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Surgery in Motion

Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction

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Abstract

Background: In the algorithm of treatment of benign prostatic obstruction (BPO), the shift from medical therapy to surgery is steep in terms of invasiveness. Recently, a lively interest has developed on alternative micro-invasive options. Transperineal interstitial laser ablation (TPLA) was recently proposed for BPO treatment.
Objective: This work aims to illustrate feasibility, efficacy and safety profile of TPLA in BPO treatment.
Design, Setting, and Participants: We prospectively analyzed the results of TPLA performed between September 2018 and March 2019 for LUTS due to BPO, in men with prostate volume <100 ml.
Surgical Procedure: TPLA was performed in OR, under local anesthesia, using Soracte Lite-EchoLaserX4. Diode laser light is conveyed through 300 μm optical fibers introduced transperineally by 21 Ga needles and placed at a security distance from urethra and bladder neck. EchoLaser Smart Interface eases needle positioning and increases the safety.
Measurements: The primary endpoint was the variation of Qmax and IPSS at 1, 3 and 6 months. We also assessed the ejaculatory function and recorded complications. These outcomes were further investigated at 12 months by phone call.
Results and Limitations: 21 men with prostate volume of 43.5 ± 8.5 ml underwent TPLA. All were discharged after 24 h, keeping the transurethral catheter for 8.7 ± 2.5d. At one month all patients but one discontinued medical therapy, showing significant advantage in Qmax ($+3.4 \pm 5.7$ ml/s; $p < 0.01$) and IPSS (-5.6 ± 7.0; $p < 0.01$). Functional results were still progressing at 6 months, with Qmax ($+4.7 \pm 6.0$ ml/s; $p < 0.01$) and IPSS improvement (-13.1 ± 4.7; $p < 0.01$). The ejaculatory function was preserved as the MSHQ-EjD increased ($p < 0.05$). The only complication was a prostatic abscess, treated with transperineal drainage and antibiotic.
Conclusions: TPLA is a micro-invasive treatment for BPO showing good functional and safety outcomes.
Patient Summary: This work illustrates the results of TPLA to treat LUTS due to BPO, showing high efficacy, preservation of the ejaculation, and low complication rate.

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1. Introduction

The link between the obstruction due to benign prostatic hyperplasia (BPH) (benign prostatic obstruction, BPO) and lower urinary tract symptoms (LUTS) is well known and the ethiopatogenetic factor is the target of all the therapeutic options now available.

The treatment of LUTS is justified by the related worsening of quality of life. On the other hand, it is paramount to consider that the natural history of the pathology is progressive and can cause, if untreated, major complications. Thus, the ideal therapy should relieve the complaints of BPO, while interrupting the progressive damage to the lower and upper urinary tract, without causing side effects.

Several attempts were made in the last decades in order to set mininvasive treatments between medical therapy and surgery. Thermotherapy [1] and transurethral needle ablation (TUNA) [2] are probably the best known, and had some clinical diffusion in the past. Recently, Rezume [3–5], i-Tind [6], Uro-lift [7] and prostatic artery embolization (PAE) [8] tried to fill the therapeutic gap, but the literature is still scant and inconclusive.

Transperineal interstitial laser ablation (TPLA) is probably the newest option, and only one study with medium term follow-up was published, showing promising results in line with the other mininvasive options [9]. Moreover, an international registry is ongoing to support, with evidence based data, objective outcomes on symptom relief and urodynamic improvement.

The aims of the present study are to describe a standardized technique of TPLA in patients with LUTS due to BPH, and report the perioperative and functional outcomes obtained in our preliminary experience with this technique.

