SA-PO0410

Finerenone safety and effectiveness across CKD stages in type 2 diabetes: analysis of four U.S. databases from the FOUNTAIN platform

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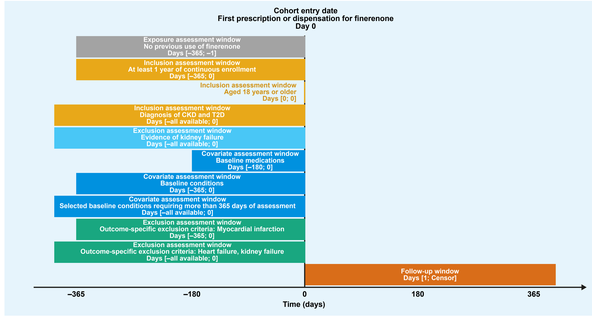
Background

- Chronic kidney disease (CKD) is a common complication of type 2 diabetes (T2D), with a concurrent prevalence of up to 40%[1,2]
- Finerenone, a nonsteroidal mineralocorticoid receptor antagonist, was first approved for use in individuals with CKD and T2D in 2021[3]
- Finerenone is increasingly used in individuals with CKD and T2D following its inclusion in guideline recommendations by the European Society of Cardiology, American Diabetes Association (ADA), Kidney Disease: Improving Global Outcomes (KDIGO) and ADA-KDIGO consensus report
  - All of these guidelines recommend finerenone in addition to a renin–angiotensin system inhibitor in individuals with T2D to reduce cardiovascular events and kidney failure[1,4–6]
- There is now an opportunity to analyze real-world data to understand finerenone utilization in clinical practice and the characteristics of individuals who initiate treatment

Methods

- This was a large-scale, observational, retrospective, single-arm cohort study of adults with CKD and T2D who initiated finerenone within the FOUNTAIN (FinerenOne mUltidatabase NeTwork for evidence generAtIoN) research platform
- Four US databases were mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). The databases included:
  - HealthVerity® Chronic Kidney Disease Masterset (referred to as HealthVerity)
  - Merative MarketScan® (referred to as MarketScan)
  - Optum® Clinformatics Data Mart (referred to as Optum CDM)
  - Optum® de-identified Electronic Health Records (referred to as Optum EHR)
- Data collection periods for baseline characteristics were 2017 to August 2025 (HealthVerity), 2012 to September 2024 (MarketScan), and 2012 to March 2025 (Optum CDM and Optum EHR). The index date of data collection for finerenone initiation was July 2021 for all four databases
- Individuals were aged ≥18 years with T2D and CKD Stages 2–4
- Individuals were excluded if they had kidney failure at any point before or including the date of first finerenone exposure
  - Kidney failure was defined as evidence of estimated glomerular filtration rate ≤15 ml/min/1.73 m^2 (also referred to as end-stage kidney disease), kidney transplant, or dialysis
- Analyses were conducted in finerenone initiators and in CKD Stage 2, 3 and 4 subgroups
  - Finerenone initiators were eligible individuals with evidence of finerenone exposure during the study period and without any finerenone exposure during the 12 months prior
- Follow-up was from the day after the date of first recorded finerenone exposure until the first occurrence of either the end of the study period, disenrollment from the database, emigration from the database catchment area, death or kidney failure (**Figure 1**)
- Effectiveness was assessed in HealthVerity and Optum EHR, defined as the percent change in urine albumin-to-creatinine ratio (UACR) at ~4 months following finerenone initiation
- Safety was assessed in all four databases by evaluating the rates of hyperkalemia using diagnostic codes and a laboratory threshold (serum potassium concentration [K^+] ≥5.5 mmol/L)

Figure 1. Study design



This was a large-scale, observational, retrospective, single-arm cohort study of adults with CKD and T2D who initiated finerenone within the FOUNTAIN research platform. Variable assessment windows are shown relative to the study index date. For any given individual, the record of a first finerenone exposure was the index date (Day 0). All cohort members were required as per the inclusion criteria to have at least 12 months of data before the index date. Baseline was considered to be 1 year before and including the index date (Day −365; Day 0)

CKD, chronic kidney disease; FOUNTAIN, FinerenOne mUltidatabase NeTwork for evidence generAtIoN; T2D, type 2 diabetes

