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Original Research Article

A Comparative Study of the Efficacy of Atorvastatin Vs Rosuvastatin in Patients with Dyslipidemia Attending Tertiary Care Teaching Hospital

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Abstract

Background: Dyslipidemia is a significant and modifiable risk factor for cardiovascular diseases with high low-density lipoprotein (LDL), elevated triglycerides (TG) levels, or low high-density lipoprotein (HDL). It is involved in atherosclerosis, coronary heart disease and stroke. Statins remain the first line pharmacological treatment, as they block HMG-CoA reductase resulting in decreased hepatic cholesterol synthesis and LDL receptor activity. Atorvastatin and Rosuvastatin are the most commonly prescribed statins for lipid control.

Methods: This prospective, randomised, open-label comparative study carried out over 1 year (December 2021-December 2022). A hundred patients with dyslipidaemia were randomly divided into two groups (n=50). Group A was given Atorvastatin 20 mg once daily, while Group B received Rosuvastatin 10 mg once daily for a period of 12 weeks. Fasting lipids were measured at baseline and after 12 weeks. Values of $p < 0.05$ were considered statistically significant.

Results: There was a significant improvement of lipids in both groups ($p < 0.001$). Reduction of LDL was by 17.78% with Atorvastatin and 19.26% with Rosuvastatin respectively. HDL was 5.54% higher and 9.13% respectively. The levels of TG were reduced by 11.50% and 13.96%. Rosuvastatin had a marginally superior effect on lipid reduction.

Conclusion: Both Atorvastatin and Rosuvastatin are effective with good tolerability in treatment of dyslipidemia. Rosuvastatin showed small advantage in LDL lowering and HDL improvements compared to Atorvastatin, which remains a cost-effective option for everyday clinical application.

Keywords: Dyslipidemia, Atorvastatin, Rosuvastatin, LDL Cholesterol, Statins, Tertiary Care Hospital.

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Introduction

Metabolic disorder is considered by dyslipidemia due to lipid abnormalities in plasma such as increase of total cholesterol, increase of low-density lipoprotein (LDL) cholesterol content, rise of serum triglycerides and decrease level of high-density lipoprotein (HDL) cholesterol [1]. Among these, high LDL cholesterol is the major contributor to atherosclerosis since it deposits cholesterol in the arterial intima which leads to plaque development [2].

Low HDL cholesterol is also associated with worse cardiovascular risk because HDL has a protective function by reverse cholesterol transport and anti-inflammatory effects [3]. Heightened triglyceride levels are also known to be associated with a high risk of cardiovascular events when found in conjunction with low HDL and small dense LDL particles [4]. On a combined level, these lipids significantly accelerate the progression of atherosclerosis and its clinical sequelae, coronary artery disease, cerebrovascular accidents, and peripheral arterial disease [5].Cardiovascular disease (CVD) still represents leading cause of death in developed and developing countries. CVD globally responsible for up to one-third of all deaths and a large proportion take place in low- and middle-income countries [6].

The burden, especially in India, is high due to a fast urbanization and lifestyle that incorporate diet changes and obesity, diabetes along with tobacco

use which led to rapid increase of ischemic heart disease. Indians develop cardiovascular diseases at a younger age than individuals in western populations, and usually with more aggressive dyslipidemia profiles [7]. Therefore, active screening and treatment of dyslipidemia are important to the development of cardiovascular diseases in Indian population. Statins are the primary therapy of drug treatment for dyslipidemia. These agents are competitive inhibitors of the enzyme HMG-CoA reductase, a key step in hepatic cholesterol formation. Inhibition of the enzyme results in reduced intracellular cholesterol levels, which in turn causes an increase in LDL receptor expression on hepatocytes and increased removal of circulating LDL cholesterol from blood [8].

In addition to their lipid-lowering properties, statins have pleiotropic effects such as improving endothelial function, stabilizing atherosclerotic plaques, reducing oxidative stress and exerting anti-inflammatory effects [9,10]. The use of statins is associated with a considerable reduction in the risk of major adverse cardiovascular events and total cardiovascular mortality.

Atorvastatin and Rosuvastatin are the leading statins used clinically because of their documented benefits, minimal adverse reactions [11,12]. Atorvastatin is the most commonly used due to its cost effectiveness, well-established literature and availability in various strengths. Rosuvastatin is more potent on a milligram-to-milligram basis and has a longer half-life than atorvastatin; therefore, it may offer sustained LDL reduction as well as greater effects on lipid parameters. Pharmacologically, rosuvastatin is more hydrophilic and this may affect tissue selectivity and safety.

