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Original article

Incidence and Risk Factors of Urinary Tract Infection in Patients with Diabetes Mellitus Using Dapagliflozin in Benghazi, Libya

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Abstract
Diabetes mellitus (DM) is the most prevalent endocrine disorder, impacting over 100 million individuals globally. Dapagliflozin has been extensively examined as an alternative therapy for type 2 diabetes, alongside metformin, sulfonylureas, sitagliptin, glucagon-like peptide-1 receptor agonists, and insulin. The objective of this study is to evaluate the association between the use of Forxiga (dapagliflozin) and the incidence of urinary tract infections among patients with diabetes. A cross-sectional study was conducted using 14 self-assessment questionnaires at the National Center for Diabetes Diagnosis and the National Cardiac Center in Benghazi, Libya. The research took place over six months, from April to October 2025. Upon examining the status of urinary tract infections (UTIs), the data show that the overwhelming majority (86.7%) of participants were not infected. Regarding the period of drug use, most participants had used Forxiga for durations ranging between one month and one year. Overall, the statistical results show no significant relationship between the incidence of UTI and the period of drug use or gender. However, they revealed a strong association between the prevalence of infection and age. This descriptive analytical study focused on evaluating the efficacy of dapagliflozin (Forxiga) in adult patients with diabetes, with particular attention to its most common side effect—urinary tract infection (UTI)—as well as treatment adherence duration. The study included a total sample of 100 participants: a main group of 70 patients using dapagliflozin and a control group of 30 patients using other glucose-lowering medications. This study affirms the high efficacy of dapagliflozin in lowering blood glucose levels. Importantly, while confirming an increased incidence of UTI associated with dapagliflozin compared to standard treatments, the study also indicates that these infections are predominantly mild to moderate in severity, supporting the drug's overall favorable risk–benefit profile.
Keywords. Forxiga, Dapagliflozin, Urinary tract infection, Diabetes.

Introduction

Diabetes mellitus (DM) is the most prevalent endocrine disorder, impacting over 100 million individuals globally, which accounts for 6% of the population. This condition arises from either a lack of insulin production or the pancreas's inability to secrete effective insulin, leading to fluctuations in blood glucose levels. It is known to harm various body systems, particularly affecting blood vessels, eyes, kidneys, heart, and nerves [1]. Diabetes mellitus is categorized into two types: insulin-dependent diabetes mellitus (IDDM, Type I) and non-insulin-dependent diabetes mellitus (NIDDM, Type II). Type I diabetes is an autoimmune disorder marked by a localized inflammatory response in and around the islets, eventually leading to the targeted destruction of insulin-producing cells. In contrast, Type II diabetes is defined by peripheral insulin resistance and impaired insulin secretion. The appearance of DM is associated with a high risk of numerous complications, including cardiovascular diseases, peripheral vascular diseases, stroke, neuropathy, renal failure, retinopathy, blindness, and amputations [2].

Alternative therapies for type 2 diabetes include metformin, sulfonylurea, sitagliptin, glucose-like peptide-1 receptor agonists, and insulin. SGLT2i, or sodium-glucose cotransporter-2 inhibitors, are contemporary therapies for type 2 diabetes that targets the kidneys [3, 4]. In the kidneys, glucose is reabsorbed in the proximal tubule of the loop of Henle. The carrier protein responsible for reabsorption is sodium-glucose cotransporter-2 (SGLT2), which contains 672 amino acids in the S1 segment of the proximal renal tubules. SGLT2i medications such as empagliflozin, dapagliflozin, and canagliflozin target this site of action [4,5]. Dapagliflozin has been extensively examined in controlled clinical studies, both alone and in combination with other antihyperglycemic medicines. It has been licensed by the US Food and Drug Administration as a therapeutic option for T2D [6,7].

Increased urine glucose emission has been linked to urinary tract infections (UTIs) [8]. High glucose levels may promote bacterial development. A study found that Escherichia coli grew in proportion as glucose levels increased [9]. The objective of this study is to evaluate the association between the use of Forxiga (dapagliflozin) and the incidence of urinary tract infections among patients with diabetes mellitus. The study aims to determine whether treatment with Forxiga increases the risk and severity of urinary tract infections compared to other antidiabetic therapies.

