Journal of Cardiovascular Disease Research
ISSN: 0975-3583, 0976-2833 VOL15, ISSUE 04, 2024

ORIGINAL RESEARCH

Comparison of Rosuvastatin and Atorvastatin in achieving the treatment goals of dyslipidemia at a tertiary centre

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Received: 12 February, 2024 Accepted: 15 March, 2024

Abstract
Background: Dyslipidemia and atherosclerosis are closely related from the beginning to the end stages that lead to clinical events. The present study was conducted to compare Rosuvastatin (10 mg) and Atorvastatin (10 mg) in achieving the treatment goals of dyslipidemia.
Materials & Methods: 70 diabetic patients were divided into 2 groups of 35 each. Group I received rosuvastatin (10 mg tablet OD) and group II received atorvastatin (10 mg tablet OD) for 12 weeks. In both groups, patients were instructed to take drugs 30 minutes before an evening meal. Parameters such as fasting blood glucose, glycated hemoglobin (HbA1C), total cholesterol, HDL and LDL cholesterol levels, and triglycerides, was recorded.
Results: Out of 70 patients, males were 40 and females were 30. BMI <25 kg/m2 was seen in 7 patients in group I and 9 in group II, 25–30 kg/m 2in 8 and 7, and ≥30 kg/m2 in 20, and 19 patients respectively. Smoking was seen in 5, and 7 and alcoholism in 6 and 4 patients in group I, and group II respectively. The difference was non-significant (P> 0.05). The % change in TC was 37% and 24%, the % change in LDL- C was 48% and 31%, the % change in HDL- C was 41% and 33%, the % change in non-HDL- C was 48% and 43%, the % change in TG was 60% and 54%, and the % change in VLDL- C was 62% and 59% in group I, and group II respectively. The difference was significant (P< 0.05).
Conclusion: In general, Rosuvastatin medication may have a greater lipid-lowering impact and produce a larger rate of LDL-C and TC achievement than Atorvastatin.
Key words: Atorvastatin, Rosuvastatin, lipid

Introduction

Dyslipidemia and atherosclerosis are closely related from the beginning to the end stages that lead to clinical events. Atherosclerosis is a common pathological process that is unquestionably the source of the most deadly and incapacitating diseases that affect people today.[1] It is a diverse set of lipid transport disorders caused by either accelerated or delayed degradation of the lipoproteins that carry triglycerides and cholesterol through plasma. The disorders manifest as elevated or decreased levels of one or more major lipids transported in plasma, and they are indicative of abnormalities in the metabolism of transport.[2]

The most likely causes include the use of medications with insufficient dosage titration and limited efficacy in decreasing LDL-C. Because higher dosages of statins are often needed during therapy to reach target LDL-C levels, goal achievement is especially low in high-risk patients with elevated LDL-C. In addition, the LDLC targets assigned to these patients are more aggressive and challenging to meet.[3]

A simple, successful treatment strategy would be the most effective statin at the lowest dose, enabling more people to reach their goals without changing their dosage. Rosuvastatin has demonstrated excellent efficacy at lowering LDL-C at a dosage of 10 mg, enabling patients with hypercholesterolemia to achieve their lipid goals. Additionally, rosuvastatin benefits other elements of the lipid profile, like high-density lipoprotein cholesterol (HDL-C), which is a substantial, independent risk factor for CVD.[4]

Atorvastatin is documented to be the most potent statin at reducing LDLC levels. Alternatively, pravastatin which is available at higher doses of 20 mg and 40 mg is found to be slightly less effective; the main reason for its prescription in patients is put down to its hydrophilic properties which make it more tolerable to patients with greater risk factors in addition to CVD.[5]

Aims and objectives: The present study was conducted to compare Rosuvastatin (10 mg) and Atorvastatin (10 mg) in achieving the treatment goals of dyslipidemia.

Materials & Methods

The present randomized open label prospective comparative study comprised 70 type II diabetic patients of both genders attaining outpatients (OPD) at Department of Medicine in collaboration with Department of Pharmacology, Nalanda Medical College and Hospital, Patna, Bihar, India from a period of December 2019 to August 2021. All were informed regarding the study and their written consent was obtained those who met the specified criteria for inclusion and exclusion. The Institutional Ethics Committee gave the study its approval. Data such as name and age etc. was recorded.

