# Effect of Saroglitazar 4mg in Patients of Diabetic Dyslipidemia with Non Alcoholic Fatty Liver Disease for 24 weeks at Diabetes Care Centre

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## Introduction

- Nonalcoholic fatty liver disease (NAFLD) is emerging as an important cause of liver disease in India.
- Nonalcoholic steatohepatitis (NASH) is a more advanced stage of NAFLD, and has a higher risk of progressing to liver cirrhosis or hepatocellular carcinoma.[1]
- NAFLD, a component of metabolic syndrome, is increasing rapidly in India along with increasing prevalence of insulin resistance, type 2 diabetes mellitus (T2DM) and obesity.[2,3,4,5]
- Insulin resistance is the key underlying pathological mechanism in the genesis of NAFLD.
- NAFLD accounts for significant morbidity and mortality and the therapeutic options are limited.
- Saroglitazar is approved in India for the treatment of diabetic dyslipidemia (DD) and hypertriglyceridemia with T2DM not controlled by statin therapy.
- Saroglitazar has dual peroxisome proliferator activated receptor (PPAR) -α/γ agonistic action.
- 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]

## Methodology

- This is an observational, single centre study.
- Patients – Total 31 patients with diabetic dyslipidemia and NAFLD, who were prescribed saroglitazar 4mg once daily at Diabetes Care Centre, Ahmedabad.
- Abdominal ultrasound, which is used for screening of NAFLD in asymptomatic patients with an incidental elevation of liver enzyme, was used to evaluate the effect of saroglitazar on hepatomegaly.
- Duration of follow up – 24 weeks.
- The main outcome measures at 24 weeks follow up were:
  - Change in body weight and BMI
  - Assessment of hepatomegaly through abdominal ultrasound
  - Change in liver enzymes (ALT, AST)
  - Change in glycemic parameters, lipid parameters
  - Adverse effects if reported

## Objective

- To evaluate the safety and efficacy of saroglitazar 4mg once daily in patients with diabetic dyslipidemia and NAFLD at 24 weeks follow up.
- Of the total 31 patients screened, 28 patients had hepatomegaly on abdominal ultrasound at entry.

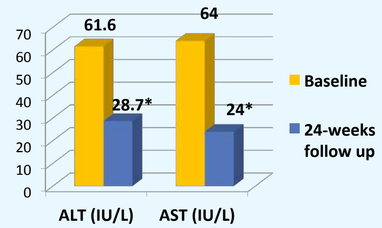
## Results

**Table 1. Baseline patients' demographics and laboratory parameters:**

| Total patients | 31 |
|---|---|
| Mean age, years | 49 |
| Male participants, n(%) | 18 (58%) |
| Body weight, kg | 80.26 ± 8.28 |
| BMI, kg/m2 | 27 ± 5.5 |
| Laboratory parameters | Values at entry |
| Serum ALT (IU/L) | 61±13.7 |
| Serum AST (IU/L) | 64±11.8 |
| Serum triglycerides (mg/dL) | 259±13 |
| Glycosylated hemoglobin, % | 9.04±1.2 |

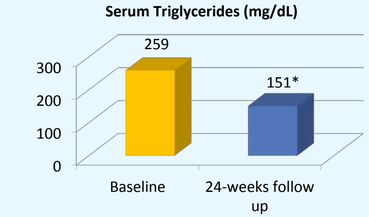
Values are in Mean ± SD

**Figure 1. Effect of saroglitazar 4mg once daily on liver enzymes:**



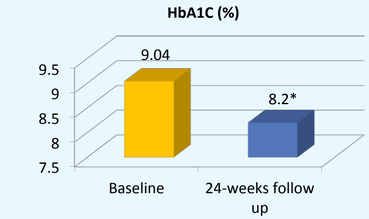

- * p<0.01 vs. baseline

**Figure 2. Effect of saroglitazar 4mg once daily on plasma triglycerides:**




* P <0.01 vs. baseline

**Figure 3. Effect of saroglitazar 4mg once daily on glycosylated hemoglobin (%):**




* P<0.01 vs. baseline

**Abdominal ultrasound – 24 patients (out of 28 patients with hepatomegaly at entry) showed decrease in hepatomegaly at 24-weeks follow up.**

## Safety

- Saroglitazar 4mg once daily was found to be safe and well tolerated.
- No weight gain or edema observed.
- No serious adverse event reported in 24 weeks follow up.
- Serum creatinine remained unchanged during entire study period.

## Conclusion

- NAFLD is a component of metabolic syndrome, and its prevalence is increasing with increasing prevalence of obesity and insulin resistance.
- Saroglitazar 4mg once daily is associated with improvement in grade of NAFLD, liver enzymes, lipid and glycemic parameters in diabetic dyslipidemia patients.

## References

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