

Short Oral Discussion Session: SO 115 Under pressure: hypertension and kidney disease in diabetes

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Tianjin Medical University
Chu Hsien-I Memorial Hospital

Effectiveness and Safety of Finerenone in Patients with Chronic Kidney Disease and Type 2 Diabetes Across Subgroups in a Real-World Cohort Population in China

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Disclosures

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* Part of the study results for the overall cohort focusing on patient characteristics, and short-term clinical outcomes were released at The American Diabetes Association's Scientific Sessions 2026. Additional evidence across subgroups of interest are provided in this presentation.

This study was initiated by Bayer Healthcare Company Ltd. and funded by Bayer AG.

Study Objectives and Design

Background

- The **coexistence of T2D and CKD** contributes to a substantial disease burden, and is associated with increased risk of cardio/renal disease, and mortality.^{1,2}
- Finerenone: a selective non-steroidal mineral corticoid receptor antagonists with **renal and cardiovascular benefits** in clinical trials.^{3,4}
- **Real-world evidence** on finerenone is needed after its approval in China in 2022.



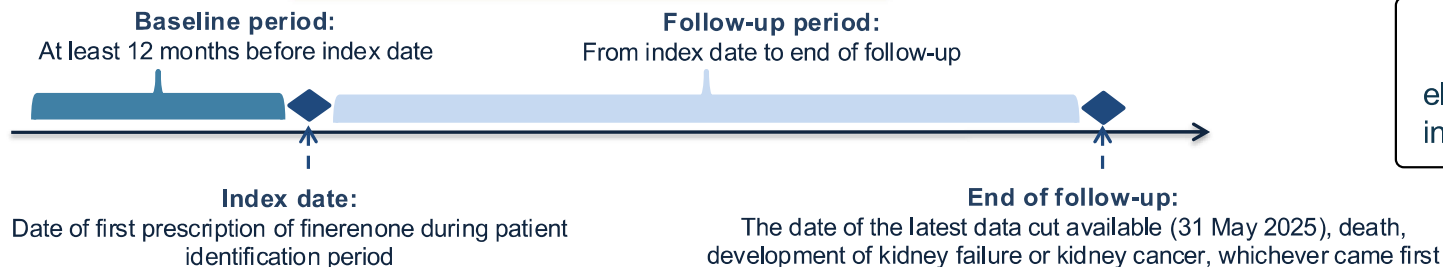
Study objectives

- To describe the **characteristics of patients** with CKD and T2D who initiated finerenone in routine clinical practice in China.
- To evaluate the **effectiveness and safety of finerenone** and **across patient subgroups**.

Study design: An observational, retrospective cohort study; **Population:** Adult patients with CKD and T2D who initiate finerenone.

Data source: The Tianjin Healthcare Big Data Platform, a regional EHR database covering ~15 million residents.

Study design scheme - Individual level



6,537

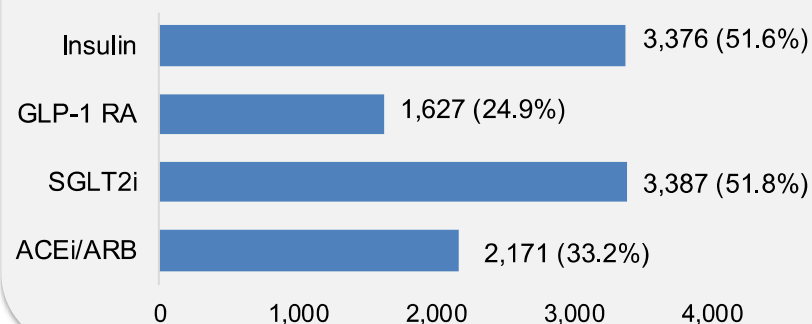
eligible adult patients with T2D +CKD initiating finerenone were included

Baseline characteristics of finerenone initiators

Characteristic	Finerenone initiators (N = 6,537)
Age	
Mean (SD)	57.6 (12.9)
Sex, n (%)	
Male	4,342 (66.4)
Female	2,195 (33.6)
Duration of T2D (years)	
Mean (SD)	6.2 (4.8)
Duration of CKD (years)	
Mean (SD)	3.5 (3.9)
eGFR ^b , mL/min/1.73m ² , n (%)	
Count with baseline value, n (%)	3,319 (50.8%)
Mean (SD)	85.7 (24.7)
UACR ^b , mg/g, n (%)	
Count with baseline value, n (%)	2,877 (44.0%)
Median (Q1, Q3)	288.4 (113.7, 756.3)
Serum potassium ^b , mmol/L, n (%)	
Count with baseline value, n (%)	2,970 (45.4%)
Mean (SD)	4.2 (0.4)
HbA1c, %, n (%)	
Count with baseline value, n (%)	3,967 (60.7%)
Mean (SD)	5.9 (1.7)

