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The influence of SGLT2 inhibitors on the risk of urinary tract infection in patients with type 2 *Diabetes Mellitus*: an integrative literature review

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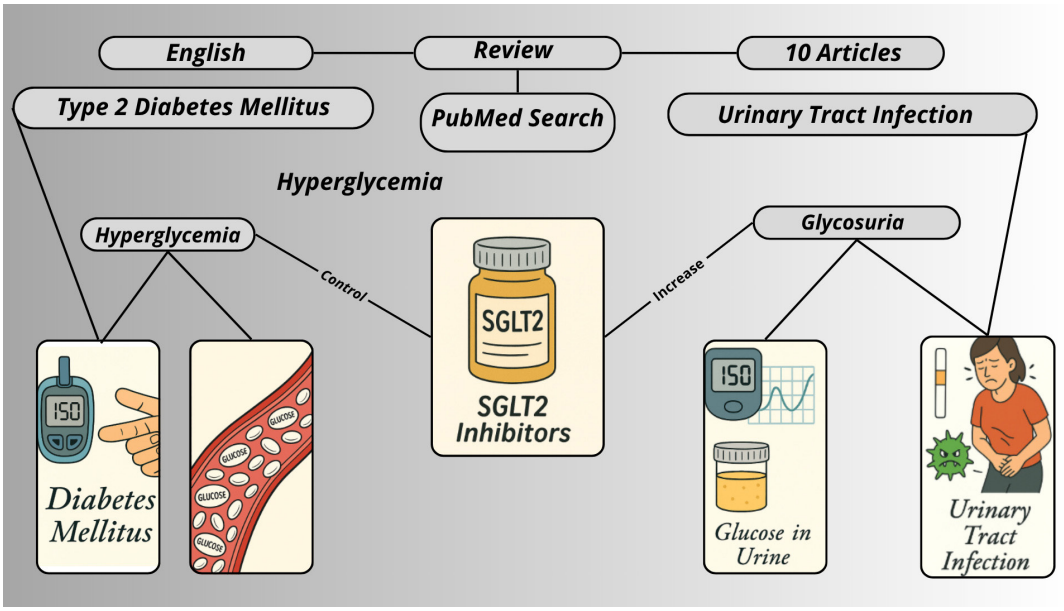
Graphical Abstract



Highlights

- *Dapagliflozin and remogliflozin increase the risk of urinary tract infection (UTI) by enhancing glycosuria.*
- *Female sex and high BMI exert a greater influence on UTI occurrence than the isolated use of SGLT2 inhibitors.*
- *The cardiovascular and metabolic benefits of SGLT2 inhibitors outweigh the associated risk of UTI.*

Abstract

The objective of the present study was to gather information on the influence of Sodium-Glucose Cotransporter 2 inhibitors (SGLT2i) on the risk of developing urinary tract infection (UTI) in patients with type 2 Diabetes *Mellitus* (T2DM). This is an Integrative Literature Review (ILR) that collected data from the following databases: Virtual Health Library (VHL) and the National Library of Medicine (PubMed). Inclusion criteria were: articles published between 2020 and 2024, in English, Portuguese, or Spanish, free of charge and available in full text. Exclusion criteria included: articles outside the scope of the topic, duplicates, paid-access publications, and monographs. A total of 73 articles were identified, of which 10 remained after selection and analysis using Zotero software. The included studies indicated an association between SGLT2i use and an increased risk of UTI and urogenital infections, mainly related to dapagliflozin, remogliflozin, and glycosuria. Factors such as higher body mass index and female sex play a more relevant role in UTI predisposition than the isolated use of these drugs. Despite the divergences, the benefits of SGLT2 inhibitors outweigh the potential risks, and their use remains recommended, provided that adequate professional supervision is ensured.

Keywords: SGLT2 Inhibitors. Urinary Tract Infection. Type 2 *Diabetes Mellitus*.

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INTRODUCTION

Urinary tract infections (UTIs) are considered one of the most frequent infections worldwide, accounting for significant economic costs and representing a threat to global public health[1]. These infections can occur in all individuals — older adults, children, men, and women — since the urethra serves as a passageway for urine and a potential entry point for microorganisms[2].