Results

- Numbers of individuals from each database were n=30,623 in HealthVerity, n=2390 in MarketScan, n=7413 in Optum CDM and n=5133 in Optum EHR (**Table 1**)

Table 1. Demographics and medical history at baseline

Database			Finerenone initiators	Subgroup: CKD Stage 2	CKD Stage 3	CKD Stage 4
HealthVerity		n	30,623	11,768	22,012	5196
	Baseline characteristics	Follow-up time in years (median [IQR])	1.3 (0.6–2.0)	1.4 (0.7–2.1)	1.4 (0.7–2.1)	1.4 (0.7–2.1)
		Age (mean ± SD)	66.1 ± 12.2	64.8 ± 11.6	67.1 ± 12.0	67.9 ± 12.6
		Sex: Female (%)	46.9	43.5	47.4	51.4
		Sex: Male (%)	53.1	56.4	52.5	48.6
		Race: White (%)	21.8	20.6	21.6	21.2
		Race: Black (%)	4.6	3.6	4.9	5.1
		Race: Asian (%)	3.7	4.0	3.6	3.2
		Ethnicity: Latino (%)	8.4	9.3	8.2	7.8
		Ethnicity: Not Latino (%)	21.7	18.9	21.9	21.6
	Comorbidities	Hypertension (%)	83.2	84.1	83.2	82.3
		Hyperlipidemia (%)	85.7	86.5	85.6	85.5
	Comedications	RASi (%)	77.4	78.6	77.4	76.0
		SGLT-2i (%)	70.0	70.8	70.4	69.9
		GLP-1RA (%)	48.3	49.2	47.5	47.5
Market Scan		n	2390	407	1439	262
	Baseline characteristics	Follow-up time in years (median [IQR])	0.9 (0.4–1.4)	0.9 (0.4–1.5)	0.9 (0.4–1.5)	0.8 (0.4–1.5)
		Age (mean ± SD)	61.3 ± 10.8	59.7 ± 9.8	62.6 ± 11.0	63.6 ± 11.5
		Sex: Female (%)	39.4	36.1	39.7	42.7
		Sex: Male (%)	60.6	63.9	60.3	57.3
	Comorbidities	Hypertension (%)	77.9	80.3	76.9	76.0
		Hyperlipidemia (%)	77.4	77.6	76.4	74.8
	Comedications	RASi (%)	76.3	79.1	75.1	71.8
		SGLT-2i (%)	69.7	70.3	70.3	69.5
		GLP-1RA (%)	53.6	53.8	52.5	48.9
Optum CDM		n	7413	2361	5862	1559
	Baseline characteristics	Follow-up time in years (median [IQR])	1.1 (0.5–1.9)	1.1 (0.5–1.9)	1.1 (0.5–1.9)	1.1 (0.5–1.9)
		Age (mean ± SD)	71.4 ± 9.1	70.2 ± 9.1	72.2 ± 8.6	73.1 ± 8.5
		Sex: Female (%)	45.9	41.7	46.8	53.0
		Sex: Male (%)	54.1	58.3	53.2	47.0
		Race: White (%)	47.9	47.9	47.9	46.6
		Race: Black (%)	22.9	20.4	24.3	26.6
		Race: Asian (%)	8.3	9.4	8.1	7.8
		Ethnicity: Latino (%)	20.1	24.5	19.1	19.7
		Ethnicity: Not Latino (%)	62.5	59.0	63.6	63.4
	Comorbidities	Hypertension (%)	81.9	81.9	81.8	80.6
		Hyperlipidemia (%)	81.5	81.4	81.6	80.5
	Comedications	RASi (%)	79.0	79.3	78.8	77.8
		SGLT-2i (%)	67.7	67.3	68.4	69.6
		GLP-1RA (%)	45.2	45.9	44.2	46.2
Optum EHR		n	5133	1721	3700	1096
	Baseline characteristics	Follow-up time in years (median [IQR])	1.1 (0.5–1.9)	1.2 (0.6–2.1)	1.1 (0.5–2.0)	1.1 (0.5–2.0)
		Age (mean ± SD)	68.9 ± 10.4	67.4 ± 10.6	69.8 ± 10.0	70.4 ± 10.0
		Sex: Female (%)	41.3	37.5	42.1	46.1
		Sex: Male (%)	58.7	62.5	57.9	53.9
		Race: White (%)	66.6	65.9	66.2	67.1
		Race: Black (%)	18.5	17.0	19.1	19.8
		Race: Asian (%)	6.9	8.3	6.8	5.3
		Ethnicity: Latino (%)	17.1	21.2	17.2	18.5
		Ethnicity: Not Latino (%)	79.9	75.6	79.6	78.6
	Comorbidities	Hypertension (%)	96.6	96.0	97.2	98.3
		Hyperlipidemia (%)	92.1	92.9	92.5	91.1
	Comedications	RASi (%)	94.4	94.9	94.2	93.5
		SGLT-2i (%)	72.9	73.9	73.4	72.9
		GLP-1RA (%)	54.0	54.5	53.4	49.9

