

# Observational study of Saroglitazar on Metabolic Parameters in Indian patients with Diabetic Dyslipidemia – A 43 weeks’ of Clinical Experience

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## Introduction

- Control of both glycemic and lipid parameters are important for management of diabetic dyslipidaemia (DD).
- Saroglitazar, the only dual peroxisome proliferator-activated receptor ( $\alpha/\gamma$ ) agonist available for clinical use, is marketed in India for the treatment of DD since September 2013.
- Objective of this study was to evaluate the efficacy and safety of saroglitazar in Indian DD patients and also to compare our results with our previous findings.

## Methods

- This study was a multicentre, retrospective analysis of clinical data of patients with type 2 diabetes and dyslipidemia.
- 75 patients, having diabetic dyslipidemia and were prescribed saroglitazar 4mg once daily, as per the approved indication and prescribing information, were identified and included in this analysis.
- Patients’ data was collected and analyzed at baseline and after a mean follow-up period 43 weeks.
- Paired two-tailed t test was done to analyse change in continuous variables.

## Results

- Total 75 patients data were included in this analysis
- At baseline, all patients were on antihyperglycemic medication.
- Mean duration of follow-up was 42.36 weeks.

Table 1. Baseline patients’ demographics

Total patients	75
Mean age, years	52.77 ± 9.59
Mean body weight, kg	68.24 ± 10.50
Male participants	64%
Patients on statin therapy, %	64%

Table 2. Effect on glycemic parameters

Parameters	Baseline	43-weeks	Mean change	P value
HbA1c (%)	7.83 ± 1.65	6.92 ± 1.16	-0.92	<0.0001
FBG (mg/dL)	151.9 ± 57.6	120.51 ± 33.44	-31.39	<0.0001
PPG (mg/dL)	231.1±105.6	180.8±53.6	-50.28	0.0002

- There was no significant change observed in HDL-C
- Serum ALT (alanine aminotransferase) was significantly reduced from 42.6 to 30.9 IU/L at 43-weeks follow-up (P<0.0001)
- No serious adverse event reported.
- Adverse event reported were mild to moderate in nature.

Figure 1 : Effect on TG and Non HDL-C (mg/dL)

