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 by 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]

Objective

- To evaluate the safety and efficacy of saroglitazar in diabetic dyslipidemic patients with elevated liver enzymes who are not controlled with statin.

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 4mg 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)

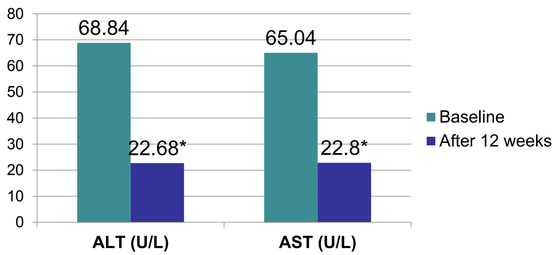
Mean age, years	49.62
Male patients, n(%)	28 (58%)
HbA1c (%)	7.51
Triglycerides (mg/dL)	272
ALT (U/L)	68.84
AST (U/L)	65.04

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

Parameter	Baseline	After 12 weeks	P Value
Total Cholesterol (mg/dL)	159.98±47.47	147.50±37.75	0.0005
TG (mg/dL)	272±51.29	119.66±23.61	0.0001
HDL (mg/dL)	39.34±12.04	40.40±10.09	0.0463
LDL (mg/dL)	88.84±16.84	84.68±15.16	0.0040
HbA1c (%)	7.51±0.35	7.21±0.35	0.0001

Values are Mean ± SD

Figure 1. Change in liver enzymes at 12 weeks follow-up



* P<0.0001 vs. baseline

- There was no significant change in serum creatinine level (from 0.72 to 0.74 mg/dL).
- No major adverse event reported during follow up

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.

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