The cohort comprised middle-aged and mostly male patients, and with longer duration of T2D than CKD

Comedications use ^c



^a The assessment window, within 1 year before or on the index date (study days [-365,0]).

^b Only direct available laboratory measurements values were counted for the summary. The recorded value is on (or else closest to and before) the index date within 90 days before the index date and including the index date (study days [-90, 0]).

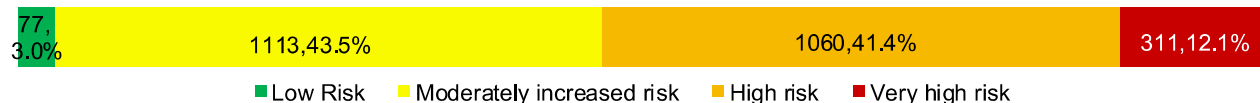
^c The lookback period for these comedications is within 180 days before the index date and including the index date (study days [-180, 0]).

Abbreviations: T2D: Type 2 diabetes; CKD: Chronic kidney disease; SD: Standard deviation; eGFR: Estimated glomerular filtration rate; UACR: Urine albumin-to-creatinine ratio; Q1: First Quartile; Q3: Third Quartile; HbA1c: Glycated hemoglobin A1c; GLP-1 RA: Glucagon-like peptide-1 receptor agonist; SGLT2i: Sodium-glucose cotransporter 2 inhibitor; ACEi: Angiotensin-converting enzyme inhibitor; ARB: Angiotensin receptor blocker.

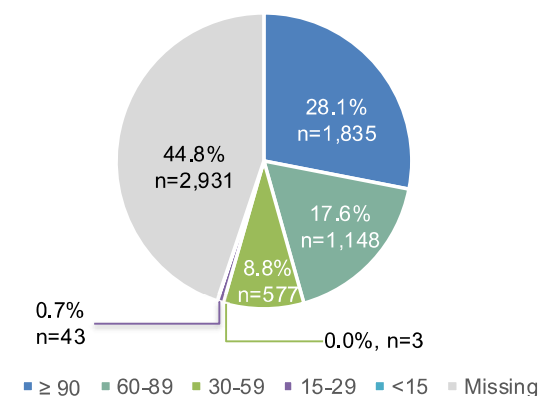
Most patients were at early-stage CKD with moderate-to-high KDIGO risk, and highly prevalent albuminuria

- Majority patients were categorized as moderate (43.5%) or high (41.4%) KDIGO risk
- More than 95% patients had UACR ≥ 30 mg/g

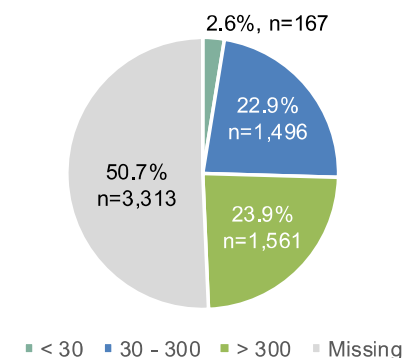
		Albuminuria categories (mg/g)			Total
		A1: < 30	A2: 30 - 300	A3: > 300	
eGFR categories (mL/min/1.73m ²)	G1: ≥ 90	38 (1.5%)	762 (29.8%)	595 (23.2%)	1395 (54.5%)
	G2: 60 - 89	39 (1.5%)	320 (12.5%)	415 (16.2%)	774 (30.2%)
	G3a: 45 - 59	31 (1.2%)	48 (1.9%)	172 (6.7%)	251 (9.8%)
	G3b: 30 - 44	2 (0.1%)	18 (0.7%)	96 (3.7%)	116 (4.5%)
	G4: 15 - 29	2 (0.1%)	2 (0.1%)	20 (0.8%)	24 (0.9%)
	G5: <15	0 (0.0%)	0 (0.0%)	1 (0.0%)	1 (0.0%)
Total		112 (4.4%)	1150 (44.9%)	1299 (50.7%)	2561