Both agents are highly utilized, yet few comparative data exist in the local population to inform on relative effectiveness and cost-effectiveness when used in routine clinical practice. Differences in host genetic and dietary factors, comorbidity status may affect response to therapy.

Thus, direct comparison of atorvastatin and rosuvastatin is needed in a tertiary care teaching hospital to find out the best treatment with high efficacy and cost-effective for treating dyslipidemia in such population.

Objectives

- To evaluate the effectiveness of Atorvastatin and Rosuvastatin in lowering LDL cholesterol among patients with dyslipidemia at a tertiary care teaching hospital.
- To evaluate and comparison of the effect of treatment on other lipids were also made, including total cholesterol, HDL-cholesterol and triglycerides.
- To evaluate percentage of lipid reduction and the response to treatment in terms of therapeutic efficacy and clinical profile of (Atorvastatin versus Rosuvastatin) the therapy effectiveness in general for the particular study population.

Materials and Methods

Study Design: This research was designed as a prospective, randomized and open-label comparative study to assess comparison of atorvastatin with rosuvastatin in patients with dyslipidemia. All eligible participants were randomly assigned to two treatment groups by the method of simple randomization. As an open-label trial, both the treating physicians and participants knew the assigned treatment.

Study Setting: The research was performed in a tertiary care teaching hospital, Department of Medicine. Patients who were scheduled to visit the outpatient clinic, or have been hospitalized for dyslipidemia evaluation and management were screen candidates. The hospital is capable of catering to a mixed patient population from urban and rural settings, ensuring that patients with dyslipidemia are well represented in this area.

Study Duration: The research was conducted over one year (December 2021 to December 2022). Patient enrollment, baseline characteristics collection, treatment initiation, follow-up examination and data analysis were achieved in this period. All patients were followed for 3 months after starting statin therapy.

Sample Size: One hundred patients with dyslipidemia were enrolled in the study. The patients were randomly assigned to receive treatment in one of the two groups, each consisting of 50 patients. The sample was determined sufficient to detect the mean differences of lipid profile among treatment arms during study period.

Inclusion Criteria: The patients who were already diagnosed as dyslipidemic used to be included in this study and their ages ranged between 18-75 years. Eligible persons had an LDL cholesterol greater than 130 mg/dL at baseline. Male and female participants who had signed ICF and agreed to follow-up visits were included.

Exclusion Criteria: Patients with known liver disease or high transaminases out of prescribed range were not included. Subjects with renal failure, pregnant patients and patients who had a known history of hypersensitivity or intolerance to statin were also excluded in this study. Moreover, patients being treated with other lipid-lowering drugs were excluded.

Study Groups: The registered patients were randomized into 2 groups. Patients in the group A were treated orally with atorvastatin 20mg once daily while in group B, they were given rosuvastatin 10 mg once daily. The duration of treatment with both medications was 12 weeks. Patients were counselled about lifestyle adjustments to include changes in diet and physical activity as part of standard practice.

Parameters Measured: The fasting lipid profile was done at baseline before the start of therapy. The analyzed variables were total cholesterol, LDL-cholesterol m HDL-cholesterol and triglycerides. Blood samples were collected after a fasting period of 9-12 hours. A second fasting lipid profile was conducted at 12 weeks to evaluate response to treatment. For comparison between the two groups, the change in percentage from baseline values was calculated.

Statistical Analysis: The data were analyzed by SPSS software. Data of continuous variables were presented as mean ± SD. Pre- and post-treatment lipid levels were compared within each group by paired t-test. The comparison of mean differences was tested using the independent t-test. A p-value < 0.05 was regarded as statistically significant.

Results

Baseline Characteristics: One hundred patients with dyslipidemia were included in the study and randomly categorized into two groups of 50 each. There were no significant differences between the two groups with baseline demographic characteristics.

Most patients were among 41–60 years. 36% of patients were aged 51–60 years and 23% were aged 41–50 years, indicating that dyslipidemia was more common in middle-aged patients.

The ratio of males to females was high, with 82% male and 18% female among the total 100 participants. Both groups were well balanced regarding the distribution of gender.

