

Holmium laser enucleation offers superior irritative symptom relief over bipolar turp without compromising sexual function: A retrospective comparative study

Holmiyum lazer prostat enükleasyonu cinsel fonksiyonları bozmadan depolama semptomlarında bipolar turp ye göre üstün başarı sağlar: Retrospektif karşılaştırmalı bir çalışma

Timucin Sipal¹, Ferhat Yakup Suceken², Çağlar Sarıoğlu³, Mehmet Umut Evcı², Eyup Veli Kucuk²

ABSTRACT

OBJECTIVE: To compare the perioperative outcomes, erectile function, and postoperative storage symptoms between bipolar transurethral resection of the prostate (B-TURP) and holmium laser enucleation of the prostate (HoLEP) in patients with benign prostatic hyperplasia (BPH).

MATERIAL and METHODS: This retrospective comparative study included 85 patients who underwent B-TURP (n=47) or HoLEP (n=38) between January 2023 and September 2024. All patients underwent preoperative evaluation, including the International Prostate Symptom Score (IPSS), International Index of Erectile Function (IIEF), and uroflowmetry. Postoperative assessments were performed at two months. Storage symptoms were evaluated using IPSS questions 2, 4, and 7, respectively. Erectile function was assessed using the IIEF-5 and subscores. Urethral stricture was confirmed using uroflowmetry, cystoscopy, and retrograde urethrography. Comparative statistics, multivariable regression, and ROC analyses were performed.

RESULTS: The baseline characteristics were similar between the groups. HoLEP was associated with significantly lower hemoglobin drop (0.57±1.05 vs. 3.48±1.82 g/dL), shorter catheterization (1.55 vs. 2.79 days), and hospitalization (1.5 vs. 3.6 days; all p <0.001). Postoperative erectile function (IIEF-5) was comparable between the groups (p=0.08). However, storage symptoms improved more significantly in the HoLEP group (IPSS 2, 4, 7 scores: 6.63 vs. 9.34; p <0.001). Multivariable regression identified surgical technique as the only independent predictor of storage symptom relief ($\beta=-3.80$, p <0.001). Receiver operating characteristic (ROC) analysis showed moderate discriminative power (AUC=0.745) for the multivariate model.

CONCLUSION: HoLEP provides superior perioperative safety and significantly better improvement in storage symptoms compared with B-TURP, with comparable preservation of erectile function. It may be preferred in patients with a high irritative symptom burden.

Keywords: benign prostatic hyperplasia (BPH), holmium laser enucleation (HoLEP), bipolar transurethral resection (B-TURP), lower urinary tract symptoms (LUTS), erectile function

ÖZ

AMAÇ: Benign prostat hiperplazisi (BPH) olan hastalarda bipolar transüretral rezeksiyonu (B-TURP) ve holmiyum lazer prostat enükleasyonu (HoLEP) arasında perioperatif sonuçları, erektil fonksiyonu ve postoperatif depolama semptomlarını karşılaştırmak.

GEREÇ ve YÖNTEMLER: Bu retrospektif karşılaştırmalı çalışmaya Ocak 2023 ile Eylül 2024 tarihleri arasında B-TURP (n=47) veya HoLEP (n=38) uygulanan 85 hasta dâhil edildi. Tüm hastalara ameliyat öncesi değerlendirmeler Uluslararası Prostat Semptom Skoru (IPSS), Uluslararası Eretil Fonksiyon İndeksi (IIEF) ve üroflowmetri uygulandı. Ameliyat sonrası değerlendirmeler ikinci ayda yapıldı. Depolama semptomları IPSS 2, 4 ve 7 soruları kullanılarak değerlendirildi. Eretil fonksiyon IIEF-5 ve alt skorları ile değerlendirildi. Üretra darlığı üroflowmetri, sistoskopi ve retrograd ürografi ile doğrulandı. Karşılaştırmalı istatistikler, çok değişkenli regresyon ve ROC analizi yapıldı.

