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Safety and Efficacy of Holmium Laser Enucleation of the Prostate (HoLEP) in Patients Requiring Anticoagulants/Antiplatelets: A Retrospective Study

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What's known on the subject? and What does the study add?

Anticoagulant/antiaggregant (AC/AP) treatments in elder patients may be a concern for the safe surgical application, when any operation is necessary. It is important to choose a surgical method that can be applied to these patients with satisfactory functional outcomes and low perioperative complication rates. In the present study, we found that there was no operation-related disadvantage in the group with patients requiring AC/AP in terms of intraoperative and postoperative complications, with the improvement of functional outcomes. HoLEP is a safe and effective surgery that improves functional parameters in benign prostatic obstruction patients requiring AC/AP, with low bleeding complications and transfusion rates.

Abstract

Objective: We evaluated Holmium Laser Enucleation of the Prostate (HoLEP) surgery performed in patients with benign prostatic obstruction (BPO) requiring anticoagulant/antiplatelet (AC/AP) therapy in terms of safety and efficacy.

Materials and Methods: The retrospective data of 250 patients who underwent HoLEP between January 2020-May 2022 were included in the study. AC/AP treatment status' of patients was recorded. The patients were divided into two groups as those requiring AC/AP (group 1, n=129) and those not using (group 2, n=121). Basic characteristics, preoperative and postoperative IPSS scores, Q_{max} and continence status' at 1st and 6th month follow-up were recorded. Intra- and postoperative complications were recorded according to Clavien-Dindo classification.

Results: No significant difference was observed between the groups in terms of preoeprative characteristics including prostate-specific antigen, hemoglobin (Hb), prostate volume, IPSS, Quality of Life score, Q_{max}, Qave and postvoiding residuel volume (p>0.05). There was no significant difference between the two groups in terms of postoperative functional parameters and urinary continence (p>0.05) and in Hb drop (0.13±0.1 g/dL vs. 0.08±0.15 g/dL, respectively; p=0.21). The blood transfusion rate was 2.3% in group 1 and 0.8% in group 2, and there was no significant difference between the groups (p=0.62). Additionally, there was no significant difference between the groups regarding complications.

Conclusion: HoLEP is a safe and effective, minimally invasive surgical method that improves functional parameters in BPO patients requiring AC/AP.

Keywords: Anticoagulant, bleeding, HoLEP, safety

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Introduction

Holmium Laser Enucleation of the Prostate (HoLEP), one of the alternative to benign prostatic obstruction (BPO) surgical treatment, is being applied with increasing frequency worldwide as the most popular prostate surgery (1). Recently, interest in HoLEP surgery has been increasing due to its success in functional results and low complication rates. The fact that it can be applied even as a daily surgical procedure shows that the method has acceptable complication rates (2).

BPO is usually seen in older men and there is an increase in the incidence of BPO with age (3,4). Similarly to BPO, the incidence of cardiovascular diseases also increases with age (5,6). Since elderly patients are more likely to receive anticoagulant/antiaggregant (AC/AP) treatment, AC/AP treatments in patients with BPO age group may be a concern for the safe surgical application, when BPO surgery is desired. The increase in bleeding and perioperative complications is one of the most important concerns (7-9). Therefore, it is important to choose a surgical method that can be applied to patients requiring AC/AP therapy with satisfactory functional outcomes and low perioperative complication rates.

Although laser enucleation of the prostate has become the most popular prostate surgery of recent years in Turkiye as well as worldwide, studies on the efficacy and safety of laser enucleation in patients requiring AC/AP are lacking in the Turkish literature. In this retrospective study, we evaluated the HoLEP surgery performed in patients with BPO requiring AC/AP therapy in terms of safety and efficacy considering our own experience.

