FR-PO323

UTILIZATION OF NON-STEROIDAL MINERALOCORTICOID RECEPTOR ANTAGONIST (MRA) FINERENONE WITH OR WITHOUT PRIOR STEROIDAL MRA

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INTRODUCTION

- Finerenone, a non-steroidal mineralocorticoid receptor antagonist (nsMRA) approved by the FDA in July 2021, demonstrated promising efficacy in reducing cardiovascular (CV) risk and slowing chronic kidney disease (CKD) progression in patients with CKD and type 2 diabetes (T2D).
- Spironolactone and Eplerenone, traditional steroidal MRAs (sMRA), have been mainstays of treatment for conditions such as heart failure with reduced ejection fraction, resistant hypertension, primary hyperaldosteronism, and decompensated cirrhosis. However, known adverse effects of hyperkalemia, hypotension, AKI, and sex hormone side effects have limited their use, especially in complex patients with multiple comorbidities.
- Treatment inertia with finerenone may stem from prior use and intolerability of sMRA, despite evidence implying the safety of finerenone in these patients.
- To examine this practice uncertainty and hesitancy, we aim to characterize patients who initiated finerenone with prior sMRA therapy and patients who do not have prior sMRA therapy in a real-world US representative claim database.

METHODS

- **Study Design:** a retrospective study of finerenone users from 7/1/2021 to 1/31/2024
- **Data sources:** the IQVIA Longitudinal Access and Adjudication Data (LAAD) with linkage to LabCorp data of eGFR and UACR.
- **Study Cohort:** Adult patients with ≥ 12 months of continuous activity prior to their first filled finerenone claim date (index) were included. We excluded patients who received finerenone prescriptions from HCPs who were the site principal investigators of finerenone clinical trials. (**Figure 1**)
- **Statistical analysis:**
  - The index date was defined as the date of first finerenone dispensation by the pharmacy
  - A look-back period of 1 year before the index finerenone date was used to define a subgroup of patients with recent prior sMRA use; and a look-back period of > 1 year before the index finerenone date was used to define a subgroup of patients with remote prior sMRA use.
  - Patient demographics (age and gender), type of insurance, comorbidities (hypertension, heart failure, retinopathy), and comedications (diuretic, calcium channel blockers, SGLT2i, insulin, metformin, and GLP1RA) stratified by prior sMRA use status were described.
    - Among the subgroup of patients with eGFR and UACR, we described the distribution of most recent eGFR and UACR, and the classification of KDIGO risk categories prior to finerenone initiation in relationship to finerenone initiation time and dose.

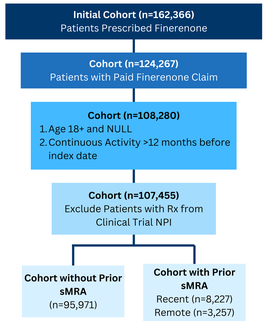


Figure 1. Patient Selection

Table 1. Finerenone user demographics, comorbidities, and comedication by prior sMRA use status

	Without prior sMRA	With prior sMRA		
		Total	Recent prior sMRA	Remote prior sMRA
N	95,971	11,484	8,227	3,257
Age/SD	67.0 (11.6)	66.9 (11.5)	66.7 (11.6)	67.4 (11.3)
Women, n %	40,338 (45%)	4,990 (47%)	3,532 (47%)	1,458 (47%)
Insurance type, n %				
Cash	308 (0%)	36 (0%)	26 (0%)	10 (0%)
Commercial	50,010 (52%)	5,967 (52%)	4,397 (53%)	1570 (48%)
FFS Medicaid	4,668 (5%)	398 (3%)	287 (3%)	111 (3%)
Managed Medicaid	2463 (3%)	3,232 (3%)	240 (3%)	83 (3%)
Medicare Part D	38,349 (40%)	4,724 (3%)	3,255 (40%)	1469 (45%)
Medicare	4 (0%)	1 (0%)	1 (0%)	NULL
Not Available	169 (0%)	35 (0%)	21 (0%)	14 (0%)
CKD Dx*, n %	52,108 (54%)	7,380 (64%)	5,146 (63%)	2234 (69%)
Type 2 Diabetes Dx*, n %	63,125 (66%)	7,538 (66%)	5,232 (64%)	2306 (71%)
Comorbidities, n % *				
Hypertension	75,410 (79%)	9,498 (83%)	6,731 (82%)	2767 (85%)
Heart Failure	15,529 (16%)	4,545 (40%)	3,152 (38%)	1393 (43%)
Retinopathy	4,261 (4%)	485 (4%)	323 (4%)	162 (5%)
Medications, n %				
ACEi	34,366 (36%)	3,142 (27%)	2,297 (28%)	845 (26%)
ARB	39,862 (42%)	5,344 (47%)	3,862 (47%)	1482 (46%)
CCB	47,155 (49%)	6,224 (54%)	4,407 (54%)	1817 (56%)
Non-Dihydropyridine	4,559 (5%)	862 (8%)	623 (8%)	239 (7%)
Dihydropyridine	43,561 (45%)	5,591 (49%)	3,948 (48%)	1643 (50%)
Diuretic	40,087 (42%)	7,454 (65%)	5,477 (67%)	1977 (61%)
Loop	22,106 (23%)	5,965 (52%)	4,385 (53%)	1580 (49%)
Thiazide	22,789 (24%)	2,906 (25%)	2,166 (26%)	740 (23%)
K-sparring	134 (0%)	70 (1%)	50 (1%)	20 (1%)
Insulin	37,770 (39%)	5,021 (44%)	3,588 (44%)	1433 (44%)
Metformin	46,646 (49%)	4,613 (40%)	3,457 (42%)	1156 (35%)
GLP1-RA	33,757 (35%)	4,077 (36%)	2,889 (35%)	1188 (36%)
SGLT2i	44,879 (47%)	5,809 (51%)	4,171 (51%)	1638 (50%)

