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COMPARISON OF EFFICACY OF DAPAGLIFLOZIN METFORMIN VERSUS SITAGLIPTIN METFORMIN IN NEWLY DIAGNOSED TYPE 2 DIABETES

Original Research

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and progressive β-cell dysfunction, necessitating effective pharmacological interventions to achieve optimal glycemic control. While metformin is the first-line therapy, adjunct agents such as sodium-glucose co-transporter-2 (SGLT2) inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors are increasingly utilized. Dapagliflozin, an SGLT2 inhibitor, has demonstrated glycemic benefits along with weight loss, whereas sitagliptin, a DPP-4 inhibitor, primarily enhances insulin secretion. Limited data exist comparing these two regimens in newly diagnosed T2DM patients, particularly in the Pakistani population.

Objective: To compare the efficacy and safety of dapagliflozin plus metformin versus sitagliptin plus metformin in newly diagnosed T2DM patients, focusing on glycemic control, weight loss, and adverse effects.

Methods: This randomized controlled trial was conducted at the Endocrinology Department of Nishtar Hospital, Multan, from March 2023 to August 2023. A total of 130 newly diagnosed T2DM patients aged 18–65 years with HbA1c between 7.0–10.0% and BMI 25–40 kg/m² were randomized 1:1 to receive either dapagliflozin (10 mg) plus metformin (500 mg twice daily) or sitagliptin (100 mg) plus metformin (500 mg twice daily) for 12 weeks. Primary outcome was the change in HbA1c, while secondary outcomes included fasting blood glucose (FBG), postprandial blood glucose (PPG), weight loss, lipid profile, and safety assessments. Statistical analysis was performed using SPSS version 26.0, with a p-value <0.05 considered statistically significant.

Results: The dapagliflozin-metformin group demonstrated significantly greater reductions in FBG (128.4 ± 18.5 mg/dL vs. 145.2 ± 21.4 mg/dL, p = 0.001), PPG (179.5 ± 24.7 mg/dL vs. 202.1 ± 26.2 mg/dL, p = 0.004), and HbA1c (7.4 ± 1.0% vs. 8.2 ± 1.2%, p = 0.001) compared to the sitagliptin-metformin group. Weight loss was also significantly greater in the dapagliflozin group (4.2 ± 1.5 kg vs. 1.8 ± 1.2 kg, p < 0.001). The incidence of urinary tract infections was higher in the dapagliflozin group (10.8% vs. 3.1%, p = 0.048), while other adverse effects were comparable between groups.

Conclusion: Dapagliflozin plus metformin was superior to sitagliptin plus metformin in improving glycemic control and promoting weight loss in newly diagnosed T2DM patients. These findings suggest that dapagliflozin may be a more effective early-stage treatment option, particularly for individuals requiring weight management. Further long-term studies are warranted to confirm these benefits and assess their durability over time.

Keywords: Blood Glucose, Dapagliflozin, Diabetes Mellitus Type 2, Glycated Hemoglobin A, Metformin, Sitagliptin, Weight Loss.

INTRODUCTION

Type 2 diabetes (T2D) is a chronic metabolic disorder characterized by insulin resistance and relative insulin deficiency, contributing to a global rise in morbidity and mortality. Driven by factors such as obesity, aging, and sedentary lifestyles, the prevalence of T2D continues to escalate, with over 460 million individuals affected worldwide—a figure projected to rise significantly in the coming decades (1-3). Among the available pharmacological interventions, metformin remains the first-line treatment due to its established efficacy, favorable safety profile, and ability to lower hepatic glucose production. However, to achieve optimal glycemic control, many patients require combination therapy, with two commonly prescribed classes being sodium-glucose co-transporter-2 (SGLT2) inhibitors, such as dapagliflozin, and dipeptidyl peptidase-4 (DPP-4) inhibitors, such as sitagliptin (4,5). Dapagliflozin, an SGLT2 inhibitor, reduces blood glucose levels by inhibiting renal glucose reabsorption, leading to increased urinary glucose excretion. This mechanism not only facilitates glycemic control but also confers additional benefits, including weight loss and blood pressure reduction, which are particularly advantageous in T2D management (6). Furthermore, dapagliflozin has demonstrated cardiovascular and renal protective effects, making it a valuable therapeutic option for patients with comorbidities. In contrast, sitagliptin, a DPP-4 inhibitor, enhances endogenous insulin secretion and suppresses glucagon release in a glucose-dependent manner. By blocking the breakdown of incretin hormones such as glucagon-like peptide-1 (GLP-1) and gastric inhibitory polypeptide (GIP), sitagliptin improves postprandial insulin response while reducing hepatic glucose production, thereby minimizing the risk of hypoglycemia (7,8,9). Despite the widespread use of both dapagliflozin-metformin and sitagliptin-metformin combinations, there remains a lack of direct comparative studies assessing their relative efficacy, particularly in newly diagnosed T2D patients.

