Long-term results of multimodal treatment of the prostate using the Thulium Laser

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Abstract

Background and aims. To evaluate a novel multimodal treatment (TLP) that integrates the use of a thulium laser, bipolar transurethral resection of the prostate (TURP), and "button-type" bipolar plasma vaporization for the endoscopic treatment of benign prostatic hyperplasia (BPH).

Methods. From March 2018 to December 2021, we prospectively evaluated 220 patients with symptomatic BPH who underwent TLP. Patients were assessed based on the International Prostate Symptom Score (IPSS), quality of life (QoL), maximum urinary flow rate (Qmax), and postvoid residual urine (PVR). Perioperative and postoperative follow-up data were analyzed.

Results. The mean age at surgery was 66.74 years (SD 8.21). The median prostate size was 80 (IQR 70 - 110). The median operative time was 45 (IQR 35 - 55) minutes and the hospital stay was 2 (IQR 1 - 2) days. Patients were discharged with the urinary catheter in place, which was removed approximately 7 days after surgery when the histopathological result was discussed with the patient. Postoperatively, IPSS, QoL, Qmax and PVR showed a significant improvement starting at 3 months and continued through the postoperative follow-up visits (6-12-24-36-48-60 months). Urethral stricture and bladder neck contracture occurred in 1 (0.45%) and 2 (0.91%) patients, respectively. Recurrence of BPH occurred in 2 patients (0.91%) who underwent a second procedure.

Conclusions. In conclusion, we report that the multimodal surgical treatment of BPH consisting of combining Thulium laser vaporization, bipolar TURP and plasma vaporization (TLP) represents an efficient and durable therapeutic method for BPH patients with low a complication rate at 5-year follow-up.

Keywords: benign prostatic hyperplasia, non-anatomic technique, long-term results, thulium laser

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Background and aims

Benign prostatic hyperplasia (BPH) is a common underlying condition in the aging male population that often leads to lower urinary tract symptoms (LUTS). Men who suffer from moderate to severe BPH-related LUTS and do not benefit from medical treatment, or who suffer from lower urinary tract obstruction should be offered the option of surgery [1]. Transurethral resection of the prostate (TURP) remains the gold standard surgical procedure for the treatment of BPH-related LUTS in patients with medium-sized prostates. Laser therapy has become increasingly popular for surgical treatment of the prostate. Laser prostatic enucleation is widely accepted as the most effective surgical procedure, along with open prostatectomy (OP), for the treatment of BPH-related LUTS in patients with large prostates. It is also considered a viable alternative to TURP for medium-sized glands. Thus, laser enucleation is an established technique for the treatment of

LUTS associated with BPH, regardless of prostate size, and in patients on anticoagulation or antiplatelet therapy [2].

The utilization of Holmium and Thulium Lasers is prevalent in laser procedures. The Thulium laser, in conjunction with the Holmium laser, has gained widespread recognition and acceptance as a valuable instrument in the field of medicine. It has been included in the guidelines for several years now. In 2005, Xia et al. presented the approach of using a continuous wave thulium laser for prostate resection [3]. Subsequently, a range of treatments has been developed involving a combination of vaporization and resection techniques that remove the prostatic lobes as completely as possible without necessarily reaching the prostatic capsule [4]. The enucleation technique employs a mostly blunt mechanical dissection that follows the anatomical enucleation plane [5]. The procedures used for prostate surgery include thulium laser vaporesection (ThuVaRP), vaporization (ThuVAP), vapoenucleation (ThuVEP), and enucleation (ThuLEP) of the prostate [6]. ThuLEP offers comparable outcomes to Holmium Laser Enucleation of the Prostate (HoLEP). However, ThuLEP demonstrated slight benefits in terms of reduced blood loss and lower prevalence of transient urine incontinence [7]. The laser's continuous wave output provides the surgeon with the ability to easily switch between techniques, accelerating the learning curve [8]. The qualities of the Thulium laser make it a precious tool because of its safety, size independence, suitability for patients taking anticoagulants, and high efficiency with long-lasting results [9,10]. Thulium laser technology has introduced two new developments: the superpulsed thulium laser fiber with a wavelength of 1940 µm, which has maximum absorption in water [11], and the thulium hybrid fiber, which can be used with either continuous wave or pulsed transmission [12].