Materials and Methods

Patients Selection and Study Design

After ethics committee approval was obtained [Acıbadem Mehmet Ali Aydınlar University Medical Research Evaluation Board (ATADEK) - date/approval number: 2021/21-38], informed consent was obtained from all patients. This study was conducted following the Helsinki Declaration. The data of 405 patients who underwent HoLEP between January 2020-May 2022 were reviewed retrospectively. All patients received alpha-blocker medication and/or 5-alpha reductase inhibitor for at least 6 months before the surgery. The status of patients receiving AC/AP therapy (warfarin, aspirin, apixaban, rivaroxaban, clopidogrel or dabigatran) was recorded. Inclusion criteria for HoLEP surgery were as follows: Failure of BPO medical treatment, discontinuation of medical therapy due to side effects, maximal urinary flow rate (Q_{max}) ≤15 mL/s, International Prostate Symptom Score (IPSS) ≥8, postvoiding residual volume (PVR) ≥50 mL, a history of refractory urinary retention and bladder stones. Exclusion criteria for HoLEP surgery were as follows: Patients with a history of BPO surgery, bladder, prostate, urethra or rectum surgery (n=27), history of a pelvic radiation therapy (n=9), neurogenic bladder (n=5), with a history of prostate or bladder cancer (n=11), urethral strictures (n=15) and with less than 6-month follow-up (n=88).

Age, preoperative serum prostate-specific antigen (PSA) levels, IPSS, Quality of Life score (QoL), mean Qmax and average urinary flow rate (Qave), PVR, prostate volume measured by transabdominal ultrasonography, hemoglobin (Hb) levels were recorded. Postoperative functional parameters, stress urinary incontinence (SUI) and urge urinary incontinence (UUI) status' at 1st and 6th month follow-up were recorded. Postoperative urinary continence status was assessed according to the standards presented by the International Continence Society (ICS) (10). All patients were questioned in terms of any leak due to coughing, exertion, sneezing, or effort. Any urine leaks were considered positive regarding SUI. Total control in urin was evaluated in favor of continence. UUI was determined as involuntary leakage preceded immediately by urgency. Complete dryness was considered in favor of continence.

Enucleated tissue weight (ETW, g), enucleation time (ET, min), enucleation efficiency (ETW/ET, g/min), morcellation time (MT, min), morcellation efficiency (ETW/MT, g/min), total operation time (OT, min) were recorded. Catheterization time (CT) (hours), hospitalization time (HT) (hours) and Hb drop levels were also recorded. Intraoperative and postoperative complications were recorded according to the modified Clavien-Dindo classification (11).

A total of 250 patients who underwent HoLEP were included in the study. The patients were divided into two groups as those requiring AC/AP (group 1, n=129) and those not receiving (group 2, n=121). Group 1 and 2 were compared in terms of perioperative and postoperative parameters. We preferred to consult the patient's cardiologist or hematologist to assess the risk/benefit of continuing AC/AP perioperatively. According to the recommendations, AC/AP therapy was discontinued 5-10 days before surgery in these patients. To prevent cardiac adverse events, bridging therapy was applied to selected patients once a day with low-molecular-weight heparin (LMWH) according to the patient's body weight (twice a day for the patients with artificial heart valves). LMWH was discontinued at least 12 h before surgery to normalize coagulation parameters. If the patient reports a significant postoperative hematuria, the AC/AP continuation plan for the postoperative period was changed according to cardiologist/hematologist recommendations.

Surgical Method and Equipments

All patients were operated by the same surgeon performing the previously described Omega Sign HoLEP technique (12). A 26-

Fr continuous flow laser resectoscope, a laser-fiber stabilizing bridge, a 120-W holmium laser (VersaPulse; Lumenis Ltd., Yokneam, Israel), and a 550-µm end-firing laser fiber (SlimLine; Lumenis Ltd.) were used. A 26-Fr nephroscope and a tissue morcellator (Versacut; Lumenis Ltd.) were used to morcellate and remove the enucleated prostate tissue.

Statistical Analysis

The Statistical Package for Social Sciences 23.0 software (SPSS 23.0, Chicago, USA) was used for the statistical analysis. The Kolmogorov-Smirnov, Kurtosis, and Skewness tests were used to assess the data normality. The clinical characteristics of the two groups were compared with Mann-Whitney U or Student t-test for continuous variables and with the Fisher's Exactor Pearson chi-square test for categorical variables. All statistical tests were two-sided, and the $p<0.05$ value was considered statistically significant.

