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Original Research Article

Comparison of the Mean Blood Pressure of Patients in Type 2 Diabetes Mellitus by Empagliflozin as Compared to Others (Oral Hypoglycemic) Non-SGLT2 Inhibitors

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Abstract:

Introduction: Sodium-glucose co-transporter 2 (SGLT-2) inhibitors are the new anti-diabetic medications that have been on the market in Pakistan for a short time but have been used for a few years worldwide. On the use of these medications in our environments, however, very little information is accessible. The aim of this study is to evaluate the mean blood pressure of individuals with type 2 diabetes mellitus treated with empagliflozin compared to other non-SGLT2 inhibitors (oral hypoglycemics), addressing a gap in the local literature and reducing morbidity.

Study design: Randomized controlled trial

Setting: Department of Medicine, Shahida Islam Teaching Hospital, Lodhran.

Study duration: 10th June 2025 to 9th September 2025.

Methodology: Total 300 patients aged 20–70 years, both genders, with type 2 diabetes mellitus and hypertension lasting longer than three months were included. Heart failure, chronic renal failure, pregnant women, and a history of hypertension prior to type 2 diabetes that lasted more than six months were excluded. Using a lottery, the patients were split into two groups. Both groups' baseline blood pressures were recorded. Group B was given non-SGLT2 inhibitors (metformin 500 mg BID), while Group A was given 10 mg empagliflozin for the first four weeks, with the dosage increased to 25 mg until week twelve. Blood pressure was recorded after 12 weeks of treatment, and all patients were monitored by a ward doctor who was not aware of the study groups.

Results: According to our study, the mean baseline and change in SBP for group A (empagliflozin) were 130.60 ± 3.79, 128.48 ± 3.26, and 2.12 ± 1.57 mmHg after 12 weeks, while the mean baseline and change in SBP for group B (control) were 130.18 ± 4.08, 129.41 ± 3.81, and 0.71 ± 0.75 mmHg after 12 weeks. Group B (control) had mean baseline and change in SBP of 80.91 ± 2.81, 79.94 ± 2.51, and 0.98 ± 0.75 mmHg after 12 weeks, whereas mean baseline and change in SBP were 80.80 ± 2.83, 77.69 ± 2.29, and 3.14 ± 1.18 mmHg, respectively.

Conclusion: According to the study's findings, empagliflozin is a medication that effectively lowers blood pressure in people with type 2 diabetes.

Keywords: Blood pressure, Empagliflozin, type 2 diabetes.

INTRODUCTION

The prevalence of diabetes mellitus (DM) in adult populations is between 6 and 10%, and it is expected to double by 2030, making it a major global public health issue. More than 90% of people with diabetes have type 2 DM.1 By 2040, that number is anticipated to rise to 642 million.2,3 Crucially, it has long been known that type 2 diabetes and hypertension are components of the metabolic syndrome; as a result, around 90% of people with type 2 diabetes also have blood pressure issues.4 The risk of cardiovascular disease is significantly increased by a factor of three when diabetes mellitus

(DM) is present, regardless of the systolic blood pressure (SBP) level, starting with prehypertensive levels. Moreover, individuals with diabetes who have hypertension have a quadrupled cardiovascular risk.5

For those with T2DM, empagliflozin, an inhibitor of the sodium-glucose cotransporter 2 (SGLT2), improves glycemic control. Apart from their positive effects on diabetes mellitus, SGLT2 inhibitors have also been shown to help lower blood pressure and the risk of cardiovascular disease.6,7

There isn't a systematic mechanism in place right now to track the prevalence of diabetes and hypertension in Pakistan as well as how they interact. For the past few years, health regulatory bodies have only been putting on educational efforts to raise public awareness, which is insufficient. SGLT-2 inhibitors are the new anti-diabetic medications that have been on the market in Pakistan for a short time but have been used for a few years worldwide. On the use of these medications in our environments, however, very little information is accessible. Therefore, the purpose of this study is to assess the mean blood pressure of patients with T2DM using empagliflozin in comparison to alternative non-SGLT2 inhibitors (oral hypoglycemic) in order to close a gap in the local literature and lower morbidity. Even though it has been known for a while, there isn't much literature about it, and no local study of this kind has ever been conducted. My research will contribute significantly to the body of existing literature and offer local statistics that will assist physicians in incorporating it into their daily practices.

