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ORIGINAL ARTICLE

Prevalence of genitourinary symptoms in people with type 2 diabetes initiated with SGLT2 inhibitors

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Abstract

Background Sodium glucose co-transporter-2 (SGLT2) inhibitors prevent the kidneys from reabsorbing glucose from the urine. In addition to glucose-lowering effect, SGLT2 inhibitors can also reduce blood pressure and result in weight loss. In spite of the benefits of this drug, it predisposes patients to genitourinary tract infections.

Objective This study aimed to assess the prevalence of genitourinary symptoms (GUS) in individuals with type 2 diabetes prescribed SGLT2 inhibitors and to evaluate the impact of these symptoms on treatment discontinuation.

Methods In this cross-sectional study, a total of 320 (M:F 216:104) participants recently initiated with SGLT2 inhibitors were included from a tertiary care center for diabetes, Chennai from January to September 2022. Basic demographic, anthropometric, biochemical parameters, clinical profile, use of concomitant diabetes medications, history of GUS prior to intake of SGLT2 inhibitors, and GUS after intake of SGLT2 inhibitors were collected.

Results The mean age of the participants was 54.5 ± 10.3 years, and the mean duration of diabetes was 12.7 ± 7.9 years. The prevalence of GUS was 18.4%. The median BMI and HbA1c were significantly high among people with GUS than without GUS (29.6 vs. 27.5 kg/m^2, $p = 0.004$) and (8.2 vs. 7.8%, $p = 0.037$). Among people with GUS, almost 3/4th (72.9%) were taking dapagliflozin. Around 16.9% were advised to discontinue the drug. In 18.6%, the drug was changed, and the remaining 47.5% were advised to continue the drug with precautions to drink plenty of water and maintain genital hygiene. Of those who had minimal symptoms, 10.2% were prescribed oral antifungal and antibiotics, and 6.8% were prescribed antifungal creams as the drug has several other health benefits.

Conclusion Genitourinary symptoms were common among people with type 2 diabetes who were initiated with SGLT2 inhibitors. Prior education about the adverse events of the drug is necessary during the initiation of the treatment.

Keywords Type 2 diabetes · Oral antidiabetic drug · SGLT2 inhibitors · Adverse reaction · GU symptoms · South India

Introduction

The management of type 2 diabetes (T2DM) typically requires multiple medications to regulate the level of blood glucose [1]. Gliflozins are a class of medications that decrease blood glucose by stopping the kidneys from reabsorbing glucose from the proximal tubules. They are also known as SGLT2 inhibitors as they function by blocking the sodium-glucose co-transporter 2 protein, which decreases the renal threshold for glucose and reduces the amount of filtered glucose reabsorption, increasing the excretion of glucose in the urine [2, 3]. SGLT2 inhibitors have a unique mechanism of action by lowering blood glucose levels without inducing the release of insulin by the pancreas [1]. It has a potential to use as an adjuvant therapy to improve reduction of glucose when used in combination with other

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glucose-lowering therapies. SGLT2 inhibitors should be regarded as appropriate second-line treatments for those who are at risk of cardiovascular events or those with underlying nephropathy [4]. DM has long-term detrimental effects on the genitourinary system in multiple ways [5]. Numerous factors, including female sex and diabetes, particularly when glycemic control is inadequate, have been linked to an increased risk of genital infection [6, 7].

SGLT2 inhibitors stop the proximal tubules in the kidney from reabsorbing glucose, which causes glucosuria. The growing concern about the possibility of UTI and genitourinary infection based on this method of action is a barrier that may restrict their usage in certain patients [8]. Benefits include a little drop in body weight and blood pressure as well as the absence of hypoglycemia as a side effect. Due to its modest diuretic action, side effects include increased frequency of urination, hypovolemia symptoms.

