Finerenone and real-world hyperkalemia in patients with chronic kidney disease and type 2 diabetes

A real-world retrospective cohort study using the Truveta® U.S. electronic health record database

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BACKGROUND

- Finerenone has established cardiovascular and kidney efficacy in CKD + T2D; However, hyperkalemia (HK) remains a principal driver of treatment inertia.
- HK was reported by investigators in 9-19% of the FIDELITY, FINEARTS-HF, and CONFIDENCE trial participants in finerenone arm, yet hospitalization related to HK was low.
- Real-world HK data is limited in key subgroups of patients with advanced CKD, elevated baseline K^+, concurrent SGLT2i/RAASi use, and comorbid HF who received finerenone.

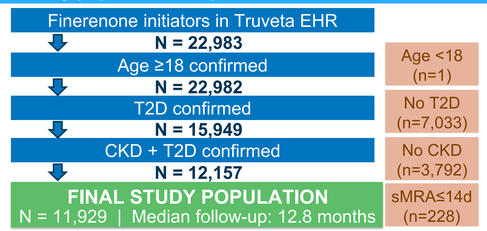
OBJECTIVE

To evaluate the real-world frequency and severity of HK outcomes in patients with CKD and T2D who received finerenone prescription in the US

STUDY DESIGN & METHODS

- **Population:** Adults with CKD + T2D with finerenone prescription
- **Data source:** Truveta® U.S. EHR database, July 2021 – June 2025
- **Index date:** First finerenone prescription (July 2021 – June 2025)
- **Follow-up:** Earliest of: qualifying HK event, study end (June 2025), death, or sMRA start
- **Outcomes:**
  - IR per 100 PY of first K^+ >5.5 or ≥6.0 mEq/L
  - IR of hospitalization related to HK (HK ICD code in the primary position of hospitalization discharge diagnosis AND serum potassium >5.5 [admin ±3 days])
- **Statistical analysis:** Descriptive summaries; Multivariable Cox PH models for predictors, reported as aHRs (95% CI)

Figure 1. Study population and patient flow



Inclusion criteria	Exclusion criteria
✓ Adults ≥18 years	✗ Kidney transplant / dialysis
✓ Concurrent CKD + T2D	✗ ESKD or Type 1 diabetes
✓ ≥12 months EHR history	✗ Pregnancy
✓ ≥1 finerenone prescription	✗ sMRA within 14 days

Table 1. Baseline characteristics (N=11,929)*

Age, mean (SD), years	**67.9 (11.2)**
Female, %	**43.4**
Black race, %	**19.7**
eGFR, mean (SD), mL/min/1.73m²	**47.6 (20.6)**
UACR, median (IQR), mg/g	**322 (86–1,057)**
Baseline K^+, mean (SD), mEq/L	**4.4 (0.5)**
Prior HK history, %	**8.4**
Heart Failure, %	**27.8**
ACEi/ARB, %	**74.0**
SGLT2i, %	**51.5**
Any diuretic, %	**49.2**
Potassium binders, %	**4.6**

* This will be defined as the 12-month period prior to the index date. Baseline medication is measured with 180 days prior to the index date

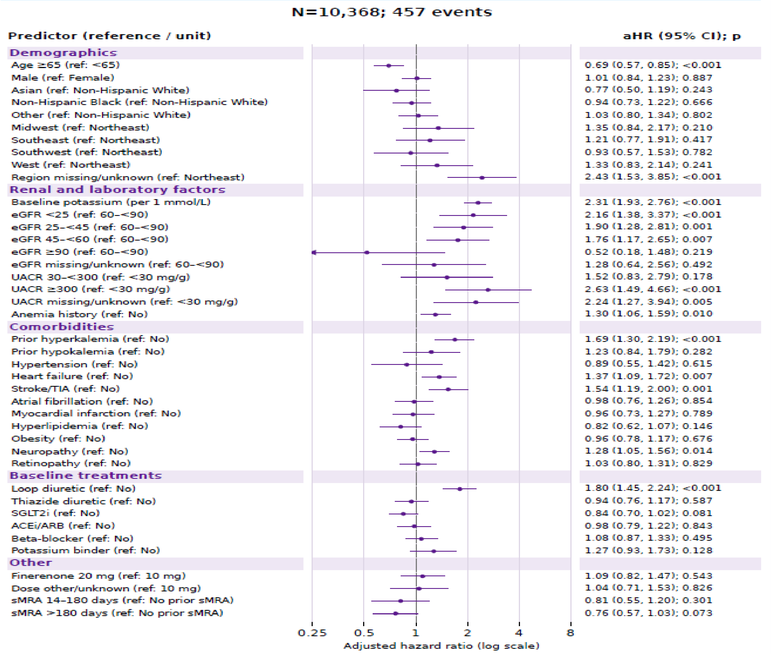
Table 2. Subgroup analyses: K^+ ≥6.0 mEq/L IR (per 100 PY)