BULGULAR: Başlangıç özellikleri gruplar arasında benzerdi. HoLEP anlamlı derecede daha düşük hemoglobin düşüşü (0,57±1,05'e karşı 3,48±1,82 g/dL), daha kısa kateterizasyon süresi (1,55'e karşı 2,79 gün) ve hastanede yatış süresi (1,5'e karşı 3,6 gün; hepsi p<0,001) ile ilişkiliydi. Ameliyat sonrası erektil fonksiyon (IIEF-5) gruplar arasında benzerdi (p=0,08). Ancak, depolama semptomları HoLEP grubunda daha anlamlı bir şekilde iyileşti (IPSS 2, 4, 7 skoru: 6,63'e karşı 9,34; p<0,001). Çok değişkenli regresyon, cerrahi tekniği depolama semptomlarının giderilmesinin tek bağımsız öngörücüsü olarak tanımladı ($\beta=-3,80$, p <0,001). Alıcı operatör karakteristiği (ROC) analizi, çok değişkenli model için orta düzeyde ayırt edici güç (AUC=0,745) gösterdi.

SONUÇ: HoLEP, B-TURP'ye kıyasla üstün perioperatif güvenlik ve depolama semptomlarında önemli ölçüde daha iyi iyileşme sağlarken, erektil fonksiyonun benzer şekilde korunmasını sağlar. Yüksek irritan semptom yükü olan hastalarda tercih edilebilir.

Anahtar Kelimeler: benign prostat hiperplazisi (BPH), holmium lazer enükleasyonu (HoLEP), bipolar transüretral rezeksiyon (B-TURP), alt üriner sistem semptomları (AÜSS), erektil fonksiyon

¹Kırıkkale University Faculty of Medicine, Department of Urology, Kırıkkale, Türkiye

²University of Health Sciences, Umraniye Training and Research Hospital, Department of Urology, Istanbul, Türkiye

³University of Health Sciences, Bilkent Training and Research Hospital, Department of Urology, Ankara, Türkiye

Yazışma Adresi/ Correspondence:

Asst. Prof. Timucin Sipal

Kırıkkale Üniversitesi Tıp Fakültesi Araştırma ve Uygulama Hastanesi Kırıkkale Üniversitesi Kampüsü Ankara Yolu 7.Km.71450 Kırıkkale - Türkiye

Tel: +90 554 843 02 18

E-mail: drtimucin@hotmail.com

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INTRODUCTION

Lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) are highly prevalent among aging men and significantly impair their quality of life.^[1] Although medical therapy, such as alpha-blockers and 5 α -reductase inhibitors, is often initially effective, approximately 30% of men eventually require surgical intervention for refractory symptoms, urinary retention, or complications such as recurrent urinary tract infections.^[2-4] Transurethral resection of the prostate (TURP) has long been considered the standard surgical treatment for BPH, but newer minimally invasive techniques, including bipolar TURP (B-TURP) and holmium laser enucleation of the prostate (HoLEP), have shown comparable efficacy with improved safety profiles, particularly regarding bleeding and fluid absorption.^[5-7]

HoLEP has emerged as a size-independent alternative to TURP, offering complete adenoma enucleation irrespective of prostate volume and the ability to treat larger glands while maintaining low morbidity.^[8] Multiple comparative studies and meta-analyses have confirmed its advantages over TURP, including reduced hemoglobin drop, shorter catheterization and hospital stays, lower transfusion rates, and minimal risk of transurethral resection syndrome.^[6,9] However, data on postoperative sexual function and irritative (storage) symptoms remain inconsistent. While most studies show no detrimental impact on erectile function, moderate short-term declines have been observed in selected patients.^[10,11]

Storage symptoms —captured by IPSS 2, 4, 7 subscores (frequency, urgency, and nocturia)— are particularly distressing and may not fully resolve after surgical treatment, especially with B-TURP. In several studies, HoLEP has been associated with superior improvements in irritative symptoms compared to TURP.^[9] Storage symptom burden correlates strongly with quality of life and is a critical secondary endpoint when counseling patients for surgery.^[12] Nevertheless, few studies have evaluated the predictors of postoperative IPSS 2, 4, 7 outcomes using multivariable or ROC-based analyses that integrate perioperative factors.