2. Patients and methods

2.1. Study population

After written informed consent, we prospectively analyzed the clinical data of patients who underwent transperineal laser ablation of prostate between September 2018 and March 2019 (to ensure a minimum 1-yr follow-up) at our institution. The indication for TPLA was the presence of moderate to severe LUTS due to BPO, defined as an International Prostate Symptom Score (IPSS) score $\geq$ 12, in patients aged from 40 to 90 years, with prostate volume up to 100 ml and lack of efficacy, intolerance or poor compliance to medical therapies. Men with previous surgical treatment for BPH were excluded from our analysis, as well as patients having indwelling catheter or performing intermittent catheterization, bladder stones, detrusor acontractility or severe hypocontractility (bladder contractility index $<$50), urethral strictures, neurogenic bladder dysfunctions, previous diagnosis of bladder cancer, previous diagnosis or clinical suspect of prostate cancer.

2.2. Surgical technique

Only one surgeon is needed for the procedure. The assistance of a clinical specialist is recommended for the first cases to set up the laser, as well as the steps of the technique.

2.2.1. Technical equipment

TPLA is a micro-invasive procedure needing a biplanar TRUS probe (in our setting Esaote TRT33 probe, Esaote MyLab Class C) and a diode laser generator, with a 1064 nm wavelength, having four independent channels for simultaneous firing (Echolaser XVG system also known as SoracteLite system; Elesta s.r.l., Calenzano, Italy).

The laser light is conveyed from the source to the tissue through 300 μm caliber flat-tipped optical fibers introduced percutaneously through 21 G Chiba needles. The energy delivered into the tissue produces a lesion of ellipsoid shape, one third of which is located behind the tip of the fiber and 2/3 in front of it. The longitudinal diameter of the ellipsoid is 22.5 mm, the transversal diameter 16 mm (Fig. 1). The diode laser wavelength of 1064 nm has an excellent tissue interaction, with low radiation absorption and high tissue penetration, and releases energy to the target tissue as heat. The consequence is irreversible necrosis of the cells inside the limits exposed, as a result of combined action of local heating and exposure time.

2.2.2. Preoperative assessments, patient positioning and anesthesia

Before the procedure, routine blood exams were performed, including standard coagulation tests. The following symptom questionnaires were administered: IPSS, International Index of Erectile Function (IIEF5), Male Sexual Health Questionnaire – Ejaculatory Dysfunction short form (MSHQ-EjD). Complete functional data including uroflowmetry and urodynamics (if clinically required) and TRUS prostate volume were recorded. Antibiotic prophylaxis was administered 1 hour before and for 7 days after the treatment session. In standard cases, neither any thromboprophylaxis nor single antiplatelet therapy suspension were required.

For the procedure the patient lays in the lithotomy position. A three-way 18-F Foley catheter was inserted to permit cooling irrigation with room temperature saline during the whole lasing period. Urethral cooling aids to prevent injuries to urethral wall. The procedure was performed under conscious sedation and with local anesthesia of the perineal region and periprostatic anesthesia using lidocaine 10 mg/mL (20 ml).

2.2.3. Planning of the procedure

The planning of the procedure was carried out under US guidance. One or two 21 G introducer needles for each lobe were inserted in the adenoma and placed on planes as parallel as possible to the longitudinal plane of the prostate (Fig. 2). In order to ease the insertion of the needles, the transrectal US biplanar probe is combined with a multichannel needle applicator, with a dedicated software displaying a grid overlaying the US image. Every line of

