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FREQUENCY OF URINARY TRACT INFECTION IN PATIENT OF TYPE 2 DIABETES MELLITUS TAKING SODIUM GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS

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ABSTRACT

Background: *Sodium-glucose cotransporter-2 (SGLT2) inhibitors are commonly used in managing type 2 diabetes mellitus. While effective, these medications lead to glycosuria (glucose in the urine), which may contribute to an increased risk of urinary tract infections (UTIs). This potential side effect is still seen as a limiting factor in the broader use of these drugs.*

Objective: *This study aimed to evaluate how frequently UTIs occur in individuals with type 2 diabetes who are being treated with SGLT2 inhibitors.*

Study design: *Cross-sectional study*

Setting: *Department of Medicine, Ghulam Muhammad Mahar Medical College (GMMMC) Hospital, Sukkur*

Study duration: *Six months (June 1, 2024 - November 30, 2024)*

Sampling technique: *Non-probability consecutive sampling*

Sample size: *A total of 215 patients diagnosed with type 2 diabetes and receiving SGLT2 inhibitors*

Patients & Methods: *Patients aged between 18 and 75 years with a confirmed diagnosis of type II diabetes and currently on SGLT2 inhibitors were enrolled, regardless of gender. Each participant was assessed for signs and symptoms of urinary tract infection. Collected data were analyzed using descriptive statistics, including means with standard deviations for continuous variables and frequencies with percentages for categorical variables.*

Results: *Out of 215 participants, 130 individuals (60.4%) were found to have a urinary tract infection. The average age was 58.95 years (±10.47 SD). UTIs showed significant associations with several variables, including age (p=0.05), gender (p=0.04), place of residence (p=0.01), presence of hypertension (p=0.04),*

educational background (p=0.04), symptoms (p<0.01), smoking status (p=0.04), obesity (p<0.01), glycemic control (p<0.01), and marital status (p=0.03). Breakdown of characteristics among the participants were as Gender: 57.7% female, 42.3% male; residence: 40.5% urban, 59.5% rural; education: 23.7% illiterate, 18.6% primary, 18.6% middle, 21.4% secondary, 17.7% higher education; smoking status: 20.5% current smokers, 42.3% ex-smokers; symptoms: Painful urination (29.3%), burning sensation (23.7%), frequent urination (47.0%); obesity present in 53.0%; marital status: Married (24.7%), single (24.2%), separated (26.0%), divorced (25.1%); occupation, housewives (30.2%), employed (27.0%), unemployed (24.2%), business owners (18.6%); uncontrolled diabetes: 61.4% had poor glycemic control

Conclusion: *The study found a high occurrence of urinary tract infections among type 2 diabetic patients using SGLT2 inhibitors, indicating a need for careful monitoring and preventive strategies when prescribing these medications.*

INTRODUCTION:

Sodium-glucose co-transporter 2 (SGLT2) inhibitors constitute an especially new group of oral medicines used to manage type 2 diabetes mellitus (T2DM). These drugs help lower blood glucose ranges by means of blocking off the reabsorption of glucose in the kidneys, which results in elevated glucose being handed out in the urine (Arakaki RF et al, 2016). While SGLT2 inhibitors have raised safety issues because of facet consequences, especially urinary tract infections (UTIs) and improved urination. The U.S. Food and Drug Administration (FDA) issued a public warning highlighting the ability for serious UTIs related to such drugs (Hsia DS et al, 2017).

