Efficacy and safety of Rosuvastatin versus Atorvastatin in patients with Hypercholesterolemia

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INTRODUCTION

Hypercholesterolemia is defined as either a low high density lipoprotein (HDL) cholesterol value or elevations in atherogenic lipoprotein particles, including cholesterol, cholesterol esters, and triglycerides. Hyperlipidemia can be caused by primary causes (genetic predisposition) or secondary causes (diet, underlying disease, or medications). Primary Hyperlipidemia is associated with high morbidity and mortality. A defect often occurs in lipid metabolism or transport in primary hyperlipidemia, resulting in reduced LDL receptor activity and accumulation of LDL cholesterol in the plasma, leading to atherogenesis.1 Diseases such as diabetes mellitus, hypothyroidism, Growth hormone deficiency, Cushing's syndrome, obstructive liver disease, nephrotic syndrome, and alcoholism are all common causes of high cholesterol.2 Age in Men is ≥ 45 years and Women is ≥ 55 years, major risk factor for hypercholesterolemia.2 This condition is defined by elevated LDL-C, CHOLESTEROL and Triglycerides and decreased level of HDL-C,1 classified based on Framingham Risk Assessment scale (Table. No 1).

Table 1: Framingham Risk Assessment Scale

<table>
<thead>
<tr>
<th>LDL-C</th>
<th>Total cholesterol</th>
<th>HDL-C</th>
<th>Triglyceride</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100</td>
<td>&lt; 200</td>
<td>&lt; 40</td>
<td>&lt; 150</td>
<td>Optimal</td>
</tr>
<tr>
<td>100-129</td>
<td></td>
<td></td>
<td></td>
<td>Near/above optimal</td>
</tr>
<tr>
<td>130-159</td>
<td>200-239</td>
<td>-</td>
<td>150-199</td>
<td>Borderline</td>
</tr>
<tr>
<td>160-189</td>
<td>&gt; 240</td>
<td>60&gt;</td>
<td>200-499</td>
<td>High</td>
</tr>
<tr>
<td>&gt;190-</td>
<td></td>
<td></td>
<td>&gt; 500</td>
<td>Very high</td>
</tr>
</tbody>
</table>

To treat the hypercholesterolemic patients, various pharmacological approaches are used, but in last few years statins are used more in comparison with other class of drugs. Atorvastatin, Rosuvastatin, Simvastatin, Lovastatin & fluvastatin are used in this class. The statins share a common mechanism of action: they bind to and inhibit the enzyme HMG-CoA Reductase, the rate-limiting step in cholesterol biosynthesis. The inhibition of HMG-CoA reductase activity results in a drop in intracellular cholesterol production, thus activating primarily hepatic LDL receptors and increasing the clearance of LDL from the bloodstream. Atorvastatin and Rosuvastatin are highly prescribed drugs in hypercholesterolemia.1 Rosuvastatin is more effective than atorvastatin even after reducing the dose to half.21 Some studies indicated that rosuvastatin 10mg dose was more effective than atorvastatin 20mg and 40 mg.29 Major side effects of statins are myalgia, liver enzyme elevation, muscle

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Submitted: 18/08/2012 Accepted: 12/03/2013
breakdown.' Hence, in this study efficacy and safety of rosuvastatin 10mg versus atorvastatin 20mg was measured in hypercholesterolemia patients.

**MATERIALS AND METHOD**

The study was single center, retrospective study to evaluate the safety and efficacy of Rosuvastatin and Atorvastatin in patients of Hypercholesterolemia.

Patients were divided in two groups:
1) Patient receiving rosuvastatin alone, (Code-R)
2) Patient receiving atorvastatin alone, (Code-A)

<table>
<thead>
<tr>
<th>Table 2: Drug and Intervention</th>
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<tbody>
<tr>
<td>Arm</td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td>1. Rosuvastatin</td>
</tr>
<tr>
<td>2. Atorvastatin</td>
</tr>
</tbody>
</table>

**Study Population**

Patient population in study : 100-150
Age eligible for study : 45 Years to 80 Years
Genders eligible for study : Both
Healthy Volunteers : No

**Inclusion criteria**
1. LDL-C : $\geq 140 - <250$ mg/dl
2. TG : $\geq 165 - <400$ mg/dl
3. TC : 200 - 240 mg/dl
4. Minimum 12 weeks data must available.

**Exclusion criteria**
1. History of hypersensitivity to statins
2. Overt proteinuria
3. Pregnant or lactating mothers
4. Diagnosis to have any other endocardial or Metabolic disease other than Type 2 DM
5. Type-1 Diabetes Mellitus
6. History of alcohol consumption > 2 drinks/day or 10 drink per week.
7. Patients having renal disease having serum creatinine $>1.5$ mg/dL
8. Documented case of homozygous familial hypercholesterolemia
9. Recent ongoing inter current infection
10. Use of concomitant medication (cyclosporine, systemic Glucocorticoids or Ketoconazole, Erythromycin or Clarithromycin, Glucocorticoids or Verapamil) known to affect the lipid profile or with potency safety concern.

**Assessment**

To measure the LDL-C, HDL-C, TG, TC and VLDL.
To measure any adverse event reported during treatment.

**Data Collection**

Data collection was done from case files at Lifecare Hospital, Ahmedabad and recorded in case record form.

The following information was collected for each patient.