Clinical studies had greater rates of vaginal mycotic infections, urinary tract infections, and side events associated with osmotic diuresis; however, these infections were often mild to moderate in severity and led to few discontinuations [9–11]. This type of infection can affect the kidneys, referred to as pyelonephritis, the bladder, referred to as cystitis, or the urethra called urethritis [12–14]. In addition to SGLT2 inhibitors, menopause, circumcision, and personal cleanliness may all be contributing factors to the observed incidence of genital infections in T2DM patients on SGLT2 inhibitors therapy [15]. Other adverse effects of dapagliflozin include dehydration (probably because of polyuria), whereas canagliflozin causes polydipsia, constipation, nausea, and polyuria [16–19]. Genital infections tend to be the most frequent adverse side effect of SGLT2 inhibitors, increasing up to four times in clinical trials [1]. SGLT2 inhibitor treatment increases glucose excretion in urine, and this may also promote fungal development in the genitourinary tract and perineum [20]. Many clinical trials showed that SGLT2 inhibitor users had 2.5–6 times higher genital infection rates than control subjects [21–23]. Less evidence is available in Indian context on SGLT2 inhibitors induced genitourinary symptoms among people with type 2 diabetes. Hence, we aimed to assess the prevalence of genitourinary symptoms after the intake of SGLT2 inhibitors among people with type 2 diabetes and also to see the impact on discontinuation of treatment.

Methods and Materials

This cross-sectional study was conducted among 320 (M:F 216:104) participants from the out-patient department of a tertiary care center for diabetes in Chennai, South India, between January and September 2022. The participants those aged above 20 years diagnosed with T2DM, both gender, those initiated on SGLT2 inhibitors (within 6 months) were included and those with GUS before the intake of SGLT2 inhibitors, people with gestational diabetes, type 1 diabetes, and people taking SGLT2 inhibitors for more than 6 months were excluded from the study. All the individuals were approached and enrolled into the study based on the inclusion and exclusion criteria. The ethics committee of the institution approved the study (IEC/N-004/01/2022), and written informed consent was obtained from the participants prior to the data collection.

A semi-structured questionnaire with two parts was used for data collection. The first part included socio-demographic variables, behavioral habits, anthropometric measurements, clinical profiles, and biochemical parameters. Anthropometric measurements included height and weight. Weight was measured using a standard portable digital scale. Stadiometer was used to measure height of the participants. BMI was calculated using the standard formula and expressed in kg/m^2. Smoking and alcohol consumption were recorded. Fasting, postprandial blood glucose, and HbA1c measurements were recorded. All the biochemical investigations were done by standard enzymatic procedure using fully automated biochemistry analyzers. The presence of other diabetic complications and co-morbidities was recorded. The medication details were also recorded. The second part had open-ended questions on the experience of the participants with GU symptoms after intake of SGLT2 inhibitors. The symptoms included itching, burning, dryness in the genital area, redness in the genital area, acute dysuria, urinary incontinence, frequent/excessive urination, and foul-smelling urination. The treatment advised for GUS was also recorded.

Statistical analysis

Baseline characteristics of all participants were descriptively analyzed and reported as numbers and percentages. Mean and SD for normally distributed variables and median (Min, Max) were reported for the variables that showed skewed distribution. Mann–Whitney *U* test was performed to see the difference between people with and without GU symptoms. Paired *T*-test was done to address the changes in anthropometric and glycemic control before and after the intake of SGLT2 inhibitors. Data were analyzed using IBM SPSS Statistics software version 29. The significance threshold of all analyses was set at $p < 0.05$.

Results

Table 1 shows the socio-demographic, behavioral habits, and clinical profile of the study participants. The mean age was 54.5 ± 10.3 years and nearly 66.9% of the study participants were aged above 50 years. Majority (67.5%) of them

