Association of Finerenone Use with Real-World Clinical Outcomes in Patients with Chronic Kidney Disease (CKD) and Type 2 Diabetes (T2D)

Roberto Pecoits-Filho,[1] Michelle Estrella,[2] Arvind Katta,[3] Zihe Zheng,[3] Mauricio Ferri,[3] Keith A. Betts,[4] Jacob Earl,[3] Aozhou Wu,[4] Manasvi Sundar,[4] Carolina Aldworth,[3] Yunxun Wang,[3] Jon Mares,[3] Yue Liu,[4] Anyu Zhu,[4] Shumin Rui,[4] Michael Shlipak[2]

[1]Arbor Research Collaborative for Health, Ann Arbor, MI, USA; [2]University of California, San Francisco, San Francisco, CA, USA; [3]Bayer, Whippany, NJ, USA; [4]Analysis Group, Inc, Los Angeles, CA, USA

Poster Number
SA-PO0399

Background

- Finerenone, a nonsteroidal mineralocorticoid receptor antagonist (ns-MRA), has improved kidney and cardiovascular (CV) outcomes in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) in the FIDELIO-DKD and FIGARO-DKD trials.[1-3]
- Current clinical guidelines recognize finerenone as an evidence-based therapy and recommend its use, alongside renin–angiotensin system inhibitors (RASi) and sodium-glucose cotransporter-2 inhibitors (SGLT2i), to reduce CV and kidney risk in patients with CKD and T2D.[4,5]
- However, real-world evidence on the clinical benefits of finerenone use, and on the impact of treatment timing, remains limited.

Objective

- To compare CV outcomes with and without finerenone use among patients with CKD and T2D.

Methods

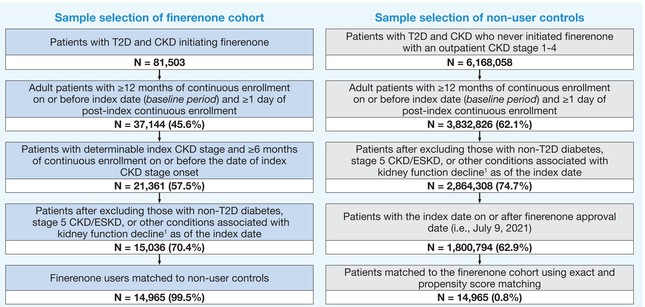
Data source

- This retrospective, non-interventional cohort study used the Komodo Research Data (KRD+), a large US administrative claims database with medical and pharmacy claims covering >330 million patients (January 1, 2016–June 30, 2025).

Study design and sample selection

- The construction of the study cohorts of adults with CKD and T2DM is presented in **Figure 1**.
  - **Finerenone users** initiated finerenone on or after July 9, 2021 (the US approval date); the index date was the date of the first finerenone fill.
  - **Non-user controls** never initiated finerenone; the index date was a randomly selected eligible outpatient visit date with a CKD diagnosis.
  - **Index CKD stage** (based on diagnosis codes) was defined as the most advanced CKD stage during the 12 months before (the baseline period) or on the index date. Patients in both cohorts were required to have CKD stage 1–4 at index.
- Controls (n = 14,965) were exact-matched 1:1 to finerenone users (n = 14,965) on index CKD stage, insurance type, concomitant SGLT2i use, heart failure (HF), atrial fibrillation, and time from index CKD stage onset to index date (≤12 vs. >12 months), followed by propensity score matching on patient demographics, comorbidity profile, treatment history, healthcare costs, and interaction terms between key baseline covariates.

Figure 1. Sample Selection



Note:
1. Other conditions associated with kidney function decline were systemic lupus erythematosus, polycystic kidney disease, and kidney cancer.

Outcomes and statistical analysis

- Clinical outcomes: A composite CV outcome comprising of myocardial infarction (MI), stroke, and hospitalization for HF.
- Covariate balance after matching was assessed using standardized mean differences (SMDs), with <0.1 indicating good balance; negative control outcomes were used to assess potential healthy patient bias.
- Clinical and negative control outcomes were characterized using cumulative incidence functions and cause-specific Cox models, with all-cause mortality treated as a competing risk.
- All-cause mortality was assessed exploratorily using standard Cox model.

Results

Study population

- Baseline demographic and clinical characteristics were well balanced between the matched finerenone and control cohorts, with all SMDs <0.1 (**Table 1**).

