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ASSOCIATION OF SGLT2 INHIBITOR USE WITH URINARY TRACT INFECTION IN NON-DIABETIC PATIENTS WITH HEART FAILURE AND EJECTION FRACTION >40%: A RETROSPECTIVE COHORT STUDY

General Medicine

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ABSTRACT

Background: Sodium-glucose cotransporter 2 (SGLT2) inhibitors are increasingly used in the management of heart failure irrespective of diabetic status. However, evidence regarding urinary tract infection (UTI) risk among non-diabetic patients with heart failure and preserved or mildly reduced ejection fraction remains limited. **Objective:** To evaluate the association between SGLT2 inhibitor use and urinary tract infection among non-diabetic patients with heart failure and ejection fraction >40%. **Methods:** This retrospective cohort study included 96 non-diabetic patients with heart failure and ejection fraction>40% identified at a tertiary care centre during an enrolment period from August 2025 through January 2026. The index date was defined as the heart failure admission during which the patient met the study eligibility criteria. Patients in whom an SGLT2 inhibitor was initiated during the index admission constituted the SGLT2 inhibitor group (n=48), while those who were not initiated on an SGLT2 inhibitor constituted the control group (n=48). UTI occurrence was assessed during the three months following the index date. Data were analysed using the chi-square test, Fisher's exact test, and univariate logistic regression. **Results:** UTI occurred in 9 of 48 patients (18.8%) in the SGLT2 inhibitor group compared with 2 of 48 patients (4.2%) in the control group. The difference was statistically significant using the chi-square test (p=0.020), although Fisher's exact test yielded a borderline result (p=0.051). In univariate logistic regression analysis, SGLT2 inhibitor use was associated with higher observed odds of UTI (OR 5.31, 95% CI 1.08-26.04, p=0.020). Female sex was also associated with increased odds of UTI (OR 9.16, 95% CI 1.87-45.26, p=0.006). **Conclusion:** SGLT2 inhibitor use was associated with a higher observed frequency of urinary tract infection among non-diabetic patients with heart failure and ejection fraction >40%. Given the retrospective design, limited sample size, small number of outcome events, and potential for residual confounding, these findings should be interpreted cautiously and considered hypothesis-generating rather than definitive. Larger prospective multicentre studies are needed to clarify this association and better define patient-specific risk factors for urinary tract infection.

KEYWORDS

SGLT2 Inhibitors; Urinary Tract Infection; Heart Failure; Non-Diabetic; Retrospective Cohort Study

INTRODUCTION

Heart failure (HF) is a complex clinical syndrome resulting from structural or functional cardiac abnormalities that impair the heart's ability to maintain adequate circulation or lead to increased intracardiac pressures. It is associated with considerable morbidity and mortality, frequent hospital admissions, limitation of functional capacity, impaired quality of life, and alterations in biomarkers with diagnostic and prognostic relevance [1,2]. Ischemic heart disease is a major underlying cause of HF worldwide; however, hypertension, valvular disorders, cardiomyopathies, myocarditis, and systemic conditions such as obesity and thyroid disease also contribute to its development [1,3].

Approximately 64 million people worldwide are estimated to be living with HF, and its overall burden is expected to increase further. Population aging, the growing prevalence of cardiovascular risk factors, and improved survival following acute cardiovascular events have contributed to this trend [3]. HF consequently accounts for substantial healthcare utilization and remains an important contributor to cardiovascular mortality across diverse populations [3,4]. Strategies that improve clinical outcomes while minimizing treatment-related complications are therefore increasingly important.

Pharmacological management of HF has undergone major advances over recent decades. Established therapies include inhibitors of the renin-angiotensin system, angiotensin receptor-neprilysin inhibitors, beta-blockers, mineralocorticoid receptor antagonists, and diuretics, with treatment tailored according to clinical characteristics and left ventricular ejection fraction [1]. Sodium-glucose cotransporter 2 (SGLT2) inhibitors have more recently become an important component of HF therapy, supported by evidence from major clinical trials [5-8].

Initially developed as glucose-lowering agents for type 2 diabetes, SGLT2 inhibitors act primarily by reducing glucose reabsorption in the proximal renal tubule and increasing urinary glucose excretion. Their clinical role subsequently broadened after cardiovascular outcome studies and HF trials demonstrated benefits extending beyond glycemic control [6-10]. Across different ranges of ejection fraction, SGLT2 inhibitor therapy has reduced the risk of HF hospitalization and improved cardiovascular outcomes, including among patients without diabetes [5-8].

