Saroglitazar in Diabetic Dyslipidemia: 1 Year Data

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Introduction

- There are 387 million and more than 65 million people suffering from diabetes worldwide and in India respectively.[1] 85-97% of diabetic patients in India suffer from dyslipidemia.[2] INTERHEART study showed that dyslipidemia is the most common risk factor associated with myocardial infarction worldwide.[3]
- In India, the most prevalent form of dyslipidemia is low HDL and high triglycerides.[4]
- Triglycerides lowering pharmacotherapy reduces coronary heart disease in patients with triglycerides ≥ 204mg/dL and HDL-C ≤ 34mg/dL.[5]
- Saroglitazar is the world's first commercially available dual peroxisome proliferator activated receptors (PPAR) α/γ agonist which was launched in September 2013 in India.
- Phase 3 clinical trials of saroglitazar have proven the safety and efficacy of saroglitazar in Indian diabetic dyslipidemia patients. It significantly improves glycemic and lipid parameters without any major adverse event in patients with diabetic dyslipidemia.[6,7] Saroglitazar is approved by Drug Controller General of India for the treatment of diabetic dyslipidemia and hypertriglyceridemia in type 2 diabetes not controlled with statin. Recommended dose is 4 mg once daily.
- This is the first study of saroglitazar with 1 year follow up data.

Objective

- To evaluate the safety and efficacy of saroglitazar for 1 year follow up in clinical practice.

Methods

- Prospective, multicenter, single-arm, post-marketing surveillance study.
- Baseline and follow up data were collected from 13 practicing physicians from India.*
- 236 diabetic dyslipidemia patients who were prescribed saroglitazar 4mg once daily were evaluated for lipid and glycemic parameters at baseline, 3-, 6-, 9- and 12 month follow up.
- The SAS system for Windows (release 9.3; SAS Institute) was used for statistical analysis.
- Significant differences in the means from baseline to post baseline were assessed by paired t-tests. P<0.05 was considered significant.

Results

Table 1. Baseline demographic profile

Total patients (n)	**236**
Male, n (%)	146 (61.9%)
Age (Mean ± SD), Years	52 ± 10
Body weight (Mean ± SD), Kg	77.4 ± 10.99
BMI (Mean ± SD), kg/m²	28.8 ± 3.99
Average duration of diabetes, years	5.91

Table 2. Baseline Medications:

Antidiabetic therapy , n (%)	**210 (89%)**
Metformin	72%
Sulfonylureas	66.9%
DPP IV inhibitors	16.1%
Insulin	20.8%
Pioglitazone	4.7%
Statin therapy, n (%)	91 (38.6%)
Atorvastatin (%)	82.4%
Rosuvastatin (%)	17.6%

Table 3. Pattern of antidiabetic medications at baseline

Total subjects = 236		
	N	%
Total no. of patients with antidiabetic therapy	210	89%
Monotherapy	33	15.7%
Dual therapy	115	54.8%
Triple therapy	56	26.7%
More than 3-drugs	6	2.8%

Figure 1. Effect of saroglitazar 4mg on HbA1C (%)

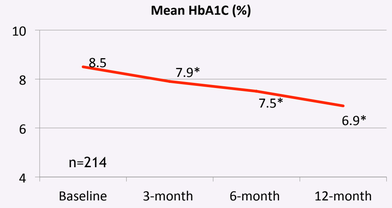


Figure 2. Effect of Saroglitazar 4mg on TG (mg/dL)

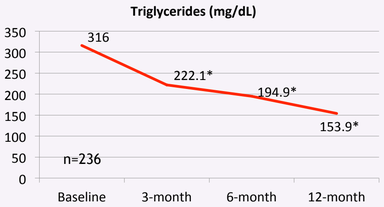
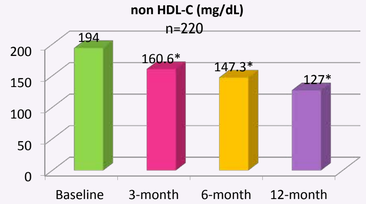


Figure 3. Effect of Saroglitazar 4mg on non HDL-C (mg/dL)



- Non HDL-C was calculated by subtracting HDL-C from total cholesterol value.
- * p<0.0001 vs. baseline

Figure 4. Effect of saroglitazar 4mg on fasting and post-prandial plasma glucose (mg/dL)

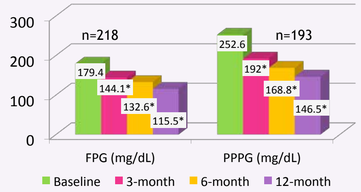


Figure 5. Effect of saroglitazar 4mg on LDL-C and HDL-C (mg/dL)

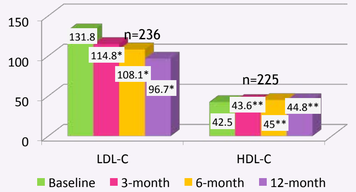
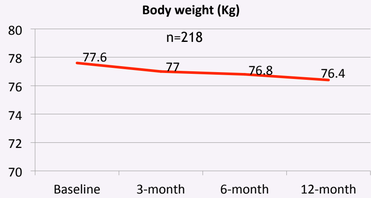


Figure 6. Effect of saroglitazar 4mg on body weight (Kg)



- * p<0.0001; ** p<0.05 vs baseline

- No serious adverse event reported.
- Saroglitazar was safe and well tolerated.

Conclusion

- Insulin resistance and associated type 2 diabetes and dyslipidemia are major modifiable risk factors contributing to cardiovascular morbidity and mortality.
- The present study shows that saroglitazar 4mg once daily in diabetic dyslipidemia patients is safe and well tolerated for long-term use of 1-year.
- Saroglitazar is not associated with weight gain or edema and no drug related adverse event reported in the current 1-year post-marketing surveillance study.
- Saroglitazar significantly improves glycemic as well as lipid abnormalities in Indian patients with diabetic dyslipidemia.

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* 13 practicing physicians participated, list available on request