ThuVaRP is an extra-anatomical technique that is frequently used and compared to TURP. ThuVaRP results in lower serum hemoglobin decrease rate and equal efficacy, but longer operative time compared to TURP [13]. The incidence of transitory urine incontinence was higher with ThuVARP than with TURP, with rates of 20.9% and 4.7% respectively [14]. "Button-type" bipolar plasma vaporization tends to have a lower transfusion rate and offers a lower rate of major complications and duration of indwelling catheterization [15]. With anatomical enucleation, there is some concern regarding bladder injury caused by morcellating [16]. Two previous studies have evaluated the combination of thulium laser with other techniques, such as plasmakinetic resection of the prostate or bipolar TURP for large prostates. Both studies report better results with the combined technique, but the follow-up period is short [17,18].

We decided to combine the advantages and try to eliminate the disadvantages of these techniques, and we have developed a novel method that integrates the use of a thulium laser, bipolar TURP, and "button-type" bipolar plasma vaporization for the endoscopic treatment of prostate. We named our technique TLP.

Our study aimed to assess the long-term follow-up (up to 5 years) outcomes of patients treated with TLP. We assessed IPSS, the quality of life, Qmax, PVR, as well as complications including retreatment in patients treated with this technique at 3, 6, 12, 24, 36, 48, and 60 months.

Methods

Study design and ethics

This study involved a retrospective analysis of a prospectively maintained database of patients who underwent TLP between March 2018 and December 2021. The study was reviewed by the Iuliu Hatieganu University of Medicine and Pharmacy Ethics Committee under reference number 236/20.09.2023. The research was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki for medical research involving human subjects. All patients included their data in the database and consented to its use for scientific research purposes.

Study population

This study included consecutive patients who underwent TLP. The study enrolled men with moderate-to-severe BPH-related LUTS, despite receiving medical therapy for BPH. Surgery was also indicated for patients with refractory acute urinary retention and an indwelling bladder catheter. The study's inclusion criteria required a Qmax of less than 15 ml/sec and an IPSS score of 7 or higher. Exclusion criteria included previous prostatic surgery, neurogenic bladder, history or incidental prostate cancer, history of bladder cancer, previous urethral surgery, and bladder stones. Patients with missing baseline data were excluded from the study. To limit the impact of the learning curve on outcomes, the initial 20 cases of TLP were also excluded [19].

Patient evaluation and outcomes

Prior to surgical treatment, all patients underwent comprehensive urological evaluations, including a digital rectal examination (DRE), abdominal ultrasonography to assess the prostate and residual postvoid (PVR) volume, uroflowmetry, evaluation of the international prostate symptom score (IPSS), quality of life score (QoL), prostate-specific antigen (PSA) level, blood analysis, urinalysis, and urine culture. If there was suspicion of prostate cancer based on PSA levels and/or DRE, the patient underwent prostate magnetic resonance imaging (MRI) and an ultrasound-guided transrectal prostate biopsy.

The perioperative outcomes assessed in this study were the operative time (the interval when the resectoscope sheath was within the urethra), decreased hemoglobin level, decreased serum sodium level, duration of postoperative catheterization, and postoperative hospital stay.

The study evaluated perioperative complications. The patients' Qmax, PVR volume, IPSS, QoL score, prostatic volume, PSA level, and complication rate were assessed at 3, 6, 12, 24, 36, 48, and 60 months. After surgery, each patient's prostate volume was measured by abdominal ultrasound. The estimated residual prostate volume was calculated as the volume of the entire gland using an elliptical formula (height x width x length x π/6) minus the central defect (also calculated using the elliptical formula). Long-term complications were noted. BPH surgical retreatment was considered to be any surgical procedure performed on the prostate after TLP to improve the patient's urinary outcomes. The definition of BPH surgical retreatment also includes surgery for hemostasis of the lower urinary tract, urethral surgery, reconstructive surgery of the bladder neck, and urinary incontinence surgery.

The primary outcome was the IPSS-total score, while the secondary outcome was the BPH surgical retreatment rate.

Surgical technique

All surgical interventions were completed by a single experienced surgeon using the same technique and devices.

