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Original Research Article

Choosing the Better Statin: A Prospective Comparison of Rosuvastatin and Atorvastatin

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Abstract

Background: Dyslipidemia is a major modifiable risk factor for atherosclerotic cardiovascular disease and contributes substantially to global morbidity and mortality. It commonly coexists with hypertension and type 2 diabetes mellitus, thereby accelerating the development of cardiovascular complications. Statins remain the cornerstone of lipid-lowering therapy, with atorvastatin and rosuvastatin being among the most frequently prescribed agents. Although both drugs effectively reduce low-density lipoprotein cholesterol (LDL-C) and cardiovascular risk, comparative evidence from routine clinical practice in the Indian population remains limited.

Aim: To comparatively evaluate the efficacy, safety, tolerability, and treatment compliance of rosuvastatin and atorvastatin monotherapy in patients with dyslipidemia, including those with associated hypertension and/or type 2 diabetes mellitus, managed at a tertiary care hospital according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guidelines.

Materials and Methods: A prospective observational comparative study was conducted in the Departments of Pharmacology and Medicine at Hamdard Institute of Medical Sciences and Research (HIMSR) and Hakeem Abdul Hameed Centenary Hospital (HAHC), Jamia Hamdard, New Delhi. A total of 300 eligible patients with dyslipidemia were enrolled, of whom 291 completed the study, while nine patients were lost to follow-up. Participants received either rosuvastatin or atorvastatin monotherapy according to the treating physician's clinical judgment. Baseline demographic characteristics, cardiovascular risk factors, lipid profile parameters, fasting blood glucose, glycated haemoglobin (HbA1c), serum creatinine, blood urea, serum glutamic-pyruvic transaminase (SGPT), treatment compliance, and adverse drug reactions were assessed at baseline and during follow-up. Statistical analysis was performed using appropriate parametric and non-parametric tests, with $p < 0.05$ considered statistically significant.

Results: Among the 300 enrolled participants, 291 completed follow-up. Both rosuvastatin and atorvastatin produced significant improvements in serum lipid parameters during the study period. Rosuvastatin demonstrated greater reductions in total cholesterol and LDL cholesterol and achieved lipid targets in a higher proportion of patients, whereas atorvastatin showed comparable improvement in triglyceride levels. Both treatments were generally well tolerated, with adverse drug reactions being mild and consistent with the established safety profile of statins. Patient compliance remained satisfactory throughout the study.

Conclusion: Rosuvastatin and atorvastatin are both effective and well-tolerated treatment options for dyslipidemia. Rosuvastatin demonstrated comparatively greater efficacy in improving LDL cholesterol and overall lipid control, while maintaining a favourable safety profile. These findings support the use of rosuvastatin as an effective therapeutic option for achieving recommended lipid targets in patients with dyslipidemia, particularly those with associated cardiovascular risk factors.

Keywords: Dyslipidemia; Rosuvastatin; Atorvastatin; Statins; LDL Cholesterol; Cardiovascular Disease; NCEP ATP III; Prospective Observational Study.

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Introduction

Dyslipidemia is one of the most important modifiable risk factors for atherosclerotic cardiovascular disease (ASCVD), which remains the leading cause of morbidity and mortality worldwide. It is characterized by abnormalities in plasma lipoprotein concentrations, including elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and triglycerides (TG), along with reduced high-density lipoprotein cholesterol (HDL-C). These lipid abnormalities accelerate the development of atherosclerosis by promoting lipid deposition within the arterial wall, endothelial dysfunction, oxidative stress, and chronic vascular inflammation, ultimately increasing the risk of coronary artery disease, cerebrovascular disease, and peripheral arterial disease [1,2,15–17].

The global prevalence of dyslipidemia has increased substantially over the past few decades owing to rapid urbanization, sedentary lifestyles, unhealthy dietary habits, obesity, and an increasing burden of diabetes mellitus and hypertension. In India, cardiovascular diseases account for a significant proportion of premature mortality, with dyslipidemia being one of the major contributing factors. The coexistence of dyslipidemia with hypertension, type 2 diabetes mellitus, obesity, and metabolic syndrome further amplifies cardiovascular risk, necessitating timely diagnosis and effective lipid-lowering therapy [2–4,19–23].

Management of dyslipidemia involves both non-pharmacological and pharmacological interventions. Lifestyle modification, including dietary changes, regular physical activity, weight reduction, smoking cessation, and moderation of alcohol intake, forms the cornerstone of treatment. However, pharmacological therapy is indicated for patients who fail to achieve recommended lipid targets through lifestyle modification alone or who are at moderate to high cardiovascular risk. Among the available lipid-lowering agents, statins remain the first-line therapy because of their proven efficacy in reducing LDL-C levels and preventing major cardiovascular events [1–6,18,19].