were males. More than 3/4th (86.3%) of the participants had diabetes for more than 5 years with a mean duration of 12.7 ± 7.9 years. High proportion (78%) of them were obese (BMI ≥ 25 kg/m^2) with a mean BMI of 28.6 ± 4.8 kg/m^2. In terms of lifestyle habits, 6.3% were currently consuming alcohol and 4.7% were current smokers. Around 65% of the participants had neuropathy followed by retinopathy (31.3%), CVD (9.7%), and nephropathy (8.8%). Comorbid conditions such as hypertension and dyslipidemia proportions were 40% and 41.6%, respectively. Less than half (47.2%) of them were taking oral hypoglycemic agents alone, while others (52.8%) were taking insulin in combination with other oral hypoglycemic agents. In the class of SGLT2 inhibitors, high proportion 220 (68.8%) were taking dapagliflozin, 10 (3.1%) were on empagliflozin, 24 (7.5%) were on remogliflozin, 4 (1.3%) were on combination of dapagliflozin + vildagliptin, 27 (8.4%) were on combination of dapagliflozin + metformin, 16 (5%) were on combination remogliflozin + vildagliptin, and 19 (5.9%) were on combination of remogliflozin + metformin + vildagliptin.

Table 1 Socio-demographic, behavioral habits, and clinical profile of the study participants ($n = 320$)

Variables	*N* (%)
Age(years) *	54.5 ± 10.3
≤ 45	58 (18.1)
46–55	105 (32.8)
56–65	106 (33.1)
> 65	51 (15.9)
Gender	
Male	216 (67.5)
Female	104 (32.5)
Duration of diabetes (years) *	12.7 ± 7.9
≤ 5	44 (13.8)
6–10	103 (32.2)
11–15	73 (22.8)
16–20	48 (15)
> 20	52 (16.3)
BMI (kg/m^2) ($n = 314$) *	28.6 ± 4.8
Normal	27 (8.6)
Overweight	42 (13.4)
Obesity	245 (78)
Behavioral habits	
Alcohol consumption	20 (6.3)
Smoking	15 (4.7)
Medication details	
OHA's	151 (47.2)
OHA + insulin	169 (52.8)
Co-morbid/complications	
Hypertension	128 (40)
Dyslipidemia	133 (41.6)
Retinopathy	100 (31.3)
Nephropathy	28 (8.8)
Cardiac problem	31 (9.7)
Neuropathy	210 (65.8)

Values are in *n* (%); *values are in mean ± SD

Figure 1 depicts the prevalence of GUS among the people initiated on SGLT2 inhibitors treatment. Of all the study participants, 59 (18.4%) developed GUS within 6 months after initiation of SGLT2 inhibitor treatment. The most commonly reported symptom was itching (40.7%), followed by both itching and burning (16.9%), excessive urination (15.3%), redness in the genital area (13.5%), burning (6.8%), dryness in the genital area (3.4%), and foul smelling urination (3.4%) (Fig. 1).

Figure 2 shows the distribution of SGLT2 inhibitors classes among participants with GUS. Among participants with GUS, 72.9% were on dapagliflozin, 6.8% were on empagliflozin and remogliflozin, respectively, 5.1% were on combination of dapagliflozin plus metformin and combination of remogliflozin plus vildagliptin, and 3.4% were on combination of remogliflozin plus metformin plus vildagliptin (Fig. 2).

Table 2 shows the comparison of the demographic, anthropometric, and biochemical parameters in participants with and without GUS. There was no significant difference noted in the median age and duration of diabetes among people without and with GUS. More than half (57.6%) of