A Thulium:YAG laser Cyber TM (Quanta System, Italy) with a wavelength of 2010 nm was used for all TLPs. Laser energy was delivered using an 800µm optical, bare-ended reusable laser fiber introduced via a 26F continuous flow Karl Storz resectoscope. The power settings of the laser device for the enucleation and coagulation of the prostatic tissue were 190 W and 50 W, respectively.

The patient was placed in the lithotomy position after spinal or general anesthesia. The procedure began with a cystoscopy to evaluate the bladder and ureteral orifices, followed by an evaluation of the prostatic lobes. A transverse incision was made above the verumontanum to mark the caudal limit (Figure 1). Two linear incisions were made at 5 and 7 o'clock, extending up to the anterior transverse incision (Figure 2). The cutting fiber was moved semi-circumferentially and the median lobe was then vaporized first starting from the verumontanum to the bladder neck (Figure 3). Next, vaporization was performed on both lateral lobes (Figure 4), followed by bipolar resection (Olympus Plasma+ system, Olympus America, Melville, NY) approaching the prostate capsule. The power level for cutting was 100 W, whereas the power setting for coagulation was 120 W. The adenoma was resected piece by piece according to standard procedures. The prostate tissue was then removed through the resectoscope. Finally, the prostatic fossa was smoothed using plasma vaporization in order to regularize the prostatic fossa (Figure 5). Isotonic saline, at room temperature, was used as an irrigation fluid throughout all interventions. At the end of the surgery, a 22 F three-way Dufour tip Foley catheter was inserted into the bladder and continuous low-flow bladder irrigation with saline solution was administered. All medications for BPH were discontinued on the day of surgery. Histological investigation was performed on the tissues received from each patient. The bladder catheter was removed on the 5th to 7th day after the operation, following a discussion of the histopathological results with the patient.

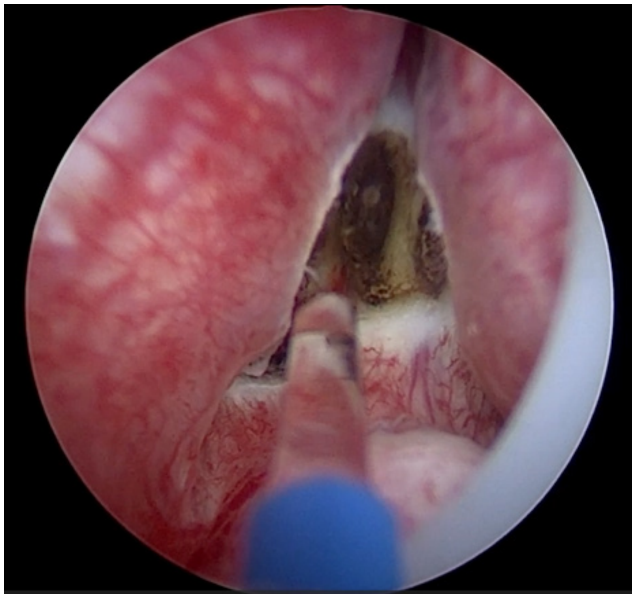

Figure 1. The caudal limit is identified by a transverse incision situated above the verumontanum.

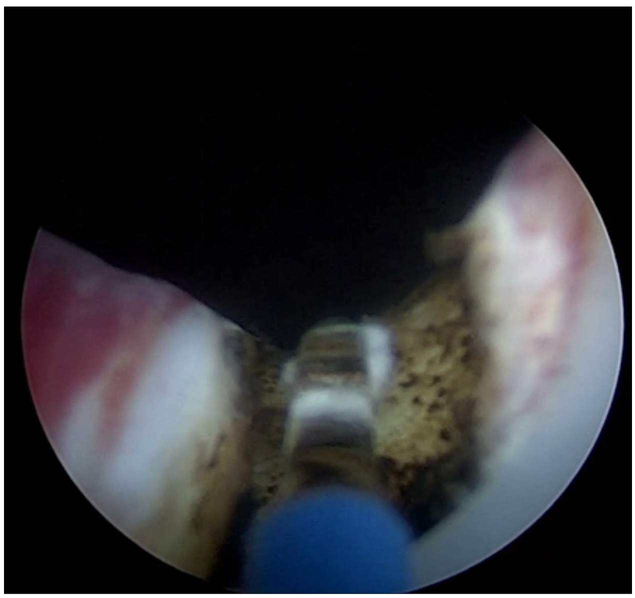

Figure 2. Two linear incisions extending to the anterior transverse incision were made at 5 and 7 o'clock.

