Early Use of Finerenone in US Patients with CKD and Type 2 Diabetes: A FOUNTAIN Analysis

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Background

Based on evidence from clinical trials, finerenone reduces the risk of cardiovascular and renal complications among patients with chronic kidney disease (CKD) and type 2 diabetes (T2D). Evidence from finerenone use in real-world clinical practice is lacking.

The presented analyses are part of the multi-database research platform FOUNTAIN which includes data sources in Europe, Japan, China, and the United States (US). All data shown are based on analyses conducted in US data sources.

Methods

Three different data sources from the US were used to identify individuals with both CKD and T2D who initiate finerenone after July 2021:

- Optum electronic health records (Optum EHR): a database containing electronic health records information from multispecialty practices, small group practices, physician providers, and integrated delivery networks throughout the US. Time period: July 2021-September 2022.
- Optum Clinformatics DataMart (Optum Claims): a database comprising administrative health claims, pharmacy claims, and laboratory data for members of a large national managed care company affiliated with Optum, including commercial health plan data and Medicare Advantage members. Time period: July 2021-March 2022.
- OM1 Real-World Data Cloud™ (OM1 RWDC): a continuously updated, deterministically linked, multi-source dataset. The OM1 RWDC's medical and pharmacy claims contain billing and coding history on inpatient and outpatient encounters from acute care facilities, ambulatory surgery centers, and clinics. The combined electronic medical record (EMR) and claims dataset provides additional insights into the complete patient journey. Time period: July 2021-September 2023.

Results

- An initial assessment of the respective databases identified 662 (Optum EHR), 353 (Optum Claims), and 19,255 (OM1 RWDC) individuals with CKD and T2D who initiated finerenone.
- Mean age (SD) across all three cohorts of finerenone initiators ranged from 68.4 (10.5) years to 72.1 (8.3) years with the majority of patients being aged 65 years or older; Optum EHR: 66.9%, Optum Claims: 86.7%, OM1 RWDC: 75.5%. (Table 1)
- The largest cohort of initiators of finerenone (n=19,255; OM1 RWDC) showed that 44.2% of individuals receiving finerenone are female and that 67.3% have a comorbidity burden of 4 or more different comorbidities (Charlson comorbidity index) detected in the database. Additional analyses using the OM1 RWDC database are currently ongoing. (Table1)
- The most common comorbidities at baseline recorded in the Optum EHR and Optum claims databases were hypertension, hyperlipidemia, peripheral vascular disease, neuropathy, congestive heart failure, and retinopathy. (Table 2)
- Baseline comedication use was common with over 70% of individuals using an angiotensin-converting enzyme inhibitor (ACE) or an angiotensin receptor blocker (ARB) (Optum EHR: 70.4%), around 60% used a beta-blocker (Optum EHR: 62.7%), and about 50% used calcium channel blockers (CCB) (Optum EHR: 54.2%). (Table 2)

Table 1: Demographic characteristics of finerenone initiators across three databases in the US

	Finerenone initiators		
	Optum EHR (N = 662)	Optum Claims (N = 353)	OM1 RWDC (N = 19,255)
Sociodemographic characteristics			
Age, years, mean (SD)	**68.4 (10.5)**	**72.1 (8.3)**	**70.5 (10.2)**
Age, 5-years categories, n (%)			
18-24	-		**4 (0.0%)**
25-34	**2 (0.3%)**	-	**60 (0.3%)**
35-44	**10 (1.5%)**	-	**272 (1.4%)**
45-54	**53 (8.0%)**	**11 (3.1%)**	**1,033 (5.4%)**
55-64	**153 (23.1%)**	**36 (10.2%)**	**3,358 (17.4%)**
65+	**443 (66.9%)**	**305 (86.7%)**	**14,528 (75.5%)**
Sex, n (%)			
Male	**357 (53.9%)**	**188 (53.4%)**	**10,739 (55.8%)**
Female	**305 (46.1%)**	**164 (46.6%)**	**8,516 (44.2%)**
Race, n (%)			
White	**420 (63.4%)**	**158 (44.9%)**	**5,368 (31.1%)**
Black or African American	**134 (20.2%)**	**65 (18.5%)**	**1,263 (16.6%)**
Asian	**23 (3.5%)**	**25 (7.1%)**	**543 (7.1%)**
Charlson comorbidity index, mean (SD)	**6.5 (2.4)**	**7.3 (2.4)**	**4.8 (2.4)**
0-1	-	-	**1,178 (6.1%)**
2-3	-	-	**5,123 (26.6%)**
4-5	-	-	**6,780 (35.2%)**
6+	-	-	**6,174 (32.1%)**

Table 1: Demographic characteristics of individuals with CKD and T2D who initiated finerenone after July 2021 in three US databases (Optum EHR, Optum Claims, OM1 RWDC).

Results (cont.)

