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Exploring a Combination Therapy for CKD and T2D: CONFIDENCE Trial Insights

Announcer:
You're listening to *Audio Abstracts* on ReachMD. Here's Dr. Janet McGill.

Dr. McGill:
Hi, I'm Dr. Janet McGill, Professor of Medicine in the Division of Endocrinology, Metabolism, and Lipid Research at Washington University School of Medicine in Saint Louis, Missouri. I'm here today to discuss the CONFIDENCE trial, which analyzed a combination of finerenone and empagliflozin in treating patients with chronic kidney disease, or CKD, and type 2 diabetes.

While both finerenone and empagliflozin are currently approved and used to treat these conditions, there's been uncertainty about whether combining them from the start would provide added benefits. To address this research gap, the CONFIDENCE trial, which was a double-blind, randomized, multi-center and international study, investigated the efficacy and safety of initial combination therapy versus monotherapy with either finerenone or empagliflozin.

A total of 800 participants with baseline albuminuria between 100 and 5,000 milligrams per gram and estimated GFR values between 30 and 90 milliliters per minute per 1.73 meters-squared of body surface area were enrolled.

Participants who were all receiving renin angiotensin system inhibitors prior to study entry were randomly assigned to receive either finerenone, empagliflozin, or both drugs simultaneously. The primary endpoint was the change from baseline in albumin-to-creatinine ratio, or uACR, at 180 days. This is a surrogate marker for kidney disease progression and cardiovascular risk.

The results clearly showed that combination therapy produced significantly greater uACR reduction of 52 percent from baseline at 180 days, compared to 32 percent with finerenone alone, and 29 percent with empagliflozin alone. uACR reductions with combination therapy began rapidly within 14 days and exceeded 40 percent by day 90.

Secondary outcomes further supported the additive benefits of the combination. More participants in the combination group achieved uACR reductions exceeding 30, 40 and 50 percent compared to monotherapy groups at 30 days after the end-of-treatment visit. The expected increase in serum potassium with finerenone was partially mitigated by concomitant use of empagliflozin, and the modest decline in GFR that we see at the beginning of these therapies, most notably with combination, reversed post-treatment.

Looking closer at the safety profile, acute kidney injury and symptomatic hypotension were rare, and adverse events leading to discontinuation of the treatment or of the study were below five percent in all groups. Combination therapy was associated with greater blood pressure reduction and a lower incidence of moderate hyperkalemia than finerenone alone.

In summary, initiation of finerenone and empagliflozin in combination offers more effective uACR lowering than the traditional stepwise approach, potentially overcoming treatment inertia that is commonly observed in CKD management in persons with type 2 diabetes. The limitations of the CONFIDENCE trial included short duration of six months and reliance on the surrogate marker of uACR reduction, rather than clinical outcomes. Still, the CONFIDENCE trial contributes valuable information to inform current therapeutic strategies in persons with CKD and type 2 diabetes.

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