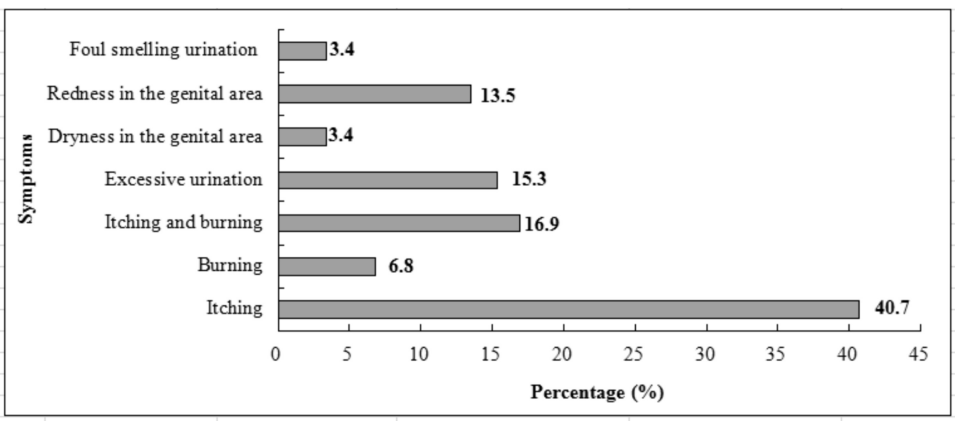

Fig. 1 GUS among participants initiated on SGLT2 inhibitor treatment

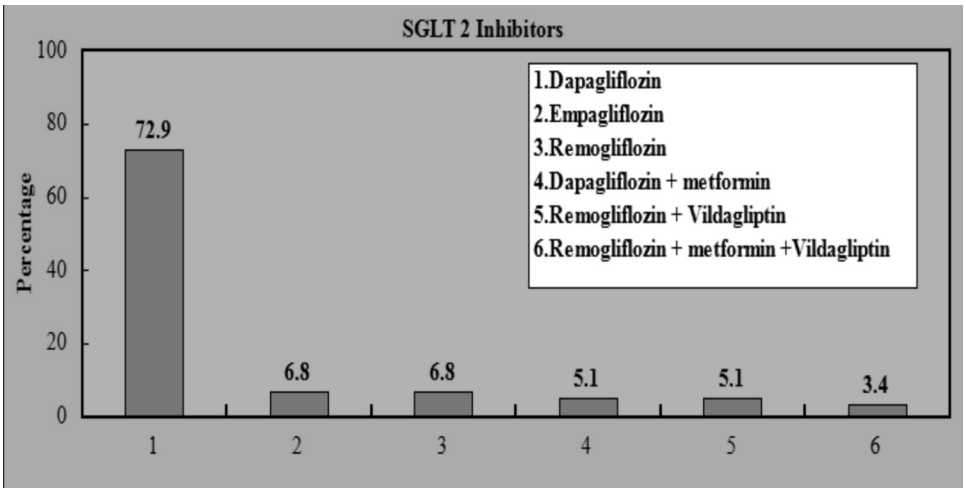

Fig. 2 Distribution of SGLT2 inhibitors drug classes among people with GUS

Table 2 Comparison of demographic, anthropometric, and biochemical parameters in participants with and without GUS

Variables	People without GUS ($n=261$)	People with GUS ($n=59$)	p value
Age (years)	56 (21, 76)	53.3 (32, 77)	0.229
Gender			
Male	182 (69.7)	34 (57.6)	0.073
Female	79 (30.3)	25 (42.4)	
Duration of diabetes (years)	12 (1, 36)	11 (1, 29)	0.922
BMI (kg/m^2)	27.5 (18.8, 45.7)	29.6 (20.3, 43.1)	**0.004**
Plasma glucose (mg/dl)			
Fasting	134 (68, 322)	140 (82, 281)	0.724
Postprandial	213 (75, 463)	248 (106, 414)	**0.025**
HbA1c (%)	7.8 (5.8, 12.2)	8.2 (6, 13.5)	**0.037**

Values are in median (min, max); Values in bold indicates significant difference between the groups

the male participants had GUS compared to female participants (42.4%), but it did not show statistical significance ($p=0.073$). The median BMI was significantly higher in participants with GUS than those without GUS. The participants with GUS had poor glycemic control compared to people without GUS. HbA1c % was significantly higher in participants with GUS as compared to participants without GUS (8.2 vs. 7.8%, $p=0.037$).

Table 3 shows the differences in demographic, anthropometric measurements, and biochemical parameters before and after intake of SGLT2 inhibitors. Weight reduced significantly after intake of SGLT2 inhibitors than before intake of drug (76.3 ± 14 vs. 75.6 ± 13.8, $p=0.001$). Glycemic control significantly improved after intake of drug compared to before intake of SGLT2 inhibitors (HbA1c 9.4 ± 1.7 vs. 8 ± 1.3, $p<0.001$).

