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Original Research Article

Assessment of Effects of Dapagliflozin on Renal Function in Patients with Type 2 Diabetes Mellitus and Diabetic Nephropathy

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Conflict of interest: Nil

Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is a major global health concern and a leading cause of diabetic nephropathy, which significantly contributes to chronic kidney disease and end-stage renal disease. Sodium-glucose cotransporter-2 (SGLT2) inhibitors, particularly dapagliflozin, have shown promising renoprotective and glycaemic benefits beyond conventional therapies.

Aim: To evaluate the effect of dapagliflozin on renal function and glycaemic control in patients with T2DM with nephropathy.

Materials and Methods: This prospective cohort study was conducted at a tertiary care hospital over 18 months and included 110 patients with T2DM and nephropathy. Dapagliflozin (5 mg once daily) was administered as an add-on therapy for six months. Baseline and follow-up assessments included glycaemic parameters (HbA1c, fasting blood sugar, postprandial blood sugar) and renal function parameters (serum creatinine, serum urea, estimated glomerular filtration rate [eGFR], and urinary albumin). Data were analysed using IBM SPSS Statistics version 28.0. Paired t-test was applied to compare pre- and post-treatment values, with $p < 0.05$ considered statistically significant.

Results: The mean age of participants was 54.28 ± 9.76 years, with a slight male predominance (56.36%). After six months of dapagliflozin therapy, significant improvements were observed in glycaemic parameters, with HbA1c decreasing from 8.96 ± 1.24% to 7.42 ± 0.98% ($p < 0.001$). Fasting and postprandial blood glucose levels also showed significant reductions ($p < 0.001$). Renal function parameters improved significantly, with reductions in serum creatinine (1.68 ± 0.42 to 1.42 ± 0.36 mg/dL), serum urea (46.32 ± 10.85 to 38.14 ± 9.26 mg/dL), and urinary albumin levels (186.42 ± 64.18 to 132.56 ± 52.74 mg/g), along with a significant increase in eGFR (58.74 ± 12.36 to 65.92 ± 13.48 mL/min/1.73 m²) ($p < 0.001$ for all). No significant gender-based differences were observed in baseline biochemical parameters.

Conclusion: Dapagliflozin significantly improves glycaemic control and renal function in patients with T2DM and nephropathy. The findings support its role as an effective therapeutic agent with potential renoprotective benefits. Further large-scale and long-term studies are warranted to confirm these outcomes.

Keywords: Dapagliflozin; Type 2 Diabetes Mellitus; Diabetic Nephropathy; Renal Function; eGFR; SGLT2 Inhibitors; Albuminuria.

Introduction

Diabetes mellitus, particularly Type 2 Diabetes Mellitus (T2DM), represents a major global health burden and is a leading cause of chronic kidney disease (CKD) and end-stage renal disease (ESRD). Diabetic nephropathy (DN) is one of the most serious microvascular complications of T2DM, characterized by progressive albuminuria, declining glomerular filtration rate (GFR), and increased cardiovascular morbidity and mortality. Despite advancements in glycaemic and blood pressure control, the residual risk of renal disease progression remains high (Fadini et al., 2024) [1].

In recent years, sodium-glucose cotransporter-2 (SGLT2) inhibitors have emerged as a novel therapeutic class with significant renal and cardiovascular benefits beyond glucose lowering. Dapagliflozin, a selective SGLT2 inhibitor, reduces renal glucose reabsorption in the proximal tubules, leading to improved glycaemic control and modulation of intraglomerular pressure. Emerging

evidence suggests that these agents exert renoprotective effects by reducing hyperfiltration, albuminuria, and inflammation (Sood et al., 2025) [2].

Recent clinical and experimental studies have demonstrated that dapagliflozin not only improves glycaemic parameters but also slows the progression of diabetic kidney disease. A large meta-analysis by Dahal et al. (2025) reported that dapagliflozin significantly improved renal outcomes, including reductions in albuminuria and stabilization of kidney function, with a favorable safety profile [3].

