

# Sex, Adiposity-Related Anthropometrics, and Clinical Outcomes in Cardiovascular-Kidney-Metabolic Disease

## Background

- Sex is an important determinant of body composition
- Whether sex modifies the association between adiposity-related anthropometrics and clinical outcomes in persons with cardiovascular-kidney-metabolic (CKM) disease is uncertain

## Study Aims

- In this participant-level analysis of 3 phase III, global, double-blind, randomized clinical trials of finerenone (FINE-HEART), we evaluated:
  - Prevalences of obesity, by sex
  - Associations between adiposity-related anthropometrics and cardiovascular (CV) outcomes, by sex
  - Treatment effects of finerenone on CV events, by anthropometrics and sex

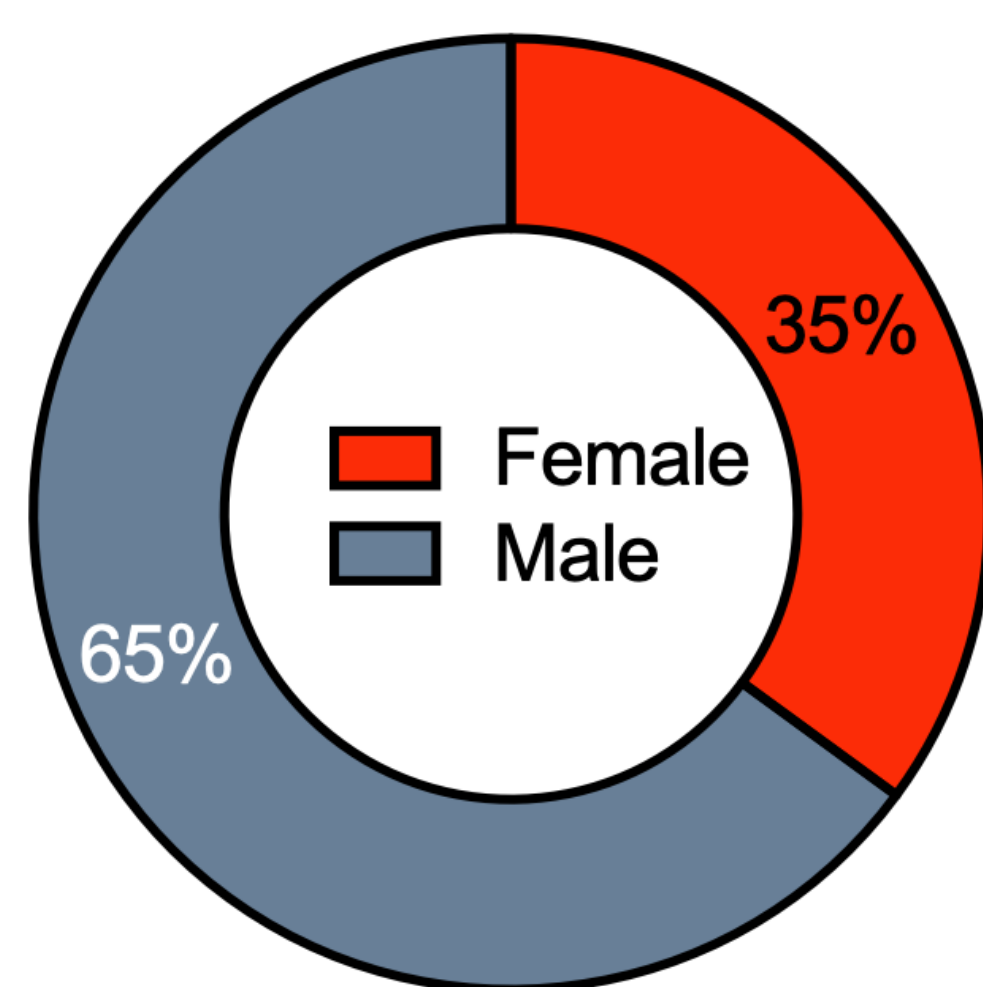
## Methods

- Participant-level data from the FIDELIO-DKD, FIGARO-DKD, and FINEARTS-HF trials were pooled with harmonized data elements
- Participants with available BMI, waist circumference (WC), waist-to-height ratio (WHtR), and waist-hip ratio (WHR) were included
- We compared the prevalence of obesity using BMI criteria alone vs. *Lancet* Commission criteria (any excess adiposity) according sex
  - Any excess adiposity was defined as elevated BMI, WC, WHtR, or WHR, using race/ethnicity-specific thresholds (as applicable)
- Multivariable-adjusted associations between BMI, WHtR, and WHR were examined using Poisson regression and restricted cubic splines
- The effect of finerenone on cardiovascular outcomes across the spectrum of BMI and WHtR was assessed by sex using Poisson regression and Cox proportional hazards regression

