

## Original Article

# Saroglitazar and vitamin E vs. lifestyle interventions in metabolic dysfunction associated steatotic liver disease: A 3-arm randomised study

Anurag Kumar Tiwari,<sup>1</sup> Gurvachan Singh,<sup>1</sup> Vinod Kumar,<sup>1</sup> Dawesh Prakash Yadav,<sup>1</sup> Sunit Kumar Shukla,<sup>1</sup> Virendra Singh,<sup>1</sup> Gaurav Mishra,<sup>1</sup> Narendra Kumar Tiwary,<sup>3</sup> Anand Anunay,<sup>1</sup> Divyanshi Singh<sup>1</sup> and Deepika Chaturvedi<sup>2</sup>

<sup>1</sup>Department of Gastroenterology, Institute of Medical Sciences, Banaras Hindu University, <sup>2</sup>Department of Medical Health and Family Welfare, PDDU Hospital, Varanasi, Uttar Pradesh and <sup>3</sup>Department of Community Medicine, RG Kar Medical College and Hospital, Kolkata, West Bengal, India

Received September 12, 2025; Accepted November 21, 2025; Published May 16, 2026

**Background and objectives:** Lifestyle interventions are a vital component for the management of metabolic dysfunction-associated steatotic liver disease (MASLD). In the present study, we investigated the differential effect of saroglitazar or vitamin E vs. lifestyle interventions only.

**Methods:** A total 150 non-diabetic patients aged 19-55 yr were recruited to receive saroglitazar and vitamin E along with lifestyle interventions and lifestyle interventions alone (n=50 in each arm, A, B and C, respectively) for 24 weeks. Liver stiffness measurements and NAFLD fibrosis score were the primary outcomes. The study was registered under Trial registration (CTRI/2022/05/042462).

**Results:** Per-protocol analysis was performed in 136 patients (n=46, 47, and 43 in arms A, B and C, respectively). The changes from baseline were not-significant for NAFLD fibrosis score [ $0.05 \pm 0.52$ ,  $0.06 \pm 0.64$  and  $-0.12 \pm 1.0$ , 95% confidence interval (CI),  $P=0.41$ ] and liver stiffness measurement [ $-1.25$  (-2.6, -0.2),  $-1.4$  (-3.7, 0.4), and  $-0.7$  (-1.8, -0.2),  $P=0.22$ ] in either arm. Changes in secondary outcomes were also not-significant except triglyceride [ $-13.95$  (-61, -18),  $-4.3$  (-28.8, 49) and  $-13$  (-127, 3)  $P=0.035$ ]. A considerable proportion of patients had at least '2 Kpa reduction' in liver stiffness measurement in arm A (39%) compared to C (19%).

**Interpretation and conclusions:** Saroglitazar or vitamin E are similar to lifestyle interventions in improving different non-invasive parameters in MASLD at 24 weeks of intervention.

**Keywords** Lifestyle interventions; Liver stiffness measurement; NAFLD fibrosis score; Saroglitazar; Vitamin E