COMPARATIVE STUDY OF ATORVASTATIN V/S ROSUVASTATIN IN HYPERLIPIDAEMIA

Krishan Kumar Oberoi¹, Hardip Singh², Upasana Oberoi³, Priyanka⁴

¹Associate Professor, Department of Medicine, Government Medical College, Amritsar.

²Assistant Professor, Department of Medicine, Government Medical College, Amritsar.

³Lecturer, Department of Obstetrics and Gynaecology, Government Medical College, Amritsar.

⁴Junior Resident, Department of Medicine, Government Medical College, Amritsar.

ABSTRACT

BACKGROUND

Atherosclerosis of coronary arteries may manifest as myocardial infarction and angina pectoris and that of central nervous system as non-haemorrhagic cerebrovascular accidents and transient ischaemic attacks.

The objective of this study is to compare the efficacy of atorvastatin and rosuvastatin on various aspects of lipid profile, viz. serum total cholesterol, serum LDL-C, serum VLDL-C, serum HDL-C and serum triglycerides in Indian patients having dyslipidaemia in this part of country.

MATERIALS AND METHODS

This was a randomised open study conducted on patients with abnormal lipid profile attending the OPD/ wards of Department of Medicine, Guru Nanak Dev Hospital, attached to Government Medical College, Amritsar in the year 2006. Based on our previous year OPD and indoor patients' records, the total number of patients with dyslipidaemia was 165. Thinking that 100 patients would be achievable within 1 year, so a total of 100 patients were included in the study and the patients were divided randomly by lottery method into two groups of 50 patients each, Group A was put on Atorvastatin 20 mg daily and Group B was put on Rosuvastatin 20 mg daily. Out of total 100 patients, 50 (50%) were males and 50 (50%) were females. In Group A and B, there were 25 (50%) males and 25 (50%) females each. Lipid profiles were recorded in every patient at 0, 6 weeks and then 12 weeks.

RESULTS

This was a randomised open study conducted on patients with abnormal lipid profile attending the OPD/ wards of Department of Medicine, Guru Nanak Dev Hospital, attached to Government Medical College, Amritsar in the year 2006. Based on our previous year OPD and indoor patients' records, the total number of patients with dyslipidaemia was 165. Thinking that 100 patients would be achievable within 1 year so a total of 100 patients were included in the study and the patients were divided randomly by lottery method into two groups of 50 patients each; Group A was put on Atorvastatin 20 mg daily and Group B was put on Rosuvastatin 20 mg daily. Out of total 100 patients, 50 (50%) were males and 50 (50%) were females. In Group A and B, there were 25 (50%) males and 25 (50%) females each. Lipid profiles were recorded in every patient at 0, 6 weeks and then 12 weeks.

CONCLUSION

Rosuvastatin lowers total serum cholesterol, serum LDL-C, serum TG and raises serum HDL-C more significantly as compared to Atorvastatin.

KEYWORDS

LDL, Atorvastatin, Rosuvastatin.

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BACKGROUND

Among conventional risk factors, dyslipidaemia is the most important modifiable risk in context of Indians. Derangement of any one or more than one of various lipid and lipoprotein constituents (e.g. total cholesterol, LDL-C, HDL-C, VLDL-C or TG) have their relative contribution to atherogenesis.¹

Atherosclerosis of coronary arteries may manifest as myocardial infarction and angina pectoris and that of central nervous system as non-haemorrhagic cerebrovascular accidents and transient ischaemic attacks. Peripheral dyslipidaemia mainly manifests two life-threatening abnormalities.

Accelerated atherosclerosis and Acute pancreatitis. Other manifestations include xanthomas (tendon, palmar, eruptive, tubo-eruptive), Lipaemia retinalis and acute abdominal crisis.²⁻³ Various drugs available to treat hyperlipidaemia include statins (HMG-CoA reductase inhibitors), nicotinic acid, fibric acid derivatives, bile acid sequestrants, cholesterol absorption inhibitors (ezetimibe) and fish oils (omega-3 fatty acids). HMG Co-A reductase inhibitors represent the major advances in prevention of coronary artery disease. In various primary and secondary prevention trial, treatment with these agents has been associated with 24% - 37% decrease in coronary mortality and morbidity.⁴ They are the most widely used hypolipidaemic drugs worldwide.

MATERIALS AND METHODS

In this open randomised comparative study, 100 patients with abnormal lipid profile attending the outpatient department as well as admitted in Guru Nanak Dev Hospital attached to Government Medical College, Amritsar, were taken in the year 2006.