Prevalence scale (%)

0–10.99	11–20.99	21–30.99	31–40.99	41–50.99	51–60.99	61–70.99	71–80.99	81–90.99	91–100

Mean age scale (years)

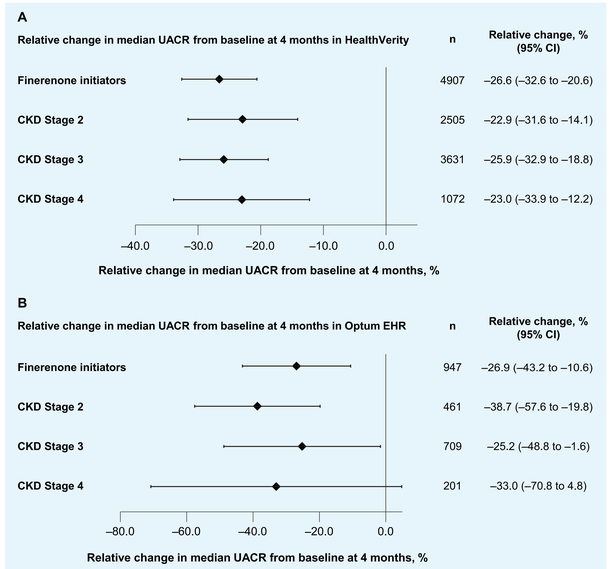
59–61.9	62–63.9	64–65.9	66–67.9	68–69.9	70–71.9	72–73.9

A finerenone initiator was defined as an eligible individual with evidence of exposure to finerenone during the study period and without any prior evidence of finerenone exposure during the previous 12 months

CKD, chronic kidney disease; GLP-1RA, glucagon-like peptide-1 receptor agonist; IQR, interquartile range; RASi, renin-angiotensin system inhibitor; SD, standard deviation; SGLT-2i, sodium-glucose co-transporter-2 inhibitor

- The median follow-up time was approximately 1 year, across all subgroups in all databases
- Throughout databases, individuals who initiated finerenone were predominantly male, White, aged ≥60 years, with common cardiometabolic comorbidities and frequent use of kidney-protective background therapies
- At ~4 months, UACR decreased to a similar extent across the spectrum of CKD severity (**Figure 2**)
  - In HealthVerity, the relative change in median UACR from baseline was –26.9% (95% confidence interval [CI] –33.5 to –20.4) for finerenone initiators
    - The relative change in median UACR from baseline was –24.3% (95% CI –34.3 to –14.3), –24.8% (95% CI –33.5 to –16.1) and –24.9% (95% CI –40.4 to –9.4) for CKD Stage 2, 3 and 4 subgroups, respectively
  - In Optum EHR, the relative change in median UACR from baseline was –29.0% (95% CI –46.9 to –11.0) for finerenone initiators
    - The relative change in median UACR from baseline was –35.8% (95% CI –59.2 to –12.3), –25.1% (95% CI –47.0 to –3.3) and –27.6% (95% CI –75.8 to –20.7) for CKD Stage 2, 3 and 4 subgroups, respectively

Figure 2. Change in median UACR among finerenone initiators and CKD stage subgroups across two US databases



A finerenone initiator was defined as an eligible individual with evidence of exposure to finerenone during the study period and without any prior evidence of finerenone exposure during the previous 12 months

CI, confidence interval; CKD, chronic kidney disease; UACR, urine albumin-to-creatinine ratio

