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EVALUATING THE EFFICACY OF SGLT2 INHIBITORS IN MANAGING BLOOD PRESSURE IN PATIENTS WITH TYPE 2 DIABETES AND HYPERTENSION: A STUDY AT PEMH RAWALPINDI

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ABSTRACT:
Objectives: To evaluate the efficacy of SGLT2 inhibitors in managing blood pressure in patients with type 2 diabetes and hypertension.
Materials and Methods: After ethical approval and informed consent, 220 eligible patients were enrolled and equally allocated into two groups. Group A received dapagliflozin (10 mg once daily) plus standard therapy, while Group B received standard treatment alone. Baseline demographic and clinical data were collected using a structured questionnaire, and patients were followed for 3 months. Blood pressure was measured at baseline and after 12 weeks to assess efficacy, defined as a reduction of ≥5 mmHg in systolic and/or ≥3 mmHg in diastolic blood pressure. Data were analyzed using SPSS version 25.
Results: The mean age was 54.3±7.87 years in Group A and 56.5±7.91 years in Group B. Overall treatment effectiveness was significantly higher in Group A than in Group B (78.2% vs. 49.1%, $p<0.001$). Stratified analysis also showed significantly greater effectiveness with dapagliflozin across most age, gender, duration of hypertension, duration of diabetes, and BMI subgroups, except among patients with hypertension >10 years, diabetes duration of 1–5 years, and normal BMI, where the differences were not statistically significant.
Conclusion: It was concluded that the addition of dapagliflozin to standard therapy was more effective than standard treatment alone in reducing blood pressure in patients with type 2 diabetes mellitus and hypertension. Dapagliflozin may provide additional metabolic and cardiovascular benefits, although larger multicenter studies with longer follow-up are needed to confirm these findings.

KEYWORDS: SGLT2 inhibitors, hypertension, type 2 diabete

INTRODUCTION:

An estimated 415 million adults worldwide suffer with diabetes mellitus, which is a major source of disease and mortality.(1) Type ll Diabetes Mellitus, which is caused by peripheral insulin resistance and decreased insulin synthesis and secretion, is diagnosed in about 90% of diabetic patients.(2) Ischemic heart disease (21.2%) and macrovascular problems (32.2%) are more common in those with type ll diabetes.(3) Patients who have both diabetes and hypertension are two to four times more likely to experience cardiovascular problems than those who only have either condition.(4) The American Diabetes Association recommends target HbA1c levels of below 7% in patients of Type II DM (5). Sodium glucose cotransporter-2 receptors are upregulated in Type ll diabetes, which increases renal glucose reabsorption and maintains hyperglycemia (6). SGLT2 inhibitors are new hypoglycemic medications that affect the kidneys and cause enhanced natriuresis, osmotic diuresis, and glycosuria. This leads to decreased blood pressure and weight loss in addition to better glycemic management (7). SGLT2 inhibitors are currently regarded as drugs for diabetic complications and cardiorenal protection since they are linked to better cardiovascular outcomes (8). Studies have tried to evaluate SGLT2 inhibitors' ability to lower blood pressure in addition to their effectiveness in treating diabetes. In a study conducted by Aloysius Ikwuka et al. (9) stated that GFR increased in 22.7% of Group II patients and reduced in 9.1% of Group I patients. BP in all Group II patients did not exceed 150/90 mmHg, which was exceeded in Group I patients. Effective blood pressure control is crucial because type 2 diabetes mellitus is frequently linked to hypertension, which raises the risk of cardiovascular and renal problems. SGLT2 inhibitors, particularly dapagliflozin, have been found to improve cardiovascular health and may lower blood pressure. However, there is little local data on their efficacy in type 2 diabetic hypertensive individuals.In order to provide evidence for better therapeutic approaches and better clinical outcomes in this high-risk population, this study is being carried out to assess the effectiveness of SGLT2 inhibitors in controlling blood pressure in individuals with type 2 diabetes and hypertension.

Objective: To evaluate the efficacy of SGLT2 inhibitors in managing blood pressure in patients with type 2 diabetes and hypertension.

MATERIALS AND METHODS:
Study Design: Quasi experimental study
Study setting: Department of Medicine, Pak Emirate Military Hospital, Rawalpindi.
Duration of the study: The study was conducted from 28 April to 28 july.
Sampling Technique:
Non-probability Consecutive sampling.
Sample size: The sample size will be calculated by using WHO sample size calculator keeping the following parameter:
Level of confidence: 95 %,
Margin of error: 5%
Power: 80 %
Anticipated population I: 9.1% (9)
Anticipated population II: 22.7% (9)
Sample size will be 220 patients
Selection criteria:
Inclusion criteria:
- Age 40–65 years
- Patients diagnosed with Type ll Diabetes Mellitus (HbA1c ≥ 7%).
- Controlled hypertension (SBP <140 mmHg, DBP <90 mmHg) with or without antihypertensive therapy.
- No prior use of SGLT2 inhibitor.

