SSR Institute of International Journal of Life Sciences
ISSN (O): 2581-8740 | ISSN (P): 2581-8732
Parashuram *et al*., 2026
doi: 10.21276/SSR-IIJLS.2026.12.4.27

Original Article

open access

Finerenone for Prevention of New-Onset Heart Failure and Reduction of Heart Failure Hospitalizations in Diabetic Kidney Disease

Parashuram[1], Prathibha Vasu[2], Nallamala Suman Krishna Chowdary[3]*

[1]Professor and HOD, Department of General Medicine, Dr B R Ambedkar Medical College and Hospital, Bengaluru, India
[2]Associate Professor, Department of General Medicine, Dr B R Ambedkar Medical College and Hospital, Bengaluru, India
[3]Junior Resident, Department of General Medicine, Dr B R Ambedkar Medical College and Hospital, Bengaluru, India

***Address for Correspondence:** Dr. Nallamala Suman Krishna Chowdary, Junior Resident, Department of General Medicine, Dr B R Ambedkar Medical College and Hospital, Bengaluru, India
E-mail: sumankrishna1997@gmail.com

Received: 14 Mar 2026/ Revised: 26 May 2026/ Accepted: 25 Jun 2026

ABSTRACT

Background: The diabetic kidney disease (DKD) which leads to an increased risk of heart failure and cardiovascular morbidity. Fierenene is a new non-steroidal drug that acts as a mineralocorticoid receptor blocker and offers cardio-renal protection through the anti-inflammatory and anti-fibrotic actions. The present study was aimed to assess the efficacy and safety of finerenone in preventing heart failure and cardiovascular outcomes in DKD patients.

Methods: The study design was an observational comparative study on 158 patients of diabetic nephropathy admitted in a tertiary care hospital for one year. The study population was further subdivided into finerenone 88 patients and control groups as 70 patients. The demographic, clinical, laboratory, cardiovascular, and renal parameters were evaluated. The statistical test was done in SPSS version 27, with a p-value of less than 0.05 being statistically significant.

Results: The number of patients was 158, including 88 in the finerenone group and 70 in the control group. There were no statistically significant differences in baseline demographic and clinical characteristics between the groups ($p>0.05$ for all variables). Patients in the finerenone group had less all-cause mortality (12 vs. 15 patients) and less cardiovascular mortality, including sudden mortality (2 vs. 3) and heart failure mortality (1 vs. 2), while stroke and myocardial infarction were comparable in both groups.

Conclusion: The study concluded that Finerenone showed low overall and cardiovascular mortality compared to the standard therapy, while also maintain the comparable baseline clinical characteristics and disease severity.

Key-words: Finerenone, Diabetic Kidney Disease (DKD), Heart Failure, Type 2 Diabetes Mellitus (T2DM), Cardiorenal Protection

INTRODUCTION

India is witnessing outbreaks of Type 2 Diabetes Mellitus (T2DM) and chronic kidney disease (CKD). DKD is a major contributor towards rising cardiovascular diseases in the country [1,2]. The CITE study, which is a multi-center trial conducted over 3,325 diabetic patients from India, revealed that CKD had an overall prevalence of around 32%, with the low eGFR being strongly correlated with old age, long diabetes duration, high levels of HbA1c, and high levels of systolic blood pressure [1]. These data demonstrate clearly the burden of DKD in India among the T2DM population [1,2].

Various Indian studies and registries highlighting the role of DKD show that it leads to even higher heart failure events and rehospitalisation rates in patients than prior statistics on non-DKD diabetic patients point to [3, 4]. This characteristic shows a pathological two-way connection between the heart and the kidney, where worsening kidney function worsens chronic stress on the heart and increases the clinical worsening process [3,4]. This provides strong evidence that DKD is a major independent factor leading to the emergence of

How to cite this article
Parashuram, Vasu P, Chowdary NSK. Finerenone for Prevention of New-Onset Heart Failure and Reduction of Heart Failure Hospitalizations in Diabetic Kidney Disease. SSR Inst Int J Life Sci., 2026; 12(4): 10340-10347.

