



Effectiveness and Adverse Effects of Dapagliflozin Compared with Sitagliptin Combined with Metformin in Type 2 Diabetes Mellitus – an Open Labelled Randomized Controlled Trial

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ABSTRACT:

Background: In the management of mild to moderate Type 2 Diabetes Mellitus (T2DM), sodium-glucose co-transporter-2 (SGLT-2) inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors are commonly preferred as add-on therapies to Metformin, owing to their more favorable safety profiles relative to sulphonylureas and insulin. Nevertheless, there is a paucity of data comparing their efficacy and safety within the South Indian population.

Objective: To compare the effectiveness and adverse effect profile of Dapagliflozin and Sitagliptin, each combined with Metformin, in patients with T2DM.

Methods: In this open-label randomized controlled trial, a total of 60 patients with Type 2 Diabetes Mellitus (T2DM) were randomized to receive either Dapagliflozin (Group A) or Sitagliptin (Group B), each in combination with Metformin, over a duration of three months. Fasting blood sugar (FBS), postprandial blood sugar (PPBS), and glycated hemoglobin (HbA1c) levels were evaluated on a monthly basis, and patients were closely monitored for any adverse events.

Results: The study demonstrated that both treatment groups—Dapagliflozin and Sitagliptin in combination with Metformin—were comparable at baseline in terms of age, gender, and glycemic parameters. The mean age was 56 ± 2.9 years in the Dapagliflozin group and 55 ± 5.2 years in the Sitagliptin group ($p = 0.826$), with no significant gender difference ($p = 0.604$). Baseline FBS, PPBS, and HbA1c were also similar between the groups: 161 ± 8.1 mg/dL, 214 ± 12.1 mg/dL, and $7.4 \pm 0.16\%$ in the Dapagliflozin group; and 160 ± 5.7 mg/dL, 207 ± 5.9 mg/dL, and $7.3 \pm 0.14\%$ in the Sitagliptin group (all $p > 0.7$). Over three months, both groups showed significant intragroup reductions in glycemic indices ($p < 0.001$). However, Sitagliptin achieved greater reductions, with FBS declining to 112 ± 2.9 mg/dL, PPBS to 138 ± 4.8 mg/dL, and HbA1c to $6.4 \pm 0.11\%$, all significantly lower than those in the Dapagliflozin group (128 ± 6.1 mg/dL, 166 ± 4.8 mg/dL, and $6.7 \pm 0.16\%$; $p < 0.001$). Liver and renal function tests remained stable in both groups throughout the study, indicating good safety and tolerability.

Conclusion: In this South Indian cohort, the combination of Sitagliptin with Metformin demonstrated superior glycemic control compared to Dapagliflozin and was associated with a more favorable safety profile, notably reflected by a lower incidence of urinary tract infections.



Introduction

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and progressive β -cell dysfunction, leading to sustained hyperglycemia and associated long-term microvascular and macrovascular complications.(1) Metformin remains the first-line pharmacological therapy due to its efficacy, safety profile, and cost-effectiveness. However, in patients with inadequate glycemic control on Metformin monotherapy, additional pharmacological agents are often required.(2) Traditionally, sulphonylureas and insulin have been the preferred second-line agents.(3) Despite their glucose-lowering efficacy, these agents are frequently associated with a higher risk of hypoglycemia and weight gain, which can negatively impact patient adherence, quality of life, and overall therapeutic outcomes.(2, 4-6) Consequently, in patients with mild to moderate T2DM, newer oral antidiabetic agents—such as dipeptidyl peptidase-4 (DPP-4) inhibitors and sodium-glucose co-transporter-2 (SGLT-2) inhibitors—are increasingly being recommended as add-on therapies.(7) These agents offer a favorable safety profile, low risk of hypoglycemia, and additional metabolic and cardiovascular benefits, making them particularly suitable in early-stage T2DM management.(8)

DPP-4 inhibitors function by enhancing endogenous incretin activity, thereby increasing insulin secretion and decreasing glucagon levels in a glucose-dependent manner.(9, 10) On the other hand, SGLT-2 inhibitors act independently of insulin by promoting urinary glucose excretion and have demonstrated additional benefits in terms of weight reduction, blood pressure control, and cardiovascular and renal protection.(11, 12) Despite growing global evidence supporting the efficacy and safety of these agents,(13) there remains a paucity of data regarding their comparative effectiveness and tolerability in specific ethnic populations, including individuals from South India.

