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UROLOGY - ORIGINAL PAPER

# Efficacy and safety of prostate vaporesection using a 120-W 2-µm continuous-wave Tm:YAG laser (RevoLix 2) in patients on continuous oral anticoagulant or antiplatelet therapy

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**Abstract** The aim of our current study was to demonstrate the efficacy and safety of vaporesection using a 120-W Tm:YAG laser (Revolix Duo) in patients with BPH receiving systemic anticoagulation or antiplatelet therapy. Between April 2010 and November 2011, a total of 76 patients using oral antiplatelet or anticoagulant (OA) agents affected by LUTS for BPH were underwent thulium vaporesection of the prostate (ThuVARP) using a 120-W 2-µm CW Tm:YAG laser and evaluated at 3- and 6-month follow-up. Of these, in 41 patients (group A) was performed vaporesection while receiving OA therapy. In 35 patients (group B), OA agents were discontinued 10 days before surgery. There were no significant differences in average vaporesection times, catheterization time, or hospital stay. There was no significant change in serum sodium level before and immediately after vaporesection in either group. Significant improvements compared to baseline were observed at each postoperative assessment in both groups for Qmax, PVR, IPSS, and QoL. More specifically, the IPSS score improved from 21.7 at baseline to 5.2 at 6 months in group A and from 20.7 to 4.5 in group B. At 6 months, Qmax increased 226 and 190 % for the 2 groups, respectively. The PVR decreased from 119 at baseline to 11 mL at 6 months in group A and from 125 to 11 mL in group B. ThuVARP is a safe and efficient procedure for patients with BPH, refractory to pharmacotherapy, who require active antiplatelet or anticoagulant therapy.

**Keywords** Vaporesection · Prostatic hyperplasia · Tm:YAG laser · Lower urinary tract symptoms · Anticoagulant · Antiplatelet

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## Introduction

Lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) are known to affect the majority of elderly men [1]. Transurethral resection of the prostate (TUR-P) is currently considered the gold standard in the treatment for BPH, even though it is associated with a relatively high morbidity rate, particularly concerning blood loss [2]. Increasing life expectancy along with the use of oral medications for extended periods has resulted in a patient population with more severe comorbidities, including cardiac and cerebrovascular diseases, as well as other conditions requiring oral antiplatelet or anticoagulation (OA) therapy. Due to the bleeding risk, however, TUR-P is contraindicated in patients on active OA therapy.

Recently, a number of laser techniques have emerged as alternatives to TUR-P and open

prostatectomy (OP) procedures [3], offering new options for patients with LUTS. Laser prostatectomy is associated with reduced perioperative and postoperative morbidities, shorter catheterization duration, and shorter hospital stay. It can also be used to treat patients with severe comorbidities, bleeding disorders, and those on anticoagulation drugs [4]. New laser technology presents certain advantages, but each type has limitations resulting from the characteristics of the individual laser [5]. The main lasers used for the treatment of prostatic hypertrophy include the neodymium-doped yttrium aluminum garnet (Nd:YAG), the holmium yttrium aluminum garnet neodymium (Ho:YAG), and the potassium titanyl phosphate (KTP, also known as the GreenLight). Holmium laser enucleation of the prostate (HoLEP) and GreenLight laser photoselective vaporization of the prostate (PVP) have been demonstrated to be safe surgical procedures with good functional outcomes comparable to TUR-P in recent clinical trials [6–8]. Unfortunately, none of the aforementioned laser methods are ideal. With HoLEP, the operation time is longer than that with TUR-P, and it requires more extensive training. Also, its pulsed mode can cause tearing of the tissue. Using PVP, tissue specimens for histologic evaluation cannot be obtained, and the speed of ablation is significantly slower than TUR-P. Further, the instrumentation costs for this technique are high [9].

Vaporesection of the prostate with a 2-μm continuous-wave (CW) thulium-doped yttrium aluminum garnet (Tm:YAG) laser has been established as a new approach for treatment of BPH [6]. This wavelength, closer to the peak absorption spectrum of water than that of the holmium laser, causes increased tissue vaporization and reduced penetration depth. However, because the thulium laser operates in CW mode, it allows for smoother and more precise cutting [10]. The aim of our current study was to demonstrate the efficacy and safety of vaporesection using a 120-W Tm:YAG laser (Revolix Duo) in patients with BPH receiving systemic OA.

