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PROSPECTIVE COMPARATIVE EFFECTIVENESS OF SITAGLIPTIN AND DAPAGLIFLOZIN IN ADULT PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

Type 2 Diabetes Mellitus is a chronic and advancing metabolic disease that shows the defining characteristic features of chronic hyperglycemia, raised risk of cardiovascular and microvascular outcomes. The latest oral anti-diabetic medications that have gained prevalence because of their better safety and efficacy evidence are dipeptidyl peptidase-4 (DPP-4) inhibitors Type and sodium-glucose co-transporter-2 (SGLT2) inhibitors. The safety and efficacy of dapagliflozin versus sitagliptin in patients with type 2 diabetes were systematically assessed. To determine and compare the impact of sitagliptin and dapagliflozin on the safety profile, glycemic control and a few clinical and demographic variables like age, gender, family history, and duration of diabetes. A total of 120 individuals with T2DM aged 25 to 70 years with HbA1c levels of 7% to 10% were chosen for this study. Patients were unbiased divided into two equal batches and received either dapagliflozin (n = 60) or sitagliptin (n = 60). Glycemic variables including fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c levels were assessed at baseline and during follow-up. SPSS software package was used to execute the statistical analysis. Dapagliflozin was statistically more in therapeutic efficacy than in sitagliptin, while sitagliptin was more therapeutically effective in managing postprandial glucose levels. Dapagliflozin was more effective than sitagliptin in maintaining overall glycemic control and additional metabolic outcomes in patients with type 2 diabetes mellitus.

Keywords: *Diabetes mellitus, Sitagliptin, Dapagliflozin, Glycemic control, HbA1c levels, Insulin.*

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INTRODUCTION

Diabetes mellitus is a chronic metabolic disease that is defined by hyperglycemia due to defects in insulin secretion, insulin action, or both. Of all the types of diabetes, type 2 diabetes mellitus (T2DM) contributes to approximately 90% of the total number of cases of diabetes worldwide, and it has become a serious and growing public health problem [1,2]. The disease is also known to be associated with high morbidity and mortality rates owning its serious complications, such as retinopathy, nephropathy, neuropathy, cardiovascular disease and peripheral vascular disease [3]. As per the International Diabetes Federation (IDF), it is estimated that in 2021, 537 million adults worldwide are living with diabetes, and this number is expected to increase to 643 million by 2030, and most of these cases are found in developing countries [4,5]. The management of T2DM has evolve over the years from conventional therapies like metformin, sulphonyl urea and insulin to the use of newer classes of drugs that target different pathophysiological mechanisms [6]. Two of these classes, dipeptidyl peptidase-4 (DPP-4) inhibitors and sodium-glucose cotransporter 2 (SGLT-2) inhibitors, have received considerable attention due of their attractive efficacy, safety, and tolerability profiles [7,8].

Sitagliptin, a DPP-4 inhibitor, works by enhancing the action of the body's natural incretin hormones, such as glucagon-like peptide-1 (GLP-1) and glucose-dependent

insulinotropic polypeptide (GIP) [7]. Dapagliflozin (SGLT-2 inhibitor) acts by inhibiting renal glucose reabsorption which increases urinary glucose excretion. This insulin-independent action of the drug provides several metabolic benefits, such as a weight loss, reduce in blood pressure, and improvement in cardiovascular and renal outcomes which shows evident from various clinical trials [9-11]. These differences underscore the importance of more evidence to inform rational drug choice according to patient characteristics and therapeutic objectives. Although there exist a large number of clinical trials assessing the efficacy of sitagliptin and dapagliflozin separately, there is a relative paucity of direct comparative data between the two drugs [12-14]. Most of the existing trials are of short duration, retrospective or performed in controlled settings that may not reflect actual clinical practice [15-17] Moreover, real-world prospective information regarding their comparative effectiveness, safety and overall impact on metabolic parameters in different patient populations is also scarce [18-20].

In view of the current focus on personalized and evidence-driven diabetes management, it was important for clinicians to have access to comparative data to help identify the drug class that may potentially provide additional benefits for a given patient population [21,22]. A prospective comparative assessment of sitagliptin and dapagliflozin is therefore the need of the hour to obtain clinically accurate meaningful evidence about the relative efficacy of these two drugs in lowering HbA1c and their impact on fasting and postprandial glucose levels, body weight, and adverse effects. This study proposes to fill this gap in existing knowledge by making a comparative assessment of the efficacy and safety to sitagliptin and dapagliflozin in patients with type 2 diabetes mellitus [23-25].

