acute renal damage and muscle soreness in addition to more mild ones like headache and nausea.[8]

The efficacy of taking statins on alternate days as opposed to everyday has been examined in recent research. Because rosuvastatin has a lengthy half-life, it may be used on alternate days. According to certain research, alternate-day medication may improve lipid profiles just as well as daily doses while perhaps lowering adverse effects and treatment expenses.[9]

Material and Methods

This prospective, randomized, open-label study was conducted for a period of 3 months (from January 2026 to March 2026) at Department of Pharmacology with collaboration of Department of Medicine, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, and Bihar. Patients were collected from the Department of Medicine, outpatient department (OPD) at the Bhagwan Mahavir Institute of Medical Sciences in Pawapuri, Nalanda, and Bihar. Patients with a confirmed diagnosis of dyslipidemia, aged 18 to 65, both male and female, were screened. The National Cholesterol Education Program (NCEP ATP III) criteria were used to identify dyslipidemia.

A sample size of 180 with an alpha error of 0.05 and a research power of 80% was determined based on previous data. Using computer software, patients were divided into three equal groups at random. One group took 10 mg of rosuvastatin every day, another 10 mg every other day, and a third 20 mg every other day. The study included both male and female patients with dyslipidemia who were between the ages of 18 and 65, willing to participate, and gave written informed consent. Patients with uncontrolled diabetes, a history of statin allergies, current use of lipid-lowering medications, or unwillingness to give consent were excluded. The trial also excluded patients with rhabdomyolysis, pregnant or nursing women, and those using medications that interact with rosuvastatin, such as amlodipine, amiodarone, nicotinic acid, gemfibrozil, CYP3A4 inhibitors, or HIV protease inhibitors.

Vital signs and physical examinations were recorded at baseline, following the collection of demographic data and medical history. For tests such CBC, urine analysis, LFTs, and RFTs at baseline, 4, 8, and 12 weeks, blood samples were taken following an overnight fast. At the beginning and after 12 weeks, the lipid profile was evaluated. All results were documented, and any unfavorable occurrences were identified and dealt with.

SPSS version 25.0 was used to analyze the data. While categorical variables were expressed as percentages, continuous variables were expressed as mean±standard deviation (SD). A paired t-test was used for intragroup comparisons (baseline vs. 12 weeks). One-way analysis of variance (ANOVA) and Tukey's post-hoc test were used to evaluate intergroup comparisons. Chi-square or Fisher's exact test were used, depending on the situation, to examine categorical data. Statistical significance was defined as a two-tailed p-value of less than 0.05.

Results

In terms of lipid-lowering efficacy in patients with dyslipidemia, this randomized, open-label, parallel-group trial showed that alternate-day rosuvastatin dose, either 10 mg or 20 mg, was equivalent to daily 10 mg therapy. The demographic and clinical parameters of the three treatment groups were well-matched at baseline, ensuring that the treatments were responsible for the changes that were later noticed.

Table 1: Baseline characteristics of study participants (n=180)

Parameter	Group A (n=60)	Group B (n=60)	Group C (n=60)	p-value
Age (years, mean±SD)	52.1± 8.3	51.6± 7.9	50.8± 9.1	0.72
Sex (%)	56.7%	53.3%	60.0%	0.81
BMI (kg/m²)	26.2± 3.8	26.5± 4.1	25.9± 3.6	0.67
Hypertension (%)	43.3%	40.0%	46.7%	0.88
Baseline TC (mg/dL)	234.5±28.7	236.1±30.4	231.9±29.6	0.91
Baseline LDL-C (mg/dL)	151.7±23.2	153.2±25.1	149.6±24.3	0.83
Baseline HDL-C (mg/dL)	39.2± 5.4	38.6± 5.9	39.8± 6.1	0.76
Baseline TG (mg/dL)	178. 4±35.7	181.2±33.9	175.6±36.1	0.69

The study participants' baseline clinical and demographic data are displayed in Table 1. Age, sex distribution, BMI, prevalence of hypertension, and baseline lipid levels did not differ statistically significantly between the three groups, suggesting good randomization and comparability at the beginning of the trial.

Table 2: Lipid profile changes within groups (baseline vs 12 weeks)

Parameter	Group A Δ(%)	Group B Δ(%)	Group C Δ(%)	p (within)
TC	-32.1*	-30.8*	-31.6*	<0.001
LDL-C	-42.7*	-41.3*	-42.1*	<0.001
HDL-C	+5.1	+4.6	+5.3	>0.05
TG	-28.9*	-27.6*	-28.4*	<0.001
p-value <0.0001 (highly significant)				

The changes in lipid profile parameters within each group from baseline to 36 weeks are summarized in Table 2. Triglycerides, LDL-C, and total cholesterol all significantly decreased with all three regimens ($p < 0.001$). All groups had a slight increase in HDL-C, although this increase was not statistically significant.

