

Research Article



INTERNATIONAL RESEARCH JOURNAL OF PHARMACY

www.irjponline.com

ISSN 2230-8407 [LINKING]

DAILY VERSUS ALTERNATE-DAY ROSUVASTATIN FOR DYSLIPIDEMIA: A RANDOMIZED CONTROLLED STUDY

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How to cite: Ajay Kumar¹, Bhanu Priya Singh², Shallini Gupta³, Pavan Malhotra⁴, Abid Manzoor⁵. **DAILY VERSUS ALTERNATE-DAY ROSUVASTATIN FOR DYSLIPIDEMIA: A RANDOMIZED CONTROLLED STUDY.** International Research Journal of Pharmacy. 2026; 17:3:1-11.

DOI: <http://doi.org/10.56802/irjp.2026.v17.i3.pp1-11>

ABSTRACT

Background: Alternate-day statin therapy has been proposed as a cost-effective strategy to maintain lipid control while potentially reducing adverse effects; however, comparative data with daily dosing remain limited.

Aim: To compare the efficacy and safety of daily 10 mg rosuvastatin with alternate-day 10 mg and 20 mg regimens in dyslipidemic patients over 12 weeks.

Methods: In this randomized controlled trial, 97 patients were enrolled; 90 completed the study (92.8% completion), with 30 patients per group analyzed. Baseline demographic, lipid, safety, and glycaemic parameters were comparable across groups ($p > 0.05$). Primary outcomes included changes in total cholesterol (TC), LDL-C, HDL-C, and triglycerides (TG). Secondary outcomes included glycaemic parameters and safety assessment.

Results: All regimens significantly reduced TC (15–21%), LDL-C (26–33%), and TG (17–18%) from baseline ($p < 0.001$ for all), with no significant inter-group differences ($p > 0.05$), demonstrating therapeutic equivalence of alternate-day dosing. HDL-C showed modest, non-significant increases. Liver enzymes and serum creatinine remained within normal ranges, with no significant differences between groups. Adverse events were mild and comparable ($p = 0.26$), with headache (9.3%) and myalgia (4.1%) most common. HbA1c showed a small but significant increase (2.7–4.4%; $p < 0.001$) in all groups, without inter-group differences, while fasting blood glucose remained unchanged.

Conclusion: Alternate-day rosuvastatin (10 mg or 20 mg) provides lipid-lowering efficacy and safety comparable to daily 10 mg dosing. It represents an effective and well-tolerated alternative dosing strategy in dyslipidemic patients.

Keywords: Rosuvastatin, Dyslipidemia, Alternate-day therapy, LDL-C reduction, Statin safety, Randomized controlled trial.

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of mortality worldwide, with atherosclerosis driven by elevated low-density lipoprotein cholesterol (LDL-C) at its core.¹ Dyslipidemia is characterized by high total cholesterol (TC), high LDL-C, high triglycerides (TG), and often low high-density lipoprotein cholesterol (HDL-C) is a major modifiable risk factor for atherosclerotic CVD.² Effective lipid management is therefore fundamental to both primary and secondary prevention of cardiovascular events.³ Statins (HMG-CoA reductase inhibitors) are the first-line therapy for dyslipidemia.⁴ By inhibiting cholesterol synthesis, they upregulate LDL receptors and markedly reduce circulating LDL-C.⁵ Rosuvastatin, a potent statin, has well-established efficacy in improving lipid profiles and reducing cardiovascular risk.⁶ Rosuvastatin possesses unique pharmacokinetic properties: it is hydrophilic with high hepatic selectivity, minimizing distribution to skeletal muscle,⁷ and undergoes minimal cytochrome P450 metabolism, reducing drug interaction potential. Crucially, its long elimination half-life of approximately 19 hours (extending to 20–30 hours with active metabolites)⁸ sustains HMG-CoA reductase inhibition beyond 24 hours. This long half-life raises the question of whether alternate-day dosing could be as effective as daily dosing. Such a strategy may improve tolerability in patients experiencing mild side effects like myalgia,⁹ and reduce pill burden and medication costs, enhancing long-term adherence.¹⁰ Despite promise in statin-intolerant populations, comparative studies of daily versus alternate-day rosuvastatin regimens remain limited.¹¹

This study therefore compared the efficacy of three rosuvastatin regimens—daily 10 mg, alternate-day 10 mg, and alternate-day 20 mg—in reducing TC, LDL-C, and TG over 12 weeks in dyslipidemic patients. Secondary objectives included safety assessment (liver and kidney function, adverse events) and effects on glycaemic parameters (FBS and HbA1c). We

hypothesized that alternate-day regimens would demonstrate therapeutic equivalence to daily dosing, offering effective and potentially safer or more affordable alternatives.

