

PHARMACOTHERAPY

Olmesartan for microalbuminuria—friend or foe?

Treatment with the angiotensin-receptor blocker olmesartan delays the onset of microalbuminuria—an early predictor of diabetic nephropathy—in patients with type 2 diabetes mellitus, show results of the ROADMAP (Randomized Olmesartan and Diabetes Microalbuminuria Prevention) trial. However, a higher rate of fatal cardiovascular events in the olmesartan group compared with the placebo group may be a cause for concern.

Haller and colleagues enrolled 4,447 patients with type 2 diabetes mellitus but without microalbuminuria, who were randomly allocated to receive 40 mg olmesartan once daily or placebo over a median of 3.2 years. The target blood pressure was <130/80 mmHg, which was achieved in 80% of patients taking olmesartan and in 71% of those on placebo with the use of additional antihypertensive drugs, aside from

angiotensin-converting-enzyme inhibitors or other angiotensin-receptor blockers.

The time until the onset of microalbuminuria was significantly increased by 23% with olmesartan compared with placebo. Nevertheless, the occurrence of fatal cardiovascular events was also higher in those receiving the drug, in particular in patients with pre-existing coronary heart disease.

Of note, given the small number of cardiovascular events reported in a large patient population, the study by Haller *et al.* is underpowered for cardiovascular endpoints, and conclusions should be made with caution. In fact, the FDA is currently evaluating data from ROADMAP and one other clinical trial in which patients with type 2 diabetes mellitus taking olmesartan had a higher rate of cardiovascular-related death compared with patients on placebo. Nonetheless, to date, the FDA states that



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the benefits of olmesartan in patients with high blood pressure continue to outweigh its potential risks.

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Original article Haller, H. *et al.* Olmesartan for the delay or prevention of microalbuminuria in type 2 diabetes. *N. Engl. J. Med.* 364, 907–917 (2011)