- Over 90% of finerenone users used anti-hyperglycemic medication as monotherapy or in multi-drug combinations, including insulins (Optum EHR: 58.8%), metformin (Optum EHR: 51.8%), sodium-glucose cotransporter-2 (SGLT2) inhibitors (Optum EHR: 53.5%), and glucagon-like peptide-1 (GLP-1) receptor agonists (Optum EHR: 42.1%). (Table 2)

Conclusions

- Finerenone initiators with CKD and T2D could reliably be detected in different databases, with the largest number of finerenone initiators captured in the OM1 RWDC (n=19,255).
- Early evidence from patients who receive finerenone as part of clinical practice in the US suggests that finerenone is used across a patient population with heterogeneous demographic and clinical characteristics.
- This analysis of early adopters suggests that finerenone is used as a complementary treatment option to other renal and cardiovascular protective medication-classes recommended for patients with CKD and T2D.

Table 2: Baseline comorbidities and comedications of finerenone initiators in the US

	Finerenone initiators	
	Optum EHR (N = 662)	Optum Claims (N = 353)
Physical examination		
Systolic BP, mm Hg, mean (SD)	**134.8 (23.8)**	**138.3 (20.8)**
Diastolic BP, mm Hg, mean (SD)	**72.4 (12.8)**	**74.0 (14.8)**
Laboratory data		
eGFR, mL/min/1.73m2, median (IQR)	**44 (32-57)**	**44.0 (35.0-75.0)**
<25	**95 (16.7%)**	**28 (7.9%)**
25-<45	**275 (48.5%)**	**139 (39.4%)**
45-<60	**119 (20.1%)**	**54 (15.35)**
≥60	**78 (13.8%)**	**14 (4.0%)**
Missing	**95**	**118**
UACR, mg/g, median (IQR)	**339 (61-1143)**	**110.0 (20.0-698.0)**
UACR measurement performed, n (%)		
Yes	**359 (54.2%)**	**136 (38.5%)**
No	**303 (45.8%)**	**217 (61.5%)**
UACR category, mg/g, n (%)		
<30	**42 (6.3%)**	**32 (9.0%)**
30-<300	**134 (20.2%)**	**53 (15.0%)**
≥300	**183 (27.6%)**	**51 (14.4%)**
Not performed	**303 (45.8%)**	**217 (61.5%)**
Diabetes data		
DCSI⁺, mean (SD)	**5.7 (2.5)**	**5.9 (2.3)**
Microvascular complications		
Retinopathy, n (%)	**141 (21.3%)**	**125 (35.5%)**
Neuropathy, n (%)	**274 (41.4%)**	**189 (53.7%)**
Cardiovascular risk factors**		
Hypertension, n (%)	**643 (97.1%)**	**346 (98.3%)**
Hyperlipidemia, n (%)	**518 (78.2%)**	**308 (87.5%)**
History of cardiovascular disease**		
Peripheral vascular disease, n (%)	**381 (57.6%)**	**235 (66.8%)**
Congestive heart failure, n (%)	**177 (26.7%)**	**121 (34.4%)**
Coronary heart disease, n (%)	**62 (9.4%)**	**50 (14.2%)**
Acute coronary syndrome, n (%)	**88 (13.3%)**	**35 (9.9%)**
Stroke, n (%)	**62 (9.4%)**	**23 (6.5%)**
Cardiovascular drugs at baseline*		
ACEI, n (%)/ARB, n (%) (Total)	**466 (70.4%)**	**248 (70.5%)**
Loop Diuretics, n (%)	**303 (45.8%)**	**142(40.3%)**
Beta-blockers, n (%)	**415 (62.7%)**	**212 (60.2%)**
CCB, n (%)	**359 (54.2%)**	**178 (50.6%)**
Statins, n (%)	**577 (87.2%)**	**291 (82.4%)**
Potassium binder, n (%)	**32 (4.8%)**	**11 (3.1%)**
Prior MRA, n (%)	**85 (12.8%)**	**29 (8.2%)**
Glucose-lowering therapies at baseline*		
Total, n (%)	**627 (94.7%)**	**320 (90.9%)**
Insulins and analogues, n (%)	**389 (58.8%)**	**164 (46.6%)**
Metformin, n (%)	**343 (51.8%)**	**151 (42.9%)**
SGLT2 inhibitors, n (%)	**354 (53.5%)**	**149 (42.3%)**
GLP-1 agonists, n (%)	**279 (42.1%)**	**124 (35.2%)**
Sulfonylureas, n (%)	**165 (24.9%)**	**82 (23.3%)**
DPP-4 inhibitors, n (%)	**117 (17.7%)**	**65 (18.5%)**

Table 2: Baseline comorbidities and comedications of individuals with CKD and T2D who initiated finerenone after July 2021 in two US databases (Optum EHR, Optum Claims). *365 days prior up to and including the index day; **Any time prior to index; ⁺DCSI: Diabetes Comorbidity Severity Index .

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