## Methods

Between April 2010 and November 2011, a total of 76 patients with LUTS for BPH were retrospectively included in the study. All patients underwent thulium vaporesection of the prostate (ThuVARP) using a 120-W 2-μm CW Tm:YAG laser (LISA laser products, OHG, Germany). The procedure was performed by a single surgeon. In addition, all patients underwent physical examination, digital rectal examination (DRE), routine urinary and serum analysis, urine culture, and serum total prostate-specific antigen (tPSA) testing. Patients with a PSA level greater than 4 mg/dL or with suspicious DRE underwent transrectal ultrasound-guided biopsy to exclude the diagnosis of prostate cancer. Prostate volume was estimated by transrectal ultrasound (TRUS). Urodynamic assessments of all patients were performed according to the International Continence Society guidelines in order to document bladder outlet obstruction. Patients with urethral stricture, bladder stones, and neurogenic bladder disease were excluded from the study. Fourteen patients had indwelling catheter because of acute urinary retention.

Baseline demographic data (Table 1) included: age, American Society of Anesthesiologists score, presence of indwelling catheter, international prostate symptom score (IPSS), quality of life score (QoL), maximum urinary flow rate (Qmax), postvoiding residual volume (PVR; measured using transabdominal ultrasound), acute urinary retention, and presence of urinary tract infection. The type of therapy was also noted and is shown in Table 2. Perioperative and postoperative endpoints were documented for two patient groups: group A, wherein ThuVARP was administered to patients receiving OA; and group B, wherein OA therapy was discontinued 10 days before surgery and replaced with low molecular weight heparin (LMWH) treatment until the next 2 weeks. Decision was made by the consultant cardiologist, considering the cardiovascular risk. Data collected included operative time, hemoglobin level, serum sodium levels, blood transfusion for anemia, return to operating room, readmission to hospital, catheterization time, and hospitalization time (Table 3). In addition, Qmax, PVR, IPSS, and QoL were assessed immediately before surgery (baseline) and at 3 and 6 months post-treatment. All perioperative and postoperative complications were also recorded.

The vaporesection procedure was performed using a 120-W 2-μm CW Tm:YAG laser (RevolixDuo) with the patient under sacral, lumbar, or general anesthesia. The RevolixDuo has 2 laser generators: (1) a 120-W CW mode for soft tissue use; (2) a 20-W pulsed head to holmium for lithotripsy of urinary stones. The lower

**Table 1** Baseline demographic data ($n = 76$ patients)

| | Group A ($n = 41$) | Group B ($n = 35$) |
|---|---|---|
| Age, years (±SD) | 69.3 (±7.4) | 68.6 (±6.7) |
| Prostate size, mL (±SD) | 65.2 (±15.1) | 65.1 (±9.2) |
| Preoperative acute urinary retention, No (%) | 14 (34) | 14 (40) |
| Preop UTI, No (%) | 8 (20) | 9 (27) |
| Preop presence of catheter, No (%) | 2 (5) | 2 (6) |
| Median ASA score | 3 | 3 |

All data are represented as mean

No = number

*ASA* American Society of Anesthesiologists

**Table 2** Type of anticoagulant used

| | Group A | Group B |
|---|---|---|
| Warfarin, No (%) | 5 (12) | 3 (8) |
| Acetylsalicylic acid, No (%) | 20 (48) | 15 (42) |
| Ticlopidine, No (%) | 12 (29) | 11 (31) |
| Association Acetylsalicylic acid and clopidogrel, No (%) | 4 (10) | 6 (17) |

No = number

**Table 3** Postoperative data

| | Group A | Group B | *P* value |
|---|---|---|---|
| Operative time (min) | 47.7 (±8.0) | 46.8 (±5.2) | >0.05 |
| Catheterization time after surgery (days) | 1.5 (±0.6) | 1.6 (±0.6) | >0.05 |
| Hospital stay (days) | 2.3 (±0.9) | 2.4 (±0.9) | >0.05 |
| Drop in hemoglobin (g/L) | 0.35 (±0.2) | 0.85 (±0.4) | >0.05 |
| Drop in sodium (g/L) | 0.53 (±2.0) | 1.34 (±1.1) | >0.05 |
| Weight of tissue send for histology (mL) | 43.1 (±11.3) | 43.2 (±6.4) | >0.05 |

