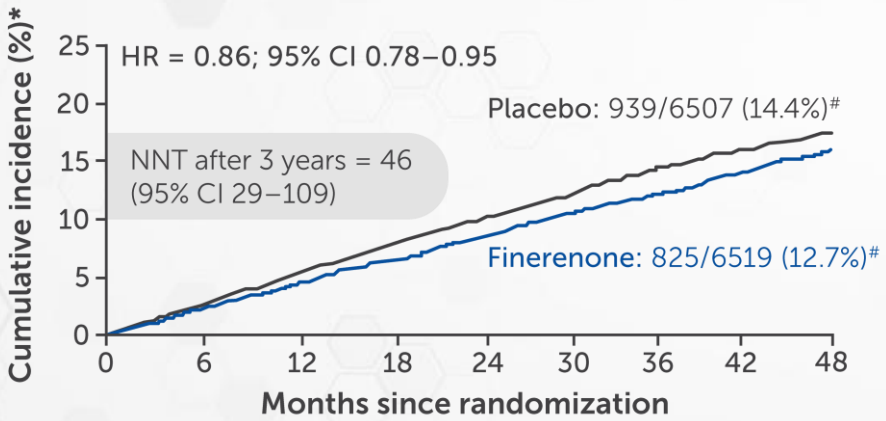
FIDELITY: Reduction in Risk of Composite CV and Kidney Outcomes

CV composite

Time to CV death, nonfatal MI, nonfatal stroke or HHF

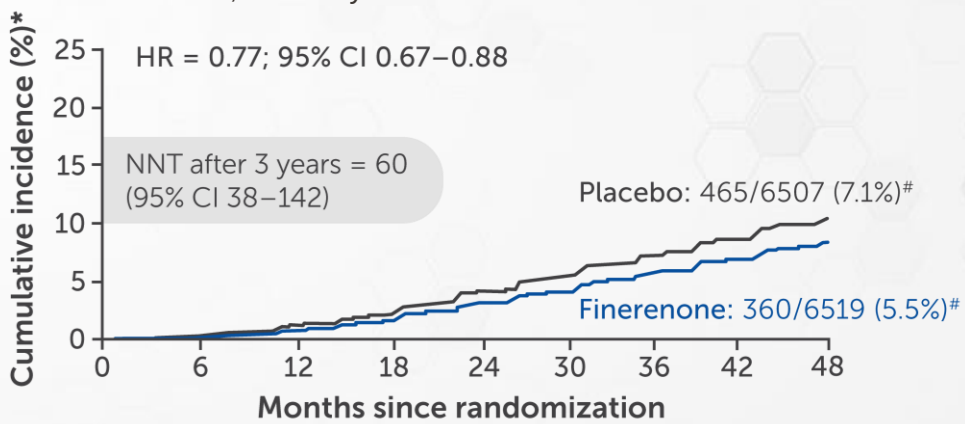


No. at risk‡									
Finerenone	6519	6360	6202	6009	5273	4207	3065	2187	1087
Placebo	6507	6330	6125	5938	5184	4147	2969	2135	1082

14% reduced risk of CV morbidity and mortality versus placebo (HR = 0.86; 95% CI 0.78–0.95); *P* = 0.0018

Kidney composite

Time to kidney failure,§ sustained ≥57% decrease in eGFR from baseline, or kidney-related death



No. at risk‡									
Finerenone	6519	6291	6107	5848	5027	3973	2815	2024	959
Placebo	6507	6292	6071	5815	4949	3932	2798	1988	962

23% reduced risk of CKD progression* versus placebo (HR = 0.77; 95% CI 0.67–0.88); *P* = 0.0002