Methodology

Study design

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A cross-sectional study adopted 14 self-assessment questionnaires to examine the therapeutic role of Forxiga (Dapagliflozin) in managing Diabetes Mellitus and its potential connection to urinary tract infections (UTIs). This study was conducted at the National Center for Diabetes Diagnosis and the National Cardiac Center in Benghazi, Libya. The research took place over six months, from April to October 2025.

Exclusion and inclusion criteria

The study included diabetic patients treated with the drug Forxiga, irrespective of their age, gender, or type of diabetes. Data were gathered from patients using other medications as part of their treatment regimen, serving as a control group, while those on Forxiga constituted the target group. In total, there were 105 participants, with 70 using Forxiga and 30 on different antidiabetic medications. Five samples were excluded due to incomplete data analysis.

Statistical analysis

The data gathered were examined using version 23 of the Statistical Package for the Social Sciences (SPSS) software, applying both descriptive and analytical statistical techniques to uncover significant relationships.

Ethical consideration

Before data collection, ethical approval was secured, and informed consent was obtained from all participants to ensure confidentiality and compliance with research standards.

Results

Standard (control) sample results

The statistical results of the standard sample (Table 1) demonstrate a clear dominance of certain categories over others. Demographically, the sample is unequally distributed between males and females, with females constituting the majority at 60.0%, surpassing the male proportion, which stood at 40.0%. As for the age groups, the sample is primarily centered on the 41-60 years (36.7%) and more than 80 years (33.3%) categories. This indicates that most participants belong to the middle and advanced age groups, as these two categories together account for 70% of the sample. In contrast, the young adult group (21-40) was the least represented, with only 6.7%.

Clinical Characteristics and Health Conditions

Regarding health conditions, it is evident that Type One Diabetes is the most common among participants, with a rate of 66.7%, which was about twice the rate of Type Two Diabetes, which was 33.3% as shown in Table 1. Upon examining the status of Urinary Tract Infection (UTI), the data shows that the overwhelming majority (86.7%) of control sample members were not infected. As for the minority who were infected (13.3%), the distribution of infection severity among them indicates that the Severe degree is the most frequent, representing 50% of the total infections. The remaining 50% was equally shared between the Mild and Moderate degrees (25% for each).

Table 1. The main parameters of the standard (use other antidiabetic drugs) sample

Parameter		Frequency	Percent %
Age group	21-40	2	6.7
	41-60	11	36.7
	61-80	7	23.3
	More than 80	10	33.3
Gender	Female	18	60.0
	Male	12	40.0
Diabetes Type	Type one	20	66.7
Urinary tract infection	yes	4	13.3
	No	26	86.7
Degree of infection	Mild	1	25
	Moderate	1	25
	Severe	2	50

Statistical Analysis of Baseline Sample Characteristics

The statistical analysis of the 70-individual sample shows (Table 2) a primary concentration in the middle and advanced age groups. The 41-60 age group is the most represented (41.4% or 29 individuals), followed by the 61-80 group (35.7% or 25 individuals), together accounting for approximately 77.1% of the total sample. Conversely, the youngest group (21-40) registered the lowest representation at just 7.1%, indicating a clear bias in the sample towards these older categories, as shown in Table 2. Regarding demographic data, females constitute a slight majority in the sample, representing 52.9% (37 individuals). Meanwhile, males account for 47.1% (33 individuals) of the total valid sample of 70 individuals. In addition, the chronic medical

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conditions show that Heart problems are the most commonly reported, affecting 45.7% (32 individuals) of the sample.

Table 2. The demographic data and the history of disease of participants in the main group.