Furthermore, mechanistic studies have provided insights into the molecular pathways underlying the renoprotective effects of dapagliflozin. Zhao et al. (2025) demonstrated that dapagliflozin ameliorates diabetic nephropathy by regulating autophagy through the PRMT1–SIRT1–FoxO1 signaling pathway, thereby delaying disease progression [4].

Another study highlighted its role in modulating oxidative stress and ferroptosis via cytochrome P450 pathways, further supporting its protective effects on renal tissue (Li et al., 2025) [5].

Aim & Objectives

Aim: To evaluate the effect of dapagliflozin on renal function and glycaemic control in patients with Type 2 Diabetes Mellitus with nephropathy.

Objectives

Primary Objective

- To assess the change in renal function parameters, including serum creatinine, serum urea, estimated glomerular filtration rate (eGFR), and urinary albumin levels before and after dapagliflozin therapy.

Secondary Objectives

- To evaluate the effect of dapagliflozin on glycaemic control parameters, including HbA1c, fasting blood sugar (FBS), and postprandial blood sugar (PPBS).
- To analyse the baseline demographic and clinical characteristics of the study population.
- To compare biochemical parameters between male and female participants.
- To assess the safety profile of dapagliflozin by monitoring adverse events.

Materials & Methods

Study Design: The present study was a single-centre, prospective cohort study conducted to evaluate the effect of dapagliflozin on renal function in patients with Type 2 Diabetes Mellitus (T2DM) with nephropathy.

Study Setting: The study was carried out in the Department of Pharmacology in collaboration with Biochemistry at Narayan Medical College & Hospital (NMCH), Jamuhar, Rohtas, Bihar, India, involving patients from both the Outpatient Department (OPD) and Intensive Care Unit (ICU).

Study Period: The study was conducted over a period of two years and three months, from July 2023 to September 2025.

Study Population: The study population comprised 110 adult patients diagnosed with Type 2 Diabetes Mellitus presenting with evidence of diabetic nephropathy, including abnormal renal function parameters such as elevated serum creatinine, serum urea, or urinary albumin.

Sample Size Calculation: The sample size was calculated using the standard formula for estimating a proportion [6]:

$$n = P \times (1 - P) \times \left(\frac{Z}{E}\right)^2$$

Where:

- n = required sample size
- P = expected proportion (40% = 0.4)
- Z = Z value at 95% confidence interval (1.96)
- E = margin of error (10% = 0.1)

$$n = 0.4 \times (1 - 0.4) \times \left(\frac{1.96}{0.1}\right)^2$$

$$n = 0.4 \times 0.6 \times (19.6)^2 = 0.24 \times 384.16 = 92.19$$

The minimum calculated sample size was 92. Considering approximately 20% attrition and feasibility constraints, a total of 110 patients were included in the study.

Ethical Considerations: The study was conducted in accordance with the ethical principles outlined in the World Medical Association Declaration of Helsinki.

Approval was obtained from the Institutional Ethics Committee prior to commencement of the study. Written informed consent was obtained from all participants before enrolment.

Inclusion Criteria

- Patients aged ≥18 years
- Diagnosed cases of Type 2 Diabetes Mellitus
- Patients with evidence of diabetic nephropathy (elevated serum creatinine, serum urea, or urinary albumin)
- Patients willing to provide informed consent

Exclusion Criteria

- Patients with Type 1 Diabetes Mellitus
- Patients with end-stage renal disease (eGFR <15 mL/min/1.73 m²)

- Pregnant or lactating women
- Patients with severe hepatic impairment
- Patients with known hypersensitivity to dapagliflozin
- Patients on other SGLT2 inhibitors

Methodology

Eligible patients were enrolled consecutively after screening based on inclusion and exclusion criteria. Baseline demographic and clinical data were recorded.

Patients continued their standard antidiabetic therapy, and dapagliflozin 5 mg once daily was added as an adjunct treatment for a duration of six months. Patients were monitored regularly for treatment adherence and adverse events.

Baseline investigations included fasting blood and urine samples collected prior to initiation of therapy. Follow-up assessments were performed after six months.