eGFR category at baseline, n(%), mL/min/1.73m²

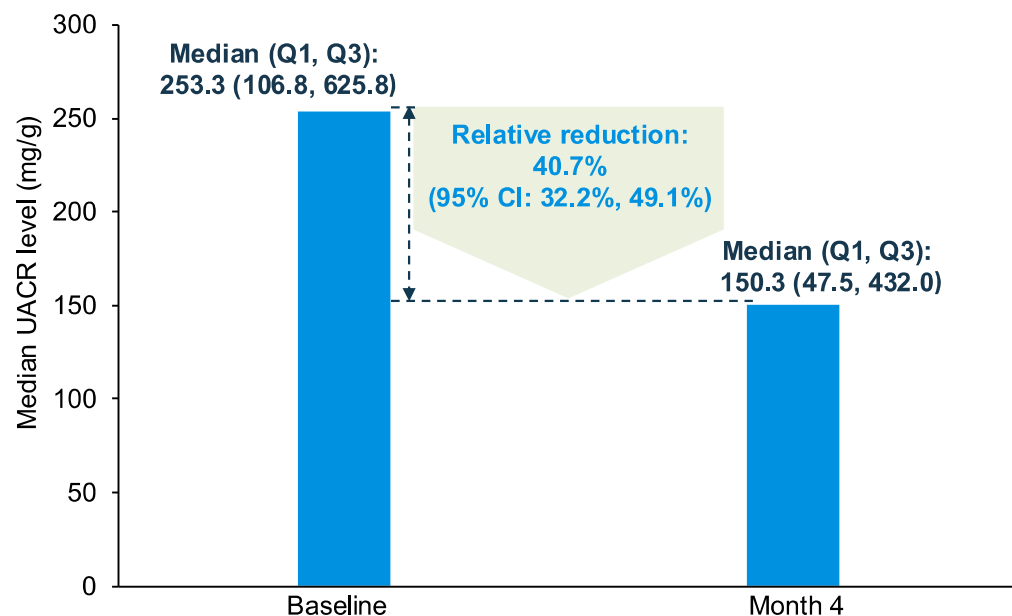


UACR category at baseline, n(%), mg/g



Substantial reduction of UACR was observed after 4 months of finerenone initiation

- **1,075 (16.4%)** patients with UACR value at baseline and month 4 were included in the change of UACR analysis during follow-up.
- **At month 4:** median UACR changed from 253.3 (95% CI, 106.8–625.8) mg/g at baseline to 150.3 (95% CI, 47.5 to 432.0) mg/g; absolute change: **-103.0** (95% CI, -130.4 to -75.6) mg/g, corresponding to a relative reduction of **-40.7%** (95% CI, -49.1% to -32.2%).
- Changes in UACR were **generally consistent across subgroups**.



Subgroups of interest	n		Median relative change, % (95% CI)
Overall	1075		-40.7% (-49.1% to -32.2%)
Age			
≥60 years	447		-43.3% (-56.4% to -30.1%)
<60 years	628		-37.8% (-49.4% to -26.3%)
Sex			
Male	721		-37.8% (-48.5% to -27.2%)
Female	354		-48.0% (-61.2% to -34.8%)
UACR			
30–300 mg/g	561		-46.5% (-55.4% to -37.6%)
>300 mg/g	483		-34.2% (-43.4% to -25.0%)
eGFR			
≥60 mL/min/1.73 m ²	800		-41.1% (-49.8% to -32.4%)
<60 mL/min/1.73 m ²	265		-38.3% (-61.3% to -15.3%)
CKD stage			
Stage 1	508		-45.4% (-55.2% to -35.5%)
Stage 2	257		-30.3% (-58.8% to -1.8%)
Stage 3	148		-44.8% (-82.3% to -7.2%)
Starting dose			
10 mg daily dose	771		-42.1% (-52.9% to -31.3%)
20 mg daily dose	105		-54.8% (-76.0% to -33.5%)
ACEi/ARB use			
Non-use	749		-38.9% (-50.8% to -27.1%)
Prior use	326		-47.1% (-65.6% to -28.6%)
SGLT2i use			
Non-use	429		-37.7% (-54.6% to -20.8%)
Prior use	646		-38.6% (-50.3% to -26.9%)
GLP-1 RA use			
Non-use	767		-37.4% (-46.7% to -28.1%)
Prior use	308		-40.7% (-59.7% to -21.8%)
Insulin use			
Non-use	508		-42.0% (-50.4% to -33.6%)
Prior use	567		-40.6% (-56.0% to -25.1%)