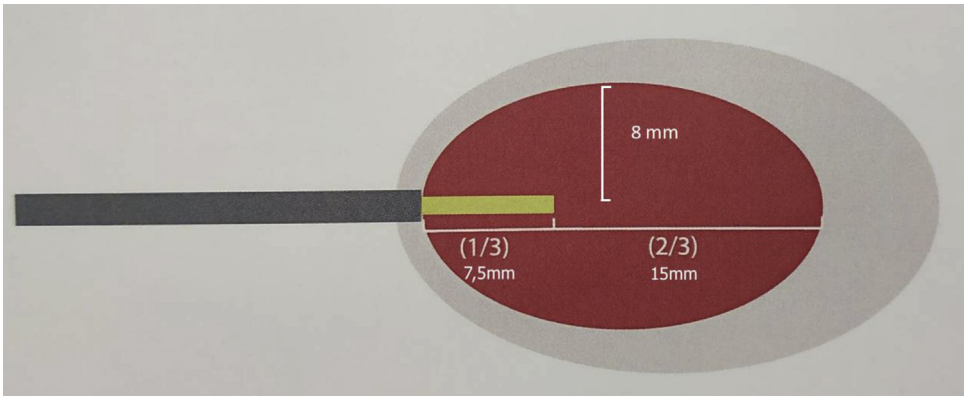

Fig. 1 – Interstitial laser coagulative necrosis area. The laser light produces an area of coagulative necrosis of ellipsoidal shape that has a longitudinal diameter of 22,5 mm and a transversal diameter of 16 mm and is localized for one third behind the tip of the fiber, and for two-thirds in front of it.

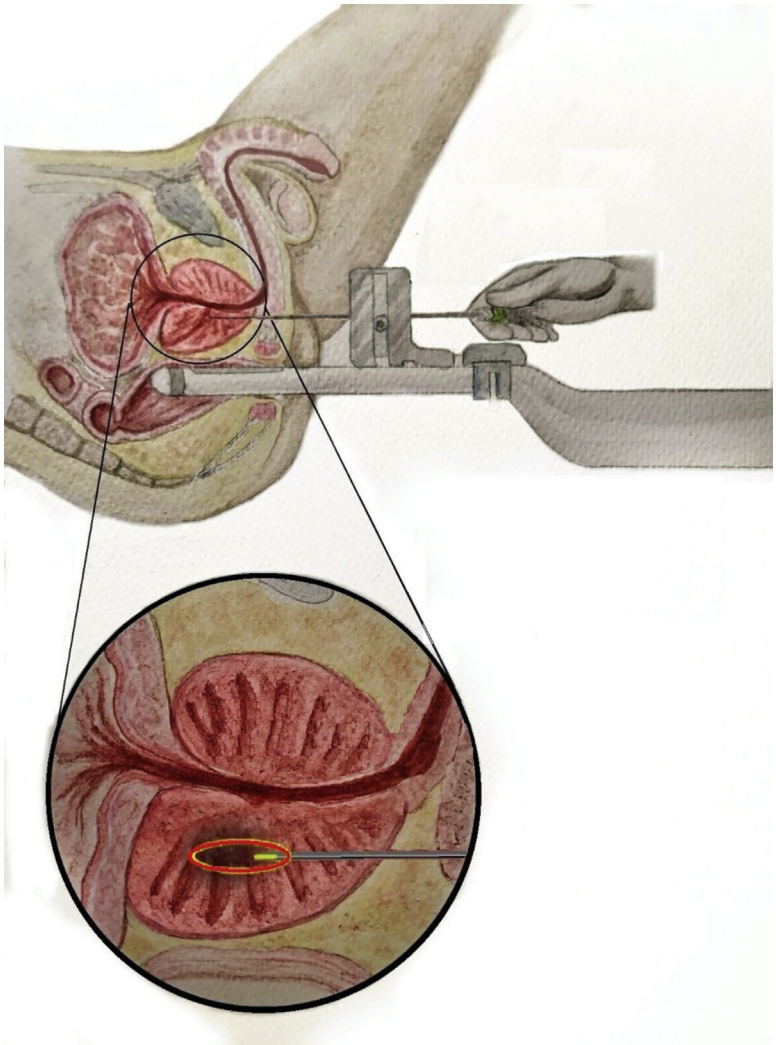

Fig. 2 – Patient position and needle positioning. The patient lays in the lithotomy position. One or two 21 G introducer needles for each lobe were inserted in the adenoma and one optical fiber per needle is placed.

the grid corresponds to a needle access of the multi-applicator system (Fig. 3).