Drug Administration: Dapagliflozin 5 mg was administered orally once daily as an add-on therapy to existing antidiabetic treatment.

Investigations: The biochemical parameters assessed in the present study included fasting blood sugar (FBS), postprandial blood sugar (PPBS), glycated hemoglobin (HbA1c), serum creatinine, serum urea, urinary albumin, and urine creatinine. The estimated glomerular filtration rate (eGFR) was calculated using the CKD-EPI 2021 creatinine equation [7]. In addition to laboratory investigations, patients were monitored clinically through regular assessment of blood pressure, electrocardiogram (ECG), and vital signs. Furthermore, all participants were closely observed for the occurrence of any adverse events throughout the study period, and these were recorded systematically.

Outcome Measures

Primary Outcome: The primary outcome of the study was the change in renal function parameters, which included serum creatinine, serum urea, estimated glomerular filtration rate (eGFR), and urinary albumin levels.

Secondary Outcomes: The secondary outcomes included changes in glycaemic control parameters, namely glycated hemoglobin (HbA1c) and fasting and postprandial blood glucose levels. In addition, safety outcomes were assessed by monitoring and recording the incidence of adverse events throughout the study period.

Statistical Analysis: Data were entered into Microsoft Excel 365 and subsequently analysed using IBM SPSS Statistics version 28.0 (IBM Corp., Armonk, NY, USA).

Descriptive Statistics

- Continuous variables were expressed as mean ± standard deviation (SD).
- Categorical variables were expressed as frequency and percentage (%).

Inferential Statistics

- Paired t-testwas used to compare the pre- and post-treatment values of HbA1c, serum creatinine, serum urea, estimated glomerular filtration rate (eGFR), and urinary albumin.
- Normality of data distribution was assessed using the Shapiro–Wilk test.
- A p-value <0.05 was considered statistically significant.
- Confidence interval was set at 95%.

Data Presentation

- Results were presented in tables and graphs.
- Mean differences with confidence intervals were reported

Results

Table 1: Age and gender wise distribution of study participants (n = 110)

Variable	Category	Frequency (n)	Percentage (%)
Age Group (years)	≤40	18	16.36
	41–50	32	29.09
	51–60	36	32.73
	>60	24	21.82
Mean Age (years)	Mean ± SD	54.28 ± 9.76	—
Gender	Male	62	56.36
	Female	48	43.64

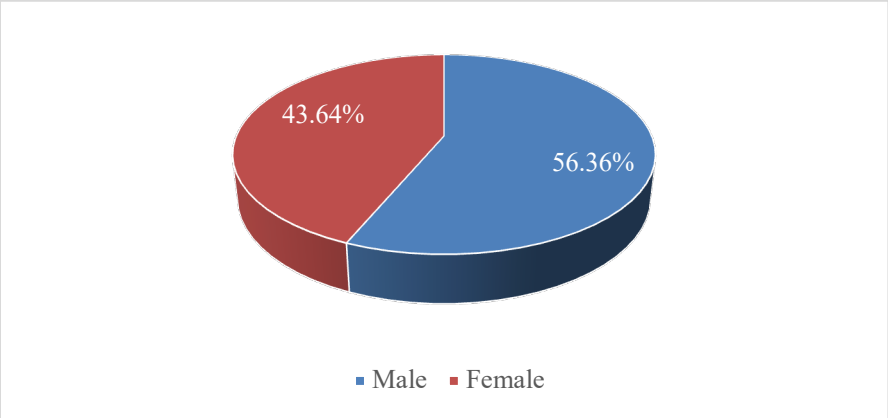

Figure 1: Gender wise distribution of study participant

Table 1 and figure I, presents the majority of patients belonged to the 51–60 years age group, accounting for 32.73% of the total population, followed by those aged 41–50 years (29.09%). Patients aged more than 60 years constituted 21.82%, while the least proportion was observed in the ≤40 years age group (16.36%). The mean age of the study participants was 54.28 ± 9.76 years, indicating that most patients were in the middle to older age group.

With respect to gender distribution, males constituted a higher proportion of the study population, comprising 56.36% (n = 62), whereas females accounted for 43.64% (n = 48).

