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Original Article

Comparative study on the efficacy of statin therapy in lowering cholesterol and assessing the risk of metabolic syndrome in patients under statins therapy

Kodipelly Ramana Raju[1], Afreen Sharifa[1], Paspula Soumya[1,*], Rumana Khanam[1], Koyala konda Banda Sanjay Bhargav[1]

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ABSTRACT

The objective of the study is to compare and evaluate the efficacy of atorvastatin (group – A) versus rosuvastatin (group – B) on baseline parameters like lipid profile tests and to assess the risk of metabolic syndrome using a Mets calculator. A total of 100 patients were enclosed in the present study who met the inclusion criteria. They were divided into two groups based on their treatment plan Group A includes 24 males and 26 females while Group B includes 23 males and 27 females. The mean differences before treatment for group A and group B are as follows, HDL (31.52±0.35 and 28.34±0.480), LDL (161.4±1.09 and 163.16±0.94), Total cholesterol (252.82±1.09 and 255.56±1.26) and Triglycerides (214.2±0.86 and 215.98±0.62), VLDL (35.98±0.56 and 36.12±0.43). The mean differences after treatment for group A and group B are as follows HDL (39.92±0.46 and 42.04±0.30), LDL (144.96±0.68 and 138.34±0.73), Total cholesterol (181.48±1.98 vs 174.32±2.08), Triglycerides (185.94±1.22 vs 181.74±1.77), VLDL (27.14±0.21 and 24.72±0.27). Group B (P=0.001) exhibited a significantly greater reduction in cholesterol levels as compared to Group A (P = 0.002). The reductions in LDL, VLDL, Total Cholesterol, and Triglycerides along with increased HDL levels were found to be significantly more in the Rosuvastatin group. In this study, we observed that patients on Rosuvastatin exhibited better control over lipid profile when compared to patients who are on Atorvastatin. Since, this study was conducted on a smaller number of patients, to make consecutive remarks about the superiority of either of the treatment regimen; further analysis of clinical trials is required for appropriate selection of the best statin therapy.

1. Introduction

Metabolic syndrome is a complex constellation of disorders that increase the risk of coronary heart disease (CHD) [1-3]. Reaven first described the metabolic syndrome in 1988 as "Syndrome X." He noted that risk factors such as dyslipidemia, hypertension, and hyperglycemia clustered together and increased CVD risk [4]. In 1998, the World Health Organization (WHO) characterized the metabolic syndrome as insulin resistance requiring either a fasting insulin level in the upper quartile in nondiabetic patients [5], a fasting plasma glucose greater than 110 mg/dL, or a plasma glucose greater than 200 mg/dL 2 hours after an oral glucose tolerance testand at least two of the following criteria: 1) hypertension

[1]*Smt. Sarojini Ramulamma College of Pharmacy, Seshadrinagar, Mahabubnagar, Telangana 509001, India*
***Corresponding Author**: Paspula Soumya (paspulasoumya07@gmail.com)*

requiring systolic or diastolic blood pressures of 160 mm Hg or greater or 90 mm Hg or greater or treatment for hypertension [6]; 2) dyslipidemia defined as triglycerides (TG) greater than 150 mg/dL or HDL cholesterol less than 35 mg/dL in men or less than 39 mg/dL in women, or treatment for dyslipidemia [7]; 3) body mass index (BMI) greater than 30 kg/m2 and/or waist-to-hip ratio greater than 0.9 in men, greater than 0.85 in women, or a waist girth of 37 inches or greater in men and 32 inches or greater in women; or 4) microalbuminuria (urinary albumin excretion rate ≥ 20 µg/min or albumin: creatinine ratio ≥ 20 µg/g) [8, 9].

2. Materials and methods

2.1. Study sites, design, and period

The study is a prospective, parallel, open-label observational study conducted in the general medicine department of a 300-bedded multi-specialty tertiary care teaching hospital, for 6 months. A total of 100 prescriptions were included in the study. The study protocol and written informed consent were approved by the institutional ethical committee of the hospital. To consider both inpatients and outpatients of the general medicine ward of SVS hospital.