Results

A total of 250 patients who underwent HoLEP were included in the study. The patients were divided into two groups as those requiring AC/AP (group 1, n=129) and those not receiving (group 2, n=121). In terms of preoperative characteristics, no significant difference was observed between the groups in terms of age, preoperative PSA level, Hb level, preoperative prostate volume, IPSS, QoL, Qmax, Qave and PVR ($p>0.05$) (Table 1). Table 2 shows the perioperative parameters of the groups. There was no statistically significant difference between the two groups in terms of ETW, ET, EE, MT, ME, OT, HT, CT and Hb-level drop (Table 2). The operative functional parameters are presented in Table 3. A significant improvement was observed in IPSS, QoL, Qmax, Qave, PVR, PSA values in both groups at the 1st and 6th months postoperatively ($p<0.001$). However, there was no significant difference between the two groups in postoperative follow-

Table 1. Baseline characteristics and preoperative data of the patients

	Group 1 (n=129)		Group 2 (n=121)		p-value
	Mean ± SD	Median [IQR]	Mean ± SD	Median [IQR]	
Age (y)	63.93±7.04	64 [8]	65.17±7.23	66 [9]	0.09
PSA (ng/mL)	2.21±1.64	1.6 [1.89]	2.26±1.81	1.7 [2]	0.93
Prostate volume (mL)	100.76±47.61	94 [58.5]	97.31±46.71	90 [57.89]	0.56
Hb level (ng/mL)	13.63±1.27	13.66 [1.41]	13.54±1.06	13.4 [1.23]	0.83
IPSS	30.17±3.67	31 [5]	29.41±4.74	30 [6]	0.29
QoL	5±0.74	5 [1]	5±0.75	5 [1]	0.4
Qmax (mL/s)	12.33±3.23	12.4 [3.35]	13±2.9	13 [3.33]	0.19
Qave (mL/s)	5.46±1.92	5.3 [1.65]	5.64±1.72	5.3 [1.95]	0.57
PVR (mL)	230.35±185.82	184.5 [92.25]	214.17±195.4	168.5 [81.75]	0.15

PSA: Prostate specific antigen, Hb: Hemoglobin, IPSS: International prostate symptom score, QoL: Quality of life score, Qmax: Maximum flow rate, Qave: Average flow rate, PVR: Postvoiding residuel volume, SD: Standard deviation, IQR: Interquartile range, Statistically analyzed with Mann-Whitney U test

Table 2. Perioperative data of the patients

	Group 1 (n=129)		Group 2 (n=121)		p-value
	Mean ± SD	Median [IQR]	Mean ± SD	Median [IQR]	
ETW (g)	56.02±35.55	50 [43.5]	54.3±40.1	43 [53]	0.37
ET (min)	72.84±32.61	66 [43]	67.85±32.3	60 [34]	0.22
EE (g/min)	1.51±0.61	1.4 [0.76]	1.49±0.56	1.39 [0.84]	0.96
MT (min)	10.82±2.06	10 [7]	10.19±7.16	8.5 [7.75]	0.46
ME (g/min)	12.25±8.3	10.71 [7.48]	13.25±10.62	10.62 [7.69]	0.8
Laser Energy (joule)	84.81±37.91	76.5 [52.87]	99.41±104.66	76 [56.3]	0.77
Laser Efficiency (g/min)	1±0.73	0.84 [0.53]	1.24±108	0.88 [0.79]	0.31
Operation Time (min)	82.73±37.61	78 [52]	78.56±36.23	71 [41]	0.33
Hospital Time (hour)	30.04±5.85	29 [6]	29.79±6.63	28 [6]	0.47
Catheter Time (hour)	27.23±7.43	26 [6]	26.66±6.17	25 [6]	0.19
Hemoglobin Drop (g/dL)	0.13±0.1	0.1 [0.1]	0.08±0.15	0.1 [0.09]	0.21

ETW: Enucleated tissue weight, ET: Enucleation time, EE: Enucleation efficiency, MT: Morcellation time, ME: Morcellation efficiency, SD: Standard deviation, IQR: Interquartile range, Statistically analyzed with Mann-Whitney U test

ups in terms of these parameters and postoperative UI (p>0.05) (Table 3).

Intra and postoperative complications and management methods according to the modified Clavien-Dindo classification are presented in Table 4. There was no significant difference between the groups regarding complications. When the complications related to bleeding were examined more closely, hematuria requiring prolonged irrigation and following blood transfusion rate was 2.3% in the group receiving AC/AP and 0.8% in the group not receiving AC/AP, and there was no significant difference between the groups in terms of blood transfusion (p=0.62). The clot formation, which refers to patients who develop glob vesicale postoperatively and was detected after bladder irrigation with a urethral catheter, was observed in 2 patients in group 1 and in 1 patient in group 2, but there was no significant difference between the groups (p=1). No clot formation was observed in any patient, which required evacuation by cystoscopic intervention (Table 4).