The South Indian population presents distinct dietary habits, cultural practices, and genetic predispositions that may influence the pharmacodynamic and pharmacokinetic responses to antidiabetic

medications. For instance, the staple diet—predominantly consisting of high-glycemic-index polished white rice—may contribute to differing glycemic patterns compared to Western or East Asian populations. Furthermore, sociocultural reluctance towards injectable therapies like insulin often necessitates reliance on oral drug combinations for glycemic control. Against this background, the objective of the present study was to compare the effectiveness and adverse effect profile of Dapagliflozin and Sitagliptin, each combined with Metformin, in patients with T2DM.

Materials and Methods

This open-label, randomized controlled trial was conducted in the Department of Pharmacology at Vinayaka Mission's Kirupananda Variyar Medical College and Hospitals, Salem, Tamil Nadu, with the objective of comparing the efficacy and safety of Dapagliflozin and Sitagliptin, each administered in combination with Metformin, among patients diagnosed with mild to moderate Type 2 Diabetes Mellitus (T2DM). A total of 60 adult patients with T2DM, who were already on Metformin monotherapy and had inadequately controlled glycemic status, were enrolled in the study after obtaining informed written consent. Eligible participants were randomized into two equal groups, with 30 patients in each group. Group A received Dapagliflozin in combination with Metformin, while Group B received Sitagliptin in combination with Metformin. The dosing of both Dapagliflozin and Sitagliptin was guided by established standard therapeutic protocols.

Inclusion criteria comprised patients aged above 18 years of either sex, diagnosed with T2DM, with HbA1c levels greater than 7% but less than 9%, and willing to participate in the study. Exclusion criteria included patients with HbA1c levels exceeding 9%, those with significant renal, hepatic, or cardiovascular abnormalities, pregnant or lactating women, individuals with other types of diabetes mellitus, and those with established diabetic complications or a history of recurrent urinary tract infections.



The total duration of the study was three months. Participants were followed up at monthly intervals, during which fasting blood sugar (FBS), postprandial blood sugar (PPBS), and glycated hemoglobin (HbA1c) levels were assessed. These parameters constituted the primary endpoints of the study. Secondary endpoints included monitoring for adverse drug reactions, particularly urinary tract infections and hypoglycemic events, as well as evaluation of renal and hepatic function and changes in blood pressure. Biochemical parameters were recorded at baseline and at each monthly follow-up. Adverse effects were documented through direct clinical examination and self-reported symptoms by the patients. All collected data were used to assess the comparative efficacy and safety profiles of the two treatment regimens in the study population.

Statistical analysis: All collected data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables such as FBS, PPBS, and HbA1c were summarized as mean \pm standard deviation (SD). Intragroup comparisons of these parameters across different time points were performed using repeated measures analysis of variance (ANOVA), while intergroup comparisons at each time point were assessed using independent sample t-tests. For variables measured only at baseline and the end of the study (e.g., HbA1c), paired sample t-tests were used for intragroup comparisons. Categorical variables, including age group and gender distribution, were expressed as frequencies and percentages, and differences between groups were evaluated using the Chi-square test. A two-tailed p-value of less than 0.05 was considered statistically significant for all analyses.

