

RESEARCH ARTICLE

Thulium: yttrium-aluminium-garnet laser transurethral vapoenucleation – a new standard in the surgical treatment of large benign prostatic hyperplasia

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Short title: Transurethral Thulium: yttrium-aluminium-garnet laser prostate vapoenucleation

What is not yet known on the issue addressed in the submitted manuscript

The treatment of large benign prostate hyperplasia is a topic of great interest. The use of laser energy in prostate surgery opens up new possibilities for minimally invasive treatment.

Research hypothesis

Transurethral Thulium:YAG laser prostate vapoenucleation becomes a new standard for surgical treatment of large benign prostate hyperplasia.

The novelty added by manuscript to the already published scientific literature

The use of laser energy in the surgical treatment of large benign prostatic hyperplasia allows the improvement of functional postoperative results, along with rapid recovery and significantly lower surgical risks.

Abstract

Introduction. According to the current recommendations of the European Association of Urology and the International Society of Urology, open simple prostatectomy is the reference standard in the surgical treatment of benign prostatic hyperplasia of large size (>80 ml). Extended trauma and a high complication rate reduce the chances to use this method. In this context, several minimally invasive laser surgical treatment techniques have been proposed in order to provide an optimal treatment to patients. Transurethral endoscopic vapoenucleation of the prostate using laser energy is a new concept in endourological surgery.

Material and methods. Between September 2019 and December 2019, 93 patients with benign prostatic hyperplasia underwent surgical treatment. Two surgical methods were applied: transurethral Thulium:YAG laser prostate vapoenucleation (45 patients) and open simple prostatectomy (48 patients). All patients were evaluated preoperatively and postoperatively (3 and 6 months) using the International Prostate Symptom Score, Quality of Life Score and International Erectile Function Index, physical examination and digital rectal examination, prostate specific antigen assessment, transrectal prostate ultrasound examination and assessment of residual urine volume, uroflowmetry. Postoperative complications were recorded according to the Clavien-Dindo classification, 2004. The inclusion criteria were total prostate volume ≥ 80 cm³, age ≤ 80 years, residual urine volume ≥ 70 ml, Qmax ≤ 10 ml/s.

Results. Transurethral Thulium:YAG laser vapoenucleation of prostate has proven a high surgical efficiency level. The baseline urodynamic and ultrasonographic indicators after transurethral vapoenucleation at 6 months postoperatively were similar to those in the control group (open simple prostatectomy). The duration of recovery of patients after classical surgery was significantly longer. At the same time, the rate of postoperative complications after prostate vapoenucleation was lower. Patients in the ThuVEP group did not require blood transfusions.

Conclusions. According to obtained results, we can assume that transurethral vapoenucleation of the prostate with laser energy will soon become a new „gold standard” in the surgical treatment of large benign prostate hyperplasia.

Keywords. Laser, benign prostatic hyperplasia

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common pathological conditions contributing to the development of lower urinary tract symptoms (LUTS) in older men [1]. The prevalence of BPH increases progressively in men aged 40, reaching approximately 100% at age 90 [2]. The progressive evolution of lower urinary tract symptoms interfere significantly the quality of life in patients with BPH [3]. According to current guidelines, the surgical approach is the treatment of choice in patients with BPH. Transurethral resection of the prostate (TURP) and open prostatectomy (OP) have been considered the reference standard for the treatment of medium (<80 ml) and large (>80 ml) BPH [4, 5]. For decades, OP has been the only surgical treatment option for large BPH. However, the extensive and traumatic surgical approach in open surgery is commonly associated with significant perioperative complications, as well as an increased morbidity, catheterization time, and long-term hospital stay [6, 7]. To minimize surgical complications and enhance rapid postoperative recovery, several minimally invasive methods were suggested for the treatment of large BPH, such as laser surgery, aquablation, etc. Due to technical features, only laser surgery makes it possible to radically treat large BPH through a minimally invasive transurethral approach [8]. However, the safety and efficacy of these surgical procedures in the treatment of large BPH is still relevant. Transurethral endoscopic vapoenucleation of the prostate using laser energy is a novel concept in transurethral surgery. This surgical approach used in the treatment of BPH is showing promise and is becoming increasingly popular for the treatment of severe LUTS secondary to large BPH. The use of Holmium: YAG, KTP, diode and Thulium: YAG lasers is becoming more widespread, as data on their effectiveness and surgical safety has become more available [9, 10]. Features of the surgical technique using laser energy make it possible to carry out complete enucleation or vapoenucleation of hyperplastic prostate tissues with preservation of the surgical capsule only, which is similar to OP. In addition, these laser endoscopic techniques show an equivalent efficiency, and are sometimes even superior to OP [11, 12]. Thus, transurethral laser enucleation of the prostate is likely to completely replace OP in the surgical treatment of large BPH.