Table 3 Differences in anthropometric and glycemic status before and after the intake of SGLT2 inhibitors among the study participants

Variables	Before intake of SGLT2 inhibitors	After intake of SGLT2 inhibitors	p value
Weight (kg)	76.3 ± 14	75.6 ± 13.8	**0.001**
BMI (kg/m^2)	28.8 ± 4.8	28.6 ± 4.8	**<0.001**
Plasma glucose (mg/dl)			
Fasting	185 ± 64	143 ± 47	**<0.001**
Postprandial	278 ± 86	223 ± 73	**<0.001**
HbA1c (%)	9.4 ± 1.7	8 ± 1.3	**<0.001**

Values are in mean ± SD, Values in bold indicate significant difference between the groups

Among people with GUS, almost 3/4th of them (72.9%) were taking dapagliflozin. Around 16.9% of the participants were advised to discontinue the drug. In 18.6%, the drug was changed, and the remaining 47.5% were advised to continue the drug with precautions to drink plenty of water and maintain genital hygiene. Of those who had minimal symptoms, 10.2% were prescribed oral antifungal and antibiotics, and 6.8% were prescribed antifungal creams as the drug has several other health benefits (Fig. 3).

Discussion

Numerous studies indicate that the use of SGLT2 inhibitors may further enhance the possible risk of genitourinary infections, which are fairly prevalent in individuals with diabetes [14, 15]. People on SGLT2 inhibitors frequently experience genitourinary problems within the first 6 months of treatment. According to this study findings, 18.4% of them initiated on SGLT2 inhibitors had GUS. Among them, the most commonly used SGLT2 inhibitor was dapagliflozin in around 72.9%.

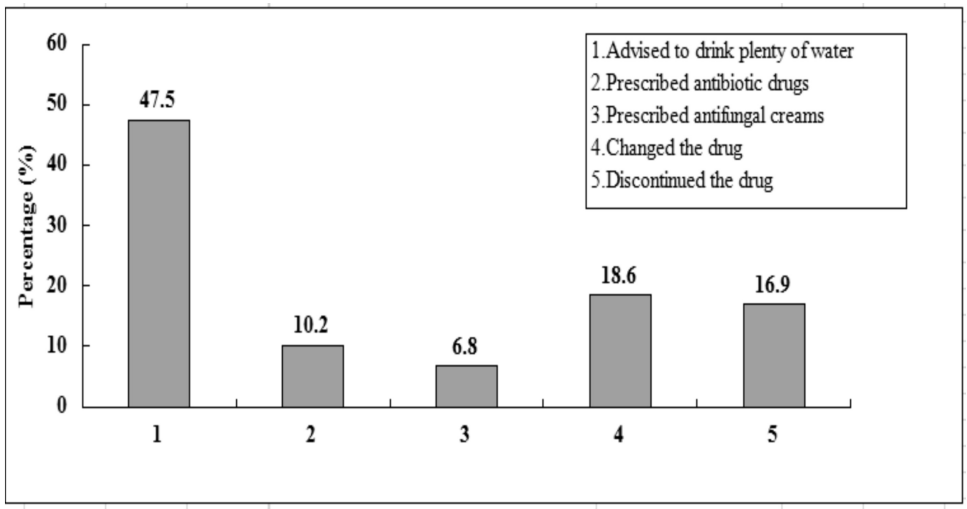

Fig. 3 Details of treatment for those with GUS

Individuals with GUS were obese and had uncontrolled diabetes. These findings pave way for the clinicians to determine which patients are more prone to experience this occurrence by having knowledge of the risk factors for genitourinary infection, and this may help clinicians to explain to patients the potential risk of developing genitourinary infections and advise them such as drinking plenty of water, maintaining proper genital hygiene, and consulting a doctor as soon as any symptoms appear before starting SGLT2 inhibitors.

