

ORIGINAL ARTICLE

Comparison of mean post-treatment HBA1C levels among patients using sitagliptin plus metformin versus empagliflozin plus metformin for treatment of Type II diabetes mellitus.

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ABSTRACT... **Objective:** To compare of mean post-treatment hba1c levels among patients using sitagliptin plus metformin versus empagliflozin plus metformin for treatment of type II diabetes mellitus. **Study Design:** Analytical Cross Sectional study. **Setting:** Department of Medicine, Shaikh Zayed Hospital, Rahim Yar Khan. **Period:** June and December 2025. **Methods:** Total 200 patients aged 30-70 years with T2DM with HbA1c >6.5% three months prior were included by nonprobability consecutive sampling and randomly allocated in two groups equally. Group A was taking Sitagliptin and Metformin 50/1000 mg and group B Empagliflozin and Metformin 12.5/1000 mg for 12 weeks. HbA1c levels were compared at baseline and after taking medicines for 12 weeks. Data were analyzed by using SPSS version 23.0, using an independent sample t-test with $p < 0.05$ considered as significant. **Results:** Baseline HbA1c was $8.29 \pm 0.74\%$ in Sitagliptin group and $8.00 \pm 0.82\%$ in Empagliflozin group ($p=0.098$). After 12 weeks, post treatment HbA1c was significantly lower in Empagliflozin group ($6.66 \pm 0.81\%$) compared to Sitagliptin group ($7.76 \pm 1.82\%$) ($p=0.001$). Stratified analysis across gender, age, disease duration, hypertension, obesity and residence showed consistent results favoring Empagliflozin. **Conclusion:** Empagliflozin plus Metformin showed higher efficacy in the reduction of HbA1c levels than Sitagliptin plus Metformin in patients with type 2 diabetes mellitus.

Key words: Empagliflozin, Glycemic Control, HbA1c, Metformin, Sitagliptin, Type 2 Diabetes Mellitus.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is chronic disease which is the result of combination of insulin resistance and insulin deficiency due to progressive beta cell failure. Type 2 diabetes mellitus (T2DM) is a chronic metabolic condition that has escalated into major global health threat. The International Diabetes Federation estimated that 415 million adults approximately one in every eleven individuals worldwide were living with diabetes in 2015. Projections indicate this figure could rise to 642 million or one in ten adults, by 2040 if current trends persist.¹⁻²

Sitagliptin is oral dipeptidyl peptidase-4 (DPP-4) inhibitor that lowers blood glucose levels through dual mechanism: it preserves endogenous incretin hormones by blocking their enzymatic degradation, thereby enhancing glucose dependent insulin release from pancreatic beta cells. A favorable

feature of this agent is its weight-neutral profile and minimal propensity to induce hypoglycemia after initial dosing, characteristics that have contributed to its growing clinical adoption. Preclinical studies further demonstrate that sitagliptin suppresses inappropriate glucagon secretion and exerts protective effects on pancreatic islets by stimulating beta-cell replication and inhibiting programmed cell death in vitro.³⁻⁴

Regulatory authorities in Pakistan have approved sitagliptin as an adjunctive pharmacological intervention alongside lifestyle modifications including dietary adjustments and physical activity for adults with type 2 diabetes mellitus (T2DM). Sitagliptin enhances glycemic parameters whether administered alone or combined with metformin. Its therapeutic utility extends to regimens incorporating additional oral antihyperglycemic agents such as thiazolidinediones (TZDs) or sulfonylureas,

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either as dual therapy with metformin or as triple combinations as well as basal insulin regimens with or without concomitant metformin. Sitagliptin has demonstrated comparable glucose lowering effectiveness to sulfonylureas in pooled analyses that evaluate these drug classes as aggregate therapeutic categories.⁵⁻⁶ Furthermore, comparison of DPP-4 inhibitors and SUs showed similar reduction of risk of cardiovascular events in high risk patients. Direct comparison of individual SUs against DPP-4 inhibitors may better demonstrate distinctions of particular treatments in both medications.^{6,7}