2.2. Inclusion criteria

- ✓ Patients of any gender of age above 20yrs age were diagnosed with dyslipidemia.
- ✓ Patients with DM, HTN, or any cardiovascular and cerebrovascular disease.
- ✓ Patients who are willing to give their consent for the study.
- ✓ The patient was prescribed any one of the drugs (atorvastatin and rosuvastatin)

2.3. Exclusion criteria

- ✓ Patients who were not treated with statin therapy.
- ✓ All patients with immunodeficient diseases like HIV.
- ✓ Patients with concomitant diseases like T.B.
- ✓ Patients who are not willing to give their consent for the study.
- ✓ Pregnant and lactating women are excluded.

2.4. Data collection

- ✓ Data collection form.
- ✓ Metabolic syndrome calculator.

2.5. Study procedure

- ✓ This is a prospective study where patient data are collected and written in the data collection form. This form contains the demographic details of the patient, chief complaint, past medical, and medication history, family history, laboratory investigations and medication chart.
- ✓ The efficacy study of statins will be compared by taking lipid profile data from patients. The risk of metabolic syndrome is assessed by the use of a metabolic syndrome calculator.
- ✓ The study will be conducted on patients of department general medicine and cardiology where anyone of a statin drug (atorvastatin, rosuvastatin) was prescribed at SVS Medical College hospital. All information relevant to the study using suitable methods for statistical analysis and results will be concluded.

3. Results

3.1. Distribution of patents according to age

During 6 months period, a total of 100 participants were collected. Collected patients were divided into two groups based on their treatment plan as group A (Atorvastatin) and group B (rosuvastatin). More participants were observed in the age group above 60yrs. It has been shown in Table 1 and Figures 1-4. Table 2 shows that before starting the treatment, there was no significant difference between the two groups. Tables 3 and 4 show

the risk assessment of metabolic syndrome in statin therapy.

Table 1. Distribution of Patients according to age

Age category	GroupA (No of Patients)	Group B (No of Patients)
20 – 35	3(6%)	5(10%)
36 – 45	4(8%)	5(10%)
46 – 60	17(34%)	15(30%)
>60	26(52%)	25(50%)
Total	50(100%)	50(100%)

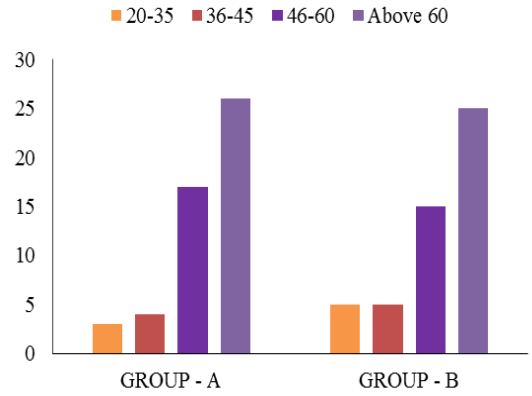

Fig. 1. Distribution of Patients according to age

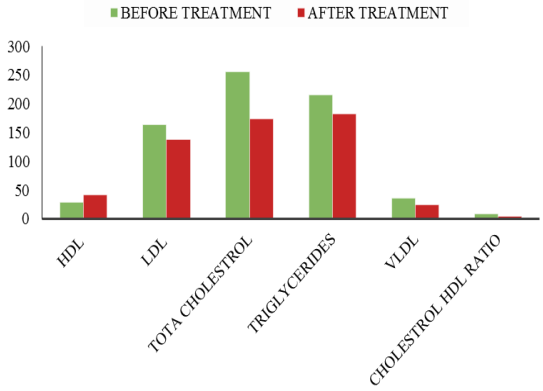

Fig. 2. Comparison of changes in biochemical parameters for group B

Table 2. Comparison of biochemical parameters

Parameters	Group A	Group B
HDL	31.52±0.35	28.34±0.48
LDL	161.4±1.09	163.16±0.94
Total cholesterol	252.82±1.10	255.56±1.26
Triglycerides	214.2±0.86	215.98±0.62
VLDL	35.98±0.56	36.12±0.43
Cholesterol HDL ratio	8.03±0.09	8.61±0.10