All data are represented as mean (±SD)

*Preop* preoperative, *Postop* postoperative, *hg* hemoglobin

section contains the cooling system, the middle contains the electronics, and the upper section contains the laser head and trigger system. The 3 modules are easily separable. This particular conformation allows it to be an excellent multifunctional tool in urology. A 550-μm core nude-ended fiber (RigiFib, LISA laser products OHG, Germany) was used in combination with a 26-F continuous-flow laser resectoscope (Karl Storz GmbH & Co. KG, Tuttlingen). To stabilize the laser fiber, the resectoscope was equipped with a specific working channel.

The ThuVARP technique we used was similar to that described in the literature [5, 9, 11, 12]. We first marked the distal resection border close to the verumontanum. Incisions were then made at the bilateral bladder neck at the 5 and 7 o'clock positions, and vaporesection was performed on the median lobe. Finally, vaporesection of the lateral lobe was performed until the prostatic capsule was reached. With this technique, it is important to resect tissue chips of a sufficiently small size to enable easy evacuation through the resectoscope sheath. For all procedures, we used normal saline at room temperature as an irrigation fluid. At the end of the operation, the patient was catheterized with a 20-F Foley catheter; bladder irrigation was performed only in cases of hematuria. All collected tissue was investigated histologically. Levofloxacin (500 mg, once per day) was administered 1 h before the procedure and for 5 days after surgery.

### Statistical analysis

Results are reported as the mean ± standard deviation (SD). Student's paired *t* test was used for statistical analysis, and $P < 0.05$ was considered to show statistical significance.

## Results

During the study period, 76 patients using OA agents underwent ThuVARP and a 3- and 6-month follow-up evaluation. Of these, 41 patients (group A) had vaporesection performed while receiving OA therapy. In 35 patients (group B), OA were discontinued 10 days before surgery and replaced with LMWH. As shown in Table 3, the average vaporesection times were similar between the 2 groups. Transfusions were necessary in only 1 patient (group A). Three patients (2 in group A and 1 in group B) required temporary bladder irrigation due to slight hematuria. Comparing the variations of hemoglobin and sodium between the two groups, there were no statistically significant variations. There were no significant differences in

catheterization time 1.5 (±0.6) days for group A and 1.6 (±0.6) days for group B or hospital stay 2.3 (±0.9) and 2.3 (±0.9), respectively, and no patients were discharged with a catheter. Only 1 patient (in group A) required recatheterization after discharge, which was due to transient urinary retention. After 3 days, the catheter was removed and this patient was able to void spontaneously.

Significant improvements compared to baseline were observed at each postoperative assessment (3 and 6 months) in both groups for Qmax, PVR, IPSS, and QoL (Table 4). More specifically, the IPSS score improved from 21.7 at baseline to 5.2 at 6 months in group A and from 20.7 to 4.5 in group B. At 6 months, Qmax increased 226 and 186 % for the 2 groups, respectively. The PVR decreased from 119 at baseline to 11 mL at 6 months in group A and from 125 to 11 mL in group B. The comparison between the two groups for the parameters analyzed at 3 and 6 months revealed no significant differences in the improvements obtained (Table 5). No postoperative bladder neck contracture or urethral stenosis occurred in any of the patients. Furthermore, 8 patients showed mild to moderate dysuria with transitory urge incontinence that resolved spontaneously within 2–3 weeks after surgery without medical treatment. No patients had urinary stress incontinence (Table 6).

## Discussion

BPH is commonly treated by TUR-P. However, patient morbidity after TUR-P is considerably high, particularly due to intraoperative and postoperative bleeding and electrolytic disorders. In BPH patients on chronic therapy (due to atrial fibrillation, recurrent thromboembolic disease, or prothesic heart valves), the risk of bleeding associated with surgery is even higher, and discontinuation of OA therapy before surgery predisposes patients to thromboembolic events caused by the release of tissue thromboplastins [13].