In this retrospective comparative cohort of 85 patients (47 B-TURP and 38 HoLEP) treated between January 2023 and September 2024, we aimed to a) compare perioperative safety and functional efficacy, b) assess postoperative erectile function via IIEF-5 and subscores, and c) explore predictors of two-month storage symptoms using linear regression and ROC curve analysis. Our goal was to determine whether HoLEP provides meaningful advantages over B-TURP in terms of postoperative irritative symptom

relief and patient-reported outcomes while preserving patients' sexual function.

MATERIALS AND METHODS

This retrospective comparative study was conducted at a single tertiary academic center between January 2023 and September 2024. The study protocol was approved by the institutional ethics committee on 3.10.2024 with decision number 337.

We initially identified 142 male patients who underwent surgical treatment for benign prostatic hyperplasia (BPH) during the study period. After applying exclusion criteria, including age >75 or less than 50 years, history of prostate or urethral surgeries, neurogenic bladder, prostate cancer at the final pathology, uncontrolled diabetes, stage 3 or more chronic kidney disease, incomplete data, missing follow-up, or lack of standardized assessments, 85 patients were included in the final analysis. Patients were stratified into two groups based on the surgical procedure received: bipolar transurethral resection of the prostate (B-TURP, Group 1) and holmium laser enucleation of the prostate (HoLEP, Group 2).

All patients underwent a standardized preoperative assessment that included a detailed medical history, physical examination, digital rectal examination, serum prostate-specific antigen (PSA) level, and prostate volume estimation via transrectal ultrasonography. Uroflowmetry, post-void residual volume, and urinalysis were also performed.

To ensure sterility, all patients were confirmed to have negative urine cultures before surgery. In cases of initial bacteriuria, appropriate antibiotic therapy was administered, and surgery was delayed until repeat cultures showed sterile urine. All patients received prophylactic antibiotics according to institutional protocols.

Most procedures were performed under spinal anesthesia. General anesthesia was used in six and five patients in Groups 1 and 2, respectively, owing to patient-specific contraindications or anesthetic complications.

B-TURP was performed using a bipolar resectoscope system (Olympus ESG-400) and a continuous-flow 26-Fr resectoscope. Normal saline was used as the irrigation fluid for all patients. A loop electrode was used to resect the prostatic adenoma systematically, starting from the bladder neck to the verumontanum. The power settings were standardized at 200 W for cutting and 120 W for coagulation. A 22-Fr three-way Foley catheter was placed at the end of the procedure for irrigation purposes.

HoLEP was performed using a holmium: YAG laser (Jena MultiPulse HoPLUS 150W) with a 550- μ m end-firing laser fiber. The laser settings were standardized at 2.0 J \times 50 Hz (100 W) for enucleation and 1.0 J \times 25 Hz for coagulation. The procedure was initiated with an incision at the 5 and 7 o'clock positions to mobilize the median lobe, followed by enucleation of the lateral lobes. The tissue was morcellated using a mechanical morcellator (VersaCut™) under direct endoscopic vision. Hemostasis was achieved using lower energy settings. A 22-Fr catheter was placed in the postoperative period.

Bladder irrigation was maintained until the hematuria subsided. The catheters were removed only when the urine became macroscopically clear and no infection was documented. Follow-up visits were scheduled at two months postoperatively.

The postoperative parameters included the IPSS total score and the IPSS 2, 4, 7 subscores, reflecting storage symptoms (frequency, urgency, and nocturia). The International Prostate Symptom Score (IPSS) ranges from 0 to 35 and is classified as mild (0–7), moderate (8–19), or severe (20–35).

