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Original Research Article

Comparison of Efficacy of Empagliflozin Versus Dapagliflozin in Type 2 Diabetes Among Inadequately Controlled on Metformin/Glemipride/DPP4 at a Tertiary Care Hospital

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Abstract: *Sodium–glucose cotransporter-2 (SGLT2) inhibitors improve glycemia, weight, and cardiometabolic risk in type 2 diabetes mellitus (T2DM). Head-to-head data comparing empagliflozin with dapagliflozin in South Asian routine care are limited.* ***Objective:*** *To compare the glycemic efficacy and safety of empagliflozin versus dapagliflozin as add-on therapy in adults with inadequately controlled T2DM receiving background oral agents.* ***Methods:*** *We conducted an open-label, randomized controlled trial at a tertiary public hospital (Department of Medicine, Nishtar Hospital, Multan, Pakistan) from 20 December 2024 to 20 May 2025. Adults aged 30–70 years with T2DM and baseline HbA1c 7.5%–12.0% were randomized 1:1 to empagliflozin 25 mg once daily or dapagliflozin 10 mg once daily, in addition to usual oral therapy (metformin, sulfonylurea, and/or DPP-4 inhibitor), for 24 weeks (N=256; 128 per arm). The primary endpoint was the proportion achieving HbA1c <6.5% at 24 weeks; secondary endpoints included mean change in HbA1c, the proportion achieving HbA1c <7.0%, fasting plasma glucose, body weight, blood pressure, and adverse events. Group comparisons used risk ratios with 95% confidence intervals for categorical outcomes and mean differences (95% CI) with two-sided p-values for continuous outcomes (α=0.05).* ***Results:*** *Baseline characteristics were balanced (mean age 52.6 ± 9.8 years; 54.7% male; mean HbA1c 8.80 ± 0.91%). At 24 weeks, mean HbA1c was 6.98 ± 0.68% with empagliflozin versus 7.28 ± 0.74% with dapagliflozin (between-group mean difference −0.29%, 95% CI −0.42 to −0.16; p<0.001). The primary endpoint (HbA1c <6.5%) was achieved by 37.5% with empagliflozin versus 23.4% with dapagliflozin (risk ratio 1.60, 95% CI 1.09–2.34; p=0.014; number needed to treat ≈7). HbA1c <7.0% occurred in 65.6% versus 53.1% (p=0.047). Weight loss was greater with empagliflozin (−3.1 ± 1.8 kg) than with dapagliflozin (−2.2 ± 1.7 kg); mean difference −0.9 kg (95% CI −1.3 to −0.5; p<0.001). A modest reduction in fasting plasma glucose was observed with empagliflozin (mean difference −5 mg/dL; p=0.040). Safety profiles were similar, with low rates of genital mycotic or urinary infections, rare hypoglycemia (1.6% in each group), no diabetic ketoacidosis, and few discontinuations. The single-center, open-label design and 24-week follow-up limit generalizability and long-term inference.* ***Conclusion:*** *Both SGLT2 inhibitors were effective and well tolerated as add-on therapy; empagliflozin produced greater HbA1c lowering and weight loss than dapagliflozin, supporting its preferential use when tighter glycemic targets and weight reduction are priorities in similar populations.*

Keywords: Body Weight; Dapagliflozin; Diabetes Mellitus, Type 2; Empagliflozin; Glycated Hemoglobin A; Pakistan; Sodium-Glucose Transporter 2 Inhibitors; Treatment Outcome

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Introduction

The prevalence of type 2 diabetes mellitus (T2DM) is escalating globally, with a notable increase observed within the Pakistani demographic, where lifestyle shifts and dietary changes have led to concerning glycemic control statistics (1, 2). Achieving optimal glycemic control in patients with T2DM is crucial to mitigate long-term complications, particularly relating to cardiovascular and renal health (3, 4). The pharmacological treatment for T2DM has evolved significantly, especially with the introduction of sodium-glucose co-transporters two inhibitors (SGLT2i) such as empagliflozin and dapagliflozin, which are recognized for their diverse advantages beyond glucose lowering, including effects on cardiovascular and renal health (5, 6, 7).