Several mechanisms may contribute to these benefits. SGLT2 inhibition produces osmotic diuresis and natriuresis, which may improve cardiac loading conditions, while additional effects on blood pressure, vascular function, renal physiology, myocardial energetics, neurohormonal pathways, and inflammation have also been proposed [9,10]. The cardiovascular effects of these drugs are therefore unlikely to be explained by glucose lowering alone.

The increase in urinary glucose excretion, however, has raised concern about genitourinary infections during SGLT2 inhibitor therapy. Glucosuria may facilitate a urinary environment conducive to microbial growth. While the association between SGLT2 inhibitors and genital mycotic infections is well recognized, studies evaluating bacterial UTI have produced less consistent findings [11-14].

Evidence regarding this safety outcome is particularly limited in non-diabetic patients with HF. Major randomized trials and subsequent observational studies examining SGLT2 inhibitors have either predominantly involved patients with diabetes or included broader HF populations, making the UTI risk in non-diabetic patients less clearly defined [5-8,12-14]. This question is increasingly relevant in patients with mildly reduced or preserved ejection fraction, as the therapeutic use of SGLT2 inhibitors in individuals with EF >40% has expanded following evidence of benefit in this population [1,5,8].

Accordingly, real-world evaluation of UTI occurrence in non-diabetic patients receiving SGLT2 inhibitors for HF may provide additional safety information. The present retrospective cohort study therefore evaluated the association between SGLT2 inhibitor use and documented UTI among non-diabetic patients with HF and an ejection fraction >40% treated at a tertiary care centre.

MATERIALS AND METHODS

Study Design and Setting

This retrospective cohort study was conducted at a tertiary care medical centre. Eligible patients were identified from hospital records during an enrollment period from August 2025 through January 2026.

Consecutive patients who fulfilled the predefined eligibility criteria during this period were included. The index date was defined as the date of heart failure admission on which the patient met the study eligibility criteria. Each patient was followed through available medical records for three months from the index date to assess the occurrence of urinary tract infection (UTI). As all eligible patients identified during the enrollment period were included, no prospective sample size calculation was performed.

Study Population

The study population comprised adults aged ≥18 years with a documented diagnosis of heart failure and left ventricular ejection fraction (LVEF) >40% who did not have diabetes mellitus. Patients were required to satisfy the predefined inclusion and exclusion criteria and have adequate medical records for assessment of the study variables and outcome.

Grouping of Participants

Participants were classified according to SGLT2 inhibitor exposure at the index admission. Patients in whom an SGLT2 inhibitor was initiated as part of heart failure management during the index admission constituted the SGLT2 inhibitor group, whereas patients who were not initiated on an SGLT2 inhibitor constituted the control group. A total of 96 patients were included, with 48 patients in each group.

Inclusion Criteria

Patients were eligible for inclusion if they were aged ≥18 years, had a documented diagnosis of heart failure with LVEF >40%, did not have diabetes mellitus, and had medical records containing the information required for the study.

Exclusion Criteria

Patients were excluded if they had diabetes mellitus, LVEF ≤40%, a history of recurrent UTI before study entry, structural abnormalities of the genitourinary tract, benign prostatic hyperplasia associated with urinary obstruction, recent genitourinary surgery, severe debilitating illness, or incomplete medical records.

Data Collection

The investigators extracted data from hospital medical records using a structured data collection form to maintain consistency in data retrieval. Information collected included age, sex, socioeconomic status, locality (rural or urban), body mass index (BMI), co-morbid conditions including hypertension, thyroid disorders, and chronic obstructive pulmonary disease (COPD), exposure to SGLT2 inhibitor therapy, and occurrence of UTI. Socioeconomic status was classified according to the Modified BG Prasad scale.

Outcome Definition

The primary outcome was a documented UTI occurring within three months of the index date. The index date was defined as the date of heart failure admission on which the patient met the study eligibility criteria. UTI occurrence during the subsequent three-month follow-up period was assessed in both the SGLT2 inhibitor and control groups.

A UTI event was identified from the medical record when urinary symptoms suggestive of infection were accompanied by a clinical diagnosis of UTI by the treating physician. Urinalysis and urine culture findings were considered supportive evidence when available. Because microbiological testing had not been performed uniformly in routine clinical practice, culture confirmation was not required for outcome classification.