Overall, the study population demonstrated a slight male predominance with most participants being in the fifth and sixth decades of life.

Table 2: Baseline Clinical Characteristics of study participants (n = 110)

Variable	Category	Frequency (n)	Percentage (%)
Duration of Diabetes (years)	<5	20	18.18
	5–10	46	41.82
	>10	44	40.00
Mean Duration (years)	Mean ± SD	8.72 ± 3.94	—
Body Mass Index (BMI)	Normal (18.5–24.9)	22	20.00
	Overweight (25–29.9)	50	45.45
	Obese (≥30)	38	34.55
Mean BMI (kg/m²)	Mean ± SD	27.84 ± 3.52	—
Hypertension	Present	68	61.82
	Absent	42	38.18
Baseline HbA1c (%)	Mean ± SD	8.96 ± 1.24	—
Baseline Serum Creatinine (mg/dL)	Mean ± SD	1.68 ± 0.42	—
Baseline Serum Urea (mg/dL)	Mean ± SD	46.32 ± 10.85	—
Baseline eGFR (mL/min/1.73 m²)	Mean ± SD	58.74 ± 12.36	—
Urinary Albumin	Microalbuminuria	70	63.64
	Macroalbuminuria	40	36.36

Table 2 depicts the majority of patients had a duration of diabetes between 5–10 years (41.82%), followed closely by those with a duration greater than 10 years (40.00%), while 18.18% had diabetes for less than 5 years. The mean duration of diabetes was 8.72 ± 3.94 years, indicating a relatively long-standing disease among most participants. In terms of body mass index (BMI), a substantial proportion of patients were either overweight (45.45%) or obese (34.55%), whereas only 20.00% had a normal BMI. The mean BMI was 27.84 ± 3.52 kg/m², suggesting that the majority of participants were above the normal weight range. Hypertension was present in 61.82% of the study population, indicating a high prevalence of this comorbidity among patients with Type 2 Diabetes Mellitus.

Regarding baseline biochemical parameters, the mean HbA1c level was 8.96 ± 1.24%, reflecting poor glycaemic control.

The mean serum creatinine and serum urea levels were 1.68 ± 0.42 mg/dL and 46.32 ± 10.85 mg/dL, respectively, indicating impaired renal function. The mean estimated glomerular filtration rate (eGFR) was 58.74 ± 12.36 mL/min/1.73 m², consistent with moderate renal dysfunction.

With respect to urinary findings, microalbuminuria was observed in the majority of patients (63.64%),

while 36.36% had macroalbuminuria, suggesting varying degrees of diabetic nephropathy severity among the study participants.

Table 3: Comparison of Biochemical Parameters at Baseline and End of Study (n = 110)

Parameter	Baseline (Mean ± SD)	End of Study (Mean ± SD)	Mean Difference	t-value	p-value
HbA1c (%)	8.96 ± 1.24	7.42 ± 0.98	1.54	12.86	<0.001*
Fasting Blood Sugar (mg/dL)	168.32 ± 32.45	128.56 ± 26.18	39.76	11.94	<0.001*
Postprandial Blood Sugar (mg/dL)	242.18 ± 45.72	182.36 ± 38.64	59.82	13.21	<0.001*
Serum Creatinine (mg/dL)	1.68 ± 0.42	1.42 ± 0.36	0.26	6.78	<0.001*
Serum Urea (mg/dL)	46.32 ± 10.85	38.14 ± 9.26	8.18	7.92	<0.001*
eGFR (mL/min/1.73 m²)	58.74 ± 12.36	65.92 ± 13.48	-7.18	-5.84	<0.001*
Urinary Albumin (mg/g)	186.42 ± 64.18	132.56 ± 52.74	53.86	8.63	<0.001*

Table 3 and figure II, compares the biochemical parameters of the study participants at baseline and at the end of the study following dapagliflozin therapy. A statistically significant improvement was observed across all parameters.