Subsequently, one 300 μm bare flat-tip optical laser fiber per needle was introduced and advanced up to the needle tip. The surgeon needs to keep in mind that 5 mm of the fiber tip stick out from the tip of the needle. The security distance of the needle from the urethral lumen wall and the prostatic capsule should be 8 mm, while the distance between the tip of the fiber and the bladder neck should be at least 15 mm (Fig. 4). The integrate Echolaser smart interface aids to

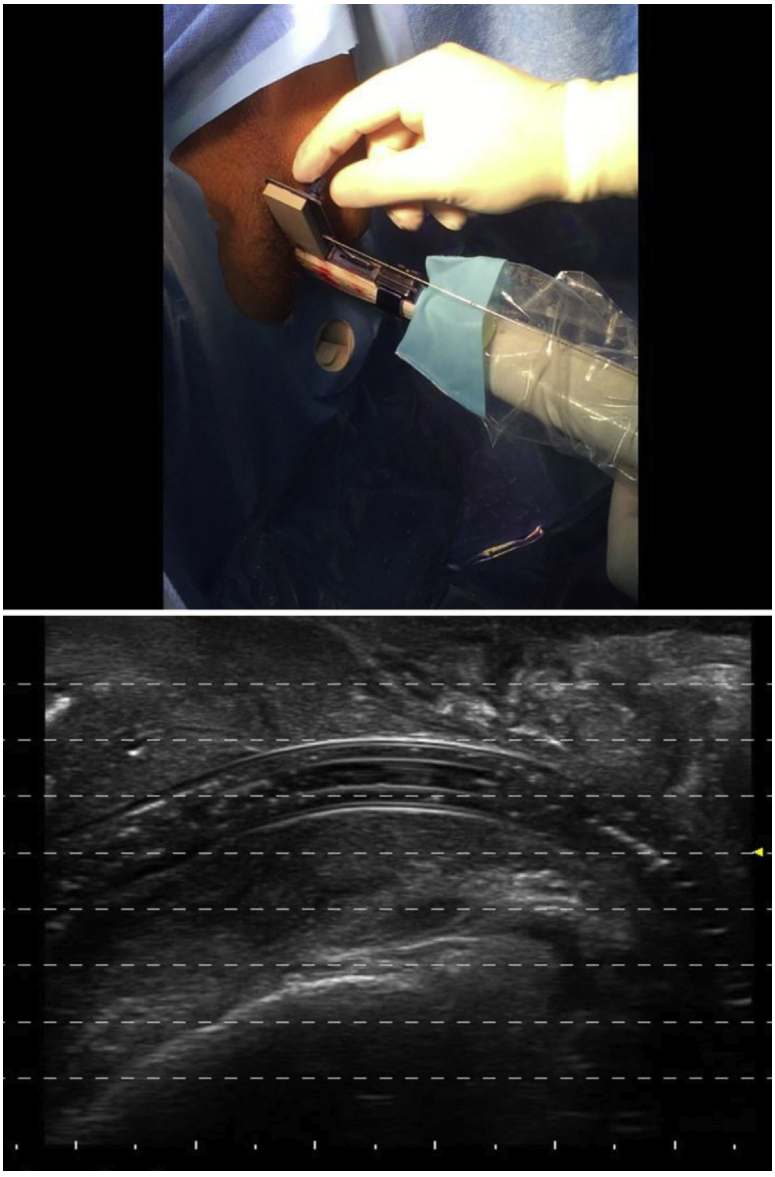

Fig. 3 – Multi-channel needle applicator. To ease the insertion of the needles, the transrectal US biplanar probe is combined with a multi-channel needle applicator, with a dedicated software displaying a grid overlaying the US image.

improve the exact and safe needle position and safety of needle positioning (Fig. 5). The optical fibers are then connected with the continuous wave diode laser source.

2.2.4. *Lasing protocol*

TPLA was performed with a fixed lasing protocol, consisting in delivering exactly 1800 J of energy in every side of firing. The tailoring of the procedure consisted in modifying the number and the site of applications per lobe, depending on the volume of the transition zone of the gland.

After the check of security distances, the lasing began delivering a starting power of 4.5 W, reduced to 3.5 W after 1-2 minutes, when bubbles of vaporized tissue became visible at ultrasound.

