Finerenone and Real-World Hyperkalemia Rates in Individuals with Triple Comorbidities-Heart Failure, Chronic Kidney Disease, and Type 2 Diabetes

Alanna A. Morris[1], Janani Rangaswami[2], Matthew R. Weir[3], Yunxun Wang[1], Mauricio Ferri[1], Arvind Katta[1], Jacob Earl[1], Carolina Aldworth[1], Zihe Zheng[1]

[1] Bayer, Medical Affairs, Whippany, New Jersey
[2] George Washington University School of Medicine and Health Sciences, Washington, DC
[3] Department of Medicine, University of Maryland School of Medicine, Baltimore, Maryland

Abstract: 2026-A-5906
Presentation: MDP1990

Scientific Sessions

American Heart Association.

November 6-9, 2026
Chicago, IL

Financial Disclosure

Presenter: Zihe (Emma) Zheng
Bayer: full-time employee of Bayer and may hold Bayer stock

Co-author: Janani Rangaswami
Bayer: advisor
Boehringer Ingelheim: advisor
AstraZeneca: advisor
Retension Pharmaceuticals: advisor
Procyrion Inc: advisor

Co-author: Matthew R. Weir
Bayer: scientific advisor
CSL Vifor : scientific advisor
AstraZeneca: scientific advisor
Novo Nordisk: scientific advisor
Mineralys: scientific advisor

Co-authors: Alanna Morris, Yunxun Wang, Mauricio Ferri, Arvind Katta, Jacob Earl, Carolina Aldworth
Bayer: full-time employee of Bayer and may hold Bayer stock

The study was funded by Bayer.

Background & Objective

Hyperkalemia & clinical inertia

- Finerenone has established efficacy in reducing cardiovascular and kidney risks among patients with HF, CKD, and T2D; however, perceived risk of hyperkalemia (HK) remains a principal driver of treatment inertia.
- In FINEARTS-HF, HF patients with LVEF ≥40% regardless of CKD or T2D status, serum K^+ >5.5 mmol/L occurred in 14.3% of finerenone-treated patients (2.6× placebo), yet hospitalization related to HK was only 0.5%.

Population of interest

- Patients with HF, CKD, and T2D represent a high-risk patient population with significant disease burden.
- There is a lack of real-world evidence on HK with finerenone among patients with concomitant HF, CKD, and T2D.

Objective: To evaluate the real-world frequency and severity of HK and hospitalization related to HK in patients with HF, CKD, and T2D who received finerenone in the US

CKD, chronic kidney disease; HF, heart failure; HK, hyperkalemia; K^+, potassium; RAASi, renin–angiotensin–aldosterone system inhibitor; SGLT2i, sodium–glucose cotransporter-2 inhibitor; T2D, type 2 diabetes.

METHODS

Study Population: Adults who initiated finerenone during the identification period, had a diagnosis of HF, CKD and T2D, and did not use an sMRA within 14 days prior to initiation of finerenone

- HF, CKD, and T2D defined as ≥1 inpatient or ≥2 outpatient diagnoses on different dates within 365 days for each condition using ICD-10-CM codes

Study Design

- Study type: Retrospective, real-world cohort study
- Data source: the Truveta® US EHR database (July 2021 – June 2025)
- Index date: date of first finerenone prescription
- Follow-up: earliest of either a qualifying HK event, study end (June 2025), death, or sMRA start

Outcomes

1. **Incidence rate (IR) per 100 PY of first serum K^+ >5.5 mEq/L**
2. **IR per 100 PY of first serum K^+ ≥6.0 mEq/L**
3. **Hospitalization related to HK**

Stratification based on:

- Baseline eGFR (≥60, 45–<60, 30–<45, <30)
- HK history (Y/N)
- K binder use (Y/N)
- Duration of HF diagnosis (≤12 vs >12 months before finerenone)
- Concomitant SGLT2i use (Y/N)