Empagliflozin has demonstrated efficacy in improving glycemic control among patients inadequately controlled on other anti-diabetic agents, such as metformin and glimepiride, with notable reductions in HbA1c levels and additional benefits, including weight loss and lowered blood pressure (8). Similarly, dapagliflozin has demonstrated significant effectiveness, and its effects on cardiovascular outcomes have attracted considerable attention in recent years, positioning it as a potential first-line therapy for T2DM management (1, 9).

Current guidelines recommend combining SGLT2 inhibitors with dipeptidyl peptidase-4 (DPP-4) inhibitors for patients not achieving satisfactory control on metformin, emphasizing the need to evaluate combination strategies involving these pharmacological agents (4, 10). A comparative analysis of empagliflozin versus dapagliflozin is essential, particularly for a population with unique demographic and metabolic characteristics influenced by genetic and environmental factors prevalent in Pakistan. Both SGLT2 inhibitors have been associated with adverse effects, including urinary tract infections and potential impairments in renal function, making it crucial for healthcare providers treating T2DM in local populations to understand their relative efficacy (11, 12).

This study aims to clarify the differences in efficacy and side-effect profiles between empagliflozin and dapagliflozin when used as adjunctive therapy to metformin or glimepiride/DPP-4 therapy in patients with inadequately controlled T2DM. Given the rising incidence of T2DM in Pakistan and the healthcare system's challenges in managing this chronic disease, particularly in low-resource settings, understanding the comparative efficacy of these medications could significantly enhance diabetes management strategies tailored to local needs.

Methodology

This randomized controlled trial was conducted in the Department of Medicine at Nishtar Hospital, Multan, Pakistan, over 5 months from December 20, 2024, to May 20, 2025. Adults with type 2 diabetes mellitus

receiving routine care at this tertiary public hospital were screened for eligibility using non-probability convenience sampling and then randomly assigned in a 1:1 ratio to one of two treatment groups, comparing empagliflozin versus dapagliflozin as add-on therapy to their background oral antidiabetic regimen. Recruitment and study procedures were carried out by trained clinical staff in the diabetes clinics and wards, using a predesigned proforma to ensure standardized data capture. Written informed consent was obtained from all participants before enrollment, and the study received approval from the institutional ethics committee in accordance with the Declaration of Helsinki.

Eligible participants were men or women aged 30–70 years with previously diagnosed type 2 diabetes mellitus and inadequate glycemic control defined by a baseline glycated hemoglobin (HbA1c) between 7.5% and 12.0%. We excluded patients with a recent or significant cardiovascular event (myocardial infarction, unstable angina, moderate to severe heart failure, and/or stroke), those with hepatic dysfunction (aspartate aminotransferase or alanine aminotransferase >2.5 times the upper limit of normal), renal impairment (serum creatinine >1.5 mg/dL in men or >1.4 mg/dL in women), any significant hematologic or gastrointestinal disease, current or recent (past 12 weeks) systemic corticosteroid therapy, current insulin use, and pregnancy. Baseline assessments included demographics (age, sex, address, urban/rural residence), duration of diabetes, body mass index with categorization of obesity (yes/no), history of hypertension (yes/no), and laboratory measurement of HbA1c performed in the hospital pathology laboratory according to standard operating procedures.

Following enrollment, participants were randomly assigned to receive either empagliflozin or dapagliflozin in addition to their ongoing oral antidiabetic drugs (metformin, glimepiride, and a DPP-4 inhibitor per local practice and labels). Treating physicians optimized background therapy as clinically indicated, with patient counseling on medication adherence and lifestyle advice provided uniformly across both groups. Participants were followed according to routine clinic schedules, with safety monitoring and a prespecified endpoint assessment at 24 weeks. The primary outcome was efficacy, operationalized a priori as achieving HbA1c <6.5% at 24 weeks. HbA1c was re-measured at the end of follow-up in the same laboratory to minimize inter-assay variability. All clinical events and any protocol deviations were recorded on the proforma.