UTIs are predominantly caused by uropathogenic *Escherichia coli* (UPEC), which is responsible for approximately 80% of cases. However, other pathogens, including *Klebsiella*, *Enterococcus*, *Pseudomonas*, *Staphylococcus,* and even yeasts such as Candida species, may also cause UTIs. Most infections arise when microorganisms enter through the urinary meatus, ascend the urethra, and reach the bladder, where they adhere to uroepithelial cells and establish colonization[3].

Certain population groups are at greater risk of developing UTIs, including infants, pregnant women, older adults, patients with spinal cord injuries and/or urinary catheters, individuals with diabetes or multiple sclerosis, patients with acquired immunodeficiency syndrome/human immunodeficiency virus, and those with underlying urological abnormalities[4].

In this context, patients with Diabetes *Mellitus* (DM) experience a variety of complications, such as macrovascular and microvascular diseases, dementia, depression, and urinary tract infections. Compared with non-diabetic individuals, those with diabetes have a higher likelihood of developing specific infections such as pyelonephritis, asymptomatic bacteriuria, and UTI[5].

Despite well-established diagnostic and therapeutic protocols, UTIs remain a major cause of mortality worldwide, leading to a considerable economic burden on governments and healthcare systems[1]. Moreover, in recent decades, there has been a marked increase in the prevalence of diabetes in nearly all regions of the world. Given that UTIs are among the most frequent infections in patients with type 2 diabetes, there is a pressing need to develop targeted screening and medical care policies for this population[6,7].

In this scenario, sodium-glucose cotransporter 2 inhibitors (SGLT2i) have emerged as a new class of medications that act by inhibiting SGLT2 channels, which mediate nearly 90% of renal glucose reabsorption. When these channels are blocked, the drug reduces glucose reabsorption in the proximal convoluted tubule, thereby promoting greater urinary glucose excretion and lowering blood glucose concentrations[8]. The mechanisms underlying this process include glycosuria, which may increase bacterial adhesion to the uroepithelium[9].

Although the association between SGLT2 inhibitor use and an increased risk of UTIs has been reported in several studies, the exact relationship between these infections and the use of such medications in patients with type 2 Diabetes *Mellitus* (T2DM) remains unclear. Understanding the mechanisms through which SGLT2 inhibitors influence UTI risk is essential for optimizing patient management and minimizing complications. Therefore, investigating the impact of SGLT2 inhibitors on the prevalence and severity of urinary tract infections is crucial for improving treatment and prevention strategies.

METHODS

The present research is characterized as an Integrative Literature Review (ILR), conducted in six methodological stages: (1) formulation of the research question; (2) definition of tools for literature search related to the guiding question; (3) selection of studies from multiple data sources; (4) categorization of studies; (5) analysis and discussion of results; and (6) synthesis of the review[10].

In the first stage, the PICO strategy was applied, consisting of: P – population (patients with type 2 Diabetes *Mellitus*); I – intervention (use of SGLT2 inhibitors); C – comparison (patients not using SGLT2 inhibitors or under other treatment modalities); and O – outcome (increased risk of urinary tract infection). Based on this framework, the following guiding question was formulated: in patients with type 2 Diabetes *Mellitus*, does the use of SGLT2 inhibitors increase the risk of urinary tract infection compared with those not using this drug class?

In the second stage, the Boolean operators "AND" and "OR" were employed in combination with the Health Sciences Descriptors (DeCS): "Sodium-Glucose Transporter 2 Inhibitors," "Urinary Tract Infection," and "Type 2 Diabetes *Mellitus*." Following the definition of these descriptors, searches were conducted for articles in the following databases: Latin

American and Caribbean Health Sciences Literature (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE), and Nursing Database (BDENF), all accessed through the Virtual Health Library (VHL); and the National Library of Medicine (PubMed). The searches were performed in January 2025.

