VER
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Comparing The Safety And Efficacy Of Sitagliptin Vs Dapagliflozin And The Risk Of Hyperkalaemia Among People With Type 2 Diabetes Mellitus And Kidney Disease

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD) are frequently coexisting conditions associated with high morbidity and mortality. Hyperlalaemia is a major electrolyte disturbance in this population, and drug choice may influence its severity. This study compares the safety and efficacy of Sitagliptin (an DPP-4 inhibitor) and Dapagliflozin (an SGLT2 inhibitor) in T2DM patients with CKD, with particular focus on glycaemic outcomes and hyperkalaemia risk.

Methods: A prospective, observational cohert study was conducted for six months among 152 adults (aged 40-80yrs) with T2DM and CKD. Participants were grouped based on therapy with Sitagliptin or Dapagliflozin. Glycaemic indices (FBS, PPBS, HbA1c, RBS) and serum potassium levels were recorded at baseline and post treatment. Data were analyzed using paired and independent t-tests and Chi-square tests.

Results: Both Sitagliptin and Dapagliflozin achieved significant reductions in HbA1c (8.86 → 7.67% , $p<0.001$) and PPBS (205.78 →147.57 mg/dl, $p<0.001$). Dapagliflozin demonstrated a slightly greater decline in PPBS ($p=0.035$) and serum potassium (5.33 →5.16 mmol/L, $p=0.044$). The incidence of moderate hyperkalaemia was significantly lower in the Dapagliflozin group ($p=0.032$).

Conclusion: Dapagliflozin showed superior overall efficacy in improving glycaemic parameters and reducing hyperkalaemia risk, while Sitagliptin remained a safe alternative, especially inn patients with mild renal impairment.

KEYWORDS: Type 2 diabetes mellitus, chronic kidney disease, Sitagliptin, Dapagliflozin, hyperkalaemia.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and progressive β-cell dysfunction, leading to sustained hyperglycaemia and multiple organ complications. Chronic kidney disease (CKD) is one of the most frequent and serious consequences of T2DM, affecting nearly 30–40% of patients and contributing to high morbidity and mortality [1]. The coexistence of T2DM and CKD increases the risk of electrolyte disturbances such as hyperkalaemia, cardiovascular events, and renal failure progression. Optimal antidiabetic therapy selection is therefore critical for improving renal and metabolic outcomes in this high-risk population [2]. Among newer glucose-lowering agents, sodium-glucose cotransporter-2 (SGLT2) inhibitors such as dapagliflozin have demonstrated significant benefits beyond glycaemic control, including slowing CKD progression and reducing hospitalization for heart failure [2][4]. Conversely, dipeptidyl peptidase-4 (DPP-4) inhibitors such as sitagliptin offer effective glycaemic management with good tolerability, particularly among elderly patients and those with multiple comorbidities [5]. Despite their widespread use, comparative data on their effects on serum potassium regulation remain limited. This study aims to evaluate and compare the safety and efficacy of dapagliflozin and sitagliptin, focusing on the incidence and severity of hyperkalaemia in patients with T2DM and CKD.

MATERIALS AND METHODS

This prospective observational cohort study was conducted from October 2024 to March 2025 at ESIC Hospital, Ayanavaram, and St. Isabel Hospital, Mylapore, Chennai, in collaboration with the Department of Pharmacy Practice, Vels Institute of Science, Technology and Advanced Studies (VISTAS). Ethical approval for the study was obtained from the Institutional Ethics Committee (Ref. No. ECR/288/Indt/TN/2018/RR-21/114). All participants provided written informed consent before inclusion in the study.

2.1 Study Population

A total of 152 patients aged between 40 and 80 years diagnosed with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD) were recruited. The participants were divided into two equal groups of 76 each based on the antidiabetic agent prescribed:

- Group A: Sitagliptin (50 mg/day)
- Group B: Dapagliflozin (10 mg/day)

2.2 Inclusion Criteria

- Adults aged ≥30 years with confirmed T2DM and CKD (Stages 2–4 based on eGFR).
- Stable on oral hypoglycaemic therapy for at least 3 months.
- Patients capable of providing informed consent.