METHODOLOGY:

From 10th June 2025 to 9th September 2025, this randomized clinical trial was carried out in the Shahida Islam Teaching Hospital's Department of Medicine in Lodhran. A successive non-probability selection method was used to choose a sample of 300 patients. Using the WHO calculator, the sample size was 300 (150 in each group), with a 5% level of significance, 80% research power, and mean systolic blood pressure of 127±9.8 mmHg after 12 weeks of empagliflozin and 129±9.7 mmHg in the group not taking SGLT2 inhibitors.8 All patients aged 20–70 years, both male and female, with type 2 diabetes mellitus lasting longer than three months, and those with hypertension lasting longer than three months were included. Heart failure, chronic renal failure, pregnant women, and a history of hypertension prior to type 2 diabetes that lasted more than six months were excluded. It was approved by the Institutional Ethical Review Committee before the patients' consent was obtained.

The following factors were recorded: age, gender, height, weight, BMI, duration of diabetes mellitus, diabetes status (controlled or uncontrolled), duration of hypertension, whether or not HTN was under control, and place of residence. Using a lottery, the patients were split into two groups. Both groups' baseline blood pressures were recorded. Group B was given non-SGLT2 inhibitors (metformin 500 mg BID), while Group A was given 10 mg empagliflozin for the first four weeks, with the dosage increased to 25 mg until week twelve. Blood pressure was recorded after 12 weeks of treatment, and all patients were monitored by a ward doctor who was not aware of the study groups. By appropriately contacting and monitoring the patients, medication compliance was guaranteed. A freshly created proforma was used to record all of the data.

The statistical study was carried out using SPSS version 25.0. The mean ± SD of the results for age, BMI, baseline, duration of diabetes mellitus, and SBP & DBP after 12 weeks were shown. The percentage and frequency for gender were calculated. A p-value of ≤0.05 was deemed significant when comparing the SBP & DBP in both groups using the independent "t" test. Stratifications were used to control effect modifiers like BMI, age, gender, and duration of DM. When there were more than two stratified groups, their effect on blood pressure was assessed using the post-stratification independent "t" test or Mann Whitney test; a p-value of ≤0.05 was deemed significant.

RESULTS

Mean age was 43.19 ± 10.66 years. Group A patients were 42.56 ± 10.85 years old, while group B patients were 44.50 ± 10.50 years old. Of the 300 patients, 158 (52.67%) were men and 142 (47.33%) were women, resulting in a male to female ratio of 1.1:1. The average duration of DM was 12.55 ± 4.38 years. A mean BMI of 28.93 ± 2.48 kg/m2 was recorded. Table I displays the distribution of the various variables.

According to our study, the mean baseline and change in SBP for group A (empagliflozin) were 130.60 ± 3.79, 128.48 ± 3.26, and 2.12 ± 1.57 mmHg after 12 weeks, while the mean baseline and change in SBP for group B (control) were 130.18 ± 4.08, 129.41 ± 3.81, and 0.71 ± 0.75 mmHg after 12 weeks (Table II). Group B (control) had mean baseline and change in SBP of 80.91 ± 2.81, 79.94 ± 2.51, and 0.98 ± 0.75 mmHg after 12 weeks, whereas mean baseline and change in SBP were 80.80 ± 2.83, 77.69 ± 2.29, and 3.14 ± 1.18 mmHg, respectively (Table III). Tables IV and V display the stratification of change in SBP and DBP by age, gender, BMI, and length of DM.

Table-I: Distribution of different variables (n=300).

		Group A (n=150)	Group B (n=150)
		Number (%)	Number (%)
Age (years)	**20-45**	84 (56.0%)	74 (49.33%)
	46-70	66 (44.0%)	76 (50.67%)
Gender	**Male**	81 (54.0%)	77 (51.33%)
	Female	70 (46.0%)	73 (48.67%)
Duration of DM	**≤10**	53 (35.33%)	41 (27.33%)
	>10	97 (64.67%)	109 (72.67%)
BMI (kg/m^2)	**≤25**	40 (26.67%)	48 (32.0%)
	>25	110 (73.33%)	102 (68.0%)

Table-II: Comparison of baseline, after 12 weeks and change in SBP.

Systolic BP (mmHg)	Group A (n=150)	Group B (n=150)	p-value
	Mean ± SD	Mean ± SD	
Baseline	130.60 ± 3.79	130.18 ± 4.08	**0.192**
After 12 weeks	128.48 ± 3.26	129.41 ± 3.81	**0.001**
Change	2.12 ± 1.57	0.71 ± 0.75	**0.0001**

Table-III: Comparison of baseline, after 12 weeks and change in DBP.