← Decrease from baseline → Increase from baseline →
Relative change in median UACR at month 4 (%)

Note:

1. Patients included: Only patients with UACR values both at baseline and at month 4 during follow-up period were included for the relative median change calculation
2. Method used: Relative change = ((post-baseline measurement median value – baseline measurement median value) / baseline measurement median value, expressed as a percentage)

Abbreviations: UACR: Urine albumin-to-creatinine ratio; CI: Confidence interval; Q1: First Quartile; Q3: Third Quartile; eGFR: Estimated glomerular filtration rate; CKD: Chronic kidney disease; ACEi: Angiotensin-converting enzyme inhibitor; ARB: Angiotensin receptor blocker; SGLT2i: Sodium-glucose co-transporter 2 inhibitor; GLP-1 RA: Glucagon-like peptide-1 receptor agonist.

Slight decrease in eGFR and mild increase in serum potassium were observed during follow-up

- **eGFR:** At month 4, among **1,702 (26.0%)** patients with measurements at baseline and month 4, mean value changed by **-3.2** (95% CI, -3.8 to -2.7) mL/min/1.73m²

→ relative reduction: **3.2%** (95% CI, 2.4% to 4.0%)

- **Serum potassium:** At month 4, among **967 (14.8%)** patients with measurements at baseline and month 4, mean value changed by **0.2** (95% CI, 0.1 to 0.2) mmol/L

→ relative increase: **4.6%** (95% CI, 3.9% to 5.3%)

Also consistent patterns **across subgroups**

- **Hyperkalemia*** was observed in **280 (4.3%)** patients
- Incidence rate of hyperkalemia: 4.1 per 100 person-years

→ Generally well tolerated during follow-up

*Hyperkalemia was defined as i) a diagnosis for hyperkalemia, or ii) at least 2 serum potassium laboratory values >5.5 mmol/L, or iii) one serum potassium value >5.5 mmol/L on either the inpatient or the outpatient record and the initiation of pharmacotherapy or other interventions for hyperkalemia not longer than 3 days apart

Conclusions



In this **real-world cohort** from China, **6,537 patients with CKD and T2D** initiated finerenone. At baseline, **84.9%** were classified as **moderate or high KDIGO risk**.



After finerenone initiation in this cohort, there was a **notable relative reduction (40.7%) in albuminuria**, and the treatment was generally well tolerated.



Across different subgroups, **the changes in key laboratory measurements** (UACR, eGFR, and serum potassium) were **generally consistent** with the overall cohort.



These findings support the **effectiveness and safety of finerenone** among **diverse patient populations** with CKD and T2D in routine clinical practice in China

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Effectiveness and Safety of Finerenone in Patients with Chronic Kidney Disease and Type 2 Diabetes Across Subgroups in a Real-World Cohort Population in China

Bei Sun¹, Chunyan Shan¹, Yan Kong¹, Zhe Xu², Hui Yang², Nikolaus G. Oberprieler³, Huan Wei⁴, Liming Chen^{1*}

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BACKGROUND & OBJECTIVES

Background

- The coexistence of T2D and CKD contributes to a substantial disease burden, and is associated with increased risk of cardiovascular disease, and mortality.^{1,2}
- Finerenone is a selective non-steroidal mineral corticoid receptor antagonists with renal and cardiovascular benefits in clinical trials.^{3,4}
- Real-world evidence on finerenone is needed after its approval for patients with CKD and T2D in China in 2022.

Study objectives

- To describe the characteristics of patients with CKD and T2D who initiated finerenone in routine clinical practice in China.
- To evaluate the effectiveness and safety of finerenone and across patient subgroups.

METHODS

- Study design:** This is an observational, retrospective, single-cohort study (as shown in Figure 1). The study was registered on ClinicalTrials.gov (Identifier NCT07124039).
- Study population:** Adults diagnosed with CKD and T2D who initiated finerenone during the patient identification period (01 Jan 2023 – 31 Dec 2024).
- New users of finerenone:** The date of first prescription of finerenone identified in the EHR database was defined as the **index date**.
- Data source:** The study used Tianjin Healthcare and Medical Big Data Platform, a regional electronic health record (EHR) database covering about 15 million residents in Tianjin, China.