Statistical Analysis

Data were entered using EpiData software and analysed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Categorical variables were summarized as frequencies and percentages, and comparisons between groups were performed using the chi-square test. Given the small number of UTI events, Fisher's exact test was also applied to compare UTI occurrence between the two groups. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated, and univariate logistic regression analysis was performed to explore factors associated with UTI occurrence.

Multivariable logistic regression was not performed because the limited number of outcome events would have made a model incorporating multiple covariates susceptible to instability and overfitting. All statistical tests were two-sided, and a p-value <0.05 was considered statistically significant.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee (Ref. No. IEC/C-P/73/2025). As the study involved retrospective review of existing medical records, the requirement for individual informed consent was waived by the Institutional Ethics Committee. Patient confidentiality and data privacy were maintained throughout the study.

RESULTS

A total of 96 patients with heart failure were included in the study, comprising 48 patients in the SGLT2 inhibitor group and 48 patients in the control group.

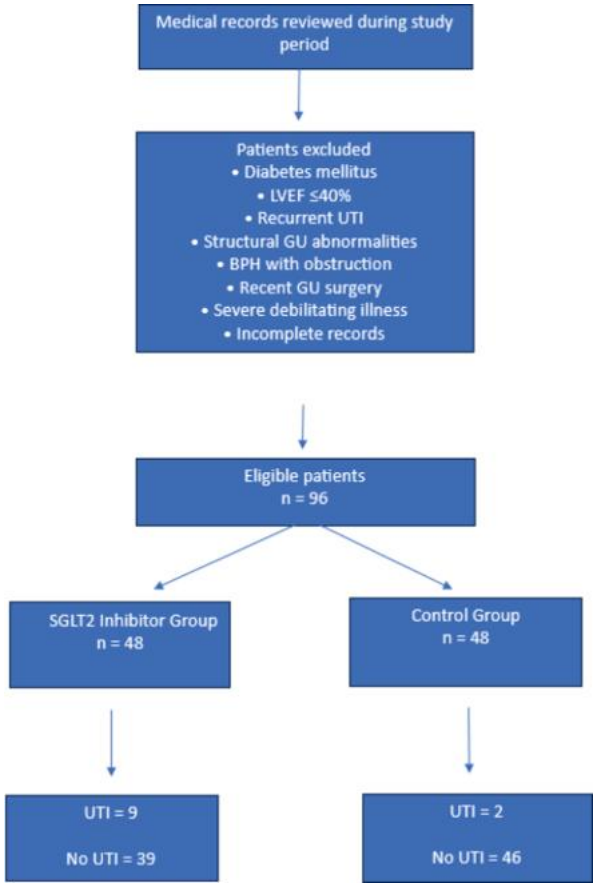

Figure 1. Flow Diagram Showing Patient Selection and Outcome Distribution.

Baseline Characteristics

The baseline demographic and clinical characteristics of the study population are presented in Table 1. In the SGLT2 inhibitor group, 22 of 48 patients (45.8%) were older than 65 years compared with 18 of 48 patients (37.5%) in the control group. Male patients constituted 29 of 48 patients (60.4%) in the SGLT2 inhibitor group and 30 of 48 patients (62.5%) in the control group.

Most patients in both groups belonged to lower socioeconomic strata, and the majority were from rural areas. A body mass index (BMI) >23 kg/m² was observed in 33 of 48 patients (68.7%) in the SGLT2 inhibitor group and 29 of 48 patients (60.4%) in the control group.

There were no statistically significant differences between the two groups with respect to age (p = 0.866), sex (p = 0.834), socioeconomic status (p = 0.773), locality (p = 0.669), or BMI (p = 0.393).