Inclusion criteria were: articles published between 2020 and January 2024, written in English, Portuguese, or Spanish, freely accessible, and available in full text. Exclusion criteria included duplicate articles, paywalled publications, and monographs.

Finally, a methodological assessment of the selected studies was performed, involving a critical appraisal and classification based on methodology, relevance of results, and level of evidence. The level of evidence of the selected studies was classified according to the methodological design, following the hierarchy proposed by Melnyk and Fineout-Overholt (2011)[11], ranging from Level I (systematic reviews or meta-analyses of randomized clinical trials) to Level VII (expert opinions).

RESULTS

From the initial search, 73 articles were identified. Of these, 18 were excluded due to duplication, and 26 were removed because they were not freely accessible. Among the remaining articles, 18 were excluded after reading the title and abstract. Finally, of the 11 articles read in full, one was excluded for not addressing the guiding question, resulting in the inclusion of 10 articles in this review. These stages are illustrated in Figure 1.

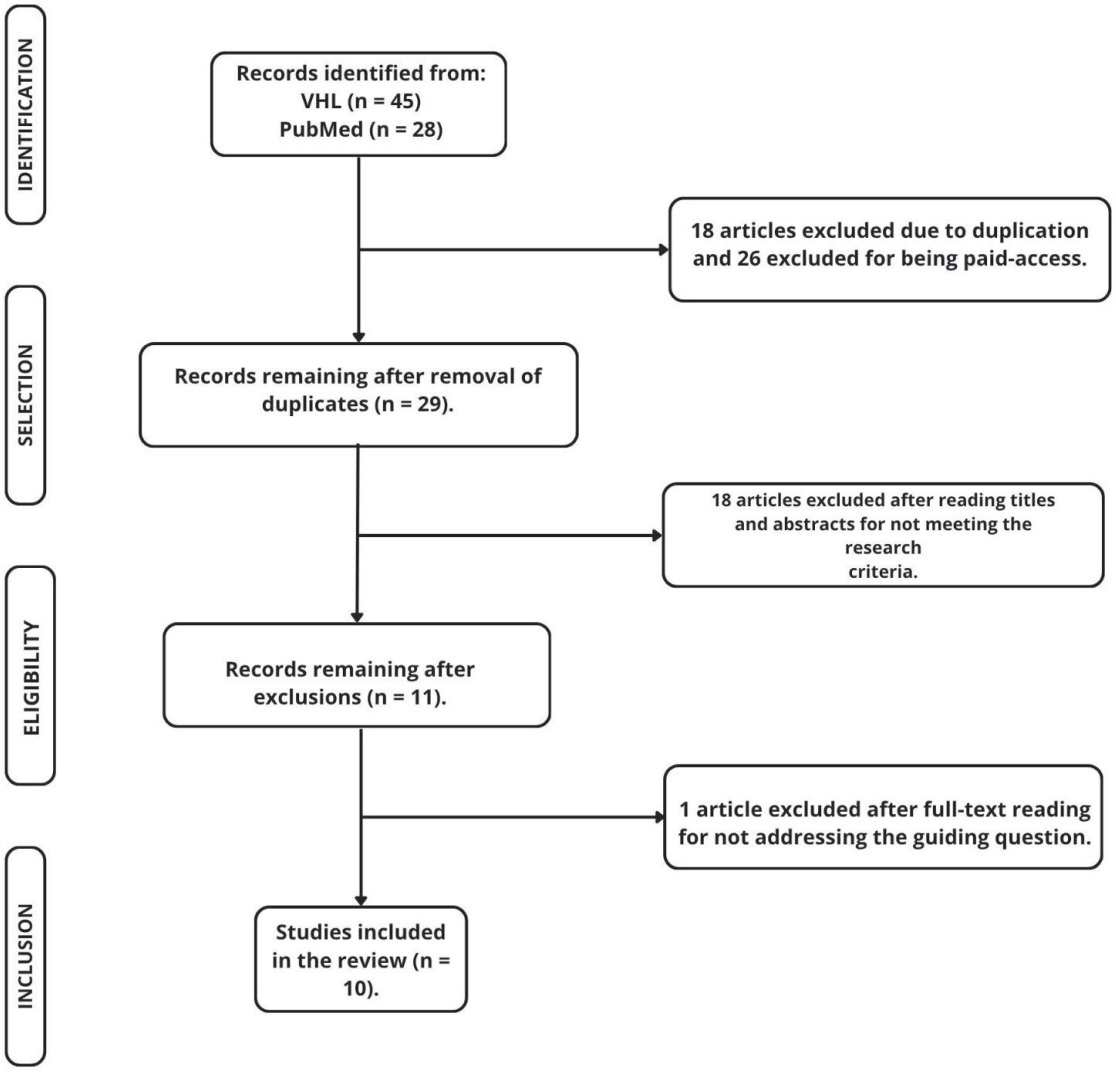

Figure 1 - Flowchart of the articles analyzed and included in the review.

A summary table was prepared containing the following information: author and year of publication, title, objective, methods, and results and conclusion, as shown in Table 1.

Table 1 - Summary of the articles included in the integrative review on the risk of urinary tract infection associated with the use of SGLT2 inhibitors.

N	Author and Year	Title	Objective	Method	Results and Conclusion
1	(LI *et al.*, 2023)[12].	Comparative safety of different sodium-glucose transporter 2 inhibitors in patients with type 2 diabetes: a systematic review and network meta-analysis of randomized controlled trials.	To evaluate the relative safety of nine SGLT2 inhibitors regarding genital tract infections (GTIs), polyuria, hypovolemia, renal failure/insufficiency, acute kidney injury (AKI), UTI, fracture, diabetic ketoacidosis (DKA), amputation, and severe hypoglycemia in patients with T2DM.	Systematic review and network meta-analysis (NMA) based on randomized controlled trials (RCTs).	Dapagliflozin and remogliflozin were significantly associated with an increased risk of UTI, with remogliflozin ranking first. Dapagliflozin ranked first for GTI risk. SGLT2 inhibitors were not associated with increased risks of hypovolemia, renal failure, fracture, DKA, amputation, or severe hypoglycemia compared with placebo.