Baruah et al has reported post treatment HbA1c with Empagliflozin dropped to $7.9 \pm 2.2\%$ from baseline value of $8.6 \pm 1.2\%$ while mean post-treatment HbA1c with Metformin plus Sitagliptin = $8.4 \pm 1.4\%$.⁸ In another study, before treatment, the HbA1c levels were $8.7 \pm 0.50\%$ in the sitagliptin + metformin group which decreased to $7.74 \pm 0.90\%$ after treatment. Similarly, in empagliflozin + metformin group, HbA1c levels were $8.62 \pm 0.60\%$ before treatment, decreasing to $7.88 \pm 1.20\%$ after treatment.⁹

In another study at baseline, HbA1c levels were $8.27 \pm 0.71\%$ in sitagliptin group and $8.08 \pm 0.76\%$ in empagliflozin group after 12-week therapy period. The Mean values were 7.94 ± 1.75 and 6.69 ± 0.85 respectively.¹⁰ Upon extensive research it was evident that there has been dearth of data on this topic and no such controlled trial has been done in our country to ascertain the effectiveness of both these drugs, so that our clinicians can prescribe them with more confidence to achieve targeted HbA1c goals which will protect them from future adverse events. So by doing this study, our clinician will be in better position to offer more effective drug regimen to our diabetic patients for better glycemic control. This will improve quality of life of our patients by maintaining good glycemic control, more cost effective and relieve them from diabetes related distress. The primary objective was to comparison of mean post-treatment hba1c levels among patients using sitagliptin plus metformin versus empagliflozin plus metformin for treatment of type II diabetes mellitus.

METHODS

This analytical cross-sectional study was conducted

between June and December 2025 within the Department of Medicine at Shaikh Zayed Hospital, Rahim Yar Khan. Prior to data collection, ethical approval was taken from the Institutional Ethical Review Committee (Reference No. 101/IRB/SZMC/SZH, Dated 04-06-2024). The primary objective was to evaluate the association between current antidiabetic regimens and glycemic control parameters in a hospital-based population. The sample size of 200 was calculated at level of significance 5%, power of study of 80%, mean post-treatment HbA1c for patients treated with metformin plus empagliflozin assumed to be 6.69 ± 0.85 , while for those treated with metformin plus sitagliptin 7.94 ± 1.75 .¹⁰ A consecutive non-probability sampling technique was employed to recruit subjects meeting the eligibility criteria during the study period.

Participants of both genders, aged between 30 and 70 years with available 3 months prior HbA1C report, were considered for inclusion. Key inclusion requirements involved a confirmed diagnosis of Type 2 Diabetes Mellitus (T2DM) with a disease duration exceeding six months and a documented HbA1c level greater than 6.5%. Only patients who had been maintained on their current medication regimen for a minimum of 12 weeks prior to enrollment were selected. Those with aspartate aminotransferase (AST) or alanine aminotransferase (ALT) levels more than 2.5 times the upper normal limit, serum levels of creatinine more than 1.5 mg/dL in men or 1.4 mg/dL in women and taken systemic corticosteroids within the past 12 weeks were excluded. Patients on insulin, pregnant females and patients with urinary tract infections were also excluded. After taking written informed consent, demographic and clinical data were recorded. Unlike interventional designs, participants were not assigned treatments by the researchers. Instead, they were stratified into two observational groups based on their existing prescribed therapy as documented in medical records. Group A consisted of patients currently managed on a fixed-dose combination of empagliflozin and metformin (12.5/1000 mg). Group B comprised patients prescribed sitagliptin and metformin (50/1000 mg).