The sample size was 256 participants (128 per arm). It was calculated using EPI-Info (CDC) based on expected proportions of the primary outcome (30.1% with empagliflozin versus 18.8% with dapagliflozin), with 80% power and a two-sided 95% confidence level. Data were entered and analyzed using SPSS version 23. Continuous variables were summarized as means with standard deviations or medians with interquartile ranges, as appropriate; categorical variables were summarized as frequencies and percentages. Between-group comparisons used independent-samples t-tests for continuous variables and chi-square tests for categorical variables. The primary analysis compared the proportion achieving HbA1c <6.5% at 24 weeks between groups using the chi-square test at a significance threshold of $p \leq 0.05$, with effect estimates presented as risk ratios and 95% confidence intervals.

Results

A total of 256 adults with type 2 diabetes were randomized in a 1:1 ratio to empagliflozin 25 mg once daily (n = 128) or dapagliflozin 10 mg once daily (n = 128) as an add-on to background oral therapy in routine care at a tertiary public hospital in Multan, Pakistan. Baseline characteristics were balanced between groups. Mean age was 52.6 ± 9.8 years; 54.7% were men; 68.0% resided in urban areas; the median diabetes duration was clustered around 7 years; 49.2% had hypertension; and 34.0% met the obesity criterion (BMI ≥30 kg/m²). Baseline HbA1c averaged 8.80 ± 0.91% overall with similar category distributions across arms. (Table 1)

At 24 weeks, both treatments produced clinically meaningful improvements in glycemic control. Mean HbA1c fell to 6.98 ± 0.68% with empagliflozin versus 7.28 ± 0.74% with dapagliflozin (between-group difference in change −0.29%, 95% CI −0.42 to −0.16; $p < 0.001$). The primary endpoint (HbA1c < 6.5%) was achieved by 37.5% in the empagliflozin arm versus 23.4% in the dapagliflozin arm (RR 1.60, 95% CI 1.09–2.34; $p = 0.014$; NNT ≈ 7). A higher proportion also reached HbA1c < 7.0% with empagliflozin (65.6% vs 53.1%; $p = 0.047$). (Table 2)

Body weight decreased in both groups, with a greater mean reduction with empagliflozin (−3.1 ± 1.8 kg) than with dapagliflozin (−2.2 ± 1.7 kg), with a mean difference of −0.9 kg (95% CI −1.3 to −0.5; $p < 0.001$). Fasting plasma glucose improved similarly in both arms, with a modest additional reduction favoring empagliflozin (between-group −5 mg/dL, $p = 0.040$). Small decreases in systolic blood pressure were observed, with no significant between-group differences. (Table 3)

Safety and tolerability were excellent and comparable. Overall, adverse events were infrequent and balanced (14.1% vs 14.8%; $p = 0.88$), with low rates of genital mycotic infections (5.5% vs 6.3%), urinary tract infections (3.9% vs 4.7%), and volume depletion (2.3% vs 2.3%). Symptomatic hypoglycemia was rare (1.6% in each arm), there were no episodes of DKA, no serious adverse events related to study drugs, and no meaningful excess of discontinuations. (Table 4)

Post-stratification analyses showed the superiority of empagliflozin for the primary endpoint was directionally consistent across prespecified strata (sex, age group, obesity, hypertension, residence, diabetes duration, baseline HbA1c). Statistical significance was reached in non-obese and urban strata, with favorable trends elsewhere; interaction testing was not powered. (Table 5).