Access this article online
https://iijls.com/

doi: 10.21276/SSR-IIJLS.2026.12.4.27

cardiorenal problems and increased heart failure risk in such patients [3,4].

Chronic hyperglycemia leads to dysfunctional intracellular signaling whose role is to instabilize and over-activate the mineralocorticoid receptor (MR) in cardiac and renal tissues. High glucose activates protein kinase C-beta (PKCβ) thereby inhibiting MR Ubiquitination which results in the increased abundance of MR and activation of SGK1 [5]. At the same time, hyperglycemia promotes the nutrient-sensing O-GlcNAc that raises MR protein stability and activity [6]. Thus, chronic hyperglycemia promotes abnormal MR activation which results in cardiovascular and vascular injuries. Experts have agreed that aldosterone-MR path is active independently of the influence on the fluid retention [7]. At the same time, the presence of the MR in different cells leads to extrarenal MR activation, i.e. cardiomyocytes and smooth muscle cells, which cause inflammation reactions [8]. Finally, this initiates degenerative processes such as left ventricular remodeling and heart failure [7,8].

Finerenone is an innovative type of mineralocorticoid receptor antagonist (ns-MRA) with the function of inhibiting the unnecessary inflammation and fibrosis connected with aldosterone in heart and kidneys [9]. Unlike the steroidal examples of MRAs represented by, for instance, spironolactone and eplerenone, finerenone has a uniform distribution across heart and kidneys and unique binding kinetics that prevent off-target effects with respect to the endocrine system [10]. This provides it with optimal distribution of tissues and ultimate selectivity which reduces the risk of hyperkalemia to make it safer for long-term use for patients with diabetes and kidney disease [9,10]. RAS inhibitors and SGLT2 can be considered the cornerstone of DKD treatment but still the risk of cardiologic phenomenon caused by the MR activation remains unaddressed [11]. Therefore, the combination of finerenone administration with the application of optimized treatment protocols results in a layered approach based on overcoming the challenges presented by progressive fibro-inflammatory pathways caused by the conventional treatment effects [11,12].

In this research, the objective is to examine the clinical effectiveness and safety of finerenone, a novel non-steroidal mineralocorticoid receptor antagonist, in preventing the onset of heart failure and heart failure events in individuals with already diagnosed chronic diabetic kidney disease.

MATERIALS AND METHODS

Research design- The study was a comparative observational study to assess the efficacy of the Finerenone to prevent the onset of the Heart Failure and to evaluate the reduction rate of hospitalizations for heart failure cases in case of Diabetic Kidney Disease. The study was conducted for 1 year in a Tertiary Care Hospital. Total 158 participants were included in the study, those who were divided into two groups on the basis of the treatment. Group A (Finerenone group) consisted of 88 patients those who had received with the finerenone along with standard medical therapy. Patients in the Group B (Control group) contained 70 patients, those who had received with the standard medical therapy in absence of finerenone. Demographic, clinical and laboratory factors were taken from all of the participants for group comparison. The study aimed to evaluate the effect of the finerenone on the cardiovascular and renal outcomes.

Inclusion criteria

- ✓ Adult patients of age more than 18 years of age were included in the study.
- ✓ Those who were diagnosed with the cardiovascular-kidney-metabolic (CKM) conditions, like CKD, heart failure (HF), and/or T2DM were included
- ✓ Patients with complete demographic, clinical, laboratory, and follow-up data were included.
- ✓ Well written and verbal consent required for the study.

Exclusion criteria

- ✓ Incomplete or missed data were not considered
- ✓ Lost follow up patients were not included.
- ✓ Patient with severe hepatic impair, or severe renal disease need dialysis or kidney transplantation were excluded.
- ✓ Lactating women were not considered
- ✓ Patients those who were diagnosed with previously hypersensitivity or contraindication to finerenone were excluded.