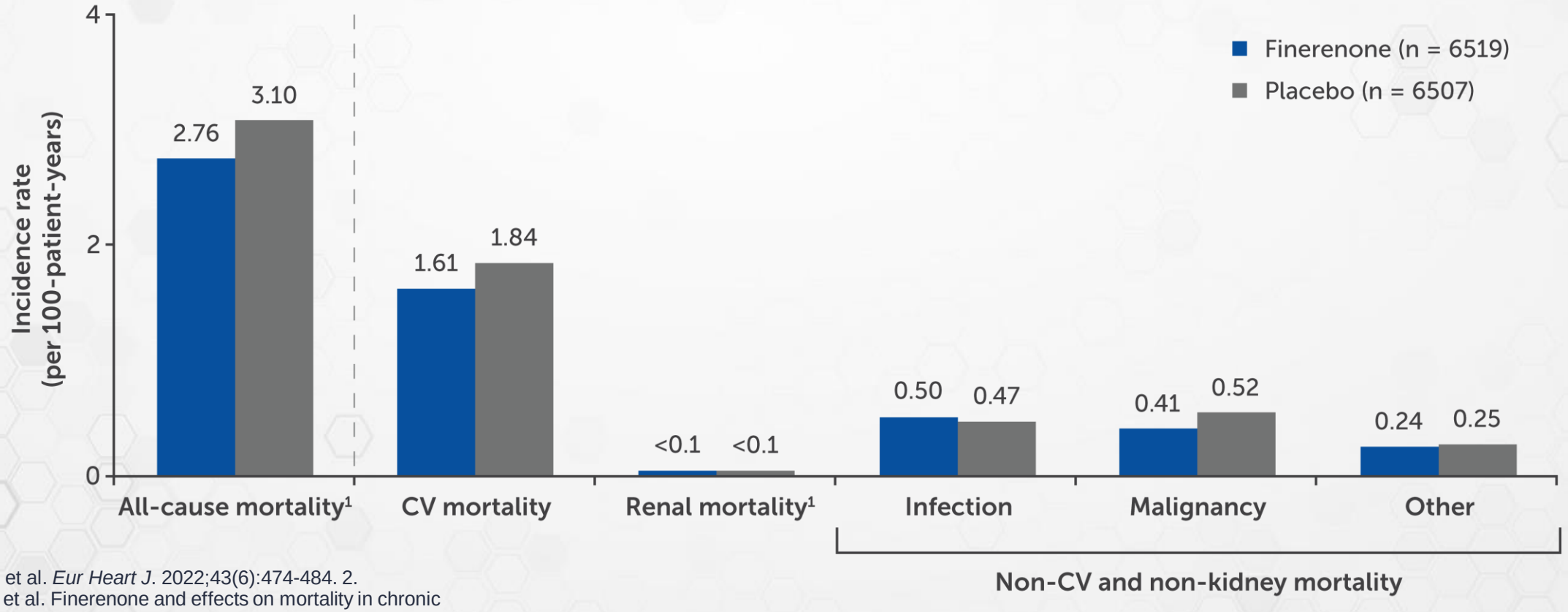
* cumulative incidence calculated by Aalen-Johansen estimator using deaths due to other causes as competing risk; # number of patients with an event over a median of 3.0 years of follow-up; ‡ at-risk subjects were calculated at start of time point; § ESKD or an eGFR <15 mL/min/1.73 m^2

CI, confidence interval; CKD; chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, heart failure hospitalization; HR, hazard ratio; MI, myocardial infarction; NNT number needed to treat.

Agarwal R, et al. *Eur Heart J.* 2022;43:474-484.

The most common cause of mortality in the overall FIDELITY population was related to CV events

Causes of mortality following treatment with finerenone versus placebo

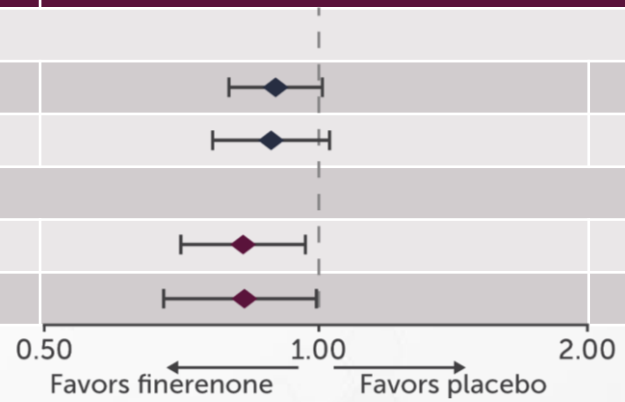


1. Agarwal R, et al. *Eur Heart J*. 2022;43(6):474-484. 2. Filippatos, G. et al. Finerenone and effects on mortality in chronic kidney disease and type 2 diabetes: A FIDELITY analysis. Presentation at ESC 2022; Barcelona Spain; August 26-29, 2022.