2	(DANYSH *et al.*, 2023)[13].	Post-Authorization Safety Studies of Acute Liver Injury and Severe Complications of Urinary Tract Infection in Patients with Type 2 Diabetes Exposed to Dapagliflozin in a Real-World Setting.	To investigate the incidence of hospitalization for acute liver injury or UTIs (pyelonephritis and urosepsis) among patients initiating dapagliflozin compared with other glucose-lowering drugs.	Two non-interventional cohort studies using three longitudinal population-based data sources.	The data sources suggested that the incidence of acute liver injury and UTI was slightly lower in dapagliflozin initiators than in those using comparator glucose-lowering agents.
3	(Ferwani *et al.*, 2022)[14].	Prevalence of Bacterial Urinary Tract Infection Among Patients With Type 2 Diabetes *Mellitus* on Sodium-Glucose Cotransporter-2 Inhibitors: A Prospective Real-World Setting Study	The objective was to determine the prevalence and causative agents of bacterial urinary tract infections (UTIs) among patients with type 2 diabetes mellitus (T2DM) using SGLT2 inhibitors.	This was a prospective longitudinal study involving patients with type 2 diabetes mellitus (T2DM) who were prescribed 2g and were not controlled with other oral antidiabetic medications, conducted at a tertiary care center.	Only one patient presented asymptomatic bacteriuria and another showed dysuria with negative urine culture. Thus, the risk of developing significant bacteriuria and/or symptomatic UTI was minimal among T2DM patients on SGLT2i therapy.
4	(Alkabbani, *et al.*, 2022)[15].	Sodium-Glucose Cotransporter-2 Inhibitors and Urinary Tract Infections: A Propensity Score–matched Population-based Cohort Study	To evaluate the UTI risk associated with the initiation of SGLT2 inhibitors in T2DM and quantify the magnitude of risk across clinically relevant comparators.	This is a systematic review and a network meta-analysis (NMA) based on randomized controlled trials (RCTs) aimed at comparing the safety of different SGLT2 inhibitors in patients with type 2 diabetes mellitus (T2DM).	None of the SGLT2 inhibitors (canagliflozin, dapagliflozin, or empagliflozin) were associated with increased UTI risk compared with other antidiabetic drugs such as DPP-4 inhibitors. No significant risk variation was found across different doses.
5	(IORDAN *et al.*, 2024)[16].	Safety of SGLT2 Inhibitors and Urinary Tract Infections in Clinical Practice—A Cross-Sectional Study	o assess the risk of developing urinary tract infections (UTIs) in patients with type 2 diabetes who are treated with SGLT2 inhibitors, and to identify the factors that make these patients more susceptible to this complication.	A cross-sectional, non-interventional assessment of 328 consecutively hospitalized patients with type 2 diabetes at the Diabetes Clinic of the 'Pius Brinzeu' County Emergency Hospital in Timișoara, between January and February 2024.	No statistically significant difference was found between patients taking SGLT2 inhibitors and those using other hypoglycemic medications regarding the risk of developing a urinary tract infection (UTI). On the other hand, a higher BMI, elevated HbA1c levels, and female sex were shown to increase the risk of developing a UTI.

