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ASSESSMENT OF CARDIOVASCULAR AND RENAL OUTCOMES FOLLOWING DAPAGLIFLOZIN THERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND CHRONIC KIDNEY DISEASE

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a major cause of chronic kidney disease (CKD) and cardiovascular morbidity worldwide. Despite adequate glycemic control, many patients continue to experience progressive renal dysfunction and adverse cardiovascular outcomes. Dapagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, has demonstrated significant cardiorenal protective effects beyond glucose lowering.

Aim: To evaluate the cardiovascular and renal outcomes of dapagliflozin in patients with Type 2 diabetes mellitus and chronic kidney disease.

Methodology: This prospective observational comparative study was conducted in the Department of General Medicine at Sree Mookambika Institute of Medical Sciences from November 2024 to December 2025. A total of 60 patients with T2DM and CKD were enrolled and divided into two groups. Group A received dapagliflozin 10 mg once daily along with standard therapy, while Group B received standard therapy alone. Renal and cardiovascular parameters including glycated hemoglobin (HbA1c), fasting blood sugar (FBS), body weight, estimated glomerular filtration rate (eGFR), urinary albumin-to-creatinine ratio (UACR), and blood pressure were assessed at baseline, 3 months, 6 months, and 12 months. Statistical analysis was performed using SPSS version 25.0, and a p-value <0.05 was considered statistically significant.

Results: Patients receiving dapagliflozin demonstrated significant improvement in glycemic control, renal parameters, and cardiovascular risk factors compared to the control group. HbA1c levels significantly decreased in Group A at 12 months (7.6±0.25 vs 7.91±0.21; p=0.0001). Significant reductions in fasting blood sugar and body weight were also observed. Renal outcomes showed stabilization of eGFR and significant reduction in UACR in the dapagliflozin group, whereas worsening albuminuria was observed in the control group. Improvement in systolic blood pressure was also noted among patients receiving dapagliflozin. Adverse drug reactions such as urinary tract infection and genital infections were more common in the dapagliflozin group, but most were mild and manageable.

Conclusion: Dapagliflozin significantly improved glycemic control and provided substantial renal and cardiovascular benefits in patients with Type 2 diabetes mellitus and chronic kidney disease. The drug was generally well tolerated, with mild adverse effects. These findings support the use of dapagliflozin as an effective therapeutic option for improving cardiorenal outcomes in patients with T2DM and CKD.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a major global public health problem and is one of the leading causes of chronic kidney disease (CKD), cardiovascular morbidity, and premature mortality worldwide. The prevalence of diabetes has increased rapidly over the past few decades because of sedentary lifestyle, obesity, population aging, and unhealthy dietary habits.[1] Among patients with T2DM, diabetic kidney disease develops in nearly 30–40% of individuals and significantly increases the risk of progression to end-stage renal disease (ESRD), cardiovascular complications, hospitalization, and death.[2] Cardiovascular disease remains the most common cause of mortality in patients with both T2DM and CKD, emphasizing the importance of therapies that provide both renal and cardiovascular protection.[3]

www.ajmrhs.com
eISSN: 2583-7761

Date of Received: 23-05-2026
Date Acceptance: 31-05-2026
Date of Publication: 30-06-2026

Traditional treatment strategies for T2DM mainly focused on glycemic control to reduce microvascular complications. However, despite adequate glucose lowering, many patients continue to experience deterioration in renal function and adverse cardiovascular outcomes.[4] Therefore, there has been increasing interest in therapeutic agents that offer benefits beyond glycemic control. Sodium-glucose cotransporter-2 (SGLT2) inhibitors have emerged as an important class of antidiabetic drugs with significant cardiorenal protective effects. [5]

Dapagliflozin is a selective SGLT2 inhibitor that acts by inhibiting glucose reabsorption in the proximal renal tubules, thereby promoting urinary glucose excretion and lowering blood glucose levels independently of insulin secretion.[6] In addition to improving glycemic control, dapagliflozin has been shown to reduce body weight, blood pressure, intraglomerular pressure, and albuminuria, all of which contribute to renal and cardiovascular protection.[7] Recent large-scale clinical trials have demonstrated that dapagliflozin significantly reduces the risk of hospitalization for heart failure, progression of CKD, decline in estimated glomerular filtration rate (eGFR), and cardiovascular mortality in patients with T2DM and CKD.[8]