## Baseline Characteristics in FINE-HEART, by Sex

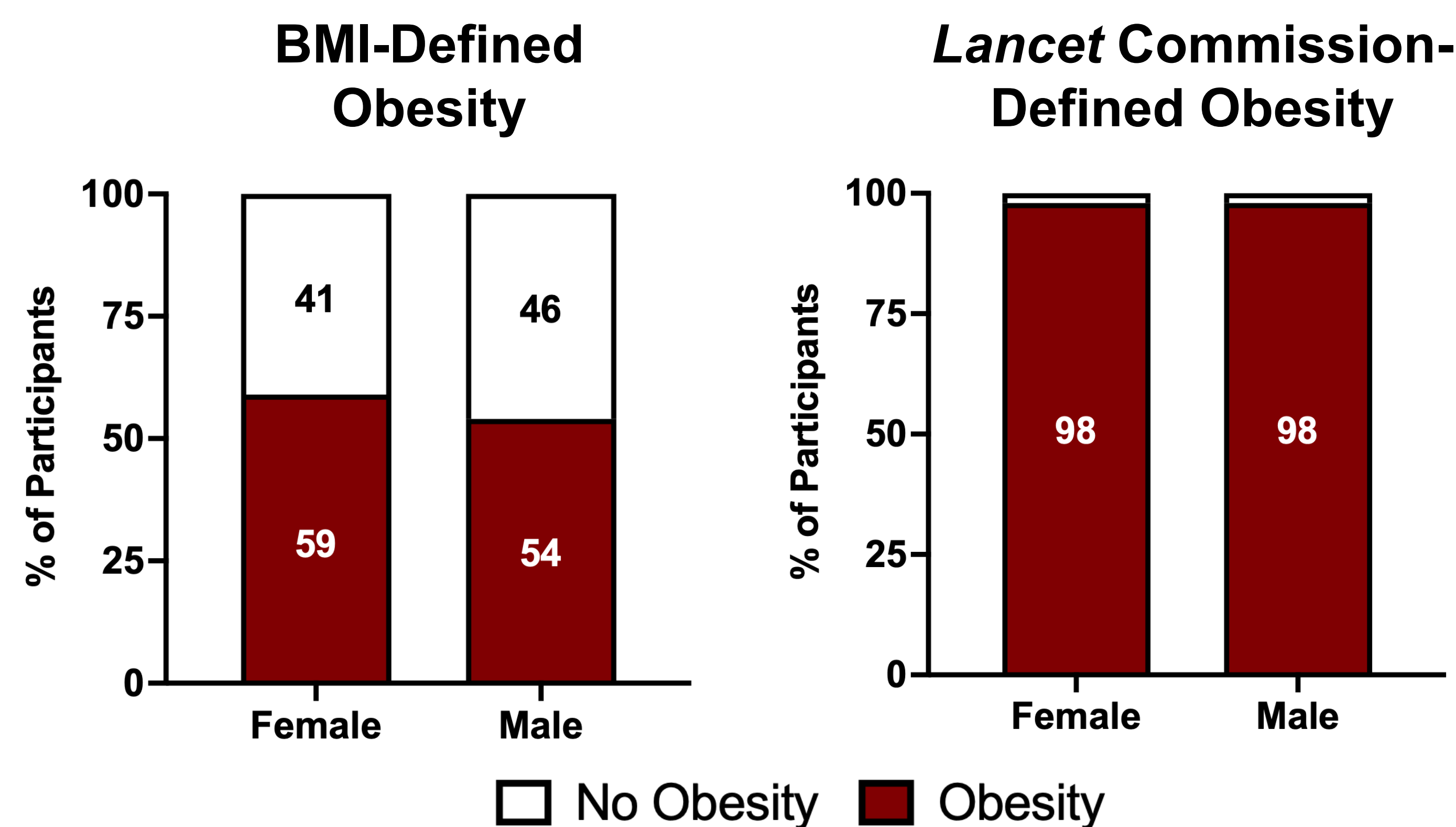


18,858 individuals with T2D and CKD and/or HF with mildly reduced or preserved ejection fraction