Statins competitively inhibit 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme in hepatic cholesterol biosynthesis. This results in increased expression of hepatic LDL receptors, enhanced clearance of circulating LDL particles, and significant reductions in plasma LDL-C concentrations. In addition to their lipid-lowering effects, statins exert several pleiotropic actions, including improvement of endothelial function, stabilization of atherosclerotic plaques, reduction of oxidative stress and vascular inflammation, and inhibition of thrombus formation, thereby contributing to overall cardiovascular risk reduction [15–17,24–27].

Among currently available statins, atorvastatin and rosuvastatin are the most widely prescribed owing to their high potency and favourable clinical outcomes. Atorvastatin is a synthetic lipophilic statin that effectively lowers LDL-C, triglycerides, and total cholesterol while modestly increasing HDL-C. Rosuvastatin is a hydrophilic statin with greater affinity for HMG-CoA reductase and a longer elimination half-life, enabling more potent LDL-C reduction at equivalent doses. Several randomized clinical trials have demonstrated that rosuvastatin may achieve greater reductions in LDL-C and improved attainment of lipid targets compared with atorvastatin; however, both agents have established efficacy in reducing cardiovascular morbidity and mortality [7–12].

Selection of an appropriate statin in routine clinical practice depends not only on lipid-lowering efficacy but also on patient characteristics, associated comorbidities, drug safety, tolerability, treatment adherence, and cost considerations. Patients with diabetes mellitus, hypertension, chronic kidney disease, and multiple cardiovascular risk factors often require individualized treatment strategies to achieve optimal lipid control while minimizing adverse effects. Consequently, comparative evaluation of commonly prescribed statins under real-world clinical conditions remains highly relevant [1–3,18–20].

Although numerous international studies have compared rosuvastatin and atorvastatin, evidence from prospective observational studies conducted in Indian tertiary care hospitals remains relatively limited. Differences in demographic characteristics, dietary habits, genetic factors, socioeconomic status, prescribing practices, and prevalence of metabolic disorders may influence therapeutic response and treatment outcomes in the Indian population. Therefore, locally generated clinical evidence is important to guide rational prescribing and optimize patient care [3,4,21,31,32]. The present prospective observational study was undertaken in the Departments of Pharmacology and Medicine at Hamdard Institute of Medical Sciences and Research (HIMSR) and Hakeem

Abdul Hameed Centenary Hospital (HAHC), Jamia Hamdard, New Delhi, to compare the efficacy, safety, tolerability, and treatment compliance of rosuvastatin and atorvastatin in patients with dyslipidemia. The study also aimed to evaluate changes in lipid profile parameters, glycaemic indices, renal and hepatic biochemical parameters, achievement of recommended lipid goals, and the incidence of adverse drug reactions during follow-up. The findings of this study are expected to provide clinically relevant evidence regarding the comparative effectiveness of these two widely prescribed statins and support evidence-based management of dyslipidemia in routine clinical practice.

Materials and Methods

Study Design and Setting: A prospective, comparative, observational study was conducted in the Departments of Pharmacology and Medicine at Hamdard Institute of Medical Sciences and Research (HIMSR) and Hakeem Abdul Hameed Centenary Hospital (HAHC), Jamia Hamdard, New Delhi.

The study was carried out over a period of 15 months, including patient recruitment, follow-up, data collection, statistical analysis, and interpretation of results. The study protocol was approved by the Institutional Ethics Committee, and all procedures were performed in accordance with the principles of the Declaration of Helsinki [35]. Written informed consent was obtained from all participants before enrolment.

Study Population: Adult patients aged 18–65 years attending the Medicine Outpatient Department and diagnosed with dyslipidemia according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guidelines were screened for eligibility [5]. Patients with isolated dyslipidemia or dyslipidemia associated with Stage I hypertension, uncomplicated type 2 diabetes mellitus, or both were considered for inclusion.

Sample Size and Allocation: A total of 300 eligible patients were enrolled in the study. Participants were assigned sequential reference numbers at recruitment and were equally allocated into two treatment groups:

- **Atorvastatin group (AT):** 150 patients
- **Rosuvastatin group (RS):** 150 patients

Allocation was performed using simple randomization based on the assigned reference number, with odd-numbered participants receiving atorvastatin and even-numbered participants receiving rosuvastatin.

During follow-up, nine participants (five in the atorvastatin group and four in the rosuvastatin group) were lost to follow-up; therefore, 291 patients completed the study and were included in the final analysis.

Treatment Protocol: Patients received either atorvastatin (20–40 mg/day) or rosuvastatin (10–20 mg/day) according to the treating physician's clinical judgment. Therapy was initiated at the lower recommended dose and was titrated after six weeks if the desired lipid targets were not achieved [1–3,18,19]. No additional lipid-lowering medications were permitted during the study period. All participants received standardized counselling regarding dietary modification, weight management, regular physical activity, smoking cessation, and adherence to prescribed therapy. [1–3]

Inclusion Criteria

Patients fulfilling all of the following criteria were included:

- Age between 18 and 65 years.
- Newly diagnosed, drug-naïve dyslipidemia or discontinuation of lipid-lowering therapy for more than six weeks.
- Dyslipidemia diagnosed according to NCEP ATP III criteria [5].
- Dyslipidemia occurring alone or in association with Stage I hypertension and/or uncomplicated type 2 diabetes mellitus.
- Willingness to participate with written informed consent.