Existing literature highlights the potential advantages of dapagliflozin in providing cardiovascular and renal protection, while sitagliptin is recognized for its well-tolerated safety profile with minimal risk of hypoglycemia (10). However, real-world data comparing these treatment regimens, especially within the South Asian population, remains scarce. Given the increasing burden of diabetes in Pakistan, an evidence-based comparison of these drug combinations is essential to guide clinical decision-making and optimize treatment strategies tailored to the local population. This study aims to evaluate and compare the efficacy of dapagliflozin-metformin versus sitagliptin-metformin in newly diagnosed T2D patients, addressing gaps in regional data and contributing to personalized diabetes care. The findings will not only help determine which combination offers superior glycemic control but also assess their cost-effectiveness and accessibility, ultimately informing clinical practice and improving patient outcomes in resource-limited settings.

METHODS

This study was a randomized controlled trial (RCT) conducted at the Endocrinology Department of Nishtar Hospital, Multan, from March 23 to August 23. Ethical approval was obtained from the Institutional Review Board (IRB), and all participants provided written informed consent before enrollment. The study adhered to ethical principles outlined in the Declaration of Helsinki, ensuring participant confidentiality and adherence to research guidelines. Sample size estimation was performed using statistical power analysis, with a total of 130 patients (65 in each group) determined as necessary to detect a clinically meaningful 0.5% difference in glycated hemoglobin (HbA1c) reduction, assuming a significance level of 0.05 and a power of 80% (10). Patients aged 18 to 65 years with newly diagnosed type 2 diabetes mellitus (T2D) were recruited based on predefined eligibility criteria. Inclusion criteria required a confirmed diagnosis of T2D, an HbA1c level between 7.0% and 10.0%, and a body mass index (BMI) between 25 and 40 kg/m². Individuals with type 1 diabetes, significant renal impairment (estimated glomerular filtration rate < 45 mL/min/1.73 m²), cardiovascular disease, or active infections were excluded. Additionally, pregnant or lactating women and those with a history of severe hypoglycemia or hypersensitivity to any study drug were not eligible for participation.

Participants were randomly assigned in a 1:1 ratio to receive either dapagliflozin (10 mg) with metformin (500 mg twice daily) or sitagliptin (100 mg) with metformin (500 mg twice daily). Randomization was performed using a computer-generated sequence to minimize selection bias. The primary outcome measure was the change in HbA1c from baseline to 12 weeks. Secondary outcomes included changes in fasting blood glucose (FBG), postprandial blood glucose (PPG), and lipid profiles. Safety assessments involved monitoring adverse events, renal function (serum creatinine and estimated glomerular filtration rate), and the occurrence of

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hypoglycemic episodes. The study duration was 12 weeks, with follow-up visits scheduled at baseline, 4 weeks, 8 weeks, and the study endpoint. At each visit, clinical parameters such as body weight, blood pressure, and laboratory investigations—including HbA1c, FBG, PPG, lipid profiles, serum creatinine, and estimated glomerular filtration rate (eGFR)—were recorded. Data analysis was performed using SPSS version 26.0. Between-group comparisons were conducted using independent t-tests for continuous variables and chi-square tests for categorical variables. Statistical significance was set at a p-value of <0.05. This study was designed to ensure methodological rigor by employing strict inclusion and exclusion criteria, standardized treatment protocols, and objective outcome assessments. The findings aim to provide clinically relevant insights into the comparative efficacy and safety of dapagliflozin-metformin versus sitagliptin-metformin in newly diagnosed T2D patients, contributing to evidence-based treatment strategies in the local population.