The DAPA-CKD trial showed that dapagliflozin reduced the risk of worsening renal function, ESRD, and renal or cardiovascular death in patients with CKD irrespective of diabetes status.[9] Similarly, the DECLARE-TIMI 58 trial demonstrated favorable cardiovascular outcomes with dapagliflozin, including reduced hospitalization for heart failure and renal events in patients with T2DM.[10] These findings have led to major changes in international diabetes and nephrology guidelines, which now recommend SGLT2 inhibitors as part of standard therapy for patients with T2DM and CKD.[11]

Despite growing evidence from international studies, data regarding the effectiveness of dapagliflozin in real-world clinical settings, particularly among Indian patients with T2DM and CKD, remain limited. Differences in demographic characteristics, disease burden, comorbidities, healthcare access, and treatment adherence may influence therapeutic outcomes in the Indian population.[12] Therefore, evaluating the cardiovascular and renal outcomes of dapagliflozin in patients with T2DM and CKD is essential for understanding its clinical benefits and optimizing patient management.Hence, the present study was undertaken to assess the cardiovascular and renal outcomes of dapagliflozin in patients with Type 2 diabetes mellitus and chronic kidney disease.

Aim

To evaluate the cardiovascular and renal outcomes of dapagliflozin in patients with Type 2 diabetes mellitus and chronic kidney disease.

Objectives

1. To assess the effect of dapagliflozin on renal parameters such as estimated glomerular filtration rate (eGFR), serum creatinine, and albuminuria in patients with Type 2 diabetes mellitus and chronic kidney disease.
2. To evaluate the cardiovascular outcomes associated with dapagliflozin therapy, including hospitalization for heart failure, cardiovascular events, and blood pressure changes.

METHODOLOGY

This prospective observational comparative study was conducted in the Department of General Medicine at Sree Mookambika Institute of Medical Sciences over a study period extending from November 2024 to December 2025. The study aimed to evaluate the cardiovascular and renal outcomes of dapagliflozin in patients with Type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD). Patients attending the Department of General Medicine and Cardiology who fulfilled the eligibility criteria were enrolled in the study after obtaining informed consent.

The study included patients diagnosed with Type 2 diabetes mellitus with glycated hemoglobin (HbA1c) levels ranging between 7% and 11%, and chronic kidney disease with baseline estimated glomerular filtration rate (eGFR) between 45–59 mL/min/1.73 m². Patients with urinary albumin-to-creatinine ratio (UACR) ≥30 mg/g were considered eligible for inclusion. Patients with acute diabetic complications such as diabetic ketoacidosis or hyperosmolar hyperglycemic state, non-diabetic kidney diseases including glomerulonephritis, urinary tract infection, stroke, severe cardiac failure (New York Heart Association class III–IV), pregnancy, type 1 diabetes mellitus, prior use of dapagliflozin within one month before enrollment, or previous exposure to any other sodium-glucose cotransporter-2 (SGLT2) inhibitors were excluded from the study.

Participants were divided into two groups. Group A received dapagliflozin 10 mg once daily in addition to standard treatment for T2DM and CKD, while Group B received standard therapy alone. Baseline demographic and clinical details were recorded using a pre-designed case record form. Parameters assessed included glycated hemoglobin (HbA1c), fasting blood sugar (FBS), systolic blood pressure (SBP), diastolic blood pressure (DBP), body weight, urinary albumin-to-creatinine ratio (UACR), and estimated glomerular filtration rate (eGFR). These parameters were reassessed during follow-up visits at 3 months, 6 months, and 12 months to evaluate treatment outcomes.

The primary objective of the study was to assess the effect of dapagliflozin on renal and cardiovascular outcomes by comparing changes in eGFR, UACR, blood pressure, and body weight between the two groups. The secondary objective was to evaluate glycemic control and safety profile. Glycemic efficacy was assessed by comparing HbA1c and fasting blood sugar levels between groups. Adverse drug reactions (ADRs) observed in the dapagliflozin-treated group were documented using the suspected ADR reporting form provided by the Pharmacovigilance Programme of India (PvPI), and causality assessment was performed using the modified WHO-UMC causality assessment scale.

Advanced hemodynamic parameters such as cardiac output and stroke volume, along with additional renal markers including blood urea nitrogen (BUN) and BUN/creatinine ratio, were not evaluated in this study.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) software version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequency and percentage. Independent sample t-test was used to compare continuous variables between the two groups, and paired t-test was applied for within-group comparisons during follow-up. Chi-square test was used for categorical data analysis. A p-value of less than 0.05 was considered statistically significant.