Erectile function was evaluated using the International Index of Erectile Function-5 (IIEF-5), which ranges from 5–25. Scores were categorized as severe ED (5–7), moderate ED (8–11), mild-to-moderate ED (12–16), mild ED (17–21), and no ED (22–25). The IIEF subscores assessed domains such as erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction.

Incontinence was evaluated using a Turkish-validated questionnaire. Urethral stricture was initially assessed by uroflowmetry ($Q_{max} < 10$ mL/s with normal bladder function prompted suspicion) and further confirmed with flexible cystoscopy. In patients with abnormal or equivocal findings, retrograde urethrography (RUG) was performed to evaluate the location and extent of stricture.

Based on prior literature and institutional pilot data, a moderate-to-large effect size (Cohen's $d=0.8$) was assumed to represent a clinically meaningful difference between the surgical groups (Bipolar TURP vs. HoLEP). With a significance level of $\alpha=0.05$ and power of 80%, the estimated sample size required was 26 patients in the Bipolar TURP group and 21 patients in the HoLEP group, accounting for an approximate group size ratio of 1.25.

To ensure sufficient statistical power across primary and secondary outcomes and to accommodate potential exclusions due to incomplete follow-up or protocol deviations,

the total target sample size was conservatively set to at least 80–90 patients.

Statistical Analysis

Statistical analyses were conducted using IBM Statistical Package for Social Sciences (SPSS) program version 27 (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as mean \pm standard deviation and were analyzed using the Student's t -test or Mann–Whitney U test, depending on the distribution. Categorical variables were expressed as counts and percentages and compared using the chi-square or Fisher's exact test.

A multivariable linear regression model was employed to identify independent predictors of postoperative storage symptoms (IPSS 2, 4, 7). Receiver operating characteristic curve analysis was used to determine the discriminative ability of the model in predicting moderate-to-severe irritative symptoms. Statistical significance was set at $p < 0.05$.

RESULTS

A total of 85 patients were included in the final analysis, with 47 undergoing Bipolar TURP (Group 1) and 38 undergoing HoLEP (Group 2). The two groups were comparable in terms of age (61.09 ± 7.6 vs. 61.47 ± 6.98 years, $p=0.80$) and baseline characteristics, including BMI (30.68 ± 2.44 vs. 29.51 ± 2.53 kg/m², $p=0.0337$), prostate volume (72.09 ± 16.51 vs. 69.5 ± 18.93 mL, $p=0.50$), and baseline uroflowmetry (6.51 ± 3.79 vs. 6.29 ± 3.56 mL/s, $p=0.78$).

Similarly, no significant differences were observed in the baseline symptom scores: total IPSS (24.66 ± 6.46 vs. 24.87 ± 6.92 , $p=0.88$), IPSS 2, 4, 7 subscores (9.57 ± 3.58 vs. 8.32 ± 3.19 , $p=0.09$), nocturia episodes (3.11 ± 0.84 vs. 2.87 ± 0.88 , $p=0.20$), or erectile function assessed by IIEF-5 (10.04 ± 6.31 vs. 11.39 ± 5.85 , $p=0.30$) (Table 1).

Operative time was significantly longer in the HoLEP group (92.95 ± 17.03 vs. 46.87 ± 7.96 min, $p < 0.001$), while postoperative recovery was more favorable in the HoLEP. The HoLEP group had a shorter hospitalization duration (1.5 ± 0.51 vs. 3.6 ± 1.04 days, $p < 0.001$), catheter time (1.55 ± 0.5 vs. 2.79 ± 0.78 days, $p < 0.001$), and lower hemoglobin drop (0.57 ± 1.05 vs. 3.48 ± 1.82 g/dL, $p < 0.001$).

Additionally, clot retention events occurred only in the TURP group (6 vs. 0 patients, $p=0.0309$). Postoperative incontinence and urethral stricture rates were comparable between the groups ($p=0.48$ and $p=0.69$, respectively) (Table 1).