In this study, majority of them were aged above 50 years and 67.5% of them were males. Majority of the participants had a diabetes duration of more than 5 years with a mean duration of 12.7 ± 7.9 years. Nearly half (43.4%) of them had poor glycemic control (> 8%) with a median HbA1c of 9.6%. Similarly, the study done by Shrikrishna et al. in Mangalore reported that many of them were aged above 50 years, and majority of the participants had diabetes of more than 5 years. They had poor glycemic control with a mean HbA1c of 8.8 ± 1.8% [23].

There was a significant reduction in weight and BMI after the intake of SGLT2 inhibitors in our study. Similarly in the study done by Bhosle et al., reduction in body weight from baseline was significantly related to dapagliflozin, canagliflozin, empagliflozin, and ipragliflozin treatment in people with type 2 diabetes [24].

Of our chosen study participants, 18.4% developed at least one genitourinary symptom within 6 months from the initiation of SGLT2 inhibitors. The finding was consistent with the study by Shrikrishna et al., done in 120 participants, around 16.6% had one or more episodes of genital mycotic infection [23], and in the study done by Andrew et al. in Glasgow, the prevalence of genital infection was found to be only 8.1% [25]. The prevalence rate in India was double to that of the UK population. This is due to India being a country where there is high carbohydrate intake, glucosuria induced by SGLT2 inhibitors is more, which raises the risk of genital infection, and this may worsen in people taking SGLT2 inhibitors. Climate conditions along with personal genital hygiene also play a major role in GUS.

In our study, male participants (57.6%) were more likely to have a GUS than the female participants which was absolutely contrast to the study done by Andrew et al. [25]. One possible explanation in the difference could have been maintaining genital hygiene by female participants, drinking plenty of water, and majority of them were homemakers and hence were using private toilet.

In our study, dapagliflozin was the most commonly used SGLT2 inhibitors with 68.8%, and only 3.1% of them were on empagliflozin. In contrast, empagliflozin was the most commonly used SGLT2 inhibitor with 60% of the patients on it, and 28.3% of the patients were on dapagliflozin [23].

Another main finding of our study was that there was a significant reduction in fasting and postprandial glucose levels and HbA1c after intake of SGLT2 inhibitors. Similar results were observed in the study done by Bhosle et al. in the year 2022 [24].

Our study found that almost 3/4th of the participants who had GUS were on dapagliflozin compared to other SGLT2 inhibitors. These findings are consistent with recent meta-analysis [26]. The reason behind is dapagliflozin causes dehydration as side effect which may lead to GUS.

Majority of the studies were on urinary tract infections and genital infections, and none of the studies assessed the prevalence of GUS among people treated with SGLT2 inhibitors. We found that itching (40.7%) was the most common among all other symptoms. Participants who had GUS were advised to drink plenty of water, prescribed antibiotics and anti-fungal creams, and changed the class of drug to get relief from the symptoms, and only 16.9% of the participants were advised to discontinue the drug and the remaining participants continued the drug as it has several other health

benefits such as weight loss, improving glycemic status, and lower the risk of heart failure and kidney failure.

The limitations of the study were as follows: convenience sampling was used and data collection was mainly based on participants' self-report which may under or over-report the GUS. The participants from the tertiary care facility were only studied limiting the generalizability of the findings. Only GUS were assessed in the current study and could not assess the severity of the symptoms.

Conclusion

In conclusion, the current study highlighted that SGLT2 inhibitors increase the risk of GUS and people with uncontrolled diabetes and who are obese are more prone to it. In addition, the results indicated that dapagliflozin was associated with significant increase in GUS, especially male participants. Health care providers should educate and advice the patients on adverse effects and self-management of mild symptoms before prescribing the drug.

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Author contributions All the authors have contributed to this manuscript.

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Data Availability Data will be made available on request.

Declarations

Ethical approval The ethics committee of Prof MVDRVC approved the study (IEC/N-004/01/2022), and written informed consent was obtained from the participants prior to the anthropometric data collection; no invasive procedures were performed in the study.

Conflict of interests The authors declare no competing interests.

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