Keeping power (1-beta error) at 80% and confidence interval (1-alpha error) at 95%, the minimum sample size required was 60 patients; therefore, we included 70 (the minimum required number of cases) patients in present study.

Inclusion criteria

- Patients to give written informed consent
- Type 2 diabetic patients uncontrolled with Metformin 500mg
- Patients of either sex aged ≥ 18 years
- HbA1c ≥ 7%
- Fasting blood sugar (FBS) ≥126 mg/dl
- Available for follow up.

Exclusion criteria

- Patients not give written informed consent
- Patients of either sex aged < 18 years
- Patients allergic/intolerant to sulfonylureas.
- Patients with systemic diseases- renal dysfunction, cardiac problems
- Patients on other diabetic medications, requiring hospitalization
- Consuming alcohol, pregnant and lactating women

Data such as name, age, gender, height, weight, and BMI were recorded. Patients were divided into 2 groups of 35 each. Group I received Rosuvastatin (10 mg tablet OD) and group II received atorvastatin (10 mg tablet OD) for 12 weeks. In both groups, patients were instructed to take drugs 30 minutes before an evening meal. Parameters such as fasting blood

glucose, glycated hemoglobin (HbA1C), total cholesterol, HDL and LDL cholesterol levels, and triglycerides, was recorded.

Statistical analysis

Data thus obtained were subjected to statistical analysis by using Microsoft 16 and Statistical Package for Social Sciences (SPSS) version 24.0. Mean difference between the two groups was done using unpaired t test. P value < 0.05 was considered significant.

Results

The mean age (Mean ± SD) of the present studied was 52.87±8.05 years in Group I and 54.96±8.15 years in Group II. The mean baseline BMI (kg/m2) was 31.5 ± 6.07 in Group I and 32.50 ± 6.98 in Group II.

Table I: Demographic distribution of patients

Total- 70		
Gender	**Group I (n=35)**	**Group II (n=35)**
Males	22	18
Females	13	17

Table I shows that out of 70 patients, males were 22 in group I and 18 in Group II whereas, Females were13 in group I and 17 in Group II.

Figure 1: Gender wie distribution of patients

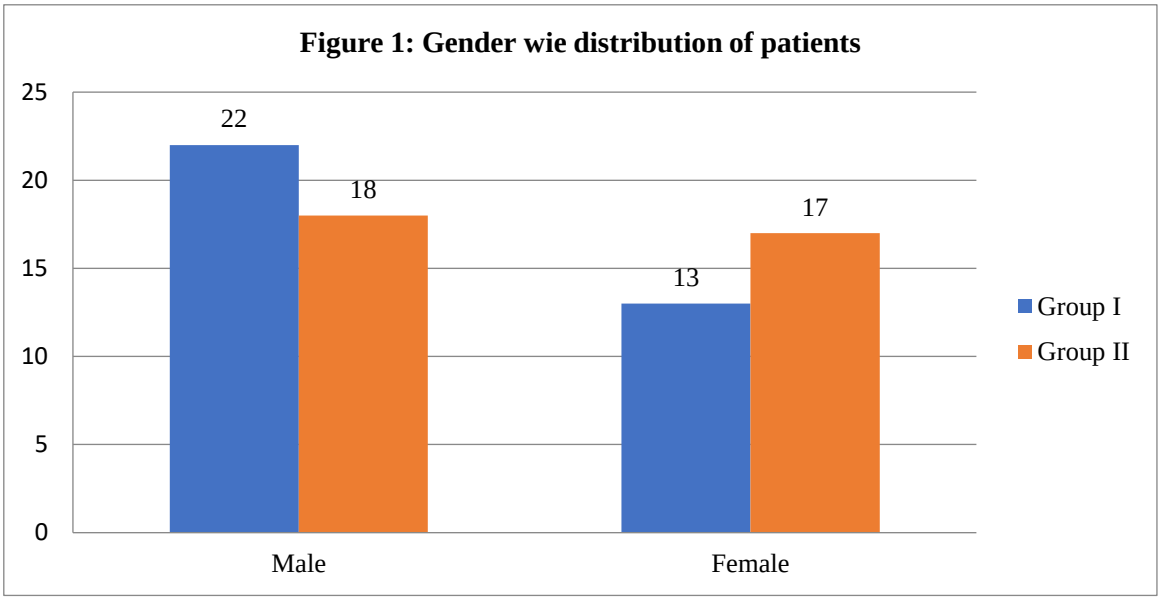

Table II: Comparison of characteristics in the present study groups

Parameters	Variables	Group I (n=35)	Group II (n=35)	P value
BMI (kg/m2)	<25	7	9	0.91
	25–30	8	7	
	>30	20	19	
Smoking	Yes	5	7	0.69
	No	30	28	
Alcoholism	Yes	6	4	0.05
	No	29	31	
Hypertension	Yes	33	30	0.40
	No	2	5	

