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An Prospective Observational Study On Therrapeutic Efficacy Of Finerenone In Patients With Chronic Kidney Disease And Type-2 Diabetes Mellitus In A Tertiary Care Hospital

Shabnam Taj N.P[1], Balakeshwa Ramaiah[2]

[1]Doctor of Pharmacy, Karnataka College of Pharmacy, Rajiv Gandhi University of health sciences, Bangalore, Karnataka, India
[2]HOD of Department of Pharmacy Practice, Karnataka College of Pharmacy, Rajiv Gandhi University of Health Sciences, Bangalore, Karnataka, India Email:balupharmacy@gmail.com

Abstract

Background: Chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM) is a major cause of renal and cardiovascular morbidity. Finerenone is a selective, non-steroidal mineralocorticoid receptor antagonist developed to reduce cardiorenal risk in patients with diabetic kidney disease. This prospective observational study evaluated the real-world effectiveness and safety of finerenone.

Objective: To evaluate the therapeutic efficacy and safety of finerenone in patients with CKD and T2DM receiving treatment in a tertiary care hospital.

Methods: This prospective observational study included 150 patients with CKD and T2DM who were prescribed finerenone. Patients were followed at baseline and at 1, 3, and 4 months. Demographic characteristics, blood pressure, renal function, albuminuria, proteinuria, electrolytes, HbA1c, edema, and adverse events were recorded. Paired t-tests and analysis of variance (ANOVA) were used for assessment of changes over follow-up, with $p<0.05$ considered statistically significant.

Results: Most participants were male (68%), aged 61–70 years, and had CKD stage G3b. Finerenone significantly reduced systolic and diastolic blood pressure, albuminuria, proteinuria, and HbA1c during follow-up. Serum creatinine and eGFR remained stable, while potassium levels showed only a slight increase. Hyperkalemia was the most common adverse event, leading to treatment discontinuation in 3.33% of patients.

Conclusion: Finerenone showed renal and cardiovascular benefits with an acceptable safety profile in routine practice. However, the observational design and follow-up limit causal interpretation.

Keywords: finerenone; chronic kidney disease; type 2 diabetes mellitus; albuminuria; proteinuria; eGFR; hyperkalaemia; mineralocorticoid receptor antagonist.

1. Introduction:

Chronic kidney disease (CKD) is a progressive disorder in which kidney function gradually declines over time, leading to substantial morbidity and mortality worldwide. Among the various causes of CKD, type 2 diabetes mellitus (T2DM) remains the most common and is responsible for a large proportion of patients who develop diabetic kidney disease (DKD). Individuals with both CKD and T2DM have a greater risk of worsening renal function, cardiovascular disease, hospitalization, and progression to end-stage kidney disease. Therefore, preventing kidney damage and reducing cardiovascular complications are major goals in the management of diabetic CKD.

Assessment of kidney disease commonly includes measurement of estimated glomerular filtration rate (eGFR) and urinary albumin or protein excretion. Persistent albuminuria reflects ongoing kidney injury and is recognized as an important predictor of CKD progression and cardiovascular events. Similarly, proteinuria is associated with deterioration of renal function and is widely used to evaluate disease severity and treatment response. Monitoring these parameters helps clinicians identify patients at higher risk and assess the effectiveness of therapeutic interventions.

Mineralocorticoid receptor activation plays an important role in the development of inflammation, fibrosis, oxidative stress, sodium retention, and structural changes affecting both the kidneys and the cardiovascular system. Persistent overactivation of this pathway contributes to progressive kidney damage and adverse cardiovascular outcomes in patients with diabetic CKD. Targeting this mechanism has therefore emerged as an important therapeutic strategy for reducing cardiorenal risk.

