



## EFFICACY AND SAFETY OF USE OF FINIRENONE ON PATIENTS WITH DIABETIC KIDNEY DISEASE THERAPY IN A TERTIARY CARE HOSPITAL IN MAHARASHTRA.

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### KEYWORDS :

#### Background And Rationale

Chronic kidney disease (CKD) is a common complication of diabetes mellitus and a major risk factor for cardiovascular morbidity and mortality. Albuminuria, especially as measured by urine albumin-to-creatinine ratio (UACR), serves as an early and sensitive marker for kidney injury and disease progression.

Finerenone, a non-steroidal mineralocorticoid receptor antagonist (nsMRA), has shown promise in reducing UACR and slowing the progression of CKD in patients with diabetes. However, real-world data in Indian populations remains limited.

#### Primary Objective:

To assess the change in UACR in diabetic CKD patients after at least 6 months of Finerenone therapy.

#### Secondary Objectives:

- To evaluate changes in serum potassium.
- To assess tolerability and adverse effects of Finerenone in this population.

#### MATERIALS AND METHODS

##### Study Design And Participants

##### Study Design

- Study Type: Cross-sectional observational study
- Study Setting: JJ hospital, Mumbai
- Duration: 6 months
- Study Period: [e.g., July 2024– December 2024]
- Sample Size: 20 patients (depending on availability and feasibility)

##### Inclusion Criteria

- Adults (>18 years) with Type 1 or Type 2 Diabetes Mellitus.
- Diagnosed CKD (eGFR 30-90 ml/min/1.73m<sup>2</sup>) and on standard care of treatment with ACEI/ARB along with one SGL2I
- UACR >300 mg/g

##### Exclusion Criteria

- Acute kidney injury at the time of evaluation.
- Pregnancy or breastfeeding.
- History of hyperkalemia (>5.5 mmol/L) before Finerenone initiation

##### Data Collection

The following clinical parameters were extracted for each patient at

baseline and after 6 months:

- Age
- Gender
- Urinary Albumin-Creatinine Ratio (UACR)
- Serum Potassium

Data were collected at two time points:

- Baseline (Start of treatment)
- 6-Month Follow-up

UACR was used as a marker of renal function, while serum potassium was monitored to assess electrolyte balance. Estimated glomerular filtration rate (eGFR) values were present in the dataset but were excluded from the analysis due to missing data.

#### Statistical Analysis

All statistical analyses were conducted using Python (pandas, scipy, seaborn, matplotlib).

Descriptive statistics were calculated for all relevant variables.

Paired t-tests were used to compare baseline and 6-month values for UACR and serum potassium within the same patients.

Independent t-tests were performed to assess gender differences in post-treatment values.

Boxplots were used for visual comparison of distributions over time and between groups.

A p-value of less than 0.05 was considered statistically significant.

#### RESULTS

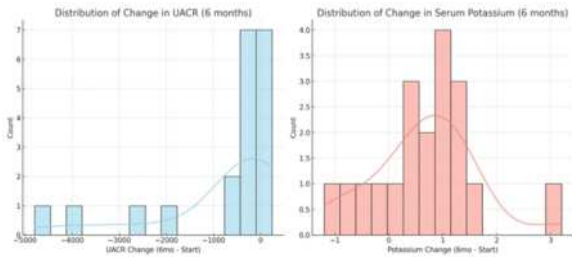
##### 1. UACR (Urinary Albumin-to-Creatinine Ratio) Trends

- Mean UACR reduced from 1552 → 753 mg/g over 6 months.
- Average change: -799 mg/g, indicating an overall improvement in albuminuria.
- However, the standard deviation is high (±1415), suggesting some patients had variable responses.
- 75% of patients had reduction, but one patient showed an increase of +240 mg/g.

##### 2. Serum Potassium Trends

- Mean potassium increased from 4.03 → 4.72 mmol/L.

- Average rise: +0.66 mmol/L, showing a trend toward hyperkalemia risk.
- Most patients had a mild rise, but one had an increase of +3.2 mmol/L, which is clinically significant.
- Minimum change observed was -1.2 mmol/L, indicating some fluctuation in effect.



