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Original Article

Dapagliflozin and Metformin Versus Sitagliptin and Metformin: A Battle for Better Glycemic Control in Type 2 Diabetes Mellitus

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a globally prevalent metabolic disorder requiring combination therapies for optimal glycemic control. Among oral agents, dapagliflozin and sitagliptin are commonly used as add-on treatments to metformin, but comparative efficacy data in South Asian populations remain limited. Objective: To compare the efficacy of dapagliflozin versus sitagliptin when combined with metformin in achieving glycemic control and weight reduction in patients with T2DM. Methods: In this randomized clinical trial, 60 adult patients with uncontrolled T2DM (HbA1c >7.5%) were randomly assigned to receive either dapagliflozin 10 mg plus metformin 850 mg twice daily (Group A) or sitagliptin 100 mg plus the same metformin regimen (Group B) for 12 weeks. Primary outcomes included change in HbA1c, fasting blood glucose (FBS), postprandial blood glucose (PPBS), and weight. Target achievement of HbA1c <7% and ≥3% weight reduction were assessed. Results: Group A showed greater reductions in HbA1c (−1.40% vs −0.91%, p<0.001), FBS (−28.00 vs −20.83 mg/dL, p=0.032), PPBS (−70.93 vs −53.83 mg/dL, p=0.029), and weight (−2.85 vs −2.11 kg, p=0.041). More patients in Group A achieved HbA1c <7% (76.7% vs 50%, p=0.032) and ≥3% weight loss (80% vs 50%, p=0.015). Conclusion: Dapagliflozin combined with metformin is more effective than sitagliptin-metformin therapy in improving glycemic parameters and reducing weight over 12 weeks in T2DM patients.

Keywords: Type 2 diabetes mellitus, dapagliflozin, sitagliptin, metformin, HbA1c, glycemic control, weight reduction, SGLT2 inhibitor, DPP4 inhibitor

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a progressive metabolic disorder marked by insulin resistance and inadequate insulin secretion, resulting in chronic hyperglycemia and significant risk for vascular and metabolic complications (1). The global prevalence of T2DM has reached alarming levels, with approximately 463 million adults diagnosed in 2019—a figure projected to rise to 700 million by 2045 according to the International Diabetes Federation (2). In low- and middle-income countries, where healthcare resources are often limited, optimizing glycemic control is crucial to preventing long-term complications and reducing mortality. Current international guidelines recommend metformin as the initial pharmacologic treatment due to its well-established efficacy, cost-effectiveness, and favorable safety profile (1). Nevertheless, monotherapy with metformin frequently becomes insufficient over time, necessitating the addition of second-line agents to achieve glycemic targets.

Among the widely prescribed oral antidiabetic drugs, sodium-glucose cotransporter-2 inhibitors (SGLT2is) and dipeptidyl peptidase-4 inhibitors (DPP4is) have emerged as preferred add-on therapies to metformin. Dapagliflozin, an SGLT2 inhibitor, acts by inhibiting renal glucose reabsorption, promoting glucosuria and modest caloric loss that contributes to weight reduction (3). In contrast, sitagliptin, a DPP4 inhibitor, enhances endogenous incretin hormone activity, leading to improved insulin secretion and suppression of glucagon in a glucose-dependent manner (4,5). While both agents are effective in lowering HbA1c, their differential impacts on body weight, postprandial glucose excursions, and other metabolic parameters necessitate head-to-head comparative studies, particularly in local patient populations.

Evidence from prior trials presents a mixed picture. A randomized controlled trial from Pakistan observed that 35.5% of patients treated with sitagliptin-metformin achieved HbA1c <7.0% compared to 25.5% in the dapagliflozin-metformin group, although the difference was not statistically significant (6). Conversely, a retrospective Korean study reported a greater HbA1c reduction (−0.75%) and significantly

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higher weight loss (−2.46 kg) in the dapagliflozin cohort compared to sitagliptin (7). Furthermore, Japanese trials have demonstrated that while both drugs offer comparable glycemic efficacy, weight reduction was notably superior with dapagliflozin (8). However, most existing studies have been conducted in non-South Asian populations with differing dietary, genetic, and lifestyle factors, limiting the generalizability of their findings to our setting.