- Hyperkalemia estimates were aligned with the known safety profile of finerenone[7–9] (**Table 2**)
  - The incidence rate (IR) per 100 person-years (PY) of hyperkalemia in the finerenone initiator group, as defined by diagnosis code with an emergency room or inpatient visit, was IR 2.06 (95% CI 1.92–2.21), IR 2.36 (95% CI 1.76–3.10), IR 1.23 (95% CI 1.00–1.49) and IR 1.06 (95% CI 0.81–1.35) for HealthVerity, MarketScan, Optum CDM and Optum EHR, respectively
  - The IR per 100 PY for hyperkalemia in the finerenone initiator group, as defined by laboratory results (≥1 record of [K+] ≥5.5 mmol/L), were IR 4.54 (95% CI 4.32–4.77), IR 5.07 (4.57–5.61) and IR 6.27 (95% CI 5.59–7.01) for HealthVerity, Optum CDM and Optum EHR, respectively
    - There were no laboratory data available in MarketScan
- As expected, the IR of hyperkalemia increased with more advanced stages of CKD
  - This trend was consistent for hyperkalemia defined by diagnostic codes and defined by laboratory results

Table 2. Incidence rate per 100 PY of hyperkalemia in finerenone initiators and CKD stage subgroups across four US databases

Database	Patient subgroup	Hyperkalemia estimate, incidence rate per 100 PY (95% CI): Safety profile: Diagnosis code with emergency room or inpatient visit	Hyperkalemia estimate, incidence rate per 100 PY (95% CI): Safety profile: laboratory results of ≥1 record of serum [K^+] ≥5.5 mmol/L
HealthVerity	Finerenone initiators (n=30,623)	2.06 (1.92–2.21)	4.54 (4.32–4.77)
	CKD Stage 2 (n=11,768)	1.58 (1.39–1.79)	4.49 (4.15–4.86)
	CKD Stage 3 (n=22,012)	2.35 (2.18–2.54)	5.45 (5.16–5.75)
	CKD Stage 4 (n=5196)	4.25 (3.74–4.82)	8.44 (7.64–9.30)
MarketScan	Finerenone initiators (n=2390)	2.36 (1.76–3.10)	No laboratory data available in MarketScan
	CKD Stage 2 (n=407)	1.88 (0.76–3.88)	
	CKD Stage 3 (n=1439)	2.62 (1.81–3.66)	
	CKD Stage 4 (n=262)	3.93 (1.70–7.75)	
Optum CDM	Finerenone initiators (n=7413)	1.23 (1.00–1.49)	5.07 (4.57–5.61)
	CKD Stage 2 (n=2361)	0.74 (0.45–1.14)	4.98 (4.13–5.96)
	CKD Stage 3 (n=5862)	1.28 (1.02–1.58)	5.53 (4.94–6.16)
	CKD Stage 4 (n=1559)	2.26 (1.60–3.10)	8.04 (6.61–9.68)
Optum EHR	Finerenone initiators (n=5133)	1.06 (0.81–1.35)	6.27 (5.59–7.01)
	CKD Stage 2 (n=1721)	0.62 (0.34–1.05)	5.06 (4.09–6.20)
	CKD Stage 3 (n=3700)	1.19 (0.89–1.56)	7.18 (6.32–8.12)
	CKD Stage 4 (n=1096)	2.53 (1.72–3.59)	12.14 (9.91–14.73)

Hyperkalemia was defined by diagnosis code with an ER or IP visit, or laboratory-defined as at least one record of serum [K^+] ≥5.5 mmol/L during follow-up after finerenone initiation. All entries are incidence rates per 100 PY with 95% CI; laboratory-based hyperkalemia indicates any serum [K^+] ≥5.5 mmol/L during follow-up after finerenone initiation; laboratory data were not available in MarketScan

A finerenone initiator was defined as an eligible individual with evidence of exposure to finerenone during the study period and without any prior evidence of finerenone exposure during the previous 12 months

CI, confidence interval; CKD, chronic kidney disease; IR, incidence rate; [K^+], potassium concentration, PY, person-years

Conclusion

- Based on the analysis of these four US data sources, finerenone initiation in individuals with T2D and CKD was associated with early reductions in albuminuria and a predictable hyperkalemia safety profile across all CKD stages. These findings support that finerenone is effective and has a predictable safety profile across the CKD spectrum in routine practice

Acknowledgments

The authors also acknowledge Joseph Wright, PhD (OHMC), who provided medical writing services with funding from Bayer AG.

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Poster SA-PO0410 presented at the American Society of Nephrology (ASN) 2026 (October 22–25, 2026, Denver, CO, USA)