Exclusion Criteria

Patients were excluded if they had:

- Significant renal impairment (serum creatinine >2 mg/dL) or diabetic nephropathy.
- Clinically significant hepatic disease (SGOT/SGPT >3 times the upper limit of normal).
- Symptomatic heart failure, significant valvular heart disease, congenital heart disease, severe vascular disease, or uncontrolled hypertension (>160/100 mmHg).
- Pregnancy or lactation.
- Current oral contraceptive use.
- Genetic disorders affecting lipid metabolism.
- Previous or concurrent treatment with other lipid-lowering agents.
- Concomitant use of corticosteroids, cyclosporine, hormone replacement therapy, NSAIDs, or drugs known to alter lipid metabolism.
- Known hypersensitivity to statins.
- History of alcohol or substance abuse.

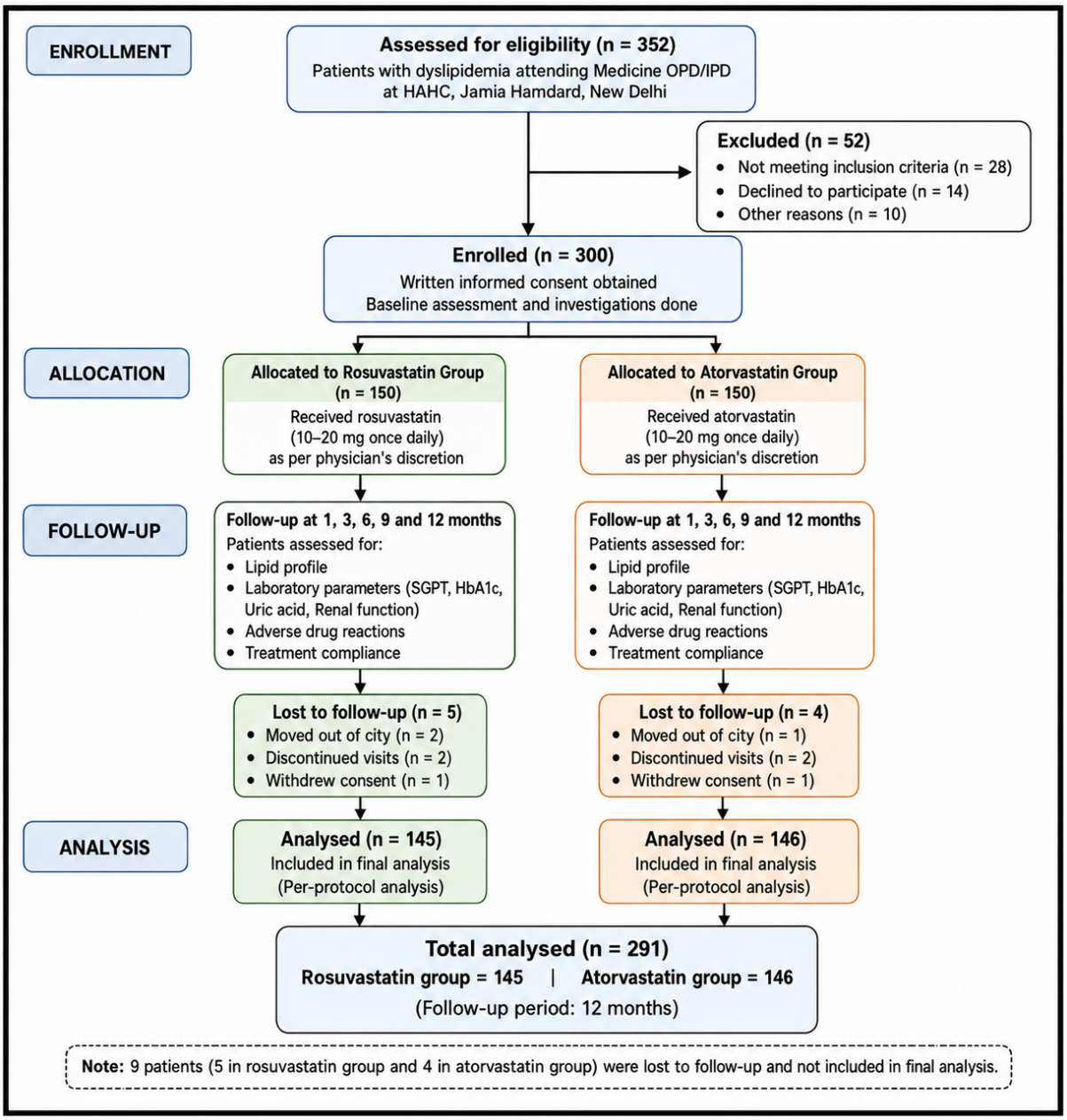

Figure 1:

Clinical and Laboratory Assessment: Baseline evaluation included detailed demographic characteristics, medical history, lifestyle factors, anthropometric measurements, blood pressure, and assessment of cardiovascular risk factors.