Table 1. Baseline Demographic and Clinical Characteristics of the Study Population

Variable	SGLT2 Inhibitor Group		Control Group		Chi-square value	p-value
	Frequency	Percentage	Frequency	Percentage		
Age						
18-35	3	6.3	4	8.3	0.728	0.866
36-50	9	18.8	10	20.8		

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51-65	14	29.2	16	33.3		
>65	22	45.8	18	37.5		
Sex						
Male	29	60.4	30	62.5	0.044	0.834
Female	19	39.6	18	37.5		
Socio-economic status						
Class I	3	6.3	4	8.3	1.794	0.773
Class II	4	8.3	7	14.6		
Class III	8	16.7	10	20.8		
Class IV	13	27.1	11	22.9		
Class V	20	41.7	16	33.3		
Locality						
Rural	32	66.7	30	62.5	0.182	0.669
Urban	16	33.3	18	37.5		
BMI						
<23	15	31.3	19	39.6	0.728	0.393
>23	33	68.7	29	60.4		

Co-morbidities

The distribution of co-morbid conditions is shown in Table 2. Hypertension was present in 11 of 48 patients (22.9%) in the SGLT2 inhibitor group and 10 of 48 patients (20.8%) in the control group. Thyroid disorder was observed in 8 of 48 patients (16.7%) in the SGLT2 inhibitor group and 7 of 48 patients (14.6%) in the control group. Chronic obstructive pulmonary disease (COPD) was present in 5 of 48 patients (10.4%) and 3 of 48 patients (6.3%) in the respective groups.

Table 2. Distribution of Co-morbidities Among Study Participants

Other co-morbidities	SGLT2 Inhibitor Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
HTN	11	22.9	10	20.8
Thyroid disorder	8	16.7	7	14.6
COPD	5	10.4	3	6.3

Incidence of Urinary Tract Infection

Urinary tract infection (UTI) was documented in 9 of 48 patients (18.8%) receiving SGLT2 inhibitors compared with 2 of 48 patients (4.2%) in the control group. The difference was statistically significant according to the chi-square test ($\chi^2 = 5.031$, $p = 0.020$). However, because of the small number of outcome events, Fisher's exact test was also performed and yielded a borderline result (two-sided $p = 0.051$) (Table 3).

Table 3. Incidence of Urinary Tract Infection in the SGLT2 Inhibitor and control Groups

UTI	SGLT2 Inhibitor Group		Control Group		Chi-square value	p-value
	Frequency	Percentage	Frequency	Percentage		
Present	9	18.8	2	4.2	5.031	0.020
Absent	39	81.2	46	95.8		

Note: Comparison of UTI incidence yielded a chi-square p-value of 0.020. Because of the small number of outcome events, a two-sided Fisher's exact test was additionally performed, yielding p = 0.051.

Predictors of Urinary Tract Infection

Univariate logistic regression analysis was performed to identify factors associated with the occurrence of urinary tract infection (Table 4). SGLT2 inhibitor use was associated with higher observed odds of UTI (OR 5.31, 95% CI 1.08-26.04, p = 0.020). Female sex was also associated with increased odds of UTI (OR 9.16, 95% CI 1.87-45.26, p = 0.006). Age, socioeconomic status, locality, and BMI were not significantly associated with UTI occurrence. These findings should be interpreted cautiously because of the limited number of outcome events and the exploratory nature of the analysis.

Table 4. Univariate Logistic Regression Analysis of Factors Associated with Urinary Tract Infection

Variable	OR	95% CI for OR	p-value
SGLT2 Inhibitor	5.307	1.082–26.039	0.020
Age	1.026	0.9736–1.081	0.383
Sex (female vs male)	9.161	1.865–45.260	0.006
SES	1.317	0.752–2.309	0.335
Locality	0.157	0.0193–1.288	0.116
BMI	3.306	0.673–16.235	0.141

Only 11 UTI events were observed during the study period. Because of the limited number of outcome events, multivariable regression analysis was not performed.

DISCUSSION

In this retrospective cohort of non-diabetic patients with heart failure and an ejection fraction >40%, documented UTI occurred more frequently among patients treated with SGLT2 inhibitors than among those who were not receiving these drugs. Univariate analysis also showed higher observed odds of UTI with SGLT2 inhibitor use. Female sex was another factor associated with greater odds of UTI in the study population.

SGLT2 inhibitors now have an established role in guideline-directed treatment of heart failure, irrespective of diabetic status, with cardiovascular and renal benefits demonstrated across different ranges of left ventricular ejection fraction [5-8]. Nevertheless, their effect on urinary glucose excretion has generated concern regarding genitourinary infections, as increased glucose availability in the urinary tract could potentially favour microbial proliferation.

The relationship between SGLT2 inhibition and genital mycotic infection is well established, whereas findings for bacterial UTI have been less uniform [11-14]. Randomized studies and pooled analyses have generally not identified a substantial increase in UTI, although some observational data have suggested a possible increase in risk [11-14]. Variation in study populations, methods of identifying UTI, duration of observation, and differences between controlled trials and routine clinical practice may contribute to these inconsistent findings.

