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Effect of Sodium-Glucose Cotransporter 2 Inhibitors on International Prostate Symptom Score Following Anatomical Endoscopic Enucleation of the Prostate: A Retrospective Study

ABSTRACT

Objective: Recently, laser-based anatomical endoscopic enucleation of the prostate (AEEP) has emerged as one of the standard surgical treatments of benign prostate obstruction (BPO). This study investigated the effects of sodium-glucose cotransporter 2 inhibitors (SGLT2i) therapy on lower urinary tract symptoms (LUTS) following AEEP in patients with type 2 diabetes mellitus (T2DM).

Methods: The study included 64 patients with T2DM who underwent AEEP with appropriate preoperative preparation. Patients' clinical, laboratory, uroflowmetry, and ultrasonography findings, along with their International Prostate Symptom Scores (IPSS), were recorded retrospectively both preoperatively and at the first postoperative month.

Results: The mean age of the patients was 66.9 ± 6.4 years, the mean HbA1c level was 6.7 ± 0.9% and 18 (28.1%) patients were receiving SGLT2i. While there were no significant differences between the SGLT2i and non-SGLT2i groups in terms of preoperative pollakiuria, nocturia, urgency, IPSS, prostate-specific antigen (PSA) level, prostate volume, and maximum urine flow rate (Qmax) ($P > .05$), the post-voiding residual urine volume (PVR) was significantly higher in the SGLT2i group ($P = .025$). Both groups experienced a significant reduction in IPSS postoperatively compared to the preoperative period ($P < .001$), with a greater reduction in IPSS observed in the SGLT2i group ($P = .031$). Postoperative improvements in Qmax and PVR reduction were similar between the groups ($P > .05$). Multiple linear regression analysis identified SGLT2i therapy, age, and preoperative IPSS level as factors associated with the reduction in IPSS ($P < .05$).

Conclusion: Despite similar symptoms and clinical findings, patients with BPO using SGLT2i might have a higher preoperative PVR. However, IPSS reduction following AEEP might be greater in patients receiving SGLT2i therapy.

Keywords: Benign prostate obstruction, lower urinary tract symptoms, post-void residual volume, type 2 diabetes mellitus

Introduction

In recent years, sodium-glucose cotransporter 2 inhibitors (SGLT2i) have become an increasingly popular class of oral antidiabetic agents (OADs) for the treatment of type 2 diabetes mellitus (T2DM).[1] Their utilization has increased as a result of their renoprotective and cardioprotective benefits.[2] Lower urinary tract symptoms (LUTS), such as urgency, nocturia, and incomplete bladder emptying, can be observed in individuals with T2DM and represent a significant health burden for patients.[3,4] The etiology of LUTS includes predisposing factors such as benign prostatic obstruction (BPO) and autonomic neuropathy.[4] While the association between SGLT2i and genital and urinary infections has been previously established, their effects on LUTS have been less extensively studied.[5,6] In a study conducted on male patients with T2DM, SGLT2i was found to be associated with pollakiuria and nocturia; however, other LUTS were already present before treatment initiation and did not worsen following SGLT2i therapy.[7]

Prostatic enlargement, which is characterized by varying degrees of LUTS, contributes to the development of BPO.[8] Symptoms tend to worsen with aging, leading to a decline in quality of life (QoL).[9,10] The International Prostate Symptom Score (IPSS) is a widely used questionnaire designed for the initial evaluation of male LUTS. It assesses bother and QoL and is also utilized for pre-treatment evaluation and post-treatment reassessment.[11] While medical therapy is

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an effective treatment option for BPO, surgical intervention remains essential in appropriately selected patients. Among surgical options, anatomical endoscopic enucleation of the prostate (AEEP), particularly when performed using laser technology, has emerged as a safe and effective approach for the management of BPO and is therefore becoming increasingly widespread. Anatomical endoscopic enucleation of the prostate is also referred to by specific names depending on the type of laser energy used, such as holmium laser enucleation of the prostate, thulium laser enucleation of the prostate, or thulium fiber laser enucleation of the prostate.[12-14]

The use of SGLT2i in male patients undergoing surgical treatment for BPO may influence postoperative outcomes through osmotic diuresis, resulting in increased urinary volume. This study aimed to investigate the IPSS before and after AEEP in male patients with both LUTS and diabetes, as well as to explore the potential effects of SGLT2i on this score.