Diastolic BP (mmHg)	Group A (n=150)	Group B (n=150)	p-value
	Mean ± SD	Mean ± SD	
Baseline	80.80 ± 2.83	80.91 ± 2.81	**0.633**
After 12 weeks	77.69 ± 2.29	79.94 ± 2.51	**0.0001**
Change	3.14 ± 1.18	0.98 ± 0.75	**0.0001**

Table IV: Stratification of change in SBP with respect to age, gender, BMI and duration of DM.

		Group A (n=150) change in SBP		Group B (n=150) change in SBP		P-value
		Mean	SD	Mean	SD	
Age (years)	**18-40**	2.09	1.41	0.69	0.88	**0.0001**
	41-60	2.16	1.74	0.73	0.63	**0.0001**
Gender	**Male**	1.83	1.66	0.90	0.84	**0.0001**
	Female	2.47	1.39	0.51	0.59	**0.0001**
BMI (kg/m^2)	**≤30**	2.08	1.57	0.66	0.68	**0.0001**
	>30	2.19	1.58	0.79	0.84	**0.0001**
Duration (years)	**≤10**	1.87	1.86	0.53	0.78	**0.0001**
	>10	2.27	1.37	0.78	0.73	**0.0001**

Table V: Stratification of change in DBP with respect to age, gender, BMI and duration of DM.

		Group A (n=150) change in DBP		Group B (n=150) change in DBP		P-value
		Mean	SD	Mean	SD	
Age (years)	**18-40**	2.66	0.98	1.05	0.65	**0.0001**
	41-60	3.69	1.14	0.93	0.82	**0.0001**
Gender	**Male**	3.64	1.29	1.11	0.72	**0.0001**
	Female	2.55	1.64	0.85	0.76	**0.0001**
BMI (kg/m^2)	**≤30**	3.07	1.17	0.96	0.74	**0.0001**
	>30	3.24	1.19	1.02	0.76	**0.0001**
Duration (years)	**≤10**	3.11	1.44	1.11	0.69	**0.0001**
	>10	3.16	1.00	0.94	0.77	**0.0001**

DISCUSSION

One prevalent comorbidity that raises the risk of CVD problems in people with T2DM is hypertension. Finding out how empagliflozin, given for 12 weeks, affects blood pressure in patients with type 2 diabetes and hypertension was the aim of this study. We compared office blood pressure measures and ABPM because the latter is not affected by the "white coat" effect.9 Twelve weeks of empagliflozin treatment resulted in notable and clinically significant improvements in 24-hour SBP and DBP when compared to a placebo. Lower blood pressure levels accompanied these gains. Blood pressure and glycemia control combined with T2DM and HTN greatly decreased the risk of cardiovascular problems and death in these patients.10. According to our study, the mean baseline and change in SBP for group A (empagliflozin) were 130.60 ± 3.79, 128.48 ± 3.26, and 2.12 ± 1.57 mmHg after 12 weeks, while the mean baseline and change in SBP for group B (control) were 130.18 ± 4.08, 129.41 ± 3.81, and 0.71 ± 0.75 mmHg after 12 weeks. In group B (control), the mean baseline and change in SBP after 12 weeks were 80.91 ± 2.81, 79.94 ± 2.51, and 0.98 ± 0.75 mmHg, respectively, whereas the mean baseline and change in SBP were 80.80 ± 2.83, 77.69 ± 2.29, and 3.14 ± 1.18 mmHg. In a clinical trial, Bosch et al.8 recruited 58 people with type 2 DM between the ages of 18 and 75. Each participating patient received 25 mg of oral empagliflozin once day for six weeks, or a placebo (crossover). The SphygmoCor System (AtCor Medical) was used to record the central systolic and central pulse pressures. The Empagliflozin group's mean systolic blood pressure dropped from 129±10.4 mmHg to 127±9.8 mmHg, while the non-SGLT2 inhibitor group's was 129±9.7 mmHg. In the group using empagliflozin, the mean diastolic blood pressure decreased from 79.2±6.3 to 77.7±6.9 mmHg, while in the group not taking SGLT2 inhibitors, it was 80±7.0 mmHg.8

Another study11 reported that giving people with T2DM and high blood pressure 10 mg or 25 mg of empagliflozin once a day made them lose weight, lower their blood pressure (BP), and lower their glycohemoglobin levels compared to a placebo in the EMPA-REG BP trial. For 12 weeks, patients received either empagliflozin 10 mg, empagliflozin 25 mg, or placebo. This study looked at how the mean 24-hour SBP and DBP changed from the start of the study to week 12 for individuals taking 0, 1, or ≥2 antihypertensive medicines. After 12 weeks, empagliflozin lowered SBP and DBP in people with type 2 diabetes mellitus and high blood pressure.11

