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Original Research Article

Clinical Effectiveness of Atorvastatin and Rosuvastatin in High-Risk Dyslipidemic Patients

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Abstract:

Background: Globally, coronary heart disease (CHD) is ranked as the leading cause of death in people. It is known that a number of risk factors, including smoking, being overweight, and hyperlipidemia, are linked to CHD. In this investigation, the effectiveness of rosuvastatin and atorvastatin in decreasing cholesterol in patients at high risk for dyslipidemia was compared.

Methods: 90 patients with high-risk dyslipidaemia who were identified using the international recommendations for the prevention of adult dyslipidaemia participated in this randomized, open-label study. These individuals were randomly assigned to receive either rosuvastatin (20 mg/day) or atorvastatin (20 mg/day), respectively, for a period of three months. The effectiveness of atorvastatin and rosuvastatin on the levels of LDL-C, HDL-C, total cholesterol (TC), and triglycerides (TG) was evaluated in both groups. Additionally, both groups' rates of meeting LDL-C or TC target values were evaluated.

Results: In comparison to Atorvastatin, Rosuvastatin significantly reduced LDL-C (43.2% and 38.1%, $p < 0.05$) and TC (34.8% Vs 28.1%, $p < 0.05$). Additionally, rosuvastatin group patients were more likely to reach the suggested goal TC and LDL-C values than atorvastatin group subjects were.

Rosuvastatin has more efficacy in lowering lipids than atorvastatin in people at high risk of hyperlipidemia.

Keywords: Rosuvastatin, Atorvastatin, Dyslipidaemia, High-density lipoprotein, Triglycerides.

Introduction

The leading cause of death among people worldwide is thought to be coronary heart disease (CHD)[1-2]. It results in more than 7 million fatalities worldwide just in 2014. Smoking, obesity, and hyperlipidemia are just a few of the risk factors that have been linked to coronary heart disease.[3-4] Numerous studies have shown that cholesterol-lowering medication is helpful for those with a high risk of developing coronary artery disease.[5-6]

Statins are cholesterol-lowering medications that can inhibit HMG-CoA reductase, stop cholesterol synthesis, and treat coronary artery disease in its early stages. A number of statins, such as atorvastatin, rosuvastatin, and simvastatin7, have been developed and are currently being used in clinical settings.

Because of its unique sulphur structure, rosuvastatin has less side effects than other statins. According to reports, rosuvastatin lowers the frequency of cardiovascular events. Numerous clinical studies have shown that rosuvastatin lowers cholesterol more effectively than other drugs in the statin class. Administration of rosuvastatin was substantially more effective than atorvastatin, pravastatin, and simvastatin at lowering total cholesterol in patients with hypercholesterolemia at all dose ranges (10-80 mg/day)[8-9].

According to a North American clinical trial, 10 mg of rosuvastatin is more effective than 10 mg of atorvastatin at helping people with hypercholesterolemia achieve the goal LDL-cholesterol levels set by the European Society of Atherosclerosis Society. Another prospective multicenter research conducted in Pakistan found that 2.5 mg/day of rosuvastatin and 10 mg/day of atorvastatin both appeared to decrease LDL-C with little adverse effects.[10] The superiority

of rosuvastatin over atorvastatin (10 mg/day) in high-risk patients of primary hypercholesterolemia and CHD was further verified by a clinical trial conducted in India, Bangladesh, and Nepal. [11-12] However, rosuvastatin's efficacy in high-risk people with dyslipidemia has not been extensively characterized in comparison to that of other comparator medications.[13] It is necessary to compare treatment responses in high-risk individuals with dyslipidemia given the impact of individual variability on drug response. In this investigation, the effectiveness of rosuvastatin and atorvastatin in decreasing cholesterol in patients at high risk for dyslipidemia was compared.

Materials and Methods

This prospective study was conducted at Department of Pharmacology, Nalanda Medical College, Patna, Bihar. Patients selected from Department of Medicine, NMCH, Patna, Bihar. Total 90 patients included with high-risk dyslipidaemia admitted to the Medicine department of NMCH, Patna, Bihar for six months duration from November 2022 to April 2023.