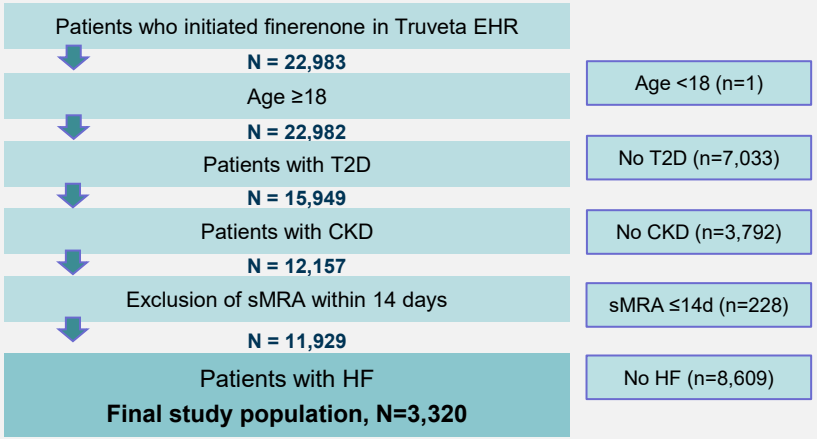
Statistical analysis

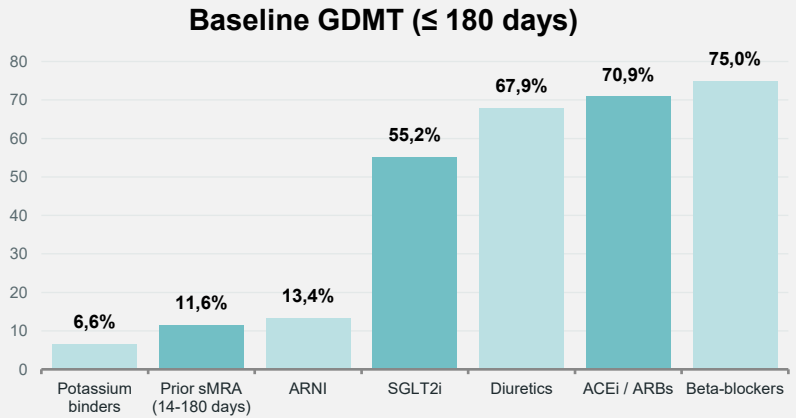
- IRs were the number of first events per 100 PYs with 95% CIs using a Poisson-based normal approximation

- Multivariable Cox PH models identified baseline predictors of serum K^+≥6.0 mEq/L, reported as aHRs (95% CI), including covariates of demographics, baseline labs, comorbidities, baseline medication and finerenone starting dose.

aHR, adjusted hazard ratio; CI, confidence interval; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; EHR, electronic health record; HF, heart failure; HK, hyperkalemia; IR, incidence rate; K^+, potassium; N, no; PH, proportional hazard; PY, person-years; sMRA, steroidal mineralocorticoid receptor antagonist; T2D, type 2 diabetes; Y, yes.

Baseline Characteristics





Characteristic	N=3,320
Age, mean (SD), years	70.1 (10.8)
Female, %	41.7%
Black race, %	18.1%
eGFR, mean (SD), mL/min/1.73m^2 Data available: 87.7%	42.4 (17.7)
≥60 mL/min/1.73m^2, %	12.7%
30-59 mL/min/1.73m^2, %	53.8%
15-29 mL/min/1.73m^2, %	19.0%
<15 mL/min/1.73m^2, %	2.1%
UACR, median (IQR), mg/g Data available: 51.2%	386.0 (94.4–1,250.2)
Baseline K$^+$, mean (SD), mEq/L Data available: 89.6%	4.3 (0.5)
Prior HK history	12.5%
Recent HF diagnosis (≤12 months)	81.2%
LVEF, mean (SD) Data available: 32.4%	52.5 (13.3)
≤40%, %	6.1%
41-50%, %	5.4%
>50%, %	20.9%
NT-proBNP, median (IQR), pg/mL Data available: 26.5%	1,240.0 (433.0–3,511.0)

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; EHR, electronic health record; GDMT, Guideline-directed medical therapy; HF, heart failure; HK, hyperkalemia; IQR, interquartile range; K$^+$, potassium; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-B-type natriuretic peptide; SD, standard deviation; sMRA, steroidal mineralocorticoid receptor antagonist; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio.

