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**Research Article** 

# Atorvastatin versus rosuvastatin in non-diabetic patients with dyslipidemia: a comparative study

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#### **ABSTRACT**

**Background:** Statins are recognized to be the first line of therapy for lowering cholesterol and have shown to reduce the morbidity and mortality caused by cardiovascular diseases. Atorvastatin and rosuvastatin are potent statins which can efficiently lower the cholesterol and triglyceride levels, we have thus undertaken this study to compare the efficacy of these two statins in non-diabetic patients.

**Methods:** 150 patients selected for the study, were over 18 years of age with dyslipidemia with no management. Using a randomized computer table, the patients were divided into 2 groups of 75 patients each; group A, who were given atorvastatin 20 mg and group B who were given rosuvastatin 10 mg for 12 weeks. History, and blood tests for fasting blood sugar, hemoglobin A1C, lipid profile such as triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol, urea, creatinine, uric acid, creatine kinase, aspartate aminotransferase, and alanine aminotreasferase. Vitamin 25(OH) D, serum insulin and hs-CRP levels were measured after taking the base line details.

**Results:** The numbers of women were lesser than that of men. There was a considerable reduction in the triglyceride levels, total and LDL levels in both the groups after 12 weeks of use although between the two groups there was not any significant difference. A slight reduction was seen in the hs-CRP levels and elevation in Vit  $D_3$  levels though this was not very significant due to the lesser duration of the study.

**Conclusions:** Both atorvastatin and rosuvastatin are equally powerful statins and very effective in reducing the triglyceride and LDL-cholesterol levels. They are also effective in lowering hs-CRP and elevating vitamin D levels.

Keywords: Atorvastatin, Rosuvastatin, Statins, Triglycerides, LDL cholesterol

## INTRODUCTION

Accumulation of adipose tissue or obesity is one of the leading concerns in the health care as it is one of the common predisposing factors for cardiovascular diseases in adults and children.1 This increases the levels of cholesterol and triglycerides in the body leading to dyslipidemia. Though most often due to fatty diet, Dyslipidemia can also be caused due to prolonged elevation in insulin levels.<sup>2</sup> It has been estimated that almost every second individual in the United States has abnormal cholesterol values and one third of the population has elevated low density lipoprotein cholesterol levels.<sup>3</sup> India is becoming a fast killer due to atherosclerosis caused by dyslipidemia. In contrast to the West and other Asians, the prevalence, incidence and hospitalization are 2-4 folds higher at all ages and 5-10 folds above the age of 40 years in India.<sup>4</sup>

Compared to Europeans, Americans & other Asians the prevalence, incidence, hospitalization and mortality from coronary heart disease in India is 2-4 folds higher at all ages and 5-10 fold higher in those 40 years of age. Indians are unique in having an atherogenic lipid profile & lipoprotein. Dyslipidemia, high blood pressure, abdominal obesity and insulin intolerance together constitute a group of cardiovascular risk factors. Their appearance increases the risk of atherosclerosis and cardiovascular disease. <sup>5,6</sup> The primary goal for therapy is said to be lipid management of the low density protein cholesterol (LDL-C), <sup>7</sup> although many persons do not achieve the target of low LDL-C levels in spite of lipid lowering therapy. <sup>8,9</sup>

Statins are recognized to be the first line of therapy for lowering cholesterol and have shown to reduce the morbidity and mortality caused by cardiovascular

diseases. <sup>10-14</sup> They are known to have antioxidant, antiinflammatory effects as well as antithrombic properties. <sup>15</sup> They are also known to improve endothelial dysfunction and reduce the growth of atherosclerotic plaque. <sup>16</sup>

Atorvastatin and rosuvastatin are potent statins which can efficiently lower the cholesterol and triglyceride levels, <sup>17-19</sup> though rosuvustatin has been reported to be more effective in various studies especially in type 2 diabetes. We have thus undertaken this study to compare the efficacy of these two statins in non-diabetic patients. <sup>20-22</sup>