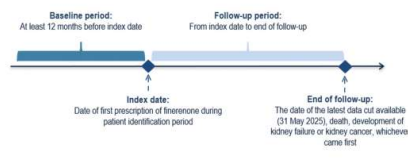


Figure 1. Study design scheme - Individual level

RESULTS

Baseline Characteristics

- A total of **6,537 patients** initiating finerenone with existing CKD and T2D were included in the analyses.
- Most patients had **preserved renal functions** (mean estimated glomerular filtration rate [eGFR] 85.7 mL/min/1.73m²), **but high albuminuria was common** (median urine albumin-to-creatinine ratio [UACR] 288.4 mg/g) (Table 1 and Figure 2).

Table 1. Baseline characteristics

Characteristic	Finerenone initiators (N = 6,537)
Age, Mean (SD)	57.6 (12.9)
Sex, n (%)	
Male	4,342 (66.4)
Female	2,195 (33.6)
Duration of T2D (years), Mean (SD)	6.2 (4.8)
Duration of CKD (years), Mean (SD)	3.5 (3.9)
eGFR, mL/min/1.73m ² , n (%)	
Count with baseline value, n (%)	3,319 (50.8%)
Mean (SD)	85.7 (24.7)
UACR ^a , mg/g, n (%)	
Count with baseline value, n (%)	2,877 (44.0%)
Median (Q1, Q3)	288.4 (113.7, 796.3)
Serum potassium ^b , mmol/L, n (%)	
Count with baseline value, n (%)	2,970 (45.4%)
Mean (SD)	4.2 (0.4)
HbA1c, %, n (%)	
Count with baseline value, n (%)	3,967 (60.7%)
Mean (SD)	5.9 (1.7)
Comedications ^c , n (%)	
Insulin	3,376 (51.6%)
GLP-1 RA	1,627 (24.9%)
SGLT2i	3,387 (51.8%)
ACEi/ARB	2,171 (33.2%)

Notes:
* The assessment window, within 1 year before or on the index date (study days [-365, 0]).
* The assessed value is on or after date to and before the index date within 90 days before the index date and including the index date (study days [-90, 0]).
* The follow-up period for these comedications is within 180 days before the index date and including the index date (study days [-180, 0]).

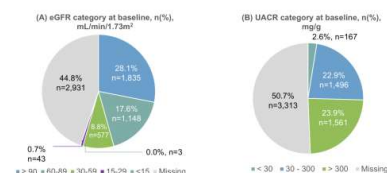


Figure 2. Baseline laboratory measurement category

- Majority patients were categorized as **moderate (43.5%) or high (41.4%)** Kidney Disease: Improving Global Outcomes (KDIGO) risk (Table 2).
- More than 95% patients had UACR ≥ 30 mg/g (Figure 2).

Table 2. KDIGO 2024 Marker of severity for kidney dysfunction at the index date by eGFR and UACR level

eGFR categories (mL/min/1.73m ²)	Albuminuria categories (mg/g)			Total
	A1: < 30	A2: 30 - 300	A3: > 300	
G1: ≥ 90	38 (1.5%)	762 (29.8%)	595 (23.2%)	1395 (54.5%)
G2: 60-89	39 (1.5%)	320 (12.5%)	415 (16.2%)	774 (30.2%)
G3a: 45-59	31 (1.2%)	48 (1.9%)	172 (6.7%)	251 (9.8%)
G3b: 30-44	2 (0.1%)	18 (0.7%)	96 (3.7%)	116 (4.5%)
G4: 15-29	2 (0.1%)	2 (0.1%)	20 (0.8%)	24 (0.9%)
G5: ≤ 15	0 (0.0%)	0 (0.0%)	1 (0.0%)	1 (0.0%)
Total	112 (4.4%)	1150 (44.9%)	1299 (50.7%)	2561



Effectiveness and safety outcomes during follow-up

- 1,075 (16.4%) patients with UACR value at baseline and month 4 were included in the change of UACR analysis during follow-up.
- Substantial reduction of UACR was observed** after 4 months of finerenone initiation: **relative reduction = -40.7%** (95% CI, -49.1% to -32.2%) (Figure 3).