Material and methods

During September 2019 - December 2019, 93 patients with BPH underwent surgical treatment. Two surgical methods were applied: ThuVEP (45 patients) and OP (48 patients). All patients were assessed preoperatively and postoperatively (at 3 and 6 months of follow-up) by using the International Prostate Symptom Scale (IPSS), Quality of Life (QoL) score and International Erectile Function Index (IIEF-5), as well as by physical examination and digital rectal examination, assessment of prostate-specific antigen (PSA), estimation of prostate gland volume with transrectal ultrasound, measurement of postvoid resid-

ual urine volume (PVR), and Q_{mean} and Q_{max} measured by uroflowmetry. Postoperative complications were recorded according to the Clavien-Dindo (2004) classification. Inclusion criteria comprised total prostate volume $\geq 80 \text{ cm}^3$, age ≤ 80 years, postvoid residual urine volume (PVR) $\geq 70 \text{ ml}$, $Q_{\text{max}} \leq 10 \text{ ml/s}$. Exclusion criteria were the neurogenic bladder, confirmed prostate or bladder cancer. In ThuVEP, patients were placed in a lithotomy position. A Karl Storz 26Fr resectoscope with continuous flow and saline irrigation was used to perform ThuVEP in all cases. The 80 W settings of Thulium:YAG laser (Revolix Duo, Lisa Laser, Germany) were used to vaporize the tissue. The laser energy was delivered through RigiFib 550mc fiber optics with terminal emission.

First, a superficial circular incision is made in the mucous membrane of the prostatic urethra posterior to veru montanum using laser energy. After performing the dissection plane along the prostatic pseudocapsule, the prostate nodes were detached via vapoenucleation providing concomitant hemostasis. Vapoenucleated nodules were removed from the bladder lumen using a morcelator or via a devascularized tissue resection technique on the pedicle. At the end of the operation, a double-lumen autostatic urethral bladder Foley 20Fr was installed in all patients for postoperative bladder drainage. The removed tissues were sent for histological examination. In cases of severe hematuria in the early postoperative period, a continuous irrigation system was applied.

OP was performed with the patient positioned in supine position under spinal anesthesia. Enucleation of the hyperplastic prostate tissue was performed based on Fuller-Freyer procedure. Lower median laparotomy was used to access the bladder. Cystotomy allowed accessing the bladder neck and the nodes of the prostatic hyperplasia. An anatomical enucleation plane is created under digital transrectal control. Once created, the enucleation trajectory is accompanied by circular enucleation movements until the hyperplastic nodules of prostate are completely dissected. Installation of a Foley autostatic probe and cystostomy was mandatory in all patients. In all cases, a system of continuous irrigation was installed for a period of 12-24 hours in order to prevent bladder tamponade. The enucleated nodules were sent for histological examination.

The data were computer processed using Excel tables. Data is presented in absolute and relative values, or in mean values and standard deviation. Descriptive statistics.

Results

All the patients included in the study completed questionnaires throughout the entire study. During their visits, all parameters presented in the study were evaluated. At the end of the follow-up, all data were analysed by using the Student's t-test. There were no statistically significant differences in the study groups. Thus, the study groups were relatively homogeneous (Table 1).

Table 1. Preoperative assessment (93 patients).