Finerenone is a selective, non-steroidal mineralocorticoid receptor antagonist developed specifically for patients with CKD associated with T2DM. Unlike traditional steroidal mineralocorticoid receptor antagonists, finerenone has a higher receptor selectivity and a lower risk of some hormone-related adverse effects. Large clinical trials have demonstrated that finerenone reduces albuminuria and lowers the risk of kidney disease progression and major cardiovascular events when added to standard therapy in appropriately selected patients. However, careful monitoring of serum potassium and renal function remains essential because hyperkalemia is a recognized adverse effect of mineralocorticoid receptor blockade.

Although randomized clinical trials provide strong evidence regarding the efficacy and safety of finerenone, information from routine clinical practice is equally important. Real-world observational studies help evaluate treatment performance in a broader patient population, including individuals with multiple comorbidities and varying clinical characteristics who may not always be represented in controlled trials. Such studies also provide valuable insights into medication safety, treatment adherence, and clinical outcomes in everyday healthcare settings.

The present prospective observational study was conducted in a tertiary care hospital to evaluate the therapeutic efficacy and safety of finerenone in patients with CKD and T2DM. The study assessed changes in blood pressure, albuminuria, proteinuria, renal function, glycemic control, electrolyte levels, edema status, adverse events, and treatment discontinuation during follow-up. The findings are intended to describe the clinical outcomes associated with finerenone use in routine practice while recognizing the inherent limitations of an observational study design.

2. Materials and Methods

2.1 Study design and setting

A prospective observational study was conducted at Bangalore Baptist Hospital, Bengaluru, over a period of 6 months. The study population comprised patients with CKD and T2DM who were prescribed finerenone during the study period.

2.2 Participants

The dissertation specified inclusion of adults aged 18–80 years with CKD stages 3–5, albuminuria (urine albumin-to-creatinine ratio ≥500 mg/g), and stable kidney function with eGFR ≥15 mL/min/1.73 m². Exclusion criteria included pregnancy or breastfeeding, eGFR <15 mL/min/1.73 m², NYHA class III–IV heart failure, uncontrolled hypertension, and known allergy to finerenone or other MRAs.

2.3 Data collection and follow-up

Data were obtained from case records, medication and treatment charts, laboratory reports, and discharge summaries using a structured data collection form. Baseline variables included age, sex, weight, CKD stage, comorbidities, and finerenone dose. Follow-up assessments were performed at 1, 3, and 4 months.

2.4 Outcomes

Clinical and laboratory parameters included systolic and diastolic blood pressure; serum creatinine; eGFR; albuminuria; urine protein-to-creatinine ratio (UPCR); serum potassium and sodium; HbA1c; edema; and adverse events, particularly hyperkalaemia and treatment discontinuation.

2.5 Statistical analysis

Continuous variables were summarized as mean ± standard deviation and categorical variables as frequency and percentage. Paired t-tests were used for comparisons between follow-up time points, and ANOVA was used to assess overall changes. A p-value <0.05 was considered statistically significant.

3. Results

3.1 Baseline characteristics

Among 150 participants, 102 (68.0%) were male and 48 (32.0%) were female. The largest age group was 61–70 years (46 patients, 30.67%), followed by 51–60 years (33, 22.00%). CKD stage G3b was the most common stage (47 patients, 31.33%), followed by G4 (37, 24.67%), G2 (28, 18.67%), G3a (22, 14.67%), G5 (11, 7.33%), and G1 (5, 3.33%). Most participants weighed 50–70 kg (63.33%). Finerenone 10 mg was prescribed to 139 patients (92.67%), whereas 11 (7.33%) received 20 mg.

