Efficacy and Safety of Saroglitazar in Management of NAFLD patients using Transient Elastography: A Single Center Observational Study

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INTRODUCTION

- Saroglitazar is a novel and potent dual PPAR-α/γ agonist which is approved in India for the management of Diabetic Dyslipidemia and Hypertriglyceridemia.
- Saroglitazar is undergoing a Phase III clinical trial in India using the "gold standard" paired liver biopsy and Phase II clinical trial in US and Mexico for NAFLD/ NASH.
- Liver biopsy is considered not feasible in all patients with NAFLD/ NASH n real world scenario.

AIM

- This study is aimed to explore the effect of Saroglitazar on Liver Stiffness Measurement (LSM) and Controlled Attenuated Parameter (CAP) using Transient Elastography (FibroScan®)

METHOD

- **Inclusion criteria**: Ultrasonography evidence of fatty liver and CAP value>238 dB/ m regardless of their LSM value using Echosens FibroScan® 530 compact.
- **Exclusion criteria**: Fatty liver due to other etiology.
- Transient Elastography (FibroScan®) has been performed and LSM and CAP are recorded at baseline, 6 month and 12 month.
- Saroglitazar 4 mg once daily along with the continuation of drugs for co-morbid illnesses was recommended for treatment till one year.
- Statistical analysis was done using Paired sample student t test.

RESULTS

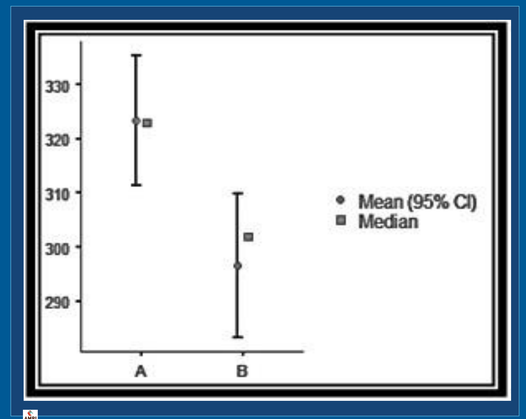
- This is an interim analysis of 44 patients at 6 month follow up with mean age of 48.3 ± 11.9 years; 81.8% males; mean BMI 26.1 ± 4.11 Kg/m^2 ; waist circumference 1.02 ± 0.11 m. 56.8 % are non diabetic .

Controlled Attenuated Parameter (CAP) :

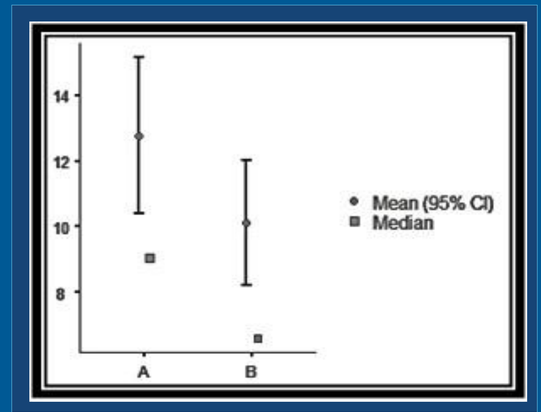
- Significant reduction from 323 ± 40.5 dB/m to 297± 44.8 dB/m (p <0.001 and 95% CI).
- Significant decline in CAP in S3 Stage (n=32) from 343 ± 26.2 dB/m to 312 ± 38.2 dB/m (p <0.001)

Liver stiffness measurement (LSM) :

- Significant reduction (21.1%) from 12.8 ± 8.05 kPa to 10.1 ± 6.41 kPa (p< 0.001 at 95% CI).
- The stage wise analysis also shown significant improvement , as in stage F0-F1 (13.7%), F2 (24.4 %) and F4 (26 %) .



CAP / Liver Steatosis : (A): At Baseline (B): After 6 month



Liver Stiffness : (A): At Baseline (B): After 6 month

	S1 Stage (n=2)	S2 Stage (n=10)	S3 Stage (n=32)
Baseline CAP (dB/m)	232 ± 2.12	280 ± 12.3	343 ± 26.2
6 month CAP (dB/m)	214 ± 12.02	264 ± 31.7	312 ± 38.2
p value at 95% CI	0.323	0.206	<0.001

Table 1: Changes in the CAP values from Baseline as per Steatosis Stage

	Fo-F1 Stage (n=13)	F2 Stage (n=13)	F3 Stage (n=5)	F4 Stage (n=13)
Baseline LSM (kPa)	6.52 ± 0.741	8.50 ± 0.737	12.5 ± 0.760	23.8 ± 7.25
6 month LSM (kPa)	5.63 ± 1.432	6.43 ± 1.365	12.6 ± 8.514	17 ± 4.75
p value at 95% CI	0.025	< 0.001	0.974	< 0.001

Table 2: Changes in the LSM values from Baseline as per Fibrosis Stage

CONCLUSIONS

- **The interim analysis of this study shows early trends for reduction in steatosis and fibrosis using FibroScan® for patients who were on Saroglitazar.**
- **Further studies, including the undergoing Phase III clinical trial would throw further light on the potential role of Saroglitazar.**

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