RESULTS

The mean age of participants was 53.9 ± 7.9 years, with a male predominance of 61.5%. The mean BMI was 28.2 ± 3.5 kg/m², and the average duration of diabetes was 2.6 ± 1.1 months. Baseline HbA1c was recorded at 9.2 ± 1.4%, reflecting poor glycemic control at study initiation. Both treatment groups exhibited similar baseline glycemic parameters, with fasting blood glucose levels of 172.5 ± 25.6 mg/dL and 171.2 ± 24.7 mg/dL (p = 0.812), postprandial blood glucose levels of 238.3 ± 30.4 mg/dL and 240.1 ± 32.1 mg/dL (p = 0.825), and HbA1c levels of 9.3 ± 1.5% and 9.1 ± 1.3% (p = 0.528) in the dapagliflozin-metformin and sitagliptin-metformin groups, respectively. After 12 weeks, a significantly greater reduction in glycemic parameters was observed in the dapagliflozin-metformin group compared to the sitagliptin-metformin group. Fasting blood glucose levels decreased to 128.4 ± 18.5 mg/dL in the dapagliflozin group and 145.2 ± 21.4 mg/dL in the sitagliptin group (p = 0.001). Postprandial blood glucose values dropped to 179.5 ± 24.7 mg/dL and 202.1 ± 26.2 mg/dL, respectively (p = 0.004). HbA1c improved significantly, with values reaching 7.4 ± 1.0% in the dapagliflozin group versus 8.2 ± 1.2% in the sitagliptin group (p = 0.001). Body weight reduction was significantly greater in the dapagliflozin-metformin group, with an average weight loss of 4.2 ± 1.5 kg, compared to 1.8 ± 1.2 kg in the sitagliptin-metformin group (p < 0.001).

Adverse effects were generally mild, with urinary tract infections occurring more frequently in the dapagliflozin-metformin group (10.8%) compared to the sitagliptin-metformin group (3.1%, p = 0.048). Although diarrhea was more common in the dapagliflozin group (12.3%) compared to the sitagliptin group (4.6%), this difference was not statistically significant (p = 0.063). Other adverse events, including nausea (7.7% vs. 6.2%, p = 0.764), hypoglycemia (4.6% vs. 9.2%, p = 0.389), and edema (6.2% vs. 1.5%, p = 0.257), were comparable between the groups. No statistically significant differences were noted in lipid profile changes between the two groups. Total cholesterol levels were 201.6 ± 15.3 mg/dL in the dapagliflozin group and 210.4 ± 17.5 mg/dL in the sitagliptin group (p = 0.074). LDL cholesterol levels were recorded at 110.3 ± 12.7 mg/dL and 115.9 ± 14.2 mg/dL, respectively (p = 0.071). HDL cholesterol levels were comparable between the groups at 52.1 ± 7.9 mg/dL and 51.4 ± 7.3 mg/dL (p = 0.654), as were triglyceride levels (158.3 ± 27.6 mg/dL vs. 162.5 ± 30.1 mg/dL, p = 0.451).

Table 1: Demographic and Baseline Characteristics of All Study Participants (n = 130)

Characteristic	Category	Value (Mean ± SD)
Age (years)	Mean±SD	53.9 ± 7.9
Gender	Male	80 (61.5%)
	Female	50 (38.5%)
BMI (kg/m²)	Mean±SD	28.2 ± 3.5
Duration of Diabetes (months)	Mean±SD	2.6 ± 1.1
HbA1c (%)	Mean±SD	9.2 ± 1.4

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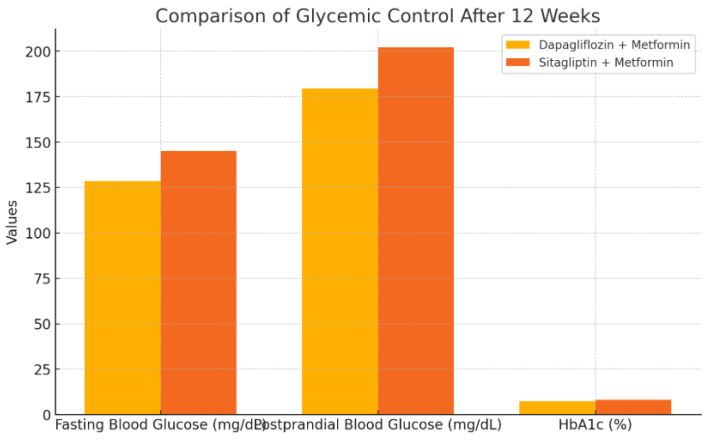
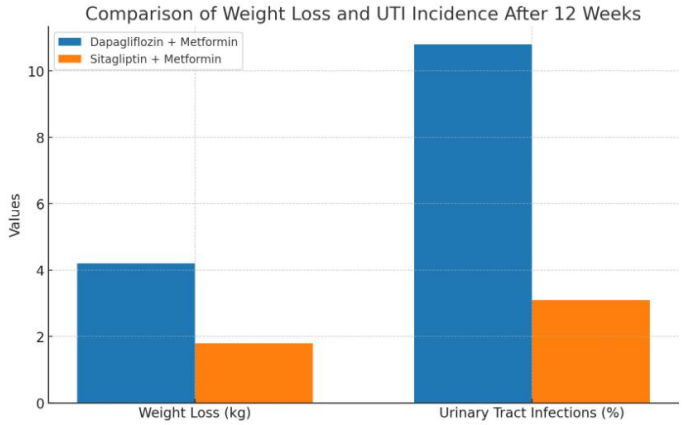
Table 2: Comparison of Glycemic Control and Weight Loss Between Treatment Groups