Table 1. Baseline Characteristics

Characteristic	Value
Sample size	150
Male	102 (68%)
Female	48 (32%)
Age 61–70 years	46 (30.67%)
CKD Stage	Predominantly Stage 3b and Stage 4
Finerenone dose	10 mg or 20 mg

3.2 Blood pressure

Mean systolic blood pressure decreased progressively from 137.4 ± 22.3 mmHg at baseline to 131.7 ± 14.1 mmHg at 1 month, 129.4 ± 12.9 mmHg at 3 months, and 125.5 ± 10.7 mmHg at 4 months. Baseline-to-4-month and other specified comparisons were statistically significant, with ANOVA showing an overall significant change ($F=15.2016$; $p<0.005$). Mean diastolic blood pressure decreased from 86.7 ± 18.3 to 82.0 ± 10.2 mmHg over the same period; overall ANOVA was reported as significant ($F=3.58106$; $p<0.005$).

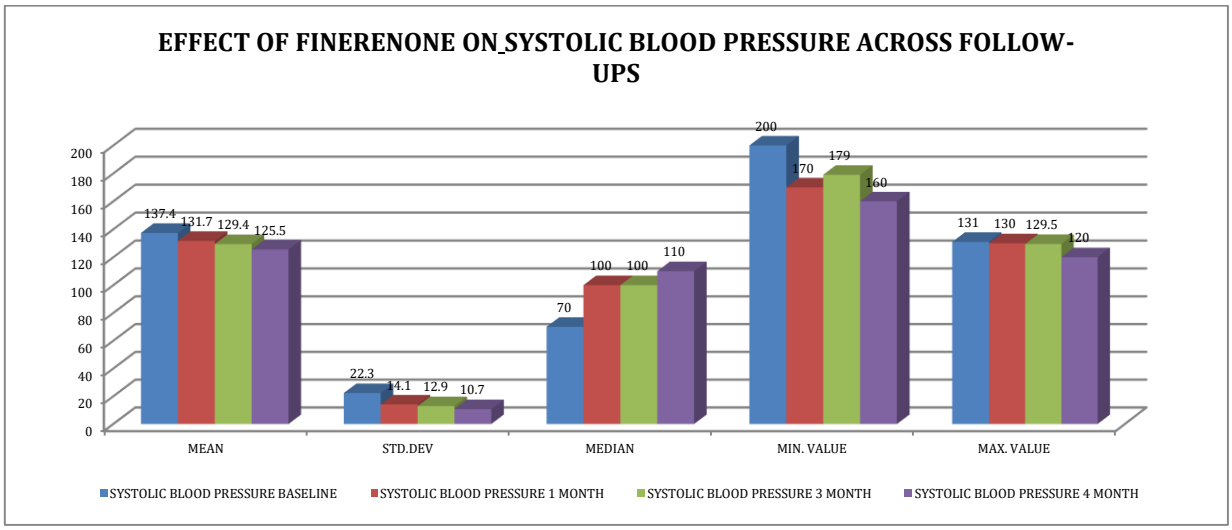

Figure 1: Effect of Finerenone On Systolic Blood Pressure Across Follow-Ups:

3.3 Albuminuria and proteinuria

Mean albuminuria declined from 229.0 ± 197.2 mg/g at baseline to 170.3 ± 167.3 mg/g at 1 month, 74.8 ± 82.6 mg/g at 3 months, and 56.0 ± 47.4 mg/g at 4 months. All reported pairwise comparisons were statistically significant ($p<0.005$), and ANOVA demonstrated a significant overall change ($F=52.4648$; $p<0.005$). Mean UPCR decreased from 93.6 ± 378.7 mg/g to 46.3 ± 106.1 mg/g, 15.9 ± 25.6 mg/g, and 8.1 ± 16.5 mg/g at 1, 3, and 4 months, respectively. Overall change was statistically significant ($F=5.79346$; $p<0.005$).