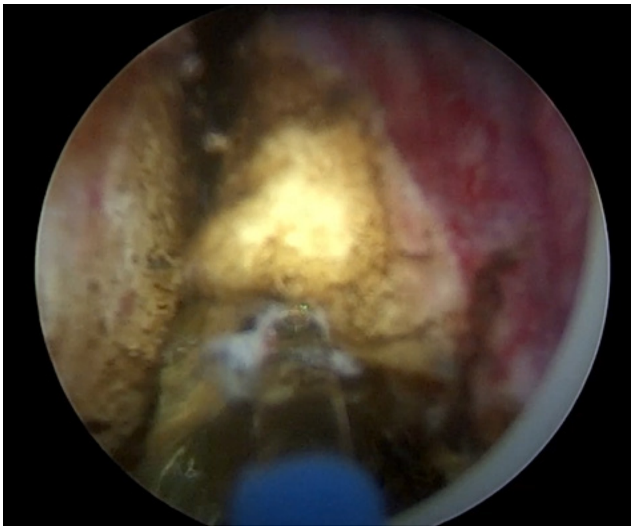

Figure 3. Middle prostatic lobe vaporization.

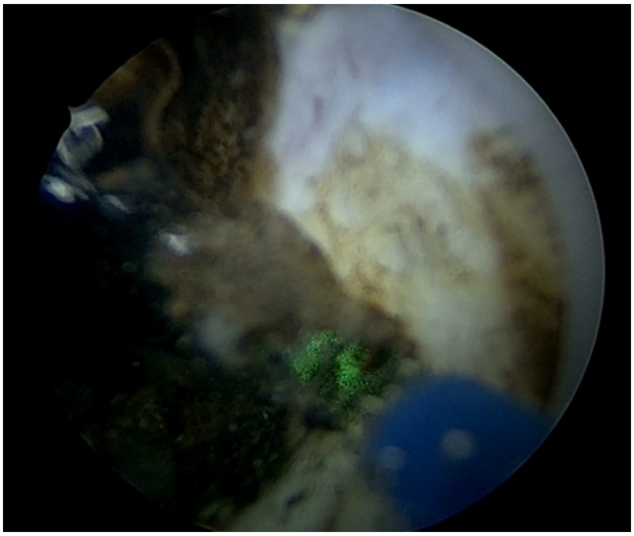

Figure 4. Lateral left prostatic lobe vaporization.

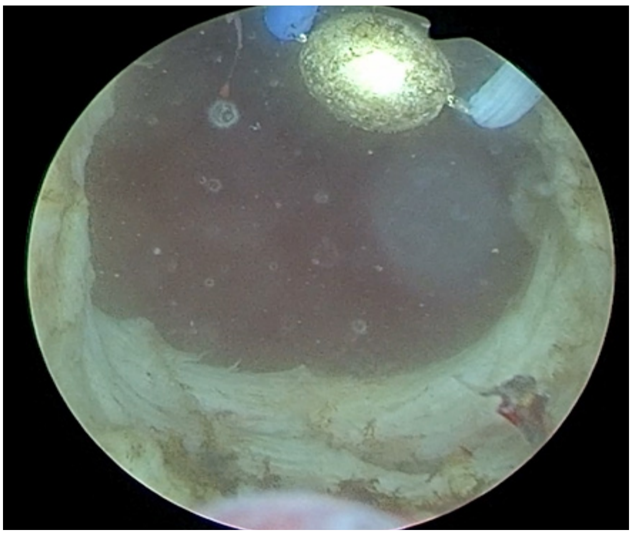

Figure 5. The final aspect of the prostatic fossa.

Statistical analysis

All statistical analyses were carried out with the R environment for statistical computing and graphics (R Foundation for Statistical Computing, Vienna, Austria), version 4.2.3 [20]. Qualitative characteristics were described by counts and percentages. Quantitative characteristics were described by median, first, and third quartiles. The Wilcoxon signed-rank test was used to compare baseline with follow-up measurements for non-normally distributed data. For all statistical tests, the bidirectional p-value was used and was considered statistically significant if the p-value was below 0.05.