According to the criteria of the Adult Dyslipidaemia Prevention Guidelines, these patients met the following criteria: high-risk dyslipidaemia: LDL-C, 3.37-4.12 mmol / L, TC, 5.18-6.19 mmol / l; Risk factors ≥1 including age (female ≥55 years, male ≥45 years), HDL-C ≤1.04 mmol /L, smoking, obesity and early-onset family history of coronary heart disease. The following patients were not included: primary hypothyroidism, secondary hyperlipidemia, renal failure or nephritic syndrome; Type I or II diabetes mellitus without satisfactory glycemic control; active liver disease, ALT and AST more than twice the normal value; Creatine kinase (CK) increased ≥ three-fold of the upper limit of normal or unexplained; allergy or intolerance to statins; long-term use of steroid hormones or thiazide diuretics in combination with statins, which may increase the risk of rehabdomyolysis; uncontrolled severe hypertension; Taking other lipid-lowering medications other than the statins used in the study. The consent was signed by each patient enrolled prior to the commencement of the study.

The Guidelines for the Prevention of Adult Dyslipidaemia state that 5–10 mg of atorvastatin and 10 mg of rosuvastatin per day are the proper amounts to reduce LDL-C by 30–40%. For three months, 90 patients were randomly assigned to take either 20 mg/day of rosuvastatin (Crestor) or 20 mg/day of atorvastatin (Lipitor). Additionally, none of the individuals who were enrolled received any other prescriptions that would have affected how well the statins worked. After a 12-hour fast, venous blood samples were taken from each patient before and after therapy, respectively. HDL-C, LDL-C, TG, and TC were examined.

Standard deviation (SD) and median are two ways that quantitative data are expressed. For the purpose of comparing variances in quantitative data, the Student's t-test was used. The chi-square test was used to assess the qualitative data. The statistical analysis was performed using the SPSS 21.0 program. Significant difference was defined as $p < 0.05$.

Results

Table 1 displays the demographic information of the 90 participants in the atorvastatin and rosuvastatin groups. With regard to gender, age, diabetes, hypertension, smoking, and body mass index, there was a minor variation between the two groups. ($p > 0.05$).

Table 1: Demographic features of the patients in Atorvastatin and Rosuvastatin groups

Characteristic	Rosuvastatin group (n=47)	Atorvastatin group (n=43)	Total N=90 60.5±9.2	t-value/X^2	P-value
Age (years)	61.2±9.4	60±8.9		0.2	0.79
Male/Female [n (%)]	25 (53.2)/22 (46.8)	24(55.8)/19 (44.2)	49 (54.4)	0.11	0.72
Body weight index (kg/m^2)	25.1±2.8	24.4±3.1	24.8±2.9	<0.001	0.9
Hypertension [n (%)]	18 (38.3)	12 (27.9)	30 (33.3)	0.01	0.80
Diabetes [n (%)]	6 (12.8)	5 (11.6)	11 (12.2)	<0.001	0.8
Smoking [n (%)]	19 (40.4)	10 (23.3)	29 (32.2)	0.014	0.8

As shown in Table 2, there was a marginal difference in TG, TC, LDL-C, and HDL-C between the atorvastatin and rosuvastatin groups prior to treatment ($P > 0.05$). Twelve weeks after starting treatment, LDL-C fell in the atorvastatin and rosuvastatin groups by 43.2% and 38.1%, respectively. In both groups, there was a substantially different level of LDL-C reduction ($p < 0.05$).

Table 2: Serum lipid variations of Atorvastatin and Rosuvastatin groups

Parameters	Rosuvastatin group (n=47)			Atorvastatin group (n=43)			
	0 week	12 weeks	Change	0 week	12 weeks	Change	p-value
TC (mmol/L)	5.98±1.18	4.18±0.94	↓34.8	6.60±0.64	4.21±0.73	↓28.1	<0.05
LDL-C (mmol/L)	4.01±0.59	2.21±0.80	↓43.2	3. 88±0.50	2.37±0.81	↓38.1	<0.05
HDL-C (mmol/L)	1.34±0.49	1.57±0.51	↑5.9	1.41±0.60	1.37±0.46	↑4.8	>0.05
TG (mmol/L)	2.83±0.45	1.67±0.48	↓20.1	2.67±0.67	1.13±0.80	↓17.8	>0.05

Similar to this, TC fell considerably more in the rosuvastatin group compared to the atorvastatin group (34.8% Vs 28.1%, P <0.05). Additionally, 12-weeks after treatment, in both groups, HDL-C rose and TG fell in comparison to baseline. However, there was no discernible difference between the two groups in terms of the rate at which TG decreased or HDL-C rose (P > 0.05).

