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Liraglutide and Renal Outcomes in Type 2 Diabetes: Results of the LEADER Trial

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Background: The effects of liraglutide, a long-acting glucagon-like peptide-1 (GLP-1) analog, on renal outcomes in type 2 diabetes are unknown. We conducted a randomized, double-blind, placebo-controlled trial comparing liraglutide vs placebo, both on a background of standard of care, in participants with type 2 diabetes and high cardiovascular risk.

Methods: The Liraglutide Effect and Action in Diabetes: Evaluation of cardiovascular outcome Results (LEADER) trial was initiated in 2010 and completed in 2015. Renal events
were key secondary outcomes. The primary renal outcome was a composite of new onset of persistent macroalbuminuria, persistent doubling of serum creatinine, end stage renal disease (ESRD), or death due to renal disease. Risk of renal outcomes was determined using intention-to-treat in time-to-event analyses; competing risk of death was taken into account. Change of eGFR and loss of eGFR by >-30% was also analyzed.

Results: 9340 patients were randomized and median follow-up was 3.84 years. The primary renal outcome occurred in fewer participants treated with liraglutide (268 of 4668) than with placebo (337 of 4672; HR 0.787 [0.670;0.924] p=0.003). The difference was primarily driven by new onset of persistent macroalbuminuria, occurring in fewer participants treated with liraglutide (161 of 4668) than with placebo (215 of 4672; HR 0.74 [0.61;0.91] p=0.004). Doubling of serum creatinine and ESRD tended to be less frequent with liraglutide. eGFR decreased significantly less and albuminuria increased less with liraglutide than placebo.
Conclusions: In conclusion, liraglutide in addition to standard of care therapy reduced the progression of diabetic nephropathy.