At least one fiber per lateral lobe was placed, inserting the second fiber if it did not impair the respect of security distances (according to our experience, in prostate larger than 55-60 ml), with a minimum distance of 10-15 mm from each other. If a median lobe was present, another needle was placed for its ablation. When the prostate mainly developed in a longitudinal direction, the pull back of the fibers allowed the ablation of the distal half of the gland. We recorded operative time, number of fibers used and any intraoperative complication.

2.3. *Postoperative management and follow-up*

Patients were discharged on first postoperative day, with indwelling transurethral catheter which was kept in place for 7 days and then removed after void trial. In case of retention, it was kept for 7 days more. Oral fluoroquinolones or cephalosporines were given for 5 days, along with prednisone 25 mg for 15 days with subsequent tapering of the dose and bromelain tablets for anti-inflammatory and

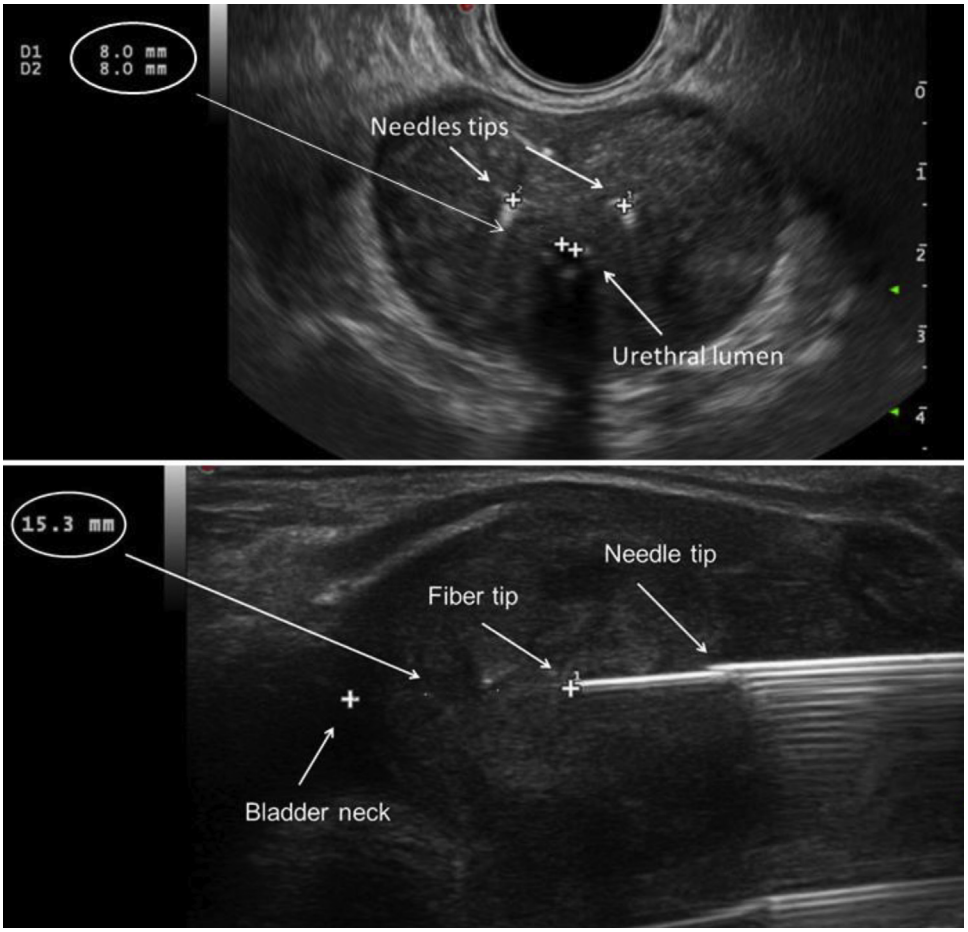

Fig. 4 – Security distances. The security distance of the needle from the urethral lumen wall and the prostatic capsule should be 8 mm, while the distance between the tip of the fiber and the bladder neck should be at least 15 mm.

anti-edema effects. The withdrawal of all oral medications for BPH was planned on the 30th postoperative day.