I. Demographic profile
II. Any significant past history
III. Concomitant medication
IV. Physical examination
V. Lipid profile at baseline and at 12 weeks.

**Statistical Analyses**

Data was evaluated using student t- test by using Graph pad 5.04 software.

**RESULT AND DISCUSSION**

Data of 117 patients was collected in this retrospective study i.e. those who had received rosuvastatin and atorvastatin. There were 64 patients in rosuvastatin group and 53 patients in atorvastatin group.

**Table 3: Baseline Demographic Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Rosuvastatin 10mg (n= 64)</th>
<th>Atorvastatin 20mg (n= 53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>Mean ±SD 55.17±6.95</td>
<td>55.79±7.09</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male n (%)</td>
<td>48(75%)</td>
<td>36(67.9%)</td>
</tr>
<tr>
<td>Female n (%)</td>
<td>16(25%)</td>
<td>17(33.3%)</td>
</tr>
<tr>
<td>Type 2 Diabetes n (%)</td>
<td>25(39%)</td>
<td>20(37.7%)</td>
</tr>
<tr>
<td>Non Diabetic n (%)</td>
<td>39(60.9%)</td>
<td>33(62.2%)</td>
</tr>
</tbody>
</table>

The baseline demographic characteristics of patients are shown in Table 3. The mean age of patients was similar in both groups (55.17±6.95 and 55.79±7.09) for rosuvastatin and atorvastatin groups respectively. There were 48 male and 16 female in rosuvastatin group as compared to 36 male and 17 female in atorvastatin group. We also included diabetic patients. There were 25 diabetic patients in rosuvastatin group as compared to 20 diabetic patients in atorvastatin group.
Changes from baseline in the various lipid parameters are shown in Table 4, Figure 1. Patients in both the groups showed statistically significant improvement in LDL-C, HDL-C, TGs, TC and VLDL at week 12. A statistically significant reduction in TC level was observed with rosuvastatin as compared to atorvastatin at week 12. Although rosuvastatin showed a better improvement in all other lipid parameter as compared to atorvastatin at week 12, this difference was not statistically significant. The percentage decreased in lipid parameter like LDL-C, TG, TC and VLDL were 22.3%, 30.1%, 16.3% and 31% in patients of rosuvastatin group as compared to 15.5%, 19.2%, 13.7% and 23.4% in atorvastatin group. The increase in HDL-C level was 17.3% in rosuvastatin group as compared to 12.8% in atorvastatin group.

Changes from baseline in various lipid parameters in male and female of rosuvastatin group are shown in Table 5 and Figure No 2. In this group, there were 48 male and 16 female. A statistically significant decreased in LDL-C, HDL-C, and TC was seen in both the groups. A statistically significant deceased in TG and VLDL were seen in female as compared to male consuming atorvastatin.
Changes from baseline in various lipid parameters in males and females of Atorvastatin group are shown in Table 6, Figure 3. In this group, there were 36 male and 17 female. A statistically significant decreased in LDL-C, TG, TC and VLDL was seen in both the groups. Similarly a statistically significant increased HDL-C level was seen in both the groups. A statistically significant decreased in LDL-C was seen in female as compared to male consuming atorvastatin.

Changes from baseline in various lipid parameters in diabetic and non-diabetic patients of rosuvastatin group are shown in Table 7, Figure 4. In this group, there were 25 diabetic and 39 non-diabetics. Reduction in lipid parameters like LDL-C, TG, TC and VLDL were 21.9%, 29%, 21.9% and 31.1% in diabetic as compared to 21.1%, 31.5%, 21.8% and 36.6% in non-diabetic patients. Whereas increase in HDL-C level was 17.2% in diabetic as compared to 17.3% in non-diabetic patients. Results showed no much difference in LDL-C and HDL-C, but there was more percentage decreased in TC, TG and VLDL in non-diabetic as compared to diabetic patients. This data indicated no statistically significant difference in diabetic patients as compared to non-diabetic patients in rosuvastatin group.
Changes from baseline in various lipid parameters in diabetic and non-diabetic of atorvastatin group are shown in Table 8 Figure 5. In this group, there were 20 diabetic and 33 non-diabetics. Reduction in lipid parameter like LDL-C, TG, TC and VLDL were 14.4%, 12.5%, 18.8% and 22.4% in diabetic as compared to 14.8%, 16%, 19.8% and 23.8% in non-diabetic patients. Whereas increased in HDL-C level was 16.2% in diabetic as compared to 11.5% in non-diabetic patients. There were no statistically significant improvements in lipid parameter in these groups of patients. Results showed no much difference in LDL-C, TC and VLDL but there was more percentage increased in HDL-C in diabetic as compared to non-diabetic patients and more increase in TG in diabetic patients as compared to non-diabetic patients.

Both rosuvastatin and atorvastatin were well tolerated with only a few incidences of mild adverse events. The common adverse events reported in both group were headache, nausea and myalgia as shown in Table no 9.

**CONCLUSION**

Rosuvastatin was more effective than atorvastatin in reducing LDL-C, Total Cholesterol, Triglyceride and VLDL. It was also better in increasing HDL-C as compared to atorvastatin. Rosuvastatin therefore seems to be a better alternative from other statins in patient having hypercholesterolemia.

**ACKNOWLEDGEMENTS**

Authors would like to acknowledge Lifecare Institute of Medical Sciences and Research for allowing to carry out the study in their institution.

**REFERENCES**