Procedure- Total 158 patients were selected for the study and were categorized into two groups on the basis of the treatment received. Patients in Group A consisted

doi: 10.21276/SSR-IIJLS.2026.12.4.27

with 88 patients, those who were treated with the standard medical therapy and patients in the Group B consisted with 70 patients, those who were treated with the standard medical therapy in absence of finerenone. Information regarding the demographic parameters like the age and sex and some clinical variables like the history of chronic kidney disease, heart failure, type 2 diabetes mellitus, hypertension, and cardiovascular disease were identified and recorded. Laboratory investigations were performed, which included the estimated amount of serum creatinine, glomerular filtration rate (eGFR), serum potassium, blood glucose/HbA1c as well as some other biochemical parameters. All of the patients were followed up according to the routine practice. Cardiovascular outcomes, renal outcomes, adverse events specifically the hyperkalemia along with the hospitalization, and mortality were measured and compared between two groups. Clinical and laboratory outcomes were investigated to analyse the efficacy and safety index of the finerenone among patients with the cardiovascular-kidney-metabolic disease.

Statistical Analysis- Statistical analysis was conducted by the use of SPSS Version 27. The mean ± standard deviation (SD) form was utilised to express the continuous variables and frequency and percentage was used for the categorical variables. The comparative analysis between the finerenone and control group was conducted by the use of independent Student's t-test for the **c**ontinuous variables, while categorical variables were compared by the use of the Chi-square test or Fisher's exact test. The p-value of <0.05 was considered for statistical analysis.

RESULTS

Table 1 demonstrated the baseline demographic and clinical parameters of the study. The mean age value for both of the groups were compared, 66.8 ± 9.7 years for the finerenone group and 67.4 ± 10.1 years for the control group. Females were 35.2% in the finerenone group and 34.3% in the control groups. Similar racial distribution was noted for both of the groups, while white participants were majorly noted. Regional distribution, body mass index, systolic blood pressure, serum potassium, and eGFR showed no difference for both of the groups, with p>0.05. While the heart failure, chronic kidney disease, and diabetes mellitus was compared between the groups. The use of medication like the diuretics, ACEi/ARB/ARNI, statins, aspirin, SGLT-2 inhibitors, GLP-1 receptor agonists, and potassium-lowering therapy was balanced and equivalent for both the group, which revealed the baseline parameters were similar prior the outcome evaluation.

Table 1: Comparative analysis for the baseline demographic and clinical parameters among Finerenone and Control Groups

Baseline Characteristic	Finerenone Group (n = 88), No. of patients [N (%)]	Control Group (n = 70), No. of pateints [N (%)]	HR (95% CI)	p-value
Age (years), mean ± SD	66.8 ± 9.7	67.4 ± 10.1	0.97 (0.74–1.27)	0.812
Female	31 (35.2%)	24 (34.3%)	0.96 (0.61–1.51)	0.856
Race				
Asian	18 (20.5%)	14 (20.0%)	1.02 (0.58–1.81)	0.947
Black	3 (3.4%)	2 (2.9%)	1.17 (0.19–7.10)	0.864
Other	4 (4.5%)	3 (4.3%)	1.05 (0.23–4.78)	0.951
White	63 (71.6%)	51 (72.9%)	0.95 (0.62–1.46)	0.821
Region				
Asia	17 (19.3%)	13 (18.6%)	1.04 (0.56–1.93)	0.912
Eastern Europe	28 (31.8%)	22 (31.4%)	1.01 (0.64–1.59)	0.974
Latin America	10 (11.4%)	8 (11.4%)	1.00 (0.39–2.57)	1
North America	12 (13.6%)	9 (12.9%)	1.08 (0.48–2.42)	0.857

