# Characteristics and Clinical Outcomes of Patients with Chronic Kidney Disease and Type 2 Diabetes using Finerenone in China: A Real-World Retrospective Cohort Study

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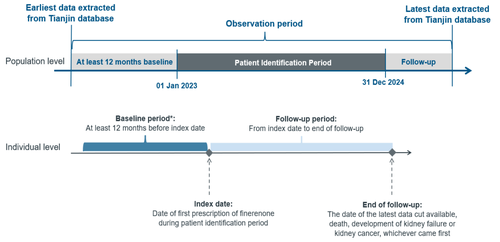
## BACKGROUND & OBJECTIVES

- Patients with type 2 diabetes mellitus (T2D) have a high prevalence and incidence of chronic kidney disease (CKD)[1]. The relationship between T2D and CKD is bidirectional and multifaceted, with an intricate network encompassing pathophysiology, clinical management, and epidemiology[2].
- Finerenone is a non-steroidal mineralocorticoid receptor antagonist (nsMRA) developed for CKD associated T2D and was approved in China in 2022 for adult patients with CKD and T2D.
- Although efficacy and safety were demonstrated in clinical trials[3,4], the benefit among patients in real-world settings may vary, creating a need for early post-marketing evidence in China.
- This study aimed to describe the characteristics and clinical outcomes of patients with CKD and T2D using finerenone under routine clinical practice in China.

## 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** were defined as patients receiving finerenone identified in the EHR database during the study period, with no prior recorded prescription in the preceding 12 months. The first prescription of finerenone was defined as the index event, and the corresponding prescription date 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, with data availability starting from around 2015.
- **Statistical Analysis:** Descriptive statistics were used to summarize patient characteristics at baseline, along with UACR and eGFR changes over time, and incidence rates of hyperkalemia.

### Figure 1. Study design scheme




## RESULTS

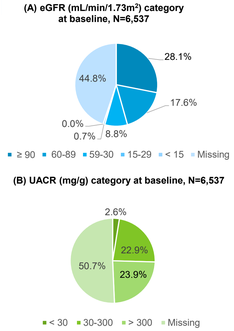
- A total of 6,537 patients initiating finerenone with existing CKD and T2D were included in the analyses (66.4% male; mean age 57.6 years). The mean T2D duration was 6.2 years (SD: 4.8) and the mean CKD duration was 3.5 years (SD: 3.9). The mean (SD) of estimated glomerular filtration rate (eGFR) was 85.7 (24.7) mL/min/1.73m$^2$, and median (Q1, Q3) of urinary albumin-to-creatinine ratio (UACR) was 288.4 (113.7, 756.3) mg/g at baseline.
- Baseline characteristics are described in **Table 1** and **Figure 2**.

### Table 1. Baseline patient characteristics

| Characteristics | Finerenone initiators (N = 6,537) |
|---|---|
| Age, years, mean (SD) | 57.6 (12.9) |
| Sex, n (%) | |
| Male | 4,342 (66.4) |
| Female | 2,195 (33.6) |
| Calendar year of index date, n (%) | |
| 2023 | 1,603 (24.5) |
| 2024 | 4,934 (75.5) |
| CKD stage based on diagnosis or eGFR*, n (%) | |
| Stage 1 | 1,762 (27.0) |
| Stage 2 | 1,184 (18.1) |
| Stage 3 | 822 (12.6) |
| Stage 3a | 281 (4.3) |
| Stage 3b | 373 (5.7) |
| Stage 3 without specification of substage | 168 (2.6) |
| Stage 4 | 110 (1.7) |
| Stage 5 | 3 (0.0) |
| No assessment of eGFR and diagnosis of CKD stage recorded in the year before index date | 2,656 (40.6) |
| Serum potassium[&], mmol/L | |
| Patient with baseline value, n (%) | 2,970 (45.4) |
| Baseline value, mean (SD) | 4.2 (0.4) |
| Obesity^, n (%) | |
| Yes (by diagnosis or BMI ≥ 28) | 1,515 (23.2) |
| No | 3,350 (51.2) |
| Missing | 1,672 (25.6) |

Abbreviations: BMI: body mass index; Max: maximum; Min: minimum; Q1: first quartiles; Q3: third quartiles; SD: standard deviation; eGFR: estimated glomerular filtration rate; UACR: urinary albumin-to-creatinine ratio.
& Based on the recorded value 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]).
* Based on the recorded value on (or else closest to and before) the index date, within 1 year before or on the index date (study days [−365,0]).

### Figure 2. Baseline laboratory measurement category




- At baseline, in 2,561 patients with UACR and eGFR values, 43.5% and 41.4% were categorized as moderate and high kidney disease according to KDIGO risk categories[5] (**Table 2**).