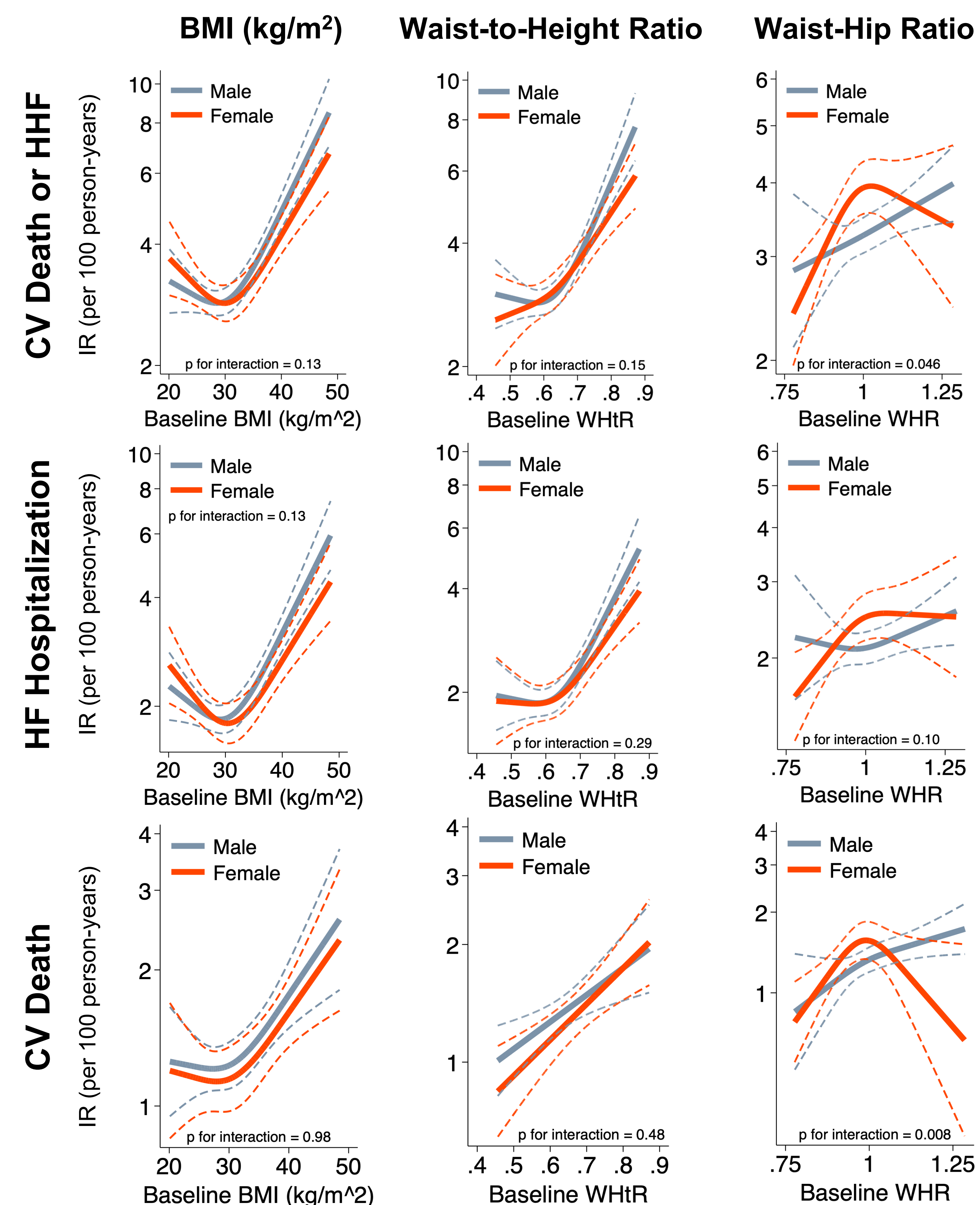


| Characteristic                   | Women (n=6,612) | Men (n=12,246) |
|----------------------------------|-----------------|----------------|
| Age, y                           | 68 ± 10         | 66 ± 10        |
| BMI, kg/m <sup>2</sup>           | 32 ± 7          | 31 ± 6         |
| WHtR                             | 0.65 ± 0.10     | 0.63 ± 0.08    |
| Systolic BP, mm Hg               | 134 ± 15        | 135 ± 15       |
| HbA <sub>1c</sub> , %            | 7.3 ± 1.5       | 7.3 ± 1.4      |
| eGFR, mL/min/1.73 m <sup>2</sup> | 58 ± 21         | 59 ± 21        |
| UACR, mg/g                       | 183 [26, 744]   | 336 [63, 902]  |
| History of T2D                   | 4931 (75%)      | 10395 (85%)    |
| History of ASCVD                 | 2266 (34%)      | 5517 (45%)     |
| History of HF                    | 3086 (47%)      | 3869 (32%)     |