Demographic data	Frequency	Percent %
Age		
21-40	5	7.1
41-60	29	41.4
61-80	25	35.7
More than 80	11	15.7
Gender		
Female	37	52.9
Male	33	47.1
History of disease		
Heart problem	32	45.7
Kidney problem	6	8.6
Others	28	40.0

This is followed closely by Other chronic conditions at 40.0% (28 individuals). Kidney problems were the least reported among the listed conditions, at just 8.6%. The analysis shows (Table 3) that Type 1 diabetes is the dominant condition, recorded in 44 individuals and constituting a clear majority at 62.9% of the total sample. Type 2 represents the minority, accounting for 26 individuals or 37.1%. This distribution makes Type 1 approximately 1.7 times more frequent than Type 2, confirming it as the predominant type within this study sample. In relation to the period of drug use, most participants have used Forxiga for durations ranging between one month and one year. The 1–3 months period is the most represented, accounting for 31.4% (22 individuals). This is immediately followed by the category of users for 1 year, at 30.0% (21 individuals). This indicates that approximately 61.4% of the sample are relatively new users or in the intermediate stages of treatment (from one month to one year). Meanwhile, long-term users whose duration of use exceeds 3 years constitute 24.3% of the sample, which demonstrates a significant group of patients committed to the medication over the long term. However, in relation to the dose of the drug, many patients received 10mg of Forxiga (97%), while only 2 patients took 5mg.

The data shows (Figure 1) that many participants (88.4%) reported a drop in their sugar level after using the drug Forxiga. This indicates that the medication is effective in achieving its goal of lowering blood sugar. On the other hand, the analysis showed that many of the participants in the sample (40 individuals) reported experiencing at least one side effect after using Forxiga, representing 58.0% of the total valid sample. Conversely, 42.0% of the participants reported experiencing no side effects.

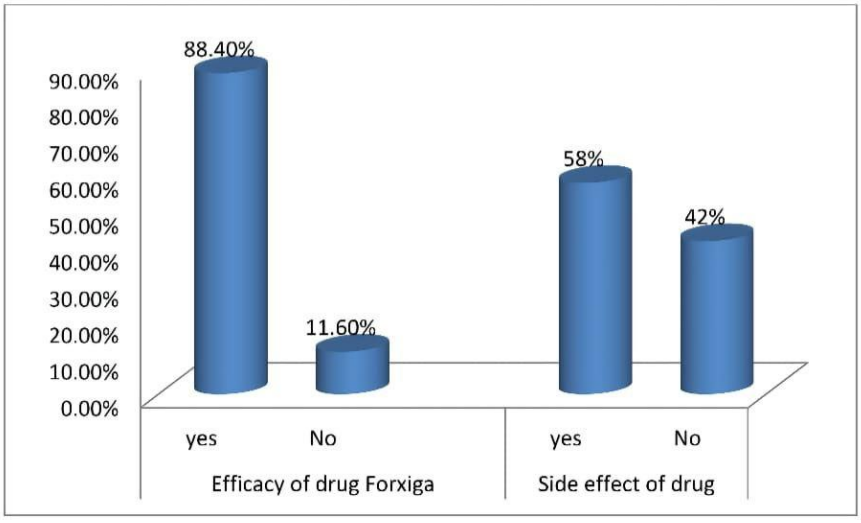

Figure 1. The efficacy of the Forxiga drug in lowering the blood sugar and the side effect distribution of the participants using the drug.

Table 3. Type of diabetes and the drug-using period of the baseline sample.

Type of diabetes			
		Frequency	Valid Percent%
Type	Type 1	44	62.9

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	Type 2	26	37.1
How long have you used Forxiga?			
		Frequency	Valid Percent%
How long	< 1 month	10	14.3
	1–3 months	22	31.4
	1 year	21	30.0
	> 3 years	17	24.3
Dose of the drug			
	5mg	2	3
	10mg	68	97

Table 4 reveals that most users did not report a Urinary Tract Infection (UTI), 77.1% of the respondents (54 individuals). However, only 22.8% (16 individuals) reported its occurrence. Meanwhile, most of the reported infections were Mild in degree, accounting for 68.8% (11 individuals) of the total cases. In contrast, the proportion of cases classified as Moderate was 31.3% (5 individuals). Moreover, the majority of respondents do not believe their urinary tract infection resulted from discontinuing Forxiga. 68.8% of individuals (11 people) indicated that the cause was not stopping the medication, while only 31.3% (5people) believed it was the reason. Regarding the time between the drug use and the UTI appearance (68.7%) of individuals who developed the infection experienced symptoms within 3 months of starting the medication. Symptoms appeared in a smaller percentage after 6 months (18.7%) and after 1 year (12.5%) of initial use.