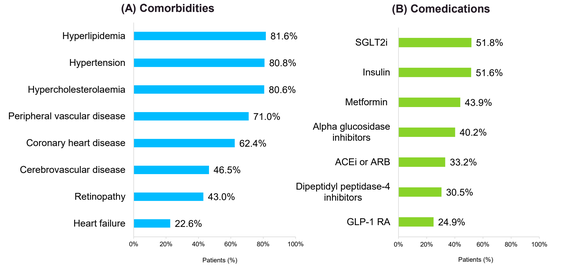
### Table 2. KDIGO marker of severity for kidney dysfunction at baseline

| | A1: UACR < 30 mg/g | A2: UACR 30 - 300 mg/g | A3: UACR > 300 mg/g | Total |
|---|---|---|---|---|
| **G1: eGFR ≥ 90 mL/min/1.73m²** | 38 (1.5%) | 762 (29.8%) | 595 (23.2%) | 1,395 (54.5%) |
| **G2: eGFR 60 - 89 mL/min/1.73m²** | 39 (1.5%) | 320 (12.5%) | 415 (16.2%) | 774 (30.2%) |
| **G3a: eGFR 45 - 59 mL/min/1.73m²** | 31 (1.2%) | 48 (1.9%) | 172 (6.7%) | 251 (9.8%) |
| **G3b: eGFR 30 - 44 mL/min/1.73m²** | 2 (0.1%) | 18 (0.7%) | 96 (3.7%) | 116 (4.5%) |
| **G4: eGFR 15 - 29 mL/min/1.73m²** | 2 (0.1%) | 2 (0.1%) | 20 (0.8%) | 24 (0.9%) |
| **G5: eGFR <15 mL/min/1.73m²** | 0 (0.0%) | 0 (0.0%) | 1 (0.0%) | 1 (0.0%) |
| **Total** | 112 (4.4%) | 1,150 (44.9%) | 1,299 (50.7%) | 2,561 |

low risk; moderate risk; high risk; very high risk

- Hyperlipidemia, hypertension, and hypercholesterolemia were the most prevalent comorbidities, each affecting over 80% of patients (**Figure 3A**).
- Sodium-glucose co-transporter 2 inhibitor (SGLT2i) and insulin were the most used comedications, each prescribed in over 50% of patients (**Figure 3B**).

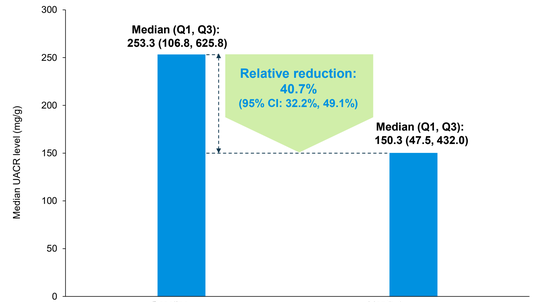
### Figure 3. Baseline comorbidities and comedications




Abbreviations: 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
1.The lookback period for baseline comorbidities is all time before the index date available in the database and including the index date (study days [-all available, 0]).
2. The lookback period for comedications is within 180 days before the index date and including the index date (study days [-180, 0]).

- Among 1075 patients with UACR available at both baseline and month 4, the median UACR decreased with a relative reduction of 40.7% (95% CI: 32.2%, 49.1%). (**Figure 4**)
- Mean eGFR decreased slightly from baseline, by 3.2% at Month 4. Mean serum potassium increased slightly from baseline, by 4.6% at month 4.

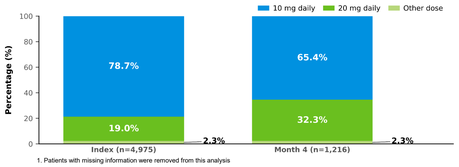
### Figure 4. Relative change in UACR during follow-up




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)

- Majority of the patients started finerenone at 10 mg daily and remained with 10 mg daily after 4 months of follow-up (**Figure 5**).

### Figure 5. Finerenone dosing patterns




1. Patients with missing information were removed from this analysis

- In this cohort, hyperkalemia* was observed in 280 (4.3%) patients, and 78 (1.2%) had hospitalization-associated hyperkalemia# during follow-up period. The incidence rate of observed hyperkalemia events was 4.1 per 100 person-years.

*Hyperkalemia was defined as i) a diagnosis for hyperkalemia, or ii) at least 2 serum potassium laboratory values >5.5 mmol/l, as follows: two serum potassium values >5.5 mmol/L on the inpatient record between 2 and 24 hours apart or one serum potassium value >5.5 mmol/L on the outpatient record and one such value on the inpatient or outpatient record not longer than 7 days apart, 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; #Record of hospitalization of a patient and the index date of a hyperkalemia event that occurs in a time-period no more than 7 days apart; ‡incidence rate, events per 100 person-years.

## CONCLUSION

- This study provides evidence on characteristics and clinical outcomes of finerenone new users based on real-world data in China. In this cohort, most patients were at early stage of CKD with preserved eGFR, but high albuminuria was common.
- Patients who initiated finerenone experienced a notable reduction in albuminuria, slight reduction in eGFR, and only mild increases in serum potassium over 4 months of follow-up.
- There is an overall low risk profile for hyperkalemia observed during follow-up period.
- The magnitude of UACR reduction and the incidence of hyperkalemia observed in this real-world study were generally consistent with the evidence of finerenone reported in clinical trials.
- These findings support the early effectiveness and safety of finerenone among Chinese patients with T2D and CKD in real-world clinical settings.

### Reference

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### Disclosure

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