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 in 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/m²; waist circumference 10.2 ± 0.11 m. 56.8% are non diabetic.
• 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 %).

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.

REFERENCES

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