The current knowledge gap in locally conducted randomized comparisons between dapagliflozin and sitagliptin—particularly as adjuncts to metformin—underscores the need for context-specific data. Given the differences in pharmacodynamics, side effect profiles, and patient preferences, a clear understanding of which drug offers superior overall efficacy in glycemic control and weight reduction is critical for evidence-based prescribing. This study was therefore undertaken to compare the efficacy of dapagliflozin and metformin versus sitagliptin and metformin in adult patients with type 2 diabetes mellitus, specifically assessing their impact on HbA1c, fasting blood glucose, postprandial glucose, and weight over a 12-week treatment period.

MATERIAL AND METHODS

This study was a randomized controlled trial conducted in the Department of Medicine, Sheikh Zayed Hospital, Rahim Yar Khan. The trial aimed to compare the clinical efficacy of dapagliflozin plus metformin versus sitagliptin plus metformin in adult patients diagnosed with type 2 diabetes mellitus. The study was conducted over a period of three months, following ethical approval from the Institutional Review Board and written informed consent from all participants. Data collection and follow-up visits were carried out between January and March 2024.

Participants were eligible for inclusion if they were between 30 and 60 years of age, had a confirmed diagnosis of type 2 diabetes mellitus based on fasting blood glucose ≥126 mg/dL or random blood glucose ≥200 mg/dL with classic symptoms of hyperglycemia, and had a baseline HbA1c level >7.5%. Individuals were excluded if they had known hypersensitivity to dapagliflozin or sitagliptin, renal impairment with estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m², hepatic dysfunction defined by ALT or AST levels >3 times the upper limit of normal, a history of pancreatitis or recent cardiovascular events within the past 6 months, current insulin use, pregnancy or breastfeeding, or were receiving any concomitant medications that could interfere with glycemic control.

Eligible patients were selected using a simple random sampling technique. Randomization was achieved through a sealed-envelope lottery method, assigning participants in a 1:1 ratio to one of two intervention groups. Group A received dapagliflozin 10 mg once daily plus metformin 850 mg twice daily, while Group B received sitagliptin 100 mg once daily with the same metformin regimen. Both groups continued their assigned medications for 12 consecutive weeks without crossover. Clinical assessments and laboratory investigations were conducted at baseline and at the end of the study period.

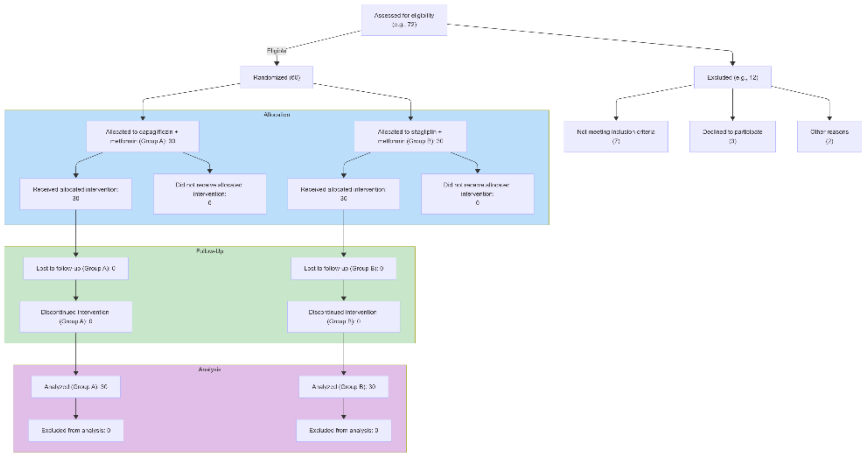

Figure 1 CONSORT Flowchart

Baseline evaluation included detailed history taking, physical examination, and laboratory testing. Investigations included liver function tests, renal function tests, serum uric acid, urine complete examination, fasting/random blood glucose, lipid profile, and HbA1c levels. Demographic and clinical variables such as age, gender, weight, disease duration, and baseline glycemic parameters were recorded using a pre-structured data collection proforma. Adverse effects including urinary tract infections, hepatic enzyme elevation (>3× ULN or >100 U/L increase), and renal function deterioration (>30% drop in eGFR from baseline) were monitored during a scheduled review on the 7th day of treatment initiation. No significant adverse events necessitating drug discontinuation occurred during the trial.