Results

A total of 279 patients underwent TLP at our institution between March 2018 and December 2021. In the course of histological examination, 15 patients were found to have incidental prostate cancer. These patients were subsequently treated for prostate cancer. Seven patients exhibited bladder tumors, 18 patients had undergone previous prostate or urethral surgeries, and one patient had a neurogenic bladder. One patient had previously undergone an endoscopic procedure for bladder stones. A total of 17 patients were lost to follow-up. A total of 220 patients were included in this study.

The baseline characteristics are summarized in table I. Table II presents the perioperative data. Table III provides a list of perioperative complications.

Table I. Patients baseline characteristics.

Age, year, mean (SD)	66.74 (8.21)
Prostate size, g, median (IQR)	80 (70 - 110)
PSA, ng/ml, median (IQR)	4.62 (2.56 - 6.98)
Alpha-blocker therapy, no. (%)	182/212 (85.85)
5-α-Reductase inhibitor therapy, no. (%)	85/211 (40.28)
History of urinary retention, no. (%)	62/220 (28.18)
IPSS, median (IQR)	27 (25.5 - 29)
QoL, median (IQR)	5 (4 - 5)
Qmax, ml/s, median (IQR)	7.2 (5.85 - 8.35)
PVR, ml, median (IQR)	80 (70 - 100)
Associated conditions, no. (%)	
Hypertension	171/220 (77.73)
Diabetes mellitus	47/220 (21.36)
Ischemic heart disease	41/220 (18.63)
Renal insufficiency	30/220 (13.63)
Anticoagulant/anti-aggregant therapy	64/220 (29.09)

SD, standard deviation; IQR, interquartile range; PSA prostate-specific antigen, IPSS International Prostate Symptom Score, QoL quality of life, Qmax maximum urinary flow rate, PVR postvoid residual urine

Table II. Perioperative data.

	Median (IQR)
Operation time (min)	45 (35 - 55)
Hemoglobin decrease (g/dl)	-0.3 (-0.5 - -0.2)
Serum sodium decrease (mmol/l)	-0.3 (-0.7 - -0.1)
Hospital stay (days)	2 (1 - 2)
Catheterization time (days)	7 (7 - 7)

No patients need a blood transfusion. The parameters of the operation efficiency measured on IPSS, QoL, Qmax, and PVR revealed improvement at 3 months after surgery and remained significantly improved during the entire follow-up period (Figure 6 a-d).

Table III. Perioperative complications of TLP.

Perioperative complications	Treatment	TLP, n(%)
Capsular perforation		0
Reoperation for bleeding		0
Urinary retention	Recatheterization	4/220 (1.82)
Cloth retention without surgical revision	Prolonged bladder irrigation	4/220 (1.82)
Urinary irritation/ UTI	Observation/oral antibiotics	14/220 (6.36)
Transient urinary incontinence, 3 months	Functional training, anticholinergics	7/220 (3.18)