Results

The baseline demographic characteristics of the study groups were comparable. The mean age of participants in the Dapagliflozin group was 56 ± 2.9 years, while in the Sitagliptin group it was 55 ± 5.2 years. The majority of patients in both groups were between 50 and 60 years of age. There was no statistically significant difference in age distribution between the groups ($p = 0.826$). In terms of gender, 53.3% of patients in the Dapagliflozin group and

60.0% in the Sitagliptin group were male, with the remaining being female, and this difference was also not statistically significant ($p = 0.604$). The mean FBS was 161 ± 8.1 mg/dL in the Dapagliflozin group and 160 ± 5.7 mg/dL in the Sitagliptin group ($p = 0.914$). The mean PPBS was 214 ± 12.1 mg/dL for Dapagliflozin and 207 ± 5.9 mg/dL for Sitagliptin ($p = 0.728$). The mean HbA1c values were $7.4 \pm 0.16\%$ and $7.3 \pm 0.14\%$ in the respective groups ($p = 0.861$). None of these differences were statistically significant, indicating that both groups were well-matched in terms of baseline glycemic parameters.

In the Dapagliflozin group, there was a statistically significant reduction in FBS, PPBS, and HbA1c levels over the three-month study period. The mean FBS decreased progressively from 161 ± 8.1 mg/dL at baseline to 128 ± 6.1 mg/dL at the end of the third month ($p < 0.001$, $f = 118.01$). Similarly, the mean PPBS showed a marked decline from 214 ± 12.1 mg/dL at baseline to 166 ± 4.8 mg/dL by the third month ($p < 0.001$, $f = 342.5$). The mean HbA1c level also significantly reduced from $7.4 \pm 0.16\%$ at baseline to $6.7 \pm 0.16\%$ at the end of the study ($p < 0.001$), indicating substantial improvement in overall glycemic control with Dapagliflozin. In the Sitagliptin group, there was a statistically significant and consistent reduction in fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c levels over the three-month period. The mean FBS decreased from 160 ± 5.7 mg/dL at baseline to 112 ± 2.9 mg/dL by the third month ($p < 0.001$, $f = 962.8$), while the mean PPBS declined from 207 ± 5.9 mg/dL to 138 ± 4.8 mg/dL during the same period ($p < 0.001$, $f = 1109$). Additionally, the mean HbA1c level significantly dropped from $7.3 \pm 0.14\%$ at baseline to $6.4 \pm 0.11\%$ at the end of three months ($p < 0.001$). These findings indicate a marked improvement in glycemic control with Sitagliptin therapy.

During the follow-up period, Sitagliptin demonstrated significantly greater reductions in FBS, PPBS, and HbA1c levels compared to Dapagliflozin. At the first month, the Sitagliptin group had a lower mean FBS (132 ± 2.7 mg/dL) and PPBS (166 ± 5 mg/dL) than the Dapagliflozin group (149 ± 7.2 mg/dL and 191 ± 4.5 mg/dL, respectively), with both differences being statistically significant ($p < 0.001$).



This trend continued through the second month, where Sitagliptin maintained significantly lower FBS (121 ± 2.1 mg/dL) and PPBS (151 ± 3 mg/dL) values compared to Dapagliflozin (138 ± 6.6 mg/dL and 178 ± 3.3 mg/dL, respectively), again with $p < 0.001$. By the third month, Sitagliptin showed superior glycemic control with FBS of 112 ± 2.9 mg/dL, PPBS of 138 ± 4.8 mg/dL, and HbA1c of $6.4 \pm 0.11\%$, all significantly lower than those in the Dapagliflozin group (128 ± 6.1 mg/dL, 166 ± 4.8 mg/dL, and $6.7 \pm 0.16\%$, respectively; $p < 0.001$ for all comparisons).

There were no statistically significant differences between the Dapagliflozin and Sitagliptin groups in liver or renal function parameters at baseline or after three months of treatment. Serum SGOT levels were comparable between the groups at both baseline (26 ± 5.5 vs. 24 ± 4.5 , $p = 0.114$) and at three months (25 ± 3.5 vs. 24 ± 5.6 , $p = 0.233$). Similarly, SGPT values showed no significant change between groups at baseline (26 ± 4 vs. 25 ± 4.2 , $p = 0.172$) or at three months (25 ± 4.3 vs. 25.1 ± 2.9 , $p = 0.446$). Renal function tests also remained stable, with no significant differences in urea levels at baseline (22 ± 5 vs. 24 ± 4.5 , $p = 0.120$) or at three months (24 ± 4.5 vs. 25 ± 4.6 , $p = 0.538$), and creatinine levels remained consistent at 0.7 mg/dL in both groups across both time points ($p > 0.3$). These findings indicate that both treatment regimens were well tolerated with no adverse impact on hepatic or renal function.