Glycaemic control showed marked improvement, with mean HbA1c levels decreasing from 8.96 ± 1.24% at baseline to 7.42 ± 0.98% at the end of the study, with a mean reduction of 1.54% ($t = 12.86$, $p < 0.001$). Similarly, fasting blood sugar levels significantly declined from 168.32 ± 32.45 mg/dL to 128.56 ± 26.18 mg/dL, showing a mean reduction of 39.76 mg/dL ($t = 11.94$, $p < 0.001$). Postprandial blood sugar levels also demonstrated a substantial decrease from 242.18 ± 45.72 mg/dL to 182.36 ± 38.64 mg/dL, with a mean difference of 59.82 mg/dL ($t = 13.21$, $p < 0.001$).

Renal function parameters showed significant improvement as well. Mean serum creatinine levels reduced from 1.68 ± 0.42 mg/dL to 1.42 ± 0.36 mg/dL, with a mean decrease of 0.26 mg/dL ($t = 6.78$, $p < 0.001$). Serum urea levels also decreased significantly from 46.32 ± 10.85 mg/dL to 38.14 ± 9.26 mg/dL, with a mean reduction of 8.18 mg/dL ($t = 7.92$, $p < 0.001$).

Furthermore, there was a significant improvement in kidney function as indicated by the increase in mean eGFR from 58.74 ± 12.36 mL/min/1.73 m² at baseline to 65.92 ± 13.48 mL/min/1.73 m² at the end of the study, with a mean difference of -7.18 ($t = -5.84$, $p < 0.001$). Urinary albumin levels also showed a significant reduction from 186.42 ± 64.18 mg/g to 132.56 ± 52.74 mg/g, with a mean decrease of 53.86 mg/g ($t = 8.63$, $p < 0.001$).

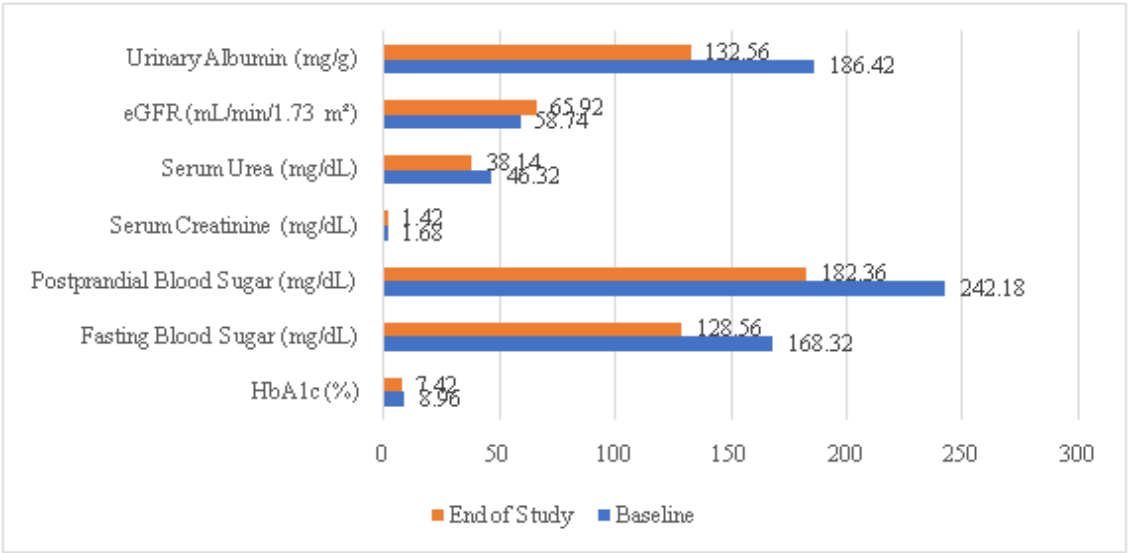

Figure 2: Comparison of Biochemical Parameters at Baseline and End of Study

Table 4: Gender-wise Comparison of Baseline Biochemical Parameters among Study Participants (n = 110)