Key Results: Incidence of Hyperkalemia

K^+ >5.5 mEq/L*	K^+ ≥6.0 mEq/L*	Hospitalization related to HK*
IR: 12.3 per 100 PY	**IR: 5.9 per 100 PY**	**IR: 1.17 per 100 PY**
(95% CI 11.2 – 13.6)	*(95% CI 5.1 – 6.7)*	*(95% CI 0.8 – 1.6)*
411 patients	**207 patients**	**43 patients**
12.4% of cohort	6.2% of cohort	1.3% of cohort

* occurrence of first serum potassium>5.5 mEq/L

* occurrence of first serum potassium ≥6 mEq/L

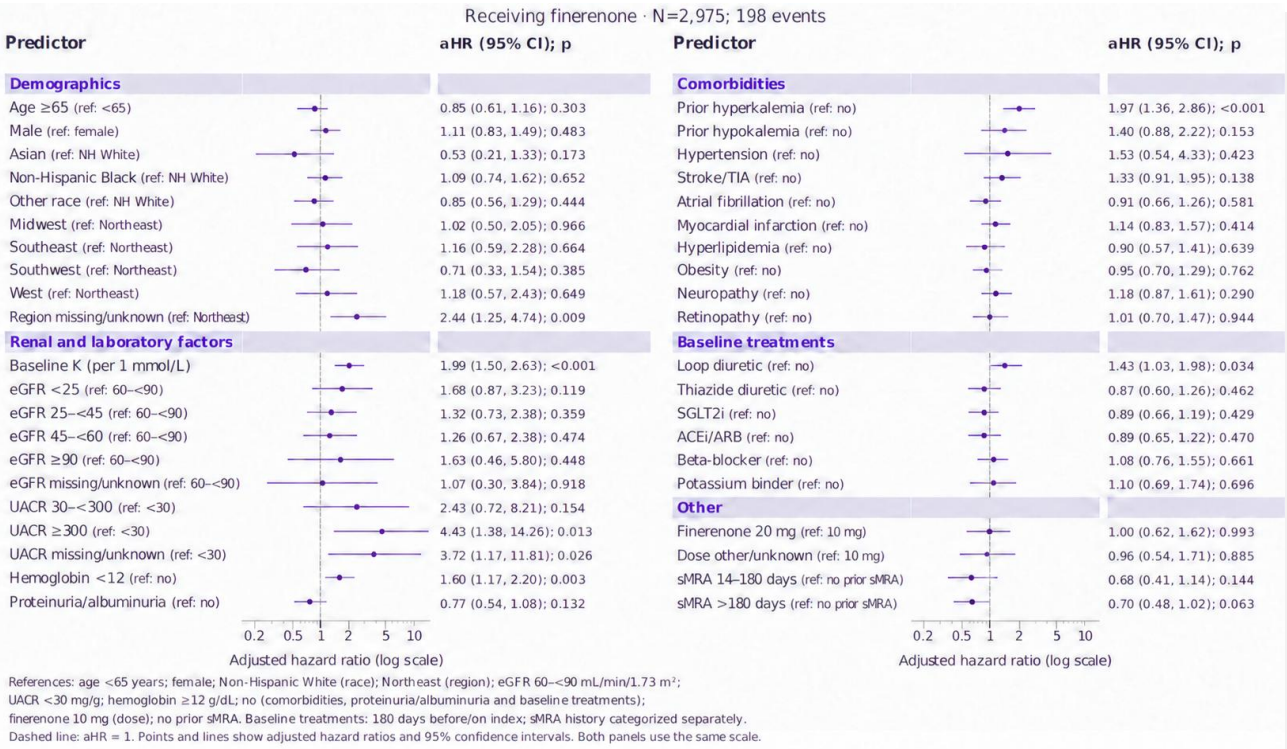
* A HK ICD code in the primary position of hospitalization discharge diagnosis AND serum potassium >5.5 mEq/L within admin ±3 days

Per 100 patients with HF, CKD, and T2D followed for 1 year: ~12 mild-to-moderate HK events, ~6 severe HK events occurred, and ~1 hospitalization event

CI, confidence interval; HK, hyperkalemia; K^+, potassium; PY, person-years.