Table 1. Baseline Characteristics of the Matched Cohorts

	Finerenone cohort N = 14,965	Control cohort N = 14,965	SMD
Duration of follow up (months)			
Mean ± SD (Median)	15.1 ± 10.7 (13.2)	13.0 ± 10.4 (10.3)	-
Age at index date (years)			
Mean ± SD (Median)	68.3 ± 10.6 (70.0)	68.2 ± 11.1 (69.0)	0.004
Male, n (%)	8,109 (54.2)	8,085 (54.0)	0.003
Insurance type,[1] n (%)			
Medicare	9,513 (63.6)	9,513 (63.6)	-
Commercial	4,456 (29.8)	4,456 (29.8)	-
Medicaid	971 (6.5)	971 (6.5)	-
Unknown	25 (0.2)	25 (0.2)	-
Index CKD stage,[1] n (%)			
Stage 1	509 (3.4)	509 (3.4)	-
Stage 2	1,832 (12.2)	1,832 (12.2)	-
Stage 3A	3,896 (26.0)	3,896 (26.0)	-
Stage 3B	3,781 (25.3)	3,781 (25.3)	-
Stage 3 Unspecified	1,858 (12.4)	1,858 (12.4)	-
Stage 4	3,089 (20.6)	3,089 (20.6)	-
Time from index CKD stage onset to index date, months[2]			
Mean ± SD (Median)	21.2 ± 22.4 (12.4)	22.5 ± 26.0 (12.3)	-0.053
Comorbidities of interest, n (%)			
Hypertension	14,590 (97.5)	14,572 (97.4)	0.008
Hyperlipidemia	13,684 (91.4)	13,666 (91.3)	0.004
Diabetes-related microvascular complications	7,859 (52.5)	7,827 (52.3)	0.004
Proteinuria	6,470 (43.2)	6,211 (41.5)	0.035
Anemia	6,017 (40.2)	5,926 (39.6)	0.012
Ischemic heart disease	4,969 (33.2)	5,055 (33.8)	-0.012
Heart failure[1]	3,445 (23.0)	3,445 (23.0)	-
Cardiac arrhythmia	2,935 (19.6)	2,897 (19.4)	0.006
Atrial fibrillation[1]	2,011 (13.4)	2,011 (13.4)	-
COPD	2,243 (15.0)	2,232 (14.9)	0.002
Any malignancy	1,580 (10.6)	1,597 (10.7)	-0.004
Hyperkalemia	1,464 (9.8)	1,485 (9.9)	-0.005
Stroke	822 (5.5)	787 (5.3)	0.010
Treatment characteristics			
Albuminuria reduction medications and other treatments for CKD, n (%)			
ACEi/ARBs	12,814 (85.6)	12,785 (85.4)	0.006
SGLT2is	8,665 (57.9)	9,010 (60.2)	-0.047
Concomitant use of SGLT2i[1,3]	7,686 (51.4)	7,686 (51.4)	-
GLP1-RAs	5,715 (38.2)	5,764 (38.5)	-0.007
Other antidiabetics	12,285 (82.1)	12,316 (82.3)	-0.005
Other antihypertensives	12,956 (86.6)	12,940 (86.5)	0.003
Steroidal MRAs	1,334 (8.9)	1,353 (9.0)	-0.004
Lipid lowering medications	13,486 (90.1)	13,520 (90.3)	-0.008
Antiplatelet agents and aspirin	2,872 (19.2)	2,868 (19.2)	0.001
Anticoagulants	2,052 (13.7)	2,057 (13.7)	-0.001

Notes:
[1] The underlined variables were exact matched between the two cohorts.
[2] Time from index CKD stage onset to index date was included in exact match as a categorical variable (≤12 vs. >12 months).
[3] Concomitant SGLT2i use was defined as having an SGLT2i claim around the index date.

- Comorbidity burden was high, including hypertension (~98%) and hyperlipidemia (~91%), and most patients were receiving ACEi/ARBs (~86%) and/or SGLT2i (58–60%) at baseline; proteinuria was present in ~40% of patients.

CV outcomes

- Over a mean follow-up of approximately 15 months, finerenone use was associated with a significantly lower risk of the composite CV outcome compared with matched controls (incidence rates 8.19 vs. 9.84 events per 100 patient-years [PY]; HR 0.85 [95% CI: 0.79–0.91]; $p < 0.001$) (**Figure 2**).
- Hospitalization for HF accounted for the majority of composite CV events, with incidence rates of 5.22 vs. 6.40 events per 100 PY among finerenone users and controls, respectively, and an HR of 0.83 (95% CI: 0.76–0.91; $p < 0.001$).
- The HR for all-cause mortality was 0.47 (0.42, 0.54), p < 0.001 (**Table 2**).