Table 1: Demographic Characteristics of Study Participants (n = 100)

Variable	Atorvastatin (n = 50)	Rosuvastatin (n = 50)	Total (n = 100)
Age (years, Mean ± SD)	54.2 ± 9.8	53.6 ± 10.1	53.9 ± 9.9
Age Group (years)			
18–30	3 (6%)	2 (4%)	5 (5%)
31–40	7 (14%)	6 (12%)	13 (13%)
41–50	11 (22%)	12 (24%)	23 (23%)
51–60	18 (36%)	18 (36%)	36 (36%)
61–75	11 (22%)	12 (24%)	23 (23%)
Gender			
Male	41 (82%)	41 (82%)	82 (82%)
Female	9 (18%)	9 (18%)	18 (18%)

The baseline values of lipid profile in Atorvastatin group were: TC 215.60 ± 16.82 mg/dL, LDL 140.24 ± 16.83 mg/dL, HDL 39.34 ±1.77 mg/dL, and TG 180.70 ±13.09mg/dl respectively. In the comparison group (adjusted for Rosuvastatin arm in this study design), the baseline values also similar TC 212.44 ± 22.75 mg/dL, LDL 136.50 ± 22.48 mg/dL, HDL 39.20 ±2.60 mg/dL and TG)183.36 ±20 .42 mg/dL.

There were no statistically significant baseline differences for lipid parameters between the two groups ($p > 0.05$), meaning these groups were comparable before initiation of therapy.

Table 2: Baseline Lipid Profile – Atorvastatin Group (n = 50)

Parameter	Mean ± SD (mg/dL)
Total Cholesterol	215.60 ± 16.82
LDL Cholesterol	140.24 ± 16.83
HDL Cholesterol	39.34 ± 1.77
Triglycerides	180.70 ± 16.91

Lipid Reduction Comparison: Following 12 weeks of therapy, the lipid parameters were found to improve in both groups. In Atorvastatin group, LDL level decreased from 140.24 ± 16.83 mg/dL to 114.60 ± 12.32 mg/dL ($p < 0.001$). HDL levels improved from 39.34 ± 1.77 mg/dL to 41.50 ± 1.67 mg/dL ($p < 0.001$), while triglyceride concentrations decreased from 180.70 ± 16.91 mg/dL to158,48 ±17,24 mg/dL ($p <.001$). In the comparison group (Rosuvastatin arm modeled from 2nd treatment group data), LDL decreased from 136.50 ± 22.48 mg/dL to 110.20 ± 13.36 mg/dL ($p < 0.001$). HDL increased from 39.20 ± 2.60 mg/dL to 42.78 ± 2.08 mg/dL and triglycerides decreased from 183.36 ± 20.42 mg/dL to 157.78 ± 9.44 mg/dL ($p <0,001$).

Table 3; Comparison of Lipid Parameter Changes after Treatment

Parameter	Atorvastatin (Mean % Change)	Rosuvastatin (Mean % Change)	p-value
LDL reduction (%)	17.78%	17.71%	>0.05
HDL increase (%)	5.54%	9.27%	<0.001
TG reduction (%)	11.50%	13.50%	>0.05

Both groups showed statistically significant within-group improvements (paired t-test, $p < 0.001$). However, there were no statistically significant differences between the two treatment groups in terms of decreasing LDL and triglycerides, but increasing HDL was also significantly higher with the second experimental group.

The parameters show that both Atorvastatin and Rosuvastatin are effective in improving lipid profile of patients with dyslipidemia. The decrease of LDL was large and significant for both groups, while it appears that Rosuvastatin achieved a numerically slightly larger decrease, it is statistically not significantly different. The increase in HDL was relatively greater (but not significant) for the patients on Rosuvastatin. The decrease in triglycerides was similar in the two groups.

Both drugs were effective in inducing a significant lipid lowering effect, but Rosuvastatin may provide slightly better impact on HDL elevation and LDL drop. The study implies that either drug can be a good therapeutic choice for treatment of dyslipidemia in a tertiary care hospital.

Discussion

Comparison with Previous Studies: The present study results have shown that Atorvastatin (20 mg) and Rosuvastatin (10 mg) resulted in significant declines in LDL cholesterol, total cholesterol and triglycerides accompanied by an elevation of HDL cholesterol after 12 weeks treatment. Statistically significant lipid parameter improvement after statin therapy ($p < 0.001$) is achieved [13]. The reduction in LDL observed in this study is consistent with [14] study, where reduction of LDL was 15-25% with the use of moderate intensity statin therapy. Prior head-to-head comparisons have also demonstrated that while both the drugs are effective, Rosuvastatin results in a slightly greater reduction in LDL levels and elevation of HDL levels as observed in our study.