MATERIALS AND METHODS

Study Design and Setting: This was a prospective, randomized, open-label, parallel-group, interventional study conducted over a 12-week period. The study was carried out in the Department of Pharmacology in collaboration with the Department of Medicine at a tertiary care hospital.

Ethical Considerations: The study protocol was approved by the Institutional Ethics Committee. The study was conducted in accordance with good clinical practice guidelines. All participants provided written informed consent after receiving a detailed explanation of the study procedures in a language they understood.

Study Participants and Sample Size: A total of 97 patients of either sex, diagnosed with dyslipidemia and aged between 18 and 65 years, were enrolled from the outpatient department of General Medicine. Patients were eligible for inclusion if they were diagnosed cases of dyslipidemia, aged between 18 and 65 years, and willing to provide informed consent. Patients were excluded from participation if they had a known hypersensitivity or allergy to statins, were currently using any lipid-lowering agents, had uncontrolled diabetes mellitus, were pregnant or lactating, had a history of rhabdomyolysis, or were concomitantly using drugs with known interactions with rosuvastatin such as gemfibrozil, cyclosporine, or protease inhibitors. The required sample size was calculated based on previously reported data, with a minimum of 71 patients needed to achieve a study power of 80% at an alpha error of 0.05. To account for potential dropouts, 97 patients were enrolled and were randomly allocated into three groups using a computer-generated random allocation software.

Study Interventions and Procedures

Eligible patients were randomized into one of three treatment groups for a duration of 12 weeks:

- **Group A (Daily 10 mg):** Received oral rosuvastatin 10 mg once daily.
- **Group B (Alt-Day 10 mg):** Received oral rosuvastatin 10 mg once on alternate days.
- **Group C (Alt-Day 20 mg):** Received oral rosuvastatin 20 mg once on alternate days.

At enrollment, demographic data and medical history were recorded, and a thorough general and physical examination was performed for all participants. Fasting blood samples were collected at baseline and at the end of the 12-week treatment period for assessment of primary efficacy parameters: lipid profile (Total Cholesterol [TC], High-Density Lipoprotein Cholesterol [HDL-C], Low-Density Lipoprotein Cholesterol [LDL-C], and Triglycerides [TG])^{17,18} and glycaemic parameters (Fasting Blood Sugar [FBS] and Glycosylated

Haemoglobin [HbA1c]).¹⁹ LDL-C levels were calculated using the Friede wald formula.²⁰ Safety was assessed by monitoring liver function (Serum Glutamic-Oxaloacetic Transaminase [SGOT], Serum Glutamic-Pyruvic Transaminase [SGPT])^{21,22} and renal function (Serum Creatinine)²³ at baseline and at week 12. Patients were followed up regularly, and all adverse events reported or observed during the study period were recorded and managed appropriately.

Outcome Measures: The primary efficacy outcomes were the mean percentage change from baseline in TC, LDL-C, HDL-C, and TG at week 12, while the secondary outcomes included the mean percentage change from baseline in FBS and HbA1c at week 12, as well as the incidence of adverse events.

Statistical Analysis: Statistical analysis was performed using SPSS software (version 23.0). Per-protocol analysis was conducted on data from patients who completed the full 12-week study. Qualitative data were expressed as percentages, and quantitative data were presented as mean $\pm$ standard deviation (SD). A one-way ANOVA was used to compare baseline characteristics and routine investigations among the three groups. The paired t-test was employed to compare lipid and glycaemic parameters within each group from baseline to week 12. Inter-group comparisons for the change in these parameters were performed using ANOVA followed by Tukey's post-hoc test. A p-value of less than 0.05 was considered statistically significant.

RESULT

Of 97 patients randomized, 90 completed the 12-week study (92.8% completion rate), with 7 lost to follow-up (4 adverse events, 3 personal reasons). Final analysis included 30 patients per group.