doi: 10.21276/SSR-IIJLS.2026.12.4.27

Western Europe/Oceania/Others	21 (23.9%)	18 (25.7%)	0.91 (0.52–1.59)	0.733
BMI (kg/m²), mean ± SD	30.8 ± 5.9	30.7 ± 6.2	1.01 (0.79–1.30)	0.931
Systolic BP (mmHg), mean ± SD	134.3 ± 14.6	134.8 ± 15.2	0.98 (0.76–1.26)	0.884
Potassium (mmol/L), mean ± SD	4.4 ± 0.5	4.4 ± 0.5	1.00 (0.77–1.31)	0.996
eGFR (mL/min/1.73 m²), mean ± SD	59.4 ± 20.5	58.7 ± 21.4	1.02 (0.79–1.32)	0.889
History of Heart Failure	32 (36.4%)	26 (37.1%)	0.97 (0.62–1.53)	0.904
Baseline CKD	74 (84.1%)	58 (82.9%)	1.05 (0.69–1.60)	0.819
History of Diabetes Mellitus	71 (80.7%)	57 (81.4%)	0.98 (0.64–1.51)	0.938
Background Medication				
Diuretics	58 (65.9%)	47 (67.1%)	0.95 (0.61–1.48)	0.816
ACEi/ARB/ARNI	82 (93.2%)	65 (92.9%)	1.04 (0.36–2.99)	0.947
Aspirin	38 (43.2%)	31 (44.3%)	0.96 (0.62–1.49)	0.853
Statins	62 (70.5%)	50 (71.4%)	0.96 (0.61–1.51)	0.858
SGLT-2 inhibitors	8 (9.1%)	6 (8.6%)	1.06 (0.37–3.03)	0.909
GLP-1 receptor agonists	5 (5.7%)	4 (5.7%)	1.00 (0.27–3.70)	1
Potassium-lowering therapy	1 (1.1%)	1 (1.4%)	0.79 (0.05–12.46)	0.866

Fig. 1 showed the comparative analysis for the distribution of the causes of death for both of the finerenone and control groups. Low value for the All-cause mortality was noted in the finerenone group (12 patients) compared with those in the control group (15 patients). Among cardiovascular causes, sudden death was not frequently observed in case of the finerenone group and deaths due to heart failure cases were also lowers. Stroke and myocardial infarction were noted in similar frequencies for both groups. The control group showed cardiovascular procedural death and renal-related death. Comparable parameters for both of groups include the non-cardiovascular deaths due to severe infection and malignancy. Thus the figure highlighted that higher mortality was noted in the control group across several categories, while the finerenone group observed with few cardiovascular and overall mortalities.

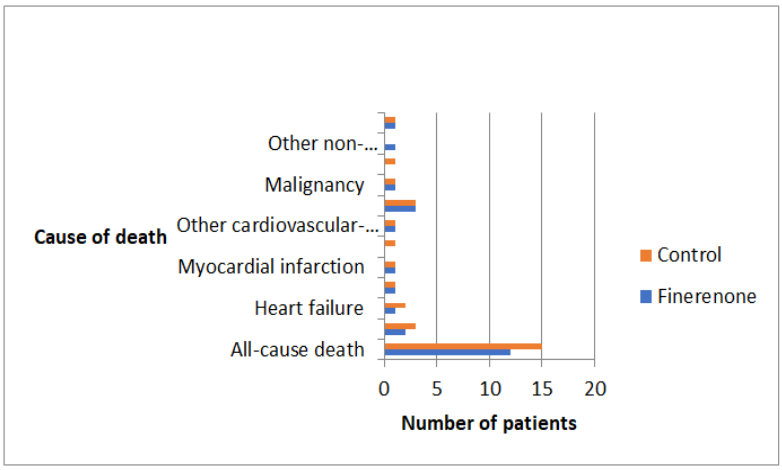

Fig. 1: Representing the comparison of the Causes of Death for both Finerenone and Control Groups

doi: 10.21276/SSR-IIJLS.2026.12.4.27

Table 2 showed the comparative analysis of the distribution of CKM conditions, KDIGO risk categories, sex, and clinical history for both of the grouos. Patients with the three CKM conditions were the largest, 51.1% in the finerenone group and 48.6% in the control group. This was followed by the patients with two conditions, and 11.4% of patients of each group showed single condition. The majority of participants were categorised on the basis of high KDIGO risk (37.5% vs. 37.1%), with identical distribution across the risk. Male participants were high for both of the groups. The prevalence rate for the heart failure, diabetes mellitus, and chronic kidney disease was compared for both of the groups, with no statistical significance for any variable, which indicated the well-balanced baseline clinical features.

