NOVEL ACTION OF SAROGLITAZAR IN PATIENTS WITH DIABETIC DYSLIPIDEMIA – AN OBSERVATIONAL STUDY

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Introduction

• Saroglitazar is the world’s first approved dual PPAR α/γ agonist available in India for the treatment of diabetic dyslipidemia and hypertriglyceridemia in type 2 diabetes not controlled with statin therapy.
• Nonalcoholic fatty liver disease (NAFLD), a component of metabolic syndrome, is increasing rapidly in India along with increasing prevalence of insulin resistance, type 2 diabetes mellitus and obesity.1,2,3,4
• Insulin resistance is the key underlying pathological mechanism in the genesis of NAFLD.
• Nonalcoholic steatohepatitis (NASH) is a more advanced stage of NAFLD, and has a higher risk of progressing to liver cirrhosis or hepatocellular carcinoma.5
• PPAR-γ action of saroglitazar improves insulin sensitivity.6
• Saroglitazar has demonstrated significant reduction in triglycerides (TG) along with favorable effect on glycemic indices in diabetic patients.7,8

Methods

• This is a single centre, observational study of saroglitazar in Indian diabetic patients who were on statin and metformin.
• Total 50 patients (58% male), with a mean age of 49.62 years were included in the study.
• All patients were on stable doses of metformin (mean dose 1070 mg/d) and statin (atorvastatin 5-20 mg/d or rosuvastatin 5-10 mg/d).
• All patients were prescribed saroglitazar 4 mg once daily for 12 weeks without changing the doses of on-going metformin and statin therapy.
• Patients were evaluated for change in lipid parameters, glycemic parameters and liver enzyme at 12 week follow up.
• The changes in laboratory parameters from baseline at 12 week follow up were statistically evaluated using paired “t” test.

Results

Table 1. Baseline demographics (n=50)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>After 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>7.51 ± 0.35</td>
<td>6.84 ± 0.09</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>272</td>
<td>22.69*</td>
</tr>
<tr>
<td>AST (U/L)</td>
<td>68.84</td>
<td>22.69*</td>
</tr>
</tbody>
</table>

* P<0.0001 vs. baseline

Table 2. Change in lipid and glycemic parameters after 12 weeks follow up

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>After 12 weeks</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol (mg/dL)</td>
<td>159.98±54.7</td>
<td>147.50±3.77</td>
<td>0.0005</td>
</tr>
<tr>
<td>TG (mg/dL)</td>
<td>272.51 ± 2.29</td>
<td>22.16*</td>
<td>0.0001</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>39.34±5.04</td>
<td>40.40±3.90</td>
<td>0.0463</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>86.84±16.84</td>
<td>94.68±15.16</td>
<td>0.0400</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>6.84 ± 0.09</td>
<td>6.50 ± 0.09</td>
<td>0.00001</td>
</tr>
</tbody>
</table>

Values are Mean ± SD

Discussion

• Saroglitazar is a dual PPAR α/γ agonist, approved in India for the treatment of hypertriglyceridemia in type 2 diabetes not controlled with statin.
• NAFLD is strongly associated with obesity, dyslipidemia, type 2 diabetes mellitus, and cardiovascular disease.
• Saroglitazar improves insulin sensitivity and it is a potent agent for controlling hypertriglyceridemia.
• The results of this study indicate that 12 week saroglitazar treatment is associated with significant improvement in liver enzymes in patients with type 2 diabetes and dyslipidemia

Conclusion

• 12 week treatment with saroglitazar 4 mg once daily significantly improves liver enzymes along with lipids and glycemic parameters in patients with type 2 diabetes and hypertriglyceridemia.

Bibliography

8. Diabetes Technol Ther. 2014 Feb;16(2):63–71