There have been few studies on TUR-P use during oral OA therapy, though all have demonstrated a high rate of bleeding [14]. Parr et al. [15] in a study on 12 patients found the blood transfusion rate to be more than 30 %, and half of those patients required fresh frozen plasma. Similarly, Dotan et al. [16] in a study on 20 patients who switched from oral therapy to perioperative LMWH injection noted a blood transfusion rate of 20 %. A study by Descazeaud et al. [17] concluded that oral anticoagulation therapy had a significant and independent impact on TUR-P bleeding complications. They found that withholding OA medications prescribed for secondary prevention resulted in an increased rate of cardiovascular and cerebrovascular complications. When used for secondary prevention, withdrawal of aspirin has been shown to be associated with a threefold increase in the risk of myocardial infarction and death; for patients with coronary stents, the risk is increased almost 90-fold [18]. In fact, Descazeaud et al. reported an increased incidence of thromboembolic events resulting from TUR-P in patients with discontinuation of regular OA therapy, with or without bridging therapy, compared to a control group (2.4 vs. 0.7 %, respectively) [17].

The introduction of laser prostatectomy offers new options for these patients. In a 2004 Cochrane systematic review of 1,898 patients with BPH, the authors found that laser prostatectomy reduced the risk of transfusion compared to TUR-P [19]. A number of laser systems, including Ho:YAG, KTP, and Tm:YAG, are available for the surgical treatment of BPH [20].

**Table 4** Follow-up data

| | PVR (mL) | | Qmax (mL/s) | | IPSS score | | QoL score | |
|---|---|---|---|---|---|---|---|---|
| | Group A | Group B | Group A | Group B | Group A | Group B | Group A | Group B |
| BL | 119 (±61) | 125 (±23) | 6.7 (±1.9) | 7.3 (±1.2) | 21.7 (±4.3) | 20.7 (±3.6) | 3.8 (±0.7) | 3.8 (±0.8) |
| 3 mo | 22 (±16) | 25 (±15) | 17.2 (±2.7) | 16.7 (±2.8) | 11.2 (±2.7) | 10.4 (±2.3) | 2.0 (±0.7) | 1.8 (±1.0) |
| 6 mo | 11 (±14) | 11 (±9) | 21.9 (±3.4) | 20.9 (±3.4) | 5.2 (±1.7) | 4.5 (±1.5) | 1.1 (±0.8) | 1.1 (±0.8) |

Postoperative months versus baseline $P < 0.05$. All data are presented as mean (±SD)

*BL* baseline, *mo* months, *PVR* postvoiding residual volume, *Qmax* maximum urinary flow rate, *IPSS* international prostate symptom score, *QoL* quality of life score

**Table 5** Comparison between the improvement of two groups at 3 and 6 months

| | | Group A | Group B | *P* |
|---|---|---|---|---|
| PVR (%) | 3 mo | 81.6 | 80 | >0.05 |
| | 6 mo | 90.7 | 91.2 | >0.05 |
| Qmax (%) | 3 mo | 156 | 128 | >0.05 |
| | 6 mo | 226 | 186 | >0.05 |
| IPSS score (%) | 3 mo | 48.4 | 49.7 | >0.05 |
| | 6 mo | 76 | 78.2 | >0.05 |
| QoL score (%) | 3 mo | 47.4 | 52.6 | >0.05 |
| | 6 mo | 71 | 71 | >0.05 |

Improvements expressed as a percentage

*mo* months, *PVR* postvoiding residual volume, *Qmax* maximum urinary flow rate, *IPSS* international prostate symptom score, *QoL* quality of life score

**Table 6** Perioperative and postoperative adverse events

| | Group A no (%) | Group B no (%) |
|---|---|---|
| Perioperative | | |
| Blood transfusions | 1 (2.4) | 0 |
| Electrolytic disorders | 0 | 0 |
| Urinary tract infections | 3 (7.3) | 2 (5.7) |
| Recatheterizations | 1 (2.4) | 0 |
| Transitory urge incontinence | 4 (9.7) | 4 (11.4) |
| Postoperative | | |
| Bladder neck strictures | 0 | 0 |
| Urethral strictures | 0 | 0 |
| Stress incontinence | 0 | 0 |
| Reoperations | 0 | 0 |

No = number

Surgical lasers differ substantially in their uses, type of ion [9], and tissue absorption, which is determined by the wavelength and type of energy emission (continuous or pulsed wave). However, they all have the ability to coagulate tissue and minimize bleeding.