Group characteristics	ThuVEP (n=45)	OP (n=48)
No. patients	45	48
Age, years	65±2	64±3
Q _{max} , ml/s	8.1±1.3	8.2±1.5
Q _{mean} , ml/s	7.4±1.1	7.5±1
IPSS	24±1	23±2
QoL	4±1	4±1
Prostate volume, ml	91±7	92±10
PVR, ml	85±14	89±11
PSA, ng/ml	3.3±0.6	3.1±0.4

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation; OP - open prostatectomy; Q_{max} - maximum urinary flow rate; Q_{mean} - average urinary flow rate; IPSS - International Prostate Symptom Score; QoL - quality of life index; PVR - postvoiding residual urine volume; PSA - prostate specific antigen.

The operator indices were also recorded and analysed (Table 2). The removed tissue volume and the intervention timing were higher in the ThuVEP group due to complete enucleation of adenomatous tissue, which subsequently underwent fragmentation. The most significant blood loss was recorded in the OP group. The catheterization timing in patients who underwent OP was significantly higher (+400%) due to surgical trauma of the bladder and unfeasible definitive hemostasis. The hospitalization length was determined by the postoperative catheterization timing, which was also incomparably longer in patients following OP (+140%).

Table 2. Operative data (93 patients).

Group characteristics	ThuVEP	OP
Operating time, min	118±11	55±11
Blood loss volume, g/l	1.2±0.4	2.7±1.2
Catheterization time, days	2±1	10±1
Hospitalization length, days	5±1	12±2

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation; OP - open prostatectomy.

After a 6-month follow-up, no statistically significant differences were found between the two study groups regarding IPSS, QoL, Q_{max} and PVR. However, at 3 months postoperatively, patients undergoing ThuVEP reported a more significant improvement in the IPSS score (15 points), QoL (2 points). PVR in the ThuVEP group showed a much faster positive trend. PVR volume decreased by 70.5% in the ThuVEP group and by 60.6% in the OP group 3 months after surgery. The trend towards greater improvement persisted 6 months postoperatively: 87% in the ThuVEP group and only 71% in the OP group). A faster improvement in reference values can easily be explained by the less traumatic features of ThuVEP (Table 3).

Table 3. Postoperative dynamics (93 patients).

Evaluation parameters	Preoperatively	Postoperatively	
		3 months	6 months
IPSS			
ThuVEP	24±1	9±1 (-62.5%)	8±2 (-66.6%)
OP	23±2	12±2 (-47.8%)	9±1 (-60.8%)
QoL			
ThuVEP	4±1	2±1 (-50%)	2±1 (-50%)
OP	4±1	3±1 (-25%)	2±1 (-50%)
PVR, ml			
ThuVEP	85±14	20±10 (-70.5%)	11±6 (-87%)
OP	89±11	35±11 (-60.6%)	25±7 (-71%)

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation; OP - open prostatectomy IPSS - International Prostate Symptom Score; QoL - quality of life index; PVR - postvoiding residual urine volume.

A significant improvement in Q_{max} was also reported in both groups, being faster in the ThuVEP group. At 6-month follow-up, the differences in Q_{max} were not so significant. Thus, the control values at 3 and 6 months were approximated. Changes in the urodynamic parameters during the study are shown in Table 4.

Table 4. Changes in urodynamic values (93 patients).

Intervention type	Preoperatively Q _{max} (ml/s)	Postoperatively	
		3 months, Q _{max} (ml/s)	6 months, Q _{max} (ml/s)
ThuVEP	8.1±1.3	17.1±1 (+111%)	18±1 (+122%)
OP	8.2±1.5	15±1 (+82%)	17.2±1 (+109%)

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation; OP - open prostatectomy; Q_{max} - maximum urinary flow rate.

In the preoperative period, 31% of patients in the ThuVEP group and 33% in the OP group reported satisfactory erectile function according to the IIEF-5 questionnaires. Erectile dysfunction in the postoperative period did not differ (Table 5). Thus, in patients who underwent OP, a significant decrease in erectile function was reported (on average -5 points (45%)). A slight improvement in erectile function in these patients was found only 6 months after surgery. At the same time, patients after ThuVEP reported a slight decrease in erectile function 3 months after surgery (on average -3 points (25%)). Repeated check-ups at 6 months of follow-up showed an improvement in erectile function reaching the preoperative values. Significant impairment of erectile function in patients undergoing open surgery is due to injury to vascular structures and peri-prostatic nerves during surgery.