UTI urinary tract infection

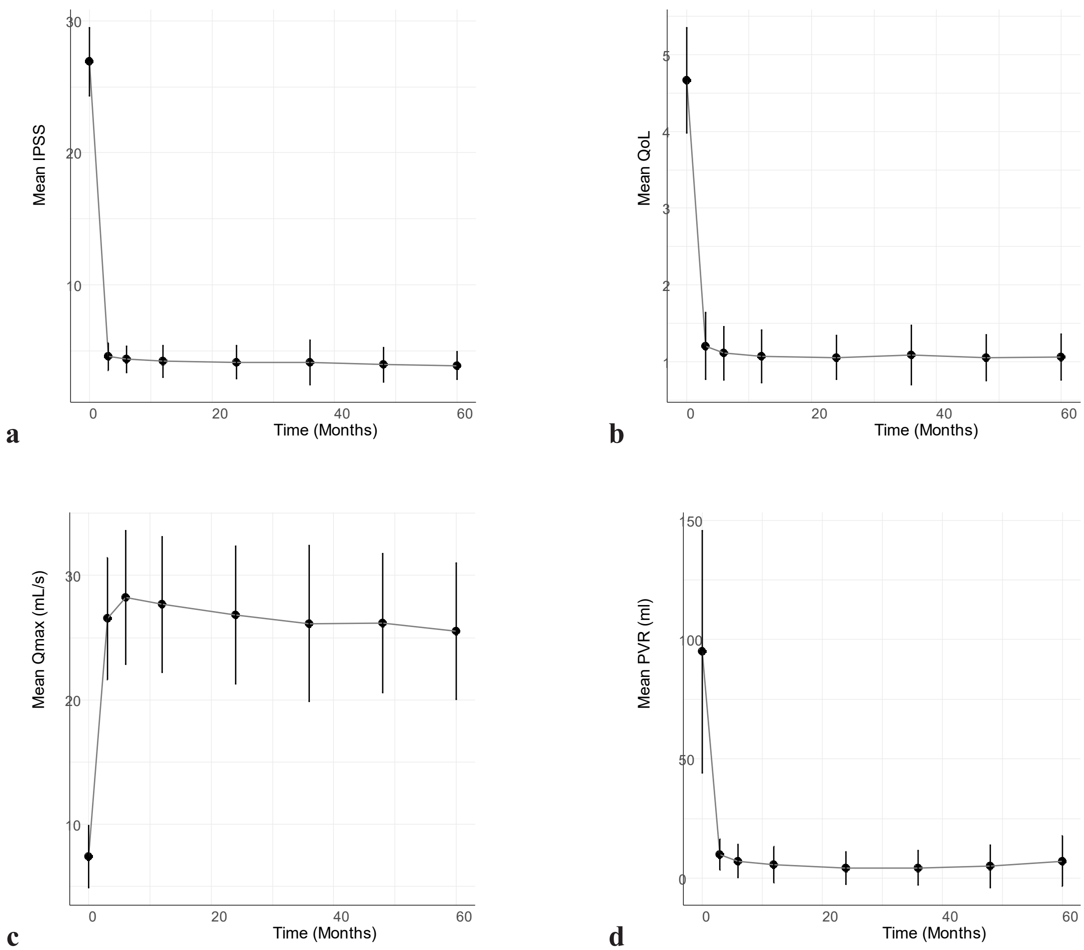

Figure 6 a-d. Operation efficacy was measured on mean IPSS, QoL, Qmax, and PVR with standard deviation evolution in time after the intervention.

Table IV. Follow-up data after TLP.

	Baseline (n=220)	3 Months (n=220)	Difference (95% CI)	P	Final (n=220)	Difference (95% CI)	P
IPSS, median (IQR)	27 (25 - 28)	4 (4 - 4)	23 (-23 - -22)	< 0.001	4 (4 - 4)	23 (22.5 - 23)	< 0.001
Qmax (mL/s), median (IQR)	7.2 (5.85 - 8.35)	27.8 (25.4 - 29.55)	20.6 (19.7 - 21.2)	< 0.001	26.8 (23 - 29.3)	19.6 (-19.85 - -18.25)	< 0.001
QoL, median (IQR)	5 (4 - 5)	1 (1 - 1)	4 (-3.5 - -3.5)	< 0.001	1 (1 - 1)	4 (3.5 - 3.5)	< 0.001
RPM (mL), median (IQR)	80 (69.75 - 100)	9.5 (4.7 - 13)	70.5 (-82 - -73.4)	< 0.001	2.5 (0 - 7)	77.5 (76.8 - 86.5)	< 0.001

IQR, interquartile range; CI, confidence interval, IPSS International Prostate Symptom Score, QoL quality of life, Qmax maximum urinary flow rate, PVR postvoid residual urine

Table V. Late-term complications.

Long-term complications	Treatment	TLP, n(%)
Urethral stricture	Internal urethrotomy and urethral dilatation	1/220 (0.45)
Bladder neck contracture	Scar excision	2/220 (0.91)
Persistent stress incontinence		0
BPH recurrence	Reoperation	2/220 (0.91)

All variables under investigation demonstrated a statistically significant improvement from three months post-surgery, with this improvement persisting throughout the entire follow-up period (p < 0.001; Table IV). The median IQR follow-up was 48 (36 - 60), and 92 (41.82%) completed the 5-year. The median IQR percentage PSA reduction at the end of the follow-up period was 68.22 (52.74 - 79.02).

Table V presents a list of late-term complications, and it is noteworthy that a reoperation rate of 5/220 (2.27%) was observed. One patient (0.45%) developed urethral stricture, while two patients (0.91%) exhibited bladder neck contracture. In our series, no patients exhibited persistent stress incontinence. Two patients (0.91%) underwent reoperation due to BPH recurrence. Both were successfully retreated with the TLP technique.