Materials and Methods

Study Design and Patients

This study was conducted retrospectively at the Urology Department of Acıbadem Hospital between July 2021 and July 2024. Enucleation was performed in all patients using AEEP with the Omega Sign Technique.[15] A Thulium fiber laser (Fiber Dust®; Quanta System) with a wavelength of 1940 nm and a maximum power output of 60 W was utilized, employing a 550 µm optical fiber (Optical Fiber; Quanta System). The inclusion criteria were: (i) male patients aged ≥18 years; (ii) a diagnosis of T2DM for at least 1 year; and (iii) treatment with insulin and/or OADs. The exclusion criteria comprised the following: (i) individuals without T2DM; (ii) those who underwent urological treatments other than laser enucleation of the prostate; (iii) patients with urinary tract infections and/or hematuria; (iv) patients with malignancy; (v) patients with a history of previous prostate surgery. The study adhered to the principles of the Declaration of Helsinki and received approval from Acıbadem University Ethical Board (decision number: 2024-10/430, date: July 18, 2024). Informed consent for the academic use of their data was obtained from all patients at the time of their admission to the urology department.

MAIN POINTS

- In patients with benign prostatic obstruction and type 2 diabetes mellitus, post-voiding residual urine volume might be significantly higher in those receiving sodium-glucose cotransporter 2 inhibitors (SGLT2i) compared to those not receiving it.
- Preoperative parameters, including pollakiuria, nocturia, urgency, International Prostate Symptom Score (IPSS), prostate-specific antigen level, prostate volume, and maximum urine flow rate, showed no significant differences between the SGLT2i and non-SGLT2i groups.
- Both groups experienced a significant reduction in IPSS postoperatively compared to the preoperative period.
- The IPSS score showed a greater reduction following anatomical endoscopic enucleation of the prostate in patients treated with SGLT2i compared to those not receiving it.
- Postoperative improvements in maximum urine flow rate and post-voiding residual urine volume reduction were similar between the groups.

Data Collection

Type 2 diabetes mellitus was diagnosed according to the criteria of the American Diabetes Association.[16] Demographic features, medical history, diabetes-related information, laboratory results, and surgical outcomes of the patients were documented retrospectively from hospital records. Preoperative assessments included maximum urine flow rate (Qmax, mL/s), voided urine volume (V, mL), post-voiding residual urine volume (PVR, mL), prostate volume (mL) measured via transabdominal ultrasound imaging, serum prostate-specific antigen (fPSA/tPSA) levels, fasting blood glucose, and glycated hemoglobin (HbA1c) levels. Additionally, the IPSS was recorded. The IPSS is a validated questionnaire widely used to assess the severity of LUTS. It includes 7 questions addressing both voiding symptoms (such as weak stream, intermittency, straining) and storage symptoms (such as frequency, urgency, nocturia). The total score ranges from 0 to 35, with scores of 0-7 indicating mild, 8-19 moderate, and 20-35 severe symptoms.[17] Postoperative evaluations were conducted at the first-month follow-up visit, including measurements of Qmax, V, PVR, and IPSS.

Statistical Analysis

Statistical analyses were conducted using IBM SPSS version 22.0 (IBM SPSS Corp.; Armonk, NY, USA). The Shapiro–Wilk test was applied to assess whether continuous data followed a normal distribution. Normally distributed continuous variables were expressed as the mean ± SD, while non-normally distributed variables were presented as the median and interquartile range (25th-75th percentile, IQR). Depending on the distribution of the data, appropriate statistical tests were selected. For comparisons between 2 independent groups, the 2-tailed Mann–Whitney *U* test was used when the data were non-normally distributed, and the independent samples t-test was applied when the data followed a normal distribution. Effect sizes were calculated for statistically significant between-group comparisons. For non-parametric tests, rank-biserial correlation (r) was used; for parametric tests, Cohen's d was applied. For paired comparisons within the same group, the Wilcoxon signed-rank test was used. Independent variables associated with the reduction rate of IPSS were identified through multiple linear regression analysis. Spearman correlation analysis and ANCOVA were used to evaluate associations between variables and to adjust for potential covariates, respectively. A *P*-value of <.05 was considered statistically significant for all analyses. Post hoc power analysis was performed for selected variables that showed statistically significant between-group differences, to evaluate the adequacy of the sample size.

