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TOPIC PAPER

RevoLix™ vaporesection of the prostate: initial results of 54 patients with a 1-year follow-up

Thorsten Bach · Thomas R. W. Herrmann · Roman Ganzer · Martin Burchardt · Andreas J. Gross

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Abstract Multiple laser systems for the treatment of benign prostatic hyperplasia (BPH) have been introduced. Current laser systems have limitations due to their laser physics. The RevoLix™ laser combines the advantages of the Holmium:YAG laser with the comfort of a continuous wave (cw) laser beam. This study reports the preliminary results of vaporesection (simultaneous vaporization and resection) of the prostate, using the 2 µm cw laser. A total of 54 consecutive patients were treated with the 70 W RevoLix™ laser for BPH. The mean age was 61 years. Mean prostate volume was 30.3 cc. A 550 µm RigiFib™ bare-ended fiber was used in combination with a 26 French laser resectoscope. Measured outcomes were resection time, decrease in hemoglobin and transfusion rate. Furthermore, the catheter time, improvement in the urinary flow rate (Q_{max}), post-voiding residual urine (PVR), International Prostate Symptom Score (IPSS) and Quality of Life Index (QoL) were recorded. Average resection time was 52 min. After crossing the learning curve, a tissue ablation of 1.5 g/min was possible. Transfusions were not necessary in any patient. Catheter time was 1.7 days. Q_{max} significantly improved from 4.2 to 20.1 ml on average. PVR decreased from 86 to 12 ml. IPSS and QoL-Score improved from 19.8 to 6.9 and 4 to 1, respectively. No patient required re-hospitalization. These preliminary results indicate that RevoLix™ vaporesection of the prostate is safe and efficient. One-year follow-up data showed a significant improvement in voiding symptoms and patients' quality of life. A longer follow-up is needed to prove the durability of these promising results.

Keywords Benign prostatic hyperplasia · Laser treatment · RevoLix · Thulium:YAG · Vaporesection

Introduction

Benign prostatic hyperplasia is a common problem in aging men. The related clinical symptoms have a serious impact on the patient's quality of life. Although transurethral resection of the prostate (TUR-P) has been the gold standard for the last decade, and is still used as the standard procedure by the majority of urologists, it is associated with substantial morbidity [1]. To overcome these problems, a variety of laser systems (e.g., neodymium:YAG (Nd:YAG), holmium:YAG (Ho:YAG), potassium titanyl phosphate (KTP)) and treatment techniques (e.g., laser ablation of the prostate, enucleation of the prostate, vaporization of the prostate) for the treatment of benign prostatic obstruction (BPO) have been introduced [2,3]. The introduced laser types have substantial differences in their function and tissue absorption, which is defined by the wavelength and type of energy emission (continuous wave or pulsed), as well as the type of ion the laser utilizes.

T. Bach and T.R.W. Herrmann contributed equally to this paper.

T. Bach (✉) · A. J. Gross
Department of Urology, Asklepios Hospital Barmbek,
Ruebenkamp 220, 22291 Hamburg, Germany
e-mail: t.bach@asklepios.com

T. R. W. Herrmann · M. Burchardt
Department of Urology, MHH Medical School of Hannover,
Carl Neuberg Str. 1, 30625 Hannover, Germany

R. Ganzer
Department of Urology, University Hospital Regensburg,
Landshuter Str. 65, 93053 Regensburg, Germany

Introduced laser-based treatment modalities, especially the holmium enucleation of the prostate (HoLEP) or the photoselective vaporization of the prostate (PVP) using the KTP laser are in use and have proven their efficacy. However, both systems have limitations, either due to laser physics, the treatable prostatic volume, the steep learning curve or the need for additional instruments like a morcellator.

This study was designed to prove the feasibility, efficacy and safety of the vaporesection of the prostate using a Thulium:YAG 2 μm 70 W continuous wave (cw) laser (RevoLix™). It reports the preliminary results of vaporesection of the prostate, after treatment of 54 patients with a 1-year follow-up.

Methods

Patients and assessed parameter

In this feasibility study, prostatic volume above 40 cc was an exclusion criterion. Patients with maximum urinary flow rates (Q_{max}) above 15 ml/s or an International Prostate Symptom Score (IPSS) below 7 were not included in the study. The preoperative workup included transrectal ultrasound, determination of the prostatic volume and PSA value. Q_{max} and post-voiding residual urine (PVR) were measured. In addition, IPSS score and Quality of Life (QoL) questionnaire were completed by the patients. Assessed outcomes were operating time, decrease in hemoglobin and transfusion rate as well as catheter time; improvement in Q_{max}, PVR, IPSS and QoL outcomes were measured at discharge and 1 year postoperatively. Complications like re-intervention rate and postoperative bleeding were recorded.