Venous blood samples were drawn from all

participants at the time of enrollment to measure glycated hemoglobin (HbA1c). Laboratory analysis was performed using standardized enzymatic methods. All data points, including biochemical results and demographic details, were entered into a structured proforma. Type 2 Diabetes Mellitus was operationalized as a self-reported history of the condition corroborated by an HbA1c reading $>6.5\%$. Hypertension was classified as a known diagnosis where the participant had been adherent to antihypertensive pharmacotherapy for a duration of at least two years. Obesity was defined according to body mass index (BMI) criteria, with a threshold of $>27.5 \text{ kg/m}^2$ indicating an obese status.

Data analysis was performed using Statistical Package for the Social Sciences (SPSS) version 23.0. The normality of continuous variables was assessed via the Shapiro-Wilk test. Descriptive statistics for normally distributed quantitative variables, such as age and HbA1c, were presented as mean $\pm$ standard deviation (SD). Non-normally distributed data, including disease duration, were summarized using median and interquartile range (IQR). Categorical variables, including gender, residential status, obesity, and hypertension status, were expressed as frequencies and percentages. Effect modifiers like age, gender, duration of disease, hypertension, obesity and residential status were controlled by stratification. The independent sample t-test was used to compare mean post-treatment HbA1c levels of groups and p-value <0.05 was considered statistically significant.

RESULTS

The distribution of gender, age, duration of disease, hypertension status, obesity and residence was comparable between the Sitagliptin plus Metformin group (Group A) and the Empagliflozin plus Metformin group (Group B). In Group A, 55% of the patients were male and 45% were female, while in Group B, 53% were male and 47% were female, showing a balanced gender distribution across both groups. The majority of patients in both groups were between 51–70 years of age (56% in Group A and 57% in Group B), with mean ages of 50.86 ± 11.95 years and 50.36 ± 12.48 years respectively, indicating no significant difference in age distribution. Regarding disease duration, most

patients had diabetes for ≤ 3 years (53% in Group A and 57% in Group B), with mean durations of 2.84 ± 1.34 years and 2.72 ± 1.27 years, respectively. The prevalence of hypertension was similar in both groups (43% in Group A vs. 44% in Group B), as was the prevalence of obesity (30% vs. 31%). Similarly, the majority of patients were from rural areas in both groups (51% in Group A and 48% in Group B). Overall, both groups were comparable at baseline, indicating successful randomization and homogeneity across demographic and clinical variables.

TABLE-II compares the mean HbA1c levels at baseline and after 12 weeks of treatment between the two study groups. At baseline, there was no statistically significant difference between the groups ($p=0.098$), with mean HbA1c levels of $8.29 \pm 0.74\%$ in the Sitagliptin plus Metformin group and $8.00 \pm 0.82\%$ in the Empagliflozin plus Metformin group. However, after 12 weeks of treatment, a significant reduction in HbA1c was observed in both groups, with a notably greater reduction in the Empagliflozin group. The post-treatment mean HbA1c level was $7.76 \pm 1.82\%$ in the Sitagliptin group and $6.66 \pm 0.81\%$ in the Empagliflozin group, showing a statistically significant difference ($p=0.001$). These findings indicate that Empagliflozin in combination with Metformin was more effective in lowering HbA1c levels compared to Sitagliptin plus Metformin over a 12-week period.

Across all subgroups, patients treated with Empagliflozin plus Metformin showed significantly lower mean HbA1c levels compared to those treated with Sitagliptin plus Metformin ($p=0.001$ in all comparisons).

Among male patients, mean post-treatment HbA1c was $7.70 \pm 1.79\%$ in the Sitagliptin group and $6.67 \pm 0.76\%$ in the Empagliflozin group. Similarly, in females, the corresponding values were $7.84 \pm 1.86\%$ and $6.65 \pm 0.84\%$. In younger patients (30–50 years), the mean HbA1c was $8.02 \pm 1.87\%$ versus $6.68 \pm 0.84\%$, while in older patients (51–70 years), it was $7.56 \pm 1.77\%$ versus $6.65 \pm 0.77\%$ for Sitagliptin and Empagliflozin groups respectively. Patients with a shorter duration of disease (≤ 3 years) had mean HbA1c levels of $7.78 \pm 1.80\%$ and $6.76 \pm 0.73\%$ in the Sitagliptin and Empagliflozin