2.3 Exclusion Criteria

- Type 1 diabetes mellitus.
- End-stage renal disease (ESRD) or patients on dialysis.
- Pregnant or lactating women.
- Individuals with severe hepatic impairment or history of kidney transplantation.

2.4 Study Design and Data Collection

After enrollment, demographic and clinical details were recorded, including age, gender, disease duration, comorbidities, and concurrent medications. Baseline and post-treatment biochemical parameters were evaluated to assess both efficacy and safety profiles.

Efficacy parameters included fasting blood sugar (FBS), postprandial blood sugar (PPBS), random blood sugar (RBS), and glycosylated hemoglobin (HbA1c). Safety parameters included serum potassium, blood urea, serum creatinine, and uric acid levels, serving as indicators of renal and electrolyte status.

2.5 Sample Collection and Laboratory Analysis

Venous blood samples were collected from fasting patients under aseptic conditions. All laboratory investigations were carried out in hospital-certified diagnostic laboratories using standardized procedures:

- HbA1c was determined by high-performance liquid chromatography (HPLC).
- Blood glucose levels were measured using the hexokinase enzymatic method.
- Serum creatinine and urea were estimated via kinetic colorimetric assays.
- Serum potassium concentration was measured using an ion-selective electrode (ISE) analyzer.

Patients were followed up regularly, and biochemical parameters were reassessed after the treatment period to determine changes in glycaemic control and potassium levels. The severity of hyperkalaemia was classified as follows:

- Mild: 5.1–5.5 mmol/L
- Moderate: 5.6–6.0 mmol/L
- Severe: >6.0 mmol/L

2.6 Statistical Analysis

All data were analyzed using SPSS Version 20.0. Descriptive statistics were employed to summarize demographic and clinical variables. Comparisons between pre and post-treatment parameters within each group were performed using paired sample t-tests, while independent sample t-tests compared means between groups. The Chi-square test was used to assess categorical variables such as adverse effects and hyperkalaemia severity.

RESULTS

3.1 Demographic Characteristics

A total of 152 patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD) were enrolled and categorized into two groups: Sitagliptin (n = 76) and Dapagliflozin (n = 76). The overall mean age of participants was 60.2 ± 9.7 years, with a nearly equal distribution of males (52.6%) and females (47.4%). There were no statistically significant differences in baseline demographic parameters such as age, gender, or disease duration between the two groups ($p > 0.05$), indicating comparable baseline characteristics (Table 1).

Table 1. Baseline demographic and clinical characteristics of study participants

Parameter	Sitagliptin (n=76)	Dapagliflozin (n=76)
Mean Age (years)	59.7 ± 9.3	60.6 ± 9.8
Gender (Male/Female)	40/36	40/36

Mean duration of diabetes (years)	8.4 ± 3.2	8.1 ± 3.5
BMI (kg/m²)	25.2 ± 2.4	24.9 ± 2.6

3.2 Glycaemic Control

Table 2. Comparison of glycaemic parameters before and after treatment

Parameter	Sitagliptin (Before → After)	Dapagliflozin (Before → After)
HbA1c (%)	8.87 → 7.67	8.85 → 7.67
RBS (mg/dL)	182.47 → 127.73	187.22 → 123.53
FBS (mg/dL)	137.70 → 100.62	136.39 → 103.17
PPBS (mg/dL)	203.36 → 148.57	208.20 → 146.57

3.3 Paired Sample T Test

Table 3: Paired Sample t-Test Results for Glycemic Parameters

Paired Samples Statistics					
		Mean	N	Std. Deviation	P value
Pair 1	HbA1c	8.86	152	0.866	<0.001
	HbA1c After	7.668	152	0.9994	
Pair 2	PPBS	205.78	152	41.457	<0.001
	PPBS After	147.57	152	20.191	
Pair 3	FBS	137.05	152	23.036	<0.001
	FBS After	101.89	152	10.946	

This table presents paired sample statistics for HbA1c, PPBS, and FBS. All parameters showed statistically significant improvements post-treatment ($P < 0.001$), validating the efficacy of both drugs in glycemic management. There was a statistically significant improvement in all glycemic parameters post-treatment ($p < 0.001$).