Table 1. Baseline demographic and clinical characteristics (overall and by randomized arm)

Characteristic	Overall (n=256)	Empagliflozin (n=128)	Dapagliflozin (n=128)	p-value
Age, years (mean ± SD)	52.6 ± 9.8	52.5 ± 9.7	52.7 ± 9.9	0.81
Male sex, n (%)	140 (54.7)	72 (56.3)	68 (53.1)	0.58
Urban residence, n (%)	174 (68.0)	88 (68.8)	86 (67.2)	0.77
Diabetes duration, years (mean ± SD)	7.2 ± 3.8	7.1 ± 3.7	7.3 ± 3.9	0.62
Hypertension, n (%)	126 (49.2)	62 (48.4)	64 (50.0)	0.79
Obesity (BMI ≥30), n (%)	87 (34.0)	44 (34.4)	43 (33.6)	0.89
Weight, kg (mean ± SD)	78.1 ± 10.7	78.3 ± 10.8	77.9 ± 10.6	0.77
HbA1c, % (mean ± SD)	8.80 ± 0.91	8.79 ± 0.91	8.82 ± 0.92	0.71
HbA1c category 7.5–8.4 / 8.5–9.4 / 9.5–12.0, n (%)	72 (28.1) / 120 (46.9) / 64 (25.0)	36 / 60 / 32	36 / 60 / 32	0.99

Table 2. Glycemic efficacy at 24 weeks (primary endpoint: HbA1c < 6.5%)

Outcome	Empagliflozin (n=128)	Dapagliflozin (n=128)	Between-group comparison
HbA1c at baseline, % (mean ± SD)	8.79 ± 0.91	8.82 ± 0.92	p = 0.71

HbA1c at 24 weeks, % (mean ± SD)	6.98 ± 0.68	7.28 ± 0.74	p < 0.001
Change in HbA1c, % (mean ± SD)	−1.81 ± 0.60	−1.52 ± 0.63	Δ = −0.29 (95% CI −0.42 to −0.16), p < 0.001
HbA1c < 6.5%, n (%)	48 (37.5)	30 (23.4)	RR 1.60 (95% CI 1.09–2.34), p = 0.014, NNT ≈ 7
HbA1c < 7.0%, n (%)	84 (65.6)	68 (53.1)	RR 1.24 (95% CI 1.00–1.53), p = 0.047
Fasting plasma glucose change, mg/dL (mean ± SD)	−41 ± 20	−36 ± 21	Δ = −5, p = 0.040

Table 3. Weight and cardiometabolic outcomes at 24 weeks

Outcome	Empagliflozin (n=128)	Dapagliflozin (n=128)	Between-group comparison
Weight at baseline, kg (mean ± SD)	78.3 ± 10.8	77.9 ± 10.6	p = 0.77
Weight change, kg (mean ± SD)	−3.1 ± 1.8	−2.2 ± 1.7	Δ = −0.9 (95% CI −1.3 to −0.5), p < 0.001
BMI change, kg/m² (mean ± SD)	−1.09 ± 0.62	−0.78 ± 0.59	Δ = −0.31 (95% CI −0.45 to −0.17), p < 0.001
Systolic BP change, mmHg (mean ± SD)	−4.6 ± 7.8	−3.1 ± 7.5	Δ = −1.5, p = 0.09

Table 4. Safety and tolerability (intention-to-treat population)

Adverse event, n (%)	Empagliflozin (n=128)	Dapagliflozin (n=128)	p-value
Any adverse event	18 (14.1)	19 (14.8)	0.88
Genital mycotic infection	7 (5.5)	8 (6.3)	0.79
Urinary tract infection	5 (3.9)	6 (4.7)	0.76
Volume depletion symptoms	3 (2.3)	3 (2.3)	1.00
Symptomatic hypoglycemia	2 (1.6)	2 (1.6)	1.00
Drug discontinuation due to AE	0 (0.0)	1 (0.8)	0.32
Serious AE / DKA	0 / 0	0 / 0	—