Table 2. Distribution of KDIGO risk categories by Finerenone initiation dose in the A) without prior sMRA cohort (n=5,799), and B) with prior sMRA cohort (n=707)

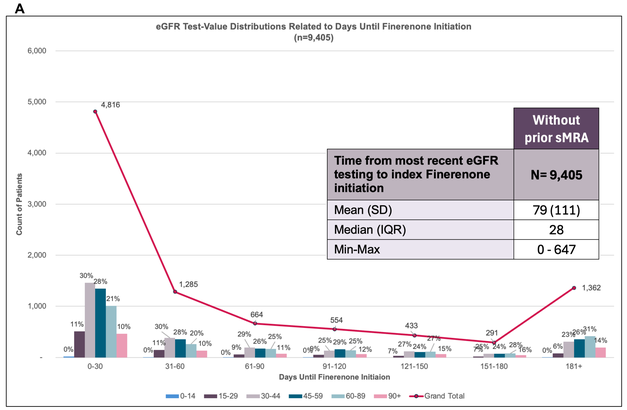
A

KDIGO Risk Category	Finerenone All	Finerenone 10mg	Finerenone 20mg
	n=5,799	**n=4,705**	**n=1,094**
Low risk, n (%)	296 (5%)	213 (5%)	83 (8%)
Moderate risk, n (%)	1,403 (24%)	1,005 (21%)	398 (36%)
High Risk, n (%)	1,817 (31%)	1,415 (30%)	402 (37%)
Very high risk, n (%)	2,283 (39%)	2,072 (44%)	211 (19%)

B

KDIGO Risk Category	Finerenone All	Finerenone 10mg	Finerenone 20mg
	n=707	**n=570**	**n=137**
Low risk, n (%)	38 (5%)	27 (5%)	11 (8%)
Moderate risk, n (%)	120 (17%)	84 (15%)	36 (26%)
High Risk, n (%)	181 (26%)	143 (25%)	38 (28%)
Very high risk, n (%)	368 (52%)	316 (55%)	52 (38%)

Figure 2. Time from most recent eGFR measurements to finerenone initiation in relationship to the eGFR in A) without prior sMRA cohort (n=9,405), and in B) with the prior sMRA cohort (n=1,325



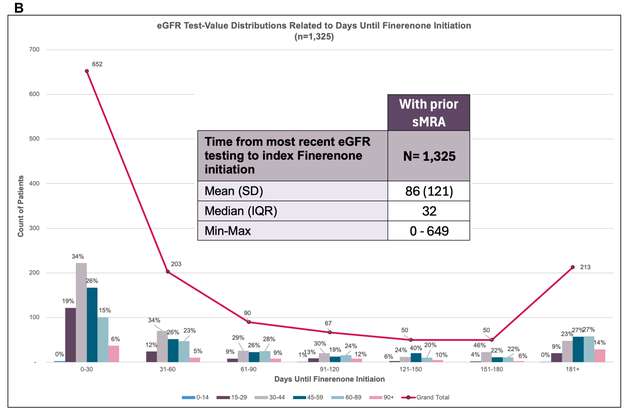


Table 3. Distribution of KDIGO risk groups in the A) without prior sMRA cohort (n=5,799), and B) with prior sMRA cohort (n=707)

