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ASN Contact: Shari Leventhal • 202-416-0658 (p) • sleventhal@asn-online.org

DIABETICS ARE NOT BENEFITING FROM ADVANCES IN KIDNEY CARE

Type 1 diabetes patients with kidney dysfunction still face high risks of kidney failure and heart-related death

Washington, DC (February 18, 2011) — Despite significant advances in kidney care over the past 20 years, efforts to improve therapy for type 1 diabetes patients with kidney dysfunction remain unsuccessful, according to a study appearing in an upcoming issue of the *Journal of the American Society Nephrology* (JASN). The results suggest that more effective therapies are needed for these patients.

One in three patients with type 1 diabetes develops a condition called macroalbuminuria, where especially high amounts of protein are lost through the urine. Patients with type 1 diabetes and macroalbuminuria face increased risks of developing kidney failure, or end stage renal disease (ESRD), and of dying from heart-related causes. Andrzej Krolewski, MD, PhD (Joslin Diabetes Center and Brigham and Women's Hospital) and his colleagues studied these risks in patients at the Joslin Clinic, a large institution that specializes in the care of patients with diabetes and where new clinical protocols are promptly adopted and implemented.

Between 1991 and 2004, the investigators enrolled 423 white patients with type 1 diabetes who developed macroalbuminuria. Ninety-eight percent of patients were followed through 2008; ESRD developed in 172 patients, and 29 died without ESRD. The majority of these outcomes occurred between ages 36 and 52 years with durations of diabetes of 21 to 37 years.

During the more than 15 years of follow-up, the use of treatments to protect the kidneys increased from 56% to 82%, and blood pressure and cholesterol levels improved significantly. However, the risks for both ESRD and pre-ESRD death did not change over that time. There were 70 post-ESRD deaths, and the mortality rate was very similar during the 1990s and the 2000s. Throughout the study, patients who received pre-emptive kidney transplants (before dialysis) were less likely to die.

“Our findings clearly indicate that the accomplishments in treatment of patients with type 1 diabetes and macroalbuminuria over the last 20 years are not effective enough, and more effective therapies to retard progression to ESRD are desperately needed,” said Dr. Krolewski. “New therapies need to be developed including more aggressive or experimental protocols to stop or retard declining renal function, which leads to ESRD,” he added.

Study co-authors include Elizabeth Rosolowsky, MD (Joslin Diabetes Center and Children's Hospital, Boston); Jan Skupien, MD, Monika Niewczas, MD, PhD (Joslin Diabetes Center and Brigham and Women's Hospital); Adam Smiles, James Warram, MD, ScD (Joslin Diabetes Center); Bijan Roshan, MD, Robert Stanton, MD (Joslin Diabetes Center and Beth Israel Deaconess Medical Center); and John Eckfeldt, MD, PhD (University of Minnesota). The study was inspired by Diego Cantarovich, MD, PhD (Nantes University Hospital, in Nantes, France), who asked the investigators for data to design the Pancreas Allograft Transplantation for Diabetic Nephropathy and Mild Chronic Renal Failure Stage Study.

In reviewing the results of this study in an accompanying editorial, Robert Nelson, MD, PhD (National Institute of Diabetes and Digestive and Kidney Diseases) noted that it raises important questions about the effectiveness of efficacious treatments in patients with type 1 diabetes and macroalbuminuria, where efficacy refers to the effect of a treatment in a controlled environment where the extraneous effects of other factors are eliminated, and effectiveness refers to the effect of the same treatment in a real-world population. For example, "what factors determine whether efficacious treatments will be clinically effective? And what roles do age, ethnicity, type of diabetes, and stage of disease play in determining effectiveness of an intervention?" he asked. He added that while the study authors argue that new therapies are needed, "a careful examination of the process of healthcare delivery may also identify points in translation where corrective steps can be taken to enhance therapeutic effectiveness."

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The article, "Risk for ESRD in Type 1 Diabetes Remains High Despite Renoprotection," (doi 10.1681/ASN.2010040354) and accompanying editorial, "Is Treatment of Nephropathy in Type 1 Diabetes Efficacious but Ineffective?" (doi 10.1681/ASN.2011010076) will appear online at <http://jasn.asnjournals.org/> on February 24, 2011.

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