

Finerenone and All-Cause Hospitalization in Cardiovascular-Kidney-Metabolic Disease

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Background

- Finerenone has been shown to reduce adverse cardiovascular and kidney outcomes in persons with cardiovascular, kidney, and metabolic (CKM) conditions.
- However, persons with CKM conditions exhibit a diverse spectrum of risk that may contribute to hospitalizations for any reason.

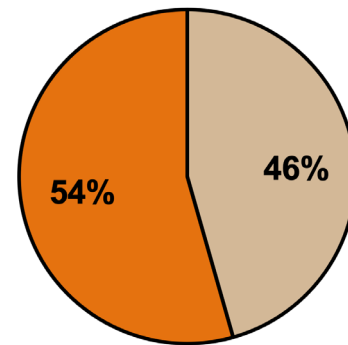
Study Aims

- In this prespecified analysis of FINE-HEART, we examined:
 1. The effect of finerenone on all-cause hospitalization

Methods

- FINE-HEART was a prespecified participant-level pooled analysis of placebo-controlled phase 3 trials (FIDELIO-DKD, FIGARO-DKD, and FINEARTS-HF) that evaluated finerenone
 - **FIDELIO-DKD:** Kidney outcomes trial in CKD with T2D and albuminuria
 - **FIGARO-DKD:** Cardiovascular outcomes trial in CKD with T2D and albuminuria
 - **FINEARTS-HF:** Cardiovascular outcomes trial in symptomatic HF with LVEF $\geq 40\%$
- All-cause hospitalization was defined *post hoc* and captured using clinical outcome events and adverse event reporting
- Baseline characteristics among participants who did and did not experience an all-cause hospitalization event were evaluated
- Treatment effects of finerenone on all-cause hospitalization were evaluated overall and in key prespecified subgroups using Cox proportional hazards regression and Poisson regression with restricted cubic splines

Baseline Characteristics Among Participants With vs. Without an All-Cause Hospitalization (n=18,991)



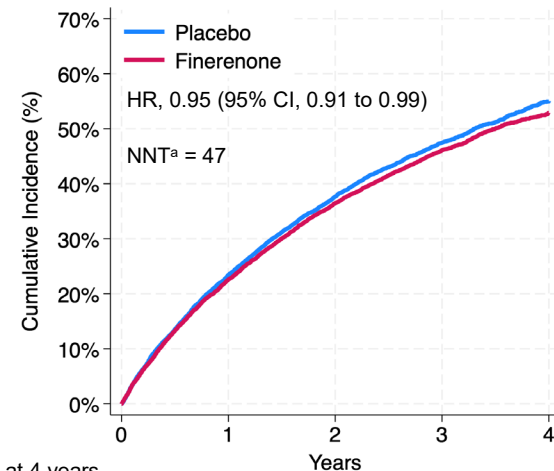
■ ≥ 1 Hospitalization (n=8,662)
■ No Hospitalization (n=10,329)

Any hospitalization associated with:

- Older age
- Male sex
- Greater abdominal obesity
- Higher blood pressure
- Lower eGFR
- Lower serum potassium
- History of ASCVD, HF, or AF

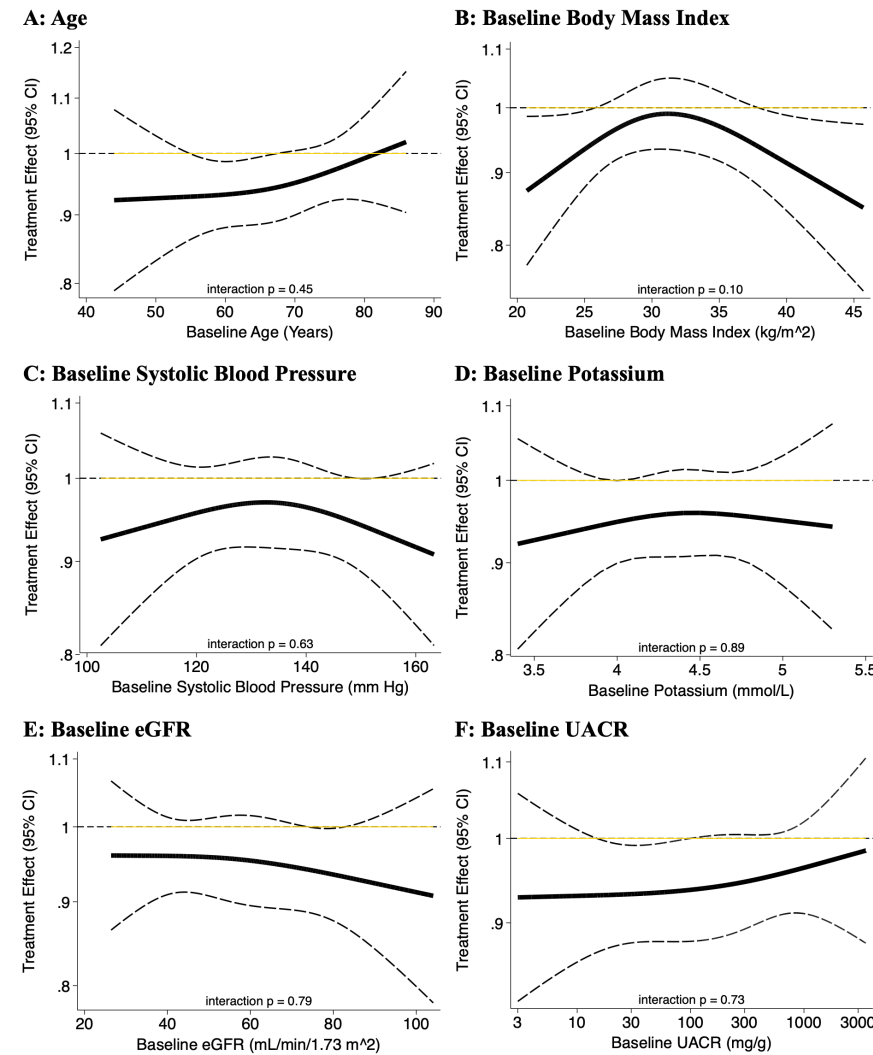
Median follow-up = 2.9 [2.2, 3.5] years

Cumulative Incidence of All-Cause Hospitalization, by Randomized Treatment



^a: NNT estimated at 4 years

Treatment Effects of Finerenone on All-Cause Hospitalization, by Subgroup



Figures show treatment effects (95% CI) of finerenone versus placebo on all-cause hospitalization according to baseline age, body mass index, systolic blood pressure, serum potassium, eGFR, and UACR, estimated through Poisson regression with restricted cubic splines (3 knots). Abbreviations: eGFR = estimated glomerular filtration rate; UACR = urine albumin-to-creatinine ratio

Key Findings

In this prespecified FINE-HEART analysis, persons with CKM disease experienced high short-term risks of all-cause hospitalization

Finerenone modestly but statistically significantly reduced the rate of hospitalization for any reason

The benefits of finerenone on all-cause hospitalization did not appear to be modified by age, sex, race, and the baseline status of key CKM risk factors

Future analyses will explore 1) cause-specific hospitalization; and 2) total all-cause hospitalization (recurrent events)

Funding

FIDELIO-DKD, FIGARO-DKD, and FINEARTS-HF were sponsored by Bayer AG.

These findings provide further support for the use of finerenone to reduce overall morbidity in adults with CKM disease