Major heart failure trials, including DAPA-HF, EMPEROR-Reduced, EMPEROR-Preserved, and DELIVER [5-8], have not demonstrated a clinically important excess of bacterial UTI attributable to SGLT2 inhibitor therapy. Evidence from pooled analyses and other studies has likewise been largely neutral or has suggested only a modest association [11-14]. The higher observed frequency in our cohort therefore contrasts with much of the existing evidence. Several factors could account for this difference, including the retrospective design, characteristics of the study population, ascertainment and definition of UTI in routine records, residual confounding, and the limited sample size.

An important feature of the present study is its focus on non-diabetic patients with heart failure and EF >40%. Evidence specifically addressing UTI in this population remains limited. Excluding patients with diabetes reduced the influence of an established risk factor for UTI and permitted a more focused assessment of the association between SGLT2 inhibitor exposure and documented infection. However, exclusion of diabetes does not eliminate other potential differences between treated and untreated patients, and the observed association should therefore not be interpreted as evidence of causality.

A biological basis for the observed association is possible because SGLT2 inhibition increases urinary glucose excretion [9,10], potentially providing conditions that facilitate bacterial colonization [11]. Susceptibility to infection in patients with heart failure may also be influenced by coexisting illnesses and other clinical factors. However, several potentially relevant factors were unavailable in the present dataset, and their contribution to the observed association cannot be determined.

Female sex was associated with greater odds of UTI in this cohort. This finding is consistent with the higher background susceptibility to UTI among women, which has been attributed to anatomical and physiological factors, including the shorter female urethra and differences in the genitourinary environment [15,16]. Recent evidence has also examined additional factors associated with UTI among patients with heart failure receiving SGLT2 inhibitors [17].

The findings should not be interpreted as a reason to routinely avoid SGLT2 inhibitors in eligible patients with heart failure. Their established cardiovascular and renal benefits need to be considered alongside potential adverse effects. In clinical practice, awareness of urinary symptoms and timely assessment of suspected infection may be appropriate, particularly in patients with additional risk factors. Given the observational design and limited number of events in this study, the association identified here should be regarded as exploratory rather than causal.

Limitations

Several limitations should be considered when interpreting these findings. The retrospective, single-centre design introduces the possibility of selection bias and residual confounding. The sample was relatively small, with only 11 documented UTI events, resulting in limited statistical precision and wide confidence intervals. Information on several potentially relevant variables, including New York Heart Association functional class, renal function, background heart failure therapy, continuation and adherence to SGLT2 inhibitor therapy during follow-up, urinary catheterization, and previous antibiotic use, was unavailable and could not be incorporated into the analysis. In addition, microbiological confirmation was not consistently available because UTI ascertainment relied on documentation in routine clinical records. Finally, although the chi-square analysis produced a statistically significant result, the corresponding two-sided Fisher's exact test yielded a borderline p-value. Taken together, these limitations support interpreting the results as exploratory and hypothesis-generating rather than definitive evidence of an association.

Future Directions

Larger prospective, multicentre studies are needed to clarify whether SGLT2 inhibitor use influences UTI risk in non-diabetic patients with heart failure. Future studies should incorporate standardized definitions and microbiological confirmation of UTI, detailed assessment of heart failure severity and renal function, information on concomitant therapies and duration of SGLT2 inhibitor exposure, and adequate longitudinal follow-up.

CONCLUSION

In this retrospective cohort of non-diabetic patients with heart failure and an ejection fraction >40%, SGLT2 inhibitor therapy was associated with a greater observed frequency of UTI, and female sex was also associated with higher odds of UTI. These observations should be interpreted cautiously because of the retrospective design, small sample size, limited number of UTI events, and inability to account for several potentially relevant confounding factors. The results should therefore be regarded as exploratory and hypothesis-generating rather than evidence of a causal relationship. Given the established cardiovascular benefits of SGLT2 inhibitors in heart failure, the present findings do not support withholding these therapies from otherwise eligible patients but highlight the importance of clinical awareness of urinary symptoms. Larger prospective, multicentre studies with more comprehensive assessment of potential confounders are needed to clarify the association and identify patients who may be at greater risk of UTI.

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