Laser system

For the vaporesection of the prostate, a RevoLix™ Thulium:YAG 2 μm 70 W continuous wave laser (LISA laser products, Katlenburg, Germany) was used. The delivery system was a bare-ended laser fiber with 550 μ optical core diameter (RigiFib™, LISA laser products, Katlenburg, Germany).

Operating technique

The laser system was used in combination with a 26 French continuous flow laser resectoscope (R. Wolf, Knittlingen, Germany) with an active working element and separate irrigation channel. To ensure excellent visibility, a low-pressure, continuous flow setup using a trocar cystostomy and continuous suction was used. The operation was performed in normal saline.

The vaporesection of the prostate was performed under direct vision using the bare-ended fiber in a contact mode. Vaporesection means simultaneous resection and vaporization of the tissue. The degree of vaporization is controlled by the speed of laser fiber movement through the tissue.

At the beginning of the operation, the distal resection border close to the verumontanum was marked and Turner-Warwick incision was performed and continued towards the previously marked resection border. Following this, the median lobe was vaporesected. After this step, the lateral lobes as well as the apical portion of the prostate were resected until the prostatic capsule was reached. During vaporesection, it is crucial to maintain the tissue chips small enough to allow easy evacuation through the resectoscope sheath at the end of the operation. A Foley catheter was placed at the end of the operation. To reduce postoperative swelling and infection, Diclofenac suppositories (50 mg, 3 × 1 for 3 days) and Ciprofloxacin (250 mg 2 × 1 for 3 days) were administered.

Results

A total of 54 consecutive patients were treated with the RevoLix™ laser for BPO. Their mean age was 61 years (56–82 years). Mean preoperative prostatic volume was 30.3 ccm (12–38 ccm) and the mean Q_{max} was 4.2 ml/s (0–11 ml/s), including 14 patients with acute urinary retention and transurethral or suprapubic catheter. Average Q_{max}, excluding these 14 patients, was 8.1 ml/s. The preoperative characteristics and demographics of the patients are summarized in Table 1. All operations were carried out by a single surgeon. Average resection time was 52 min (28–72 min). After crossing the learning curve, a tissue ablation of approximately 1.5 g/min is possible. The results are summarized in Table 2 and Fig. 1.

Mean catheter time was 1.7 days (1–3 days). No patient was discharged with a catheter. Average hospital stay was

Table 1 Patient characteristics and demographics

Age (years)	61 (56–82)
PSA (μg/dl)	3.6 (1.2–12)
Prostate size (cc)	30.3 (12–38)
Tissue for histologic workup (gram)	8 (4–11)
Transurethral or suprapubic catheter	
Preoperative	14 (25.9)
At discharge	0
Serum hemoglobin (g/dl)	
Preoperative	14.2 (11.2–16.8)
Postoperative (day 1)	13.4 (10.0–16.3)

Data presented as number (percent) or mean (range)

Table 2 Functional results of vaporesection compared to alternative laser treatments

Author	Method	Patients (n)	Prostate size (g)	Catherization time (d)	Hospital stay (d)	Increase Q_{max} (ml/s)	Transfusion (%)	Recatherization (%)	UTI (%)	Re-Operation (%)
Kuo (2003)	HoLEP	206	n.a.	1.1	1.1	n.a	1	7.7	n.a.	3.4
Kuo (2003)	HoLEP	108	163.8	1.2	1.2	n.a.	1.8	2.8	n.a.	1.8
Vavassori (2004)	HoLEP	196	54.3	n.a.	1.5	20.2	0	n.a.	4	4
Kuntz (2004)	HoLEP	100	53.5	1.1	2.2	23	0	0	n.a.	2
Elzayad (2006)	HoLEP	225	126	1.3	1.2	18.8	1.3	n.a.	1.7	0.9
Sandhu (2004)	KTP-PVP	64	101	0.75	<1	11	0	5	2	5
Sulser (2004)	KTP-PVP	65	51.2	1.5	5	10.5	0	15.4	7.7	0
Bachmann (2005)	KTP-PVP	108	n.a.	1.6	4.3	17.9	0	10	5	0
Current study (2007)	RevoLix vaporesection	54	30.3	1.7	3.5	15.9	0	0	11.1	0

