Analysis hints at sudden cardiac death reduction with finerenone

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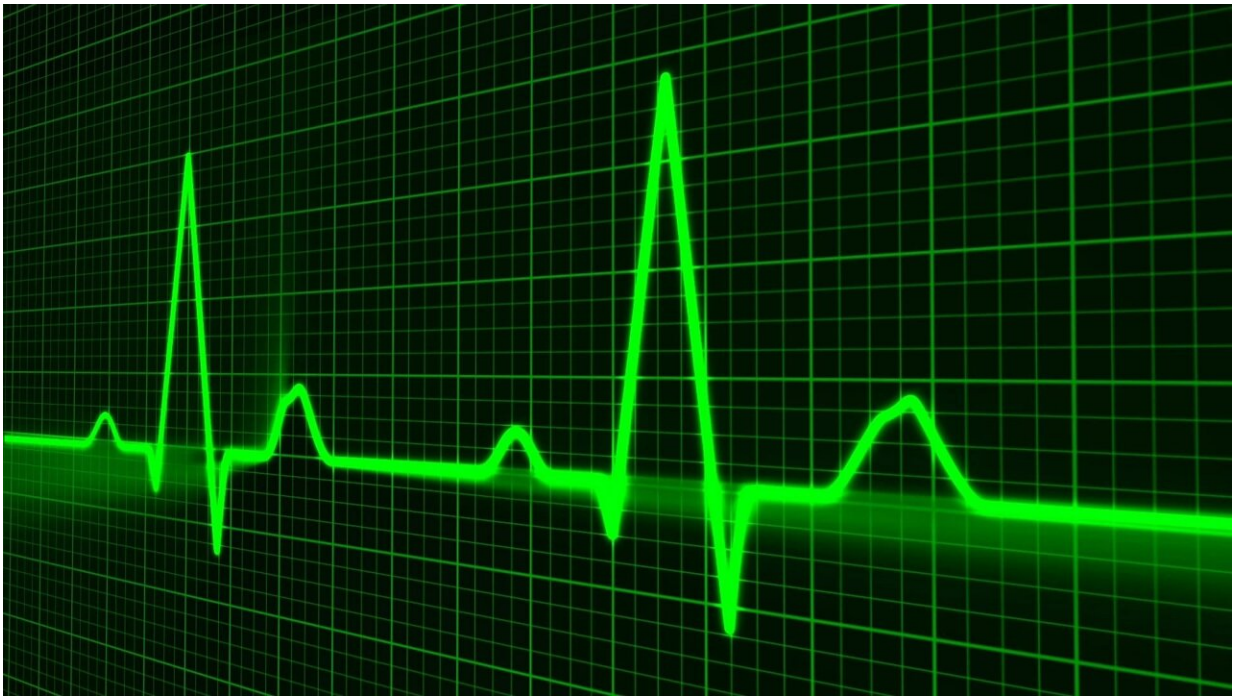

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Finerenone does not reduce the risk of all-cause death in patients with type 2 diabetes and kidney disease but does lower the likelihood of sudden cardiac death, according to late breaking research presented in a Hot Line session on 29 August at ESC Congress 2022.

It is estimated that patients with type 2 diabetes and chronic kidney

disease have a 16-year shorter life expectancy than their peers without these conditions. Most deaths in these patients are due to cardiovascular disease, with an incidence up to six-fold higher than the general population. With the prevalence of chronic kidney disease and type 2 diabetes rising, more efforts are needed to improve survival in this patient population.

A previous FIDELITY analysis, presented at ESC Congress 2021, showed that the nonsteroidal mineralocorticoid receptor antagonist finerenone reduced the risk of cardiovascular and renal outcomes compared with placebo in 13,026 patients with type 2 diabetes and chronic kidney disease enrolled in the FIDELIO-DKD and FIGARO-DKD trials. The current analysis evaluated the causes of mortality in the FIDELITY population. Causes of death were adjudicated by an independent clinical event committee blinded to treatment allocation.

This was a prespecified, exploratory analysis of individual patient data pooled from FIDELIO-DKD and FIGARO-DKD. The analysis included 13,026 patients with type 2 diabetes and chronic kidney disease randomized to treatment with finerenone or placebo. All patients were optimally treated with a renin-angiotensin system inhibitor. The median duration of follow up was 3.0 years. The average age of participants was 64.8 years and 69.8% were men.

The main analysis of this substudy examined rates of all-cause mortality and different causes of mortality in the intention-to-treat population. The incidence of all-cause mortality was 8.5% with finerenone (2.76 events per 100 patient-years) compared with 9.4% with placebo (3.10 events per 100 patient-years; hazard ratio [HR] 0.89; 95% confidence interval [CI] 0.79–1.00; p=0.051), where the between-group difference narrowly missed statistical significance. Mortality was most commonly attributed to cardiovascular causes (4.9% in the finerenone group vs. 5.6% in the placebo group), followed by infection (1.5% vs. 1.4%, respectively) and

malignancy (1.2% vs. 1.6%, respectively). An analysis of the components of cardiovascular mortality showed that finerenone significantly reduced the relative risk of sudden cardiac death (the most common form of cardiovascular mortality) by 25% compared with placebo (HR 0.75; 95% CI 0.57–0.996; p=0.046).

All-cause mortality and cardiovascular mortality were also assessed in a prespecified on-treatment analysis, which included events that occurred while patients were receiving treatment and for up to 30 days after the last dose of study medication. In this analysis, finerenone was associated with an 18% relative risk reduction in all-cause mortality (HR 0.82; 95% CI 0.70–0.96; p=0.014) and cardiovascular mortality (HR 0.82; 95% CI 0.67–0.99; p=0.040) versus placebo.

Professor Gerasimos Filippatos of the National and Kapodistrian University of Athens, Greece said, "In this analysis of patients with type 2 diabetes and kidney disease, mortality was primarily attributed to cardiovascular events. The effect of finerenone on all-cause mortality, cardiovascular mortality and sudden cardiac death was consistent irrespective of estimated glomerular filtration rate (eGFR) or urine albumin-to-creatinine ratio (UACR) at baseline, but seemingly more pronounced in patients with a higher baseline eGFR. This indicates that earlier initiation of finerenone might be warranted to maximize its protective effects in these patients."

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