to be continued...

...continuation - Table 1.

N	Author and Year	Title	Objective	Method	Results and Conclusion
6	(MASHRAQI *et al.*, 2021)[17].	Biocomputational Prediction Approach Targeting FimH by Natural SGLT2 Inhibitors: A Possible Way to Overcome the Uropathogenic Effect of SGLT2 Inhibitor Drugs.	Formononetin, (+)-pteryxin, and quinidine are speculated to be promising inhibitors with less severe uropathogenic side effects.	Natural SGLT2 inhibitors were selected to explore their potential against an emerging uropathogenic bacterial therapeutic target, namely FimH, as it plays a critical role in the colonization of uropathogenic bacteria on the surface of the urinary tract.	Formononetin, (+)-pteryxin, and quinidine were identified as potential SGLT2 inhibitory drug candidates, with additional inhibitory potential against FimH, thereby reducing the likelihood of uropathogenic side effects.
7	(UEDA *et al.*, 2024)[18].	Comparison over Time of Adverse Drug Reactions in Diabetes Patients Treated with Sodium-Glucose Cotransporter 2 Inhibitors.	To understand real-world clinical practice regarding adverse drug reactions (ADRs) to SGLT2 inhibitors.	This is a retrospective observational study in which 391 diabetic patients with a history of SGLT2 inhibitor prescriptions were selected. Of these, 21 patients discontinued SGLT2i for various reasons, and 47 patients discontinued early due to the risk of developing serious adverse drug reactions.	The study revealed that the prescription of SGLT2 inhibitors for elderly patients tends to increase among older individuals with lower hemoglobin levels, as the safety and efficacy of these inhibitors are well recognized for chronic heart failure and chronic kidney disease. Additionally, it was observed that treatment discontinuation due to serious adverse drug reactions was more frequent among elderly patients with longer disease duration and lower body mass index.
8	(CHEN *et al.*, 2023)[19].	Comparative safety of different recommended doses of sodium-glucose cotransporter 2 inhibitors in patients with type 2 Diabetes *Mellitus*: a systematic review and network meta-analysis of randomized clinical trials.	The results of the analysis are expected to contribute to clinical decision-making, enabling the development of optimal treatment strategies for patients with type 2 diabetes in the future.	A search was conducted across multiple databases, including double-blind randomized clinical trials comparing SGLT2 inhibitors with placebo or other oral antihyperglycemic agents as monotherapy in adults diagnosed with type 2 diabetes.	It was found that among the drugs and dosages studied, dapagliflozin 10 mg/day showed a significant increase in the risk of developing urinary tract infections compared to other active SGLT2 inhibitors and placebo. Furthermore, retrospective studies reported that discontinuation of dapagliflozin 10 mg/day was primarily due to urinary tract infections.
9	(TANRIVERDI *et al.*, 2023)[20].	Association of SGLT-2 inhibitors with bacterial urinary tract infection in type 2 diabetes	To investigate factors associated with urinary tract infections (UTIs) in patients with type 2 Diabetes *Mellitus* (T2DM), whether treated with SGLT2 inhibitors or not.	This was a retrospective observational study in which medical records of patients with type 2 Diabetes *Mellitus* (T2DM) treated at a university hospital were analyzed	As a result of the comparative study between the two groups of patients with UTIs, it was found that clinical symptoms and laboratory signs of UTI were more frequent in patients treated with SGLT2 inhibitors compared to those who received placebo. In addition to the association of HbA1c and BMI with UTI, SGLT2i use and glycosuria were identified as predictors of UTI.
10	(LIN; LEE CHEN, 2021)[21].	Clinical Adverse Events Associated with Sodium-Glucose Cotransporter 2 Inhibitors: A Meta-Analysis Involving 10 Randomized Clinical Trials and 71 553 Individuals.	To investigate the occurrence of adverse events associated with SGLT2 inhibitors and evaluate risk levels across underlying conditions.	Quantitative meta-analysis of RCTs including four general safety outcomes and 12 specific safety outcomes, with subgroup analyses.	The analysis revealed increased risk of genital infections, UTIs, and volume depletion but no increased risk for severe adverse events, acute kidney injury, or hyperkalemia. Overall, SGLT2 inhibitors were deemed safe for clinical use.