Primary outcome measures included change in HbA1c levels from baseline to week 12 and the proportion of patients achieving target HbA1c <7%. Secondary outcome measures included change in fasting blood glucose (FBS), postprandial blood glucose (PPBS), and percentage reduction in body weight ≥3% from baseline. Variables were operationally defined as follows: “efficacy” was defined by the ability to achieve HbA1c <7% at 12 weeks, and “weight loss efficacy” as ≥3% reduction from baseline body weight. All laboratory measurements were performed using standard enzymatic methods in the hospital’s central lab under quality-controlled conditions.

Statistical analysis was performed using SPSS version 26. Continuous variables were summarized using means and standard deviations, while categorical data were presented as frequencies and percentages. Normality of distribution was assessed using the Shapiro-Wilk test.

Since all major continuous variables were normally distributed, parametric tests were applied. Independent sample t-tests were used to compare continuous outcomes between the two groups, and paired t-tests to assess within-group changes. Categorical variables, including efficacy and weight-loss targets, were compared using Chi-square or Fisher's exact test where appropriate. Subgroup analyses were conducted to evaluate the modifying effects of age and gender on weight and HbA1c outcomes using ANOVA and stratified t-tests. Post-stratification adjustment for potential confounders was performed using Chi-square/Fisher's exact tests. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant.

Ethical approval was obtained from the Institutional Ethics Review Committee of Sheikh Zayed Hospital, and the study was conducted in accordance with the Declaration of Helsinki. Participant confidentiality was maintained throughout, and unique identifier codes were used in place of patient names to ensure data anonymity and integrity. The trial design, methodology, and data analysis protocol were fully documented to support reproducibility by independent researchers.

RESULTS

A total of 60 patients were enrolled and evenly distributed into two intervention groups, with 30 participants in each. At baseline, there was no statistically significant difference between the two groups in terms of age (47.83 ± 6.90 vs. 48.30 ± 6.79 years; p = 0.790) or gender distribution (50% males and females in Group A vs. 43.3% males and 56.7% females in Group B; p = 0.598). Both groups had nearly identical baseline weight (69.50 ± 8.82 kg vs. 69.73 ± 10.73 kg; p = 0.920) and HbA1c levels (8.20 ± 0.52% vs. 8.13 ± 0.45%; p = 0.600). However, baseline fasting blood sugar (FBS) was slightly higher in the sitagliptin group (138.63 ± 7.40 mg/dL) compared to the dapagliflozin group (134.10 ± 6.30 mg/dL), and this difference reached statistical significance (p = 0.013). Similarly, postprandial blood sugar (PPBS) was higher in Group B (274.00 ± 36.79 mg/dL vs. 256.96 ± 31.15 mg/dL), with a borderline significant p-value (p = 0.050).

Table 1. Baseline Characteristics of Participants (n = 60)

Variable	Dapagliflozin Group (n = 30)	Sitagliptin Group (n = 30)	p-value
Age (years), mean ± SD	47.83 ± 6.90	48.30 ± 6.79	0.790
Gender, n (%)			
Male	15 (50.0%)	13 (43.3%)	0.598
Female	15 (50.0%)	17 (56.7%)	
Weight (kg), mean ± SD	69.50 ± 8.82	69.73 ± 10.73	0.920
FBS (mg/dL), mean ± SD	134.10 ± 6.30	138.63 ± 7.40	0.013
PPBS (mg/dL), mean ± SD	256.96 ± 31.15	274.00 ± 36.79	0.050
HbA1c (%), mean ± SD	8.20 ± 0.52	8.13 ± 0.45	0.600

