

# Safety and efficacy of photoselective vaporization of the prostate using the 180-W GreenLight XPS laser system in patients taking oral anticoagulants

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## Abstract

**Objective:** To evaluate the safety and efficacy of the 180-W GreenLight XPS laser system for the treatment of benign prostatic hyperplasia in patients taking oral anticoagulants.

**Methods:** All consecutive patients admitted for lower urinary tract symptoms associated with benign prostatic hyperplasia from November 2012 to October 2016 and who underwent photoselective vaporization of the prostate with the 180-W GreenLight XPS laser were included in the study. The perioperative outcomes examined were the operating time, laser time, energy usage, and duration of postoperative catheterization. Functional parameters (International Prostate Symptom Score, maximum urinary flow rate, and post-void residual urine volume), prostate volume, and serum prostate-specific antigen concentration were examined at baseline and 3 months. Perioperative complications, if any, were noted.

**Results:** All functional parameters (International Prostate Symptom Score, maximum urinary flow rate, and post-void residual urine volume) significantly improved from baseline to 3 months. A small number of patients experienced at least one minor adverse event. There was no difference in the rate of adverse events between patients who were and were not taking anticoagulants.

**Conclusions:** Photoselective vaporization with a 180-W laser is an efficacious and safe treatment for benign prostatic hyperplasia, even in patients taking anticoagulant medications.

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## Keywords

Prostatic hyperplasia, anticoagulant, photoselective vaporization, 180 W, GreenLight, benign prostatic obstruction

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## Introduction

Benign prostatic hyperplasia (BPH) is a chronic condition associated with progressive lower urinary symptoms. It affects approximately 75% of men aged >60 years.<sup>1</sup> First-line therapy is medical and involves the use of alpha blockers, 5-alpha-reductase inhibitors, and anticholinergics either singly or in combination.<sup>2</sup> For many patients, however, these medications do not provide adequate symptom relief, and surgical intervention is necessary to relieve bladder outlet obstructions.

Transurethral resection of the prostate (TURP) has long remained the benchmark surgical modality for BPH because it has a high rate of success in improving symptom scores, urinary flow, urinary post-void residue, and the retreatment rate. However, multiple complications have been observed, including perioperative bleeding, blood transfusions, transurethral resection syndrome, prolonged catheterization, long hospital stays, urinary incontinence, and retrograde ejaculation.<sup>3</sup>

During the last two decades, various alternative therapies have been developed with the aim of reducing complications while maintaining efficacy. Photoselective vaporization of the prostate (PVP) was initially performed using a 60-W prototype laser, which was subsequently introduced into the clinical setting using an 80-W system (American Medical Systems, Minnetonka, MN, USA). This system used an Nd:YAG laser beam that passed through a potassium titanyl phosphate

crystal, halving the wavelength to 532 nm, doubling the laser's frequency, and resulting in the production of green light. The use of this system reduced the frequency and severity of clinical complications, but it could only be used for treatment of smaller prostates. Lithium triborate (LBO) was subsequently used to significantly increase the power of this laser device to 120 W (HPS system, developed in 2006) and 180 W (XPS system, developed in 2010). These increases in power, with improvements in laser beam collimation, have allowed for more time-efficient tissue treatment. However, few reports have described surgeons' experiences with the 180-W LBO laser (GreenLight XPS system). The aim of this study was to evaluate the safety and efficacy of PVP using the GreenLight XPS 180-W LBO laser for surgical treatment of benign prostatic obstruction.

## Patients and methods

### *Study population*

This study was conducted at the Urology Department of the Acıbadem Adana Hospital, Adana, Turkey, from November 2012 to October 2016. All consecutive patients who underwent PVP with the 180-W GreenLight XPS LBO laser for treatment of lower urinary tract symptoms associated with BPH were included. Patients with prostate cancer or neurogenic voiding disorders and those with known

neurological diseases such as Parkinsonism were excluded.