Exclusion criteria:
- Patients diagnosed with Type I DM.
- Patients with systolic blood pressure of > 180 mmHg or diastolic blood pressure of > 110 mmHg.
- Patients with poor compliance with treatment.
- Patients with a prior history of SGLT2i use.
- Patients with Grade IV or V CKD (eGFR < 3Oml/min).
- Patients with active, untreated genitourinary infection.
- Patients hypersensitive to Dapagliflozin.
- Pregnant females.

Methods: Patients who met the inclusion criteria were enrolled in the study after obtaining approval from CPSP and the Ethical Committee of Pak Emirates Military Hospital, Rawalpindi. Written informed consent was obtained from all patients or their guardians. A total of 220 patients were enrolled and divided into two groups. Group A received SGLT2 inhibitors (dapagliflozin 10 mg once daily) in addition to standard antidiabetic and antihypertensive therapy, while Group B (control group) received standard treatment without SGLT2 inhibitors. A structured predesigned questionnaire was used to collect demographic and clinical data, including age, gender, duration of diabetes, duration of hypertension, BMI, HbA1c level, and systolic and diastolic blood pressure. All patients were followed for 3 months. Blood pressure readings were recorded at baseline and during follow-up visits to assess changes in systolic and diastolic blood pressure. The primary outcome of the study was the reduction in systolic and diastolic blood pressure, while the secondary outcomes were changes in HbA1c and body weight. Efficacy was assessed by the change in systolic and diastolic blood pressure (mmHg) from baseline to 12 weeks of treatment. A reduction of ≥5 mmHg in systolic and/or ≥3 mmHg in diastolic blood pressure was considered effective. The SPSS version 25 was used to enter and analyze the gathered data.

RESULTS:
The mean age was 54.3±7.87 years in Group A and 56.5±7.91 years in Group B. In Group A, 59 (53.6%) patients were male and 51 (46.4%) were female, while Group B included 63 (57.3%) males and 47 (42.7%) females. Most patients in Group A were aged 51–60 years (43.6%), whereas the majority in Group B were older than 60 years (41.8%). The mean duration of hypertension was 5.91±2.17 years in Group A and 5.66±2.03 years in Group B. The mean systolic blood pressure was 149.6±10.8 mmHg in Group A and 148.9±10.5 mmHg in Group B, while the mean diastolic blood pressure was 91.4±7.3 mmHg and 90.8±6.9 mmHg, respectively. The mean duration of diabetes was 7.98±2.45 years in Group A and 7.28±2.49 years in Group B. The mean HbA1c level was 8.5±1.20% in Group A and 8.4±1.13% in Group B. The mean BMI was 27.39±3.66 kg/m² in Group A and 26.59±3.71 kg/m² in Group B. Regarding BMI categories, obesity was the most common category in Group A (43.6%), whereas overweight and obesity were equally common in Group B (34.5% each). (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics (n=220)

Variables	Groups	
	Group A (n=110)	Group B (n=110)
Age (Years)	54.3±7.87	56.5±7.91
Gender		
Male	59(53.6%)	63(57.3%)
Female	51(46.4%)	47(42.7%)
Age Groups		
40-50 years	39(35.5%)	28(25.5%)
51-60 years	48(43.6%)	36(32.7%)
>60 years	23(20.9%)	46(41.8%)
Duration of hypertension (years)	5.91±2.17	5.66±2.03
Systolic BP (mmHg)	149.6±10.8	148.9±10.5
Diastolic BP (mmHg)	91.4±7.3	90.8±6.9
Duration of diabetes (years)	7.98±2.45	7.28±2.49
HbA1c level	8.5±1.20	8.4±1.13
BMI	27.39±3.66	26.59±3.71
BMI Categories		
Normal	25(22.7%)	34(30.9%)
Over weight	37(33.6%)	38(34.5%)
Obese	48(43.6%)	38(34.5%)

The effectiveness of treatment was significantly higher in Group A than in Group B. Effective blood pressure reduction was achieved in 86 (78.2%) patients in Group A compared with 54 (49.1%) patients in Group B, while treatment was not effective in 24 (21.8%) and 56 (50.9%) patients, respectively. This difference was statistically significant ($p<0.001$) (Table 2).

