

Risk of Urinary Tract Infections in Diabetic Patients Taking Sodium Glucose Inhibitors

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ABSTRACT

Objective: To examine the frequency and potential factors associated with urinary tract infections in patients on sodium-glucose co-transporter-2 inhibitor therapy.

Study Design: Cross-sectional study.

Place and Duration of Study: Diabetic Clinic and Medical Outpatients Department, Pak Emirates Military Hospital, Rawalpindi, Pakistan; from Nov 2023 to Apr 2024.

Methodology: This study included 185 adult patients with type-2 diabetes mellitus using sodium-glucose co-transporter-2 inhibitor for at least three months. The patients with a prior history of chronic kidney disease, urinary tract abnormalities, or recent genitourinary surgery were excluded. The data was collected on demographics, clinical parameters, urinary tract infection history, and adherence to hygiene practices to evaluate urinary tract infection frequency.

Results: The majority of patients were aged 46-65 years 99(53.5%), with female predominance 110(59.5%). Amongst these, 56(30.3%) individuals reported a history of urinary tract infections. Risk factor analysis showed age ($p=0.04$), gender ($p=0.02$), body mass index ($p=0.04$) and comorbidities ($p=0.05$) were significantly associated with urinary tract infections. In the univariate analysis, gender and BMI showed significant associations with UTI, whereas age, comorbid conditions, smoking, and SGLT-2 inhibitor use did not reach statistical significance. Specifically, gender was associated with 2.7-fold higher odds of UTI, and higher BMI was linked to a 42% reduction in odds.

Conclusions: A notable frequency (30.3%) of urinary tract infections was observed in patients who were prescribed sodium-glucose co-transporter-2 inhibitors. Certain factors, such as being female, being older, and having a higher body mass index, can increase the risk.

Keywords: Diabetes mellitus, Glycemic control, SGLT-2 inhibitors, Urinary tract infections.

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INTRODUCTION

Diabetes mellitus (DM) is a significant public health issue, with more than 11.3% of the worldwide adult population having it by 2030.¹ In recent years, novel drug classes have surfaced for the treatment of type 2 diabetes mellitus (DM), such as inhibitors of renal sodium-glucose co-transporter-2 (SGLT-2). These medications induce moderate glycosuria by impeding glucose reabsorption into proximal tubular cells. Due to glycosuria -induced calorie loss and natriuresis, they therefore provide clinically significant but mild reductions in body weight and blood pressure, in addition to a reduction in blood glucose.² Urinary tract infections (UTIs) and polyuria are two of the documented side effects linked to the usage of SGLT-2 inhibitors, according to some research.^{3,4}

In patients with type 2 diabetes, urinary tract infection (UTI) is indeed a prevalent complication.^{5,6} The incidence of urinary tract infections (UTIs) is a crucial aspect to consider in patients with type 2

diabetes mellitus (T2DM) using SGLT-2 inhibitors, particularly due to the increased urinary glucose excretion associated with these medications.⁷ Elevated urinary glucose levels can create a conducive environment for bacterial proliferation, potentially contributing to UTIs. This mechanism is supported by research indicating that *Escherichia coli*, a common bacterium associated with UTIs, shows proportional growth in response to increasing glucose levels.⁸ Several meta-analyses and systematic reviews indicated that people with type 2 diabetes mellitus who used SGLT-2 inhibitors had a considerably greater incidence of UTI than those who took a placebo or other oral anti-diabetic medications.^{9,10}

Given the limited availability of published studies on the incidence of urinary tract infections (UTIs) among type 2 diabetes mellitus (T2DM) patients using SGLT-2 inhibitors in Pakistan, the single investigation conducted in this context becomes particularly significant. The study revealed varying rates of UTIs among T2DM patients using dapagliflozin and empagliflozin, ranging from 10.1% to 14.7%. This underscores the need for further

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research to understand the UTI risk profile in this population comprehensively. Thus, our study aimed to assess the prevalence of UTIs in patients with T2D receiving SGLT-2 inhibitors.

METHODOLOGY

The cross-sectional study from November 2023 to April 2024 was conducted at Pakistan Emirates Military Hospital (PEMH), Rawalpindi, Pakistan. The study setting was a Diabetic clinic and Medical OPDs of the hospital. The study commenced following approval of the proposal by the Institutional Ethical Committee, vide certificate number# A/28/ERC/510/2023. The sample size for this study was calculated by using a population prevalence of 13.6% reported by a local study.¹¹ A statistical power of 80% and a significance level of 0.05 was used. Consequently, the required sample size for the study came out to be 185 patients. After informed consent, patients were enrolled by using a consecutive convenience sampling technique.