Table 1. Comparison between bipolar TURP and HOLEP groups

Variable (unit)	Bipolar TURP (n=47)	HOLEP (n=38)	p-value
Age (years)	61.09±7.6	61.47±6.98	0.80†
BMI (kg/m ²)	30.68±2.44	29.51±2.53	0.03†
Prostat volume (mL)	72.09±16.51	69.5±18.93	0.50†
Uroflow max preop (mL/s)	6.51±3.79	6.29±3.56	0.78†
IPSS preop (points)	24.66±6.46	24.87±6.92	0.88†
IPSS 2, 4, 7 preop (points)	9.57±3.58	8.32±3.19	0.09†
Nocturia preop (episodes/night)	3.11±0.84	2.87±0.88	0.20†
IIEF preop (points)	10.04±6.31	11.39±5.85	0.30†
Hb preop (g/dL)	13.98±1.82	14.47±1.05	0.12†
Cre preop (mg/dL)	0.91±0.24	0.87±0.23	0.40†
Op time (minutes)	46.87±7.96	92.95±17.03	<0.001†
Hospitalisation (days)	3.6±1.04	1.5±0.51	<0.001†
Catheter time (days)	2.79±0.78	1.55±0.5	<0.001†
Clot retention – yes (n)	6	0	0.03*
Clavien Grade 0 (n)	20	16	0.09°
Clavien Grade I (n)	18	13	0.82°
Clavien Grade II (n)	6	5	0.09°
Clavien Grade III (n)	3	4	0.31°
Readmission (n)	9	5	0.06°
Postop UTI (n)	3	1	0.08°
Urethral stricture (n)	3	4	0.69°
Cre postop (mg/dL)	0.95±0.22	0.87±0.21	0.08†
Hb postop (g/dL)	10.5±0.9	13.9±0.6	<0.001†
Hb drop (g/dL)	3.48±1.82	0.57±1.05	<0.001†
Postop incontinence (n)	4	6	0.48*
IIEF postop (points)	13.04±0.81	12.74±0.79	
IPSS 2, 4, 7 postop (points)	9.34±1.54	6.63±1.98	<0.001†
Nocturia postop (episodes/night)	2.87±1.54	2.39±1.33	0.12†

† independent t-test; * Chi-square test; ° Fisher's exact test. Values are expressed as mean ± standard deviation for continuous variables and as frequency for categorical variables. Statistical significance is set at p <0.05.

Table 2. Predictors of IPSS 2, 4, 7 postop (storage symptoms)

Variable	Coefficient	Std. Error	p-value
const	16.7758	3.6621	0.0
Group binary	-3.8039	0.6735	<0.001
Age (year)	0.0143	0.028	0.61
BMI (kg/m ²)	-0.0415	0.0811	0.61
Prostate volume (CC)	-0.0024	0.0116	0.83
IPSS_2.4.7_preop	-0.1503	0.0613	<0.001
Hospitalization (day)	-0.1712	0.2265	0.45
Catheter time (day)	-0.2655	0.3	0.37
Clot_retention	-0.8193	0.8171	0.31
Clavien	-0.1614	0.2256	0.47
IPSS_preop	-0.008	0.0305	0.79
postop_incontinence	1.6527	0.6683	<0.001
Postop_UTI	0.3437	0.9996	0.732

BMI: body mass index; IPSS: international prostate symptom score; IIEF: international index of erectile function. Statistical significance was considered at p <0.05.