Laboratory investigations included fasting lipid profile, fasting blood glucose, HbA1c, serum creatinine, blood urea, liver function tests (SGPT/SGOT), serum uric acid, electrocardiography, and other investigations when clinically indicated[1–3,20,23].

Participants were reviewed at 1, 3, 6, 9, and 12 months. At each follow-up visit, fasting lipid profile, fasting blood glucose, HbA1c, serum creatinine, blood urea, liver enzymes, treatment adherence, and adverse drug reactions were documented[10,21].

Outcome Measures

Primary Outcome: Comparative reduction in LDL cholesterol following treatment with rosuvastatin and atorvastatin.

Secondary Outcomes

- Changes in total cholesterol, HDL cholesterol, triglycerides, and VLDL cholesterol.
- Achievement of NCEP ATP III lipid targets [5].
- Changes in fasting blood glucose, HbA1c, serum creatinine, blood urea, liver enzymes, and serum uric acid.
- Incidence of adverse drug reactions.
- Patient compliance with prescribed therapy.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using appropriate statistical software. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Between-group comparisons were performed using Student's t-test or Mann–Whitney U test, whereas within-group comparisons over time were analysed using paired t-test or repeated-measures analysis where appropriate. Categorical variables were compared using the Chi-square test or Fisher's exact test. A p value <0.05 was considered statistically significant.

Results

Patient Recruitment and Study Flow: A total of 400 patients were screened for eligibility during the study period. Of these, 100 patients were excluded because they did not meet the inclusion criteria or declined participation. The remaining 300 eligible patients were enrolled and allocated equally to the atorvastatin (AT; n = 150) and rosuvastatin (RS; n = 150) groups. During follow-up, five patients in the atorvastatin group and four patients in the rosuvastatin group were lost to follow-up. Consequently, 291 participants (145 in the atorvastatin group and 146 in the rosuvastatin group) completed the study and were included in the final analysis.

Baseline Demographic Characteristics

Age Distribution: The mean age of patients in the atorvastatin group was 45.89 ± 11.11 years, whereas the mean age in the rosuvastatin group was 47.60 ± 10.33 years. There was no statistically significant difference in age between the two treatment groups (p = 0.406), indicating that both groups were comparable at baseline.

Table 1: Baseline Age Distribution

Parameter	Atorvastatin (n=150)	Rosuvastatin (n=150)	p-value
Mean age (years)	45.89 ± 11.11	47.60 ± 10.33	0.406

Gender Distribution: Among the 300 enrolled participants, 117 (39.0%) were males and 183 (61.0%) were females, giving an overall male-to-female ratio of 0.64:1. The atorvastatin group comprised 68 males and 82 females, whereas the rosuvastatin group included 49 males and 101 females.

Although females predominated in both treatment groups, the gender distribution did not differ significantly between groups (p = 0.171).

Table 2: Gender Distribution

Gender	Atorvastatin n (%)	Rosuvastatin n (%)	p-value
Male	68 (45.3)	49 (32.7)	
Female	82 (54.7)	101 (67.3)	0.171

Distribution According to Locality: Of the enrolled participants, 177 (59.0%) belonged to urban areas and 123 (41.0%) were from rural areas. Urban residence was more common in both groups. There were 101 urban and 49 rural participants in the atorvastatin group, while the rosuvastatin group consisted of 76 urban and 74 rural participants.

No statistically significant difference in locality was observed between the two groups (p = 0.081).

Table 3: Distribution According to Locality

Locality	Atorvastatin n (%)	Rosuvastatin n (%)	p-value
Urban	101 (67.3)	76 (50.7)	
Rural	49 (32.7)	74 (49.3)	0.081

Dietary Habits: Among the study participants, 142 (47.3%) followed a vegetarian diet, whereas 158 (52.7%) consumed a non-vegetarian diet. The atorvastatin group included 74 vegetarians and 76 non-vegetarians, while the rosuvastatin group included 68 vegetarians and 82 non-vegetarians.

Dietary habits were comparable between the two groups, with no statistically significant difference (p = 0.702).

Table 4: Dietary Habits of Participants

Diet	Atorvastatin n (%)	Rosuvastatin n (%)	p-value
Vegetarian	74 (49.3)	68 (45.3)	
Non-vegetarian	76 (50.7)	82 (54.7)	0.702

Body Mass Index (BMI): The mean body mass index (BMI) of participants was comparable between the atorvastatin and rosuvastatin groups at baseline. The majority of patients were either overweight or obese, reflecting the close association between increased body weight and dyslipidemia. No statistically significant difference in BMI was observed between the treatment groups

at enrolment, indicating comparable baseline anthropometric characteristics.

Smoking Status: A proportion of study participants reported current or previous smoking. The distribution of smokers and non-smokers was similar in both treatment groups, with no statistically significant difference at baseline. Smoking status was considered an important cardiovascular risk factor during patient assessment.