Inclusion Criteria: Adult patients with type 2 diabetes mellitus (T2DM) who had been prescribed SGLT-2 inhibitors for a minimum of three months were included in this study.

Exclusion Criteria: The patients with a prior history of chronic kidney disease, urinary tract abnormalities, recent genitourinary surgery, and indwelling urinary tract devices were excluded. Moreover, patients not willing to participate and those who didn't consent were also excluded.

Demographic and clinical information, such as age, gender, duration of diabetes, type of SGLT-2 inhibitor used, glycosylated hemoglobin (HbA1c) levels, and history of urinary tract infections (UTIs), were gathered from patients or their attendants. Information on symptoms suggestive of UTIs, previous UTI episodes, and adherence to genital hygiene practices was collected through patient interviews. Laboratory investigations, including complete blood counts and midstream urine samples for urine routine examination (Urine RE), were also collected and analyzed. The confidentiality of patients' data was maintained throughout the study as per institutional data safety guidelines.

The Statistical Package for Social Sciences (SPSS) version 25 was used for statistical analysis. The qualitative variables were represented using frequency and percentages, while quantitative variables were represented using Mean $\pm$ SD. The

statistical association was checked using a Chi-square test and binary logistic regression analysis. The *p*-value of ≤ 0.05 was taken as significant.

RESULTS

The study encompassed 185 diabetic patients taking SGLT-2 inhibitors, among the age groups, patients aged 46-65 years constituted the largest segment, comprising 99(53.5%) participants. This was followed by individuals aged >66 years, accounting for 49(26.5%). In terms of gender, there were 75(40.5%) male and 110(59.5%) female participants. Regarding BMI categories, 44(23.8%) individuals had a normal BMI while 97(52.4%) individuals were overweight. The majority of participants reported comorbidities 133(71.9%) individuals. The usage of SGLT-2 inhibitors 82(44.3%) individuals were using dapagliflozin, and 103(55.7%) individuals were using empagliflozin. The details are shown in Table-I.

Table-I: Demographic and Clinical Characteristics of the Study Sample (n=185)

Variables	n (%)
Age	
25-45 years	37 (20.0%)
46-65 years	99 (53.5%)
>66 years	49 (26.5%)
Gender	
Male	75 (40.5%)
Female	110 (59.5%)
BMI	
Normal	44 (23.8%)
Underweight	23 (12.4%)
Overweight	97 (52.4%)
Obese	21 (11.4%)
Comorbidities	
Yes	133 (71.9%)
No	52 (28.1%)
Smoking Status	
Yes	61 (33.0%)
No	124 (67.0%)
SGLT-2 inhibitors	
Dapagliflozin	82 (44.3%)
Empagliflozin	103 (55.7%)

**SGLT-2 inhibitors: Sodium-glucose co-transporter-2, BMI: Body mass index*

The frequency of urinary tract infection (UTI) history among the participants using SGLT-2 inhibitors was 56 individuals reported a history of UTI, representing 30.3% of the sample, while 129 individuals had no history of UTI, accounting for 69.7% of the sample as shown in Figure.

The analysis of risk factors associated with urinary tract infections (UTIs) among SGLT-2 inhibitor

users revealed several findings. Age was found to have a significant impact on UTI frequency ($p=0.04$). Participants aged 25-45 years had a frequency of 14(37.8%), while those in the 46-65 years and >66 years age groups exhibited lower frequency of 22(22.2%) and 20(17.0%), respectively. Gender also showed a significant association with UTIs ($p=0.02$), with females experiencing a higher frequency of 43(76.7%) compared to males at 13(23.2%). BMI was identified as another significant factor ($p=0.04$), with overweight individuals recording the highest frequency of 31(55.4%), followed by obese individuals at 17(30.4%). Comorbidities were significantly linked to UTIs ($p=0.05$), where participants with comorbidities had a frequency of 36(64.3%) compared to 20(35.7%) for those without comorbidities. Although not statistically significant ($p=0.07$), smoking status exhibited a potential trend, with smokers reporting a frequency of 13(23.2%) and non-smokers at 43(76.7%). Interestingly, the type of SGLT-2 inhibitor used did not yield a significant difference in UTI frequency ($p=0.95$), with dapagliflozin users at 19(33.9%) and empagliflozin users at 37(66.1%) as shown in Table-II.