Results

A total of 64 patients were included in the study. The mean age of the study population was 66.9 ± 6.4 years, with an average HbA1c level of 6.7 ± 0.9%. The median serum creatinine (sCr) level was 0.9 (0.8-1.0) mg/dL. A total of 18 individuals (28.1%) were receiving SGLT2i, while 57 (89.1%) were on metformin, 28 (43.8%) were treated with DPP-4 inhibitors, 8 (12.5%) were using sulfonylureas, and 3 (4.7%) were receiving pioglitazone. Additionally, insulin therapy was administered to 7 participants (10.9%), and statin treatment was reported in 19 cases (29.7%).

The characteristics of the SGLT2i and non-SGLT2i groups are summarized in Table 1. The mean age was similar between the groups (*P* = .246). HbA1c and serum creatinine (sCr) levels were significantly higher in the SGLT2i group compared to the non-SGLT2i group

Table 1. Characteristics of the Patients with and Without Sodium-Glucose Cotransporter 2 Inhibitors

	SGLT2i Group (n = 18)	Non-SGLT2i Group (n = 46)	*P*
Age, years	65.4 ± 6.2	67.5 ± 6.4	.246
HbA1c, %	7.0 (6.3-7.8)	6.4 (6.0-7.0)	**.017**
Cr, mg/dL	1.0 (0.9-1.3)	0.9 (0.8-1.0)	**.032**
Pollakiuria	5.5 (4.0-6.2)	5.0 (4.0-7.0)	.721
Nocturia	2.5 (2.0-5.0)	3.0 (2.0-4.0)	.873
Urgency	9 (50)	26 (56.5)	.640
Preoperative IPSS	31.0 (28.7-33.2)	31.0 (27.0-33.0)	.553
Preoperative PSA, ng/mL	3.5 (1.2-7.1)	3.9 (2.2-7.0)	.487
Prostate volume, mL	72.0 (33.7-107.7)	73.5 (50.2-120.2)	.395
Preoperative PVR urine, mL	173.5 (91.2-273.7)	93.0 (53.0-151.2)	**.025**
Preoperative Qmax, mL/s	8.2 ± 3.3	8.9 ± 3.4	.386
Preoperative V, mL	172.0 (106.7-237.0)	174.5 (130.7-233.2)	.596
Postoperative IPSS	12.0 (10.0-15.0)	14.5 (11.7-16.2)	**.029**
Postoperative PVR urine, mL	23.0 (8.1-56.2)	27.5 (10.0-40.0)	1.000
Postoperative Qmax, mL/s	23.5 (18.7-31.1)	24.0 (20.0-30.2)	.617
Postoperative urine volume, mL	258.5 (170.2-350.0)	255.0 (193.5-296.5)	.982
IPSS reduction percentage	59.7 (53.5-64.1)	52.3 (44.0-61.3)	**.031**
PVR reduction percentage	85.5 (72.9-92.6)	75.6 (53.1-89.0)	.096
Qmax increase percentage	65.2 (60.4-78.0)	66.4 (54.2-78.1)	.900
Urine volume increase percentage	32.3 (24.0-47.5)	27.8 (2.3-44.8)	.375

The Shapiro–Wilk test was used to assess normality. Normally distributed data are presented as mean ± SD; non-normally distributed data are shown as median and interquartile range (IQR). The independent samples t-test was used for normally distributed variables, and the Mann–Whitney *U* test was used for non-normally distributed variables. Effect sizes are reported as rank-biserial correlation (r) for statistically significant comparisons. Statistically significant P values are given in bold.
Cr, creatinine; HbA1c, glycated hemoglobin; IPSS, International Prostate Symptom Score; PSA, prostate-specific antigen; PVR, post-voiding residual urine volume; Qmax, maximum urine flow rate; V, voided urine volume.

(*P* = .017 and *P* = .032, respectively). Although preoperative IPSS, serum PSA level, prostate volume, Qmax, and V were similar between the groups (*P* > .05), PVR was found to be significantly higher in the SGLT2i group (*P* = .025). In both groups, IPSS was significantly reduced in the postoperative period compared to the preoperative period (*P* < .001) (Figure 1). However, the reduction percentage in IPSS was found to be greater in the SGLT2i group compared to the non-SGLT2i group (*P* = .031). At the first postoperative month, IPSS scores showed that 40 patients (87.0%) in the non-SGLT2i group had moderate symptoms, while 6 patients (13.0%) had severe symptoms. In contrast, all 18 patients (100%) in the SGLT2i group were classified as having moderate symptoms. The increase in Qmax and V, as well as the decrease in PVR at the postoperative first-month follow-up, were similar between the 2 groups (*P* > .05).