Table 1: Baseline Characteristics of Study Participants

Parameter	Group A (Daily 10 mg) (n=30)	Group B (Alt- Day 10 mg) (n=30)	Group C (Alt- Day 20 mg) (n=30)	p- value
Demographics				
Age (years)	47.73 $\pm$ 11.59	47.67 $\pm$ 8.01	47.77 $\pm$ 8.35	0.999
Male/Female (%)	40/60	40/60	53.3/46.7	0.492
Lipid Profile (mg/dL)				

Parameter	Group A (Daily 10 mg) (n=30)	Group B (Alt- Day 10 mg) (n=30)	Group C (Alt- Day 20 mg) (n=30)	p- value
Total Cholesterol	221.68 ± 11.20	217.66 ± 10.86	218.92 ± 11.67	0.370
LDL-C	144.32 ± 27.86	142.95 ± 15.34	156.89 ± 29.27	0.060
HDL-C	50.18 ± 11.11	49.18 ± 8.91	49.74 ± 8.84	0.920
Triglycerides	174.01 ± 16.84	175.85 ± 14.54	176.03 ± 14.86	0.860
Safety Parameters				
SGOT (U/L)	33.48 ± 14.44	33.21 ± 15.83	33.08 ± 11.98	0.990
SGPT (U/L)	32.21 ± 11.38	30.45 ± 16.75	31.96 ± 11.29	0.860
Serum Creatinine (mg/dL)	0.96 ± 0.16	1.03 ± 0.13	0.98 ± 0.16	0.150
HbA1c (%)	5.65 ± 0.18	5.62 ± 0.16	5.63 ± 0.17	0.900

*Data presented as mean ± SD or %. All p-values >0.05 (ANOVA/Chi-square), confirming successful randomization. *

Table 2: Lipid Parameters at Week 12 and Percentage Change from Baseline

Parameter	Group A (Daily 10 mg)	Group B (Alt- Day 10 mg)	Group C (Alt- Day 20 mg)	p-value* (Inter-group)
Total Cholesterol				
Week 12 (mg/dL)	175.05 ± 16.27	183.90 ± 18.96	179.62 ± 18.65	0.140

Parameter	Group A (Daily 10 mg)	Group B (Alt-Day 10 mg)	Group C (Alt-Day 20 mg)	p-value* (Inter-group)
% Change	-21.04 ± 7.81†	-15.51 ± 10.57†	-17.95 ± 10.25†	0.068
LDL-C				
Week 12 (mg/dL)	97.04 ± 14.58	105.72 ± 15.30	111.10 ± 17.17	0.072
% Change	-32.76 ± 12.52†	-26.04 ± 9.22†	-29.18 ± 7.76†	0.112
HDL-C				
Week 12 (mg/dL)	51.18 ± 10.92	51.65 ± 8.76	51.72 ± 8.70	0.991
% Change	+1.99 ± 14.62	+5.03 ± 9.95	+3.99 ± 12.11	0.993
Triglycerides				
Week 12 (mg/dL)	142.07 ± 9.12	145.88 ± 7.18	144.98 ± 15.04	0.276
% Change	-18.35 ± 10.50†	-17.04 ± 7.99†	-17.64 ± 12.13†	0.941

Inter-group comparison by One-way ANOVA

All regimens significantly reduced TC, LDL-C, and TG from baseline ($p < 0.001$). No statistically significant differences were observed between any groups for any lipid parameter ($p > 0.05$ for all inter-group comparisons), demonstrating therapeutic equivalence of alternate-day dosing.

Table 3: Safety Parameters and Adverse Events

Week 12 Safety Labs	Group A (Daily 10 mg) (n=30)	Group B (Alt-Day 10 mg) (n=30)	Group C (Alt-Day 20 mg) (n=30)	p-value
SGOT (U/L)	39.61 ± 12.45	35.02 ± 14.75	39.87 ± 11.91	0.280*
SGPT (U/L)	38.92 ± 11.42	36.84 ± 15.01	37.22 ± 12.06	0.800*
Serum Creatinine (mg/dL)	1.02 ± 0.18	1.09 ± 0.15	1.01 ± 0.20	0.180*

*Repeated measures ANOVA (inter-group at Week 12)

All safety parameters remained within normal ranges. No significant differences in adverse event rates between groups (p=0.26). Headache (9.3%) and myalgia (4.1%) were most common. (p-value=0.260*)