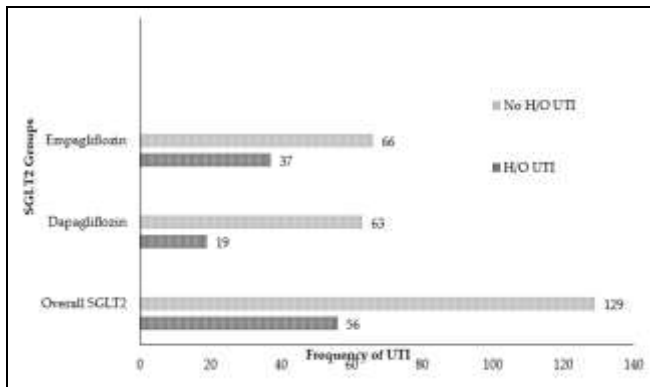


Figure: Frequency of UTIs in different SGLT-2 inhibitors (n=185)

In the univariate analysis, gender and BMI showed significant associations with UTI, whereas age, comorbid conditions, smoking, and SGLT-2 inhibitor use did not reach statistical significance. Specifically, gender was associated with 2.7-fold higher odds of UTI ($p=0.003$, OR = 2.697, 95% CI: 1.459–6.036), and higher BMI was linked to a 42% reduction in odds ($p=0.004$, OR = 0.584, 95% CI: 0.407–0.839) as shown in Table-III. In the multivariate model, after adjusting for other factors, gender remained significant but demonstrated a reversed effect, with the reference gender group having 67.5% lower odds of UTI. Smoking, age, and comorbidities were not

significantly associated with UTI in the adjusted analysis. These findings suggest that gender, BMI, and SGLT-2 inhibitor use are independent predictors of UTI.

Table-II: Risk Factors Associated with Urinary Tract Infections Among SGLT-2 Inhibitor Users (n=185)

Variables	Urinary Tract Infections		p-value
	Yes (n=56)	No (n=129)	
Age, n (%)			
25-45 years	14(37.8%)	23(62.2%)	0.04
46-65 years	22(22.2%)	77(77.8%)	
>66 years	20(17.0%)	29(15.6%)	
Gender, n (%)			
Male	13(23.2%)	62(48.0%)	0.02
Female	43(76.7%)	67(51.9%)	
BMI, n (%)			
Normal	2(3.5%)	42(32.6%)	0.04
Underweight	6(10.7%)	17(13.2%)	
Overweight	31(55.4%)	66(51.2%)	
Obese	17(30.4%)	4(3.1%)	
Comorbidities, n (%)			
Yes	36(64.3%)	97(75.2%)	0.05
No	20(35.7%)	32(24.8%)	
Smoking Status, n (%)			
Yes	13(23.2%)	48(37.2%)	0.07
No	43(76.7%)	81(62.8%)	
SGLT-2 inhibitors, n (%)			
Dapagliflozin	19(33.9%)	63(48.8%)	0.95
Empagliflozin	37(66.1%)	66(51.2%)	
SGLT-2 inhibitors: Sodium-glucose co-transporter-2, BMI: Body mass index			

SGLT-2 inhibitors: Sodium-glucose co-transporter-2, BMI: Body mass index

Table-III: Univariate and Multivariate Logistic Regression Analysis of Factors Associated with the Urinary tract infections

Factors	Univariate Logistic Regression			Multivariate Logistic Regression		
	p	Unadjusted OR	95% CI for UOR	p	Adjusted OR	95% CI for AOR
Median Age	0.577	0.876	0.551, 1.393	-	-	-
Gender	0.003	2.697	1.459, 6.036	0.03	0.325	0.153, 0.688
BMI	0.004	0.584	0.407, 0.839	0.07	0.594	0.406, .868
Comorbid Conditions	0.574	0.900	0.466, 1.738	-	-	-
Smoking	0.065	0.510	0.249, 1.044	0.084	0.502	0.230, 1.907
SGLT-2 Inhibitor	0.062	1.859	0.698, 3.568	0.022	0.433	0.212, 0.885

SGLT-2 inhibitors: Sodium-glucose co-transporter-2 inhibitors, BMI: Body mass index

DISCUSSION

SGLT-2 inhibitors (SGLT-2i) are a recently developed group of medications used to lower blood sugar levels. Studies indicate that these treatments are strongly linked to an increased likelihood of urinary

tract infections (UTIs).^{12,13} SGLT-2 inhibitors, like dapagliflozin, raise the glucose levels in the urine, creating a favourable condition for the colonisation and proliferation of bacteria. This, in turn, contributes to the development of urinary tract infections (UTIs).