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Corresponding Author:

Dr. Krishan Kumar Oberoi,

H. No. 13-C, Mata Kaulan Marg,

Kashmir Avenue, Amritsar.

E-mail: drkrishanoderoi@gmail.com

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Sample Size

The design selected was randomised, double-blinded study. A total of 100 patients were included in the study. The samples of the study were selected by randomisation procedure without replacement. Lottery was done to randomly select the subjects in Group A (50) and Group B (50). The name of patients who fulfilled the inclusion criteria and who were available were written on a slip of paper and put in a bowl and mixed thoroughly. The investigator picked up slips blindfolded and they were the subjects for study. The first pick was taken for Group A and the second one was considered for Group B. Each time before drawing a slip, slips were mixed thoroughly in the bowl. Group A was put on atorvastatin 20 mg daily and Group B on Rosuvastatin 20 mg daily. Out of total 100 patients 50 (50%) were males, 50 (50%) were females. In Group A and B, there were 25 (50%) males and 25 (50%) females each. Lipid profile was recorded at 0, 6 and 12 weeks.

Inclusion Criteria

Patients selected for the present study had-

1. S. cholesterol > 200 mg%.
2. S. LDL-C > 100 mg%.
3. S. TG > 200 mg%.

Exclusion Criteria

1. Hypersensitivity to statins.
2. Patients with diabetes mellitus.
3. Pregnant/ nursing mothers.
4. Active liver disease/ Renal insufficiency/ Nephrotic syndrome.
5. Uncontrolled hypothyroidism.
6. Chronic alcoholics.
7. Acute myocardial infarction within preceding 3 months.
8. Known gastric acid disease/ peptic ulcer disease.
9. Pancreatitis/ cholelithiasis without cholecystectomy.
10. Concurrent intake of drugs affecting plasma lipid concentration or known to interact with statins.

Clinical Examination and Investigations

Detailed history and thorough general physical examination was done. Investigations were-

Followup

The Lipid profile was done on followup at 6 weeks and 12 weeks.

Statistical Tools

The information collected regarding all the selected cases was recorded in a Master chart. Data analysis was done with the help of computer using software SPSS (Version 15). Results were tabulated in the form of mean $\pm$ S.D. and analysed using student's 't' test and the level of significance was determined as its 'p' value with $p < 0.05$, taken as statistically significant.

RESULTS

Our study was conducted on 100 patients with abnormal lipid profile, of which males and females were almost equal in number (50 males and 50 females) and there was no sex bias.

In Group A the mean age among males was 56.5 ± 9.73 years, in females it was 55.25 ± 9.35 years. In Group B the mean age among males was 53.80 ± 6.56 years and in females it was 54.41 ± 4.49 years. Distribution of other risk factors for coronary artery disease was also similar in Group A/B (Hypertension 27/33, Smoking 11/7 and Family History of CAD 12/10). In both Groups A and B, at the end of 6 and 12 weeks the decrease was highly significant (p value < 0.001). Maximum fall occurred in first 6 weeks in both groups. In Group B, the percentage reduction was more than Group A and was highly significant (p value < 0.001).

Comparison	0 vs 6 Weeks	6 vs 12 Weeks	0 vs 12 Weeks
Group A	27.44%	9.036%	33.99%
Group B	33%	10.77%	40.21%

Table 1. Mean Percentage Decrease in Serum Total Cholesterol at 6 and 12 Weeks

In both Groups A and B, at the end of 6 and 12 weeks the decrease was highly significant ($p < 0.001$). Maximum fall occurred in first 6 weeks in both groups. In Group B, the percentage reduction was more than Group A and was highly significant ($p < 0.001$).

Comparison	0 vs 6 Weeks	6 vs 12 Weeks	0 vs 12 Weeks
Group A	38.89%	14.62%	47.82%
Group B	45.78%	18.10%	55.56%

Table 2. Mean Percentage Decrease in Serum LDL-C Levels at 6 and 12 Weeks

Mean percentage decrease in serum triglyceride levels at 6 and 12 weeks

In both Groups A and B, at the end of 6 and 12 weeks the decrease was highly significant ($p < 0.001$). Maximum fall occurred in first 6 weeks in both groups. In Group B, the percentage reduction was more than Group A and was highly significant ($p < 0.001$).