The follow-up schedule consisted in visit, uroflowmetry and administration of questionnaires at 1, 3 and 6 months after surgery. At 12 months, a telephone interview was performed in order to assess the persistency of improvement in symptoms and record any further complications according to Clavien-Dindo classification [10].

2.4. Surgeons' experience

In our experience, two surgeons performed the procedures, both skilled in perineal and transrectal ultrasound (TRUS)-guided procedures. None of them had performed TPLA before.

2.5. Statistical analysis

The statistical analysis was carried out with the software Stata MP15 (StataCorp LLC, College Station, TX, USA). Perioperative data were analyzed using descriptive statistics: frequencies were expressed as percentages while continuous variable were presented as medians and interquartile ranges. Qmax and IPSS, as well as the other continue variables, were compared between two times by Wilcoxon test; the categorical variables were compared between times by means of the Fisher's exact test. We considered a two-sided p-value of <0.05 as statistically significant.

3. Results

3.1. Patients characteristics

Twenty-one patients underwent transperineal laser ablation of the prostate. Preoperative characteristics are summarized in Table 1. The median age was 62 years (IQ range 54 - 69), with a median prostate volume of 40 ml (40 - 50). The vast majority had a long story of moderate to severe LUTS, having a mean IPSS 18.3 ± 3.9 and QoL score 4.1 ± 1.0. Sixteen patients had received treatment with at least one oral medication (14 with alpha-blockers, 10 with 5-alpha reductase inhibitors and 8 were in combination therapy) and five men underwent TPLA after refusing medical therapy. All patients but two declared a normal erectile function before treatment (mean IIEF 17.9 ± 6.9), whilst most of patients had impaired ejaculatory function, mean MSHQ-EjD being 5.7 ± 4.5 points.

