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Efficacy Of Finerenone In Asian Patients With Type 2 Diabetes And Chronic Kidney Disease: A FIDELITY Analysis

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Objectives : Finerenone significantly reduced the risk of cardiovascular (CV) and kidney outcomes versus placebo in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) in FIDELITY, a prespecified pooled analysis of the phase III FIDELIO-DKD and FIGARO-DKD trials. This FIDELITY post-hoc subanalysis assessed the efficacy of finerenone in Asian patients.
Methods : Patients with CKD (urine albumin-to-creatinine ratio [UACR] 30–<300 mg/g and estimated glomerular filtration rate [eGFR] 25–≤90 ml/min/1.73 m^2, or UACR 300–≤5000 mg/g and eGFR ≥25 ml/min/1.73 m^2) and T2D, and on optimised renin–angiotensin system blockade were randomised 1:1 to finerenone or placebo in FIDELIO-DKD and FIGARO-DKD. For this subgroup analysis, composite CV (CV death, non-fatal myocardial infarction, non-fatal stroke or hospitalisation for heart failure) and ≥57% eGFR composite kidney (kidney failure, sustained ≥57% eGFR decrease from baseline over ≥4 weeks or renal death) outcomes were assessed. Additional analyses included ≥40% eGFR kidney composite outcome (kidney failure, sustained ≥40% eGFR decrease from baseline over ≥4 weeks or renal death), all outcomes by baseline eGFR (<60 and ≥60 ml/min/1.73 m^2) and UACR (<300 and ≥300 mg/g) subgroups and eGFR slope.
Results : Of 13,026 patients randomised, 22.2% self-identified as Asian. Asian patients receiving finerenone had a lower risk of the composite CV outcome (hazard ratio [HR] 0.90; 95% confidence interval [CI] 0.70–1.15), and nominally significant reductions in the risk of ≥57% and ≥40% eGFR composite kidney outcomes (HR=0.66; 95% CI 0.52–0.84 and HR=0.68; 95% CI 0.57–0.81, respectively) versus those receiving placebo. Similar trends were observed for these outcomes irrespective of baseline eGFR and UACR (p-value for interaction not significant) (Figure 1). CKD progression was also slower with finerenone compared with placebo (Figure 2).
Conclusions : In FIDELITY, finerenone lowered the risks of CV and kidney outcomes versus placebo in Asian patients irrespective of eGFR and UACR levels at baseline.

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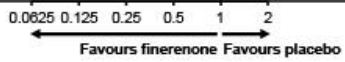
Outcome	Finerenone n/N	Finerenone n per 100 PY	Placebo n/N	Placebo n per 100 PY	HR (95% CI)	p-value for interaction between subgroups
Composite CV outcome	**122/1432**	**2.82**	**139/1462**	**3.16**	**0.90 (0.70–1.15)**	**N/A**
By eGFR						
<60 ml/min/1.73 m²	83/920	3.13	92/930	3.51	0.87 (0.64–1.18)	0.9521
≥60 ml/min/1.73 m²	39/512	2.32	47/532	2.65	0.96 (0.62–1.48)	
By UACR						
<300 mg/g	28/411	1.89	33/410	2.29	0.89 (0.53–1.51)	0.8166
≥300 mg/g	94/1021	3.30	106/1052	3.59	0.91 (0.69–1.20)	
eGFR ≥57% composite kidney outcome	**109/1432**	**2.61**	**170/1462**	**4.06**	**0.66 (0.52–0.84)**	**N/A**
By eGFR						
<60 ml/min/1.73 m²	85/920	3.34	121/930	4.88	0.70 (0.53–0.92)	0.3881
≥60 ml/min/1.73 m²	24/512	1.47	49/532	2.86	0.53 (0.32–0.88)	
By UACR						
<300 mg/g	4/411	0.27	9/410	0.64	0.39 (0.12–1.28)	0.3867
≥300 mg/g	105/1021	3.87	161/1052	5.78	0.68 (0.53–0.87)	
eGFR ≥40% composite kidney outcome	**222/1432**	**5.50**	**318/1462**	**7.90**	**0.68 (0.57–0.81)**	**N/A**
By eGFR						
<60 ml/min/1.73 m²	160/920	6.50	210/930	8.80	0.72 (0.58–0.88)	0.4364
≥60 ml/min/1.73 m²	62/512	3.93	108/532	6.59	0.61 (0.44–0.84)	
By UACR						
<300 mg/g	27/411	1.88	25/410	1.80	0.93 (0.52–1.65)	0.2171
≥300 mg/g	195/1021	7.48	293/1052	11.13	0.66 (0.55–0.79)	



CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HR, hazard ratio; N/A, not applicable; PY, patient-years; UACR, urine albumin-to-creatinine ratio

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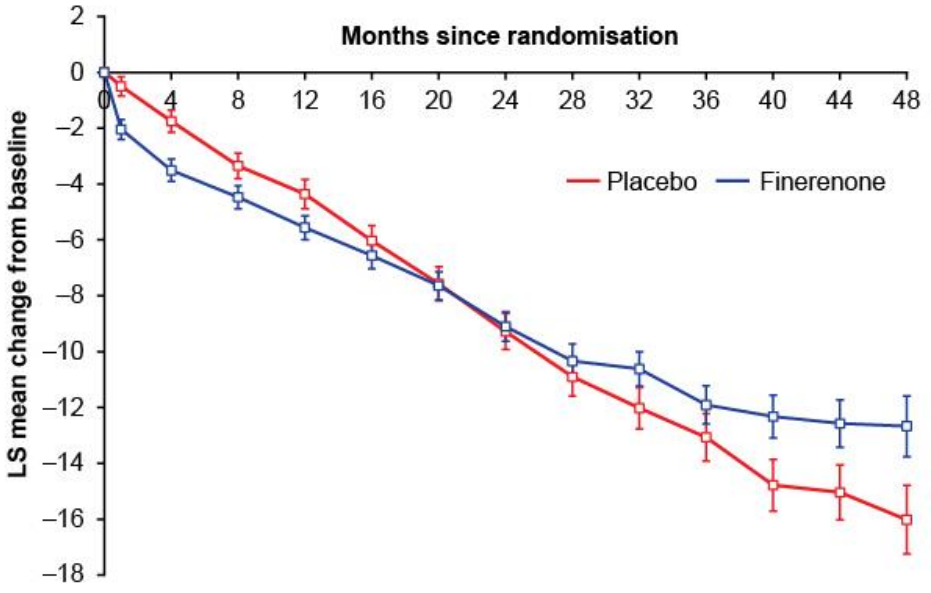

No. of patients

Finerenone	1470	1372	1160	678	226
Placebo	1429	1382	1161	692	226

CI, confidence interval; eGFR, estimated glomerular filtration rate; LS, least-squares