METHODOLOGY

Study Design and Setting

A prospective observational study was conducted at the department of diabetology, Sahana multi-speciality hospital, Chittoor, Andhra Pradesh, India. The study compared the real-world effectiveness and safety of sitagliptin and dapagliflozin in patient with type 2 diabetes mellitus (T2DM). This study protocol was reviewed and approved by the Institutional Ethical Committee (IEC) prior to initiation.

Study Duration

The study was carried out over a period of six months from November 2024 to May 2025.

Study Population

A total of 120 patients diagnosed with T2DM were enrolled and equally allocated into two groups: Sitagliptin group (n = 60) and Dapagliflozin group (n = 60) Both inpatients and outpatients attending the diabetology department were included.

Eligibility Criteria

Inclusion criteria:

- Patients aged 25 – 70 years.
- Diagnosed cases of T2DM.
- HbA1c levels between >7% and <10%.
- Patients receiving either sitagliptin or dapagliflozin as part of their treatment regimen.
- Patients willing to provide informed consent.

Exclusion criteria:

- Patient with type 1 diabetes mellitus or gestational diabetes and other co-morbidities.
- Patients with severe renal impairment.
- Patients with known hypersensitivity to sitagliptin or dapagliflozin.

Data Collection

Data were collected using a structured, pre-validated questionnaire through direct patient interviews and medical record reviews. Confidentiality and privacy of patients were strictly maintained.

Baseline Assessment

- Demographic data (age, gender).
- Social and family history.
- Duration of diabetes.

Laboratory parameters

- Fasting blood sugar (FBS)
- Post-prandial blood sugar (PPBS)
- Glycated haemoglobin (HbA1c).

Follow-Up Assessment

Patients were followed up at 1 month, 3 months, 6 months, during which:

- FBS, PPBS and HbA1c levels were reassessed.
- Adverse drug reactions and safety parameters were monitored.

Outcome Measures

- Primary outcome: Change in glycemic parameters (HbA1c, FBS, PPBS) from baseline to 6 months.
- Secondary outcome: Incidence of adverse drug reactions and association of demographic variables with treatment outcomes.

Statistical Analysis

Data were entered and analysed using SPSS software and Microsoft excel. Descriptive statistics were used to summarize demographic and clinical characteristics. Paired t-test was applied to compare pre and post-treatment glycemic values. Independent t-test was used to compare outcomes between the two treatment groups. Chi-square test was used to assess associations between categorical variables. The p- values <0.05 was considered statistically significant.

RESULTS

Descriptive Analysis

A total of 120 patients with type 2 diabetes mellitus were enrolled and equally distributed between the Sitagliptin (n=60) and Dapagliflozin (n=60) groups. The balanced allocation ensured appropriate comparability for outcome assessment.

Glycaemic parameters

Significant improvements were observed in all glycemic parameters following treatment initiation. Fasting blood sugar (FBS) decreased from 140.20 ± 25.68 mg/dL to

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83.11 ± 7.15 mg/dl ($p < 0.001$). Postprandial blood sugar (PPBS) decreased from 223.53 ± 37.79 mg/dL to 108.23 ± 17.26 mg/ dL ($p < 0.001$). HbA1c levels improved from 7.49 ± 0.52% to 6.60 ± 0.52% ($p < 0.001$). Increased urination was reported by 26.7% of patients, with a comparable frequency in both the sitagliptin (28.3%) and dapagliflozin (25%) groups. Most patients (73.3%) did not report this side effect.

