UT SOUTHWESTERN MEDICAL CENTER NEWS

Media Contact: Jeff Carlton
214-648-3404
Jeffrey.Carlton@utsouthwestern.edu

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Drug shows improved kidney function for patients with type 2 diabetes, UT Southwestern researchers report

DALLAS – June 24, 2011 – A new anti-inflammatory drug used by patients with type 2 diabetes improved their kidney function during a year-long study involving researchers from UT Southwestern Medical Center.

The study findings, reported in today's *New England Journal of Medicine*, mark the first time a drug therapy has led to improved kidney function for patients with type 2 diabetes and chronic kidney disease. Previous studies have identified drugs that slowed the deterioration of kidney function, said Dr. Robert Toto, director of the Houston J. and Florence A. Doswell Center for the Development of New Approaches for the Treatment of Hypertension at UT Southwestern.

"In diabetes, kidney function tends to deteriorate over time," Dr. Toto said. "No prior studies of this duration have shown what appears to be an increase in kidney function by any therapy, which makes this a very exciting development."

Type 2 is the most common form of diabetes, the leading cause of kidney failure in the U.S. Diabetics account for nearly half of all new cases of end-stage renal disease, the point at which patients require dialysis or a kidney transplant, said Dr. Toto, professor of internal medicine.

The study involved 227 adult patients with type 2 diabetes and chronic kidney disease. They were divided into four groups – three receiving different dosages of bardoxolone methyl, an anti-inflammatory drug, and the fourth group receiving a placebo and acting as a control.

The patients were tracked for 56 weeks, with measurements of their kidney function taken every four weeks. At study-highlighted weeks 24 and 52, researchers saw an overall significant increase in the estimated glomerular filtration rates, which are measurements of how well the kidneys are functioning, for the patients receiving the drug.

At 56 weeks, four weeks after researchers stopped administering the drug, a third measurement showed that patients continued to maintain a slightly higher level of kidney function compared to baseline measurements taken at the study's start.

"That is important because it implies the beneficial effect of the drug lasts for quite some time

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after it is discontinued," Dr. Toto said.

The most common side effects included muscle spasms, low blood magnesium levels and nausea.

The next step, Dr. Toto said, will be a longer-term clinical trial with a larger patient pool, necessary to confirm the effectiveness and safety of using the anti-inflammatory in people with type 2 diabetes and chronic kidney disease. He noted that it is important to interpret the current study's results cautiously, given the small number of patients and one-year duration of the study.

"The results of this study show promise for bardoxolone methyl in the treatment of kidney disease in those with type 2 diabetes," he said. "If it's confirmed to be effective and safe in the long term, this drug could potentially have a major positive impact on kidney disease and become part of the standard of care."

Dr. Philip Raskin, professor of internal medicine who leads the University Diabetes Treatment Center and the diabetes clinic at Parkland Memorial Hospital, also participated in the study, as did researchers at Reata Pharmaceuticals, Renal Associates in San Antonio, the University of Alabama-Birmingham, and Statistics Collaborative in Washington, D.C.

The study was funded by Reata, an Irving-based biopharmaceutical company founded in part by UT Southwestern faculty members.

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