UTIs are already a not unusual hassle among people with type 2 diabetes. Research through Hirji and associates confirmed that diabetic patients had an infection rate of 46.9 per 1000 person-years (Hirji I et al, 2012). Several other studies have additionally stated a quite higher rate of UTIs among diabetic people handled with SGLT2 inhibitors. Treatment options for T2DM typically consist of medicinal drugs such as metformin, sulfonylureas, sitagliptin, GLP-1 receptor agonists, and insulin. SGLT2 inhibitors like dapagliflozin, empagliflozin, and canagliflozin are a newer addition that target glucose reabsorption within the kidneys, especially inside the proximal tubule wherein the SGLT2 transporter is positioned (Lee DH et al, 2024; Chamberlain JJ et al, 2017 & Heald AH et al, 2018). Clinical research has evaluated the effectiveness and protection of these tablets (Lupsa BC et al, 2018 & Plosker GL et al, 2014). The study by Uitrakul et al pronounced a UTI occurrence of 33.49% in sufferers on SGLT2 inhibitors, compared to 11.72% in those not using those (Uitrakul S et al, 2022). No huge distinction became found among dapagliflozin and empagliflozin, with infection rates of 34.00% and 33.03% respectively. The threat of UTI turned into observed to be 3.7 times higher in patients on. A study conducted in Peshawar found that urinary tract infections (UTIs) occurred in 5.3% of diabetic patients using SGLT2 inhibitors (Khan S et al, 2022). The condition was significantly more common in women, who accounted for 76.2% of cases, and in individuals over the age of 50, who made up 85.7% of the affected group. Another study by Ashfaq et al. reported a UTI incidence of 12.46% (46 out of 369 patients) among SGLT2 inhibitor users, with 10.1% of those taking dapagliflozin and 14.7% of those on empagliflozin developing the infection (Ashfaq M et al, 2022).

The primary goal of our study was to assess how frequently UTIs occur in patients prescribed SGLT2 inhibitors. Although the FDA has issued warnings regarding the potential risk of UTIs with this class of drugs, the prescription of SGLT2 inhibitors has not declined significantly in our clinical setting. Additionally, the available research shows considerable variation in reported UTI rates among users. The results of this study aim to contribute valuable local data and offer practical insights for healthcare providers to promote more rational and evidence-based use of SGLT2 inhibitors in patients with diabetes.

PATIENTS AND METHODS:

This cross-sectional study was carried out over a six-month period, from June 1 to November 30, 2024, in the Department of Medicine at Ghulam Muhammad Mahar Medical College. Ethical clearance for the study was obtained from the College of Physicians and Surgeons Pakistan (CPSP). Patients attending the endocrinology and general medicine outpatient departments who met the predefined eligibility criteria were included through a non-probability consecutive sampling technique. Prior to participation, written informed consent was obtained after providing a clear explanation of the study's purpose, as well as the potential risks and benefits.

At the time of recruitment, detailed demographic and clinical information was recorded for each participant. The sample size was calculated using OpenEpi software, based on an anticipated UTI prevalence of 5.3% among users of SGLT2 inhibitors (Wiegley N et al, 2022), 95% confidence level, and a 3% margin of error, yielding a required sample size of 215 patients.

ELIGIBILITY CRITERIA:

Inclusion:

Adults aged 18 to 75 years

Both male and female participants

History of pain or burning during urination for at least 7 days

Diagnosed with type 2 diabetes mellitus for two or more years and on SGLT2 inhibitors for a minimum of 3 months

Exclusion:

History of recurrent UTIs

Immunocompromised status

Known cases of chronic kidney or liver disease

Pregnant women

Urinary tract infection was diagnosed based on microscopic urine analysis showing more than 5 pus cells per high-power field and/or a urine culture with over 100,000 colony-forming units of a single urinary pathogen per milliliter of urine.

Type 2 diabetes mellitus was defined according to standard criteria, with a fasting blood sugar level of ≥126 mg/dL or a random blood sugar level of ≥200 mg/dL on two separate occasions.

All eligible patients on SGLT2 inhibitors were screened for UTIs, and additional variables including age, gender, residence, height, weight, BMI, duration of SGLT2 use, smoking status, symptoms, glycemic control, marital and occupational status, and education level were recorded using a structured proforma.

Data entry and statistical analysis was conducted using SPSS. Quantitative data, such as age, height, weight, BMI, HbA1c, and duration of diabetes and medication use, were expressed as means with standard deviations or medians with interquartile ranges, depending on distribution assessed using the Shapiro-Wilk test. Categorical variables, including gender, place of residence, smoking status, presenting symptoms, glycemic control, marital status, occupation, education level, and presence of UTI, were reported as frequencies and percentages. To identify the influence of potential confounders, stratification was performed based on variables like age, gender, residence, BMI, marital status, symptoms, occupation, education, and smoking. Post-stratification analysis was done using the chi-square test or Fisher's exact test, and a p-value ≤ 0.05 was considered statistically significant.