Figure 1. International Prostate Symptom Score change in sodium-glucose cotransporter 2 inhibitors and non-sodium-glucose cotransporter 2 inhibitors groups. IPSS, International Prostate Symptom Score; SGLT, sodium-glucose cotransporter.

In the multiple linear regression analysis examining the factors affecting the reduction rate of IPSS in the overall patient group, SGLT2i therapy, age, and preoperative IPSS level were identified as associated factors (Table 2). ANCOVA analysis showed that after adjusting for baseline PSA, prostate volume, age, and HbA1c levels, SGLT2i usage remained a significant predictor of IPSS score reduction ($F(1,58) = 4.680$, $P = .035$). None of the covariates were significantly associated with IPSS reduction. Furthermore, a negative correlation

Table 2. Linear Regression Analysis Examining Factors Associated with International Prostate Symptom Score Reduction Percentage

	β Coefficient	95% CI	*P*
Preoperative PSA, ng/mL	.050	−0.006 to 0.008	.682
Prostate volume, mL	.094	0.000-0.001	.446
SGLT2 inhibitor, yes/no	.292	0.011-0.144	**.022**
Age, years	−.260	−0.010 to 0.000	**.040**
HbA1c, %	−.137	−0.052 to 0.015	.274
IPSS, preoperative	.283	0.001-0.017	**.026**

Dependent Variable: Squared IPSS reduction percentage. Statistically significant values are given in bold.
IPSS, International Prostate Symptom Score, PSA, prostate-specific antigen, SGLT, sodium-glucose cotransporter.

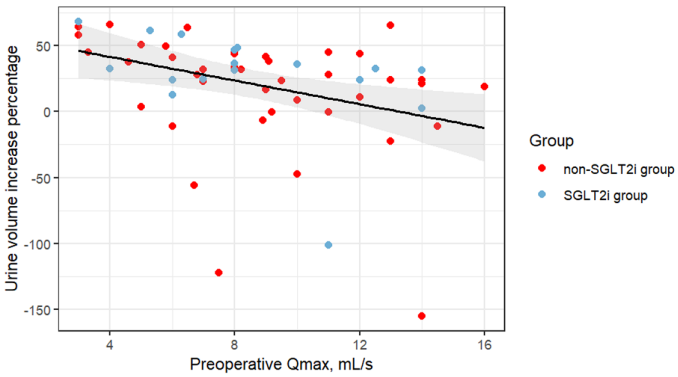

Figure 2. Correlation analysis between preoperative Qmax and the percentage increase in urine volume. Qmax: Maximum urine flow rate; SGLT, sodium-glucose cotransporter.

was observed between preoperative Qmax and the urine volume increase percentage ($r = -0.493$, $P < .001$) (Figure 2).

A post hoc power analysis for the difference in preoperative PVR urine (173.5 [91.2-273.7] mL vs. 93.0 [53.0-151.2] mL, $P = .025$) indicated a large effect size (Cohen's $d = 0.86$), with an estimated power of approximately 85.8%.

Discussion

The relationship between SGLT2i therapy and genital and/or urinary tract infections in patients with T2DM is well-known; however, its impact on LUTS is still under investigation, with some reports suggesting that it may exacerbate LUTS.[7,18,19] As an example, Shikuma et al[19] demonstrated that the administration of SGLT2 inhibitors to patients with T2DM without a pre-existing diagnosis of overactive bladder led to an increase in daytime urinary frequency, whereas no change was observed in nocturnal frequency. A recent large-scale retrospective study found that SGLT-2i use in males with HbA1c ≥7% was associated with higher rates of early urologic referral, balanitis/balanoposthitis, overactive bladder, urinary frequency, urgency, and LUTS medication use. In contrast, among males with HbA1c <7%, only balanitis/balanoposthitis was observed more frequently.[20] Therefore, LUTS have been associated with HbA1c levels. The similar symptom profiles observed between SGLT2i users and non-users in the study may be attributed to the lower HbA1c levels in the study population.