#### **METHODS**

This prospective randomized study was conducted over a period of two years at department of Pharmacology at NRI Medical College. 150 patients were selected for the study after thoroughly explaining the procedural techniques and obtaining the Informed consent. All the patients were over 18 years of age with dyslipidemia, but did not meet the goal for LDL-C, according to the European Society of Cardiology (SC) and the European Atherosclerosis Society guidelines for management of dyslipidemia.<sup>23</sup> Patients with diabetes mellitus, and those on antidiabetic drugs, thyroid or parathyroid dysfunction, any type of malignancy, pregnant women, and breast feeding women were excluded from the study. Patients with more than twice the transaminase levels and three time more creatine kinase levels, those on medications such as those for lipid reduction, vitamin D supplementation or calcium supplementation were also excluded from the study.

Using a randomized computer table, the patients were divided into 2 groups of 75 patients each group A, who were given Atorvastatin 20 mg and group B who were given rosuvastatin 10 mg for 12 weeks. 23 subjects 13 from group A and 10 from Group B showed intolerance to the statins and were excluded. 23 fresh patients were recruited after obtaining informed consent from them and assigned to the groups so as to add up to 75 patients each.

A thorough physical and clinical examination was done on all patients. Demographic details such as age, sex, weight, height were noted. Other details such as waist circumference, blood pressure, both systolic and diastolic were noted and body mass index was calculated. All patients were asked to fast overnight and blood was collected and sent to the biochemistry lab for the detection of fasting blood sugar, hemoglobin A1C, lipid profile such as triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol, urea, creatinine, uric acid, creatine kinase, aspartate aminotransferase, and alanine aminotreasferase. Vitamin 25(OH) D, serum insulin and hs-CRP levels were also measured and all these baseline parameters were noted. Insulin resistance was calculated using the formula:

(Fasting serum Insulin x Fasting plasma glucose)/22.524.

All statistical analysis was done using SPSS 17.0 software. Paired t test, Mann-Whitney test, Pearson's coefficient were used and a p value of 0.05 was considered as significant.

#### **RESULTS**

Table 1: General characteristics of the patients in both groups.

Parameters	Group A (n=75)	Group B (n=75)	
Male	45	43	
Females	30	32	
Age	58.1±4.6	57.2±6.1	
Body mass index			
Base line	30.1±1.2	30.4±0.9	
After 12 weeks	29.9±0.9	30.1±0.8	
Waist circumference (cm)			
Base line	98.8±2.7	98.2±2.1	
After 12 weeks	96.1±2.2	95.8±1.9	
Systolic blood pressure (mmHg)			
Base line	141±4	140±6	
After 12 weeks	136±6	134±3	
Diastolic blood pressure (mmHg)			
Base line	89±5	88±4	
After 12 weeks	80±2	78±3	

Out of the 150 patients who completed the study, there was not any significance in the general characteristics between the two groups in terms of age, weight sex body mass index etc. The numbers of women were lesser than that of men, but this also was not a significant parameter which was taken into the account in the study (Table 1).

There was no difference in the different parameters between the two groups at baseline. But, there was a considerable reduction in the triglyceride levels, total and LDL levels in both the groups after 12 weeks of use although between the two groups there was not any significant difference. The base line and after 12 weeks values in both the groups were similar for all the other parameters (Table 2).

# **DISCUSSION**

The HMG CoA reductase inhibitors are known to be powerful pharmacological agents that are commonly used for the reduction of triglyceride levels and as a result in decreasing the incidence of coronary heart disease. Their use in the treatment of high cholesterol levels has increases rapidly over the years. The reduction of CHD due to the use of statins has been reported to be 25-60%. This success in the statin action on the cholesterol levels has led to the development of newer synthetic molecules such as rosuvostatin. <sup>26</sup>

Table 2: Biochemical parameters in the two groups.