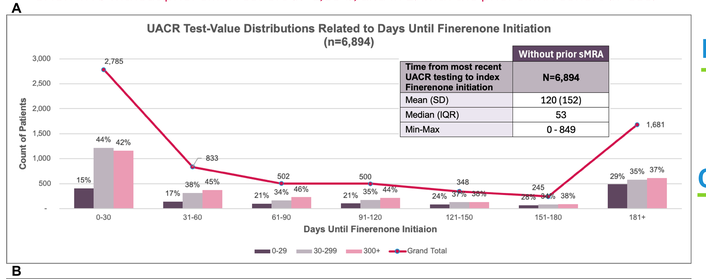
A

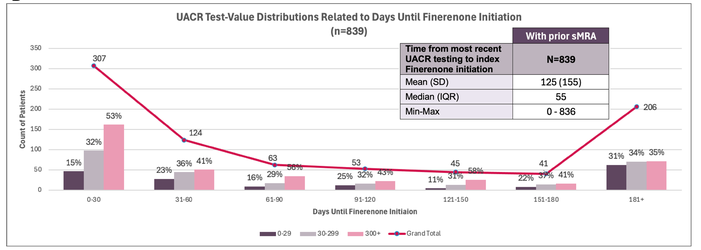
Ranges		All Finerenone Patients with UACR Test and eGFR Test			
		UACR Categories			Total (%)
		<30	30-300	>300	
eGFR Categories	>= 90	93 (1.6%)	364 (6.3%)	254 (4.4%)	711 (12.3%)
	60-89	203 (3.5%)	609 (10.5%)	589 (10.2%)	1401 (24.2%)
	45-59	430 (7.4%)	608 (10.5%)	512 (8.8%)	1550 (26.7%)
	30-44	366 (6.3%)	549 (9.5%)	677 (11.7%)	1592 (27.5%)
	15-29	78 (1.3%)	121 (2.1%)	327 (5.6%)	526 (9.1%)
	<15	3 (0.1%)	1 (0.0%)	15 (0.3%)	19 (0.3%)
Total (%)		1,173 (20.2%)	2,252 (38.8%)	2,374 (40.9%)	5,799 (100.0%)

B

Ranges		All Finerenone Patients with UACR Test and eGFR Test			
		UACR Categories			Total (%)
		<30	30-300	>300	
eGFR Categories	>= 90	5 (0.7%)	23 (3.3%)	18 (2.5%)	46 (6.5%)
	60-89	33 (4.7%)	52 (7.4%)	64 (9.1%)	149 (21.1%)
	45-59	45 (6.4%)	59 (8.3%)	84 (11.9%)	188 (26.6%)
	30-44	40 (5.7%)	73 (10.3%)	110 (15.6%)	223 (31.5%)
	15-29	17 (2.4%)	25 (3.5%)	56 (7.9%)	98 (13.9%)
	<15	(0.0%)	(0.0%)	3 (0.4%)	3 (0.4%)
Total (%)		140 (19.8%)	232 (32.8%)	335 (47.4%)	707 (100.0%)

Figure 3. Time from most recent UACR measurements to finerenone initiation in relationship to the UACR in A) without prior sMRA cohort (n=6,894), and in B) with the prior sMRA cohort (n=839)





RESULTS

Finerenone user characteristics

- In the study cohort of 107,455 finerenone users, 11,484 (10.7%) had prior sMRA use before initiating finerenone, among them, 8,227 patients used sMRA within a year of starting finerenone.
- Patients with prior sMRA use had higher prevalence of baseline HF (40%), CKD (64%) and diuretic use (65%) compared to those with no prior sMRA prescription (16%, 54% and 42%, respectively). The use of SGLT2i and GLP1-RA are comparable by prior sMRA use status.

Baseline eGFR and UACR in relation to Finerenone initiation

- Among the 6,506 patients with both eGFR and UACR measurements prior to finerenone initiation, patients with prior sMRA use had a higher percentage of having very high KDIGO risk prior to finerenone initiation compared to patients without prior sMRA use (52% vs 39%) while the distribution of finerenone starting dose was similar between the two groups.
- Patients with prior sMRA use were more likely to have a higher UACR and lower eGFR prior to finerenone initiation compared to patients without prior sMRA use (Table 3).

LIMITATIONS

- Only a subset of finerenone users have tokenized eGFR and UACR lab values. Generalization of the baseline laboratory findings should be done with caution.

CONCLUSIONS

- In a large real-world claim database of new finerenone users, 10.7% patients had a prior prescription of traditional sMRA. These patients exhibited different comorbidities, comedication, and kidney function profiles from those without sMRA prescription prior to finerenone initiation.
- Future studies should examine cardiovascular, kidney, and safety outcomes of finerenone users who recently used sMRA to further inform clinical practice.

References. [1] Bayer Pharmaceuticals. Kerendia Prescribing Information. U.S. Food and Drug Administration. label (fda.gov). Approved 2021. Accessed October 2024. [2] KDIGO Diabetes Work Group. *Kidney Int* 2022;102(5S):S1-S127. [3] Nuha A. ElSayed, et al., *Diabetes Care.* 2023; 46 (Supplement_1): S191–S202. [4] Nicholas SB, et al., *Diabetes Obes Metab.* 2023; 25(10): 2970-2979.

Abbreviations: ACEi, angiotensin-converting enzyme inhibitors; ARB, angiotensin II receptor blocker; CCB, calcium channel blockers; CKD, chronic kidney disease; Dx, diagnosis; eGFR, estimated glomerular filtration rate; FFS Medicaid, fee-for-service medicaid; GLP1-RA, glucagon-like peptide-1 receptor agonist; IQR, interquartile range; KDIGO, kidney disease: improving global outcomes; MRA, mineralocorticoid receptor antagonist; nsMRA, non-steroidal mineralocorticoid receptor antagonist; sMRA, steroidal mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose cotransporter-2 inhibitors; RASi, renin-angiotensin system inhibitors; Rx, prescription; SD, standard deviation; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio.

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