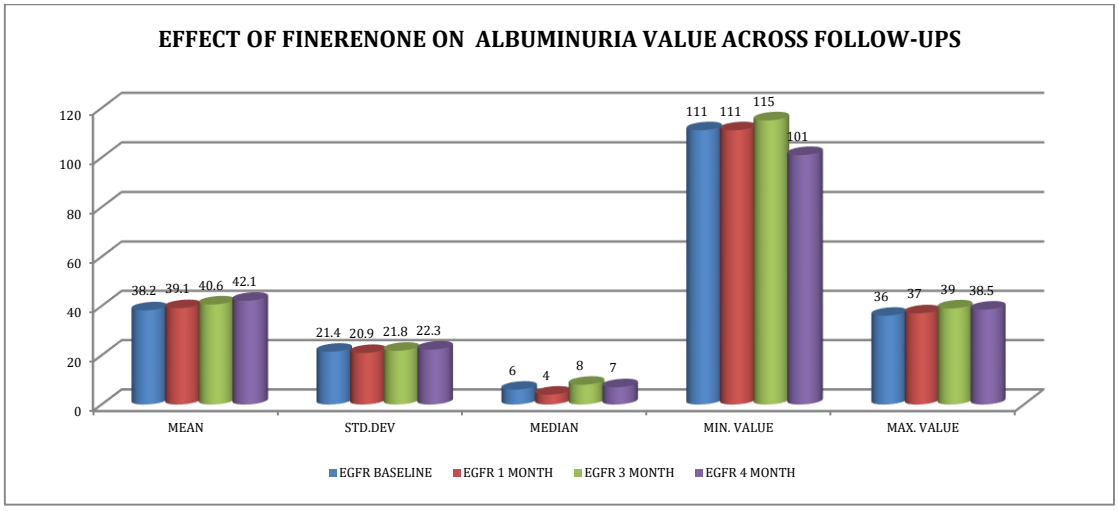

Figure 02: Effect of Finerenone On Albuminuria Value Across Follow-Ups

3.4 Renal function

Mean serum creatinine decreased from 2.4 ± 1.4 mg/dL at baseline to 2.2 ± 1.2 mg/dL at month 4; the overall change was not statistically significant (F=0.173544; p>0.005 as reported in the source). Mean eGFR increased from 38.2 ± 21.4 to 42.1 ± 22.3 mL/min/1.73 m², but the overall change was not statistically significant (F=0.94467; p=0.418).