Table 2. The significant difference before and after treatment in group B

Parameters	Before treatment	After treatment	P-value
HDL	28.34±0.48	42.04±0.30	0.0001
LDL	163.16±0.94	138.34±0.73	0.01
Total cholesterol	255.56±1.26	174.32±2.08	<0.0001
Triglycerides	215.98±0.62	181.74±1.77	<0.0001
VLDL	36.12±0.43	24.72±0.27	0.0001
Cholesterol HDL ratio	8.61±0.10	4.15±0.05	<0.0001

Table 3. Significant changes in parameters in statin therapy

Parameters	Category	Atorvastatin	Rosuvastatin
BMI	Above 30 kg/m^2	33	26
	below 30kg/m2	17	24
Triglycerides	below 150mg/dl	22	15
	above 150mg/dl	28	35
HDL	above 50mg/dl	1	5
	40-49mg/dl	23	27
	below 40mg/dl	26	18
Blood pressure	below 130/85mmHg	15	12
	above 130/85mmHg	35	38
Type II diabetes	yes	32	34
	No	18	16
Blood pressure	below 130/85mmHg	15	12
	above 130/85mmHg	35	38
TYPE II DIABETES	yes	32	34
	No	18	16

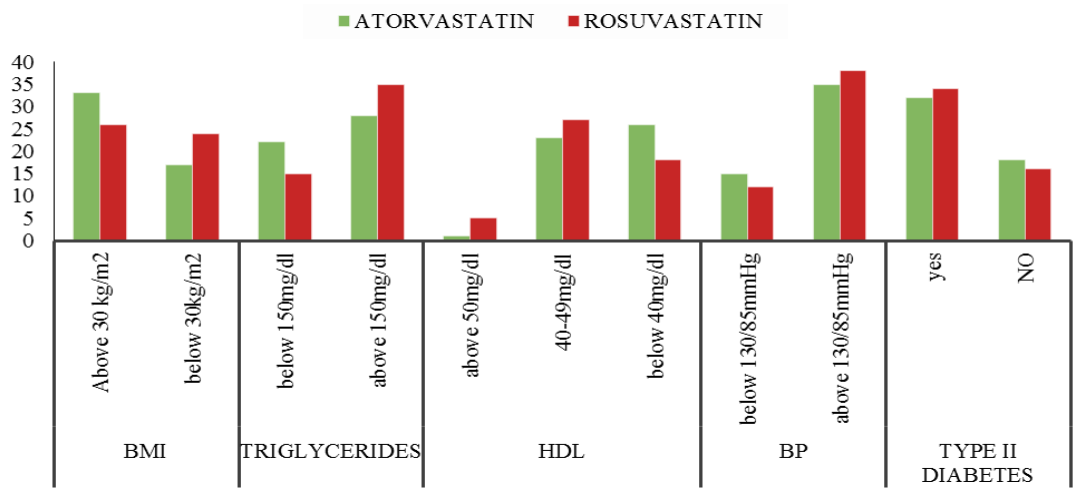

Fig. 3. Significant changes in parameters in statin therapy

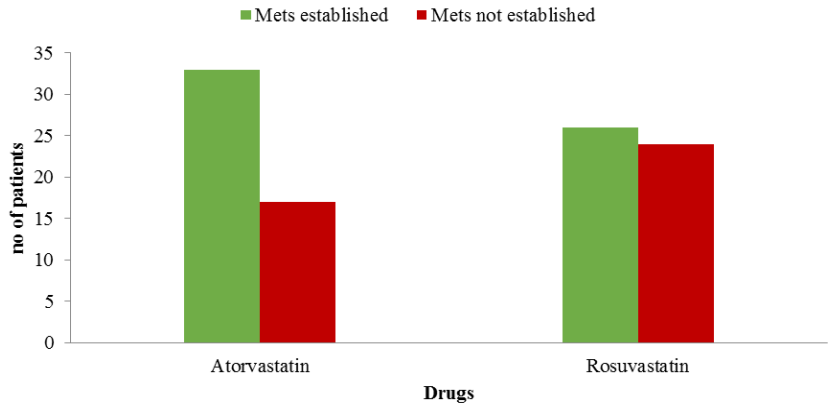

Fig. 4 . Comparison of Mets in both group A and group B.