Table 4. The incidence and degree of infection for UTI in the baseline sample.

Parameters		**Frequency**	**Percentage**
Urinary tract infection	Yes	16	22.8%
	No	54	77.1%
Degree of infection	Mild	11	68.8%
	Moderate	5	31.2%
Infection resulting to discontinued the drug	Yes	5	68.8%
	No	11	31.2%
Time between drug use and UTI symptoms	3 m	11	68.7%
	6 m	3	18.75%
	1 y	2	12.5%

Table 5 explores the effect of different variables on the appearance of urinary tract infection in the participants who receive Forxiga as an anti-diabetic agent in Benghazi, including the demographic parameters, period of using Forxiga, and dose of the drug (5mg or 10mg). Overall, by using the Chi-square test, the statistical results show no significant relationship between the incidence of the UTI and period of drug use, gender, and dose of drug (*P value=0.51,0.569 and 0.447)*, while they revealed a strong relationship between the prevalence of infection and the age (*P value=0.009).*

Table 5. Correlation between the appearance of urinary tract infection and different variables.

Variable	**Urinary Tract Infection** ***P-value according to the Chi-square test***
How long have you used Forxiga	0.51
Gender	0.569
Age	0.009
Dose of drug	0.447

Discussion

This descriptive analytical study focused on evaluating the efficacy of dapagliflozin (Forxiga) in adult patients with diabetes, with particular attention to its most common side effects, specifically urinary tract infections (UTIs), in addition to examining treatment adherence duration. The study was conducted on a total sample of 100 participants, including a main (Sample) group of 70 patients using dapagliflozin and a comparison (control) group of 30 patients using other glucose-lowering drugs. SGLT2 inhibitors, including dapagliflozin, are a vital addition to diabetes management due to their insulin-independent mechanism that effectively lowers glucose. However, this efficacy must always be balanced against potential side effects, especially in a real-world setting. To ensure comparability and generalizability, the demographic data for both study groups were analyzed. Regarding gender, the study's Sample group showed a slight majority of females (52.9%) over males (47.1%), a finding consistent with the control group. For age groups, most participants in both groups were concentrated in the 41 to 60 age range. This age and gender distribution is generally comparable with the findings of many major clinical trials and observational studies concerning diabetes,

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which typically represent middle-aged and older adults diagnosed with the disease, thus enhancing the comparability of our results with previous literature [10].

In relation to the medical history of the participants, we found that a significant number of diabetic patients using Forxiga also had other chronic health conditions. Notably, a substantial percentage of participants reported a history of heart problems. The continued use of dapagliflozin in this subgroup underscores the drug's importance, as recent evidence has demonstrated its key role in cardiovascular protection. Studies have shown that dapagliflozin provides sustained cardiac and renal benefits, reducing major adverse cardiovascular events in diabetic patients [11]. This positive usage pattern aligns with clinical recommendations that position SGLT2i as a foundational treatment for patients with co-existing cardiac and renal conditions.

The study results demonstrated a strong therapeutic response in the sample, reflected in the following findings compared to the literature. First, many participants (88.4%) reported experiencing low blood sugar. This exceptionally high rate should be interpreted as a reflection of the superior metabolic response to the treatment in this cohort, confirming the drug's potent efficacy in achieving its primary goal. This finding is in line with Anderson, S. L. (2014) approach [12]. In addition, there are major clinical trials confirming that SGLT2 inhibitors are characterized by a low risk of severe hypoglycemia, often comparable to placebo [10], [13]. This acute discrepancy is likely due to concomitant medication use, suggesting the high-rate results from dapagliflozin being used alongside other powerful glucose-lowering drugs, thereby raising the overall therapeutic efficacy of the drug regimen [10]. Secondly, concerning treatment duration, approximately 61.4% of the sample were short-to-medium-term users (one month to one year). However, the presence of a significant proportion (24.3%) who continued using the drug for over three years provides strong evidence of its long-term acceptability and tolerability, consistent with the sustained clinical benefits highlighted in Uitrakul, S., etc study [14].