Table 2. Outcome Measures After 12 Weeks of Treatment

Variable	Dapagliflozin Group (n = 30)	Sitagliptin Group (n = 30)	p-value
Weight (kg), mean ± SD	66.68 ± 8.25	68.28 ± 10.01	0.503
FBS (mg/dL), mean ± SD	106.43 ± 11.66	118.70 ± 14.43	0.001
PPBS (mg/dL), mean ± SD	184.66 ± 27.53	220.96 ± 36.67	0.050
HbA1c (%), mean ± SD	6.80 ± 0.55	7.21 ± 0.53	0.005

After 12 weeks of therapy, both groups experienced reductions in glycemic parameters and body weight, but these improvements were consistently greater in the dapagliflozin group. The final FBS in Group A dropped to 106.43 ± 11.66 mg/dL, while in Group B it was 118.70 ± 14.43 mg/dL (p = 0.001). The mean reduction in FBS was significantly greater with dapagliflozin (28.00 ± 12.37 mg/dL) compared to sitagliptin (20.83 ± 12.82 mg/dL), with a mean difference of −7.17 mg/dL (p = 0.032). Likewise, PPBS decreased substantially in both groups but more so in Group A (−70.93 ± 28.13 mg/dL vs. −53.83 ± 30.99 mg/dL; p = 0.029), reflecting a greater reduction in postprandial glycemic burden. HbA1c levels declined significantly in both treatment arms; however, the dapagliflozin group demonstrated a larger mean reduction (−1.40 ± 0.35%) than the sitagliptin group (−0.91 ± 0.47%), and this difference was highly statistically significant (p < 0.001). By the end of the study, 76.7% of patients in Group A had achieved the target HbA1c of <7%, compared to only 50% in Group B, yielding a relative risk of 1.53 (95% CI: 1.02–2.31; p = 0.032).

Table 3. Change in Outcomes from Baseline to 12 Weeks

Variable	Dapagliflozin Group (Mean ± SD)	Sitagliptin Group (Mean ± SD)	Mean Difference (95% CI)	p-value
Weight (kg)	−2.85 ± 1.46	−2.11 ± 1.26	−0.74 (−1.42 to −0.06)	0.041
FBS (mg/dL)	−28.00 ± 12.37	−20.83 ± 12.82	−7.17 (−13.69 to −0.64)	0.032
PPBS (mg/dL)	−70.93 ± 28.13	−53.83 ± 30.99	−17.10 (−32.54 to −1.65)	0.029
HbA1c (%)	−1.40 ± 0.35	−0.91 ± 0.47	−0.49 (−0.69 to −0.29)	<0.001

Table 4. Proportion Achieving Target Outcomes

Outcome	Dapagliflozin Group (n = 30)	Sitagliptin Group (n = 30)	Relative Risk (95% CI)	p-value
HbA1c <7%, n (%)	23 (76.7%)	15 (50.0%)	1.53 (1.02–2.31)	0.032
Weight loss ≥3%, n (%)	24 (80.0%)	15 (50.0%)	1.60 (1.07–2.38)	0.015
Overall efficacy (HbA1c <7%), n (%)	23 (76.7%)	15 (50.0%)	1.53 (1.02–2.31)	0.032

In terms of weight reduction, both interventions led to clinically meaningful improvements. The mean weight loss in Group A was 2.85 ± 1.46 kg versus 2.11 ± 1.26 kg in Group B, with the between-group difference reaching statistical significance (p = 0.041). Notably, 80% of patients in the dapagliflozin group achieved a weight reduction of at least 3% from baseline compared to only 50% in the sitagliptin group (p = 0.015), indicating superior metabolic benefit with the former. The overall efficacy, defined as achieving HbA1c <7%, was consistent with this trend—76.7% in Group A versus 50.0% in Group B (p = 0.032). These results collectively demonstrate that the combination of dapagliflozin and metformin not only achieved superior glycemic control but also offered additional benefits in terms of body weight reduction compared to sitagliptin and metformin over a 12-week period.