Figure 1: Distribution of Adverse events among the groups

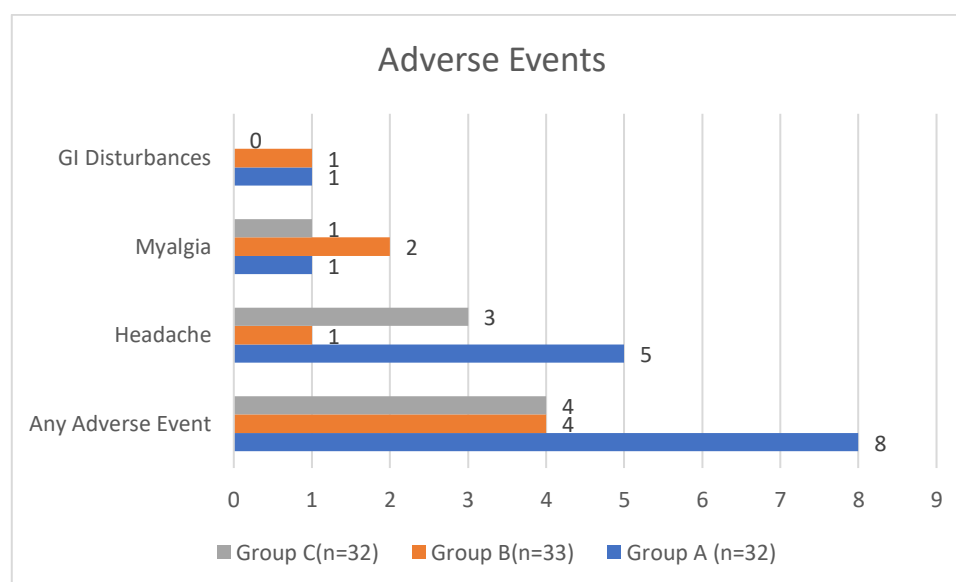


Table 4: HbA1c Levels at Baseline and Week 12

Parameter	Group A (Daily 10 mg) (n=30)	Group B (Alt-Day 10 mg) (n=30)	Group C (Alt-Day 20 mg) (n=30)	p-value* (Inter-group)
Baseline HbA1c (%)	5.65 ± 0.18	5.62 ± 0.16	5.63 ± 0.17	0.900
Week 12 HbA1c (%)	5.78 ± 0.22	5.74 ± 0.20	5.76 ± 0.21	0.840
Absolute Change	+0.13 ± 0.08†	+0.12 ± 0.07†	+0.13 ± 0.09†	0.910

% Change	+2.30 ± 1.40†	+2.14 ± 1.32†	+2.31 ± 1.56†	0.905
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DISCUSSION

Dyslipidemia, a major modifiable risk factor for cardiovascular disease, is commonly managed with statin therapy.¹ Rosuvastatin, a potent HMG-CoA reductase inhibitor, is widely used due to its efficacy and long half-life of 20-30 hours.⁸ This pharmacokinetic property raises the possibility that alternate-day dosing could be as effective as daily dosing, potentially improving patient adherence and reducing costs.¹⁰ This prospective, randomized study was undertaken to compare the efficacy and safety of daily versus two different alternate-day rosuvastatin regimens over 12 weeks in patients with dyslipidemia.

Our study demonstrated that all three rosuvastatin regimens—daily 10 mg, alternate-day 10 mg, and alternate-day 20 mg—produced significant and clinically meaningful improvements in the lipid profile after 12 weeks of treatment. As shown in Table 2, each regimen led to highly significant reductions from baseline in total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and triglycerides (TG) ($p < 0.001$ for all within-group comparisons). The percentage reduction in LDL-C, the primary therapeutic target, was substantial across all groups: -32.76% in the daily 10 mg group, -26.04% in the alternate-day 10 mg group, and -29.18% in the alternate-day 20 mg group. Crucially, the inter-group comparisons for the percentage change in all lipid parameters (TC, LDL-C, HDL-C, and TG) were not statistically significant ($p > 0.05$ for all). This key finding demonstrates the therapeutic equivalence of the three regimens. Furthermore, all regimens were well-tolerated, with no significant differences in safety parameters or adverse event rates between the groups (Table 3, Figure 1). A small but statistically significant increase in HbA1c was observed in all groups ($p < 0.001$), with no difference between regimens, suggesting a class effect independent of dose or frequency (Table 4).