Table 3: Intergroup comparison of mean% change in lipid profile (baseline to 12 weeks)

Parameter	A vs B (p)	A vs C (p)	B vs C (p)
TC	0.71	0.83	0.79
LDL-C	0.66	0.92	0.81
HDL-C	0.84	0.72	0.77
TG	0.69	0.88	0.74

The percentage changes in lipid parameters between the three treatment groups are shown in Table 3. Alternate-day dosing schedules were just as successful as daily dosing, since no statistically significant differences were seen between the groups.

Table 4: Glycemic parameters (baseline vs 12 weeks)

Parameter	Group A	Group B	Group C	P (within)
HbA1c (%)	+0.4*	+0.3*	+0.4*	<0.001
FBS (mg/dL)	+2.6	+2.1	+2.4	>0.05

The glycemic parameter changes are shown in Table 4. Although the absolute increase was small, all groups showed a statistically significant increase in HbA1c. There was a modest increase in FBS, but it was not statistically significant, indicating that there was no clinically meaningful deterioration of glycemic control.

Table 5: Adverse events during 12 weeks

Adverse Event	Group A (%)	Group B (%)	Group C (%)
Headache	10.0%	6.7%	6.7%
Myalgia	13.3%	6.7%	6.7%
GIupset	6.7%	3.3%	3.3%
No AE	70.0%	83.3%	83.3%

The adverse events that were recorded over the course of the 12-week treatment are listed in Table 5. The most often reported side effects were headaches and myalgia, which were more common in the daily dosage group. The majority of incidents were minor and didn't necessitate stopping treatment. In the alternate-day groups, most participants reported no negative experiences.

Discussion

In terms of lipid-lowering efficacy in patients with dyslipidemia, this randomized, open-label, parallel-group trial showed that alternate-day dosing of rosuvastatin, either 10 mg or 20 mg, was equivalent to daily 10 mg therapy. The demographic and clinical parameters of the three treatment groups were well-matched at baseline, guaranteeing that the treatments were responsible for the variations that were later noted.

All regimens significantly decreased total cholesterol, LDL-C, and triglycerides throughout a 12-week period, with the LDL-C reduction nearing 42% in all groups.

These results are in line with global data that rosuvastatin significantly lowers LDL-C, such as the JUPITER trial and smaller investigations. [10] Notably, the lack of statistically significant differences across groups indicates that daily dosing is not inferior to alternate-day therapy. Although not statistically significant, the slight rise in HDL-C across all regimens is consistent with rosuvastatin's established pharmacological profile, which has a stronger impact on LDL-C and triglycerides than on HDL-C. [11]

All groups showed a minor but statistically significant increase in HbA1c, although there was no statistically significant increase in fasting blood glucose.

The absolute changes were small and unlikely to have a short-term clinical impact, despite the fact that these results are consistent with other publications that linked statins to slight glycemic changes. [12–14] However, as statin medication is long-term, it is still recommended to monitor glycemic status, particularly in patients who already have a pre-existing risk of diabetes [13].

Myalgia, headaches, and gastrointestinal distress were among the relatively minor adverse effects. While most individuals in the alternate-day groups reported no side effects, these happened more frequently in the daily dosage group. [14]

Previous research has shown that alternate-day dosage reduces the incidence of side effects, which may enhance patient adherence to treatment. [15–16]. The overall safety of rosuvastatin in all tested regimens is supported by the fact that no significant adverse events or treatment discontinuations occurred during the research.

Conclusion

This prospective, randomized, open-label trial showed that rosuvastatin (10 mg or 20 mg) administered on alternate days improves lipid profiles in patients with dyslipidemia just as well as daily 10 mg therapy.

Triglycerides, LDL-C, and total cholesterol were all significantly lowered by all regimens, but HDL-C increased somewhat but not significantly. Only a modest increase in HbA1c was seen in the glycemic parameters, which is unlikely to be clinically significant in the near future. Alternate-day dosage resulted in fewer and milder adverse events, indicating improved tolerability and adherence potential. Alternate-day rosuvastatin is a practical and secure treatment choice for long-term dyslipidemia therapy in Indian patients because to its comparable efficacy, cost advantage, and enhanced tolerability. To validate these results and assess the advantages of cardiovascular outcomes, more multicentric studies with longer follow-up are necessary.

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