RESULTS:

Over a six-month period, a total of 215 individuals diagnosed with type 2 diabetes mellitus for at least two years and currently being treated with SGLT2 inhibitors visited the Medical and Endocrinology Outpatient Department at Ghulam Muhammad Mahar Medical College Hospital in Sukkur.

Details regarding the participants' demographic and clinical characteristics are outlined in Table 01. Table 02 summarizes the average age, duration of diabetes, and HbA1c levels (expressed as mean ± standard deviation). Statistical analysis showed that the skewness and kurtosis values were -0.10 and -1.27 for age, -0.32 and -1.48 for disease duration, and 0.57 and -0.27 for HbA1c levels, respectively. The median values recorded for age, duration of disease, BMI, and HbA1c were 49 years, 8 years, 29 kg/m², and 7.3% accordingly. The Shapiro-Wilk test for normality indicated a statistically significant deviation from normal distribution for age, disease duration, and HbA1c levels, all with p-values less than 0.01.

Further analysis explored the occurrence of urinary tract infections (UTIs) among these patients, stratifying the data across multiple variables including age, gender, disease duration, place of residence, education level, symptoms at presentation, smoking status, obesity, marital status, occupation and uncontrolled diabetes mellitus (see Tables 3). Statistically significant associations with UTIs were found for age ($p = 0.05$), gender ($p = 0.04$), residence ($p = 0.01$), hypertension ($p = 0.04$), education level ($p = 0.04$), presenting symptoms ($p < 0.01$), smoking ($p = 0.04$), obesity ($p < 0.01$), poor glycemic control ($p < 0.01$), and marital status ($p = 0.03$). However, no significant relationship was observed between UTIs and either duration of diabetes ($p = 0.27$) or occupational status ($p = 0.26$).

TABLE 1: AN OVERVIEW OF THE PARTICIPANTS' DEMOGRAPHIC AND CLINICAL PROFILES

PARAMETER	FREQUENCY (n=215)	PERCENTAGE (%)
AGE (yrs)		
18-29	29	13.5
30-39	30	14.0
40-49	43	20.0
50-59	46	21.4
60-69	35	16.3
70+	32	14.9
GENDER		
Female	124	57.7
Male	91	42.3
DURATION OF DISEASE (yrs)		
2-6	59	27.4
7-9	61	28.4
≥10	95	44.2
RESIDENCE		
Urban	87	40.5
Rural	128	59.5
EDUCATIONAL STATUS		
Illiterate	51	23.7
Primary	40	18.6
Middle	40	18.6
Secondary	46	21.4
Higher	38	17.7
SMOKING		
Yes	44	20.5
No	80	37.2
Ex-smoker	91	42.3
SYMPTOMS		

Dysuria	63	29.3
Burning micturition	51	23.7
Frequent urination	101	47.0
OBESITY		
Yes	114	53.0
No	101	47.0
MARITAL STATUS		
Married	53	24.7
Single	52	24.2
Separated	56	26.0
Divorced	54	25.1
OCCUPATION		
House wife	65	30.2
Employed	58	27.0
Unemployed	52	24.2
Businessman	40	18.6
UNCONTROLLED DIABETES MELLITUS		
Yes	132	61.4
No	83	38.6
URINARY TRACT INFECTION		
Yes	130	60.4
No	85	39.5

TABLE 2: THE MEAN ±SD FOR QUANTITATIVE VARIABLES

QUANTITATIVE VARIABLES	MEAN ± SD
Age (yrs)	58.95 ± 10.47
Duration of disease (yrs)	8.92 ± 3.21
Duration of SGLT inhibitors use (months)	4.81 ± 1.92
HbA1c (%)	7.75 ± 2.05
BMI (kg/m^2)	31.51 ± 4.43

TABLE 3: THE OCCURRENCE OF URINARY TRACT INFECTIONS IN RELATION TO DIFFERENT STUDY VARIABLES

	URINARY TRACT INFECTION n = 215 (%)			
AGE (years)	Yes	No	Total	P-value
18-29	20	9	29	0.05*
	(15.4%)	(10.6%)	(13.5%)	

