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Comparative Efficacy Of Dapagliflozin And Empagliflozin For Blood Pressure Control In Type 2 Diabetes Mellitus With Hypertension

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Abstract

Objective: To find out the efficacy of empagliflozin and dapagliflozin for blood pressure control in patients having type 2 diabetes mellitus with hypertension.

Methods: A Quasi-experimental study was performed at the Medicine department of Tertiary Care Hospital, Rawalpindi, from March 2024 to September 2024. All patients were categorised into two groups, with group A receiving Empagliflozin (10 mg), while group B received Dapagliflozin (10 mg). Initial measurements were taken from both groups and repeated after three and six months of treatment to evaluate changes in HbA1c levels and blood pressure. SPSS-24.0 was used for all the above-mentioned analyses. Differences between groups at baseline and 3 months were analysed using independent samples t-tests. Within-group differences measured at baseline and 3 months were analysed using paired-sample t-tests, with $p \leq 0.05$ considered statistically significant.

Results: A total of 128 patients were included in this study, out of which 64 received 10 mg of dapagliflozin, while the other 64 received 10 mg of empagliflozin. HbA1c was decreased by 2.35% and 3% after 3 months and 6 months, respectively, by using 10mg dapagliflozin. In the empagliflozin group, this level was reduced by 2.70% and 3.40% after treatment of 3 and 6 months, respectively. Blood pressure was also decreased significantly in both groups, with a value of $p<0.001$.

Conclusion: In conclusion, both empagliflozin and dapagliflozin have similar effects on significantly reducing the HbA1c level and blood pressure in patients with T2DM and hypertension.

Keywords: Empagliflozin, Dapagliflozin, Hypertension, Type 2 Diabetes Mellitus

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EM, FAS, FH, LY, KAS - Conception, Design
EM, MNQ, - Acquisition, Analysis, Interpretation
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Introduction

Type 2 diabetes mellitus(T2DM) is one of the most frequent types of diabetes, which is growing rapidly worldwide.[1] The latest statistics show that the total number of individuals with diabetes has climbed to 240 million over the past two decades.[2] This diabetes epidemic has a more significant impact on developing nations than on developed ones. This situation places Pakistan in the fourth position globally for diabetes, with a prevalence rate of 19.4% as of 2019.[3,] The number of individuals diagnosed with diabetes in Pakistan is projected to reach 6.8 million between 2019 and 2030.[4] This is essential to manage diabetes effectively to decrease the strain on the public health system.

The common presence of hypertension alongside T2DM is widely acknowledged, with the ratio of hypertension among individuals with T2DM being nearly double that of those without diabetes.[5] In people with diabetes, hypertension not only worsens the already high risk of developing significant atherosclerotic vascular conditions, but it also raises the chance of microvascular problems.[6] Systolic hypertension is a well-established factor to increase cardiovascular illness in individuals with diabetes. According to data from the United Kingdom Prospective Diabetes Study (UKPDS), every 10 mm Hg increase in systolic blood pressure is associated with a 15% increased risk of coronary artery disease.[7]

Antidiabetic medications are the most effective option for managing type 2 diabetes mellitus. The method of action of newly developed anti-diabetic pharmaceuticals known as sodium-glucose co-transporter (SGLT-2) inhibitors is fundamentally different from that of standard antidiabetic therapies.[8] Anti-glucose reuptake inhibitors, such as SGLT-2, exert hypoglycemic effects through elevated elimination of glucose via urine. The Food and Drug Administration (FDA) has approved dapagliflozin, canagliflozin, and empagliflozin for use in this category. Current guidelines recommend SGLT-2 inhibitors as second-line therapies when initial antidiabetic treatments do not sufficiently manage blood glucose levels. Nonetheless, they can also serve effectively as standalone treatments.

Empagliflozin and Dapagliflozin function through distinct mechanisms compared to traditional antidiabetic medications.[9] They manage blood glucose levels by decreasing the reabsorption of sodium and glucose in the proximal convoluted tubule of the kidneys. In addition, they offer extra advantages such as reducing body weight, addressing dyslipidemia, managing uric acid levels, lowering blood pressure, reducing subclinical inflammation, improving insulin sensitivity, alleviating fatty liver conditions, and mitigating oxidative stress.

Researchers are becoming concerned about the SGLT-2 inhibitors' cardiovascular safety profile in several research trials. Four large clinical studies, including SGLT-2 inhibitors (Canvas, Empagliflozin-outcome, Credence, and Declare), have shown a substantial reduction in the incidence of heart failure hospitalisations and diabetes-related kidney damage. Empagliflozin has shown proven cardiovascular advantages in individuals with Type 2 diabetes mellitus. Recently, the FDA has approved the use of dapagliflozin as well as empagliflozin for patients with heart failure, regardless of their glycemic status.[10]

The current study focused on finding the efficacy of empagliflozin as well as dapagliflozin to control blood pressure among patients with type 2 diabetes mellitus as well as hypertension.

