
Authors and Disclosures

Journalist

Nancy A Melville

Nancy Melville is a freelance writer for Medscape.

From Medscape Medical News Novel Anti-Inflammatory Bardoxolone Improves GFR in CKD



Nancy A. Melville

November 24, 2010 (Denver, Colorado) — A novel anti-inflammatory drug bardoxolone methyl (Reata Pharmaceuticals) shows efficacy in the treatment of patients with chronic kidney disease (CKD) and may even have the potential to reverse disease progression, according to findings presented here at Renal Week 2010: American Society of Nephrology 43rd Annual Meeting.

Results from week 24 of an ongoing 52-week multicenter placebo-controlled study of 227 patients with either type 2 diabetes or moderate to severe CKD showed a rapid increase in glomerular filtration rate (GFR) in the treatment group; there were no improvements in the placebo group at week 24.

"Bardoxolone treatment was associated with a fairly rapid increase in GFR that was seen as early as 4 weeks, with a continuous increase to up to week 12," Pablo E. Pergola, MD, PhD, lead author of the study, told meeting attendees. "The increase was sustained [and continued to] increase through week 24, where the average increase in GFR was 10.1 mL/min per 1.73 m², compared with no change in the placebo group."

"We believe these results are very clinically significant," said Dr. Pergola, who is from the University of Texas Health Science Center at San Antonio.

The study also showed that 59% of patients in the bardoxolone group had an improvement in CKD status of at least 1 stage, compared with only 16% of patients in the placebo group.

CKD status dropped at least 1 stage in 14% of patients in the placebo group, but in only 4% of patients in the bardoxolone group. In addition, bardoxolone reduced the number of patients with stage 4 CKD by 50%; there was no change in the placebo group.

Dr. Pergola said that patients in the study had baseline characteristics typical of CKD, including a mean age of 67 years and long-term diabetes; 75% of subjects were obese. Patients had moderate to severe disease, with a mean estimated GFR of 32 mL/min per 1.73 m².

Thirty-eight percent of subjects had stage 4 CKD, and 62% had stage 3b. Nearly all patients were receiving the standard of care, with 98% taking an angiotensin-converting enzyme (ACE) inhibitor or and angiotensin II receptor blocker. Mean blood pressure was 130/69 mm Hg.

The most common adverse effect was muscle spasms, reported by 49% of patients in the bardoxolone group and 12% in the placebo group; however, Dr. Pergola said, the spasms were transitory.

"The spasms were typically transient and, importantly, there were no markers of muscle damage or increase in pain," Dr. Pergola said. "In general, patients tolerated the drug very well."