Table II shows that BMI <25 Kg/m^2 was seen in 7 patients in group I and 9 in group II, 25–30 kg/m2 in 8 and 7, and ≥30 kg/m2 in 20, and 19 patients respectively. Smoking was seen in 5, and 7 and alcoholism in 6 and 4 patients in group I, and group II respectively. Hypertension was seen in 33, and 30 patients in group I, and group II respectively. The difference was non-significant (P> 0.05).

Figure 2: Comparison of BMI (Kg/m^2) in study groups

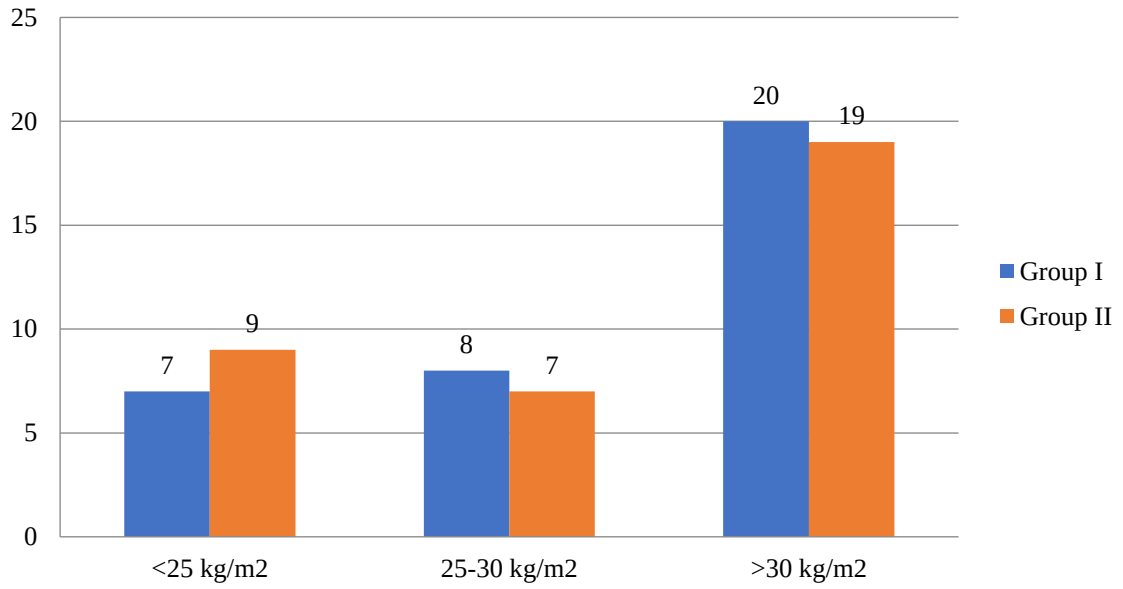

Table III: Efficacy of statins

Variables	Group I (n=35)	Group II (n=35)	P value
% change in TC	37	24	0.01
% change in LDL- C	48	31	0.02
% change in HDL- C	41	33	0.04
% change in non- HDL- C	48	43	0.05
% change in TG	60	54	0.04
% change in VLDL- C	62	59	0.02

Table III shows the% change in TC was 37% and 24%, the % change in LDL- C was 48% and 31%, the % change in HDL- C was 41% and 33%, the % change in non-HDL- C was 48% and 43%, the % change in TG was 60% and 54%, and the % change in VLDL- C was 62% and 59% in group I, and group II respectively. The difference was significant (P< 0.05).