Materials And Methods

This quasi-experimental study was performed at the Medicine Department of the Tertiary Care Hospital, Rawalpindi, from March 2024 to September 2024 after getting the approval from the Institutional Review Board (IRB), vide reference number 705. After a thorough literature search, we calculated a sample size of 127via the WHO calculator, keeping the margin of error at 5%, a confidence level at 95%, and the prevalence of co-occurrence of diabetes mellitus and hypertension at 3.8%.[11] For sampling, non-probability consecutive sampling criteria were used.

The study included all individuals aged 25 to 65 years who have been diagnosed with type 2 diabetes mellitus and hypertension and are currently receiving treatment with oral antidiabetic medications, with a serum HbA1c level ranging from 7.5% to 11%.

Participants with a prior medical history of liver disease, neurological disorders, kidney failure or cancer were not included in this study.

Written consent was gained before enrolling any patient, as well as their privacy was protected at every turn. Furthermore, before the project's start, institutional ethics committee permission was secured.

All patients were classified into two different groups. Patients of group A received Tab. Empagliflozin at a dosage of 10 mg, while those in group B were given Tab. Dapagliflozin at the same dosage of 10 mg. The patients were contacted weekly to check on their medication intake. The dosage for each medication was adjusted based on the individual's blood glucose levels. The main objective of this study was to find how dapagliflozin, as well as empagliflozin, impacted blood pressure. Initial measurements were taken from both groups and repeated after three months and six months of treatment to evaluate changes in HbA1c levels and blood pressure. A digital weighing scale and a Microtoise stature meter were utilised to measure body weight and height, respectively. The standard method for calculating Body Mass Index (BMI) includes the division of weight in kg of an individual by the square of the height in meters (kg/m²)of that individual. A mercury sphygmomanometer was used to measure the blood pressure in a supine position twice during a 15-minute interval. Blood glucose levels and HbA1c were assessed using the Microlab 300 by established protocols.

The analysis was conducted using the Statistical Package for Social Sciences version 24.0 (SPSS-24.0). For assessing the normality of the continuous variables, the Shapiro-Wilk test was applied. The normally distributed values were presented as mean ± standard deviation, while for data that do not follow the normal distribution, values were reported as median along with the interquartile range. Categorical variables were presented using frequencies and percentages. Group differences at baseline and after 3 months were compared using independent samples t-tests, whereas within-group changes over the same period were evaluated using paired-sample t-tests. A p-value of ≤ 0.05 was considered statistically significant.

Results

A total of 128 patients were included in this study. Out of the total, 62 were male, having a mean age of 47.11±10.50 years, as well as 66 were female, having a mean age of 48.60±10.56 years. In this study, 64 patients received daily therapy with 10 mg of dapagliflozin, while another 64 patients received 10 mg of empagliflozin. The demographic and baseline characteristics, including age, BMI, Height, Weight, HbA1c, SBP, and DBP, were comparable between both groups ($p > 0.05$) as shown in Table 1.

Table 1: Baseline Characteristics of Patients in Empagliflozin (Group A) and Dapagliflozin (Group B) Treatment Groups

Variables	Empagliflozin Group A (n=64)	Dapagliflozin Group B (n=64)	p-Value
Age (years)	48.00 (59.00-40.25)	45.50 (55.00-40.25)	0.633
Height (cm)	165.00 (180.50-155.50)	163.00 (176.75-155.00)	0.971
Weight (kg)	71.75 (79.08-66.02)	69.80 (77.92-65.03)	0.265
BMI (kg/m^2)	25.45 (29.25-22.90)	25.30 (28.58-22.95)	0.788
HbA1c (%)	9.80 (11.00-7.53)	9.50 (10.10-9.00)	0.781
SBP (mmHg)	135.00 (160.00-115.00)	135.00 (145.00-121.25)	0.355
DBP (mmHg)	85.00 (95.00-78.00)	85.00 (95.00-78.00)	0.816

Table 2 presents the variations in systolic blood pressure (SBP), diastolic blood pressure (DBP), and HbA1c over 6 months for patients receiving treatment with empagliflozin (Group A) and dapagliflozin (Group B). Both groups experienced comparable reductions in HbA1c, SBP, and DBP throughout the study period, which were not significantly different by statistics between the two different treatment groups at any instant ($p > 0.05$). The variations in diastolic blood pressure (DBP), HbA1c, as well as the systolic blood pressure (SBP) from baseline to 3 months for patients treated with empagliflozin (Group A) and dapagliflozin (Group B) are shown in Table III. Both groups showed significant reductions in HbA1c, SBP, and DBP, with p-values less than 0.001, indicating a statistically significant decrease in these parameters over the study period. This suggests that both treatments effectively improved glycemic control and blood pressure in patients with type 2 diabetes mellitus and hypertension.