In the rosuvastatin group, a higher percentage of patients (51.1% vs. 32.6%, p> 0.05) met the suggested TC target than in the atorvastatin group (Table 3). The variations in LDL-C and TC success rates, however, were not statistically significant (P>0.05).

Table 3: Goal achievement rates of Atorvastatin and Rosuvastatin groups

Parameters	Rosuvastatingroup (n=47)	Atorvastatin group (n=43)	X^2	P-value
LDL-C	27(57.4%)	19(44.2%)	1.8	0.2
TC	24(51.1%)	14(32.6%)	1.5	0.21

When comparing the two groups' liver enzymes, creatinine, CK, and glucose levels before and after the 12-week therapy period, a small difference was found (P> 0.05). One patient using rosuvastatin experienced an increase in aspartate aminotransferase (AST) to 63 U/L, while two other patients had their AST rise to 63 U/L and their alanine aminotransferase (ALT) rise to 45 U/L.

Without a change in test medication, these anomalous elevations subsided within two weeks to revert to normal. Aside from that, only two patients in the atorvastatin group saw an elevation in AST to 45 U/L, which was afterwards brought back to normal with the help of the medication atorvastatin. During the research, both medications displayed comparable safety and tolerability.

Discussion

A member of the statin family of HMG-CoA reductase inhibitors is rosuvastatin. It significantly lowers cholesterol [14] and is quite effective. This study compared the lipid-lowering effects of atorvastatin and rosuvastatin in patients with high-risk hyperlipidemia in order to better understand the safety and efficacy of both drugs. According to the study, rosuvastatin 20 mg twice daily for 12 weeks reduced LDL-C more effectively than atorvastatin at the same dose. The results will support rosuvastatin's superiority over atorvastatin in patients with hyperlipidemia. Patients with high-risk hyperlipidemia have shown to benefit from LDL-C lowering medication, which lowers the risk of cardiovascular disease and improves patients' quality of life. The NCEP ATP III produced a set of recommendations for the management of blood cholesterol in 2014 based on the persuasive findings of a number of randomized, controlled studies with a large sample size.[16-17] The ATP III recommendations for managing cholesterol have received broad acceptance in both research and clinical trials. It was therefore acknowledged in this investigation as well. Another point of view contends that the rise of LDL-C should not be the main focus of ATP III cholesterol lowering medication in the absence of strong clinical evidence.

With a daily dose of 20 mg rosuvastatin for 12 weeks, the study found that LDL-C and TC decreased more effectively than with the same amount of atorvastatin.[18] Additionally, compared to the medicine atorvastatin, the drug rosuvastatin led to a larger proportion of patients achieving the suggested target LDL-C and TC values. According to our research, rosuvastatin was more tolerable by patients with high-risk dyslipidaemia than atorvastatin. These results were consistent with a prior trial, which discovered that rosuvastatin (10–40 mg) helped more patients attain LDL-C levels.[19-20]. There is proof that rosuvastatin (10 mg and 20 mg) helps 63.95% of Indian individuals with dyslipidemia attain their total ATP III cholesterol target. Based on clinical experience, either 10 mg atorvastatin or 20 mg rosuvastatin was utilized in this investigation. Similar to atorvastatin, rosuvastatin is sufficient to reduce LDL-C by 30–40%.[21-22]

The study is constrained. Your samples are relatively tiny, to start. The outcomes of the research should be expanded upon and validated by large-scale studies. Second, it should be highlighted that despite minor

variations in baseline information and demographics between the two groups, there was an imbalance in the number of treatment withdrawals, which could be a cause of bias between the atorvastatin and rosuvastatin groups.

Conclusion

Overall, rosuvastatin may decrease cholesterol more effectively than atorvastatin at the same dose in patients with high-risk hyperlipidemia and has a higher rate of success in TC and LDLC studies. The study offered more proof that rosuvastatin has better therapeutic efficacy than atorvastatin.

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