

Telmisartan Did Not Prevent Renal Disease in Patients Without Proteinuria

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The full report is titled “Effect of Telmisartan on Renal Outcomes. A Randomized Trial.” It is in the 7 July 2009 issue of *Annals of Internal Medicine* (volume 151, pages 1-10). The authors are J.F.E. Mann, R.E. Schmieder, L. Dyal, M.J. McQueen, H. Schumacher, J. Pogue, X. Wang, J.L. Probstfield, A. Avezum, E. Cardona-Munoz, G.R. Dagenais, R. Diaz, G. Fodor, J.M. Maillon, L. Rydén, C.M. Yu, K.K. Teo, and S. Yusuf, for the TRANSCEND (Telmisartan Randomised Assessment Study in ACE Intolerant Subjects with Cardiovascular Disease) Investigators.

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What is the problem and what is known about it so far?

Diabetes and problems with blood vessels (vascular disease) can damage the kidney’s filter system. The damaged system first leaks small and then large amounts of protein into the urine, and the damaged kidneys eventually fail (this condition is called *end-stage renal disease*). The affected person may need dialysis or a transplant. Several studies show that treatments, such as angiotensin-converting enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs), may prevent worsening of kidney disease in people who already are leaking large amounts of protein in their urine (a condition called *macroalbuminuria*). Few studies, however, have assessed whether these treatments can prevent kidney disease in people who are not yet leaking large amounts of protein in their urine.

Why did the researchers do this particular study?

To see whether an ARB (telmisartan) prevents kidney disease more often than a dummy pill (placebo) in patients without large amounts of protein in their urine.

Who was studied?

5926 adults with cardiovascular disease or diabetes who did not have macroalbuminuria or heart failure and had tried ACE inhibitors but could not tolerate them because of side effects.

How was the study done?

The researchers randomly assigned patients to telmisartan or placebo. Neither the patients nor their doctors were told who got which treatment. The researchers then followed patients for about 4 to 5 years. They assessed the number of patients who had worsening kidney function (doubling of serum creatinine) and end-stage kidney disease that required dialysis. They also assessed changes in the kidney’s estimated glomerular filtration rate and amounts of protein leaked in the urine.

What did the researchers find?

Patients given telmisartan had a little less protein in their urine than those given placebo, but they more often had doubling of serum creatinine and slight declines in estimated glomerular filtration rate. Few patients in either group required dialysis. Symptomatic low blood pressure (1% vs. 0.5%) and high serum potassium levels greater than 5.5 mmol/L (3.8% vs. 1.4%) were more common with telmisartan than placebo.

What were the limitations of the study?

The researchers had limited ability to detect important differences in kidney outcomes between groups because few patients developed end-stage renal disease that required dialysis. Only patients who could not tolerate ACE inhibitors were included. Patients were followed for only a few years. End-stage renal disease may not occur until many years after a person first develops macroalbuminuria.

What are the implications of the study?

In patients with vascular disease or diabetes but without macroalbuminuria, telmisartan given for 4 to 5 years did not prevent clinically important kidney disease more than placebo.

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