In patients with BPO, an emerging surgical approach known as AEEP has become increasingly popular in recent years.[12,21] There are limited publications in the literature suggesting that the presence of diabetes may adversely affect AEEP outcomes in patients with T2DM.[22] Edmonds et al[23] reported that patients with metabolic syndrome had a higher likelihood of developing complications such as urinary incontinence, irritative voiding symptoms, and bleeding within both 30 and 90 days. However, to the best of the authors' knowledge, this study is the first to investigate the impact of SGLT2i therapy in patients undergoing AEEP. Although preoperative symptoms and clinical findings were similar between patients receiving and not receiving SGLT2i therapy in this study, PVR was found to be higher in those on SGLT2i treatment. HbA1c levels were significantly higher in the SGLT2i group (7.0%, corresponding to an estimated average glucose of 154 mg/dL) compared to the non-SGLT2i group (6.6%, corresponding to 143 mg/dL).[24] Under physiological conditions, the renal threshold for glycosuria is approximately 180 mg/dL,[25] however, this threshold is lower in patients receiving SGLT2i, with glycosuria occurring at glucose levels as low as 90 mg/dL.[26] This mechanism may partly explain the higher PVR volumes observed in SGLT2i users.

One of the interesting findings of this study was the greater improvement in IPSS scores observed in the group receiving SGLT2i therapy after AEEP. Additionally, the analyses examining factors that may influence the reduction in IPSS scores identified SGLT2i therapy and higher preoperative IPSS as significant factors. Notably, the higher the preoperative IPSS score, the greater the improvement in symptoms. However, baseline IPSS scores were similar between the SGLT2i and non-SGLT2i groups in this study. A limited number of studies in the literature indicate possible anti-inflammatory effects of SGLT2i,[27] which may contribute to symptom improvement in benign prostatic hyperplasia (BPH). In an experimental model of BPH, Elbaz et al[28] demonstrated that canagliflozin mitigates prostate enlargement, reduces inflammation, restores hormonal balance, inhibits cellular proliferation, and induces cell cycle arrest in prostatic tissue. These findings suggest that, beyond their systemic metabolic effects, SGLT2 inhibitors may exert direct local effects on prostatic tissue. In this study, although preoperative IPSS scores, including components such as pollakiuria, nocturia, and the sensation of incomplete emptying, were similar between the SGLT2i and non-SGLT2i groups, PVR volumes were significantly higher in the SGLT2i group. This finding might be related to the potential anti-inflammatory effects of SGLT2i, which might reduce the perception of residual urine. Furthermore, the higher PVR in SGLT2i users might reflect functional rather than structural changes, which might not necessarily correlate with the subjective sensation of incomplete emptying reported in the IPSS. This could have contributed to a comparable overall IPSS score at baseline. However, further studies are warranted to better elucidate the underlying mechanisms of these observations.

The strongest aspect of this study is that it was conducted on a homogeneous patient population who underwent surgery using this relatively new laser-based technique for BPO. The fact that the same surgical team performed the procedure following their defined technique in all patients minimized the impact of surgical variations on postoperative outcomes. Nevertheless, the present study has some limitations. Firstly, due to its retrospective design, no causal relationship could be established. The number of patients was also limited because AEEP was a new technique applied in a limited number of centers. Additionally, postoperative first-month follow-up data were used in this study, and noteworthy results were obtained. However, the presence of glycosuria and increased urinary volume in SGLT2i users might lead to differences in symptom improvement over time. Therefore, it may be necessary to evaluate longer-term outcomes, and more detailed prospective studies could contribute to a better understanding of the underlying pathophysiology.

To the best of the authors' knowledge, this study is the first to investigate the effect of SGLT2i therapy in patients undergoing AEEP. Despite similar symptoms and clinical findings, patients with BPO who are treated with SGLT2i for T2D might have a higher preoperative PVR. However, the findings suggest that the reduction in IPSS following AEEP, when performed with appropriate preparation in selected patient groups, might be greater in patients using SGLT2i.

Data Availability Statement: The findings generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics Committee Approval: The study was approved by the Ethics Committee of Acıbadem University (Decision No.: 2024-10/430; Date: July 18, 2024).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – I.S.B., T.B., L.T.; Design – I.S.B., T.B., L.T.; Supervision L.T.; Materials – I.S.B., L.T.; Data Collection and/or Processing – I.S.B.; Analysis and/or Interpretation – I.S.B., T.B., L.T.; Literature Search – I.S.B., T.B.; Writing Manuscript – I.S.B., T.B.; Critical Review – L.T.

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