Preoperative evaluation included a complete medical history, physical examination, urine and blood sample analysis (including complete blood count), electrolyte evaluation, renal function tests, and quantification of serum prostate-specific antigen (PSA). Medications used for anticoagulation (e.g., aspirin, warfarin sodium, and clopidogrel) and for BPH (alpha blockers and 5-alpha-reductase inhibitors) and their durations of use were noted. A transrectal ultrasonography-guided prostate biopsy was performed if the patient was found to have an elevated serum PSA concentration ( $>3.5$  ng/dL) and/or an abnormal digital rectal examination. The indications for surgery were those described in the guidelines of the European Association of Urology; namely, a maximum urinary flow rate (Qmax) of  $<15$  mL/s, post-void residual volume (PVR) of  $>100$  mL, or an International Prostate Symptom Score (IPSS) of  $>7$ .<sup>2</sup>

### Technique

Transurethral PVP was performed using the 180-W GreenLight XPS side-firing laser system as described by Elterman.<sup>4</sup> A 21-F laser cystoscope was used with the laser set at 180 W for vaporization and 30 W for coagulation. Normal saline was used as the irrigation fluid. A 20-F Foley catheter was placed postoperatively and removed once the patient showed normal vital signs and had adequate urine output, an absence of clots in the urine, and acceptable color in the catheter effluent. A patient was recatheterized if unable to void following catheter removal. Procedures were performed under spinal anesthesia unless comorbid conditions indicated the need for general anesthesia.

### Assessment

Perioperative outcomes such as the operating time, laser time, energy usage, and postoperative duration of catheterization were noted in all patients. Functional outcomes in terms of the IPSS, Qmax, and PVR were examined at baseline and after 3 months. Perioperative complications, if any, were noted.

### Statistical analysis

IBM SPSS Statistics, Version 21 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Independent-sample *t* tests were used for numerical data. Paired *t* tests were used to compare measures before and after surgery. The chi-square test was used for categorical data. Statistical significance was recognized when  $P < 0.05$  for two-sided probabilities. Results are expressed as mean  $\pm$  standard deviation or number (percentage) of cases.

### Ethics

This study was performed in compliance with the ethical principles of the World Medical Association Declaration of Helsinki and was approved by the Institutional Review Board. Informed consent was waived because this study involved analysis of existing medical records.

### Results

From November 2012 to October 2016, 233 men with BPH-induced lower urinary tract symptoms underwent PVP with the 180-W GreenLight XPS LBO laser. The mean age of the patients was  $70.16 \pm 6.40$  years (range, 49–88 years). The mean prostate volume was  $57.2 \pm 19.4$  mL (range, 27–185 mL). The anticoagulation group comprised 73 (31.3%) patients who used aspirin, 11 (4.7%) who used clopidogrel, and 9 (3.8%) who used warfarin sodium.

**Table 1.** Baseline parameters in patients in the anticoagulation and non-anticoagulation groups

	Anticoagulation (n = 59)	Non-anticoagulation (n = 174)	P value
Age (years)	74.8 ± 9.1	69.2 ± 5.5	<0.05
ASA score	2.17 ± 0.49	1.42 ± 0.38	<0.05
IPSS	22.5 ± 7.6	21.6 ± 5.3	0.24
Qmax (mL/s)	7.9 ± 2.2	8.3 ± 3.1	0.21
PVR (mL)	280 ± 150	220 ± 110	0.17
Prostate volume (mL)	61.5 ± 20.7	54.8 ± 16.9	0.35
PSA (ng/dL)	3.3 ± 2.8	3.0 ± 2.4	0.28

Data are presented as mean ± standard deviation. ASA, American Society of Anesthesiologists; IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; PVR, post-void residual volume; PSA, prostate-specific antigen

**Table 2.** Perioperative outcomes

	mean ± S.D.	Range
Operating time (min)	41.8 ± 11.9	(25–110)
Laser time (min)	28.7 ± 8.2	(12–60)
Energy usage (kJ)	268 ± 151	(89–616)
Duration of postoperative catheterization (hours)	24.3 ± 11.6	(6–74)

Data are presented as mean ± standard deviation (range). The mean operating time/laser time ratio was 68.7%. The mean energy density was 4.36 kJ/mL of prostate volume.

Aspirin was discontinued prior to surgery in 14 of those using it. All patients using clopidogrel or warfarin sodium stopped use 3 days prior to surgery and began receiving subcutaneous low-molecular-weight heparin. The non-anticoagulation group comprised all other patients.

Alpha blockers were used by 78% of the patients, and a combination of alpha blockers and 5-alpha-reductase inhibitors were used by 5%. After 3 months, the data for nine patients were missing: three patients were converted to TURP and six were lost to follow-up because they moved to another city (n = 2), died of a condition unrelated to the surgery (n = 1), or were absent from the follow-up visit for unknown reasons (n = 3).