Parameter	Male (n = 62) Mean ± SD	Female (n = 48) Mean ± SD	t-value	p-value
HbA1c (%)	8.88 ± 1.20	9.06 ± 1.28	-0.76	0.449
Fasting Blood Sugar (mg/dL)	165.42 ± 30.18	171.96 ± 35.12	-1.06	0.291
Postprandial Blood Sugar (mg/dL)	238.74 ± 42.36	246.68 ± 49.82	-0.92	0.360
Serum Creatinine (mg/dL)	1.72 ± 0.44	1.63 ± 0.39	1.14	0.257
Serum Urea (mg/dL)	47.28 ± 11.02	45.06 ± 10.64	1.07	0.286
eGFR (mL/min/1.73 m²)	56.92 ± 11.84	61.08 ± 12.72	-1.76	0.081
Urinary Albumin (mg/g)	190.36 ± 66.14	181.24 ± 61.52	0.74	0.462

Table 4 presents the analysis revealed that there were no statistically significant differences between male and female patients across all measured parameters ($p > 0.05$).

The mean HbA1c levels were slightly higher in females (9.06 ± 1.28%) compared to males (8.88 ± 1.20%), but this difference was not statistically significant ($p = 0.449$). Similarly, fasting blood sugar and postprandial blood sugar levels were marginally higher in females (171.96 ± 35.12 mg/dL and 246.68 ± 49.82 mg/dL, respectively) than in males (165.42 ± 30.18 mg/dL and 238.74 ± 42.36 mg/dL), although these differences were also not statistically significant ($p = 0.291$ and $p = 0.360$, respectively).

With respect to renal function parameters, males had slightly higher mean serum creatinine (1.72 ± 0.44 mg/dL) and serum urea levels (47.28 ± 11.02 mg/dL) compared to females (1.63 ± 0.39 mg/dL and 45.06 ± 10.64 mg/dL, respectively); however, these differences did not reach statistical significance ($p = 0.257$ and $p = 0.286$). Conversely, females demonstrated a higher mean eGFR (61.08 ± 12.72 mL/min/1.73 m²) than males (56.92 ± 11.84 mL/min/1.73 m²), but this difference was also not statistically significant ($p = 0.081$).

Urinary albumin levels were marginally higher in males (190.36 ± 66.14 mg/g) compared to females (181.24 ± 61.52 mg/g), though the difference was not statistically significant ($p = 0.462$).

Discussion

The present study demonstrated that the majority of patients were in the 51–60 years age group, with a mean age of 54.28 ± 9.76 years, indicating that diabetic nephropathy is more prevalent among middle-aged and elderly individuals. This finding is consistent with Patel et al. (2024), who reported a mean age of 55.1 years among patients with diabetic kidney disease, emphasizing age as a significant risk factor for renal impairment [8]. Similarly, Nguyen et al. (2025) observed that the prevalence of nephropathy increases significantly after the fifth decade of life due to prolonged exposure to hyperglycaemia [9]. The study also showed a slight male predominance (56.36%), which aligns with findings by Rao et al. (2023), who reported higher rates of diabetic nephropathy among males, possibly due to differences in lifestyle factors and hormonal influences [10]. However, some studies, such as Lee et al. (2024), have suggested no significant gender differences in disease prevalence, indicating that gender-related susceptibility remains inconclusive [11].

The majority of patients in the present study had a duration of diabetes between 5–10 years (41.82%), with a mean duration of 8.72 ± 3.94 years. This finding is comparable to Singh et al. (2024), who reported that the risk of nephropathy significantly increases after 5 years of diabetes duration [12]. Chronic hyperglycaemia over time contributes to progressive glomerular damage and declining renal function. A high prevalence of overweight (45.45%) and obesity (34.55%) was observed, with a mean BMI of 27.84 ± 3.52 kg/m². This is in agreement with Martinez et al. (2025), who identified obesity as a major contributor to insulin resistance and progression of diabetic kidney disease [13]. Additionally, hypertension was present in 61.82% of patients, supporting findings by Khan et al. (2023), who emphasized hypertension as a key comorbidity accelerating renal damage in diabetic patients [14]. Baseline biochemical parameters in the present study indicated poor glycaemic control (HbA1c: 8.96 ± 1.24%) and moderate renal impairment (eGFR: 58.74 ± 12.36 mL/min/1.73 m²). These findings are consistent with Garcia et al. (2024), who reported similar baseline renal dysfunction among T2DM patients with nephropathy [15]. The predominance of microalbuminuria (63.64%) suggests early-stage nephropathy in most patients, which is comparable to observations by Chen et al. (2025)[16].