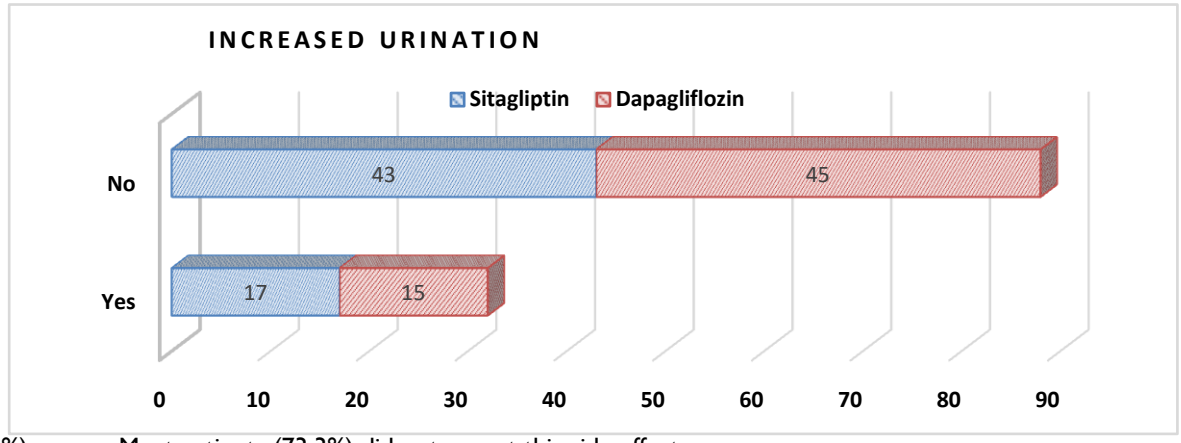

Figure 01: Comparison of increased urination between sitagliptin and dapagliflozin

Swelling of feet was reported by 21.7% of patients, slightly more in the Sitagliptin group (25%) compared to the Dapagliflozin group (18.3%). Most patients (78.3%) did not report this side effect.

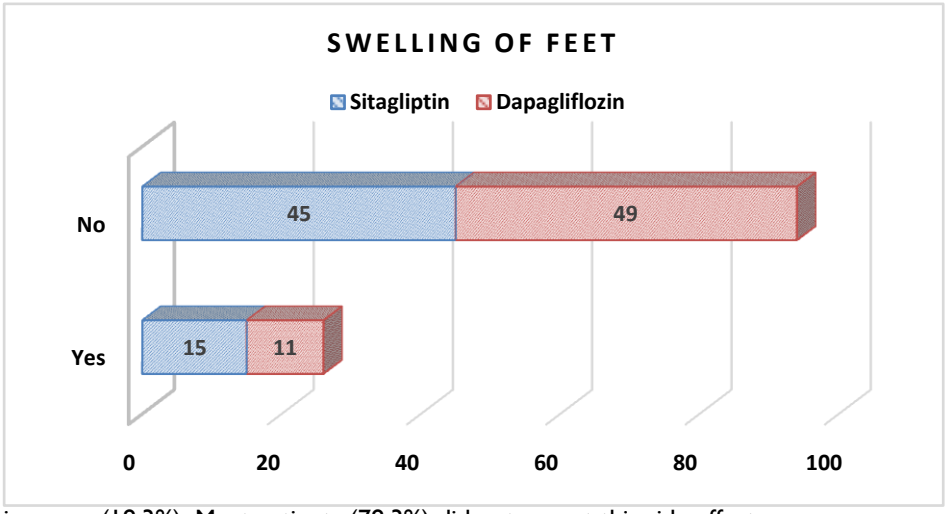

Figure 02: Comparison of swelling of feet between sitagliptin and dapagliflozin

Significant improvements were observed in all glycemic parameters following treatment initiation which are given in table 01.

Table 01: Significant improvements in glycemic Parameters

Descriptive Statistics					
Variables	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Age	120	27.00	75.00	49.98	12.74
Duration of T2DM (Years)	120	0.60	15.00	5.87	3.00
Systolic Blood Pressure	120	98.00	136.00	117.93	9.12
Diastolic Blood Pressure	120	60.00	90.00	78.20	6.76
FBS Before Drug	120	96.00	198.00	140.20	25.68
PPBS Before Drug	120	148.00	310.00	223.53	37.79
HbA1C Before Drug	120	6.50	8.60	7.49	0.52
FBS After Drug	120	70.00	99.00	83.11	7.15
PPBS After Drug	120	73.00	140.00	108.23	17.26
HbA1C After Drug	120	5.50	8.00	6.60	0.52

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The **mean age** of participants was **49.98 ± 12.74 years**, ranging from 27 to 75 years. The **average duration of type 2 diabetes** was **5.87 ± 3.00 years**, indicating a predominantly mid-duration diabetic population. Baseline mean **systolic and diastolic blood pressures** were **117.93 ± 9.12 mmHg** and **78.20 ± 6.76 mmHg**, respectively. Significant improvement was observed in glycemic parameters **after drug therapy**: **FBS decreased** from **140.20** to **83.11 mg/dL PPBS dropped** from **223.53** to **108.23 mg/dL HbA1C improved** from **7.49%** to **6.60%.** These findings suggest effective glycemic control following therapy initiation across the study population.