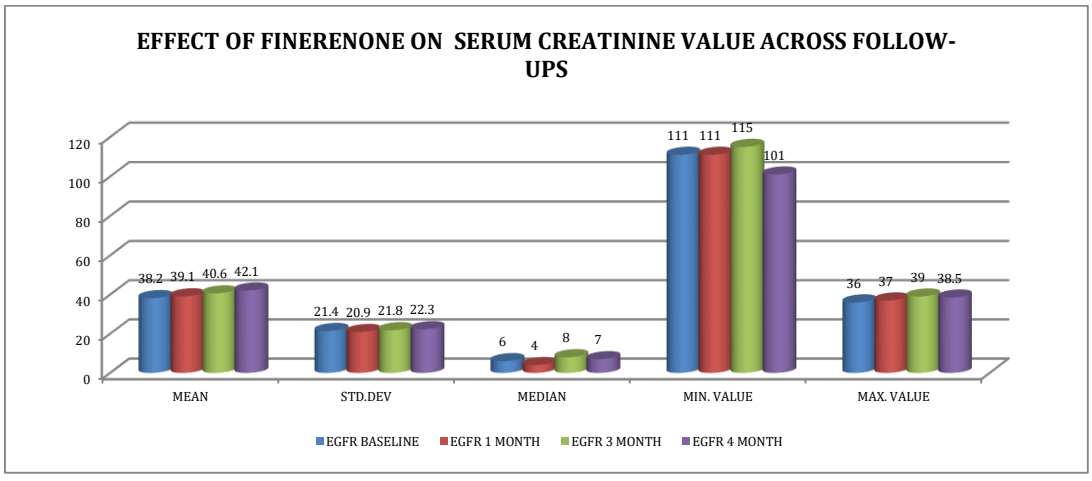

Figure 03: Effect of Finerenone On Serum Creatinine Value Across Follow-Ups

3.5 Glycaemic and electrolyte parameters

Mean HbA1c decreased from 7.3 ± 2.0% at baseline to 7.2 ± 1.8% at 1 month, 6.2 ± 1.4% at 3 months, and 6.1 ± 1.5% at 4 months. The overall change was statistically significant (F=21.31; p<0.005). Mean serum potassium changed from 4.6 ± 0.6 to 4.7 ± 0.6 mmol/L, with no significant overall change (F=1.04167; p=1). Mean sodium changed from 136.8 ± 3.7 to 137.7 ± 3.9 mmol/L; ANOVA did not demonstrate a significant overall change (F=1.66411; p=0.173).

3.6 Edema and treatment discontinuation

The study recorded changes in edema status over follow-up. Bipedal edema was recorded in 34 patients at baseline and 2 patients at 4 months, while the number recorded as having no edema increased from 112

to 128. Five patients (3.33%) discontinued treatment because of adverse events. The dissertation identifies hyperkalaemia as the principal reason for discontinuation.

The source also reports hyperkalaemia during follow-up. In the detailed discussion, clinically significant hyperkalaemia (>6.0 mmol/L) was reported in 9 patients (6%), of whom 5 (3.33%) discontinued treatment because of persistent potassium elevation. These patients were managed through treatment interruption and dietary advice where appropriate.

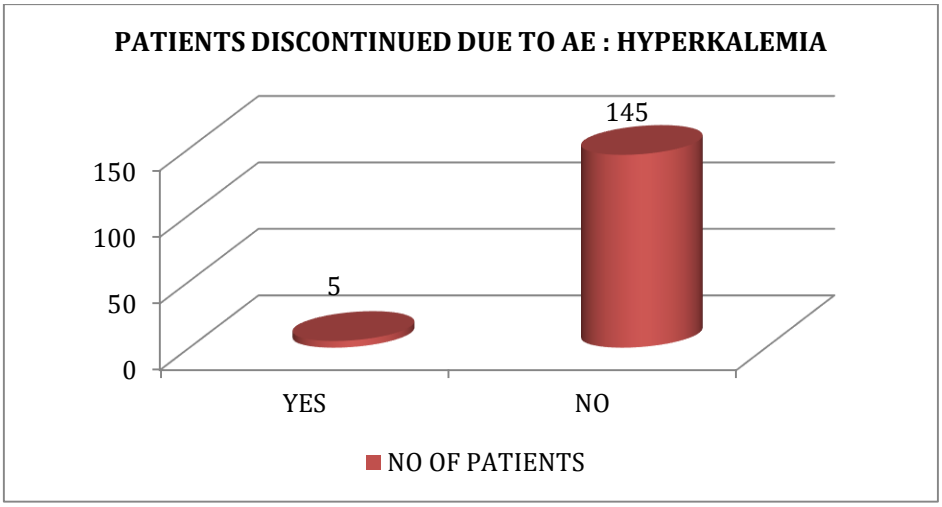

Figure 04: Patients Discontinued Due To Hyperkalemia.

4. Discussion

This prospective observational study of 150 patients with CKD and T2DM found that finerenone treatment was accompanied by improvements in several clinical and laboratory parameters over 4 months. The study population was predominantly older adults and included a substantial proportion of patients with G3b and G4 CKD. The real-world findings complement randomized evidence supporting finerenone in diabetic CKD, while the observational design requires cautious interpretation.