The therapeutic equivalence of alternate-day rosuvastatin dosing observed in our study is consistent with a growing body of evidence. Our findings align with those of Panchavarthi et al., who reported comparable and significant reductions in TC, LDL-C, and TG with both daily and alternate-day rosuvastatin 10 mg over 6 weeks, with no significant inter-group differences.¹² Similarly, Dulay et al. found that rosuvastatin 10 mg daily and 20 mg on alternate days both produced highly significant decreases in TC, LDL-C, and TG after 6 weeks, with comparable effects on HDL-C.¹³ The LDL-C reduction of 48.5% in their daily group and 40.9% in their alternate-day 20 mg group mirrors the substantial, though slightly lower, reductions seen in our study, which may be attributable to differences in baseline lipid levels or study duration.¹³ Wongwiwatthanakit et al. also reported comparable LDL-C reductions of 48% with daily therapy and 39% with alternate-day therapy after 8 weeks, further supporting the non-inferiority of an alternate-day approach.¹⁴ Regarding the slight increase in HbA1c, our results are consistent with findings from large-scale studies and meta-analyses that have identified a modest diabetogenic effect associated with potent statin therapy. Ooba et al., for instance, demonstrated that high-potency statins like rosuvastatin can lead to small but

significant increases in HbA1c, an effect our study confirms is not mitigated by alternate-day dosing.¹⁵ The safety profile in our study, with a numerically higher but statistically non-significant rate of adverse events in the daily dosing group, echoes the findings of Ghia et al., who reported more adverse events with daily atorvastatin compared to an alternate-day regimen.¹⁶

The comparable efficacy of daily and alternate-day dosing can be attributed to the unique pharmacokinetic properties of rosuvastatin. Its long elimination half-life of approximately 19 hours, extending to 20-30 hours when considering its active metabolites, results in sustained HMG-CoA reductase inhibition well beyond 24 hours.⁸ This pharmacodynamic effect allows for continued suppression of cholesterol synthesis even on "off" days, preventing a significant rebound in lipid levels. The therapeutic equivalence between the two alternate-day doses (10 mg and 20 mg) in our study population suggests that for patients with moderate dyslipidemia, a lower potency dose every other day may be sufficient to achieve significant LDL-C reduction, and that doubling the dose does not necessarily confer an additional advantage. The observed increase in HbA1c is thought to be mediated by statin-induced effects on insulin signalling pathways and pancreatic beta-cell function, a mechanism that appears to be a class effect and not circumvented by less frequent dosing.¹⁵

The findings of this study have significant clinical implications. The demonstration that alternate-day rosuvastatin (10 mg or 20 mg) is therapeutically equivalent to daily 10 mg therapy provides clinicians with a valuable alternative for the long-term management of dyslipidemia. This is particularly relevant for several patient populations. First, for patients who experience mild, intolerable side effects with daily dosing, switching to an alternate-day regimen may offer a way to maintain effective lipid-lowering therapy while improving tolerability, as suggested by the numerically lower adverse event rate in our alternate-day groups.¹⁶ Second, an alternate-day regimen can reduce pill burden and medication costs, which are well-documented barriers to long-term adherence.¹⁰ Improving adherence is critical for achieving sustained cardiovascular risk reduction. Finally, for patients with moderate lipid derangements, initiating therapy with an alternate-day dose could be a practical and effective starting strategy, potentially reserving daily dosing for those with higher baseline risk or who do not achieve their lipid goals on an alternate-day schedule.

We acknowledge the limitations of this study. The open-label design may introduce performance bias, although the objective nature of the primary lipid outcomes mitigates this concern. The 12-week study duration, while adequate to assess lipid-lowering efficacy, is insufficient to evaluate long-term cardiovascular outcomes or adherence. The sample size, while sufficiently powered to detect differences in lipid parameters, was relatively small for comparing rare adverse events. Finally, our findings are specific to patients with moderate dyslipidemia and may not be generalizable to those with very high baseline LDL-C or established cardiovascular disease requiring more intensive LDL-C reduction.

FUNDING: NIL

CONFLICT OF INTEREST: NONE

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