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Outcome of Dapagliflozin Use in Real-Life Clinical Settings in Endocrinology

Dr Ayesha Altaf[1], Dr Azher Nawaz Khan[2], Dr Amnah Khan[2], Dr Muhammad Usama Khan[3], Dr Taab Khan[3], Dr Mahnoor Rehman[4], Dr Mubashir Habib[5], Dr Saba Fatima[6]

1. Faisalabad Medical University, Faisalabad, Pakistan
2. Our lady's hospital Navan, Co. Meath, Ireland
3. Punjab Rangers Teaching Hospital, Pakistan
4. Zainab Panjwani Memorial Hospital, Pakistan
5. Nishtar Medical University, Multan, Pakistan
6. Jinnah Sindh Medical University, Karachi, Pakistan.

Corresponding Author: Dr Ayesha Altaf, Faisalabad medical University.

Abstract

Introduction: Dapagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, has emerged as a significant therapeutic agent in the management of type 2 diabetes mellitus (T2DM). **Objectives:** This study aims to explore the outcomes of dapagliflozin use in real-life clinical settings, focusing on its impact on glycemic control, cardiovascular health, renal function, and overall patient quality of life. **Methodology of the study:** This observational study was conducted at Faisalabad Medical university from June 2023 to March 2024. Data were collected from 240 patients who visited the OPD of the hospital. Data were collected from electronic medical records (EMRs). Demographic information, age, gender, body mass index (BMI), duration of diabetes was noted in a systematically designed performa. Clinical parameters, HbA1c, fasting blood glucose (FBG), systolic and diastolic blood pressure (SBP, DBP) were measured. **Results:** The study included 240 patients with T2DM who were prescribed dapagliflozin. The cohort comprised 130 males (54.2%) and 110 females (45.8%), with a mean age of 58.3 ± 10.2 years. The average body mass index (BMI) was 31.5 ± 4.8 kg/m², and the mean duration of diabetes was 8.6 ± 5.1 years. At the 6-month follow-up, patients demonstrated a significant reduction in HbA1c, with a mean decrease of 1.2% ± 0.8% ($p < 0.001$). FBG levels also showed a notable decline, with a mean reduction of 35 ± 30 mg/dL ($p < 0.001$). **Conclusion:** This study reinforces the effectiveness and safety of dapagliflozin in managing T2DM. The significant improvements in glycemic control, blood pressure, and weight, along with a favorable safety profile, highlight dapagliflozin's utility in routine clinical practice.

Introduction

Dapagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, has emerged as a significant therapeutic agent in the management of type 2 diabetes mellitus (T2DM). Initially approved for its glucose-lowering effects, dapagliflozin has demonstrated a broad spectrum of benefits extending beyond glycemic control [1]. Clinical trials have highlighted its efficacy in reducing cardiovascular events and improving renal outcomes, leading to a paradigm shift in the treatment strategies for patients with T2DM. However, while randomized controlled trials (RCTs) provide invaluable insights, the real-world applicability of these findings necessitates investigation in routine clinical settings [2].

Pakistan is on the fourth number in percentage of people affected with diabetes mellitus around the world and it is having 26.3% [3]. It is for this reason that suitable therapeutic therapies are so crucial in managing diabetes and more importantly averting the diagnosis of diabetes related microvascular and macrovascular diseases. SGLT2i are a relatively new class of antidiabetic drugs used for the management of T2DM and belong to non-insulin catareme medications [4]. This class of drugs includes one molecule called dapagliflozin in particular, that is a highly selective, potent SGLT2 inhibitor first launched in Pakistan in 2017. Those are the respective real-life experiences of dapagliflozin regarding its efficacy, risks, benefits and its potential overall effects on the health of patients apart from the strict clinical trial setting [5]. The following are some of the benefits of real-world data generally; Real-world data is important in order to evaluate how well dapagliflozin does in different population of patients, with different medical conditions, and interacting with other medications used in endocrinology

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practice [6].

Real-world evidence showing effectiveness of dapagliflozin is important to understand in light of the multifaceted and diverse nature of T2DM care [7]. Dapagliflozin has been found to affect therapeutic outcomes in hypertension, dyslipidemia, and CKD complications that are comorbid with patient clinical conditions in different clinical practices [8]. Conversely, cultural beliefs about taking medications, changes in behavior and diets, and other socio-economic factors can also explain the balance of effectiveness of a certain treatment. Several studies have evaluated and confirmed the safety and efficacy of dapagliflozin in real-life clinical settings. Pakistani populations differ in genetic characteristics, as well as in demographic, cultural, and lifestyle characteristics, from the populations of Western countries [9].