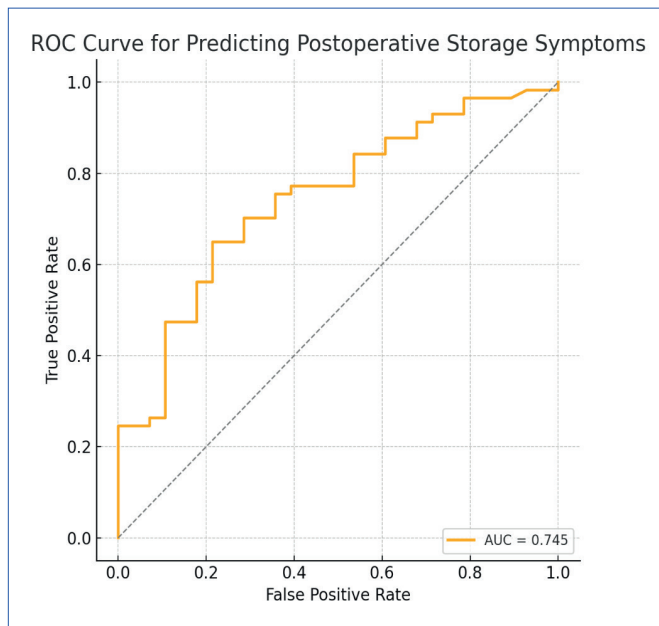


Figure 1. Receiver operating characteristic (ROC) curve for multivariable prediction of postoperative storage symptoms. The model includes surgical group (HoLEP vs. Bipolar TURP), preoperative IPSS 2, 4, 7 score, hospitalization duration, catheter time, Clavien grade, postoperative incontinence, and UTI. The area under the curve (AUC) was 0.745, indicating moderate discriminative performance in identifying patients with moderate-to-severe irritative (storage) symptoms at postoperative 2 months.

Postoperative erectile function scores significantly improved in both groups. Although the mean IIEF-5 score at 2 months was slightly higher in the Bipolar TURP group (13.04 ± 0.81 vs. 12.74 ± 0.79), this difference did not reach statistical significance ($p=0.0837$), suggesting comparable erectile recovery between the groups (Table 1).

Storage symptoms, as assessed by IPSS 2, 4, 7, demonstrated a marked difference between the groups. Postoperative scores were significantly lower in the HoLEP group (6.63 ± 1.98 vs. 9.34 ± 1.54 , $p < 0.001$), indicating superior alleviation of irritative symptoms following HoLEP (Table 1).

Regression analysis confirmed that surgical technique was the only independent predictor of postoperative IPSS 2, 4, 7 scores ($\beta = -3.80$, $p < 0.001$), with HoLEP being associated with improved storage symptom outcomes (Table 2).

A multivariable logistic regression model incorporating perioperative variables predicted moderate-to-severe storage symptoms with moderate accuracy (AUC=0.745). The ROC curve is shown in Figure 1.

DISCUSSION

Benign prostatic hyperplasia (BPH) is one of the most common urological conditions affecting elderly men, characterized by progressive enlargement of the prostate gland,

leading to lower urinary tract symptoms (LUTS). These symptoms, which include voiding difficulties and irritative complaints such as urgency and nocturia, significantly impair the quality of life. Although pharmacological therapy with alpha-blockers and 5-alpha-reductase inhibitors is effective in many patients, approximately one-third eventually require surgical intervention.^[1,4,7,9] The mainstay of surgical management has long been transurethral resection of the prostate (TURP), which is traditionally performed using monopolar energy. However, limitations such as bleeding, transurethral resection (TUR) syndrome, and the inability to effectively treat large prostates have spurred the development of newer techniques, notably bipolar TURP (B-TURP) and holmium laser enucleation of the prostate (HoLEP).^[5-7]

Both B-TURP and HoLEP aim to relieve bladder outlet obstruction by removing adenomatous tissue. Bipolar TURP utilizes saline irrigation, which reduces the risk of TUR syndrome and allows larger resection volumes than monopolar TURP. In contrast, HoLEP is a size-independent endoscopic enucleation technique that removes the entire prostatic adenoma along the surgical capsule using a holmium: YAG laser.^[6] Numerous randomized trials and meta-analyses have demonstrated that HoLEP results in less intraoperative bleeding, lower transfusion rates, shorter hospitalization and catheterization times, and faster recovery than B-TURP, albeit with longer operative times.^[9] Our findings are consistent with these results: operative time was significantly longer in the HoLEP group (92.95 vs. 46.87 min), but patients experienced a lower hemoglobin drop (0.57 vs. 3.48 g/dL), shorter catheterization (1.55 vs. 2.79 days), and shorter hospitalization (1.5 vs. 3.6 days), with no cases of clot retention in the HoLEP group (Table 1).