There have been many studies on laser prostatectomy for BPH, and many different individual lasers have been investigated. Chung et al. [21] used 532-nm laser light for photoselective vaporization of the prostate in 162 high-risk patients on systemic anticoagulation. Only 3 of those patients required blood transfusion, while 1 required reoperation and 6 experienced delayed bleeding. They also found significant improvements in IPSS, Qmax, and PVR. However, this study does not include a group of patients who, having discontinued therapy, could be compared to the data of the benefits and complications.

Ruszat et al. [22] compared 116 patients on OA with 92 control cases, all of whom were treated with a KTP laser for BPH. No cases of persistent bleeding or blood transfusions were reported in any patient, and the operative duration and intraoperative bleeding were comparable between the groups. Because of slight hematuria, 17 % of OA patients and 5 % of the control group received bladder irrigation for 24 h after surgery. In that study, there were no statistically significant differences in symptom scores, quality of life score, Qmax, or PRV at up to 18 month post-treatment.

In accordance with our study, Elzayat et al. [13] analyzed 83 BPH patients on chronic OA therapy (33 with OA discontinuation, 34 with LMWH substitution, and 14 with continuation of complete therapy) that underwent laser treatment of the prostate (Ho-LEP). They found that blood transfusion was required in 7 of patients: 1 who had ceased OA, 5 on LMWH substitution, and 1 remaining on complete OA therapy. The peak urinary flow rate, postvoid residual urine, IPSS, and quality of life all significantly improved after surgery.

Several studies have been published regarding ThuVARP and the thulium laser. Fu et al. [6] compared ThuVARP with monopolar TUR-P. They found ThuVARP to be superior in terms of safety, while the efficacy was comparable, and has the advantage of significantly less blood loss, shorter hospitalization, and shorter catheter indwelling time ($P < 0.05$).

Xia et al. [11] comparing thulium laser resection of the prostate-tangerine technique (TmLRP-TT) and standard TURP. TmLRP-TT was significantly superior in terms of catheterization time ($P < 0.0001$), hospital stay ($P < 0.0001$), and drop in hemoglobin ($P < 0.001$), whereas it required equivalent time to perform ($P > 0.05$) at a 1-year follow-up.

Bach et al. [23] have evaluated the ablative and hemostatic properties of the 120-W Tm: YAG laser comparing them with the 70-W Tm: YAG laser and concluded that the 120-W Tm: YAG laser ablation offers significantly higher ablation rates than those of the device 70-W, with a rate of bleeding and penetration depth in the tissue comparable.

Netsch et al. [24] evaluated the safety and efficacy of Thulium VapoEnucleation of the prostate (ThuVEP) for patients treated with oral anticoagulants, concluding that ThuVEP seems to be a safe and effective procedure for the treatment of symptomatic BPO in patients at high cardiopulmonary risk on OA. Although the authors studied a different surgical prostate technique showing results comparable to our ones, the work seems to show a limitation for the absence of a control group.

Our study evaluated the use of a 120-W thulium laser in patients with BPH receiving OA therapy. This laser has a wavelength of 2,013 nm, with elective absorption by water, and is therefore greatly absorbed by all tissue independent of the degree of vascularization. It provides good hemostasis and coagulation, precise incisions, and sufficient vaporization of the prostatic tissue [9].

The operator can alternate the modes of resection and vaporization by changing the distance between the fiber-end and the tissue [6]. Other advantages of thulium vaporesection are its short learning curve, high tissue ablation rates of up to 1.6 g/min [25], the lack of requiring a morcellator, and the good histologic quality of the resected chips. In addition, the system employs reusable laser fibers, reducing procedure costs.

## Conclusions

ThuVARP is a safe and efficient procedure for patients with BPH, refractory to pharmacotherapy, who require active OA therapy. We observed many significant clinical improvements with this technique comparable to ThuVARP performed after suspension OA therapy with comparable intra and postoperative complications. However, more follow-up and a larger cohort of patients need to express definitive opinion.

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