3.4 Independent T Test

Table 4: Independent T-Test Comparing Post-Treatment Parameters

Group Statistics					
Variables		N	Mean	Std. Deviation	P value
RBS After	Sitagliptin	76	131.42	18.073	0.625
	Dapagliflozin	76	129.93	19.361	
FBS After	Sitagliptin	76	100.62	11.100	0.496
	Dapagliflozin	76	103.17	10.711	
PPBS After	Sitagliptin	76	148.57	20.123	0.035
	Dapagliflozin	76	146.57	20.343	
HbA1c After	Sitagliptin	76	7.668	0.9915	0.026
	Dapagliflozin	76	7.667	1.0138	
Potassium after	Sitagliptin	76	5.1616	0.57257	0.044
	Dapagliflozin	76	5.3062	0.56147	

The independent T-test was used to assess the significance of differences between the two groups.

- RBS and FBS post-treatment did not show statistically significant differences between the groups ($p = 0.625$ and $p = 0.496$, respectively).
- PPBS levels showed a statistically significant reduction in the Dapagliflozin group compared to Sitagliptin ($p = 0.035$), indicating better postprandial glycemic control.
- HbA1c levels were nearly equal in both groups, but Dapagliflozin maintained slightly lower values, showing significance ($p = 0.026$).
- Serum potassium levels post-treatment were significantly lower in the Dapagliflozin group ($p = 0.044$), suggesting a safer electrolyte profile and lower risk of hyperkalemia.

Interpretation: Dapagliflozin demonstrated significantly better control of postprandial blood sugar and reduced potassium levels, indicating enhanced glycemic control and renal-electrolyte safety.

3.5 Severity of Hyperkalaemia

Hyperkalaemia severity was analyzed using the Chi-square test. Among Sitagliptin users, 7 (9.2%) patients developed moderate hyperkalaemia (5.6–6.0 mmol/L), compared to 4 (5.2%) in the Dapagliflozin group. No severe hyperkalaemia (>6.0 mmol/L) cases

were recorded. The difference in hyperkalaemia distribution was statistically significant (p = 0.032), favoring Dapagliflozin for better potassium balance.

Table 5. Severity of hyperkalaemia among study participants

Severity	Sitagliptin (n)	Dapagliflozin (n)	Total
None	50	41	91
Mild	19	27	46
Moderate	7	4	11

3.6 Adverse Effects

Both agents were well tolerated. Common non-serious adverse events included nausea and fatigue. No significant difference was found in adverse effect frequency between groups (p=0.817).