Parameters	Group A (n=75)	Group B (n=75)	
Total cholesterol (mg/dl)			
Base line	281.9±5.1	269.8±6.7	
After 12 weeks	176.3±4.7*	170.1±4.9*	
HDL cholesterol (mg/c			
Base line	59.5±3.5	61.2±3.1	
After 12 weeks	59.2±3.1	59.4±2.5	
LDL cholesterol (mg/dl)			
Base line	195.1±9.3	187.4±3.5	
After 12 weeks	100.9±12.3*	98.4±4.2*	
Triglycerides (mg/dl)			
Base line	171.8±3.0	177.4±5.3	
After 12 weeks	112.9±3.98*	109.8±6.9*	
Vit D <sub>3</sub> (ng/ml)			
Base line	20.5±2.1	23.5±2.1.	
After 12 weeks	24.1±1.9	28.1±6.0	
Serum glucose (mg/dl)			
Base line	99.1±11.3	92.5±3.5	
After 12 weeks	98.1±4.2	91.4±3.1	
Serum calcium (mg/dl)			
Base line	9.1±0.6	9.3±0.9	
After 12 weeks	9.1±0.9	9.2±1.2	
Insulin (µIU/ml)			
Base line	$6.4\pm0.9$	6.5±0.7	
After 12 weeks	7.1±0.6	6.5±0.3	
hs-CRP (mg/l)			
Base line	$4.4 \pm 1.1$	2.9±0.5	
After 12 weeks	3.2±0.7	2.4±0.9	
AST (IU/I)			
Base line	26.1±3.1	22.5±6.2	
After 12 weeks	26.9±2.8	24.1±2.1	
ALP (IU/l)			
Base line	25.1±5.3	23.7±3.5	
After 12 weeks	25.7±3.4	23.1±1.8	
CK (IU/l)			
Base line	$100\pm6.3$	109.2±7.9	
After 12 weeks	107.5±7.4	118.8±3.6	
HbA1c (%)			
Base line	$5.8\pm0.5$	5.7±0.4	
After 12 weeks	4.3±0.8	4.7±0.5	
*p<0.001			

High level of LDL-cholesterol is one of the important factors in causing coronary heart disease. 1% increase of serum cholesterol and 1.5% increase of serum LDL-Cholesterol increases the incidence of MI by 2-3%.<sup>4</sup>

We tried to compare and evaluate the efficacy of rosuvastatin and atorvastatin in lowering of cholesterol levels in our area.

The general characteristics in both the groups were similar. The number of males was more than the females in our study with the males accounting for around 60%.

This was in concordance to a study by Jhala et al<sup>27</sup> who reported an incidence of males to be around 61%, although a higher incidence of males was found in other studies. 11,13,14

The prevalence in the higher cholesterol levels were seen more in the age group above 50 years while in the west, the incidence was much later. 13,14

Along with the high cholesterol levels in these patients, the most common condition to prevail was hypertension. Hypertension as comorbidity was observed in other studies such as the study by Jhala et al,<sup>27</sup> Scandinavian study,<sup>11</sup> Sacks et al.<sup>13</sup>

After 12 weeks of treatment, there was significant reduction in the total cholesterol, LDL cholesterol levels and triglyceride levels from the base line levels. But, there was no difference to be seen between the two groups, though there was a slightly more reduction in the triglyceride levels due to rosuvastatin, though it was not significant. This shows that both the statins were equally efficient in reducing the cholesterol levels. Both the drugs were well tolerated by the patients with no side effects.

Rosuvastatin has shown to improve the triglyceride levels better than atorvastatin, though in our study too, there was a slightly more reduction, though this was not significant. This could be because; in the study by Schwartz ET al<sup>28</sup> the treatment was for 24 weeks while in our study it was only for 12 weeks. With a longer period of treatment of the statins, probably a significant difference would have been seen.

Statins are said to have beneficial effects on other levels such as vitamin D Levels, hs-CRP levels and insulin levels. We found a slight lowering of hs-CRP levels and elevation of vit  $D_3$  levles by use of these statins, though this difference was not statistically different, though there were studies by other authors where a significant lowering of these levels were observed.  $^{29-32}$ 

### **CONCLUSION**

Both atorvastatin and rosuvastatin are equally powerful statins and very effective in reducing the triglyceride and LDL-cholesterol levels. They are also effective in lowering hs-CRP and elevating vitamin D levels. Our study found no significant difference in the action and efficacy between these two statins.

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Institutional Ethics Committee

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