The objective of our study was to evaluate the frequency of urinary tract infections (UTIs) in patients with type 2 diabetes (T2D) who were treated with two different types of SGLT-2 inhibitors. Our findings revealed a potential risk of urinary tract infections (UTIs) in individuals using SGLT-2 inhibitors. The frequency reported was 30.3% of the total sample. However, the UTIs seen were of mild to moderate intensity and could be effectively treated. None of the urinary tract infections (UTIs) resulted in the termination of treatment with SGLT-2 inhibitors in any of the patients. The reported frequency (30.3%) in our study is consistent with a previous study by Uitrakul et al. when compared with non-SGLT-2 diabetic patients.¹⁴ In non-diabetic patients, a meta-analysis found that SGLT-2 inhibitors were linked to higher chances of genital infections and urinary tract infections.¹⁵ A study conducted on patients with both type 2 diabetes and chronic kidney disease revealed a notable rise in urinary uric acid and glucose fractional excretion following the initiation of SGLT-2 inhibitors. Surprisingly, this occurred without any significant decrease in uricemia levels.¹⁶

The reported frequency of UTI in our study is significantly higher compared to previous studies. Typically, UTI incidences related to SGLT-2 inhibitors ranged from 3-9%.^{13,16} When it comes to individual drugs, most other studies have also found lower incidences compared to the current study. For example, in patients who were prescribed dapagliflozin, the occurrence of urinary tract infections was 5.3%, while this study found it to be 34%.¹⁷ In other studies, UTI events were reported by 4% of patients who used empagliflozin.^{18,19} The differences in UTI rates between our study and others can be traced back to how we collected data. Previous studies mostly looked at UTIs in labs, while we considered all types of UTIs, including self-reported ones. Also, the way we diagnosed UTIs, based on symptoms, signs, self-reports, and urine culture, varied from other studies that mainly relied on lab tests. Our approach was broader, including clinical diagnoses from medical records since many UTIs clear up without specific lab tests, and doctors often diagnose based on symptoms.

In line with previous studies, gender significantly influences the susceptibility to UTIs among individuals using SGLT-2 inhibitors. Our study findings indicate that female participants consistently exhibit a higher frequency of UTIs compared to males, which aligns with well-established trends.^{11,20} The research contexts did identify age and BMI as risk factors for urinary tract infections (UTIs) among diabetic patients using SGLT-2 inhibitors. In a recent study, it was found that patients treated with SGLT-2 inhibitors had a higher risk of UTIs as they got older.^{14,21} In another study, it was discovered that BMI had a connection to genitourinary infections in patients with type 2 diabetes who were taking SGLT-2 inhibitors. Overweight or obese BMI was found to be a contributing factor to both genitourinary and genital infections.¹⁵ These findings underscore the significance of taking into account age and BMI as potential risk factors for UTIs in diabetic patients receiving treatment with SGLT-2 inhibitors, underscoring the necessity for thorough patient evaluation and monitoring in clinical practice.

LIMITATIONS OF STUDY

There are certain limitations in our study. As it cross-sectional study with a small sample size conducted in a single centre, it brings inherent limitations of generalizability, and also the inherent bias of selection as the study centre was a tertiary care hospital. Therefore, we suggest a multicenter study should be conducted with a larger sample size to fully understand the impact of SGLT-2 inhibitors on urinary tract infections.

CONCLUSION

A notable frequency (30.3%) of urinary tract infections was observed in patients who were prescribed SGLT-2 inhibitors to manage type 2 diabetes. Certain factors, such as being female, being older, and having a higher BMI, can increase the risk of developing UTIs.

Conflict of Interest: None.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

ZAJ & MI: Data acquisition, data analysis, critical review, approval of the final version to be published.

IA & MHR: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SA & MA & MI: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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