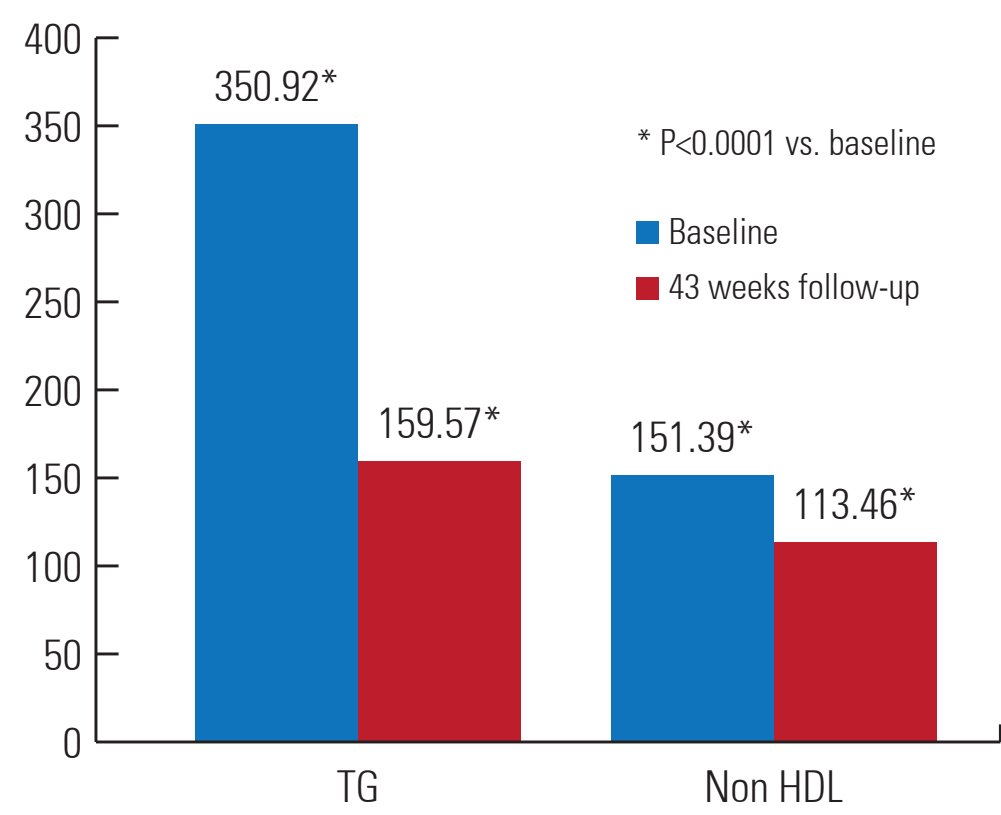
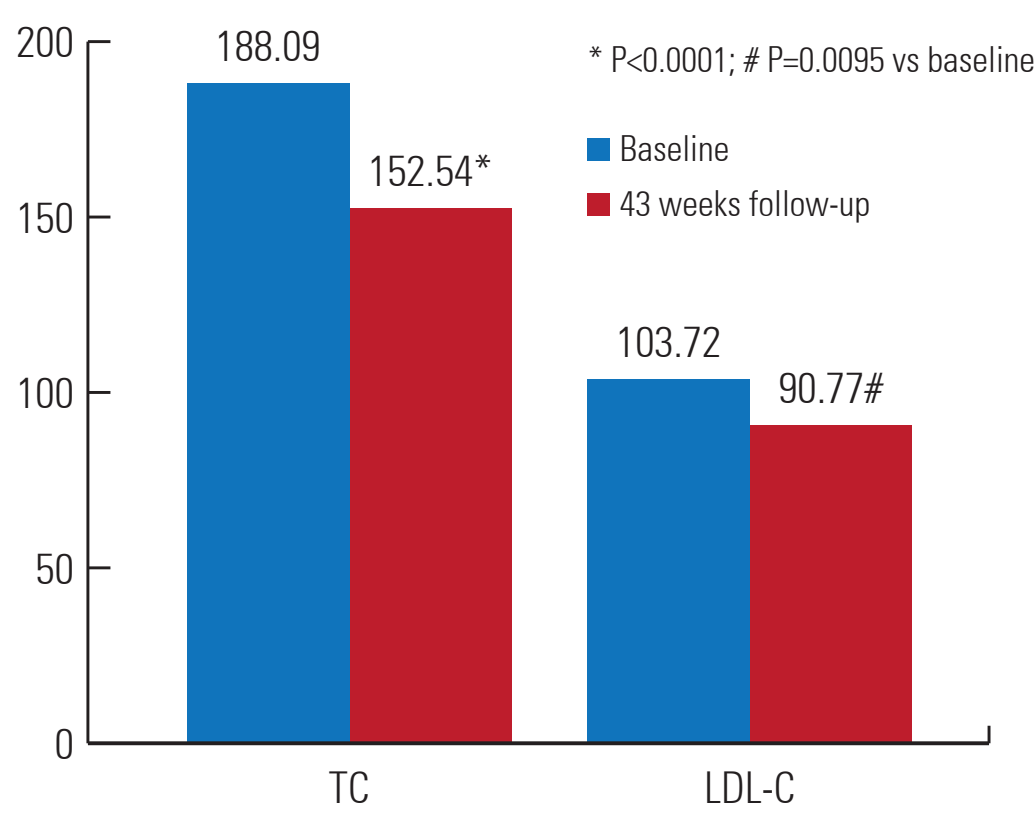


Figure 2 : Effect on other lipid parameters (mg/dL)



- No significant change observed in serum creatinine level.
- These results are consistent with our previous reports with lesser number of patients and smaller duration of study<sup>1</sup>

## Conclusion

Our results showed that saroglitazar is:

- Effective for controlling atherogenic dyslipidemia associated with diabetes and also improves glycemic parameters.
- Safe and well tolerated upto 43 weeks follow-up for the treatment of type 2 diabetes with dyslipidemia

1. Chatterjee S, Majumder A, Ray S. Observational study of effects of Saroglitazar on glycaemic and lipid parameters on Indian patients with type 2 diabetes. Sci Rep. 2015 Jan 9;5:7706. doi: 10.1038/srep07706