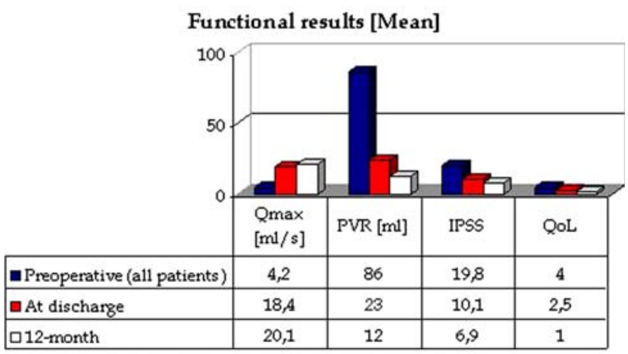

Fig. 1 Functional results (mean)

3.5 days (2–6 days). Transfusions were not necessary in any patient. No patient required re-hospitalization. However, six patients showed urinary tract infection with irritative voiding symptoms 1–2 weeks postoperatively, which required antibiotic therapy. So far, no postoperative bladder neck contracture or urethral stenosis has occurred (Table 2).

Discussion

In 1999, Madersbacher and Marberger concluded that TUR-P is still the gold standard for the treatment of BPH. This statement followed a review of 11 alternative operating techniques to TUR-P [5]. Improvements in voiding parameter and in quality of life after TUR-P seemed to be superior to any alternative treatment. Furthermore, it has been accepted that TUR-P has proven long-term durability of results and an acceptable re-treatment rate [6].

However, TUR-P remains a technically demanding procedure with a learning curve of up to 100 procedures [7] and an associated risk of complications, especially intra- and postoperative bleeding [8]. A postoperative morbidity rate of 13–24%, including a transfusion rate of 0.4–6.4%, TUR syndrome up to 2%, a 12-month re-treatment rate of 2.3–4.3% [9–11] and a long-term re-treatment rate of up to 15% [5] prompted the development of other minimally invasive treatment options for BPO.

In the following, previously introduced laser systems for the treatment of benign prostatic obstruction are characterized to point out the differences to this new system. Table 2 compares the clinical outcome of the current study to the previously published PVP and HoLEP studies. All laser systems are operated with normal saline as irrigation fluid, which eliminates the risk of TUR syndrome.

Nd-YAG laser

Nd-YAG laser prostatectomy was first described by Costello et al. [12]. With its wavelength of 1,064 nm, the invisible Nd:YAG laser has low tissue absorption in water and hemoglobin. Prostatic tissue penetration is high and up to 18 mm. In water, the laser beam travels 7.7 cm before it is attenuated by 63%. Compared to the extent of prostatic tissue or bladder wall, the absorption length is long and the likelihood of deep penetration and risk of uncontrolled necrosis caused by this wavelength is high.

However, due to thermal coagulation, which leads to necrosis [13, 14], hemostasis is excellent. Different techniques were introduced. During visual laser ablation of the prostate (VLAP), deep coagulation necrosis of the prostatic tissue was created. Postoperative tissue sloughing via the urethra results in ablation of the prostatic tissue [15]. However, the clinical results were inferior to TUR-P [16] and the reoperation rate was up to 26.7% after 2 years [15], and therefore VLAP has been abandoned in clinical practice [17]. Another technique, the interstial laser coagulation of the prostate, was introduced by Hofstetter in 1991 [18], in which laser fibers are placed directly into the prostatic tissue and a circular coagulative necrosis is conducted. Although almost no morbidity exists [14], the clinical results are in favor of TUR-P in randomized trials and the durability is low [13, 14].

KTP laser

Passing a Nd:Yag laser beam through a KTP crystal doubles the frequency and halves the wavelength, which is 532 nm and is in the green part of the spectrum. The KTP laser receives no significant absorption in water (absorption length 3000 cm), meaning that white tissue is almost transparent for this laser. The chromophore of hemoglobin at this wavelength has an extremely strong absorption for the KTP laser and the absorption length is only 80 nm [19], which causes vaporization of the prostatic tissue and creates a TUR-like cavitiy [20]. However, hemoglobin is thermally unstable. The molecule denaturizes at around 65°C, loses its red color and the ability to absorb green light. This may impair the cutting efficiency after the first laser pass.

Clinical trials showed reduction of the prostatic volume from 30 to 44% [7, 21]. The intraopertive tissue reduction was up to 0.5 g/min. The improvement in the voiding parameter is similar compared to TUR-P. Since only one clinical trial reports durable long-term results, the durablitiy of vaporization of the prostate still has to been proven. Another problem with this technique is the high material cost per treatment, with laser fiber costs of above 1000 € per laser fiber.

Ho:YAG

The Ho:YAG laser is a multifunctional tool in urology and has multiple applications like calculi lithotripsy, incision of urethral stricture and treatment of BPO. It operates at a wavelength of 2,140 nm and is highly absorbed by water. The emission of the laser beam is in a pulsed mode. Due to the high absorption in water, the tissue penetration is only 0.4 mm [3]. Different techniques have been introduced.