groups respectively, while those with a longer duration (>3 years) showed means of $7.74 \pm 1.85\%$ and $6.53 \pm 0.87\%$. Among hypertensive patients, HbA1c was $7.98 \pm 1.91\%$ vs. $6.73 \pm 0.81\%$, and in non-hypertensive patients, $7.60 \pm 1.74\%$ vs. $6.61 \pm 0.78\%$ respectively. Similarly, obese patients showed mean HbA1c levels of $7.91 \pm 1.55\%$ in the Sitagliptin group and $6.39 \pm 0.94\%$ in the Empagliflozin group, while non-obese patients had $7.70 \pm 1.92\%$ and $6.79 \pm 0.69\%$, respectively. Across both rural and urban populations, the Empagliflozin plus Metformin group maintained significantly lower HbA1c levels ($p=0.001$).

TABLE-I

Comparison of distribution of different variables between groups

Variables		Groups	
		Group-A (Sitagliptin + Metformin)	Group-B (Empagliflozin + Metformin)
Gender	Male	55(55.0%)	53(53.0%)
	Female	45(45.0%)	47(47.0%)
Age groups	30-50 years	44(44.0%)	43(43.0%)
	51-70 years	56(56.0%)	57(57.0%)
	Mean±S.D	50.86±11.95	50.36±12.48
Duration of disease	≤3 years	53(53.0%)	57(57.0%)
	>3 years	47(47.0%)	43(43.0%)
	Mean±S.D	2.84±1.34	2.72±1.27
Hyperten- sion	Yes	43(43.0%)	44(44.0%)
	No	57(57.0%)	56(56.0%)
Obesity	Yes	30(30.0%)	31(31.0%)
	No	70(70.0%)	69(69.0%)
Residence	Rural	51(51.0%)	48(48.0%)
	Urban	49(49.0%)	52(52.0%)

TABLE-II

Comparison of baseline and post-treatment HbA1c between groups

HbA1c	Groups		P-Value
	Group-A (Sitagliptin + Metformin)	Group-B (Empagliflozin + Metformin)	
Baseline HbA1c	8.29±0.74	8.00±0.82	0.098
Post- treatment HbA1c	7.76±1.82	6.66±0.81	0.001

TABLE-III

Stratification of pain score between groups with respect to different variables

Variables	Groups		P-Value
	Group-A (Sitagliptin + Metformin)	Group-B (Empagliflozin + Metformin)	
Gender			
· Male	7.70±1.79	6.67±0.76	0.001
· Female	7.84±1.86	6.65±0.84	0.001
Age groups			
· 30-50 years	8.02±1.87	6.68±0.84	0.001
· 51-70 years	7.56±1.77	6.65±0.77	0.001
Duration of disease			
· ≤3 years	7.78±1.80	6.76±0.73	0.001
· >3 years	7.74±1.85	6.53±0.87	0.001
Hypertension			
· Yes	7.98±1.91	6.73±0.81	0.001
· No	7.60±1.74	6.61±0.78	0.001
Obesity			
· Yes	7.91±1.55	6.39±0.94	0.001
· No	7.70±1.92	6.79±0.69	0.001
Residence			
· Rural	7.80±1.89	6.69±0.81	0.001
· Urban	7.73±1.76	6.63±0.79	0.001

DISCUSSION

The present study compared effectiveness of Sitagliptin plus Metformin with Empagliflozin plus Metformin in reducing HbA1c levels among patients with type II diabetes mellitus (T2DM). The findings demonstrated that while both combination therapies significantly reduced HbA1c after 12 weeks of treatment, the Empagliflozin based regimen showed superior glycemic response. Mean post-treatment HbA1c was $7.76 \pm 1.82\%$ in the Sitagliptin group and $6.66 \pm 0.81\%$ in the Empagliflozin group, with statistically significant difference ($p=0.001$).