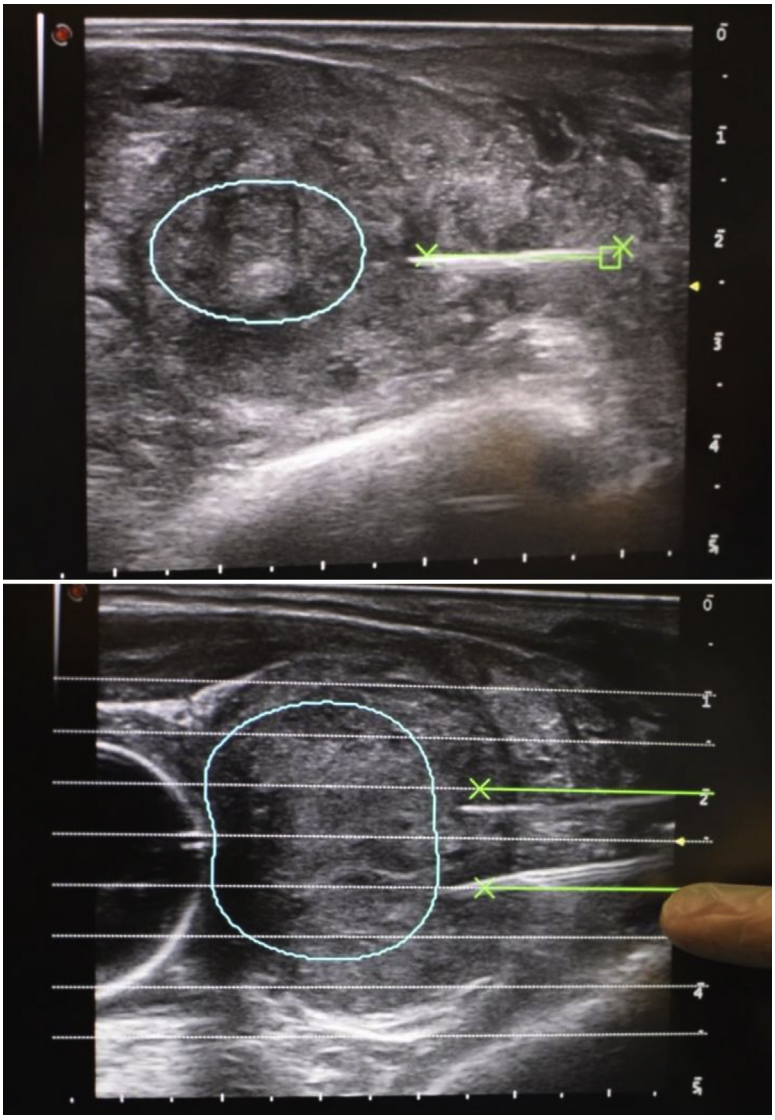

Fig. 5 – Echolaser smart interface. The integrate Echolaser smart interface aids to improve the exact and safe needle position and safety of needle positioning.

3.2. *Perioperative outcomes*

The mean operative time was 36.0 ± 9.5 min, using 2 laser fibers in 18 pts, 3 in 2 pts (of them one for the presence of a median lobe and one for an asymmetric prostate with predominant development of one lobe). In one patient two needles per lobe were placed, owing to the larger volume of the gland.

Table 1 – Patients characteristics.

Age (y); median (interquartile range)	62 (54-69)
BMI; median (interquartile range)	27 (25-28)
CCI; median (interquartile range)	2(1-2)
Preoperative PSA (ng/mL); median (interquartile range)	2.0 (1.33-3.0)
Prostate volume (mL); median (interquartile range)	40 (40-50)
Alpha-blockers (%)	14 (66.7)
5-ARI (%)	10 (47.6)
Combined therapy (%)	8 (38.1)

No intraoperative complication was recorded. In 19/21 pts catheter was removed as scheduled at seventh postoperative day. Only two patients needed transurethral catheter for a week more. Table 2 illustrates complete perioperative outcomes.

3.3. *Functional outcomes*

Functional outcomes at any time of the follow-up are summarized in Table 3, while difference compared to baseline values are reported in Table 4. After one month, all patients stopped oral medications ($p < 0.05$), except one,

Table 2 – Operative data.

Operative time (min); mean ± SD (range)	36.0 ± 9.5 (25-60)
Postoperative lenght of stay (h); mean ± SD (range)	20.8 ± 3.6 (14 - 28)
Catheterization time (d); mean ± SD (range)	8.7 ± 2.5 (5-14)
N. of fibres; mean ± SD (range)	2.2 ± 0.5 (2-4)

Table 3 – Functional outcomes.

	Preoperative	1 month	3 months	6 months
Qmax (ml/s); mean ± SD (range)	9.2 ± 3.4 (4.0-16.0)	12.1 ± 6.4 (5.0-33.7)	13.3 ± 6.7 (3.0-32.0)	13.9 ± 6.2 (5.0-32.0)
PVR (ml); mean ± SD (range)	81.8 ± 62.6 (0-190)	37.4 ± 25.7 (0-90)	18.7 ± 21.2 (0-70)	14.0 ± 16.7 (0-50)
IPSS; mean ± SD (range)	18.3 ± 3.9 (14-27)	12.0 ± 5.6 (2-23)	8.3 ± 3.8 (3-17)	6.1 ± 2.6 (3-12)
QoL; mean ± SD (range)	4.1 ± 1.0 (2-6)	2.4 ± 1.6 (0-6)	1.4 ± 0.9 (0-3)	1.7 ± 0.8 (1-3)
IIEF-5; mean ± SD (range)	17.8 ± 6.6 (1-25)	17.4 ± 5.0 (1-23)	17.7 ± 6.7 (2-25)	18.3 ± 5.7 (3-25)
MSHQ-EjD 3 item; mean ± SD (range)	5.7 ± 4.5 (1-16)	9.6 ± 4.1 (4-16)	6.8 ± 3.5 (3-13)	8.6 ± 3.1 (5-13)
MSHQ-EjD bother; mean ± SD (range)	1.2 ± 0.5 (1-2)	1.9 ± 1.2 (1-5)	1.3 ± 0.4 (1-2)	1.4 ± 0.8 (1-4)
PSA (ng/mL); mean ± SD (range)	2.0 ± 1.1 (0.4-4.4)	3.0 ± 1.9 (1-7.8)	1.7 ± 0.8 (0.8-3.8)	1.7 ± 0.8 (0.8-4.1)

who did not withdraw alpha-blockers due to poor urine flow and fear of acute urinary retention. However, he was no longer taking the drug at three months follow-up.