Discussion

The present study was undertaken to determine the more efficacious and safer oral hypoglycemic agent to be used as an add-on therapy to Metformin in patients with mild to moderate T2DM. This investigation was particularly contextualized within the South Indian population, where the predominant staple food is polished white rice—characterized by a high glycemic index. Despite receiving nutritional counselling, it was observed that patients continued to consume diets high in carbohydrates with relatively inadequate intake of proteins and fats, potentially contributing to suboptimal glycemic control.

Contrary to findings reported by Daisuke et al.,(13) our study did not observe a significant reduction in body weight among patients treated with Dapagliflozin. However, it is important to note that previous studies have indicated that Dapagliflozin reduces fasting insulin levels, as demonstrated by DeFronzo et al. Additionally, our results align with those of Ferrannini et al.,(14) showing that Dapagliflozin effectively reduced HbA1c levels without any reported episodes of hypoglycemia, thus reinforcing its glycemic efficacy and safety profile. Both treatment groups in our study demonstrated significant reductions in HbA1c levels from baseline, a finding consistent with systematic reviews conducted among Asian populations by Yang et al. and Zaccardi et al., which confirmed the HbA1c-lowering potential of Dapagliflozin.(15, 16)

Given the rising prevalence of obesity and insulin resistance in the Indian population, SGLT-2 inhibitors such as Dapagliflozin, when combined with Metformin, present a compelling therapeutic strategy due to their complementary mechanisms of action and potential metabolic benefits. Previous studies have also highlighted the cardiovascular advantages of SGLT-2 inhibitors, particularly in reducing hospitalization rates and improving symptoms in patients with heart failure, thereby supporting their expanded role beyond glycemic control.(17)

Sociocultural factors in the study population revealed a reluctance among many patients to initiate insulin therapy, even when clinically indicated. This underscores the practical value of effective oral regimens such as the combination of Metformin with SGLT-2 inhibitors, which may improve adherence and patient satisfaction. Nevertheless, the Dapagliflozin group in our study exhibited a 30% incidence of genital or urinary tract infections, a known class effect of SGLT-2 inhibitors. This observation is consistent with the findings reported by Henry et al. Most of these infections were mild to moderate in severity and responded well to standard antibiotic therapy or resolved spontaneously.(17)

Sitagliptin, when used in combination with Metformin, led to significant reductions in FBS, PPBS, and HbA1c over the study period. These outcomes are in line with previous clinical trials, including those conducted by



Henry et al., which have confirmed the glycemic efficacy of this combination.(17) The non-inferiority of Sitagliptin–Metformin therapy compared to the widely used Glimepiride–Metformin combination was also highlighted in studies such as that by Harinika et al.(18) Notably, Sitagliptin has been shown to exert a neutral or even favorable effect on cardiovascular and renal parameters, without adversely affecting uric acid levels or cardiac metabolism. Additional studies have demonstrated that Sitagliptin contributes to a reduction in proinsulin-to-insulin ratios and improves insulin sensitivity as reflected by lower HOMA-IR scores.(19, 20) Furthermore, significant improvements in lipid parameters—specifically, reductions in total cholesterol and triglyceride-to-HDL cholesterol ratios—have also been observed in patients receiving Sitagliptin, with statistical significance reported in earlier studies.

Conclusion

In conclusion, the present study demonstrated that both Sitagliptin and Dapagliflozin, when used in combination with Metformin, significantly improved glycemic parameters, including FBS, PPBS, and HbA1c levels, in patients with mild to moderate Type 2 Diabetes Mellitus. However, Sitagliptin exhibited superior glycemic control compared to Dapagliflozin, with the differences reaching statistical significance. Additionally, Sitagliptin was better tolerated, with fewer adverse effects, whereas the Dapagliflozin group showed a higher incidence of urinary tract infections. These findings suggest that Sitagliptin may be a more effective and safer add-on therapy to Metformin in the South Indian population, particularly in the Tamil Nadu subset.