Table 2: Comparison of Treatment Effectiveness between Groups (n=220)

Variables	Groups		
	Group A	Group B	P-Value
Effectiveness			
Yes	86(78.2%)	54(49.1%)	0.00
No	24(21.8%)	56(50.9%)	

Treatment effectiveness was significantly higher in Group A than Group B among both males (79.7% vs. 46.0%, $p<0.001$) and females (76.5% vs. 53.2%, $p=0.01$). Across all age groups, Group A demonstrated significantly greater effectiveness than Group B, including patients aged 40–50 years (79.5% vs. 57.1%, $p=0.04$), 51–60 years (77.1% vs. 41.7%, $p<0.001$), and >60 years (78.3% vs. 50.0%, $p=0.01$). Similarly, among patients with hypertension for 1–5 years and 6–10 years, treatment effectiveness was significantly greater in Group A (78.7% vs. 53.0%, $p<0.001$ and 76.9% vs. 44.4%, $p<0.001$, respectively), whereas the difference for those with hypertension >10 years was not statistically significant (80.0% vs. 37.5%, $p=0.06$). According to the duration of diabetes, no significant difference was observed in patients with diabetes for 1–5 years (57.1% vs. 48.1%, $p=0.58$); however, Group A showed significantly higher effectiveness among patients with diabetes for 6–10 years (79.7% vs. 48.4%, $p<0.001$) and >10 years (85.2% vs. 52.4%, $p=0.01$). Regarding BMI categories, treatment effectiveness was comparable in patients with normal BMI (68.0% vs. 55.9%, $p=0.34$), while significantly higher effectiveness was observed in Group A among overweight (83.8% vs. 50.0%, $p<0.001$) and obese patients (79.2% vs. 42.1%, $p<0.001$) (Table 3).

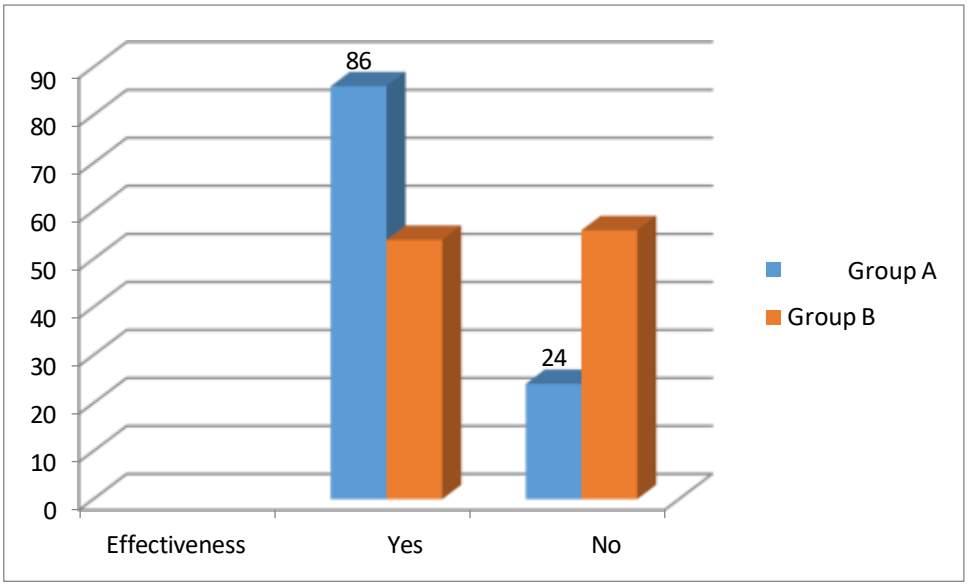


Fig 1: Frequency of effectiveness among both groups

Table 3: Stratification of Treatment Effectiveness Between both Groups according to Demographic and Clinical Variables (n=220)