Discussion

Surgery is a highly effective treatment for lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH). The procedure involves selectively targeting the hyperplastic transitional zone of the prostate, rather than removing the entire organ, in order to reduce the likelihood of severe consequences [21]. Nevertheless, it exposes patients to the potential dangers of prostate tissue regrowth, worsening of lower urinary tract symptoms (LUTS), and the potential need for further medical treatment or surgical intervention [22]. Accurate assessment of the functional outcomes of BPH surgery can only be achieved through long-term research. This is because it takes many years for the prostate to re-grow if a sufficient amount of hyperplastic tissue is removed during surgery, and for micturion to be affected. Various factors, such as the specific surgical procedure, the expertise of the surgeon, the age of the patient, and the size of the prostate, can impact the likelihood of experiencing recurring LUTS and requiring retreatment for BPH, in addition to the duration since the operation. Nevertheless, the existing evidence regarding the topic is restricted [23,24].

TURP has long been regarded as the most effective and cost-effective method, supported by extensive evidence, in the previous several decades [25]. Monopolar TURP is associated with a high rate of perioperative complications (11.1%) and the most relevant were: failure to urinate (5.8%), the need for additional surgery (5.6%), severe urinary tract infection (3.6%), bleeding that necessitated blood transfusions (2.9%), and transurethral resection syndrome (1.4%) [26]. Instead, bipolar TURP using normal saline reduces the risk of TUR syndrome and allows for longer operative times, which implies the possibility of operating on larger prostate volumes [27]. For high-volume prostates, open prostatectomy has been utilized, but it is now being replaced by robotic [28] or laser technology. Since its introduction in 1998, HoLEP has been a significant advancement in the surgical field due to its size independence [29,30]. Additionally, it has maintained good functional results in long-term follow-ups [31]. Thulium laser was introduced later, in 2005 [3]. The Thulium fiber operates in a continuous wave mode, emitting light with a wavelength range of 1.94 - 2.0 µm. It is also capable of delivering pulsed laser energy [32]. Thulium:YAG offers exceptional adaptability due to its physical features, which enable it to have a greater capacity for vaporization. The most effective way to perform procedures that include tissue vaporization is by using the continuous-wave mode. The shift from vapoenucleation to mechanical enucleation can be accomplished by utilizing either the mechanical energy generated by pulsed thulium:YAG laser or by mechanical preparation using the sheath [33]. Thulium laser was first used for vaporization in medical procedures [3]. Subsequently, many techniques that harness its vaporization capabilities have been developed, such as vaporization (ThuVAP), vapoenucleation (ThuVEP), and ThuLEP. This laser allows for a wide range of transitions between the surgical techniques, depending on the specific clinical situation and the surgeon's preference [34].

By utilizing this combined technique, we aimed to leverage the benefits of both methods while mitigating their drawbacks. Some studies have found no significant differences in efficiency, reoperation rates, transfusion rates, or short-term complication rates between ThuVARP and TURP [35,36]. However, one disadvantage of this technique is longer operative times [33]. The durability of the long-term results of ThuVARP was demonstrated by a prospective multicenter study that included 2216 patients during the 8-year postoperative monitoring period. Only 1.2% (27) of patients required re-operation due to BPH recurrence [37].

The application of anatomical enucleation techniques necessitates the acquisition of specific skills to identify the surgical plane between the adenoma and the prostatic capsule and to maintain this plane without capsular perforation throughout the procedure. The combined non-anatomical technique enabled the removal of a significant portion of the prostate adenoma while leaving only a minimal adenoma attached to the prostatic capsule, thus creating a safe margin. No cases exhibited prostate capsule perforation.

In our cohort of 220 patients who underwent TLP, we observed a surgical retreatment incidence of 2.27% for BPH after a period of 5 years. Furthermore, we discovered that the duration between BPH surgery and prostate volume, as well as prostate volume itself, could potentially serve as indicators for the need of surgical retreatment. The correlation between the size of the prostate and adverse outcomes related to BPH has been reported [38]. The baseline prostate volume was found to be a strong predictor of BPH reoperation. This is likely because larger prostate volumes lead to more complex surgeries with inadequate tissue removal or faster tissue regrowth after surgery.