Paired T-Test Results (Before vs After):

UACR (Urinary Albumin-Creatinine Ratio):

t-statistic: 2.40

p-value: 0.027

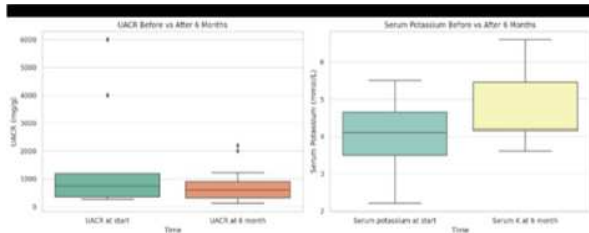
Interpretation: The decrease in UACR over 6 months is statistically significant - suggesting improvement in kidney function.

**Serum Potassium:**

t-statistic: -2.91

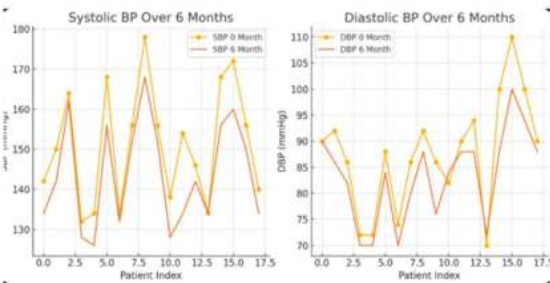
p-value: 0.009

Interpretation: The change in serum potassium levels over 6 months is also statistically significant, indicating a notable shift (on average, a slight increase).



There is a notable reduction in both SBP and DBP after 6 months.

The mean decrease in SBP by ~7 mmHg and DBP by ~4 mmHg suggests a modest antihypertensive effect of Finerenone, possibly as part of its overall cardiorenal protective role in CKD.



**DISCUSSION**

This study analyzed the effects of a 6-month treatment period on urinary albumin-creatinine ratio (UACR) and serum potassium levels in 20 patients, stratified by gender. The primary goal was to evaluate potential renal benefits and safety considerations associated with treatment.

**1. Reduction in UACR**

A statistically significant reduction in UACR was observed over the 6-month period ( $p = 0.027$ ), indicating a potential improvement in renal function. UACR is a key marker of kidney damage, and its decrease suggests that the intervention may have exerted a protective effect on the kidneys. Notably, the reduction occurred across both male and female patients, although males tended to have slightly higher UACR values post-treatment. However, this gender difference was not

statistically significant ( $p = 0.127$ ).

**2. Increase in Serum Potassium**

Serum potassium levels demonstrated a statistically significant increase over the treatment period ( $p = 0.009$ ). While this shift is notable, the average values remained within the clinically acceptable range for most patients. This finding highlights the importance of regular monitoring of electrolytes during treatment, particularly in patients with existing risk factors for hyperkalemia.

**3. Gender-Based Analysis**

No significant differences were found between males and females in terms of UACR or serum potassium levels at the 6-month endpoint. This suggests that the treatment effect and metabolic response were broadly consistent across genders.

**4. Clinical Implications**

The dual finding of improved renal markers and a modest but significant increase in serum potassium underscores the potential utility and risks of the therapy. The favorable UACR trajectory suggests efficacy, whereas the rise in serum potassium signals the need for close biochemical monitoring. This balance is especially critical in patients with chronic kidney disease (CKD), where both proteinuria and hyperkalemia carry significant clinical consequences. The modest fall in eGFR observed over 6 months is consistent with the expected initial hemodynamic effect of finerenone, reflecting reduced intraglomerular pressure rather than true kidney damage. Similarly, a reduction in blood pressure aligns with finerenone's mineralocorticoid receptor blockade, contributing to its cardiovascular and renal protective effects.

**CONCLUSION**

This analysis demonstrates that the 6-month treatment was associated with a statistically significant reduction in UACR, suggesting improved renal function in patients. Simultaneously, a modest but significant increase in serum potassium was observed, underscoring the importance of monitoring for hyperkalemia during therapy. No significant gender differences were detected in either outcome, indicating consistent effects across male and female patients. Finerenone demonstrated a modest decline in eGFR and blood pressure, consistent with its expected renoprotective and antihypertensive effects.

Overall, the treatment appears to be effective in improving kidney health, but clinicians should remain vigilant regarding electrolyte balance to ensure patient safety. Further studies with larger sample sizes and extended follow-up are recommended to validate these findings.

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