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Table 1: Comparison of demographic variables between the two groups

Variable		Dapagliflozin	Sitagliptin	P value
Age (in years), n (%)	<50	1 (3.3)	3 (10.0)	0.826
	50 – 55	14 (46.6)	12 (40.0)	
	56 – 60	13 (43.3)	14 (46.6)	
	60 – 65	2 (6.6)	1 (3.3)	
Age (in years), Mean ± SD		56 ± 2.9	55 ± 5.2	
Gender	Male	16 (53.3)	18 (60.0)	0.604
	Female	14 (46.6)	12 (40.0)	
P value derived by applying chi-square test				
*Statistically significant at p<0.05				



Table 2: Comparison of baseline values of blood sugar between the two groups

Blood sugar (Baseline)	Dapagliflozin	Sitagliptin	P value
FBS, Mean \pm SD	161 \pm 8.1	160 \pm 5.7	0.914
PPBS, Mean \pm SD	214 \pm 12.1	207 \pm 5.9	0.728
HbA1C, Mean \pm SD	7.4 \pm 0.16	7.3 \pm 0.14	0.861
P value derived by applying student T test *Statistically significant at $p < 0.05$			

Table 3: Intragroup comparison of blood sugar values in dapagliflozin group

Duration	FBS	PPBS	HbA1C
0 months, Mean \pm SD	161 \pm 8.1	214 \pm 12.1	7.4 \pm 0.16
1 st month, Mean \pm SD	149 \pm 7.2	191 \pm 4.5	NA
2 nd month, Mean \pm SD	138 \pm 6.6	178 \pm 3.3	NA
3 rd month, Mean \pm SD	128 \pm 6.1	166 \pm 4.8	6.7 \pm 0.16
P value	<0.001 (f= 118.01) [#]	<0.001 (f=342.5) [#]	<0.001 [*]
[#] p value derived using one way ANOVA [*] p value derived using student T test			

Table 4: Intragroup comparison of blood sugar values among sitagliptin group

Duration	FBS	PPBS	HbA1C
0 months	160 \pm 5.7	207 \pm 5.9	7.3 \pm 0.14
1 st month	132 \pm 2.7	166 \pm 5	NA
2 nd month	121 \pm 2.1	151 \pm 3	NA
3 rd month	112 \pm 2.9	138 \pm 4.8	6.4 \pm 0.11
P value	<0.001 (f=962.8) [#]	<0.001 (f=1109) [#]	<0.001 [*]
[#] p value derived using one way ANOVA [*] p value derived using student T test			

Table 5: Comparison of blood sugar parameters between the two groups during the follow up period

Group	FBS	PPBS	HbA1C
1 st month			



Dapagliflozin	149 ± 7.2	191 ± 4.5	
Sitagliptin	132 ± 2.7	166 ± 5	
P value	<0.001	<0.001	
2 nd month			
Dapagliflozin	138 ± 6.6	178 ± 3.3	
Sitagliptin	121 ± 2.1	151 ± 3	
P value	<0.001	<0.001	
3 rd month			
Dapagliflozin	128 ± 6.1	166 ± 4.8	6.7 ± 0.16
Sitagliptin	112 ± 2.9	138 ± 4.8	6.4 ± 0.11
P value	<0.001	<0.001	<0.001
P value derived by applying student T test			

Table 6: Liver and renal parameters between the two groups

	Duration	Dapagliflozin	Sitagliptin	P value
SGOT	0 month	26 ± 5.5	24 ± 4.5	0.114
	3 months	25 ± 3.5	24 ± 5.6	0.233
SGPT	0 month	26 ± 4	25 ± 4.2	0.172
	3 months	25 ± 4.3	25.1 ± 2.9	0.446
Urea	0 month	22 ± 5	24 ± 4.5	0.120
	3 months	24 ± 4.5	25 ± 4.6	0.538
Creatinine	0 month	0.7 ± 0.06	0.7 ± 0.05	0.347
	3 months	0.7 ± 0.08	0.7 ± 0.09	0.362
P value derived by applying student T test				