In 1994, holmium laser ablation of the prostate (HoLAP) was introduced [22] as the first described technique using the Ho:YAG laser. However, since the introduction of the holmium laser resection of the prostate (HoLRP) and the holmium laser enucleation of the prostate (HoLEP), the efficiency has increased. In HoLRP, the prostatic tissue is cut into pieces that are small enough to be evacuated through the urethra. Clinical results showed significant improvement in AUA symptom score and mean Q_{max} . However, the operating time was significantly longer in HoLRP than in TUR-P [23].

The development of a sufficient transurethral tissue morcellator led to the technique of HoLEP, which is the transurethral counterpart to open simple prostatectomy. The prostatic lobes are enucleated and placed into the bladder, where tissue morcelation is performed. Advantages of HoLEP over TUR-P are the size independency [24, 25] as well as reduced bleeding, hospital stay and catheter time (Table 2) [26, 27]. However, there are problems with this technique. The operation time remains longer than in TUR-P and the learning curve is steep, requiring longer training than TUR-P [28, 29]. Another criticism is not only the cost, but also the risk of bladder injury and perforation occurring in up to 6.6% of the patients on using the tissue morcellator [30]. Irritative voiding symptoms were reported in up to 23% of the patients and recatherization was necessary in up to 8% [30, 31].

Thulium:YAG (RevoLix™)

The RevoLix™ laser operates at a wavelength of 2,013 nm, which is close to the absorption peak of water. Other than in KTP vaporization, the surgical effect is entirely independent of vascularization or tissue color, since the laser energy is absorbed by the interstitial water, which is ubiquitous in all tissues. Hemostasis is comparable to that of the well-known Ho:YAG laser, with the advantage of a continuous wave laser beam. This allows even more precise incision, combined with sufficient vaporization of the prostatic tissue. By movement of the laser probe, the vaporizing effect can by increased while the heat penetration is reduced [4]. The opposite bladder wall is protected from the laser radiation due to the opaqueness of the irrigation fluid at this laser wavelength.

Due the combination of vaporization and resection of TUR-P like tissue chips, tissue ablation rates of up to 1.5 g/min can be achieved, which eliminates the prolonged operation time, the problem of HoLRP. By creating tissue chips small enough to be evacuated, an additional tissue morcellation is not necessary and the risk of bladder injury is hereby decreased. In contrast to other vaporization techniques, it is possible to evaluate the vaporesected tissue histologically. Due to the shallow penetration of the laser, the coagulation zone has no influence on pathologic quality.

Since RevoLix™ vaporesection uses a bare-ended reusable laser fiber, treatment cost can be lowered. The fiber costs per treatment are below the 20 € border.

To the best of our knowledge, this study reports the first clinical results on the treatment of BPO with the RevoLix™ 70 W cw laser. Our results indicate not only the safety of the procedure, but also the clinical efficiency after a 1-year follow-up period. Hoffmann et al. summarized in a meta-analysis 16 studies and 1,488 patients comparing laser techniques with standard TUR-P. Pooled improvement of urinary peak flow ranged from 96–127% in TUR-P patients [16]. Compared to this data, the short-term follow-up in this study showed improvement from 4.2 to 20.1 ml/s (15.9 ml/s), including patients with acute urinary retention and catheter. Excluding these 14 patients, the average Q_{max}

improved from 8.1 to 20.3 ml/s after 12 months (12.2 ml/s, 150%).

Corresponding to these results, the IPSS improved from 19.8 to 6.9 points (12.9), which is comparable to published results in PVP (11.2–17.4) [21, 32] and HoLEP (14.8–23.7) [28, 30]. The Quality of Life score improved as well from 4 to 1 points after 12 months, indicating sufficient relief for treated patients. No major complications occurred and no reoperations were necessary. Transfusions were not necessary.

Due to the small complication rate and the minimal blood loss during the procedure, RevoLix™ vaporesection of the prostate is also suitable for older patients with rising co-morbidity.

Although a peri- and postoperative antibiotic therapy was performed in these patients, six patients developed postoperative urinary tract infection. This is a slightly higher infection rate than in previously published studies (Table 2), indicating that discontinuing the antibiotics with removal of the catheter might be too early and should be continued at least for 2 or 3 days. However, only four patients suffered from acute dysuria and fever after discontinuing the antibiotic therapy.

Conclusions

The preliminary results indicate that RevoLix™ 2 µm cw vaporesection of the prostate is a safe and efficient procedure. One-year follow-up data showed a significant improvement in voiding symptoms and patients' quality of life. Longer follow-up is needed to prove the durability of these promising results.

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