## Prevalence of Obesity, by Sex

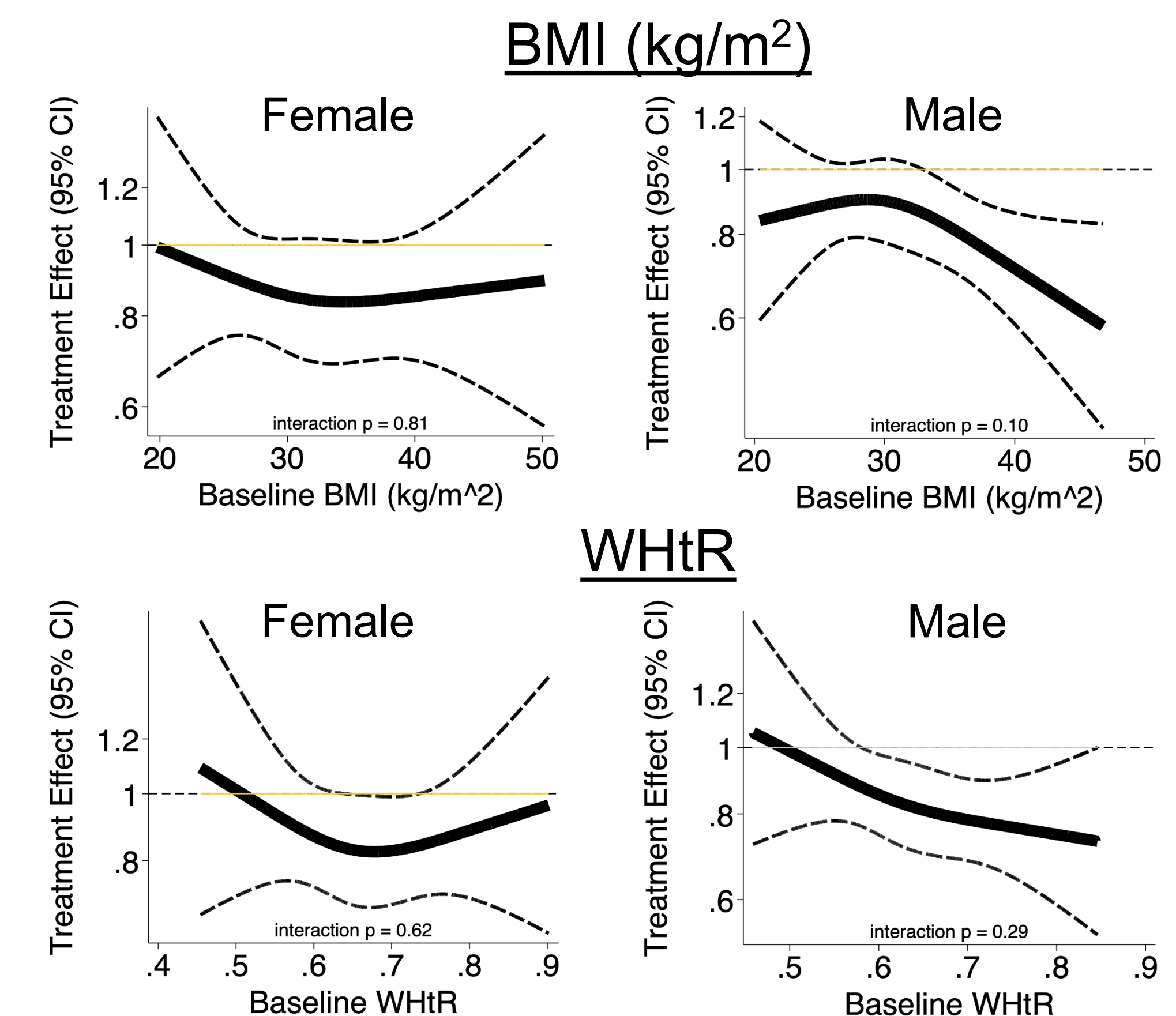


## Association Between Adiposity-Related Anthropometrics and CV Outcomes, by Sex



Incidence rates (and 95% CI) estimated through Poisson regression with restricted cubic splines (number of knots selected to minimize the AIC), adjusted for age, geographic region, trial, randomized treatment, smoking history, history of atherosclerotic cardiovascular disease, and estimated glomerular filtration rate. Abbreviations: CV = cardiovascular; HHF = heart failure hospitalization; IR = incidence rate

## Effect of Finerenone on CV Death or HHF by BMI and WHtR, by Sex



## Key Findings

In this prespecified pooled analysis of the complementary FINE-HEART trials, obesity was near-universally present in women and men when anthropometrics capturing abdominal adiposity were considered

Sex appeared to significantly modify the association between WHR, but not BMI or WHtR, and adverse cardiovascular outcomes

Finerenone consistently reduced CV death and HF hospitalization irrespective of BMI or WHtR in women and men with CKM disease

## Funding

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

**Excess adiposity was widespread and similarly associated with CV events among women and men with CKM disease in FINE-HEART. Finerenone consistently reduced CV events across the spectrum of adiposity among women and men.**