Alcohol Consumption: History of alcohol consumption was recorded for all participants. Most patients were non-alcoholic, while a smaller proportion reported occasional alcohol intake. The prevalence of alcohol consumption did not differ significantly between the atorvastatin and rosuvastatin groups.

Educational Status: Participants represented different educational backgrounds ranging from illiterate individuals to graduates and postgraduates. Educational status was comparable between treatment groups and did not influence treatment allocation.

Socioeconomic Status: The majority of enrolled patients belonged to the middle socioeconomic class, followed by lower and upper socioeconomic groups. Distribution across socioeconomic categories was similar in both treatment arms without statistically significant differences.

Family History

A positive family history of dyslipidemia, diabetes mellitus, hypertension, or cardiovascular disease was documented in a proportion of participants. Family history was evenly distributed between both groups, indicating comparable inherited cardiovascular risk.

Baseline Comorbidities: Hypertension and type 2 diabetes mellitus were the most common associated comorbid conditions observed among study participants. Several patients presented with isolated dyslipidemia, whereas others had dyslipidemia associated with hypertension, diabetes mellitus, or both. The distribution of these clinical conditions was comparable between the atorvastatin and rosuvastatin groups at baseline, confirming homogeneity of the study population before initiation of statin therapy.

Summary of Baseline Characteristics: The atorvastatin and rosuvastatin groups were well matched with respect to age, gender, place of residence, and dietary habits. None of the baseline demographic variables showed statistically significant differences between the treatment groups ($p > 0.05$), indicating that the two cohorts were comparable before initiation of statin therapy.

Comparative Changes in Lipid Profile

Total Cholesterol: At baseline, the mean total cholesterol (TC) levels were comparable between the atorvastatin and rosuvastatin groups (216.11 ± 24.47 mg/dL vs. 218.90 ± 24.13 mg/dL; $p = 0.549$). Both treatment groups demonstrated a progressive reduction in TC throughout the 12-month follow-up. However, intergroup comparisons at each follow-up visit showed no statistically significant differences ($p > 0.05$), indicating that both statins were equally effective in lowering total cholesterol concentrations over time.

Table 5: Comparative Evaluation of Mean Total Cholesterol

Visit	Atorvastatin (mg/dL)	Rosuvastatin (mg/dL)	p value
Baseline	216.11 ± 24.47	218.90 ± 24.13	0.549
1 Month	190.18 ± 20.65	186.48 ± 21.62	0.372
3 Months	176.14 ± 21.71	173.56 ± 18.05	0.510
6 Months	162.88 ± 19.15	162.28 ± 16.47	0.863
9 Months	156.45 ± 17.82	155.53 ± 15.66	0.780
12 Months	153.53 ± 17.97	151.07 ± 15.20	0.451

Triglycerides: Mean triglyceride (TG) values decreased progressively in both treatment groups. Baseline TG values were similar ($p = 0.552$). No significant difference was observed between groups up to six months.

However, rosuvastatin demonstrated significantly greater triglyceride reduction at 9 months ($p = 0.0327$) and 12 months ($p = 0.0391$), suggesting superior long-term efficacy compared with atorvastatin.

Low-Density Lipoprotein Cholesterol (LDL-C): Baseline LDL-C values were comparable between the two groups ($p = 0.792$). Both statins significantly reduced LDL-C during follow-up.

However, rosuvastatin produced significantly greater LDL-C reduction beginning at one month ($p < 0.001$), and this superiority persisted throughout the study. Highly significant differences were observed at 1 month and 6 months ($p < 0.001$), while significant differences remained at 3 months ($p = 0.007$), 9 months ($p = 0.032$), and 12 months ($p = 0.018$). These findings indicate that rosuvastatin was more effective than atorvastatin in lowering LDL-C over the study period.

Table 6: Comparative Evaluation of Mean LDL-C

Visit	Atorvastatin	Rosuvastatin	p value
Baseline	127.21 ± 13.51	126.49 ± 14.22	0.792
1 Month	106.47 ± 11.75	98.38 ± 10.79	<0.001
3 Months	90.72 ± 9.62	85.63 ± 9.49	0.007
6 Months	82.62 ± 8.76	76.33 ± 8.35	<0.001
9 Months	77.92 ± 8.28	73.42 ± 8.53	0.032
12 Months	74.37 ± 7.75	70.75 ± 7.70	0.018

High-Density Lipoprotein Cholesterol (HDL-C): HDL-C levels increased steadily in both treatment groups during follow-up. Baseline HDL-C values were comparable ($p = 0.634$), and no statistically significant difference was observed up to six months. However, rosuvastatin produced a significantly greater increase in HDL-C at 9 months ($p = 0.0366$) and 12 months ($p = 0.0245$), indicating superior improvement in cardioprotective HDL-C levels.

Safety Assessment

Adverse Drug Reactions: A total of 68 adverse drug reactions were documented during the study, comprising 41 events in the atorvastatin group and 27 events in the rosuvastatin group.

Gastrointestinal adverse effects—including diarrhoea, flatulence, constipation, abdominal pain, and nausea—were the most frequently reported reactions in both groups. Asthenia and mild musculoskeletal complaints such as myalgia and arthralgia were also observed.