Discussion

Although it has not yet taken its place in the guidelines as the gold standard, the use of laser in the surgical treatment of BPO is now accepted as an alternative minimally invasive approach to transurethral resection of the prostate (TURP) (13,14). HoLEP has low morbidity, short hospital stay, and can be applied to a wide variety of prostate sizes (15). In this study, we observed improvement in functional outcomes after HoLEP in all patients, and there was no significant difference in functional outcomes between groups requiring AC/AP and not receiving. Moreover,

Table 3. Postoperative parameters of the groups

	IPSS	QoL	Qmax	Qave	PVR	PSA	SUI	UUI
Preoperative								
Group 1	30.17±3.67	5±0.74	12.33±3.23	5.46±1.92	230.35±185.82	2.21±1.64		
Group 2	29.41±4.74	5±0.75	13±2.9	5.64±1.72	214.17±195.4	2.26±1.81		
p-value	0.29	0.4	0.19	0.57	0.15	0.93		
Postop. 1st month								
Group 1	2.41±2.51+	0.63±0.63+	28.1±5.73+	13.75±2.83+	22±19.52+	1.16±0.77+	2 (1.6%)	2 (1.6%)
Group 2	2.32±2.7+	0.59±0.69+	28.22±5.23+	13.6±2.68+	20.52±19.93+	1.08±0.81+	2 (1.7%)	1 (0.8%)
p-value	0.39	0.45	0.82	0.7	0.84	0.35	1	1
Postop. 6th month								
Group 1	1.55±1.81+	0.38±0.5+	35.43±3.66+	18.1±3.23+	7.06±12.7+	0.91±0.52+	0 (0%)	0 (0%)
Group 2	1.32±1.71+	0.36±0.5+	35.07±3.74+	17.77±2.33+	7.13±13.92+	0.86±0.51+	0 (0%)	0 (0%)
p-value	0.3	0.69	0.56	0.33	1	0.44	N/A	N/A

IPSS: International Prostate Symptom Score, QoL: Quality of Life, Qmax: Maximum urinary flow rate (mL/s), Qave: Average urinary flow rate (mL/s), PVR: Postvoiding residual volume (mL), PSA: Prostate specific antigen(ng/mL), SUI: Stress urinary incontinence, UUI: Urge urinary incontinence, Statistically analyzed with Wilcoxon and Mann-Whitney U test; *Others analyzed with Fisher's Exact test, + p<0.001 compared to baseline

Table 4. Intra- and postoperative complications according to the modified Clavien-Dindo classification and managements

	Group 1	Group 2	p	Management
Intraoperative complications				
Hematuria required prolonged irrigation	3	1	0.62	Blood transfusion and irrigation (G3a)
Capsular perforation	1	1	1	Longer catheterization (G1)
Superficial bladder mucosal injury	1	0	1	Longer catheterization (G1)
Postoperative complications				
UTI*	3	2	0.7	Intravenous antibiotic (G2)
Clot evacuation using urethral catheter	2	1	1	Irrigation (G3a)
Clot evacuation with cystoscopy	0	0	NA	
Re-catheterization	1	0	1	3 days with antiinflamatory drug (G3a)
Bladder neck contracture	1	1	1	Bladder neck laser incision (G3b)
Urethal stricture	1	1	1	Internal urethrotomy (G3b)
Meatal stenosis	1	0	1	Meatoplasty (G3b)

*Statistically analyzed with Pearson chi-square test; others analyzed with Fisher's Exact test

we found that there was no operation-related disadvantage in the patient group requiring AC/AP in terms of intraoperative and postoperative complications. There was no significant difference in complications between the two groups. In terms of bleeding complications, although the rate of blood transfusion and clot formation was higher in the group requiring AC/AP, there was no significant difference between the groups.

HoLEP has less perioperative blood loss and lower transfusion rates compared with TURP and open prostatectomy (OP) (8,15,16). This can be explained by the nature of the Ho:YAG laser: The holmium laser has a penetration depth of 0.4 mm in the prostate tissue, and the heat dissipation allows simultaneous coagulation of small and medium vessels up to 2-3 mm deep, resulting in excellent hemostasis (16). This allows the surgeon to control bleeding during this procedure (17). Furthermore, Holmium laser has a unique wavelength and energy density to achieve hemostasis. This effect can be adjusted by reducing the energy pulse or increasing the distance from the tip of the laser to the target tissue (8). Additionally, Holmium laser has a wavelength of 2140 nm, it is strongly absorbed by water and cell fluids (1,13,14). The high water content of the prostatic tissue, resulting in excellent thermal conductivity, enables the Holmium laser to coagulate and ablate the tissue (13).