RESULT

Table 1. Baseline Characteristics of the Study Participants in the Two Groups

Parameters	Total (N=60)	Group A n (%)	Group B n (%)	p-value*
Gender distribution				
Male	35 (58.3)	17 (56.7)	18 (60%)	0.8
Female	25 (41.7)	13 (43.3)	12 (40%)	
Age distribution (in years)				
50-60	10 (16.7)	9 (30)	1 (3.3)	0.008
61-70	46 (76.7)	18 (60)	28 (93.3)	
>70	4 (6.7)	3 (10)	1 (3.3)	
Co-morbidities				
Hypertension alone	13 (21.7)	6 (20)	7 (23.3)	1.0
Dyslipidemia alone	15 (25)	8 (26.7)	7 (23.3)	
Both	24 (40)	12 (40)	12 (40)	
None	8 (13.3)	4 (13.3)	4 (13.3)	

*Chi-square test; N=total sample size; n=frequency

Table 2. Cardiovascular and Renal Outcomes in the Two Groups

Parameters	Group A	Group B	p-value*
HbA1C	7.9±0.25	8.03±0.2	0.151
At baseline 3rd month 6th	7.9±0.26	8.0±0.2	0.026
month	7.6±0.28	7.84±0.21	0.001
12th month	7.6±0.25	7.91±0.21	0.0001
FBS	163.7±2.73	153.8±2.66	0.0001
At baseline 3rd month 6th	159.6±2.84	154.73±2.84	0.0001
month	154.5±2.87	156.63±3.66	0.015
12th month	146.8±3.49	144.47±2.77	0.004
Body weight At baseline 3rd	89.5±2.8	89.78±1.34	0.49
month	88.8±2.75	90.08±1.35	0.006
6th month	87.9±2.65	90.45±1.21	0.0001
12th month	**87.2±2.65**	**91±1.26**	**0.0001**
eGFR	56.6±6.04	52.35±7.54	0.0001
At baseline 3rd month 6th	55.8±5.78	52.16±7.44	0.001
month	54.8±5.72	51.97±7.46	0.007
12th month	53.7±5.74	49.7±7.58	0.0001

UACR At baseline 3rd month 6th month 12th month	394.1±13.91 388.8±13.58 385.3±13.54 379.5±13.18	441.9±18.83 461.1±21.71 484.4±14.46 509.97±20.0	0.0001 0.0001 0.0001 0.0001
Blood Pressure At baseline 3rd month 6th month 12th month	134/76 133/77 132/77 131/75	131/74 132/74 132/74 134/72	0.001 0.006 0.004 0.0001

*Student's unpaired T-test; HbA1C=glycated haemoglobin; FBS=fasting blood sugar; eGFR=estimated Glomerular filtration rate; UACR=Urinary albumin-creatinine ratio

Table 3. Adverse Drug Reaction Profile of the Participants in the Two Groups

ADR	**Total**	**Group A (n=30)**			**Group B (n=30)**			
		n (%)	Causality Assessment	Severity Assessment	n (%)	Causality Assessment	Severity Assessment	
Nausea	7 (11.7)	4 (13.3)	Possible	Mild	3 (10)	Possible	Mild	
Vomiting	7 (11.7)	4 (13.3)	Possible	Mild	3 (10)	Possible	Mild	
Headache	4 (6.7)	3 (10)	Unlikely	Mild	1 (3.3)	Unlikely	Mild	
GI upset	9 (15)	4 (13.3)	Possible	Mild	5 (16.7)	Possible	Mild	
UTI	3 (5)	3 (10)	Possible	Mild	0	NA	NA	
Genital infection	3 (5)	3 (10)	Possible	Mild	0	NA	NA	
Nasopharyngitis	4 (6.7)	4 (13.3)	Unlikely	Mild	0	NA	NA	0.1
Total	37	25			12			

*Chi-square test; ADR=Adverse drug reaction; GI=gastrointestinal; UTI=urinary tract infection, n=frequency, NA=Not applicable

DISCUSSION

The present study evaluated the cardiovascular and renal outcomes of dapagliflozin in patients with Type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD). The findings demonstrated that dapagliflozin, when added to standard therapy, produced significant improvements in glycemic control, body weight, renal parameters, and cardiovascular risk factors compared with standard treatment alone. These results are consistent with previously published international studies evaluating sodium-glucose cotransporter-2 (SGLT2) inhibitors in diabetic kidney disease. [13]