Objectives

This study aims to explore the outcomes of dapagliflozin use in real-life clinical settings, focusing on its impact on glycemic control, cardiovascular health, renal function, and overall patient quality of life. By analyzing data from everyday clinical practice, we aim to provide comprehensive insights into the benefits and potential challenges associated with dapagliflozin, thereby guiding endocrinologists in optimizing treatment strategies for their patients with T2DM. So, the basic aim of the study is to find the outcome of dapagliflozin use in real-life clinical settings in different endocrinology fields.

Methodology of the study

This observational study was conducted at Faisalabad Medical university from June 2023 to March 2024. Data were collected from 240 patients who visited the OPD of the hospital.

Inclusion Criteria

- Adults aged 18 years and older
- Diagnosed with T2DM
- Prescribed dapagliflozin as part of their diabetes management
- Available baseline and follow-up data for at least 6 months after initiating dapagliflozin

Exclusion Criteria

- Patients with type 1 diabetes mellitus
- Patients with a history of hypersensitivity to dapagliflozin or other SGLT2 inhibitors
- Pregnant or breastfeeding women
- Patients with severe renal impairment (eGFR < 30 mL/min/1.73 m^2)

Data Collection

Data were collected from electronic medical records (EMRs). Demographic information, age, gender, body mass index (BMI), duration of diabetes was noted in a systematically designed performa. Clinical parameters, HbA1c, fasting blood glucose (FBG), systolic and diastolic blood pressure (SBP, DBP) were measured. Renal function, serum creatinine, estimated glomerular filtration rate (eGFR) were also measured in a laboratory. Safety outcomes includes incidence of adverse events (AEs), including hypoglycemia, urinary tract infections (UTIs), and genital infections. The primary outcome was the change in HbA1c from baseline to 6 months. Secondary outcomes included changes in FBG, body weight, blood pressure, renal function, and the incidence of MACE and AEs.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. Paired t-tests were employed to compare changes in clinical parameters from baseline to follow-up. The incidence of AEs was reported as proportions. A p-value of <0.05 was considered statistically significant.

Results

The study included 240 patients with T2DM who were prescribed dapagliflozin. The cohort comprised 130 males (54.2%) and 110 females (45.8%), with a mean age of 58.3 ± 10.2 years. The average body mass index (BMI) was 31.5 ± 4.8 kg/m^2, and the mean duration of diabetes was 8.6 ± 5.1 years. Baseline characteristics showed a mean HbA1c of 8.4% ± 1.2%, fasting

blood glucose (FBG) of 165 ± 45 mg/dL, systolic blood pressure (SBP) of 138 ± 18 mmHg, and diastolic blood pressure (DBP) of 84 ± 12 mmHg. The mean estimated glomerular filtration rate (eGFR) was 72.3 ± 14.8 mL/min/1.73 m².

Table 01: Demographic data of participants

Characteristic	Value
Number of patients	240
Age (years)	58.3 ± 10.2
Gender, n (%)	Male: 130 (54.2%) Female: 110 (45.8%)
BMI (kg/m²)	31.5 ± 4.8
Duration of diabetes (years)	8.6 ± 5.1
HbA1c (%)	8.4 ± 1.2
Fasting Blood Glucose (mg/dL)	165 ± 45
Systolic Blood Pressure (mmHg)	138 ± 18
Diastolic Blood Pressure (mmHg)	84 ± 12
eGFR (mL/min/1.73 m²)	72.3 ± 14.8

At the 6-month follow-up, patients demonstrated a significant reduction in HbA1c, with a mean decrease of 1.2% ± 0.8% ($p < 0.001$). FBG levels also showed a notable decline, with a mean reduction of 35 ± 30 mg/dL ($p < 0.001$). These results underscore the efficacy of dapagliflozin in improving glycemic control in a real-world clinical setting.

Table 02: Changes in glycemic parameters after use of dapagliflozin

Parameter	Baseline	6 Months	Change	p-value
HbA1c (%)	8.4 ± 1.2	7.2 ± 1.0	-1.2 ± 0.8	< 0.001
Fasting Blood Glucose (mg/dL)	165 ± 45	130 ± 35	-35 ± 30	< 0.001
Systolic Blood Pressure (mmHg)	138 ± 18	129.5 ± 17.4	-8.5 ± 10.2	< 0.01
Diastolic Blood Pressure (mmHg)	84 ± 12	79.7 ± 11.3	-4.3 ± 7.5	< 0.01
Weight (kg)	85.3 ± 15.2	82.1 ± 14.7	-3.2 ± 2.5	< 0.001
eGFR (mL/min/1.73 m²)	72.3 ± 14.8	71.8 ± 14.5	-0.5 ± 3.2	0.45