Finerenone Reduced All-Cause Mortality, CV Mortality, and Risk of Sudden Cardiac Death Versus Placebo

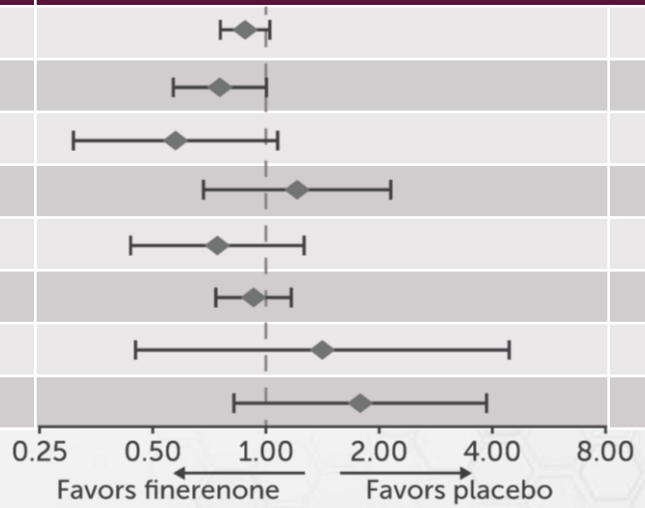
Risk of all-cause mortality and CV mortality

Endpoint	Finerenone (n = 6519)		Placebo (n = 6507)		HR (95% CI)	*P* value
	n (%)	Events per 100 PY	n (%)	Events per 100 PY		
Intention to treat (primary) analysis[1]						
All-cause mortality	552 (8.5)	2.76	614 (19.4)	3.10	0.89 (0.79->1.00)	0.051
CV mortality	322 (4.9)	1.61	364 (5.6)	1.84	0.88 (0.76-1.02)	0.092
On-treatment analysis*						
All-cause mortality	280 (4.3)	1.62	344 (5.3)	1.98	0.82 (0.70-0.96)	0.014
CV mortality	189 (2.9)	1.09	233 (3.6)	1.34	0.82 (0.67-0.99)	0.040



Risk of CV mortality and its components

Endpoint	Finerenone (n = 6519)		Placebo (n = 6507)		HR (95% CI)	*P* value
	n (%)	Events per 100 PY	n (%)	Events per 100 PY		
CV Mortality	**322 (4.9)**	**1.61**	**364 (5.6)**	**1.84**	**0.88 (0.76-1.02)**	**0.092**
Sudden cardiac death	88 (1.3)	0.44	115 (1.8)	0.58	0.75 (0.57-<1.00)	0.046#
Fatal HF	15 (0.2)	0.08	27 (0.4)	0.14	0.58 (0.31-1.08)	0.083#
Death due to acute MI	26 (0.4)	0.13	21 (0.3)	0.11	1.20 (0.68-2.14)	0.531#
Fatal stroke	25 (0.4)	0.13	33 (0.5)	0.17	0.75 (0.44-1.26)	0.268#
Undetermined death	143 (2.2)	0.72	153 (2.4)	0.77	0.93 (0.74-1.17)	0.552#
Death due to CV procedures	7 (0.1)	0.04	5 (<0.1)	0.03	1.41 (0.45-4.44)	0.557#
Death due to other CV causes	18 (0.3)	0.09	10 (0.2)	0.05	1.78 (0.82-3.86)	0.139#



P value was calculated in a post hoc analysis. * Time frame of the primary analysis was restricted up to 30 days after last study drug intake. PY, patient years