Variables		Groups		P-Value
		Group A	Group B	
Gender	Effectiveness			
Male	Yes	47(79.7%)	29(46.0%)	0.00
	No	12(20.3%)	34(54.0%)	
Female		39(76.5%)	25(53.2%)	0.01
		12(23.5%)	22(46.8%)	
Age Groups				
40-50 years	Yes	31(79.5%)	16(57.1%)	0.04
	No	8(20.5%)	12(42.9%)	
51-60 years	Yes	37(77.1%)	15(41.7%)	0.00
	No	11(22.9%)	21(58.3%)	
>60 years	Yes	18(78.3%)	23(50.0%)	0.01
	No	5(21.7%)	23(50.0%)	
Duration of hypertension (years)				
1-5 years	Yes	48(78.7%)	35(53.0%)	0.00
	No	13(21.3%)	31(47.0%)	
6-10 years	Yes	30(76.9%)	16(44.4%)	0.00
	No	9(23.1%)	20(55.6%)	
>10 years	Yes	8(80.0%)	3(37.5%)	0.06
	No	2(20.0%)	5(62.5%)	
Duration of diabetes (years)		7.98±2.45	7.28±2.49	
1-5 years	Yes	8(57.1%)	13(48.1%)	0.58
	No	6(42.9%)	14(51.9%)	
6-10 years	Yes	55(79.7%)	30(48.4%)	0.00
	No	14(20.3%)	32(51.6%)	
>10 years	Yes	23(85.2%)	11(52.4%)	0.01
	No	4(14.8%)	10(47.6%)	
BMI Categories				
Normal	Yes	17(68.0%)	19(55.9%)	0.34
	No	8(32.0%)	15(44.1%)	
Over weight	Yes	31(83.8%)	19(50.0%)	0.00
	No	6(16.2%)	19(50.0%)	

Obese	Yes	38(79.2%)	16(42.1%)	0.00
	No	10(20.8%)	22(57.9%)	

DISCUSSION:

Over the past forty years, there has been a significant increase in the prevalence of diabetes worldwide.(10) About 95% of the 34.2 million persons with diabetes in the United States alone have type 2 diabetes mellitus.(11) Compared to people without diabetes, adults with diabetes have a significantly greater risk of cardiovascular disease, which accounts for 10–12% of all vascular deaths.(12, 13) Hypertension and diabetes mellitus are independent risk factors for cardiovascular disease.(12) Patients with type 2 diabetes have approximately a threefold higher risk of developing cardiovascular disease compared with individuals without diabetes.(14) Myocardial infarction, stroke, and chronic kidney disease (CKD) are among the major cardiovascular and renal problems that patients with type 2 diabetes mellitus and hypertension are significantly more likely to experience.(15)

In order to lower blood pressure in individuals with type 2 diabetes mellitus and hypertension, the current study assessed the efficacy of adding dapagliflozin to routine antihypertensive and antidiabetic medication. The results showed that compared to patients getting standard treatment alone, those receiving dapagliflozin considerably reduced their blood pressure. SGLT2 inhibitors offer significant antihypertensive benefits beyond conventional medication, as evidenced by the overall treatment effectiveness of 78.2% of patients in the dapagliflozin group vs to 49.1% in the control group ($p<0.001$). A more recent family of oral antidiabetic medications called SGLT2 inhibitors lowers blood pressure and blood sugar by decreasing renal salt and glucose reabsorption.(16) Additionally, they have less adverse effects on the heart, liver, and kidneys than many traditional antidiabetic drugs and have cardioprotective and renoprotective advantages through enhanced salt homeostasis. Sha Chen et al.(17) proposed that myocardial cells will start intracellular plasmalemma sodium loaders when stimulated by hypoxia, oxidative stress, validation, acidosis, etc. The present study's fnding of dapagliflozin's greater efficacy is in line with results from earlier clinical studies. The EMPA-REG OUTCOME, DECLARE-TIMI 58, and CANVAS investigations are just a few of the large cardiovascular outcome trials that have repeatedly shown that SGLT2 inhibitors lower systolic and diastolic blood pressure in individuals with type 2 diabetes mellitus in a moderate but clinically significant way. These effects are thought to be caused by natriuresis, osmotic diuresis, improvement in arterial stiffness, reduction in plasma volume, and mild weight loss, all of which help to improve blood pressure regulation. Subgroup analysis showed that dapagliflozin's positive effects persisted in all age groups and both sexes. Both male and female patients showed notable improvements, indicating that SGLT2 inhibitors' antihypertensive effects are gender-neutral. Similarly, patients who were 40–50 years old, 51–60 years old, and older than 60 years old all showed significantly higher treatment effectiveness when compared to controls, suggesting that age did not reduce the therapeutic response. Treatment results were also affected by the duration of hypertension. Individuals with hypertension for up to ten years showed considerable improvements, however individuals with hypertension for more than ten years showed no statistically significant change. This result could be explained by the subgroup's comparatively small patient population, which lowers statistical power.

CONCLUSION:

It was concluded that in patients with type 2 diabetes mellitus and hypertension, the adding of dapagliflozin to standard antidiabetic and antihypertensive therapy was considerably more successful in lowering blood pressure than standard treatment alone. These results imply that, in this high-risk group, dapagliflozin is a useful supplementary treatment for enhancing blood pressure control while providing extra metabolic and possible cardiovascular advantages. To validate these results and assess long-term cardiovascular and renal outcomes, further extensive, multicenter trials with extended follow-ups are advised.

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