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Table 2: Changes in HbA1c, Systolic Blood Pressure (SBP), as well as Diastolic Blood Pressure (DBP) Over Time in Empagliflozin (Group A) as well as the Dapagliflozin (Group B) Treatment Groups

Variables	Empagliflozin Group A (n=64)	Dapagliflozin Group B (n=64)	p-Value
HbA1c (%)			
Baseline	9.80 (11.00-7.53)	9.50 (10.10-9.00)	0.781
3 months	7.10 (8.00-6.40)	7.15 (7.70-6.80)	0.649
6 months	6.40 (7.25-5.83)	6.50 (7.00-6.20)	0.401
SBP (mmHg)			
Baseline	135.00 (160.00-115.00)	135.00 (145.00-121.25)	0.355
3 months	127.50 (148.75-105.00)	122.00 (134.25-108.25)	0.193
6 months	125.00 (146.75-103.00)	119.00 (131.25-105.25)	0.153
DBP (mmHg)			
Baseline	85.00 (95.00-78.00)	85.00 (95.00-78.00)	0.816
3 months	82.00 (91.50-75.00)	80.00 (89.00-72.75)	0.230
6 months	80.00 (89.50-73.00)	79.00 (88.00-71.75)	0.621

Table 3: Variations in diastolic blood pressure (DBP), HbA1c, as well as the systolic blood pressure (SBP)from the Baseline to 3 Months in Empagliflozin (Group A) and Dapagliflozin (Group B) Treatment Groups

Group A Empagliflozin (n=64)				Group B Dapagliflozin (n=64)			
Parameters	**Baseline**	**3 Months**	**p-Value**	**Parameters**	**Baseline**	**3 Months**	**p-Value**
HbA1c (%)	9.80 (11.00-7.53)	7.10 (8.00-6.40)	<0.001	**HbA1c (%)**	9.50 (10.10-9.00)	7.15 (7.70-6.80)	<0.001
SBP (mmHg)	135.00 (160-115)	127.50 (148-105)	<0.001	**SBP (mmHg)**	135.00 (145-121)	122.00 (134-108)	<0.001
DBP (mmHg)	85.00 (95-78)	82.00 (91-75)	<0.001	**DBP (mmHg)**	85.00 (95-78)	80.00 (89-72.75)	<0.001

Discussion

Sodium-glucose cotransporter 2 inhibitors, commonly known as SGLT2 inhibitors, are a group of antihyperglycemic drugs that block glucose reabsorption in the proximal convoluted tubule of the kidneys, resulting in increased glucose excretion in the urine.[12,13] These medications also positively influence blood pressure and help with weight management.[14] However, there is limited national data on the safety and effectiveness of dapagliflozin and empagliflozin, and the existing studies and literature tend to yield inconclusive results. This research aimed to examine the effects of SGLT2 inhibitors on HbA1c levels and blood pressure.

In our study, after three and six months of therapy, the HbA1c, SBP, and DBP decreased substantially by dapagliflozin and empagliflozin. HbA1c was reduced by 2.35% and 3% after 3 and 6 months, respectively, by using 10mg dapagliflozin. In the empagliflozin group, this level was reduced by 2.70% and 3.40% after treatment of 3 and 6 months, respectively. Varshney Et *al*.,[15] and Mazharet *al*.,[4] also found similar results as in our study and revealed that HbA1c level was reduced by using empagliflozin and dapagliflozin medication.

Comparable results were found in a randomised controlled trial where empagliflozin notably lowered body weight and HbA1c levels over 12 and 24 weeks, respectively.[16] In a different controlled clinical trial, dapagliflozin used as an additional therapy effectively reduced body weight by -1.21 Kg ($p<0.0001$) as well as the HbA1c by -0.60% ($p<0.0001$) in patients with type 2 diabetes experiencing insufficient glycemic control, with no occurrences of severe hypoglycemia.[17] In our research, we compared two SGLT-2 inhibitors, whereas the previously mentioned studies contrasted SGLT-2 inhibitors with a placebo.

Our study results also revealed that the patients who were using 10mg dapagliflozin had a decrease in SBP of 13 mmHg after 3 months and 16 mmHg after 6 months, and the patients who were using empagliflozin had an 8mmHg reduction in SBP from the baseline after 3 months and a 10 mmHg fall after 6 months. While the decrease in DBP in the dapagliflozin group was 5 mmHg and 6 mmHg after 3 and 6 months, respectively, and in the empagliflozin group, the DBP was reduced by 3mmHg and 5mmHg after 3 and 6 months, respectively. Varshney Et *al*.,[15] also performed a study on T2DM with hypertension patients and found that after usage of 3 months of 10mg of dapagliflozin, the SBP decreased by 3.24 mmHg and after 6 months of usage, it reduced by 3.77 mmHg. In the patients who were taking 10mg of empagliflozin, SBP decreased by 3.3 mmHg. Other studies by Michael Et *al*.,[18] Papadopoulou et *al*.,[19] Kario et *al*.,[20] also found similar results to those in our research. They concluded that there was a decrease in SBP and DBP after 3 months in the patients who were using 10mg dapagliflozin.

The results of this study revealed that dapagliflozin and empagliflozin are medications that can reduce blood sugar and blood pressure.

Limitations Of The Study:

The current study contains a few limitations because it was a single-centred study, along with the small sample size of sample as well as only 6 months of follow-up. For more accurate and precise results, this study should have been conducted on a large scale. Also, this study has not discussed the side effects of empagliflozin and dapagliflozin.

Conclusions

In conclusion, empagliflozin and dapagliflozin have similar effects on significantly reducing the HbA1c level as well as blood pressure among patients with T2DM and hypertension.

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