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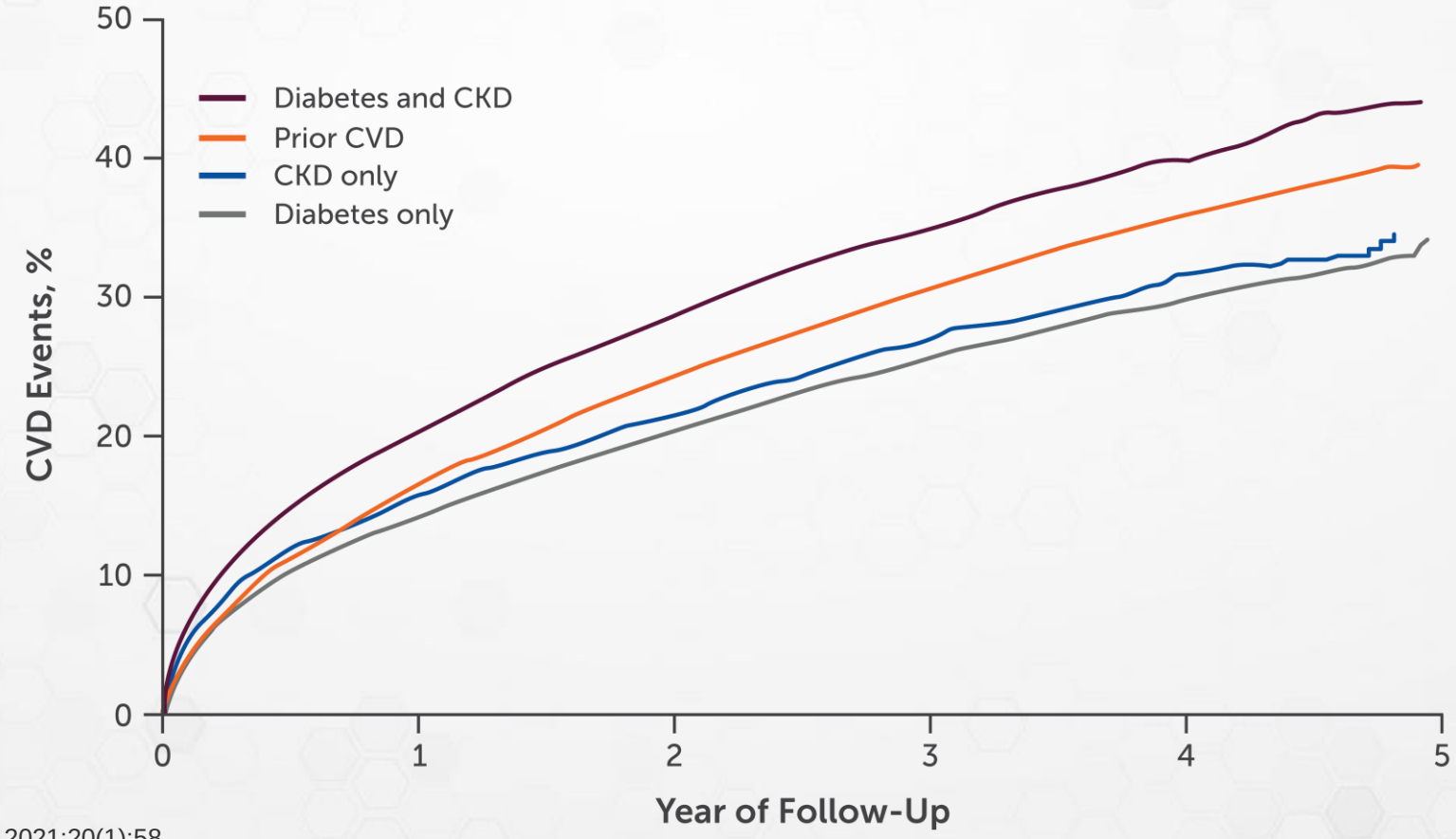
1. Agarwal R, et al. *Eur Heart J.* 2022;43(6):474-484. 2. Filippatos, G. et al. Finerenone and effects on mortality in chronic kidney disease and type 2 diabetes: A FIDELITY analysis. Presentation at ESC 2022; Barcelona Spain; August 26-29, 2022.

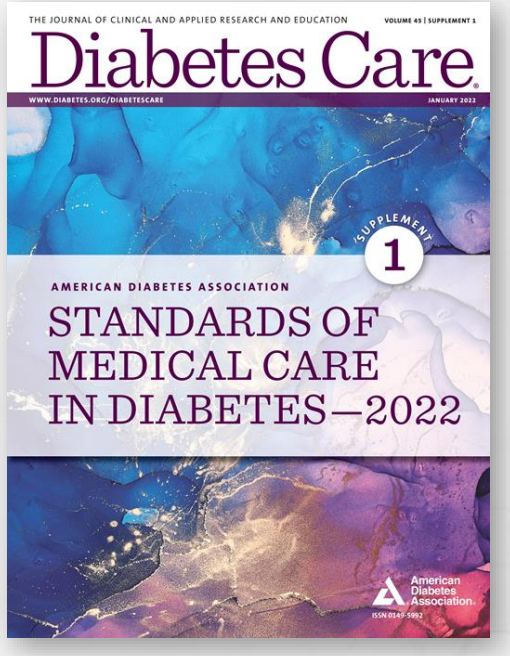
Diabetes with CKD Is a CVD Risk Accelerator



Hubbard D, et al. *Cardiovasc Diabetol*. 2021;20(1):58.

Standards of Medical Care in Diabetes 2022 American Diabetes Association

	Chronic Kidney Disease and Risk Management	Class
11.3d	In patients with chronic kidney disease who have ≥300 mg/g urinary albumin, a reduction of 30% or greater in mg/g urinary albumin is recommended to slow chronic kidney disease progression	**B**



American Diabetes Association Professional Practice Committee; Draznin B, et al. *Diabetes Care.* 2022;45(Suppl 1):S175-S184.