Subgroup	N	IR (95% CI)
eGFR ≥90	536	0.6 (0.2–1.6)
eGFR 60–<90	1,645	1.5 (1–2.2)
eGFR 45–<60	2,689	3.0 (2.4–3.6)
eGFR 25–<45	4,178	4.3 (3.7–4.9)
eGFR <25	923	**8.8 (7.0–10.8)**
Prior HK history: Yes	1,004	**10.6 (8.8–12.7)**
Prior HK history: No	10,925	2.7 (2.5–3.0)
HF diagnosis ≤12 mo	2,697	6.5 (5.6–7.5)
HF diagnosis >12 mo	623	3.0 (1.9–4.7)
UACR ≥300	3,572	4.3 (3.7–5.0)
UACR 30–299	2,588	2.0 (1.5–2.5)
UACR <30	723	1.3 (0.7–2.1)
K binder: Yes	439	**15.8 (12.3–19.9)**
K binder: No	11,490	3.0 (2.7–3.3)
SGLT2i: Yes	5,330	3.2 (2.8–3.7)
SGLT2i: No	6,599	3.5 (2.7–3.3)
Finerenone 10 mg	9,464	3.4 (3.1–3.7)
Finerenone 20 mg	1,781	2.8 (2.2–3.7)

Key findings

- HK rates rose with worsening eGFR, ~15-fold from eGFR ≥90 to <25
- Prior HK history and K^+ binder use identified the highest risk patients at about 4 times the overall rate
- SGLT2i use or finerenone starting dose did not impact HK IR

Figure 2. Multivariable predictors of K^+ ≥6.0 mEq/L (Adjusted HR, 95% CI)



Log scale; dashed line: aHR = 1. Arrows indicate CIs extending beyond the axis.
Baseline treatment window: 180 days before/on index; sMRA history categorized separately.

Key findings Increased risk of K+ ≥6.0 associated with baseline K+, UACR ≥300, eGFR <25, loop diuretic use, prior HK, stroke/TIA, HF, Hgb <12, and neuropathy

LIMITATIONS

- Retrospective EHR design without comparator; confounding by indication cannot be ruled out
- Surveillance bias: infrequent monitoring may under-count mild HK events
- Adherence, discontinuation, and dose-titration not captured due to lack of data

Abbreviations: ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; EHR, electronic health records; ESRD, end-stage renal disease; HK, hyperkalemia; IR, incidence rate; K^+, potassium; PY, patient-years; RAASi, renin–angiotensin–aldosterone system inhibitor; SGLT2i, sodium–glucose cotransporter-2 inhibitor; sMRA, steroidal mineralocorticoid receptor antagonist; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio.

Disclosures: YW, MF, AK, JE, CA, ZZ are full-time employees of Bayer and may hold Bayer stock. JR is an advisor for Boehringer Ingelheim, Bayer, AstraZeneca, Retension Pharmaceuticals, and Procyrion Inc. MW was a scientific advisor for AstraZeneca, Bayer, CSL Vifor, Novo Nordisk, and Mineralys. The study was funded by Bayer.

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KEY RESULTS: INCIDENCE OF HYPERKALEMIA

K^+ >5.5 mEq/L	K^+ ≥6.0 mEq/L	hospitalization related to HK
8.3	**3.4**	**0.3**
per 100 PY (95% CI 7.8–8.7)	**per 100 PY (95% CI 3.1–3.7)**	**per 100 PY (95% CI 0.2–0.4)**
1,142 patients (9.6%)	488 patients (4.1%)	44 patients (0.4%)

CONCLUSIONS

HK burden

In a real-world cohort of patients with CKD and T2D, we did not observe excessive risks or severity of hyperkalemia beyond what was reported in the pivotal trials with finerenone.

Risk-based management approach

The findings support a risk-based approach to HK management, with a higher hazard observed among patients with lower baseline eGFR, higher baseline UACR, a history of HK, recent HF, stroke/TIA, neuropathy, or loop diuretic use, whereas hazards were generally similar regardless of concomitant SGLT2i use or finerenone starting dose.

Support for real-world use

These data support the real-world safety of finerenone and could help address treatment inertia.

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