Grüne et al. reported long-term outcomes of ThuLEP. They conducted a retrospective analysis of 1,097 patients with a median prostate volume of 90 mL who underwent ThuLEP at a single center. The median follow-up period was 72 months. Of the total patients, 42 (3.8%) underwent surgical retreatment for BPH. The majority (33, 78.6%) underwent surgery within 5 years of their initial procedure (median: 24 months). According to multivariate analysis, surgical retreatment was only predicted by an enucleation weight of 60 g or greater (Hazard Ratio 1.19, 95% CI 1.03 - 1.36; $p = 0.014$) [22]. Manfredi et al. supported these findings in their study, which included 410 patients with high-volume prostates (≥ 80 ml) and a 10-year follow-up period. They found a significant improvement in IPSS score after the first year, which was maintained at 5 years follow-up. However, at 10 years follow-up, symptoms worsened but still remained statistically and clinically better than before the surgery (13.8 ± 4.5 vs. 22.1 ± 4.3; $p < 0.001$). The authors demonstrated the durability of the technique, reporting a low rate of patients (5.9%) who required surgical intervention due to prostatic obstruction. They also concluded that preoperative prostatic volume and time from surgery could be significant predictors of the need for surgical retreatment [39].

This study showed a low rate of perioperative complications and no need for blood transfusion. Late complications included urethral stricture, bladder neck contracture, and BPH recurrence. Our results showed a lower incidence rate of re-operation for BPH recurrence, which was 0.91 (2/220) at 5 years follow-up. Other studies reported 2.1% (1/47) after 4 years of follow-up [35] and 1.2% (28/2216) after a mean of 5 years of follow-up [36]. A retrospective study of 949 patients who underwent the HoLEP technique reported durable long-term follow-up results and bladder neck contracture, urethral stricture, and reoperation for residual adenoma developed in 0.8, 1.6, and 0.7% of patients, respectively. Transient stress urinary incontinence was reported in 4.9% (47/949) at the first 3-month follow-up. Persistent urge incontinence was reported in 1% of patients [40]. Our results were comparable to the functional results of patients treated with HoLEP, despite being a non-anatomic technique with a lower incidence of urinary incontinence.

Our technique involves vaporizing the central part of the adenoma, after which we proceed to perform standard TURP in the proximity of the prostatic capsule. This approach allows for the histological analysis of prostatic tissue. The incidence of prostate cancer following treatment for BPH is estimated to be between 7% and 23% [41,42] and in our study was 5.37%. The necessity of systematic histopathological analysis was previously highlighted, and the conclusion was reached following the evaluation of a large cohort of 1045 patients who underwent OP, TURP, and HoLEP. The incidence of iPCa was 8.8% and 1.4% exhibited an ISUP score of ≥ 2. Age and PSA density were found to be independent predictive factors of incidental prostate cancer. In patients younger than 70 years with a PSA density of less than 0.05 ng/mL/mL, the incidence of prostate cancer was 0% [43]. The variables associated with the detection of incidental prostate cancer, the strategies to reduce incidental prostate cancer, as well as the natural history and management of this condition have been extensively studied. However, further work in this area is still needed [44]. Following surgery, despite a benign result, we continue to recommend to our patients that they perform a PSA test every six months. Based on the PSA velocity and digital rectal exam, we continue to perform or not prostate cancer screening.

There are several limitations to this study. First, the median follow-up was 4 years, and only 92 (41.82%) of the patients completed the 5-year follow-up. Second, the lack of a control group could potentially bias the results. A comparative analysis with the standard technique is needed to validate our novel multimodal treatment. A multicenter study design is needed to further evaluate the efficacy and durability of TLP and to increase the generalizability of the results.

There are some strengths of our research. This is the first study, to our knowledge, to report long-term results for TLP intervention for BPH. The prospectively maintained database offers high-quality data for long-term follow-up.

Conclusions

In conclusion, we report that the multimodal surgical treatment for BPH consisting of combining Thulium laser vaporization, bipolar TURP, and plasma vaporization (TLP) represents an efficient and durable management option for BPH patients with low a complication rate at 5-years follow-up. Further validation of this surgical technique in larger patient cohorts, multicentric studies, and longer follow-up is required.

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