Table 2: Comparison of Cardio-Kidney-Metabolic Profile and Clinical Characteristics

Characteristic	Finerenone Group (n = 88)	Control Group (n = 70)	Total (n = 158)	p-value
Cardio-kidney-metabolic (CKM) conditions				
1 Condition	10 (11.4%)	8 (11.4%)	18 (11.4%)	0.987
2 Conditions	33 (37.5%)	28 (40%)	61 (38.6%)	0.754
3 Conditions	45 (51.1%)	34 (48.6%)	79 (50.0%)	0.758
KDIGO Risk Categories				
Low Risk	12 (13.6%)	10 (14.3%)	22 (13.9%)	0.912
Moderately Increased Risk	18 (20.5%)	15 (21.4%)	33 (20.9%)	0.885
High Risk	25 (28.4%)	19 (27.1%)	44 (27.8%)	0.861
Very High Risk	33 (37.5%)	26 (37.1%)	59 (37.3%)	0.964
Sex				
Male	56 (63.6%)	46 (65.7%)	102 (64.6%)	0.783
Female	32 (36.4%)	24 (34.3%)	56 (35.4%)	
History of Heart Failure				
Present	30 (34.1%)	25 (35.7%)	55 (34.8%)	0.835
Absent	58 (65.9%)	45 (64.3%)	103 (65.2%)	
History of Diabetes Mellitus (DM)				
Present	60 (68.2%)	46 (65.7%)	106 (67.1%)	0.739
Absent	28 (31.8%)	24 (34.3%)	52 (32.9%)	
History of Chronic Kidney Disease (CKD)				
Present	52 (59.1%)	40 (57.1%)	92 (58.2%)	0.806
Absent	36 (40.9%)	30 (42.9%)	66 (41.8%)	

DISCUSSION

Finerenone considerably reduces the risk of heart failure in patients with diabetic kidney disease and offers applicable data regarding Asian populations [13, 14]. As per fidelity report, finerenone treatment resulted in a significant decrease of 22% in first heart failure-related hospitalization cases (HR 0.78; 95% CI 0.66–0.92), reduction of 21% in recurrent heart failure cases (HR 0.79; 95% CI 0.64–0.96), and reduction of combined endpoints of heart failure hospitalization and cardiovascular death resulting in 17% decrease of the cases (HR 0.83; 95% CI 0.74–0.93) [13]. The 2024 standards of care report the advantages of FIGARO-DKD where the number of heart failure cases was reduced by 29% (HR 0.71; 95% CI 0.56–0.90) and set the framework for the application of finerenone in order to stop the progression to heart failure [14]. The above-stated information can be used in Indian practice to avoid clinical admissions although it should be accompanied with regular control of potassium serum levels to avoid hyperkalemia [13,14].

doi: 10.21276/SSR-IIJLS.2026.12.4.27

Data from India demonstrate the translational efficacy of finerenone in altering cardiorenal issues without changes in glycemia [15,16]. In a two-center study conducted in Mumbai involving 149 patients having type 2 diabetes and CKD, a three-month course of finerenone treatment enables a 58% decrease in the mean urinary albumin-to-creatinine ratio (UACR), while maintaining or improving the eGFR strata. There were no incidents of hyperkalemia during the study [15]. The results of a retrospective study performed on 83 patients corroborates this earlier conclusion showing that the use of finerenone yielded 44.6% mean relative reduction in UACR (from 274.6 mg/g to 144.8 mg/g, p = 0.0033) and a 30% or more clinically meaningful response in 78% of the studied population [16]. Both studies showed that the use of finerenone along with background SGLT2 inhibitors provided a positive synergistic effect in the reduction of proteinuria, thus being in line with the results of large clinical trials carried out earlier [15,16].