All the included articles were published after 2020 and written in English. The studies incorporated in this integrative review presented varying levels of evidence, predominantly ranging from levels I to IV, according to the hierarchy proposed by Melnyk and Fineout-Overholt (2011)[11]. Meta-analyses and systematic reviews based on randomized clinical trials (Li *et al.*, 2023; Chen*et al.*, 2023; Lin *et al.*, 2021)[12,19,21] correspond to level I, representing the highest quality of evidence. Individual randomized clinical trials are classified as level II, providing strong experimental support. Cohort and observational studies (Danysh *et al.*, 2023; Ferwani *et al.*, 2022; Alkabbani *et al.*, 2022; Iordan et al., 2024; Tanriverdi *et al.*, 2023; Ueda *et al.*, 2024)[13,14,15,16,20,18]correspond to levels III and IV, offering moderate evidence of association. Finally, the in silico predictive study (Mashraqi *et al.*, 2021)[17], though relevant for mechanistic elucidation, is considered to have a low level of evidence (level VI) as it does not involve clinical data. Overall, the sample reveals a predominance of quantitative studies with solid methodological consistency, lending reliability to conclusions regarding the safety and adverse events associated with SGLT2 inhibitors.

DISCUSSION

The literature has extensively discussed the risks of urinary tract infection (UTI) associated with the use of sodium-glucose cotransporter 2 inhibitors (SGLT2i), highlighting discrepancies among clinical trials. While some studies report a higher risk of UTIs with SGLT2i use, several retrospective cohorts have demonstrated a lower-than-expected incidence of UTIs under the influence of these agents, even when compared with other hypoglycemic drugs or control/placebo groups[22].

In this regard, a systematic review and network meta-analysis conducted in 2023 found a positive association between the use of SGLT2 inhibitors and an increased risk of UTIs in patients with type 2 Diabetes *Mellitus* (T2DM) compared with placebo. Moreover, remogliflozin was identified as the SGLT2 inhibitor most strongly associated with UTI risk relative to other drugs in the same class[12]. Conversely, another study showed that dapagliflozin at a dose of 10 mg/day was significantly associated with a higher UTI risk compared with other SGLT2i and placebo, indicating inconsistency regarding which specific drug presents the greatest risk, especially given the lack of dosage standardization[19].

Additional retrospective and observational studies conducted in 2023, which investigated factors related to UTIs among T2DM patients, identified SGLT2 inhibitors and glycosuria as UTI predictors, likely due to increased potential for bacterial colonization[20]. However, despite the glycosuric effect of SGLT2i — which creates an environment favorable to bacterial growth — the improvement in urinary flow and glucose elimination appears to compensate for potential infection risks[23].