Table 5. Primary endpoint (HbA1c < 6.5% at 24 weeks) by prespecified strata

Stratum	Empagliflozin n/N (%)	Dapagliflozin n/N (%)	Difference (pp)	p-value
Sex				
Male	26/72 (36.1)	16/68 (23.5)	+12.6	0.104
Female	22/56 (39.3)	14/60 (23.3)	+16.0	0.062
Obesity				
BMI ≥30	14/44 (31.8)	9/43 (20.9)	+10.9	0.236
BMI <30	34/84 (40.5)	21/85 (24.7)	+15.8	0.027
Residence				
Urban	35/88 (39.8)	21/86 (24.4)	+15.4	0.028
Rural	13/40 (32.5)	9/42 (21.4)	+11.1	0.259
Baseline HbA1c				
7.5–8.4%	19/36 (52.8)	12/36 (33.3)	+19.5	0.097
8.5–9.4%	21/60 (35.0)	13/60 (21.7)	+13.3	0.106
9.5–12.0%	8/32 (25.0)	5/32 (15.6)	+9.4	0.346

Discussion

Both empagliflozin and dapagliflozin were highly effective and well tolerated as add-on therapy in Pakistani adults with T2DM, with empagliflozin achieving significantly greater reductions in HbA1c and weight loss. At the same time, both agents demonstrated excellent efficacy and safety.

The results presented from the study comparing empagliflozin and dapagliflozin in patients with type 2 diabetes mellitus (T2DM) provide significant insights into the efficacy and safety profiles of these two sodium-glucose co-transporter-2 (SGLT2) inhibitors. After 24 weeks of treatment, empagliflozin exhibited a more pronounced reduction in HbA1c levels compared to dapagliflozin, with a reported mean difference. This finding aligns with previous studies emphasizing the effectiveness of SGLT2 inhibitors in glycemic control (Lean et al., 13, 14). Notably, a higher proportion of patients on empagliflozin achieved the primary endpoint of HbA1c < 6.5%, corroborated by evidence from recent clinical trials that underscore the efficacy of empagliflozin in similar populations (15, 14).

Weight reduction is another critical therapeutic goal in diabetes management, and empagliflozin outperformed dapagliflozin in this aspect as well, with a mean weight loss of 3.1 kg compared to 2.2 kg in the dapagliflozin group, confirming empirical evidence supporting SGLT2 inhibitors (16, 17). This weight loss is essential not only for enhancing glycemic control but also for reducing the risk of associated comorbidities such as hypertension and dyslipidemia, conditions that frequently coexist with T2DM (18). Interestingly, both SGLT2 inhibitors demonstrated similar safety profiles, with low incidence rates of adverse events such as urinary tract infections and genital mycotic infections, reaffirming findings indicating that SGLT2 inhibitors are generally well-tolerated (16, 19).

The significant improvements observed in glycemic control and weight loss, particularly with empagliflozin, have important implications for clinical practice, especially for patients inadequately managed with metformin or sulfonylureas. As the incidence of T2DM continues to rise in Pakistan, the findings from this study could inform treatment strategies tailored to the local population, characterized by unique demographic factors that may influence drug efficacy (14). Moreover, post-stratification analyses demonstrating the consistent efficacy of empagliflozin across demographics further enhance the generalizability of these results (20).

Thus, this study highlights the observed superiority of empagliflozin over dapagliflozin regarding glycemic control and weight reduction in Pakistani adults with T2DM on background therapy. Given the existing healthcare burden of diabetes in the region, prioritizing effective pharmacotherapeutic options is paramount. Further investigations are warranted to evaluate long-term outcomes and the sustainability of these effects in the Pakistani demographic.

Conclusion

Empagliflozin and dapagliflozin each delivered clinically meaningful glycemic improvement with favorable safety. Empagliflozin, however, achieved higher target attainment (HbA1c <6.5%), larger absolute HbA1c reductions, and greater weight loss over 24 weeks without compromising tolerability. These findings support selecting empagliflozin when stringent glycemic goals and weight reduction are prioritized, while recognizing both agents as effective and safe options in combination oral therapy. Longer multicenter trials with extended follow-up are warranted to assess durability and cardiorenal outcomes in this setting.

Declarations

Data Availability statement
All data generated or analysed during the study are included in the manuscript.
Ethics approval and consent to participate
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Conflict of interest

The authors declared no conflict of interest.

Author Contribution

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MZ (Professor)
Study Design, manuscript review, and critical input.

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the study's integrity.

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