**Table 3.** Comparison of functional parameters at baseline and at 3-month follow-up

	Baseline (n = 233)	3 months (n = 224)	P value
IPSS	21.9 ± 6.3	7.9 ± 3.6	<0.05
Qmax (mL/s)	8.2 ± 2.8	19.8 ± 7.1	<0.05
PVR (mL)	240 ± 150	40 ± 6	<0.05
Prostate volume (mL)	57.2 ± 19.4	30.4 ± 9.1	<0.05
PSA (ng/dL)	3.1 ± 2.4	1.8 ± 1.4	< 0.05

Data are presented as mean ± standard deviation. IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; PVR, post-void residual volume;

Table 1 shows the baseline parameters for the anticoagulation and non-anticoagulation groups. Patients in the anticoagulation group tended to be older (mean age, 74.8 vs. 69.2 years) and have higher mean American Society of Anesthesiologists scores. Other parameters were comparable between the groups.

Table 2 shows the perioperative outcomes, and Table 3 shows how the baseline functional outcomes compared with those after 3 months. Clinically meaningful and statistically significant improvements were seen in all functional parameters at 3 months compared with those at baseline.

Figure 1 shows a sagittal view of the prostate and prostatic urethra at 1 month.

Table 4 shows the intraoperative and postoperative complications experienced by patients in the anticoagulation and



**Figure 1.** Sagittal view of a pelvic magnetic resonance image. One-month postoperative view of the prostate and prostatic urethra.

non-anticoagulation groups. Forty-nine of 233 men (21%) experienced at least one complication, and in total, 68 adverse events were experienced. Intraoperative bleeding was seen in 10 (4.3%) patients. No difference in the incidence of bleeding was found between the anticoagulation and non-anticoagulation groups. In three patients, this prompted conversion to standard TURP. No blood transfusions were required in any patient.

## Discussion

TURP has long been the gold standard surgical treatment for benign prostatic obstruction. During the past two decades, however, PVP has emerged as a safe and efficacious alternative. The advantages of TURP include a shorter duration of postoperative catheterization, a shorter hospital stay, and reduced blood loss, the last of which has made PVP particularly useful in patients taking antiplatelet or anticoagulant medications.

We found that PVP using the 180-W LBO laser affords good perioperative outcomes. The mean operating time was

**Table 4.** Intraoperative and postoperative complications in the anticoagulation and non-anticoagulation groups

Complication	Anticoagulation (n = 59)	Non-anticoagulation (n = 174)	Total
Intraoperative bleeding	3 (5.1)	7 (4.0)	10 (4.3)
Conversion to TURP	1 (1.7)	2 (1.1)	3 (1.3)
Recatheterization	3 (5.1)	11 (4.7)	14 (6.0)
Clot retention	2 (3.4)	2 (1.1)	4 (1.7)
Transient hematuria	4 (6.8)	6 (3.4)	10 (4.3)
Dysuria-urgency	3 (5.1)	12 (6.9)	15 (6.4)
UTI (oral antibiotics)	2 (3.4)	5 (2.9)	7 (3.0)
Reoperation	1 (1.7)	4 (2.3)	5 (2.1)
Total	19 (32.2)	49 (28.2)	68 (29.2)

Data are presented as n (%). TURP, transurethral resection of the prostate; UTI, urinary tract infection. There was no significant difference in the total number of complications between the two groups ( $P = 0.56$ ).

41.8 minutes, 28.7 of which were direct laser use, consuming an average of 268 kJ. The mean duration of indwelling catheter placement was 24 hours. These parameters are comparable with those found in earlier studies.<sup>5-8</sup>

All procedures in this study were performed by two surgeons with combined experience exceeding 300 procedures using the 120-W LBO laser. The mean lasing/operation time ratio was 68.7%, and the mean energy density was 4.36 kJ/mL of prostate volume. Experts in the field suggest that competence with the procedure is evident when these parameters are 66% to 80% and 5 kJ/mL, respectively.<sup>9,10</sup> Our findings are consistent with these results.

We found clinically and statistically significant improvements in all functional parameters (IPSS, Qmax, and PVR) between baseline and the 3-month follow-up, similar to that reported by other researchers using the 180-W LBO laser.<sup>5-8</sup> The prostate volume decreased by 47% and PSA concentration by 42%, similar to the findings of Bachmann et al.<sup>5</sup> and Misrai et al.<sup>11</sup>

Although the 180-W LBO laser has been associated with good perioperative and functional outcomes, it is not without complications. Intraoperative bleeding was observed in 10 (4.3%) of our 233 patients, but no difference in frequency was found between the anticoagulation and non-anticoagulation groups. Sohn et al.<sup>12</sup> and Shao et al.<sup>13</sup> reported no difference in bleeding complications between patients taking anticoagulants and aspirin, respectively, suggesting that PVP is a safe surgical option in patients taking these medications.