Systolic blood pressure (SBP) decreased by an average of 8.5 ± 10.2 mmHg ($p < 0.01$), while diastolic blood pressure (DBP) reduced by 4.3 ± 7.5 mmHg ($p < 0.01$). Additionally, patients experienced a mean weight loss of 3.2 ± 2.5 kg ($p < 0.001$). Renal function, assessed by changes in eGFR, remained stable with a mean change of -0.5 ± 3.2 mL/min/1.73 m² ($p = 0.45$), indicating that dapagliflozin did not adversely affect renal function over the study period. During the 6-month follow-up, 10 patients (4.2%) experienced MACE, including non-fatal myocardial infarction (n = 3), non-fatal stroke (n = 2), and hospitalization for heart failure (n = 5). This incidence aligns with existing literature on the cardiovascular benefits of dapagliflozin.

Table 03: Major adverse events

Event	Number of Patients (%)

Major Adverse Cardiovascular Events (MACE)	10 (4.2%)
Non-fatal Myocardial Infarction	3 (1.3%)
Non-fatal Stroke	2 (0.8%)
Hospitalization for Heart Failure	5 (2.1%)
Urinary Tract Infections (UTIs)	15 (6.3%)
Genital Infections	10 (4.2%)
Hypoglycemia	5 (2.1%)

Adverse events (AEs) were monitored, with the most common being urinary tract infections (UTIs) in 15 patients (6.3%) and genital infections in 10 patients (4.2%). Hypoglycemic events were rare, occurring in 5 patients (2.1%), none of which were severe. These findings corroborate the known safety profile of dapagliflozin, suggesting it is well-tolerated in the majority of patients.

Discussion

This study provides valuable real-world evidence on the effectiveness and safety of dapagliflozin in the management of type 2 diabetes mellitus (T2DM). The findings align with previous clinical trials, demonstrating that dapagliflozin significantly improves glycemic control, reduces blood pressure, and promotes weight loss in patients with T2DM. The significant reduction in HbA1c levels (mean decrease of 1.2% ± 0.8%) and fasting blood glucose (mean reduction of 35 ± 30 mg/dL) highlights dapagliflozin's efficacy in improving glycemic control in a diverse patient population [10,11]. These results are consistent with findings from large-scale randomized controlled trials (RCTs) such as the DECLARE-TIMI 58 and CANVAS programs, which reported similar reductions in HbA1c levels. The sustained improvement over 6 months underscores dapagliflozin's role as a valuable addition to the therapeutic arsenal for T2DM [12]. Dapagliflozin's ability to lower systolic and diastolic blood pressure (mean reductions of 8.5 ± 10.2 mmHg and 4.3 ± 7.5 mmHg, respectively) and promote weight loss (mean decrease of 3.2 ± 2.5 kg) offers additional benefits beyond glycemic control [13]. These findings are in line with previous studies indicating that SGLT2 inhibitors confer cardiovascular benefits, including reductions in blood pressure and body weight, contributing to improved cardiovascular outcomes. Notably, the incidence of major adverse cardiovascular events (MACE) in this cohort (4.2%) is comparable to rates observed in RCTs, supporting dapagliflozin's cardioprotective effects in routine clinical practice [14]. Renal function remained stable, with no significant decline in eGFR over the 6-month period, suggesting that dapagliflozin does not adversely affect renal function in the short term. This finding aligns with the renal benefits observed in the DAPA-CKD trial, where dapagliflozin was shown to slow the progression of chronic kidney disease (CKD) in patients with T2DM [15]. The safety profile of dapagliflozin in this study is consistent with known adverse effects of SGLT2 inhibitors. The most common adverse events were urinary tract infections (6.3%) and genital infections (4.2%), which were generally mild and manageable [16]. Hypoglycemia was rare (2.1%) and non-severe, underscoring the safety of dapagliflozin in real-world use. These findings are in agreement with previous safety analyses from clinical trials and post-marketing surveillance data [17]. While this study provides important insights, it has several limitations. The retrospective design may be subject to selection bias and confounding factors. Additionally, the follow-up period of 6 months is relatively short for assessing long-term outcomes and safety. Future studies with longer follow-up periods and prospective designs are needed to confirm these findings and explore long-term effects.

Conclusion

This study reinforces the effectiveness and safety of dapagliflozin in managing T2DM. The significant improvements in glycemic control, blood pressure, and weight, along with a favorable safety profile, highlight dapagliflozin's utility in routine clinical practice. These findings support the integration of dapagliflozin into comprehensive T2DM management

strategies to enhance patient outcomes.

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