Discussion

The elevated risk of CVD is explained by the lipid profile discrepancies between nondiabetics and diabetics, particularly type 2 diabetics.[6] Triglyceride (TG) rises (>2 mmol/L) and reductions in high-density lipoprotein cholesterol (HDLC) are the main components of T2DM lipid profiles. The particles are smaller and denser than low-density lipoprotein cholesterol (LDL-C), which is thought to increase their atherogenic potential even while the concentration levels are normal.[7] Diabetes mellitus (DM) is one of the major non-communicable diseases with increasing prevalence in both the developed and developing world. Middle East region has seen some of the largest growth in DM in the world.[8] Diabetes

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE 04, 2024

is now commonly recognized as a 'coronary heart disease risk equivalent'. This is mainly attributed to the high rates of dyslipidemia among diabetic patients which is believed to be one of the major factors accounting for the high percentage of deaths among diabetics due to cardiovascular disease (CVD).[9]

The present study was conducted to compare Rosuvastatin (10 mg) and Atorvastatin (10 mg) in achieving the treatment goals of dyslipidemia.

We found that out of 70 patients, males were 40 and females were 30. BMI <25 kg/m2 was seen in 7 patients in group I and 9 in group II, 25–30 kg/m2 in 8 and 7, and ≥30 kg/m2 in 20, and 19 patients respectively. Smoking was seen in 5, and 7 and alcoholism in 6 and 4 patients in group I, and group II respectively. Hypertension was seen in 33, and 30 patients in group I, and group II respectively.

Barakatet al.[10] examined the effectiveness and safety of the three most widely prescribed statins (pravastatin, atorvastatin, and rosuvastatin) in the treatment of dyslipidemia in 350 patients with diabetes. Reducing LDL-C (29.03%) was most successfully achieved with rosuvastatin (10 mg). The highest LDL-C reductions were seen with atorvastatin at 40 mg (22.8%) and pravastatin at 20 mg (20.3%). Regarding the effects on hepatic and muscle functioning, all three statins were safe. When it came to renal function, atorvastatin was the least dangerous statin since, after two years of treatment, the lowest percentage of patients had microalbuminuria (10.9%). This was followed by rosuvastatin (14.3%) and pravastatin (26.6%).

We observed that the % change in TC was 37% and 24%, the % change in LDL- C was 48% and 31%, the % change in HDL- C was 41% and 33%, the % change in non-HDL- C was 48% and 43%, the % change in TG was 60% and 54%, and the % change in VLDL- C was 62% and 59% in group I, and group II respectively.

Padma et al[11] in their study a total of 250 patients were screened for the study, of which males represented 63.60% (n = 159), female 36.40% (91) of the population, male and female ratio was 1.7:1. A total of 250 patients were divided randomly into two groups of 125 patients each and assigned as group I (male 80, female 30) and Group II (male 79, female 31. The group-I mean age was 53.66 ± 7.69 years and in groupII,the mean age was 52.75 ± 6.89 years. Group I received rosuvastatin (10 mg tablet OD) and Group II received atorvastatin (10 mg tablet OD) for 12 weeks. The levels of serum TC and LDL-C are decreased by 38.01% and 47.55 % respectively with the use of rosuvastatin (Group-I) after 12 weeks. atorvastatin 10 mg/day (Group-II)for 12 weeks resulted in a statistically significant fall in levels of serum TC and LDL-C by 23.50 % and 29.79 %

Beneret al[12] studiedthe efficacy safety of rosuvastatin, atorvastatin, pravastatin, and simvastatin in the treatment of dyslipidemia among diabetic patients. Rosuvastatin (10 mg) was the most effective in reducing low-density lipoprotein cholesterol (LDL-C; 28.59%), followed by simvastatin 20 mg (16.7%), atorvastatin 20 mg (15.9%), and pravastatin 20 mg (11.59.3%). Atorvastatin was the safest statin as it resulted in the least number of patients with microalbuminuria (10.92%) as compared to other statins. Treatment with rosuvastatin 10 mg was more effective in allowing patients to reach European and Adult Treatment Plan (ATP) III LDL-C goals as compared to other statins.

Limitations of the study

The limitation of the study is the small sample size and short duration of study.

Conclusion

Authors found that in general, Rosuvastatin medication may have a greater lipid-lowering impact and produce a larger rate of LDL-C and TC achievement than Atorvastatin.

Acknowledgment
The authors would like to acknowledge the entire faculty and staff of the Department of Pharmacology, Nalanda Medical College and Hospital, Patna, Bihar, India, for their valuable support and time- to- time suggestion in undertaking the present study. Special thanks to Dr. Asha Singh, Associate Professor, Department of Pharmacology, Nalanda Medical College and Hospital, Patna, Bihar, India, for their valuable suggestions during the study.

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