Table 5. Perioperative changes in erectile function (IIEF-5) (93 patients).

Intervention type	Preoperatively	Postoperatively	
		3 months	6 months
ThuVEP	12±2	9±1	11±1
OP	11±2	6±1	9±1

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation; OP - open prostatectomy; IIEF-5 - International Index of Erectile Function.

The incidence of postoperative complications varied in the studied groups (Table 6) due to the extremely different surgical technique, various operative traumas and long-term catheterization in patients after OP. In sexually active patients, retrograde ejaculation in the postoperative period was reported in 35 patients out of 45 (77%) in the ThuVEP group and in 41 patients out of 48 (85%) in the OP group. Retrograde ejaculation has been shown to be stable over time and persisted in all patients, who reported this type of complication throughout the follow-up. During the follow-up period, a series of complications of a varying severity were identified, however not posing any threat on

patient's life. No major bleeding events were reported in the ThuVEP group. At the same time, blood transfusions were required in 2 patients of the OP group, one of whom underwent a second operation with secondary hemostasis. Postoperatively, 5 patients (11%) in the ThuVEP group and 8 patients (16.6%) in the OP group reported transient urinary incontinence, which disappeared within 3 months of follow-up. One episode of acute urinary retention was recorded in both groups. A 48-hour re-catheterization with non-steroidal anti-inflammatory drugs was used for this type of complication.

Table 6. Postoperative complications based on the 2004 Clavien-Dindo classification. (93 patients).

Complication type	ThuVEP, no. patients (%)	OP, no. patients (%)	Complication severity
Transient urinary incontinence	5 (11%)	8 (16.6%)	Grade I
Repeated catheterization	1 (2.2%)	1 (2%)	
Blood Transfusion	-	2 (4%)	Grade II
Urinary tract infections	2 (4.5%)	5 (10.4%)	Grade III
Urethral stricture	1 (2.2%)	-	Grade IIIb
Bladder neck sclerosis	-	2 (4%)	
TURP syndrome	-	-	Grade IV
Total	9 (19.9%)	18 (35%)	

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation; OP - open prostatectomy; TURP syndrome - transurethral prostate resection syndrome.

During the 6-month follow-up, only one case of urethral stricture was reported in the ThuVEP group. At the same time, 2 patients with cervical sclerosis were identified in the OP group. These complications were corrected surgically by incision of the stricture with a cold blade and a bipolar incision of the bladder neck.

Urinary tract infections were reported in the early postoperative period in 2 patients (4.4%) in the ThuVEP group and in 5 patients (10.4%) in the OP group. An increase in the frequency of infectious and inflammatory complications after OP can probably be explained by a long-term bladder catheterization in the postoperative period. It is also worth mentioning that postoperative infectious complications were much more common among patients who underwent a prolonged bladder catheterization due to urinary retention (Table 7). Grade IV complications were not registered.

Table 7. Incidence of infectious postoperative complications (93 patients).

Complication type	ThuVEP		Open prostatectomy	
	Catheterized patients	Non-catheterized patients	Catheterized patients	Non-catheterized patients
Urethritis	1 (2,2%)	-	2 (4%)	1 (2%)
Orchoepididymitis	1 (2,2%)	-	2 (4%)	-

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation.

The role of the infectious-inflammatory factor in postoperative evolution is even more obvious when examining the urine cultures obtained from patients with preoperative bladder catheterization. Thus, the results of microbiological

studies highlighted two main problems: the importation of nosocomial infections and an increasing antibacterial resistance. Among microorganisms found, Klebsiella pneumonia, Enterococcus faecalis and Proteus mirabilis, well known for their antibiotic resistance, were increasingly being detected. At the same time, Escherichia coli, being one of the most common bacteria in urinary tract infections, has acquired a higher resistance to conventional antibacterial drugs (Table 8). The titer of pathogens detected in urine cultures varied, however no relationship between bacteriuria and the incidence of postoperative infectious complications was found.

Table 8. Incidence of asymptomatic bacteriuria. (93 patients).