Parameter	Dapagliflozin + Metformin (n = 65)	Sitagliptin + Metformin (n = 65)	p-value
Fasting Blood Glucose (mg/dL) - Baseline	172.5 ± 25.6	171.2 ± 24.7	0.812
Fasting Blood Glucose (mg/dL) - 12 Weeks	128.4 ± 18.5	145.2 ± 21.4	0.001
Postprandial Blood Glucose (mg/dL) - Baseline	238.3 ± 30.4	240.1 ± 32.1	0.825
Postprandial Blood Glucose (mg/dL) - 12 Weeks	179.5 ± 24.7	202.1 ± 26.2	0.004
HbA1c (%) - Baseline	9.3 ± 1.5	9.1 ± 1.3	0.528
HbA1c (%) - 12 Weeks	7.4 ± 1.0	8.2 ± 1.2	0.001
Weight Loss (kg) - 12 Weeks	4.2 ± 1.5	1.8 ± 1.2	<0.001
Change in Lipid Profile After 12 Weeks			
Total Cholesterol (mg/dL)	201.6 ± 15.3	210.4 ± 17.5	0.074
LDL Cholesterol (mg/dL)	110.3 ± 12.7	115.9 ± 14.2	0.071
HDL Cholesterol (mg/dL)	52.1 ± 7.9	51.4 ± 7.3	0.654
Triglycerides (mg/dL)	158.3 ± 27.6	162.5 ± 30.1	0.451

Table 3: Comparison of Side Effects Between Treatment Groups (n = 130)

Side Effect	Dapagliflozin + Metformin (n = 65)	Sitagliptin + Metformin (n = 65)	p-value
Nausea	5 (7.7%)	4 (6.2%)	0.764
Diarrhea	8 (12.3%)	3 (4.6%)	0.063
Hypoglycemia	3 (4.6%)	6 (9.2%)	0.389
Urinary Tract Infections (UTI)	7 (10.8%)	2 (3.1%)	0.048
Edema	4 (6.2%)	1 (1.5%)	0.257





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DISCUSSION

Type 2 diabetes mellitus (T2D) is a progressive metabolic disorder characterized by insulin resistance and β-cell dysfunction, necessitating individualized treatment strategies to optimize glycemic control and reduce complications. The rising prevalence of T2D has placed an increasing burden on healthcare systems, reinforcing the need for effective and well-tolerated therapeutic options. While metformin remains the cornerstone of first-line therapy, adjunct agents such as sodium-glucose co-transporter-2 (SGLT2) inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors have gained prominence due to their distinct mechanisms of action. The current study aimed to compare the efficacy and safety of dapagliflozin-metformin versus sitagliptin-metformin in newly diagnosed T2D patients, providing insights into their comparative benefits in real-world clinical settings (11-13). The findings demonstrated a significant reduction in glycemic parameters in both treatment groups, with superior outcomes observed in the dapagliflozin-metformin cohort. Fasting blood glucose and postprandial blood glucose levels were significantly lower in the dapagliflozin group after 12 weeks, with a greater reduction in HbA1c compared to the sitagliptin-metformin combination. This aligns with prior research indicating that dapagliflozin, through its renal glucose excretion mechanism, provides enhanced glycemic control while concurrently offering additional metabolic benefits. The ability of dapagliflozin to lower glucose levels independently of insulin secretion further distinguishes it as a potent therapeutic option, particularly in patients with progressive β-cell dysfunction. In contrast, sitagliptin primarily exerts its effect by enhancing endogenous insulin secretion and suppressing glucagon release in a glucose-dependent manner. Although effective, this mechanism may have contributed to the comparatively modest reduction in glycemic indices observed in the sitagliptin group (14-16).