A prospective observational study of 500 patients in Northern India with T2DM and CKD that was conducted for 12 months demonstrates the decrease in UACR, slower eGFR decline, and lower number of cardiovascular events with a rare occurrence of hyperkalemia [17]. In addition, a systematic review that combined nine randomized controlled trials with 21,731 participants confirmed that finerenone has a significant cardioprotective effect by reducing the number of major cardiovascular events by 15% (RR 0.85), heart failure hospitalizations by 18% (RR 0.82), and the overall mortality by 8% (RR 0.92) as well as decreasing the number of patients with sustained eGFR drop that exceeds 57% [18]. Hyperkalemia has a high RR of 2.05 in the meta-analysis; however, both studies agree on the importance of finerenone as an efficient added treatment for optimizing cardiorenal protection in real life [17,18].

Clinical registries of the country India show high incidence of serious cardiorenal comorbidity represented by late presentation and marked social differences, which puts a heavy strain on health systems of the country [19, 20]. Comprehensive cohort studies demonstrate high co-morbidity of hypertension and CVD in regional DKD populations [19, 20]. Sequentially conducting treatment with finerenone, a nonsteroidal mineralocorticoid receptor antagonist, on top of basic medication with renin - angiotensin system (RAS) inhibitors and SGLT2 blockers suppresses the source of inflammatory and fibrotic processes [19,20].

In the future, the approaches of the therapy of DKD in the Indian population need to focus on advocating for combination therapy approaches as well as phenotypic effectiveness evaluation [21,22]. Therefore, one of the most important issues is to conduct research on the effectiveness of the combination of long-term therapy using Finerenone and incretin drugs including GLP-1 receptor agonists and multi-receptor incretin drugs to understand their potential benefits [21, 22]. Another important issue is to ensure stratification of patients based on basic eGFR stages and specific subtypes of systolic heart failure [21,22]. Thus, the fact that the initial signals suggest a potential for heart failure hospitalization reduction and kidney protection creates a great opportunity to clarify the information about the most effective mixture of treatments and formulate precise guidelines for the changes occurring in DKD treatment in India [21,22].

CONCLUSIONS

The study concluded that patients on finerenone had significant clinical utility than those in the control group. The demographic and clinical baseline characteristics, such as age, sex, race, body mass index, blood pressure, renal function, history of heart failure, chronic kidney disease, diabetes mellitus, and background medication usage, were balanced in the study groups. Although there were no statistically significant differences in demographic and clinical baseline characteristics, the group of patients on finerenone had fewer cases of mortality from any cause (12 vs. 15 patients), as well as few cardiovascular deaths, which included sudden death and mortality from heart failure compared to the control group. Both groups had similar incidences of stroke and myocardial infarction, but the control group had cardiovascular procedure deaths and renal deaths. The results indicated the possibility of the positive influence of finerenone on cardiovascular outcomes and mortality in the cardio-kidney-metabolic population.

CONTRIBUTION OF AUTHORS

Research concept – Nallamala Suman Krishna Chowdary, Parashuram, Prathibha Vasu

Research design – Nallamala Suman Krishna Chowdary, Parashuram, Prathibha Vasu

doi: 10.21276/SSR-IIJLS.2026.12.4.27

Supervision – Parashuram
Materials – Nallamala Suman Krishna Chowdary, Parashuram
Data collection – Nallamala Suman Krishna Chowdary, Prathibha Vasu
Data analysis and interpretation – Nallamala Suman Krishna Chowdary, Parashuram
Literature search – Nallamala Suman Krishna Chowdary, Prathibha Vasu
Writing article – Nallamala Suman Krishna Chowdary, Prathibha Vasu
Critical review – Parashuram
Article editing – Nallamala Suman Krishna Chowdary, Parashuram, Prathibha Vasu
Final approval – Nallamala Suman Krishna Chowdary, Parashuram, Prathibha Vasu

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