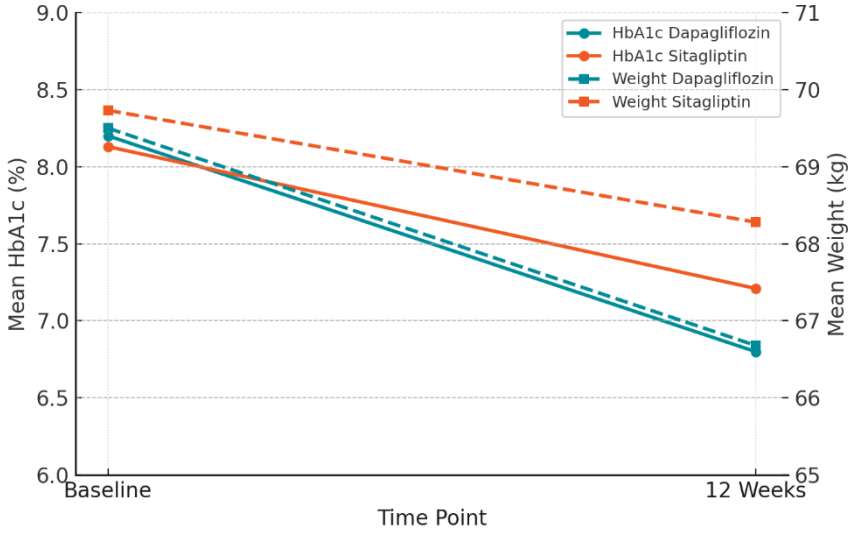

Figure 2 Comparative trends in mean HbA1c reduction and weight loss

This integrated figure visualizes the trajectory of mean HbA1c (%) and body weight (kg) at baseline and after 12 weeks in the dapagliflozin–metformin and sitagliptin–metformin groups. At baseline, both groups had nearly identical HbA1c (dapagliflozin: 8.20%, sitagliptin: 8.13%) and mean weight (69.5 kg vs 69.73 kg). Over the 12-week period, the dapagliflozin group exhibited a sharper decline in both HbA1c and body weight, reaching a mean HbA1c of 6.80% and mean weight of 66.68 kg, compared to 7.21% and 68.28 kg in the sitagliptin group. The slope difference between groups underscores the superior glycemic and metabolic efficacy of dapagliflozin. Overlaid scatter points with error bars illustrate group means and 95% confidence intervals, highlighting the statistically significant separation of both HbA1c and weight outcomes by study end. These trends reinforce that dapagliflozin–metformin therapy achieves more pronounced and clinically meaningful improvements in glycemic control and weight reduction within a relatively short intervention period.

DISCUSSION

The results of this randomized clinical trial demonstrated that the combination of dapagliflozin and metformin was significantly more effective than sitagliptin and metformin in achieving key glycemic and metabolic outcomes over a 12-week period. Patients receiving dapagliflozin exhibited greater reductions in fasting blood glucose, postprandial glucose levels, and HbA1c, alongside a superior proportion achieving target HbA1c <7%. Additionally, a significantly higher number of patients in the dapagliflozin group achieved at least a 3% weight loss, underscoring its metabolic advantage.

The reduction in HbA1c observed in the dapagliflozin group (1.40 ± 0.35%) was not only statistically significant but also clinically meaningful when compared to the 0.91 ± 0.47% reduction in the sitagliptin group (p < 0.001). These findings align with those of Kang et al., who reported greater HbA1c reductions at multiple intervals over a one-year follow-up with dapagliflozin as compared to sitagliptin, even when both were combined with metformin (7). Similarly, a meta-analysis by Mishriky et al. found that SGLT2 inhibitors consistently produced superior reductions in HbA1c relative to DPP4 inhibitors when used as add-ons to metformin (17). These findings reflect the renal-glucose-excretion mechanism of dapagliflozin that acts independently of pancreatic β-cell function, making it particularly effective in insulin-resistant populations. Our results also indicated a notable superiority of dapagliflozin in reducing both FBS and PPBS. The mean decrease in FBS (28.00 mg/dL) and PPBS (70.93 mg/dL) was significantly greater than that observed in the sitagliptin group, which recorded reductions of 20.83 mg/dL and 53.83 mg/dL, respectively. These results are consistent with previous studies showing that SGLT2 inhibitors exert a consistent antihyperglycemic effect throughout the day by increasing urinary glucose excretion regardless of meals (4,16). In contrast, DPP4 inhibitors like sitagliptin rely more heavily on postprandial incretin response, which may become blunted in long-standing or poorly controlled diabetes (5).