Pathogenic agent	ThuVEP		Open prostatectomy	
	Catheterized patients	Non-catheterized patients	Catheterized patients	Non-catheterized patients
Klebsiella pneumonia	2	-	2	-
Proteus mirabilis	1	-	2	-
Enterococcus faecalis	1	-	1	-
Escherichia coli	2	2	1	1
Other microorganisms	-	1	-	1
Sterile urine culture	4	32	5	35

Note: ThuVEP - transurethral Thulium:YAG laser prostate vapoenucleation.

Pre- and postoperative antibiotic therapy is becoming increasingly important, especially for the prevention of septic complications. Therefore, it seems very important to diagnose large BPH and timely establish indications for surgical treatment in order to avoid catheterization due to acute urinary retention leading to urinary tract infections.

Discussions

The study results confirmed the priority of the new minimally invasive method. Postoperative recovery and improvement in reference indices were much faster in patients treated with ThuVEP. This is due to massive surgical trauma in OP and the need for delayed bladder drainage by cystostomy with concomitant bladder catheterization in the postoperative period.

Surgical efficacy was assessed by changes in uroflowmetry and symptom scaling. Thus, in both groups, there was a significant improvement in Qmax. Patients who underwent ThuVEP resumed spontaneous urination much faster (on average 2 days after surgery) and reported a satisfactory and stable improvement in Qmax as early as 3 months after surgery. The Qmax values after OP reached similar values only 6 months after the intervention. The positive dynamics observed by the patients on the IPSS and QoL scale was faster in the ThuVEP group. Symptom assessment 6 months after surgery showed comparable results. Thus, it is worth mentioning that the ThuVEP efficacy is similar to the standard classical surgery, namely, open prostatectomy, showing faster functional outcomes. The data obtained during the study are also confirmed by a series of recent studies [13-15].

The overall incidence of postoperative complications was significantly higher in the OP group. Thus, patients after OP showed a significant decrease in the level of hemoglobin (2.7 ± 1.2 g/l) due to the unfeasibility of definitive hemostasis intraoperatively. Subsequently, the frequency of blood transfusions after open surgery is relatively high - 4%. Due to the good hemostatic properties of the Thulium:YAG laser, the decrease in hemoglobin level was significantly lower - 1.2 ± 0.4 g/l, and none of the patients included in the study required a blood transfusion. Similarly, there is a two-fold increase in the incidence of infectious complications after OP - 10.4% compared with 4.5% after ThuVEP. The data obtained during the study are similar to other researches found in specialized literature [4, 16]. This

is due to the long-term urinary catheterization within the postoperative period. The presence of bacteriuria in patients was also assessed. The incidence of bacteriuria was reported significantly higher in patients with preoperative urinary catheterization, which directly affected the number of infectious complications in this category of patients. In the ThuVEP group, infectious complications occurred only in patients with preoperatively installed urinary catheters - 4.5% of patients, and in the OP group - 8% (compared to patients who urinate on their own - only 2%). Erectile dysfunction was more pronounced in patients who underwent OP, whereas full recovery occurred only in the ThuVEP group during the follow-up period. Postoperative sclerotic complications were also more common in patients after OP - 4% of cases developed bladder neck sclerosis during the follow-up period. Only one patient (2.2% of cases) experienced urethral stricture after ThuVEP. The results obtained in the study demonstrate the high efficacy of ThuVEP in combination with a significantly lower complication rate compared to OP, which have also been confirmed by other researchers [4, 17, 18].

Conclusions

Evaluation of patients under study during the postoperative period showed a significant progressive improvement in the patients' overall condition according to the IPSS scale and QoL in both groups. A positive evolution of Q_{max} was also reported, characterized by a 122% improvement in maximum flow in the ThuVEP group and 109% in the OP group. Ultrasound examination showed a significant decrease in the total prostate volume and post-void residual urine volume. At the same time, a significantly lower complication rate was registered in the ThuVEP group (19.9%) compared with OP (35%). Postoperative recovery after ThuVEP was also significantly faster, being 5 days on average. Based on the obtained results, it can be assumed that laser transurethral vapoenucleation of the prostate will soon become the new "gold standard" of surgical treatment of large BPH.

Declaration of conflict of interests

Nothing to declare

Authors' contribution

All authors contributed equally to the research, data analysis, and writing of the manuscript. All authors read and approved the final article.

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