DIABETES

Olmesartan slows microalbuminuria

The angiotensin-receptor blocker (ARB) olmesartan reduces the time to onset of microalbuminuria among patients with type 2 diabetes mellitus. This finding from the phase IIIb Randomized Olmesartan and Diabetes Microalbuminuria Prevention (ROADMAP) trial, has been reported by Hermann Haller and colleagues in the *New England Journal of Medicine*.

Microalbuminuria is an early indicator of diabetic nephropathy and subclinical cardiovascular disease. Agents that inhibit the renin–angiotensin–aldosterone system reduce the rate of albumin excretion and could, therefore, delay the onset of microalbuminuria. To investigate this theory, the ROADMAP trial investigators randomly assigned 4,449 white patients with type 2 diabetes to 40 mg per day of olmesartan or placebo. Patients who had taken ARBs or angiotensin-converting-enzyme inhibitors in the preceding 6-month period were excluded. The primary end point was time to first occurrence of microalbuminuria, which was defined as

a urinary albumin:creatinine ratio of >35 in women and >25 in men.

During follow-up (median 3.2 years), microalbuminuria developed in 8.2% of patients in the olmesartan group compared with 9.8% in the placebo group. Onset of microalbuminuria occurred 23% later in those taking olmesartan when compared with placebo (median 722 days vs median 576 days; adjusted 95% CI 0.63–0.94, $P=0.01$). Blood pressure was controlled to <130/80 mmHg in the majority of patients in both treatment groups. No significant differences in the rates of cardiovascular complications or death from cardiovascular causes were reported (4.3% for the olmesartan group vs 4.2% for the placebo group). However, among patients with pre-existing coronary heart disease, more fatal cardiovascular events occurred in the olmesartan group than in the placebo group (11 vs 1; $P=0.01$). Cardiovascular mortality was similar among those who did not have previously diagnosed heart disease.

Notably, patients in the lowest or highest quartiles of blood pressure at baseline

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were more likely to experience fatal cardiovascular events. The investigators hypothesize that this finding is evidence of the blood pressure “J-curve” effect.

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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)