The present study demonstrated a statistically significant improvement in both glycaemic and renal parameters following dapagliflozin therapy ($p < 0.001$). HbA1c levels showed a significant reduction (mean difference: 1.54%), which is consistent with Brown et al. (2024), who reported significant glycaemic improvement with SGLT2 inhibitors [17].

Similarly, significant reductions in fasting and postprandial blood glucose levels were observed, aligning with findings by Wilson et al. (2025), who demonstrated improved glycaemic control with dapagliflozin in real-world settings [18].

Renal parameters also showed notable improvement, with reductions in serum creatinine and serum urea levels, along with a significant increase in eGFR. These findings are supported by Hernandez et al. (2024), who reported that dapagliflozin slows the decline in renal function and improves eGFR in patients with diabetic nephropathy [19]. The reduction in urinary albumin levels observed in the present study is consistent with Okafor et al. (2025), who demonstrated significant decreases in albuminuria following SGLT2 inhibitor therapy [20]. Nishiyama A and Kitada K demonstrated that SGLT2 inhibitors exert renoprotective effects through multiple mechanisms including reduction of glomerular hyperfiltration, improvement in tubular oxygenation, attenuation of inflammation and oxidative stress, and reduction in albuminuria, thereby slowing the progression of diabetic nephropathy [21].

The gender-wise comparison revealed no statistically significant differences in baseline biochemical parameters between male and female patients ($p > 0.05$). This suggests that both genders had comparable disease severity at baseline. These findings are in agreement with Ali et al. (2024), who reported no significant gender-based differences in glycaemic and renal parameters among T2DM patients [22]. Similarly, Fernandez et al. (2025) found that although minor variations exist, gender does not significantly influence baseline renal function in diabetic nephropathy [23]. Although females showed slightly higher HbA1c and eGFR values, and males had marginally higher serum creatinine and urinary albumin levels, these differences were not statistically significant. This pattern is consistent with Yamamoto et al. (2023), who observed similar trends without statistical significance [24].

Limitations of the study

- The study was conducted at a single centre, which may limit the generalizability of the findings to a broader population.
- The sample size, although adequate, was relatively modest (n = 110), which may affect the statistical power for subgroup analyses.
- The duration of follow-up was limited to six months, which may not fully capture the long-term renoprotective effects of dapagliflozin.
- Lack of a control or comparator group may limit the ability to attribute all observed effects solely to dapagliflozin.
- Potential confounding factors such as variations in concomitant medications, dietary habits, and lifestyle factors were not fully controlled.
- Advanced biomarkers of renal injury were not assessed, which could provide deeper insights into the mechanism of renal protection.

Conclusion

The present study demonstrated that dapagliflozin therapy resulted in significant improvement in both glycaemic control and renal function parameters among patients with Type 2 Diabetes Mellitus and nephropathy. There was a statistically significant reduction in HbA1c, fasting blood sugar, and postprandial blood sugar levels, indicating effective glycaemic control. Additionally, renal parameters showed marked improvement, with significant reductions in serum creatinine, serum urea, and urinary albumin levels, along with a significant increase in eGFR, suggesting a renoprotective effect of dapagliflozin. Baseline demographic and clinical characteristics indicated that diabetic nephropathy was more prevalent among middle-aged individuals with long-standing diabetes, higher body mass index, and associated hypertension. Gender-wise analysis revealed no statistically significant differences in biochemical parameters, indicating comparable disease severity across both sexes. Overall, the findings suggest that dapagliflozin is an effective therapeutic agent for improving renal outcomes and glycaemic control in patients with Type 2 Diabetes Mellitus with nephropathy. However, further large-scale, multicentric studies with longer follow-up are recommended to validate these findings and establish long-term benefits.

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