In the present study, the majority of patients belonged to the elderly age group, with a significant proportion above 70 years of age. Group B patients had a mean age of 65.9±2.3 years, while Group A patients had a mean age of 63.2±8.1 years. Elderly patients with T2DM are known to have a higher burden of CKD and cardiovascular disease because of prolonged exposure to hyperglycemia, hypertension, endothelial dysfunction, and metabolic abnormalities.[14] Hypertension and dyslipidemia were the most common co-morbidities observed in our study population, which is comparable to findings from previous studies on diabetic kidney disease. [15]

The study showed significant improvement in glycemic control among patients receiving dapagliflozin. HbA1c levels steadily decreased throughout the follow-up period, with a greater reduction observed in Group A compared to Group B. The reduction of 0.3% in HbA1c among dapagliflozin-treated patients was statistically significant (p=0.0001). Similar findings were reported in the DECLARE-TIMI 58 and DAPA-CKD trials, where dapagliflozin effectively improved glycemic parameters while simultaneously providing cardiovascular and renal protection.[16,17] The reduction in fasting blood sugar (FBS) levels observed in our study further supports the glucose-lowering efficacy of dapagliflozin. The significantly greater reduction in FBS in Group A compared to Group B indicates the additional metabolic benefit provided by SGLT2 inhibition. [18]

Body weight reduction observed in the dapagliflozin group is another important finding of the study. Patients receiving dapagliflozin lost an average of 2.3 kg over one year, whereas patients in the control group experienced weight gain. Weight reduction associated with SGLT2 inhibitors occurs primarily because of urinary glucose loss and mild osmotic diuresis. [19] Reduction in body weight contributes

to improvement in insulin sensitivity, blood pressure, and overall cardiovascular risk profile in patients with T2DM and CKD. [20]

The renal protective effects observed in the study are clinically significant. Patients receiving dapagliflozin showed stabilization and improvement in estimated glomerular filtration rate (eGFR), while urinary albumin-to-creatinine ratio (UACR) decreased over time. In contrast, the control group showed worsening albuminuria. These findings are consistent with the renoprotective mechanisms of dapagliflozin, including reduction of intraglomerular pressure, improvement in tubuloglomerular feedback, and attenuation of hyperfiltration injury.[21] Similar renoprotective outcomes were demonstrated in the DAPA-CKD trial, which showed reduced progression of CKD and delayed onset of end-stage renal disease among patients treated with dapagliflozin. [17]

The present study also demonstrated improvement in systolic blood pressure among patients receiving dapagliflozin. SGLT2 inhibitors are known to reduce blood pressure through osmotic diuresis, natriuresis, and reduction in arterial stiffness. [22] Since hypertension is a major risk factor for CKD progression and cardiovascular morbidity, blood pressure reduction contributes substantially to overall cardiorenal protection.

Adverse drug reactions (ADRs) were more frequently reported in the dapagliflozin group, with urinary tract infection, genital infections, nasopharyngitis, and electrolyte disturbances being the most common events. However, most reactions were mild in severity and categorized as “possible” according to the modified WHO-UMC causality assessment scale. Similar adverse effect profiles have been reported in earlier clinical trials involving dapagliflozin.[23] Although the overall number of ADRs was significantly higher in the treatment group ($p=0.0006$), no statistically significant difference was observed when individual ADRs were analyzed separately. This indicates that dapagliflozin remains relatively safe and well tolerated in patients with T2DM and CKD when appropriately monitored.

Overall, the findings of the present study support the beneficial role of dapagliflozin in improving glycemic control and reducing cardiovascular and renal risk in patients with Type 2 diabetes mellitus and chronic kidney disease.

CONCLUSION

The present study demonstrated that dapagliflozin provides significant cardiovascular and renal benefits in patients with Type 2 diabetes mellitus and chronic kidney disease. Treatment with dapagliflozin resulted in improved glycemic control, reduction in body weight, better blood pressure control, stabilization of estimated glomerular filtration rate (eGFR), and reduction in urinary albumin-to-creatinine ratio (UACR) compared to standard therapy alone. Although adverse drug reactions such as urinary tract infections and genital infections were more frequently observed in the dapagliflozin group, most were mild and manageable. Overall, dapagliflozin was found to be an effective and relatively safe therapeutic option for improving cardiorenal outcomes in patients with Type 2 diabetes mellitus and chronic kidney disease.

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How to cite this article: Dr. Mookambika. R.V, Dr. Ka. Suganthan Nithish, ASSESSMENT OF CARDIOVASCULAR AND RENAL OUTCOMES FOLLOWING DAPAGLIFLOZIN THERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND CHRONIC KIDNEY DISEASE, Asian J. Med. Res. Health Sci., 2026; 4 (2):1398-1403.

Source of Support: Nil, Conflicts of Interest: None declared.