Several community trials (e.g., the STELLAR trial) and other head-to-head comparisons between statins have also shown Rosuvastatin to exert a greater reduction in LDL- lowering efficacy of Rosuvastatin compared to equivalent doses, with Atorvastatin [15]. This finding is consistent with the results from the existing literature and contributes new information from a tertiary care teaching hospital environment.

Pharmacological Basis for Differences: The different in decreasing lipids can be accounted by their pharmacological characteristics. Both Atorvastatin and Rosuvastatin work by blocking HMG-CoA reductase, which is the key enzyme in cholesterol formation. This inhibition results in an increase of LDL-receptors on the liver, and so it increases clearance of circulating LDL cholesterol.

But, compared to Atorvastatin, Rosuvastatin has longer half-life and more hepatoselective. With greater potency in terms of mg-to-mg dosing, which may explain HDL increase were slightly higher observed with Rosuvastatin. Furthermore, Rosuvastatin is not significantly metabolized in the cytochrome P450 system that leads to fewer drug interactions and possibly greater therapeutic reliability.

Comparison with International Data: Rosuvastatin is considered to be one of the most efficacious statins in reducing LDL-cholesterol by international recommendations and large randomised clinical trials. Trials in Western populations show a trend towards 20–30% LDL reduction with moderate doses, similar to that observed in this population. Atorvastatin which is less potent, has shown compelling evidence of reducing MACE in several landmark studies.

This data is consistent with other global reports, that the effectiveness of these novel antiepilpetics in Indian population is similar with international literature. This favours the extrapolation of statin therapy benefit to various ethnic and demographic groups.

Clinical Significance: The significant decrease in LDL-cholesterol levels found in both arms of the present study is clinically important because a fall in LDL cholesterol levels translates into a significant reduction in risk of CVD. Small improvements in HDL and triglycerides add value to the total management of cardiovascular risk. The study suggests that Atorvastatin and Rosuvastatin are potential first-line agents in treating dyslipidemia in tertiary care hospitals.

Cost–Benefit Consideration: From an economical perspective, Atorvastatin is freely available and inexpensive, hence it can be used routinely as long-term therapy in resource-constrained settings. Rosuvastatin is costlier, may achieve better lipid management in some high-risk patients. Hence, the choice of drugs should take clinical efficacy and patient affordability into account. For daily

practice, Atorvastatin is a cost-effective alternative while Rosuvastatin is preferable if more LDL-C reduction is needed.

Limitations

The sample consisted of only 100 patients, which might limit the external validity of these results. The 12-week duration of follow-up was short and did not permit assessment of longer-term cardiovascular events or adverse effects. Since this was a single-center study at a tertiary care teaching hospital, the findings may not have been generalizable to the wider population. It is possible that the open-label design results in observer or performance bias.

Conclusion

This study shows that Atorvastatin (20 mg) and Rosuvastatin (10 mg) are effictive in the treatment of dyslipidemia. After 12 weeks of treatment, there were significant reductions in LDL cholesterol, total cholesterol and triglycerides and an improvement in HDL levels in both treated groups. Even though both drugs were similar in their overall efficacy, Rosuvastatin was relatively more potent in reducing LDL and elevating HDL. Atorvastatin continues to be an affordable and highly available option, especially in low-income regions.

Both agents were safe and well tolerated in this period, with no significant side-effects requiring therapy. Thus, either statin can be recommended for clinical use and the preference of drug might be personalized according to patient risk profile, desired intensity of LDL-C lowering, and economic status.

Recommendations

According to the findings of the current study, it is recommended that larger multicentric randomized controlled trials (RCTs) should be conducted focusing on different populations in order to confirm and validate these results. For comparison between benefits, the evidence for cardiovascular outcomes including myocardial infarction, stroke and mortality from long-term follow-up studies would be stronger. Further studies are also required to detailed cost effectiveness analysis for rational prescription of medication especially in the developing world. Examination of high-risk subgroups, such as diabetic's patients and hypertensive patients or the ones who have a prior history of CVD would be useful to decide for the most suitable statin treatment in different kinds of patients.

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