SERUM K^+ ≥6.0 MEQ/L: SUBGROUPS & PREDICTORS

Subgroup	N	IR, per 100 PY (95% CI)
Overall	3,320	5.9 (5.1–6.7)
eGFR* ≥90	59	5.6 (1.2–16.4)
eGFR 60–<90	363	3.7 (2–6.4)
eGFR 45–<60	704	4.9 (3.5–6.8)
eGFR 25–<45	1,397	6.3 (5.2–7.7)
eGFR <25	388	**11.2 (8.1–15.1)**
HK history: Yes	416	**13.9 (10.7–17.9)**
HK history: No	2,904	4.7 (4–5.5)
K binder: Yes	169	**17.4 (11.8–24.9)**
K binder: No	3,151	5.3 (4.5–6.1)
Finerenone 10 mg	2,677	5.9 (5–6.8)
Finerenone 20 mg	429	5.3 (3.3–8)
HF Dx ≤12 mo	2,697	**6.5 (5.6–7.5)**
HF Dx >12 mo	623	3.0 (1.9–4.7)
ACEi/ARB: Yes	2,075	5.7 (4.7–6.7)
ACEi/ARB: No	1,245	6.2 (4.9–7.7)
SGLT2i: Yes	1,593	5.3 (4.2–6.6)
SGLT2i: No	1,727	6.3 (5.2–7.5)



- HK rates generally rose with worsening eGFR, ~4 fold from eGFR 60-<90 to <25
- Baseline eGFR <25, prior HK, and K^+ binder identified the highest risk patients at about 2–3 times the overall IR
- SGLT2i use, ACEi/ARB use, and finerenone starting dose did not impact HK IR

ACEi, angiotensin-converting enzyme inhibitor; aHR, adjusted hazard ratio; ARB, angiotensin II receptor blocker; CI, confidence interval; Dx, diagnosis; eGFR, estimated glomerular filtration rate; HK, hyperkalemia; IR, incidence rate; K^+, potassium; PY, patient year; SGLT2i, sodium–glucose cotransporter-2 inhibitor.
* The results are presented among 9,971 patients with available eGFR lab results.
Values to the right of the dashed line (aHR >1) indicate higher risk vs. the reference category, and values to the left (aHR <1) indicate lower risk

CONCLUSIONS

HK burden

In a real-world cohort of patients with HF, CKD, and T2D, finerenone demonstrated an **acceptable hyperkalemia risk profile**, supporting its net benefit in this high-risk population.

HK risk can be predicted and managed proactively

Higher rates were clustered in patients with baseline eGFR <25, a prior HK episode, K^+ binder use, or HF diagnosed within the past year, whereas rates were generally similar regardless of concomitant SGLT2i use or finerenone starting dose. These findings support a **risk-based approach to HK management**.

Support for real-world use of finerenone

These results may help address prescriber hesitancy and **support broader finerenone adoption** in the high-risk and high disease burden population of patients with HF, CKD, and T2D.

Limitations

- Surveillance bias: HK detection depends on testing frequency; infrequent monitoring in routine care may under-count mild events
- Adherence, discontinuation, and dose-titration patterns not captured; real-world discontinuation likely attenuates exposure-time and HK rates
- Direct comparisons to clinical trial populations are limited, as those populations were different from the HF, CKD, and T2D subgroup examined in this study

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; EHR, electronic health record; HF, heart failure; HK, hyperkalemia; K^+, potassium; SGLT2i, sodium–glucose cotransporter-2 inhibitor; T2D, type 2 diabetes.

References

- Agiro A, Cook E, Mu F, et al. Hyperkalemia and Risk of CKD Progression: A Propensity Score-Matched Analysis. Kidney360. 2024;5(12):1824-1834.
- Agarwal R, Joseph A, Anker SD, et al.; FIDELIO-DKD Investigators. Hyperkalemia Risk with Finerenone: Results from the FIDELIO-DKD Trial. Journal of the American Society of Nephrology. 2022b;33(1):225-237.
- Solomon SD, McMurray JJV, Vaduganathan M, et al.; FINEARTS-HF Investigators. Finerenone in Heart Failure with Mildly Reduced or Preserved Ejection Fraction. New England Journal of Medicine. 2024;391(8):725-737.
- Bakris GL, Agarwal R, Anker SD, et al.; FIDELIO-DKD Investigators. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. New England Journal of Medicine. 2020;383(23):2219-2229.
- Pitt B, Filippatos G, Agarwal R, et al. Cardiovascular outcomes in patients with CKD and type 2 diabetes: results from the FIGARO-DKD trial. Journal of the American Society of Nephrology. 2021;32(12):3042-3053