Although hemostasis is achieved with a Holmium laser, bleeding may occur during the operation and in the postoperative period of HoLEP surgery. In previous studies, the hemoglobin drop after HoLEP was found in the range of 0.8-1.67 g/dL (18-21). El Tayeb et al. (22) compared 116 patients requiring AC/AP and 1558 patients non-recieving AC/AP who underwent HoLEP for BPO. In the study, no significant difference was observed between the two groups in terms of postoperative lowest hemoglobin levels and transfusion rates (3.5% vs. 1.6%, p=0.128). Similarly, in our study, there was no significant difference in Hb drop between patients who received and did not receive AC/AP (0.13±0.1 g/dL vs. 0.08±0.15 g/dL, respectively; p=0.21).

Adverse reactions to blood product transfusions are rare and often associated with significant morbidity and mortality (23,24). Transfusion also has metabolic complications such as citrate toxicity, hyperkalemia, and hypothermia (23). Low blood transfusion rates after HoLEP surgery can be considered one of the most important advantages of HoLEP surgery. Elzayat et al. (25) compared patients who received HoLEP while anticoagulating with warfarin or low-molecular-weight heparin, and those who received HoLEP after stopping anticoagulant therapy. Perioperative transfusion rates of 14.2% and 14.7% were found in patients on continued anticoagulant and low-molecular-weight heparin therapy. The transfusion rate was reported as 3% in patients whose treatment was stopped. In another study, Tyson and Lerner (26) reported no transfusions in the first 76 patients who underwent HoLEP and continued anticoagulation therapy with a mean INR of 1.5. In a meta-analysis, it was found that patients who received HoLEP had a lower blood transfusion rate (OR 0.21, 95% CI 0.10-0.45, p<0.0001) in those who did not receive antithrombotic therapy (27). Consistent with the literature, in our study, blood transfusion rate was 2.3% in the group requiring AC/AP and 0.8% in the group not receiving AC/AP, and there was no significant difference between the groups in terms of blood transfusion (p=0.62).

Study Limitations

This study has some limitations. Firstly, its design is retrospective and the follow-up period was short and the number of patients included in the study is relatively small. Secondly, we stopped AC/AP treatment before surgery, there was no continuous use. As is known, AC/AP drugs significantly increase the tendency to bleed. In this respect, the use of these drugs causes concern in surgeons in clinical practice, even if they are discontinued. we stopped these drugs 5-10 days before surgery in accordance with consultation with cardiologists/hematologists and heparinized patients up to 12 h before surgery if necessary. Of course, the discontinuation of these drugs reduces the bleeding tendency during and after surgery. However, we believe that they do not have the same bleeding profile as patients who have never used these drugs. Furthermore, the discontinuation of these drugs (if possible) before any kind of surgery is essential for both patient safety and surgeon comfort. Thirdly, we evaluated the urinary continence status only in the postoperative period and urinary incontinence was not quantified; we assessed urinary continence according to the ICS definition of incontinence. Lastly, we also did not stratify patients according to the types of AC/AP they were treated with.

Conclusion

HoLEP is a safe and effective, minimally invasive surgical method that improves functional parameters in BPO patients requiring AC/AP, with low bleeding complications and transfusion rates.

Ethics

Ethics Committee Approval: Ethics committee approval was obtained. [Acıbadem Mehmet Ali Aydınlar University Medical Research Evaluation Board (ATADEK) - date/approval number: 2021/21-38].

Informed Consent: Informed consent was obtained from all patients.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: E.G., L.T., Concept: M.Y., O.A., K.Y.Y., E.G., L.T., Design: M.Y., O.A., H.Ç.A., E.G., L.T., Data Collection

or Processing: O.A., H.Ç.A., K.Y.Y., Analysis or Interpretation: M.Y., H.Ç.A., K.Y.Y., E.G., L.T., Literature Search: M.Y., K.Y.Y., Writing: M.Y., O.A., H.Ç.A.

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