30-39	17	13	30	
	(13.1%)	(15.3%)	(14.0%)	
40-49	33	10	43	
	(25.4%)	(11.8%)	(20.0%)	
50-59	26	20	46	
	(20.0%)	(23.5%)	(21.4%)	
60-69	15	20	35	
	(11.5%)	(23.5%)	(16.3%)	
70-75	19	13	32	
	(14.6%)	(15.3%)	(14.9%)	
GENDER				
Male	62	29	91	
	(47.7%)	(34.1%)	(42.3%)	
Female	68	56	124	0.04*
	(52.3%)	(65.9%)	(57.7%)	
DURATION OF DISEASE (years)				
2-6	35	24	59	
	(26.9%)	(28.2%)	(27.4%)	
7-9	42	19	61	
	(32.3%)	(22.4%)	(28.4%)	0.27**
10	53	42	95	
	(40.8%)	(49.4%)	(44.2%)	
RESIDENCE				
Urban	61	26	87	
	(46.9%)	(30.6%)	(40.5%)	
Rural	69	59	128	0.01*
	(53.1%)	(69.4%)	(59.5%)	
EDUCATIONAL STATUS				
Illiterate	38	13	51	
	(29.2%)	(15.3%)	(23.7%)	
Primary	18	22	40	
	(13.8%)	(25.9%)	(18.6%)	
Middle	26	14	40	0.04*
	(20.0%)	(16.5%)	(18.6%)	
Secondary	28	18	46	
	(21.5%)	(21.2%)	(21.4%)	
Higher	20	18	38	
	(15.4%)	(21.2%)	(17.7%)	
PRESENTING SYMPTOMS				
Painful urination	48	15	63	
	(36.9%)	(17.6%)	(29.3%)	
Burning urination	29	22	51	
	(22.3%)	(25.9%)	(23.7%)	<0.01*
Frequent urination	53	48	101	
	(40.8%)	(56.5%)	(47.0%)	
SMOKING				

Yes	27	17	44	
	(20.8%)	(20.0%)	(20.5%)	
No	56	24	80	
	(43.1%)	(28.2%)	(37.2%)	
Ex-smoker	47	44	91	0.04*
	(36.2%)	(51.8%)	(42.3%)	
OBESITY				
Yes	82	32	114	
	(63.1%)	(37.6%)	(53.0%)	
No	48	53	101	<0.01*
	(36.9%)	(62.4%)	(47.0%)	
MARITAL STATUS				
Married	33	20	53	
	(25.4%)	(23.5%)	(24.7%)	
Single	34	18	52	
	(26.2%)	(21.2%)	(24.2%)	
Separated	39	17	56	0.03*
	(30.0%)	(20.0%)	(26.0%)	
Divorced	24	30	54	
	(18.5%)	(35.3%)	(25.1%)	
OCCUPATION				
Housewife	39	26	65	
	(30.0%)	(30.6%)	(30.2%)	
Employed	38	20	58	
	(29.2%)	(23.5%)	(27.0%)	
Unemployed	34	18	52	0.26**
	(26.2%)	(21.2%)	(24.2%)	
Businessman	19	21	40	
	(14.6%)	(24.7%)	(18.6%)	
UNCONTROLLED DM				
Yes	95	37	132	
	(73.1%)	(43.5%)	(61.4%)	<0.01*
No	35	48	83	
	(26.9%)	(56.5%)	(38.6%)	

*Statistically significant;
**Statistically non-significant

DISCUSSION:

In this study, symptoms and supportive laboratory findings of urinary tract infection (UTI) were usually seen in patients using SGLT2 inhibitors (SGLT2I). This trend is consistent with previous research, which also reported a smooth link between SGLT2I use and UTI development (Dave CV et al, 2019). These medicines work by blocking glucose generations in adjacent channels in the kidney, leading to glucosuria (increased glucose in urine), which is considered an important factor in promoting urinary infection in these individuals (Pishdad R et al, 2024). In people with type 2 diabetes (T2D), kidneys often express more SGLT2-transports, improving the threshold for glucose emissions, which means that once disturbed, even more glucose spreads to urine than non-diabetics (Anan G et al, 2023).

