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Clinical outcomes in US patients initiating finerenone – a report from the FOUNTAIN platform

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INTRODUCTION

- Evidence from clinical trials demonstrates that finerenone reduces the risk of cardiovascular and kidney complications among patients with chronic kidney disease (CKD) and type 2 diabetes (T2D)
- Evidence from real-world clinical practice may provide additional insights into treatment effectiveness and safety to inform decision-making
- Gathering real-world evidence (RWE) is made difficult by heterogeneity within healthcare systems and patient populations, as well as bias and inconsistent application of methodologies across studies
- By harmonising RWE generation across a portfolio of research projects, the FOUNTAIN platform has been designed to allow description of clinical practice and related outcomes in patients prescribed finerenone, and to assess the real-world effectiveness and safety of finerenone
- This analysis includes patients with CKD and T2D from the US with documented initiation of finerenone through electronic health records

AIM

- We report the baseline characteristics and clinical outcomes of a US population with CKD and T2D initiating finerenone

METHODS

- This analysis is based on a longitudinal, single-arm cohort study of patients initiating finerenone between July 2021 and August 2023, with prior diagnoses of CKD and T2D. Data were obtained from US electronic health records (OM1 Real-World Data Cloud™)
- CKD was defined as any of the following:
  - One diagnostic code for CKD stage 2–4 or unspecified stage
  - Two estimated glomerular filtration rate (eGFR) measurements of ≥15 and <60 ml/min/1.73 m^2, recorded 90–548 days apart
  - Two urine albumin-to-creatinine ratio (UACR) measurements ≥30 mg/g, recorded 90–548 days apart
- T2D was defined as having a diagnostic code for T2D
- Here, we describe patient demographics, comorbidities (using all available lookback time), and comedications at baseline (180 days before and including index date), along with UACR and eGFR changes over time, and incidence rates of hyperkalaemia. This analysis is part of the multi-national, multi-database, observational research platform, FOUNTAIN

RESULTS

- We identified 15,948 patients initiating finerenone with existing CKD and T2D. Baseline characteristics are described in **Table 1**

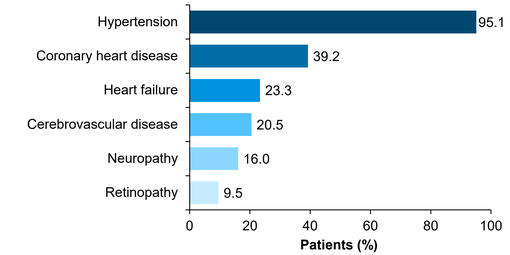
Table 1. Baseline characteristics of patients initiating finerenone

Characteristic	Finerenone (N=15,948)
Female, n (%)	7036 (44.1)
Age, years, mean ± SD	70.3±10.1
Race/ethnic group,* n (%)	
White	3874 (69.5)
Black/African American	872 (15.6)
Asian	465 (8.3)
Other	365 (6.5)
Calendar year of index date, n (%)	
2021 (July–December)	1061 (6.7)
2022	7888 (49.5)
2023 (January–August)	6999 (43.9)

SD, standard deviation
*Patients with unknown or missing information were removed from this analysis

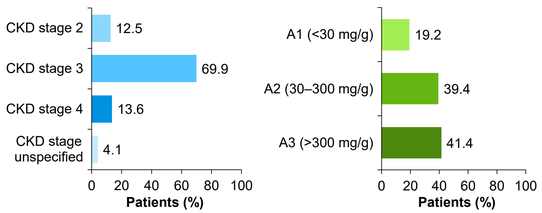
- Nearly all patients (95.1%) in this analysis had hypertension; other baseline conditions are shown in **Figure 1**

Figure 1. Baseline comorbidities of patients initiating finerenone



- The majority of patients initiating finerenone had CKD stage 3 (69.9%) (**Figure 2A**) and albuminuria ≥30 mg/g (80.8%) (**Figure 2B**)

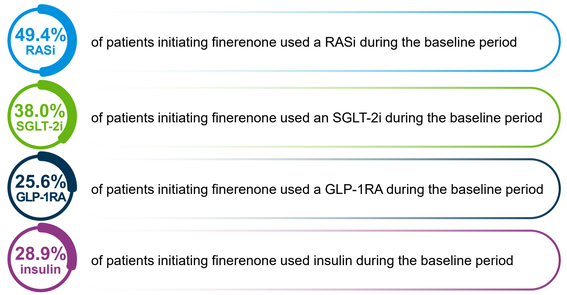
Figure 2. (**A**) Baseline CKD stage and (**B**) Baseline albuminuria category



Patients with missing information were removed from this analysis
*Last available CKD diagnosis code or eGFR measurement in the 365 days before finerenone initiation; #last available UACR measurement in the 365 days before finerenone initiation

- Finerenone was initiated in combination with other treatment options, including SGLT-2is (38.0%) and GLP-1RAs (25.6%), in the 180 days before and including the index date (**Figure 3**)

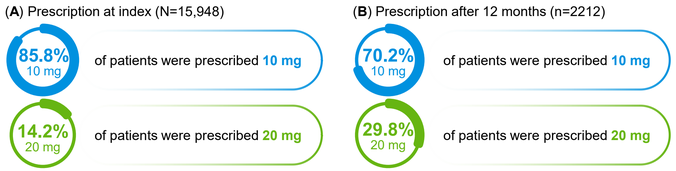
Figure 3. Baseline comedications in the 180 days before and including the index date (N=15,948)