No cases of myopathy, myositis, or rhabdomyolysis occurred during the study. Five patients receiving atorvastatin discontinued treatment because of arthralgia and asthenia, whereas only one patient receiving rosuvastatin discontinued therapy due to headache. Overall, rosuvastatin demonstrated a more favourable tolerability profile than atorvastatin.

Liver Function: Mean serum SGPT values remained stable throughout the study in both treatment groups. Although a marginal increase in SGPT was observed during follow-up, intergroup comparisons revealed no statistically significant differences at baseline or at any follow-up visit ($p > 0.05$). These findings indicate that both atorvastatin and rosuvastatin were well tolerated without clinically significant hepatotoxicity.

Glycaemic Control: HbA1c values were comparable at baseline ($p = 0.459$). During follow-up, a gradual increase in HbA1c was observed in both treatment groups. Statistically significant differences emerged by three months ($p = 0.0356$) and became highly significant at six months and twelve months ($p < 0.001$). Rosuvastatin was associated with a greater increase in HbA1c than atorvastatin, suggesting a more pronounced effect on glycaemic indices during long-term therapy.

Serum Uric Acid: Serum uric acid concentrations were comparable at baseline. During follow-up, both treatment groups demonstrated changes in serum uric acid levels; however, rosuvastatin showed a greater increase over time, with statistically significant differences becoming evident during later follow-up visits.

Overall Findings: Both atorvastatin and rosuvastatin produced significant improvements in lipid profile over the 12-month study period. Rosuvastatin demonstrated significantly greater reductions in LDL-C and triglyceride concentrations, together with a more pronounced increase in HDL-C during long-term follow-up. Total cholesterol reduction was comparable between the two treatment groups. Both statins exhibited favourable safety profiles with no clinically significant hepatic toxicity or serious muscle-related adverse events. Although rosuvastatin showed superior lipid-lowering efficacy, it was associated with a relatively greater increase in HbA1c during follow-up.

Renal Function Assessment

Blood Urea: Mean blood urea values remained within the normal physiological range throughout the study period in both treatment groups.

No statistically significant changes were observed either within or between the atorvastatin and rosuvastatin groups during follow-up, indicating that neither statin adversely affected renal function.

Serum Creatinine: Baseline serum creatinine values were comparable between the two treatment groups. Serial measurements during follow-up demonstrated no clinically or statistically significant increase in serum creatinine concentrations. These findings suggest preservation of renal function during long-term statin therapy.

Hepatic Safety: In addition to SGPT evaluation, serial liver function monitoring revealed no clinically significant hepatic dysfunction during treatment. Mild fluctuations in liver enzyme values remained within acceptable limits and did not necessitate discontinuation of therapy. No participant developed clinically significant drug-induced liver injury during the study period.

Treatment Compliance: Patient compliance with prescribed statin therapy remained satisfactory throughout the study period.

Regular follow-up visits, patient counselling regarding lifestyle modification, and reinforcement of medication adherence contributed to the high completion rate of the study. Of the 300 enrolled participants, 291 (97.0%) successfully completed the 12-month follow-up schedule.

Study Withdrawals: Nine participants did not complete the study. Five patients receiving atorvastatin and four patients receiving rosuvastatin were lost during follow-up. The principal reasons for withdrawal included loss to follow-up and treatment discontinuation secondary to adverse events. Arthralgia and asthenia accounted for most discontinuations in the atorvastatin group, whereas headache was responsible for one withdrawal in the rosuvastatin group. Overall, the withdrawal rate remained low and did not materially affect study outcomes.

Summary of Major Findings: The present prospective comparative study demonstrated that both atorvastatin and rosuvastatin produced significant improvement in lipid parameters over a 12-month treatment period. Total cholesterol decreased substantially with both agents without a statistically significant difference between groups. Rosuvastatin, however, achieved significantly greater reductions in LDL cholesterol from the first month onwards and maintained this superiority throughout follow-up. Significant improvement in HDL cholesterol became evident after nine months in the rosuvastatin group, while triglyceride reduction was also greater during later follow-up visits.

Both statins were generally safe and well tolerated. Gastrointestinal adverse events were the most frequently reported reactions, followed by asthenia and mild musculoskeletal complaints. No cases of rhabdomyolysis, myositis, or clinically significant hepatotoxicity were observed. Liver and renal function remained stable throughout the study. Although both drugs were associated with a modest increase in HbA1c, the increase was more pronounced among patients receiving rosuvastatin. Overall treatment compliance was excellent, with 97% of enrolled patients completing the study, supporting the effectiveness and tolerability of long-term statin therapy in routine clinical practice.

Discussion

The present prospective observational study compared the efficacy, safety, and tolerability of rosuvastatin and atorvastatin in the management of dyslipidemia among patients attending a tertiary care teaching hospital. A total of 300 patients were enrolled, of whom 291 completed the 12-month follow-up. Both statins produced significant improvements in lipid parameters during the study period and were generally well tolerated. However, rosuvastatin demonstrated superior efficacy in reducing low-density lipoprotein cholesterol (LDL-C), improving high-density lipoprotein cholesterol (HDL-C), and reducing triglyceride (TG) levels during long-term follow-up[10–12,21].