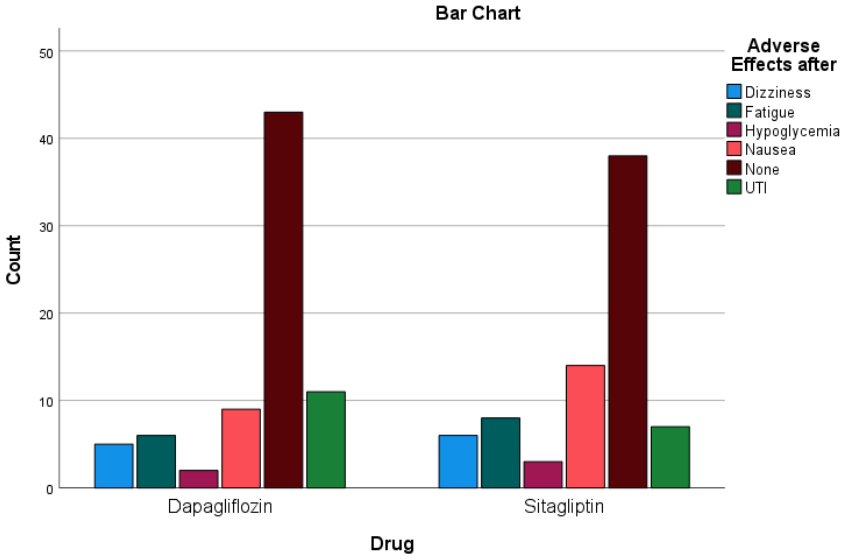

Figure 1: Bar Chart Representing Drug vs. Adverse Effects

DISCUSSION

The findings of this study demonstrate that both Sitagliptin and Dapagliflozin are effective and well-tolerated therapeutic options in patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD). Significant reductions in HbA1c, fasting, and postprandial glucose levels were observed in both groups, confirming their glycaemic efficacy ($p < 0.001$). However, Dapagliflozin provided superior postprandial glucose control and exhibited favorable effects on potassium regulation compared with Sitagliptin.

These findings are in line with large-scale studies and meta-analyses that have highlighted the renoprotective and cardioprotective roles of SGLT2 inhibitors. Trials such as DAPA-CKD and analyses by Fu et al. (2024) confirmed that Dapagliflozin not only improves glycaemic control but also lowers the risk of hyperkalaemia and hospitalization for heart failure [2][4]. The potassium-lowering effect observed may be attributed to its natriuretic and osmotic diuretic mechanisms, which promote renal potassium excretion and intravascular volume balance.

Conversely, Sitagliptin, a DPP-4 inhibitor, showed stable potassium levels and effective glycaemic control, supporting its safety in mild to moderate CKD. Previous studies, including the CompoSIT-R trial, have reported similar findings, establishing Sitagliptin as a reliable alternative in elderly or renally impaired patients [5].

The reduced incidence of moderate hyperkalaemia in the Dapagliflozin group ($p = 0.032$) supports its emerging role in potassium homeostasis, complementing its renal and cardiovascular benefits. These observations collectively affirm that SGLT2 inhibitors may be preferred in diabetic kidney disease where hyperkalaemia poses a therapeutic challenge, while DPP-4 inhibitors remain an appropriate option when SGLT2 inhibitors are contraindicated.

Overall, this study reinforces the growing clinical consensus that integrating Dapagliflozin into the management of T2DM with CKD offers both metabolic and renal advantages. Nevertheless, larger, long-term randomized studies are warranted to evaluate sustained potassium outcomes and cardiovascular mortality effects in diverse patient populations.

CONCLUSION

This study compared the safety and efficacy of Dapagliflozin and Sitagliptin in patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD), focusing on the risk of hyperkalemia. Both agents produced significant reductions in glycemic parameters, including HbA1c, fasting, and postprandial blood glucose ($p < 0.001$), confirming strong glucose-lowering efficacy. However, Dapagliflozin demonstrated superior postprandial glycemic control and better renal-electrolyte outcomes, with a decline in serum potassium from 5.33 to 5.16 mmol/L and fewer cases of moderate hyperkalemia ($p = 0.032$). Sitagliptin achieved comparable HbA1c improvement (7.67%) but showed a minimal rise in potassium levels (5.29 to 5.31 mmol/L). Both therapies were well tolerated, with no significant differences in adverse events ($p = 0.817$). These findings align with prior evidence suggesting SGLT2 inhibitors such as Dapagliflozin reduce hyperkalemia risk while maintaining renal protection [2][4]. Overall, Dapagliflozin appears to

provide a broader therapeutic advantage through effective glycemic control, renal safety, and improved potassium regulation. Sitagliptin remains a reliable alternative, particularly for elderly patients or those with mild kidney impairment. Therefore, individualized therapy selection remains essential, emphasizing both glycemic efficacy and electrolyte stability in T2DM with CKD.

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