4.1 Blood pressure effects

Systolic and diastolic blood pressure decreased progressively during follow-up. The reduction in systolic blood pressure was statistically significant, whereas the magnitude of diastolic reduction was smaller. Blood-pressure effects are clinically relevant because hypertension contributes to glomerular injury and cardiovascular risk in CKD. Finerenone has also been associated with modest reductions in blood pressure in randomized studies.[8],[11]

4.2 Renal outcomes

The most pronounced changes in this cohort were reductions in albuminuria and UPCR. Albuminuria fell by approximately 75.5% from baseline to month 4, while UPCR fell substantially over the same period. These findings are directionally consistent with the antiproteinuric effects reported in FIDELIO-DKD, FIGARO-DKD, and FIDELITY.[8–10] Mediation analyses have suggested that albuminuria reduction contributes materially to the kidney benefit observed with finerenone.[12]

Serum creatinine remained relatively stable and the observed increase in eGFR was not statistically significant. Because this was a short-term, uncontrolled observational study, the findings should be

interpreted as evidence of stability rather than proof of renal protection. Longer follow-up and comparator-controlled designs are needed to assess sustained eGFR decline, kidney failure, and other hard renal outcomes.

4.3 Glycaemic control

HbA1c declined from 7.3% to 6.1% over 4 months. Finerenone is not primarily a glucose-lowering drug, and the present study cannot establish that finerenone caused the HbA1c reduction. Changes in concomitant antidiabetic treatment, adherence, diet, or other clinical factors may have contributed. Previous analyses have examined finerenone outcomes across baseline glycaemic characteristics, but interpretation of glycaemic change should remain cautious.[13]

4.4 Safety and hyperkalaemia

Mean potassium changed only slightly from 4.6 to 4.7 mmol/L and the overall statistical analysis did not show a significant change. Nevertheless, hyperkalaemia remains an important known safety consideration with MR antagonism. In the present cohort, five patients discontinued therapy because of adverse events, and the detailed study discussion reports clinically significant hyperkalaemia in nine patients. The FIDELIO-DKD safety analysis similarly identified hyperkalaemia as an important adverse event requiring monitoring and dose management.[14]

The observed improvement in edema status is clinically interesting, but because edema can be influenced by concomitant diuretics, dietary sodium, cardiac status, and other therapies, the present observational data cannot isolate the contribution of finerenone. Fluid and electrolyte monitoring remains important in patients with CKD.[6],[15]

4.5 Clinical interpretation

Overall, the pattern of findings—particularly the reduction in albuminuria and proteinuria with relatively stable renal function—is compatible with the established pharmacologic and clinical profile of finerenone. The results also resemble the direction of benefit observed in large randomized trials and pooled analyses.[8–10] However, the present study has no comparator group, was conducted at a single centre, and followed participants for only 4 months. Accordingly, the results should be interpreted as real-world observational associations rather than evidence of causal treatment effects.

5. Limitations

- Single-centre design, limiting generalizability to other populations and healthcare settings.
- Short follow-up of 4 months, preventing assessment of long-term renal and cardiovascular outcomes.
- Absence of a comparator or placebo group, limiting causal attribution of observed changes to finerenone.
- Potential confounding from concomitant medicines, dietary factors, disease severity, and treatment adherence.
- Limited capture of long-term and less frequent safety outcomes.

6. Conclusion

In this prospective observational cohort of 150 patients with CKD and T2DM, finerenone use was associated with progressive reductions in systolic and diastolic blood pressure, albuminuria, proteinuria, and HbA1c over 4 months. Serum creatinine and eGFR remained relatively stable, while mean potassium showed only a small increase. Five patients discontinued treatment because of adverse events, highlighting the need for continued potassium and renal-function monitoring. The findings are consistent with the direction of effects reported in pivotal finerenone trials, but the study design does not permit causal inference. Larger, multicentre studies with longer follow-up and appropriate comparator groups are warranted.

7. Future Research

- Longer follow-up to assess sustained eGFR decline, kidney failure, dialysis initiation, and cardiovascular outcomes.
- Multicentre observational or pragmatic studies with larger and more diverse populations.
- Comparative effectiveness studies evaluating finerenone alongside other guideline-directed therapies.
- Evaluation of combination treatment strategies, including finerenone with SGLT2 inhibitors and RAAS blockade.
- Patient-reported outcomes, quality of life, healthcare utilization, and cost-effectiveness measures.

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