The potential benefits of SGLT2 inhibitor use, even when associated with a higher risk of UTI, were also demonstrated in a meta-analysis encompassing ten randomized clinical trials and 71,553 individuals. That study showed a significant increase in the risk of genital infections, approximately 3.5 times higher than in the placebo group. However, it also reported several clinical advantages, including enhanced diuresis contributing to better blood pressure control and cardiovascular function, as well as a reduction in the risk of acute kidney injury (AKI) and hyperkalemia[21].

Given the potential adverse effects and risks associated with SGLT2 inhibitors, research has explored the use of natural SGLT2 inhibitors that may have less severe uropathogenic effects than certain synthetic drugs, such as canagliflozin. In this context, several naturally derived inhibitors — formononetin, (+)-pteryxin, and quinidine — have shown strong interactions with the FimH protein, which mediates bacterial adhesion to the mannosylated proteins of urinary tract epithelial cells. These compounds demonstrated potential antidiabetic effects while presenting a lower risk of severe uropathogenic outcomes[17].

Conversely, in a prospective longitudinal study analyzing patients with type 2 Diabetes *Mellitus* (T2DM) who initiated SGLT2 inhibitor therapy and were previously uncontrolled with other oral antidiabetic medications, the risk of developing bacteriuria and/or other symptomatic UTIs was minimal. Among the 75 patients evaluated, only one individual using dapagliflozin 10 mg/day developed a symptomatic UTI. It is noteworthy that participants received prior guidance on proper genital and perineal hygiene, which may have contributed to these results, there-

by supporting the lack of a direct correlation between UTI incidence and SGLT2 inhibitor use[14].

In another study that analyzed two non-interventional cohort investigations combining secondary data from three major databases — the Clinical Practice Research Datalink (CPRD) in the United Kingdom, and the HealthCore Integrated Research Database (HIRD) and Medicare in the United States — the incidence of UTIs and acute liver injury among patients treated with dapagliflozin compared with other glucose-lowering drugs (GLDs) was minimal or statistically insignificant, indicating no harmful effect of the drug on T2DM patients[13].

Similarly, a 2022 study demonstrated that none of the SGLT2 inhibitor classes (canagliflozin, dapagliflozin, and empagliflozin) presented an increased risk of UTI when compared with other hypoglycemic agents, such as DPP-4 inhibitors, even across different dosages[15]. These findings are supported by other results showing no statistically significant difference in UTI risk between individuals treated with SGLT2 inhibitors and those on other hypoglycemic medications. However, a higher risk of UTI was associated with elevated body mass index (BMI), higher HbA1c levels, and female sex[16].

A retrospective observational study further assessed severe adverse drug reactions (ADRs) leading to treatment discontinuation or hospitalization among diabetic patients using SGLT2 inhibitors. Two groups were compared: the first monitored from 2017 to 2020 and the second from 2020 to 2023. The study found that ADRs, including urinary and genital infections, were less frequent in the 2020 cohort compared to the earlier group, likely due to increased awareness and improved clinical guidance from academic societies and regulatory bodies. Nevertheless, treatment discontinuation remained more common among older patients, highlighting the need for closer monitoring in this population[18].

CONCLUSION

The findings of this review suggest that, although some studies indicate a possible association between SGLT2 inhibitor use and increased UTI risk—particularly with dapagliflozin and remogliflozin—other investigations do not support this relationship, showing that the risk is not higher than that observed with other glucose-lowering agents. Moreover, factors such as high body mass index and female sex appear to play a more significant role in UTI predisposition than the isolated use of these drugs.

In summary, despite the divergences in results, the cardiovascular and metabolic benefits of SGLT2 inhibitors outweigh their potential risks, and their use remains recommended when accompanied by appropriate professional supervision. Nevertheless, further studies are needed to clarify the relationship between SGLT2 inhibitors and UTIs to ensure a safer and more targeted therapeutic approach for patients with type 2 *Diabetes Mellitus*.

CRediT author statement

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All authors have read and agreed to the published version of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the workreported in this paper.

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