GLP-1RA, glucagon-like peptide-1 receptor agonist; RASi, renin–angiotensin system inhibitor; SGLT-2i, sodium-glucose co-transporter 2 inhibitor

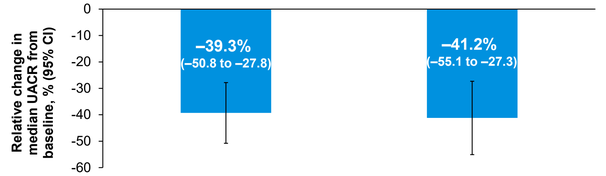
- 85.8% of patients were initiated on a 10 mg once-daily finerenone regimen and 14.2% on a 20 mg once-daily finerenone regimen (N=15,948) (**Figure 4A**)
- For patients with 12 months of follow-up (n=2212), 70.2% were prescribed finerenone 10 mg once daily and 29.8% were prescribed finerenone 20 mg once daily (**Figure 4B**)
  - The recommended target dose of finerenone is 20 mg once daily,[1] which is also the recommended starting dose for patients with eGFR ≥60 ml/min/1.73 m^2 (for patients with eGFR ≥25–<60 ml/min/1.73 m^2, the recommended starting dose is 10 mg once daily)

Figure 4. Finerenone daily dosing patterns observed (**A**) at baseline and (**B**) after 1 year



- Finerenone was associated with a relative median reduction in UACR of 39.3% from baseline at month 4, and this was sustained with a 41.2% reduction from baseline at month 12 (**Figure 5**)
- Mean eGFR also decreased from baseline, by 3.5% at Month 4 and by 5.2% at month 12

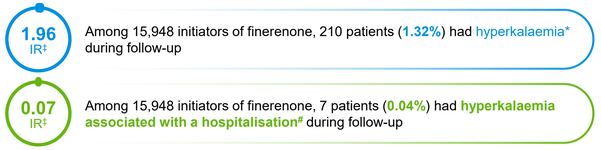
Figure 5. Relative change in median UACR from baseline



	Baseline	Month 4	Month 12
Number of patients	2137	1617	900
Median UACR, mg/g (Q1–Q3)	211 (56–750)	128 (31–551)	124 (26–544)

- In clinical practice, hyperkalaemia* following finerenone initiation was observed in 210 patients (1.32%), and 7 patients (0.04%) had hyperkalaemia associated with a hospitalisation# during the follow-up period (**Figure 6**)
  - These observations are equivalent to an incidence rate (IR) of 1.96 events per 100 patient-years for hyperkalaemia, and 0.07 events per 100 patient-years for hyperkalaemia associated with a hospitalisation

Figure 6. Observed incidence of hyperkalaemia



*Hyperkalaemia was defined as i) a hospitalisation or emergency department visit with a diagnosis code for hyperkalaemia, or ii) at least 2 serum potassium laboratory values >5.5 mmol/l, as follows: two inpatient serum potassium values >5.5 mmol/l on the inpatient record within 7 days or one serum potassium value >5.5 mmol/l in a non-hospitalised setting and another value in any setting within 7 days, or iii) a serum potassium laboratory value >5.5 mmol/l in any setting and the occurrence of an inpatient or outpatient diagnosis code for hyperkalaemia within 3 days; #hyperkalaemia associated with a hospitalisation: a medical diagnosis code or increased serum potassium (>5.5 mmol/l) 7 days before or after a hospitalisation record; ‡incidence rate, events per 100 person-years

CONCLUSIONS

- The FOUNTAIN platform can provide valuable real-world evidence on the use of finerenone in clinical practice, complementary to randomised clinical trial data, giving a holistic view of the potential impact of finerenone for patients with CKD and T2D
- This analysis suggests that in routine clinical practice in the US, finerenone is used along with other kidney- and cardiovascular-protective medication classes recommended for patients with CKD and T2D, and across CKD stages and UACR categories
- There was a robust reduction in UACR from baseline to month 4, sustained at month 12, and incidence of hyperkalaemia appeared low
- Further analyses are needed to fully understand whether up-titration to the target dose of finerenone in clinical practice follows recommendations. These data from the FOUNTAIN platform suggest that real-world use of finerenone differs from that observed in the FIDELITY programme[2]
- Further analyses are planned to determine the impact of finerenone dosing and comedication use on real-world clinical outcomes

ACKNOWLEDGEMENTS

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DISCLOSURES

CPK: consultant for Abbott, Akebia, AstraZeneca, Bayer, Boehringer Ingelheim, Cara Therapeutics, CSL Vifor, GlaxoSmithKline, Prokidney, Pharmacosmos, Takeda. **JBL:** employee of RTI Health Solutions. **BT:** employee of OM1, Inc. **GC:** employee of OM1, Inc. **AEF:** employee of Bayer AG. **FL:** employee of Bayer AG. **CJ:** employee of RTI Health Solutions. **DV:** employee of Bayer AG. **NGO:** employee of Bayer AG.

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