Table 4 . Comparison of Mets in both group A and group B

Source	Atorvastatin (no of patients)	Rosuvastatin (no of patients)
Mets established	33 (66%)	26 (52%)
Mets not established	17 (34%)	24 (48%)

4. Discussion

Metabolic syndrome is a disorder that increases the risk of CHD [10-14]. During 6 months period, a total of 100 participants were collected. Collected patients were divided into two groups based on their treatment plan as Group A (Atorvastatin) and Group B (Rosuvastatin). More participants were observed in the age group above 60 yrs. Among 100 patients, out of 50 patients belonging to Group A, 24 were male, and 26 were female. Out of 50 patients belonging to Group B, 23 were male, and 27 were female. Females are affected more than males. Data from two groups were analysed for an efficacy comparison in the intention-to-treat population. Baseline values of all parameters were similar between the two groups. The mean Serum TC, TG, LDL-C, and VLDL-C levels were significantly reduced on therapy.

Coming to the lipid profile, in group A, the mean triglyceride levels before and after treatments were found to be 214.2±0.86 and 185.94±1.22, respectively. Mean HDL levels before and after treatment were found to be 31.52±0.35, and 39.92±0.46 respectively. Mean LDL values before treatment are 161.4±1.09 and after treatment is 144.96±0.68. Whereas the mean VLDL values before and after treatment are 35.98±0.56 and 27.14±0.21 respectively.

In group B, the mean triglyceride levels before and after treatments were found to be 215.98±0.62 and 142.04±0.30 respectively. Mean HDL levels before and after treatment were found to be 28.34±0.48 and 42.04±0.30 respectively. Mean LDL values before treatment are 163.16±0.94 and after treatment is 138.34±0.73. Whereas the mean VLDL values before and after treatment are 36.12±0.43 and 24.72±0.27 respectively.

Rosuvastatin reduced the level of TC by 215.98±0.62 to 42.04±0.30 ($p<0.0001$) and LDL by 163.16±0.94 to 138.34±0.73 ($p<0.01$) and VLDL-C by 36.12±0.43 to 24.72±0.27 ($p=0.0001$). The level of HDL was from 28.34±0.48 to 42.04±0.30 ($p=0.0001$). After 3 months of treatment, greater reductions in total cholesterol (181.48±1.98 vs 174.32±2.08), LDL (144.96±0.68 vs 138.34±0.73), triglycerides (185.94±1.22 vs 181.74±1.77), and increased high-density lipoprotein (39.92±0.46 vs 42.04±0.3) levels were observed in the atorvastatin group and Rosuvastatin group respectively. The Rosuvastatin group ($P=0.01$) exhibited a significantly greater reduction as compared to the atorvastatin group ($P = 0.002$) [15, 16].

Among patients with MetS, rosuvastatin therapy resulted in significantly higher low-density lipoprotein cholesterol and total cholesterol reduction as compared with Atorvastatin [17-20]. Similarly, the significantly higher percentage of patients receiving rosuvastatin therapy was successful in achieving the target of total cholesterol and triglycerides as compared to atorvastatin [21, 22]. This resulted in reducing the risk of metabolic syndrome in patients receiving rosuvastatin (48%) than atorvastatin (34%) [17, 23].

5. Conclusion

In the present study, both Atorvastatin and Rosuvastatin were well tolerated in lowering cholesterol. This study revealed a significant reduction in lipid levels (total cholesterol, and LDL), an increase in HDL levels was achieved by rosuvastatin and atorvastatin respectively. An intermediate significant difference in the reduction of other lipid levels was observed between Atorvastatin and Rosuvastatin after 3months of treatment. Metabolic syndrome is a constellation of cardiac risk factors that increases CVD risk. Statins have been repeatedly shown to decrease risk in a variety of patient groups. There are no studies directly addressing statin treatment in metabolic syndrome, but the present study confirmed that rosuvastatin therapy is commonly prescribed doses is the most effective statin for low-density lipoprotein cholesterol goal achievement and for improving the lipid profile in with MetS.

Conflict of Interest

The authors hereby declare that they have no conflict of interest.

Author's contributions

All authors equally participated in designing experiment analysis and interpretation of data. All authors read and approved the final manuscript.

Consent for publications

All authors have read and approved the final manuscript for publication.

Availability of data and material

The authors have embedded all data in the manuscript.

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Ethics approval and consent to participate

The authors did not use human or animals in the research

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