Conversion to standard TURP was required in three (1.3%) patients; this is a low rate similar to that reported by Bachmann et al.<sup>5</sup> and Ruszat et al.<sup>14</sup> (1.8%–8.0%). In the present study, the prostate volume ranged from 27 to 185 mL. Bachmann et al.<sup>5</sup> reported use of the TURP loop in 2.0% of men with

prostate volumes of <40 mL, 6.5% of men with prostate volumes of 40 to 80 mL, and 16.0% of men with prostate volumes of >80 mL.

Recatheterization was required in 14 (6.0%) patients, 4 (1.7%) of which were a result of clot retention. This was managed conservatively by prolonging the duration of indwelling catheter placement. Mild dysuria/urgency was observed in 10 (4.3%) patients and hematuria in 10 (4.3%), but these complications were transient. Seven patients (3%) developed urinary tract infections (UTIs), but each case was satisfactorily managed using oral antibiotics.

Chung et al.<sup>15</sup> reported a recatheterization rate of 10%, which is higher than that in our study possibly because they performed a voiding trial 6 hours postoperatively. They observed clot retention in 4% and UTIs in 11% of their patients. Bachmann et al.<sup>5</sup> reported a recatheterization rate of 2.7% of their patients, as well as mild to moderate dysuria at 1 month in 11.8% and UTIs in 4.0%.

Ben-Zvi et al.<sup>6</sup> reported that no reoperations were required during a 6-month follow-up period in patients treated with the 180-W LBO laser. Reoperation was required in five (2.1%) of our patients during a 3-month follow-up period, which was too short to allow for any conclusions regarding this complication.

Because of cardiovascular or coagulation problems, anticoagulation therapy is more frequently needed in the aging population than in their younger counterparts. TURP and open simple prostatectomy are associated with potential bleeding complications. Although the former has a 0.4% to 7.1% incidence of bleeding requiring blood transfusion,<sup>16</sup> the latter has a 2% to 36% risk of blood transfusion due to bleeding, and this risk may reach 50% in some cases.<sup>17</sup> In 2014, Bachmann et al.<sup>18</sup> reported the GOLIATH study, which aimed to compare the GreenLight XPS system with TURP in

patients with BPH. It was the largest prospective randomized trial to make such a comparison, assigning 139 patients to the XPS group and 142 to the TURP group. Primary outcomes (Qmax, IPSS, and PVR) at 6 months were comparable, and no statistically significant differences in any of these parameters were found between the two groups. During the first 6 months, the complication-free rate was 87.3% in the XPS group and 83.2% in the TURP group. Bleeding-related adverse events were more common after TURP than laser treatment (6.8% vs. 2.9%, respectively). In the early postoperative period, one patient from the XPS group and six from the TURP group required reoperation for bleeding. The authors considered that the GreenLight XPS might provide more advantages in terms of hemostatic events, and this difference increased further when attention was focused on patients using antiplatelet or anticoagulant drug therapy. The authors concluded that the GreenLight XPS system is comparable to the gold standard, TURP, but has greater a complication-free rate. Additionally, when the secondary end points were examined, the duration of catheterization and hospitalization were superior using the GreenLight XPS system.<sup>18</sup> In 2016, Thomas et al.<sup>19</sup> aimed to determine the effects of the GreenLight XPS system after 2 years of maintenance. The 6-month improvements in Qmax, IPSS, and PVR were maintained throughout the 2-year follow-up. TURP seemed slightly favorable in a comparison of functional outcomes, but the differences were not statistically or clinically significant. The authors concluded that the GreenLight XPS system is a durable, effective, and safe therapy for the surgical management of BPH and offers efficacy and safety comparable with those provided by TURP.

The primary limitation of this study is the short follow-up duration. Additionally,

sexual function was not assessed at baseline or follow-up.

## Conclusions

Our experience indicates that PVP using the 180-W GreenLight XPS LBO laser is an efficacious and safe treatment for benign prostatic obstruction, even in patients taking anticoagulant or antiplatelet medications.

## Declaration of conflicting interest

The authors declare that they have no conflicts of interest.

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