Comparative Effectiveness

Independent sample t-tests revealed no significant differences in baseline FBS, PPBS, or HbA1c between the two groups. However, post-treatment comparisons showed: Dapagliflozin shows significantly lowering FBS (78.88 ± 5.98 mg/dL) compared to sitagliptin (87.35 ± 5.55 mg/dL) ($p < 0.001$). Sitagliptin shows more postprandial glucose control (102.96 ± 17.49 mg/dL) compared to dapagliflozin (113.55 ± 15.42 mg/dL) ($p < 0.001$). HbA1c reduction was significantly greater with dapagliflozin (6.41 ± 0.44%) than sitagliptin (6.79 ± 0.52%) ($p < 0.001$).

Table 02: Paired T Test (Pre vs Post) FBS, PPBS, HbA1C

Paired Samples Test									
Parameters		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	FBS Before Drug - FBS After Drug	57.08	22.27	2.03	53.05	61.11	28.06	119	<0.001
Pair 2	PPBS Before Drug - PPBS After Drug	115.20	28.58	2.60	110.10	120.44	44.16	119	<0.001
Pair 3	HbA1C Before Drug - HbA1CAfter Drug	0.88	0.28	0.02	0.83	0.94	34.30	119	<0.001

This paired analysis compares glycemic values before and after drug intervention across all 120 patients.

1. Fasting Blood Sugar (FBS)

- Before: 140.20 ± 25.68 mg/dL
- After: 83.12 ± 7.15 mg/dL
- Mean difference: 57.08 mg/dL
- $p < 0.001$
- Significant reduction in FBS post-treatment. The result is statistically and clinically meaningful.

2. Postprandial Blood Sugar (PPBS)

- Before: 223.53 ± 37.79 mg/dL
- After: 108.26 ± 17.26 mg/dL
- Mean difference: 115.20 mg/dL
- $p < 0.001$
- A large and statistically significant drop in PPBS, indicating effective post-meal glucose control.

3. HbA1C

- Before: 7.50 ± 0.52%
- After: 6.61 ± 0.52%
- Mean difference: 0.88%
- $p < 0.001$
- HbA1C levels showed a highly significant improvement, confirming long-term glycemic control.

There is a statistically significant reduction in all three glycemic parameters-FBS, PPBS, and HbA1C-after drug therapy. Correlations between pre- and post-values are moderate to strong (FBS r = 0.58, PPBS r = 0.69, HbA1C r = 0.85), showing the consist therapeutic effect. This confirms the effectiveness of the anti-diabetic medications in improving glycemic control [5,6].

Regarding patients with type 2 diabetes mellitus, the findings from this prospective observational study on the real-world efficacy of dapagliflozin, an SGLT2 inhibitor, and sitagliptin, a DPP-4 inhibitor, suggest that dapagliflozin has better glycemic control and additional metabolic benefits over sitagliptin. [26]

Moreover, during the study period, patients receiving dapagliflozin showed better cardiovascular parameters, greater weight reduction, and substantial reduction in HbA1c levels. [27]. Dapagliflozin was associated with statistically significant reductions in systolic blood pressure and body weight, which are not commonly observed with sitagliptin. The prevalence of obesity and hypertension in T2DM patients makes these secondary benefits highly relevant. Notably, these findings are in line with previous studies showing that SGLT2 inhibitors are associated with cardio-renal protection, which is becoming increasingly important in the management of diabetes [28].

By contrast, the efficacy of sitagliptin appears to reach a plateau, particularly in patients with higher baseline

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HbA1c levels or co-existing metabolic syndrome, despite being well-tolerated and providing moderate benefits in glycemic parameters [29]. The results of the study concludes that dapagliflozin is a preferable treatment to sitagliptin in patients with type 2 diabetes, particularly those requiring weight loss and cardiovascular outcomes in addition to glycemic control. The results of this study confirm the growing evidence that SGLT2 inhibitors are a crucial part of modern diabetic therapy [30].

CONCLUSION

The efficacy of dapagliflozin and sitagliptin in managing patients with type 2 diabetes mellitus (T2DM) was compared in prospective observational research. The reduction in body weight, systolic blood pressure, and HbA1c levels was the primary outcome measure. The study showed that dapagliflozin was superior to sitagliptin in achieving these objectives. Specially, dapagliflozin showed an increase in the proportion of patients who achieved a complete response of HbA1c, body weight, and systolic blood pressure. Moreover, dapagliflozin was associated with greater reduction in body weight compared with sitagliptin.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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