In our study, approximately 60.4% of individuals on SGLT2 inhibitors developed UTIs, suggested a

strong association. This rate appears to be higher than previously reported; possibly reinforcing the idea that glucosuria significantly contributes to infection risk. However, other factors likely play a role as well. Poor personal hygiene, insufficient fluid intake, and obesity were also found to influence UTI risk, with a notable link observed between higher body mass index (BMI) and infection. It is suggested that obesity may indirectly raise the risk by making personal hygiene more challenging (Alkabbani W et al, 2022).

The clinical signs of UTI reported in this group such as frequent, painful, or burning urination might not always indicate infection alone. In some cases, these symptoms could result from glucosuria-driven osmotic diuresis (Kittipibul V et al, 2024 & Zheng H et al, 2021). Previous studies by Tanrıverdi and Zhou have shown that such symptoms may be related to temporary increases in urine sodium and glucose, and are often short-lived (Tanrıverdi M et al, 2023 & Zhou Y et al, 2024).

In addition, complications such as autonomous neuropathy, a common result of long -scale diabetes, can affect the urinary patterns.

In addition, persistent high blood sugar can in itself cause continuous urination due to the sky -bound effect, regardless of infection. Therefore, clinical symptoms alone for diagnosis may not be sufficient. Objective test, especially urine cultures are important to identify exactly if the symptoms are actually due to urinary tract infection (Krepostman N et al, 2021).

Findings from the DURATION-8 trial highlighted a rise in urinary tract infections (UTIs) following the use of dapagliflozin, a trend that was also seen with empagliflozin (Jabbour SA et al, 2020). However, various SGLT2 inhibitors (SGLT2I) are limited comparative research that evaluates the risk of UTI in diabetes. A meta-analysis found that the risk of developing out, in general, is similar to individual SGLT2 inhibitors and doses, with the exception of dapagliflozine, where high doses were associated with a high risk (Donnan JR et al, 2018). Interestingly, another systematic review suggested that empagliflozin can take a greater risk of UTI than dapagliflozin (Pelletier R et al, 2021).

In addition to uncomplicated UTIs, the use of SGLT2 inhibitors has occasionally been linked to more severe infections, including urosepsis and pyelonephritis, though these complications remain relatively uncommon (Fisher A et al, 2020). The potential for hospitalization increases when UTIs involve resistant bacterial strains such as Klebsiella pneumoniae or Escherichia coli, which are sometimes difficult to treat due to their antibiotic resistance. For instance, Klebsiella pneumoniae is resistant to nitrofurantoin in over 30% of cases and to fluoroquinolones in 10-20%. Around a quarter of Klebsiella strains also produce extended-spectrum beta-lactamase (ESBL), which further complicates treatment especially when oral antibiotics like fosfomycin or nitrofurantoin are less effective. Therefore, urine culture remains a vital diagnostic tool in patients with type 2 diabetes, particularly those on SGLT2 inhibitors.

SGLT2 inhibitors are also known to increase the risk of genital fungal infections, especially in uncircumcised men and individuals with a prior history of such infections (McGill JB et al, 2019).

Compared to previous literature, this study reported a significantly higher incidence of UTI in patients taking SGLT2 inhibitors. While earlier studies reported UTI rates between 3% and 9% (Liu J et al, 2017). These rates are considerably higher than the 5.3% and 4% figures reported in previous studies for dapagliflozin and empagliflozin, respectively (Khan S et al, 2022). While meta-analyses have found that SGLT2 inhibitors increase UTI risk by approximately 1.1 to 1.3 times compared to placebo, some studies have found no statistically significant difference between SGLT2 inhibitors and other antidiabetic agents (Figueiredo IR et al, 2019 & Min SH et al, 2018).

In particular, dapagliflozin has shown a modest but consistent increase in UTI risk in the literature (Donnan JR et al, 2019). Figueiredo et al. noted a 1.18-fold rise in risk, while Puckrin et al. reported an increase of 1.33 times (Figueiredo IR et al, 2019 & Puckrin R et al, 2018). Despite the fact that this study confirms a strong link between SGLT2i use and UTIs, the frequency observed here exceeds that seen in earlier research (Li D et al, 2017).

One possible explanation for this discrepancy lies in the diagnostic criteria used. Many previous studies relied primarily on urine lab results, whereas this study considered a broader range of factors including patient-reported symptoms and clinical diagnoses

from both inpatient and outpatient settings (Wilding JP et al, 2014).