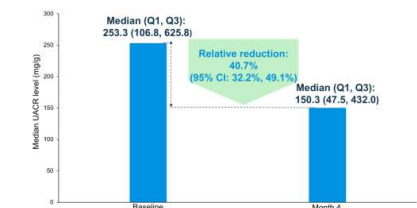


Figure 3. Changes in UACR relative to baseline throughout follow-up

Notes:
1. Patients included: Only patients with UACR values both at baseline and at month 4 during follow-up period were included for the relative change calculation.
2. Method used: Relative change = (post-baseline measurement median value - baseline measurement median value) / baseline measurement median value, expressed as a percentage.

- Changes in UACR were generally consistent across subgroups** (Figure 4).

Subgroups of interest	n	Median relative change, % (95% CI)
Overall	1075	-40.7% (-49.1% to -32.2%)
Age		
< 60 years	447	-41.0% (-50.4% to -31.2%)
60 years	628	-37.0% (-46.0% to -27.2%)
Sex		
Male	721	-37.0% (-46.0% to -27.2%)
Female	354	-40.0% (-49.1% to -30.9%)
UACR		
< 30 mg/g	112	-40.0% (-50.0% to -30.0%)
30-300 mg/g	1150	-34.2% (-43.8% to -24.6%)
> 300 mg/g	1299	-41.1% (-49.8% to -32.4%)
eGFR		
< 60 mL/min/1.73 m ²	803	-39.1% (-47.8% to -30.3%)
60-89 mL/min/1.73 m ²	774	-37.0% (-46.0% to -27.2%)
90-119 mL/min/1.73 m ²	595	-40.0% (-49.1% to -30.9%)
≥ 120 mL/min/1.73 m ²	251	-40.0% (-49.1% to -30.9%)
Duration of T2D		
≤ 5 years	248	-40.0% (-49.1% to -30.9%)
6-10 years	375	-41.0% (-50.4% to -31.2%)
> 10 years	452	-34.0% (-43.8% to -24.6%)
Duration of CKD		
≤ 5 years	331	-41.0% (-50.4% to -31.2%)
6-10 years	447	-40.0% (-49.1% to -30.9%)
> 10 years	699	-37.0% (-46.0% to -27.2%)
Comedications		
Insulin	429	-37.0% (-46.0% to -27.2%)
GLP-1 RA	163	-40.0% (-49.1% to -30.9%)
SGLT2i	338	-40.0% (-49.1% to -30.9%)
ACEi/ARB	217	-40.0% (-49.1% to -30.9%)
Other	107	-40.0% (-49.1% to -30.9%)

Figure 4. Changes in UACR by baseline characteristics subgroups

- Slight decrease in eGFR and mild increase in serum potassium** were observed during follow-up.

- eGFR:** Among 1,702 (26.0%) patients with measurements at baseline and month 4: **relative reduction = 3.2%** (95% CI, 2.4% to 4.0%).
- Serum potassium:** Among 967 (14.8%) patients with measurements at baseline and month 4: **relative increase = 4.6%** (95% CI, 3.9% to 5.3%).
- Hyperkalemia*** was observed in 280 (4.3%) patients
- Generally well tolerated during follow-up

CONCLUSIONS

- In this real-world cohort from China, **6,537 patients with CKD and T2D initiated finerenone**. At baseline, 84.9% were classified as moderate or high KDIGO risk.
- After finerenone initiation in this cohort, there was a **notable relative reduction (40.7%) in albuminuria**, and the treatment was generally well tolerated.
- Across different subgroups, the changes in key laboratory measurements (UACR, eGFR, and serum potassium) were generally consistent with the overall cohort.

Abbreviations: ACEi, Angiotensin-converting enzyme inhibitor; ARB, Angiotensin receptor blocker; CI, Confidence interval; CKD, Chronic kidney disease; eGFR, Estimated glomerular filtration rate; GLP-1 RA, Glucagon-like peptide-1 receptor agonist; HbA1c, Glycated hemoglobin; Q1, First Quartile; Q3, Third Quartile; SD, Standard deviation; SGLT2i, Sodium-glucose cotransporter 2 inhibitor; UACR, Urinary albumin-to-creatinine ratio. References: 1. Jha, R., et al. *Biomedicine*, 2024, 12(5), 2. Swamy, S., et al. *J Clin Med*, 2023, 12(22), 3. Bakris, G.L., et al. *N Engl J Med*, 2020, 383(23), 4. Pitt, B., et al. *N Engl J Med*, 2021, 385(24).

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