Comparison	0 vs 6 Weeks	6 vs 12 Weeks	0 vs 12 Weeks
Group A	17.79%	8.81%	25.03%
Group B	22.38%	10.28%	30.36%

Table 3. Mean Percentage Decrease in Serum Triglyceride Levels at 6 and 12 Weeks

Mean percentage increase in serum HDL-cholesterol at 6 and 12 weeks

In Group A, the decrease in serum triglyceride at the end of 6 weeks was very significant ($p < 0.01$) and at the end of 12 weeks it was highly significant ($p < 0.001$). In Group B, the change at end of 6 and 12 weeks was highly significant ($p < 0.001$). The maximum fall occurred in first 6 weeks in both the groups.

Comparison	0 vs 6 Weeks	6 vs 12 Weeks	0 vs 12 Weeks
Group A	5.17%	3.89%	9.27%
Group B	7.34%	4.73%	12.42%

Table 4. Mean Percentage Increase in Serum HDL-C at 6 and 12 Weeks

In Group A the increase at the end of 6 weeks was not significant ($p > 0.05$), but very significant ($p < 0.01$) at the end

of 12 weeks. In Group B, the percentage increase at the end of 6 and 12 weeks was highly significant ($p < 0.001$).

DISCUSSION

In the present study, there was statistically highly significant ($p < 0.001$) fall in serum total cholesterol and serum LDL-C levels from baseline in both the groups.

The mean percentage fall at 12 weeks with atorvastatin 10 mg as reported by Olsson et al.⁵ is 28%, 39% and 16% respectively. The mean percentage fall at 12 weeks with Atorvastatin 10 mg was reported to be 26.8%, 35.0% and 17.8% respectively by Schwartz et al.⁶ The percentage fall in serum triglyceride levels in Group A at the end of 6 weeks was less, but very significant ($p < 0.01$), but it was highly significant ($p < 0.001$) at the end of 12 weeks; whereas in case of Group B the percentage fall in serum triglyceride levels was highly significant ($p < 0.001$) both at the end of 6 and 12 weeks.

The difference in mean percentage fall in the levels of total serum cholesterol, serum triglycerides and serum LDL-C (Group A vs Group B) was highly significant ($p < 0.001$) and in favour of Group B (Rosuvastatin group).

Both Atorvastatin and Rosuvastatin brought a rise in serum HDL-C levels. In Group A, the rise was less but very significant ($p < 0.01$) at the end of 6 weeks. But it was highly significant ($p < 0.001$) at the end of 12 weeks. In Group B, the rise was highly significant ($p < 0.001$), both at the end of 6 and 12 weeks.

The difference in mean percentage rise in the levels of serum HDL-C (Group A vs Group B) was statistically significant ($p < 0.005$) and was in favour of Group B.

The present study has shown that both Atorvastatin and Rosuvastatin have their effects on all lipid parameters. Both reduce total serum cholesterol, serum LDL-C levels, serum triglycerides and raised serum HDL-C levels with Rosuvastatin having more potent effect on all parameters.

In the present study, in Group A 39 (78%) patients achieved the serum LDL-C ATP III goal and in Group B 45 (90%) patients achieved the serum LDL-C ATP III goal at the end of 12 weeks. This difference is statistically significant ($p < 0.05$) and in favour of Group B. The percentage of patient achieving the serum LDL-C goals was almost similar in present study to that reported by various landmark studies.

Both the drugs in present study were well tolerated. No patient had any serious side effects and no patient withdrew from the study. GI tract disturbances were main side effects occurring in 10% patients in Group A and 8% patients in Group B. In the present study, Myalgia occurred in 2% patients of Group A and 4% patients of Group B. No patient in the present study had raise in serum ALT levels. Comparing the overall incidence of side effects between Group A and Group B, there was no significant difference between the two groups ($p > 0.05$).

CONCLUSION

- Both Atorvastatin 20 mg/day and Rosuvastatin 20 mg/day led to high significant ($p < 0.001$) fall in levels of serum total cholesterol, serum LDL-C and serum triglycerides, Rosuvastatin having more potent effect on these parameters.
- Rise in serum HDL-C levels with Rosuvastatin was highly significant ($p < 0.001$). Atorvastatin also raises serum

HDL-C levels, but less as compared to rosuvastatin ($p < 0.01$).

3. The primary goal of serum LDL-C was achieved by 78% of Group A and 90% of Group B and the difference was statistically significant ($p < 0.05$).
4. There was statistically no significant difference ($p > 0.05$) in gastrointestinal and other side effects of Group A and B.

To conclude, the results of this study suggest that when both Atorvastatin and Rosuvastatin are used in the same dose and for same duration in comparable to dyslipidaemic groups Rosuvastatin lowers Total Serum Cholesterol, Serum LDL-C, Serum Triglycerides and raises Serum HDL-C more significantly as compared to Atorvastatin. Further larger studies in this regard are required.

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