Figure 2. Cumulative Incidence Curve for Composite CV Outcome

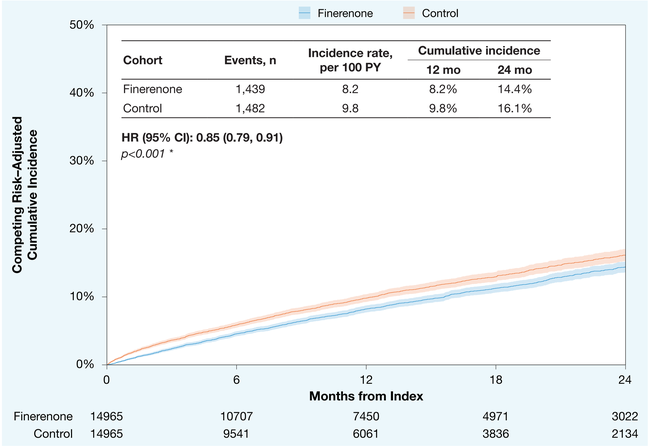


Table 2. HR for Components Included in Composite CV Outcome and All-Cause Mortality

Outcome	HR (95% CI)	P-value
Hospitalization for HF	0.83 (0.76, 0.91)	< 0.001*
MI	0.96 (0.84, 1.09)	0.524
Stroke	0.81 (0.71, 0.92)	< 0.001*
All-cause mortality	0.47 (0.42, 0.54)	< 0.001*

* p < 0.05

Negative control outcomes

- The hazard ratios (HR) for negative control outcomes were non-significant: 1.09 (95% confidence interval [CI]: 0.97–1.21), p = 0.153 for cataract surgery and 0.99 (0.92–1.07), p = 0.797 for colon cancer screening.

Conclusions

- **In this large, real-world study of US patients with CKD and T2D, finerenone use was associated with a significantly lower risk of the composite CV outcome compared with matched non-users, driven primarily by lower risk of hospitalization for HF.**
- **These findings support the real-world cardiovascular effectiveness of finerenone and reinforce the potential value of timely initiation of the treatment in patients with CKD and T2D.**

Limitations

- Claims data may be subject to miscoding and missingness, potentially introducing measurement error; however, such errors are less likely to be differential between cohorts.
- eGFR and UACR measurements were available for only a small subset of patients and therefore could not be included in the matching algorithm.
- Unmeasured and residual confounding is possible; however, the null associations observed for the negative control outcomes reduce concerns about substantial residual bias or confounding.
- CV-related mortality was not assessed due to the lack of valid cause-of-death information. To account for this, all-cause mortality was treated as a competing risk for all outcomes.
- Follow-up was relatively short for patients with more recent index years, which may limit power to detect certain outcomes. Database enrollment was also short relative to the disease duration of CKD and T2D, so the exact timing of CKD onset may be imprecise.

References

1. Triozzi JL, et al. 2021.
2. Bakris GL, et al. *N Engl J Med.* 2020. (FIDELIO-DKD)
3. Pitt B, et al. *N Engl J Med.* 2021. (FIGARO-DKD)
4. Stevens PE, et al. 2024. (KDIGO CKD guideline)
5. American Diabetes Association Professional Practice Committee. 2025.

Disclosures

Funding for this research was provided by Bayer, which also funded the development of the abstract; the study sponsor was involved in all stages of the study research and abstract preparation.

RPF is an employee of Arbor Research Collaborative for Health, which receives global support for the DOPPS Programs, and has received research grants from Fresenius Medical Care and consulting fees from AstraZeneca, Akebia, Novo Nordisk, Bayer, and Boehringer Ingelheim.

MS has received research funding from Bayer, AHA, NIDDK, NIA, and NHLBI and serves on advisory boards for Bayer and Boehringer Ingelheim.

ME has collaborative agreements with Bayer and serves on a Bayer advisory board.

Z.Z., M.F., A.K., J.E., C.A., and Y.W. are employees of Bayer. JM was an employee of Bayer at the time of analysis. K.A.B., A.W., M.S., Y.L., A.Z., and S.R. are employees of Analysis Group, Inc., a company that has provided paid consulting services to Bayer.

Scan QR code to obtain a copy of the E-poster

Materials obtained through this QR code are for personal use only and may not be reproduced without permission from the authors of this poster.