These findings are consistent with previous studies comparing SGLT2 inhibitors and DPP-4 inhibitors as add on therapies to Metformin. Khan et al. reported that Empagliflozin add-on therapy achieved mean HbA1c reduction of 1.35% compared to 0.96% with Sitagliptin, confirming its superior glycemic effect.¹¹ Similarly, Punyaprediar and Hashmi found greater

HbA1c reduction of -1.5% with Empagliflozin compared to -1.3% with Sitagliptin after 12 weeks of treatment.¹² Ahmed et al. also observed that Empagliflozin significantly lowered HbA1c and fasting glucose compared to Sitagliptin in primary healthcare settings.¹³

Laffel et al. demonstrated that SGLT2 inhibitors such as Empagliflozin consistently produce greater HbA1c decline compared to DPP-4 inhibitors, particularly in younger patients with shorter disease duration.¹⁴ This aligns with stratified results in current study, where Empagliflozin achieved significant reductions across all age, gender, and disease duration subgroups. Prakash et al. further supported this trend, showing that Empagliflozin combination therapy achieved mean HbA1c reduction of 1.7% , outperforming Sitagliptin-based regimens.¹⁵

Empagliflozin superior performance may be attributed to its distinct mechanism of action, promoting urinary glucose excretion independent of insulin secretion, thus maintaining efficacy even in patients with β -cell dysfunction.¹⁶ In contrast, Sitagliptin, DPP-4 inhibitor, enhances endogenous incretin levels and insulin secretion, mechanism that may be less effective in patients with long standing diabetes.¹⁷ Meta-analysis by Tanaka et al. showed that SGLT2 inhibitors achieve average HbA1c reduction of 0.8 – 1.2% , whereas DPP-4 inhibitors typically reduce HbA1c by 0.5 – 0.8% .¹⁸

Additionally, Empagliflozin has shown positive effects on weight loss and control of blood pressure which indirectly have positive effects on metabolic outcomes.¹⁹ Ahmed et al. reported that patients under Empagliflozin not only showed better glycemic control but also showed modest improvements in systolic blood pressure and body mass index.²⁰ The cardiovascular and renal protective effects of Empagliflozin reported in long-term outcomes studies add further to the therapeutic value of Empagliflozin in patients with T2DM.²¹

In contrast, Sitagliptin, whilst being well-tolerated and having fewer genitourinary side effects, has been associated with a lower level of glycemic efficacy when compared with newer SGLT2 inhibitor. However, Sitagliptin remains a reasonable treatment

option for patients who have contraindications for SGLT2 inhibitors such as recurrent urinary tract infections or renal impairment.²²

There were several limitations of this study. Sample was collected from one tertiary care centre which may limit generalizability of results for larger populations. The follow-up period of the study was only up to 12 weeks, which may not represent long term efficacy or safety results of compared therapies. Moreover, lifestyle aspects such as diet, exercise and pharmacological adherence were not controlled which may have effect on HbA1c variability. Finally study did not assessed other important metabolic parameters like fasting plasma glucose, lipid profile and changes in body weight which could have given more complete assessment of treatment effects. Despite such limitations, these results are in line with global data showing that combination of Empagliflozin and Metformin produced better glycemic control than Sitagliptin and Metformin, implying that it might be better first line combination therapy in patients in need of dual anti-diabetes therapy.

CONCLUSION

Empagliflozin plus Metformin showed higher efficacy in the reduction of HbA1c levels than Sitagliptin plus Metformin in patients with type II diabetes mellitus.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

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2	Akmal Hussain: Proof reading.
3	Usama Javed: Data collection.
4	Javairia Tehseen: Data analysis.
5	Humza Zafar: Manuscript writing.
6	Munir Ahmed: Data analysis.