The baseline demographic and clinical characteristics of participants were comparable between the two treatment groups, with no statistically significant differences in age, gender distribution, dietary habits, place of residence, or associated cardiovascular risk factors. This baseline comparability minimized selection bias and strengthened the validity of the comparative analysis. The predominance of middle-aged individuals observed in the present study is consistent with the increasing prevalence of dyslipidemia among adults with sedentary lifestyles, obesity, diabetes mellitus, and hypertension [2–4,19,20].

Both atorvastatin and rosuvastatin significantly reduced total cholesterol concentrations throughout the study period. Although rosuvastatin demonstrated numerically greater reductions, the difference between the two treatment groups was not statistically significant at any follow-up visit. These findings suggest that both statins are equally effective in lowering total cholesterol when administered at clinically recommended doses. Similar observations have been reported in previous comparative studies evaluating intensive statin therapy [7–10,21].

Low-density lipoprotein cholesterol remains the primary therapeutic target in dyslipidemia management because of its well-established role in the development of atherosclerosis and cardiovascular disease [1,2,15]. In the present study, rosuvastatin produced significantly greater reductions in LDL-C beginning from the first month of therapy, and this superiority persisted throughout the 12-month follow-up period. The difference was highly significant at one month and six months and remained statistically significant thereafter. These findings are consistent with the greater inhibitory potency of rosuvastatin against HMG-CoA reductase and its higher affinity for hepatic LDL receptors, resulting in enhanced clearance of circulating LDL particles [24–27]. Similar observations have been reported in major comparative trials, including the STELLAR study, which demonstrated superior LDL-C lowering with rosuvastatin across equivalent dose ranges [10,21].

Triglyceride concentrations declined progressively in both treatment groups. Although no significant differences were observed during the initial six months, rosuvastatin demonstrated significantly

greater reductions at nine and twelve months. This suggests that prolonged therapy with rosuvastatin may provide additional benefits in patients with mixed dyslipidemia or elevated triglyceride levels. These findings are consistent with previous reports evaluating high-potency statins in patients with mixed dyslipidemia [10,12,21].

High-density lipoprotein cholesterol plays a protective role against atherosclerosis through reverse cholesterol transport and anti-inflammatory mechanisms [15–17]. Both statins increased HDL-C during follow-up; however, rosuvastatin produced a significantly greater increase after nine months of therapy. Similar findings have been reported in comparative clinical trials where rosuvastatin consistently demonstrated modest but significant superiority over atorvastatin in increasing HDL-C concentrations [10,12,21].

Safety evaluation demonstrated that both statins were generally well tolerated throughout the study period. Gastrointestinal adverse effects, including diarrhoea, constipation, abdominal discomfort, flatulence, and nausea, constituted the most frequently reported adverse events. Mild musculoskeletal complaints such as myalgia and arthralgia were observed in a small proportion of participants, but no patient developed myopathy, myositis, or rhabdomyolysis. The overall incidence of adverse drug reactions was lower in the rosuvastatin group than in the atorvastatin group, indicating a slightly more favourable tolerability profile. These observations are consistent with the established safety profiles of statins reported in large randomized clinical trials and meta-analyses [7–14,21].

Monitoring of hepatic function showed no clinically significant elevation in serum transaminases during treatment. Although small increases in SGPT were observed in both groups, these changes remained within acceptable clinical limits and did not require discontinuation of therapy. Similarly, renal function parameters remained stable throughout follow-up, confirming that both statins were safe for long-term use in the study population [1,2,18,19].

An important observation of the present study was the gradual increase in HbA1c values during follow-up, with a comparatively greater increase among patients receiving rosuvastatin. While both statins were associated with modest deterioration in glycaemic indices, the overall cardiovascular benefits of statin therapy substantially outweigh the relatively small increase in diabetes risk [1,20]. These findings are supported by large meta-analyses demonstrating that the reduction in cardiovascular events with statins exceeds the modest increase in incident diabetes [13,14]. Nevertheless, periodic monitoring of blood glucose and HbA1c should be considered in patients receiving long-term, high-intensity statin therapy, particularly those with pre-existing diabetes mellitus or impaired glucose tolerance [20].

Treatment adherence remained excellent throughout the study, with approximately 97% of enrolled participants completing the 12-month follow-up. The low dropout rate reflects effective patient counselling, regular follow-up, and good tolerability of both medications. High adherence strengthens the reliability of the observed treatment outcomes and enhances the external validity of the study [18,19].

The present study possesses several strengths. It was conducted prospectively under routine clinical practice conditions, included a relatively large sample size, and evaluated both efficacy and safety outcomes over a one-year follow-up period. Furthermore, assessment of biochemical parameters, adverse drug reactions, and treatment compliance provided a comprehensive evaluation of statin therapy in patients with dyslipidemia.