Beyond glycemic control, weight reduction emerged as a notable advantage of dapagliflozin. The dapagliflozin-metformin group exhibited a significantly greater reduction in body weight compared to the sitagliptin-metformin group, reinforcing the role of SGLT2 inhibitors in weight management. This weight loss is attributed to the glucosuric action of dapagliflozin, leading to calorie loss through urinary glucose excretion. Given the strong association between obesity and T2D progression, weight reduction confers additional metabolic benefits, including improved insulin sensitivity and cardiovascular risk reduction. Sitagliptin, by contrast, demonstrated a neutral effect on body weight, which is consistent with findings from previous studies indicating that DPP-4 inhibitors neither induce significant weight loss nor contribute to weight gain (18,19). The safety profile of both treatment regimens was largely favorable, with no severe adverse events reported. However, urinary tract infections (UTIs) were significantly more prevalent in the dapagliflozin-metformin group, an expected outcome given the increased urinary glucose excretion associated with SGLT2 inhibition. Despite this, the incidence of UTIs remained relatively low and did not necessitate treatment discontinuation. Other adverse events, such as nausea, diarrhea, and hypoglycemia, occurred at comparable rates between the two groups, suggesting that both drugs are generally well-tolerated in newly diagnosed T2D patients. The potential for increased infection risk with dapagliflozin highlights the importance of patient education regarding hydration and hygiene measures to mitigate this side effect (20).

Lipid profile changes did not differ significantly between the treatment groups, suggesting that neither dapagliflozin nor sitagliptin exerts a pronounced impact on lipid metabolism within the short-term follow-up period. Previous studies have shown that while SGLT2 inhibitors may contribute to modest improvements in lipid parameters, these effects are often more pronounced over longer durations. The absence of significant lipid changes in the present study may be attributed to the relatively short 12-week follow-up period, underscoring the need for extended studies to evaluate long-term cardiovascular effects (21). This study possesses several strengths, including its randomized design, direct comparison of two commonly used therapeutic regimens, and comprehensive evaluation of glycemic, metabolic, and safety outcomes. By focusing on newly diagnosed patients, the study provides valuable insights into the early-stage effectiveness of these combination therapies, which is crucial for guiding treatment decisions. However, certain limitations must be acknowledged. The follow-up duration was relatively short, precluding an assessment of long-term cardiovascular and renal benefits, which are increasingly recognized advantages of SGLT2 inhibitors. Additionally, the study was conducted at a single center, which may limit the generalizability of the findings to broader populations with varying demographic and clinical characteristics. Future research should incorporate multicenter trials with extended follow-up to confirm these findings and explore additional outcomes such as long-term β-cell function preservation and cost-effectiveness comparisons (12,18). The findings indicate that dapagliflozin-metformin is superior to sitagliptin-metformin in terms of glycemic control and weight reduction in newly diagnosed T2D patients. The safety profile of both regimens was generally comparable, although a higher incidence of UTIs was observed with dapagliflozin. These results support the preference for dapagliflozin as an effective early-stage treatment option, particularly in patients for whom weight loss is a therapeutic goal. Future studies with longer follow-up periods and broader patient populations are warranted to further elucidate the long-term benefits and optimize individualized treatment strategies for T2D management.

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CONCLUSION

The findings of this study highlight the superior efficacy of dapagliflozin combined with metformin in improving glycemic control and promoting weight loss compared to sitagliptin-metformin therapy in newly diagnosed type 2 diabetes patients. The enhanced glucose-lowering effects, along with the additional metabolic benefits observed, suggest that dapagliflozin may be a more effective early-stage treatment option, particularly for individuals requiring weight management. Both regimens demonstrated a favorable safety profile, though dapagliflozin was associated with a higher incidence of urinary tract infections. These results reinforce the role of individualized treatment approaches in diabetes management, emphasizing the potential advantages of SGLT2 inhibitors in optimizing long-term therapeutic outcomes.

Author Contribution

Author	Contribution
Humayun Riaz Khan*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Muhammad Sajid	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Tamoor Chughtai	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published

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