

# Prevention of Microalbuminuria with Olmesartan

*This drug delayed onset slightly but did not change overall incidence.*

In patients with diabetes mellitus (DM), microalbuminuria predicts early development of nephropathy and cardiovascular (CV) disease; treatment with angiotensin-converting-enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) is recommended for patients with established microalbuminuria. In this trial, investigators assessed the value of the ARB olmesartan (Benicar) for *preventing* development of microalbuminuria. The drug's maker funded the study, and most of the authors had financial relationships with the company.

About 4400 patients (mean age, 58) with type 2 DM, normoalbuminuria, and mean blood pressure of 136/81 mm Hg were randomized to daily olmesartan (40 mg) or placebo, with unrestricted use of antihypertensives other than ARBs or ACE inhibitors. Most patients in both groups achieved blood pressures <130/80 mm Hg. During median follow-up of 3.2 years, the incidence of microalbuminuria did not differ significantly between the olmesartan and placebo groups (8.2% vs. 9.8%), but onset was delayed significantly in the olmesartan group (median, 722 days vs. 576 days). Mean glomerular filtration rate declined more with olmesartan than with placebo (−5 vs. −1 mL/minute/1.73 m<sup>2</sup>). In a secondary endpoint, significantly more olmesartan patients died from any CV cause (0.7% vs. 0.1%).

**Comment:** The authors emphasize the 5-month delay in onset of microalbuminuria with olmesartan, but the clinical importance of this outcome is unclear. In addition, the authors concede that whether the observed parallel decline in GFR and albuminuria with olmesartan represents "a favorable hemodynamic (functional) response to lower glomerular pressure or an adverse underlying structural change" is unclear. Even more worrisome was the excess risk for fatal CV events. In our view, olmesartan should not be used as preemptive therapy in diabetic patients who have reasonably controlled blood pressure and no microalbuminuria.

— [Thomas L. Schwenk, MD](#), and [Allan S. Brett, MD](#)

Published in [Journal Watch General Medicine](#) March 17, 2011