However, certain limitations should be acknowledged. The study was conducted at a single tertiary care centre, which may limit generalizability to other healthcare settings. The observational study design precludes complete elimination of residual confounding and treatment selection bias. In addition, long-term cardiovascular outcomes such as myocardial infarction, stroke, hospitalization, and mortality were not evaluated. Future multicentre randomized controlled trials with longer follow-up durations are warranted to validate these findings and assess the long-term cardiovascular benefits of different statin therapies in the Indian population [1–3,19,21].

Overall, the findings of the present study demonstrate that both atorvastatin and rosuvastatin are effective lipid-lowering agents for the management of dyslipidemia.

Rosuvastatin, however, showed superior efficacy in reducing LDL-C and triglyceride levels and in increasing HDL-C while maintaining a favourable safety profile. These findings support the preferential use of rosuvastatin in patients requiring intensive lipid lowering to achieve recommended therapeutic targets, provided that glycaemic parameters are monitored during long-term treatment [1–3,10,20,21].

Conclusion

The present prospective observational study demonstrated that both atorvastatin and rosuvastatin are effective and well-tolerated statins for the treatment of dyslipidemia in patients attending a tertiary care hospital.

Significant improvements in lipid parameters were observed with both treatment regimens over the 12-month follow-up period.

Rosuvastatin showed superior efficacy in reducing low-density lipoprotein cholesterol (LDL-C) and triglyceride levels and produced a greater increase in high-density lipoprotein cholesterol (HDL-C) compared with atorvastatin. Reduction in total cholesterol was comparable between the two treatment groups. Both statins exhibited favourable safety profiles, with only mild adverse drug reactions and no clinically significant hepatic or renal toxicity during follow-up.

Although a modest increase in HbA1c was observed in both treatment groups, the increase was more pronounced among patients receiving rosuvastatin. Therefore, periodic monitoring of glycaemic parameters should be considered in patients receiving long-term statin therapy, particularly those with diabetes mellitus or individuals at high risk of developing diabetes.

Overall, the findings of the present study suggest that rosuvastatin may be preferred when intensive lipid lowering is required to achieve recommended therapeutic targets. Nevertheless, individualized treatment decisions should consider patient-specific cardiovascular risk factors, associated comorbidities, safety profile, treatment adherence, and cost-effectiveness.

Strengths of the Study

- Prospective observational design reflecting routine clinical practice.
- Relatively large sample size comprising 300 enrolled participants.
- Twelve-month follow-up allowing assessment of both efficacy and safety.
- Comprehensive evaluation of lipid profile, glycaemic status, liver function, renal function, adverse drug reactions, and treatment adherence.
- Inclusion of patients with dyslipidemia alone as well as those with associated hypertension and type 2 diabetes mellitus.

Limitations of the Study

- Single-centre study conducted at a tertiary care teaching hospital.
- Observational design without blinded treatment allocation.
- Lack of long-term cardiovascular outcome assessment, including myocardial infarction, stroke, cardiovascular mortality, and all-cause mortality.
- Lifestyle factors, dietary adherence, and physical activity were not quantitatively assessed during follow-up.
- Findings may not be generalizable to all populations because the study was conducted at a single institution.

Clinical Implications: The findings support the continued use of statins as first-line therapy for dyslipidemia. Rosuvastatin demonstrated greater LDL-C reduction and superior overall lipid control while maintaining an acceptable safety profile. These results may assist clinicians in selecting appropriate statin therapy for patients requiring intensive lipid lowering, particularly those at high cardiovascular risk. Regular monitoring of blood glucose and HbA1c should be considered during prolonged treatment with high-potency statins.

Future Recommendations: Future multicentre randomized controlled trials with larger sample sizes and longer follow-up periods are required to confirm these findings. Further studies evaluating cardiovascular outcomes, pharmacoeconomic aspects, patient-reported outcomes, quality of life, and pharmacogenomic predictors of statin response in the Indian population would provide additional evidence for individualized treatment strategies.

Ethical Approval: The study was conducted after obtaining approval from the Institutional Ethics Committee of Hamdard Institute of Medical Sciences and Research (HIMSR) and Hakeem Abdul Hameed Centenary Hospital (HAHC), Jamia Hamdard, New Delhi. Written informed consent was obtained from all participants prior to enrolment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

(Institutional Ethics Committee approval number -00265)

Informed Consent: Written informed consent was obtained from all participants before inclusion in the study.

Author Contributions

Dr. Riputa Shourie: Conceptualization, study design, patient recruitment, data collection, data analysis, interpretation of results, manuscript preparation, and final manuscript review.

Dr. Tanveer Ahmad Khan: Study supervision, methodology, critical revision of the manuscript, and final approval.

Dr. Shreshth Khanna: Study design, data interpretation, manuscript editing, and critical review.

Dr. Mohammad Anwar Habib: Patient recruitment, clinical supervision, patient management, and manuscript review.

Dr. Nadisha Oberoi: Data validation, literature review, manuscript editing, and final review.

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Data Availability Statement: The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

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