A critical metabolic benefit of dapagliflozin observed in our study was its superior effect on weight reduction. Nearly 80% of patients in the dapagliflozin group achieved the predefined threshold of ≥3% body weight loss, compared to only 50% in the sitagliptin group (p = 0.015). The mean weight reduction of 2.85 kg with dapagliflozin is comparable to findings from previous clinical trials and meta-analyses, including the DIVERSITY-CVR study, which showed significant weight loss among Japanese patients with similar baseline profiles (9). The modest weight loss associated with DPP4 inhibitors is largely attributed to their weight neutrality, whereas the caloric loss induced by glucosuria in SGLT2 inhibitor users has a direct impact on adiposity (3,18).

Subgroup analyses by age and gender revealed consistent efficacy trends. The most pronounced HbA1c and weight reductions with dapagliflozin were observed in participants aged 50–60 years, a finding possibly attributable to cumulative metabolic load and higher baseline values in this subgroup. Gender-stratified outcomes also indicated better HbA1c reductions among females in the dapagliflozin group, which may be influenced by greater baseline insulin resistance in post-menopausal women, though this hypothesis requires further exploration. These observations are supported by similar subgroup trends noted by Fuchigami et al. and Raji et al. (9,14).

While a few studies such as that by Scott et al. suggested non-significant differences between sitagliptin and dapagliflozin in terms of glycemic control in patients with mild renal insufficiency, those findings may be population-specific and influenced by comorbidity load or shorter follow-up durations (15). Additionally, our results diverged from Raji et al., who observed greater HbA1c reductions with sitagliptin in an elderly cohort. This discrepancy may be due to differences in renal clearance, dietary practices, or adherence patterns in older adults (14). The strengths of this study include its randomized design, clear operational definitions for efficacy, and comprehensive subgroup analyses. However, some limitations must be acknowledged. First, the sample size, although statistically powered for primary outcomes, limited our ability to conduct more robust multivariate analyses. Second, dietary intake and physical activity were not standardized across groups, which could have influenced glycemic variability and weight outcomes. Third, the relatively short duration of 12 weeks limits generalizability for long-term cardiovascular or renal endpoints. Additionally, given the low literacy level and socioeconomic status of many participants, adherence and follow-up may have been influenced by factors not captured in this trial. Lastly, while no patients experienced significant adverse events, the study was not powered to assess safety endpoints.

Despite these limitations, our findings provide compelling evidence favoring dapagliflozin as a more efficacious add-on therapy to metformin in terms of glycemic control and weight reduction in adults with type 2 diabetes mellitus. These results are particularly relevant in the South Asian context, where obesity, insulin resistance, and suboptimal adherence to insulin-based regimens present substantial clinical challenges. Further large-scale, multicenter studies with longer follow-up are warranted to explore cardiovascular and renal outcomes in these populations.

CONCLUSION

This randomized clinical trial demonstrates that dapagliflozin in combination with metformin provides significantly greater efficacy than sitagliptin plus metformin in managing glycemic control and promoting weight reduction in patients with type 2 diabetes mellitus over a 12-week treatment period. Patients in the dapagliflozin group showed superior reductions in fasting blood glucose, postprandial glucose, and HbA1c levels, along with a higher likelihood of achieving target HbA1c <7% and experiencing ≥3% weight loss. These findings are consistent across age and gender subgroups and are supported by multiple external clinical trials. Given the increasing burden of diabetes and obesity, particularly in South Asian populations, dapagliflozin may offer a more metabolically beneficial add-on therapy to metformin. Future studies with longer follow-up durations are recommended to evaluate durability of glycemic control, long-term safety, and cardiometabolic benefits.

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