Gender also appears to play a major role. Numerous studies have shown that females are more likely to experience UTIs, including recurrent and complicated infections, compared to males. Occupational factors have also been explored, with some jobs such as cleaning or driving commercial vehicles possibly contributing to increased risk, although research in this area remains limited (Markland A et al, 2018).

Several contributing factors have been linked to a higher occurrence of urinary tract infections (UTIs) (Pereira MJ et al, 2019). One such factor is an increased body mass index (BMI), particularly when it exceeds 30 kg/m². This level of obesity may impair the ability to fully empty the bladder, which can increase the risk of developing UTIs (Yang H et al, 2022). Additionally, poorly controlled blood sugar levels, reflected by elevated HbA1c levels, and is another common risk factor among individuals living with diabetes.

When UTIs occur in patients taking SGLT2 inhibitors, prompt and proper management is essential to prevent serious complications. In such cases, temporarily stopping the medication may be necessary, depending on the severity of the infection. Antibiotic treatment should be guided by sensitivity testing to ensure effective therapy. For individuals with recurrent UTIs, preventive use of antibiotics like trimethoprim or nitrofurantoin may be considered (Covington EW et al, 2022).

Beyond medication, holistic diabetes management plays a key role in reducing UTI risk. This includes maintaining stable blood glucose levels through a combination of balanced diet (medical nutrition therapy), regular physical activity, and continuous patient education. Patients should also be encouraged to stay well-hydrated and to ensure complete bladder emptying during urination, both of which are simple yet important steps in preventing urinary infections.

CONCLUSION:

Urinary tract infections (UTIs) were identified in 130 out of 215 participants, accounting for 60.4% of the total diabetic patients on SGLT2 inhibitors. The average age of patients was approximately 59 years (mean ± SD: 58.95 ± 10.47 years). Statistical analysis revealed significant associations between UTI occurrence and several variables, including age ($p = 0.05$), gender ($p = 0.04$), area of residence ($p = 0.01$), presence of hypertension ($p = 0.04$), educational background ($p = 0.04$), presenting urinary symptoms ($p < 0.01$), smoking status ($p = 0.04$), obesity ($p < 0.01$), poorly controlled diabetes ($p < 0.01$), and marital status ($p = 0.03$). Looking at the demographics, females made up 57.7% of the UTI cases, while males accounted for 42.3%. Rural residents were more affected (59.5%) compared to urban dwellers (40.5%). In terms of education, 23.7% were illiterate, 18.6% had primary or middle-level education, 21.4% had completed secondary schooling, and 17.7% had higher education. Regarding smoking habits, 20.5% were current smokers and 42.3% were former smokers. The most commonly reported symptoms included frequent urination (47.0%), painful urination (29.3%), and a burning sensation during urination (23.7%). Obesity was present in 53.0% of the UTI cases. When classified by marital status, 24.7% were married, 24.2% single, 26.0% separated, and 25.1% divorced. Occupationally, 30.2% were housewives, 27.0% were employed, 24.2% were unemployed, and 18.6% were businessmen. A notable 61.4% of UTI patients had poorly controlled diabetes. These findings suggest that urinary tract infections are a common complication among diabetic patients using SGLT2 inhibitors, potentially leading to more severe infections. However, further research is warranted to confirm these results and to explore the underlying mechanisms more thoroughly.

LIMITATION OF THE STUDY:

This study had some limitations that should be considered when interpreting the findings. It was conducted at a single healthcare facility and followed a cross-sectional design, which may limit how well the results apply to different or larger populations. The relatively small number of participants and the brief duration of the study also made it difficult to draw conclusions about long-term effects. To better understand the link between SGLT-2 inhibitors and urinary tract infections, future research should involve longer-term, prospective studies with diverse populations across multiple clinical centers. This

approach would help strengthen the relevance and generalizability of the results.

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AUTHOR'S CONTRIBUTION:

Collection and acquisition of data & designing	*Dr. Safdar Ali*
Concept & design of study & proof read	*Dr. Altaf Ahmed Shaikh*
Drafting the article and finalizing the manuscript	*Dr. Ali Mohsin*
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