Since the initial research12 done on diabetic individuals, the advantages of SGLT2 inhibitors on blood pressure have been clear. The EMPA-REG BP investigation looked at how empagliflozin changed the blood pressure of diabetic patients with stage 1 hypertension after they had taken the drug for 12 weeks. The diastolic blood pressure (DBP) decreased significantly, with values of −1.36 mmHg for empagliflozin 10 mg and −1.72 mmHg for empagliflozin 25 mg. The 24-hour systolic blood pressure (SBP) also decreased significantly, with values of −3.44 mmHg for empagliflozin 10 mg and −4.16 mmHg for empagliflozin 25 mg.12 In a similar experiment, individuals with uncontrolled type 2 diabetes who received 10 mg of dapagliflozin, with SBP and DBP values ranging from 140 to 165 mmHg and 85 to 105 mmHg, respectively, had a decrease of 4.28 mmHg in SBP.13

One of the first meta-analyses14 to look at how SGLT2 inhibitors affect blood pressure in persons with type 2 diabetes reported that they lowered SBP by 4 mmHg and DBP by 1.6 mmHg. No matter what kind of experiment it was or what SGLT2 inhibitor was used, this decrease was clear.14 SGLT2 inhibitors lower the 24-hour blood pressure of persons with diabetes by a lot.15 SGLT2 inhibitors decreased the SBP and DBP of people who walked around for 24 hours by 3.62 and 1.7 mmHg, respectively. During the day, SBP and DBP dropped by −4.32 and −2.03 mmHg, respectively. At night, they dropped by −2.62 and −1.39 mmHg, respectively.16

The Department of Medicine at Mayo Hospital conducted a randomized, double-blind study17 in which 270 patients with T2DM were randomized to receive either empagliflozin 10 mg or dapagliflozin 10 mg daily. The groups receiving empagliflozin and dapagliflozin experienced comparable drops in HbA1c levels (-0.9±0.8% vs. -0.8±0.8%, P=0.40). The groups did not

differ significantly in terms of systolic blood pressure (-5 mmHg each) or weight loss (-3.3 kg each). A similar percentage of cardiovascular events occurred (10.4% vs. 11.1%, P=0.84).17

Empagliflozin reduced considerable cardiovascular mortality. The way empagliflozin improves endothelial function and makes arteries less rigid may be the reason why SGLT2i decreases blood pressure.18 SGLT2i led to clinically meaningful reductions in both systolic blood pressure and HbA1c in individuals with hypertension and type 2 diabetes.

Recent guidelines have prioritized the management of systolic blood pressure, as it serves as a more dependable indicator of cardiovascular disease risk. This research provided preliminary evidence that SGLT2 inhibitors can lower both office and 24-hour systolic blood pressure in persons with T2DM & HTN. When compared to the same dose of a placebo, SGLT2 lowered SBP by an average of 4.53 mmHg and 24-hour systolic blood pressure by an average of 5.06 mmHg. SGLT2i also had some effect on lowering the average DBP and the 24-hour blood pressure. The effectiveness of SGLT2i as an antihypertensive is influenced by the selection of first-line antihypertensive medications.19,20

Advantages and disadvantages: A randomized double-blind design, a high follow-up rate, and a comprehensive assessment of metabolic, cardiovascular, and renal outcomes are among the advantages of our study. Patients who are probably candidates for SGLT2 inhibitors in clinical practice were the ones we specifically enrolled. Cardiologists and diabetes specialists can better apply this to real-world T2DM populations.

We are aware of such restrictions. First, the 12-month study period and sample size were sufficient to identify variations in surrogate markers, but not enough to compare clinical CV event rates conclusively, which were low. One cannot overlook long-term variations in results, like death. Determining whether any divergence appears over a number of years may be aided by ongoing, extensive observational comparisons and post-marketing research. Second, we looked into taking 10 mg of empagliflozin daily. Although the effects of higher dosages of empagliflozin (25 mg) might change slightly, prior research indicates that most outcomes, with the exception of glycemic effectiveness, have a flat dose-response. Third, the results may need to be verified in other ethnic groups because our population was South Asian, but evidence from Western cohorts indicates that there are no appreciable differences between drugs. Lastly, even though some mechanistic endpoints (such variations in arterial stiffness or ketone levels) may vary between agents and have questionable clinical importance, we did not assess them.

CONCLUSION:

The study's results show that empagliflozin is a drug that works well to decrease blood pressure in persons with type 2 diabetes. Consequently, we recommend empagliflozin as the primary treatment for type II diabetes mellitus, as it will also aid in reducing blood pressure and cardiovascular events in these patients.

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