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Saroglitazar: One Molecule for Managing Two Diseases, Type 2 Diabetes and Hypertriglyceridemia

India is becoming a capital of diabetes world with estimated 80 million people are living with diabetes in the year 2022 [1]. Cardiovascular diseases (CVD) remain the most common cause of mortality in people with type 2 diabetes (T2D). Asian Indian T2D phenotype is characterized by abdominal obesity despite relatively low body mass index, insulin resistance, higher triglycerides (TG > 150 mg/dL) and low high density lipoprotein cholesterol (HDL-C, < 40 mg/dL in males and < 50 mg/dL in females) [2]. ICMR INDIAB study showed higher prevalence of dyslipidemia, mainly hypertriglyceridemia, in Indian population with T2D [3]. Therefore, medications that can improve glycemic control as well as lower TG levels are much needed for managing Asian Indian with T2D.

Saroglitazar is a molecule developed by the Zydus Research Centre (Ahmedabad, India) with a predominant affinity to peroxisome proliferator-activated receptor (PPAR) alpha isoform and moderate affinity to PPAR gamma isoform [4]. The molecule has shown beneficial effects on lipids and glycemic control without concerning side effects. The Drug Controller General of India (DCGI) approved this molecule in 2013 for management of hypertriglyceridemia in patients with T2D in India [5]. Recently, based on newer evidence, saroglitazar received DCGI approval for treatment of non-alcoholic fatty liver disease (NAFLD) in India [6]. It has been available for management of T2D in India for almost 10 years now and post-marketing surveillance has not indicated any potential worrisome long-term adverse effects [7]. However, this molecule is currently not available in other developed countries given no approval by the United State Food and Drug Administration (FDA) or European Medical Agency (EMA).

In this issue of Clinical Diabetology, Baidya et al. [8] presented results of a single-center, retrospective observational study evaluating effect of saroglitazar 4 mg once daily on TG levels at week 12 and 52, among 150 T2D who had hypertriglyceridemia (TG > 500 mg/dL) at baseline despite on stable lipid lowering and diabetes therapy. At week 52, T2D patients treated with saroglitazar had significant reduction in TG (221.51 ± ± 61.81 from 669.93 ± 81.22 mg/dL , p-value < 0.001) and LDL-c (118.88 ± 12.16 from 167.68 ± 10.881, p-value < 0.001) from baseline in addition, there was significant reduction in A1c by almost 1% (8.02 ± 0.3 to 7.12 ± 0.2%, p < 0.001) over 52 weeks. No major adverse event was reported during the study period. Creatine phosphokinase (CPK), liver enzymes and creatinine did not change significantly.

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The findings of this study are clinically important for Indian patients with T2D who had higher degree of hypertriglyceridemia and increased CVD risk. There are many limitations of this study given that it is a retrospective and observational in nature. Moreover, it is important to remember that most previous clinical trials with fibrates showed significant reduction in triglyceride levels but failed to demonstrated reduction in CVD events [9]. Therefore, long-term cardiovascular outcome trial is needed to prove CVD risk reduction benefit of saroglitazar in Indian patients with T2D.

Conflict of interest

None declared.

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