Sexual function, particularly erectile performance, is a major concern for men who undergo prostate surgery. The International Index of Erectile Function (IIEF-5) is widely used to evaluate erectile status, with scores stratified to define the severity of erectile dysfunction (ED). While both B-TURP and HoLEP may impact ejaculatory function due to retrograde flow, their effects on erectile function are more variable. Previous studies have reported that HoLEP does not negatively affect erectile function and may even lead to improvement due to symptom resolution and increased confidence.^[10,11] In our study, postoperative IIEF scores were similar between the groups (13.04 ± 0.81 for B-TURP vs. 12.74 ± 0.79 for HoLEP; $p=0.0837$), with no statistically significant difference, supporting the notion that both procedures are equally safe in terms of preserving erectile function (Table 1). These findings reinforce the

conclusions of prior investigations showing no long-term detrimental impact of HoLEP on sexual function.^[12]

One of the most clinically relevant findings in our study concerns the postoperative resolution of storage symptoms, which are often underappreciated in the surgical literature. Irritative symptoms, including frequency, urgency, and nocturia (captured by IPSS questions 2, 4, and 7), are more bothersome to patients than obstructive voiding symptoms and may persist even after the anatomical relief of obstruction. Our study found that postoperative IPSS 2, 4, 7 scores were significantly lower in the HoLEP group than in the B-TURP group (6.63 ± 1.98 vs. 9.34 ± 1.54 ; $p < 0.001$), suggesting a more effective resolution of storage symptoms (Table 1). Furthermore, regression analysis identified the surgical technique (HoLEP) as the only independent predictor of better IPSS 2, 4, 7 outcomes ($\beta = -3.80$, $p < 0.001$; Table 2). Receiver operating characteristic (ROC) analysis of a multivariable model incorporating group, preoperative IPSS 2, 4, 7, incontinence, and catheter time yielded an area under the curve (AUC) of 0.745, confirming moderate predictive accuracy for persistent storage symptoms (Figure 1). These results align with previous findings, suggesting that more complete anatomical removal of transitional zone tissue in HoLEP correlates with superior symptom relief.^[3,12,13]

While our findings are robust and consistent with the prior literature, this study is not without limitations. Its retrospective design inherently carries the risk of selection bias, and the relatively small sample size ($n=85$) limits the statistical power, particularly for subgroup analysis. Follow-up was limited to two months postoperatively, which may not capture the full extent of functional recovery, especially in the sexual and irritative domains. Additionally, the study was conducted at a single tertiary center, potentially limiting its generalizability to other populations or community-based settings. However, the strengths of the study include the standardized preoperative evaluation, the use of validated instruments (IPSS, IIEF), the inclusion of both functional and anatomical outcomes, and the integration of regression and ROC analyses to identify predictors of postoperative recovery.

In clinical practice, our findings suggest that HoLEP should be preferred in patients with a high baseline storage symptom burden or those at an increased risk of bleeding. The enhanced anatomical clearance provided by enucleation appears to translate into superior early symptom control. Simultaneously, erectile outcomes were not significantly different between groups, underscoring that HoLEP does not compromise sexual health. Future randomized studies

with long-term follow-up are needed to confirm these benefits over time and to investigate strategies for preserving antegrade ejaculation.

In conclusion, our study contributes to the growing body of evidence supporting HoLEP as a safe and effective alternative to TURP, particularly for patients prioritizing early recovery, symptom resolution, and low perioperative morbidity rates.

Ethics Committee Approval

The study was approved by the Ethics Committee of the University of Health Sciences, Ümraniye Training and Research Hospital. (date and number of approval: 03.10.2024/337).

Peer-review

Externally peer-reviewed.

Conflict of Interest

No conflict of interest was declared by the authors.

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Research involving human participants and/or animals

This article does not contain any studies with animals performed by any of the authors. All procedures performed in studies involving human participants were by the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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