Regarding the incidence of UTI among dapagliflozin (Sample) group participants, the results revealed that 22.8% (16 individuals) reported developing a UTI, while the vast majority (77.1%) did not. This finding is crucial as it demonstrates that while UTIs are a recognized risk, they affect a significant minority of users in a real-world setting. A comparative analysis against the control group (patients on other glucose-lowering drugs) is essential here. By comparing the 22.8% incidence in the Sample group against the incidence reported in the control group (13.3%), it suggests an elevated risk associated with dapagliflozin, confirming the hypothesis that the drug's promotion of glucose excretion creates an environment conducive to bacterial growth [15]. This corresponds with meta-analyses showing SGLT2 inhibitors are consistently associated with a statistically higher risk of genital and urinary tract infections compared to placebo or non-SGLT2i treatments [15]. Concerning the severity of the reported infections in the Dapagliflozin group, 2 68.8% of the infections were classified as Mild, accounting for 11 cases, while 31.2% were classified as Moderate. Crucially, no severe infections requiring hospitalization were reported. This severity profile is a reassuring finding when compared to the broader clinical literature. Although dapagliflozin increases the risk of UTI, studies consistently indicate that these infections are often uncomplicated and non-severe, rarely progressing to pyelonephritis (kidney infection) or urosepsis [12,15].

Laterally, regarding UTI incidence and onset time, we found that the vast majority (68.7%) of individuals who developed an infection experienced symptoms within the first three months of starting the medication. This aligns with (Siriyotha, S, etc) observational studies [13], which suggest that most dapagliflozin-related UTIs occur early in treatment, supporting the importance of close monitoring during the initial period. A further analytical step involved assessing whether demographic characteristics or treatment parameters influenced the risk of UTI occurrence. The statistical analysis revealed a significant relationship solely between advanced age and the prevalence of infection (P value=0.009). Crucially, the results indicated no statistically significant correlation with the duration of drug use, patient gender, or the dosage of dapagliflozin. This finding, which singles out age as the key predictor of UTI risk in this cohort, aligns with broader epidemiological data that universally recognize older age as an established risk factor for UTIs in diabetic populations, irrespective of the specific glucose-lowering medication used [16]. Furthermore, the lack of relationship with drug duration reinforces the hypothesis that UTIs associated with dapagliflozin are an early-onset event related to the initial glycosuria effect, rather than a cumulative risk that increases over time. The absence of correlation with gender, however, contrasts with certain clinical trials that have observed a slightly higher incidence of genital infections in female patients using SGLT2i [15].

The following study has some limitations, such as, firstly, accessing data was challenging due to the low usage of the drug among patients, primarily because of its high cost. Secondly, it was not possible to control all factors that may contribute to urinary tract infections, such as dehydration, poor personal hygiene, or the use of other medications. Finally, the data collection period for the questionnaires was prolonged due to the limited number of patients using medication in public diabetic health centers.

In conclusion, this study affirms the high efficacy of dapagliflozin in lowering blood glucose levels. Furthermore, the long-term adherence demonstrated by a quarter of the sample confirms the drug's long-term acceptability, consistent with its vital role in preventing renal and cardiac complications. Most importantly, while confirming an elevated incidence of UTI associated with dapagliflozin compared to standard treatments, the study assures that these infections are predominantly mild to moderate in severity, aligning with the drug's overall favorable risk-benefit profile. Emphasizing the need for proactive patient

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education and close monitoring, especially during the initial months of treatment, to ensure safe and successful integration into standard clinical practice.

Conflict of interest. Nil

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