Table 4 – Functional outcomes.

	Δ T1-T0	p	Δ T2-T0	p	Δ T3-T0	p
Qmax (ml/s); mean ± SD (range)	3.4 ± 5.7 (-7.0 ; 21.9)	<0.01	4.1 ± 5.7 (-6.0 ; 20.2)	<0.01	4.7 ± 6.0 (-6.0 ; 20.2)	<0.01
PVR (ml); mean ± SD (range)	-52.8 ± 71.4 (-200 ; 70)	>0.05	-73.6 ± 75.1 (-230 ; 50)	<0.01	-78.3 ± 77.4 (-230 ; 50)	<0.01
IPSS; mean ± SD (range)	-5.6 ± 7.0 (-25 ; 6)	<0.01	-10.9 ± 5.3 (-21 ; -3)	<0.01	-13.1 ± 4.7 (-22 ; -6)	<0.01
QoL; mean ± SD (range)	-1.5 ± 1.3 (-5 ; 0)	<0.01	-2.7 ± 1.2 (-4 ; -1)	<0.01	-2.4 ± 1.3 (-5 ; 0)	<0.01
IIEF-5; mean ± SD (range)	-0.3 ± 4.6 (-9 ; 6)	>0.05	0.9 ± 4.8 (-8 ; 7)	>0.05	1.6 ± 5.9 (-8 ; 10)	>0.05
MSHQ-EjD 3 item; mean ± SD (range)	3.8 ± 4.4 (-3 ; 13)	<0.01	2.8 ± 3.3 (-2 ; 11)	<0.01	2.9 ± 3.6 (-3 ; 11)	<0.01
MSHQ-EjD bother; mean ± SD (range)	0.5 ± 1.0 (0 ; 4)	<0.01	0.1 ± 0.6 (-1 ; 1)	>0.05	0.2 ± 0.9 (-1 ; 1)	>0.05
PSA (ng/mL); mean ± SD (range)	-0.9 ± 2.2 (-1.9 ; 5.8)	>0.05	-0.2 ± 1.1 (-2.5 ; 1.8)	>0.05	-0.2 ± 1.3 (-2.7 ; 2.1)	>0.05

The first follow-up uroflowmetry showed mean Qmax 12.1 ± 6.4 ml/s and post-void residual volume (PVR) 37.4 ± 25.7 ml, with an improvement from the baseline values respectively of 3.4 ± 5.7 ml/s ($p < 0.01$) and -52.8 ± 71.4 ml ($p > 0.05$). This improvement was persistent at 3 and 6 months and became significant with regard to PVR as well.

Mean score in IPSS was significantly improved by -5.6 ± 7.0 within 1 month ($p < 0.01$) and even more at 3 (-10.9 ± 5.3; $p < 0.01$) and 6 months (-13.1 ± 4.7; $p < 0.01$), with simultaneous improvement in quality of life score ($p < 0.01$).

No change in IIEF5 questionnaire was reported after the procedure. Ejaculatory function was not only preserved, but also improved as showed by a significant increase in MSHQ-EjD mean score at all the follow-up visits. Nevertheless, the bother item of MSHQ-EjD showed an increase in discomfort during the ejaculation at the first month (+0.5 ± 1.0; $p < 0.01$), no longer observed at 3 and 6 months.

The only Clavien-Dindo 3 complication occurred within the first 30 days was a prostatic abscess, treated with percutaneous drainage and antibiotic therapy for 7 days. No other complications, intraoperative or during the follow-up, were recorded.

So far, the median follow-up have been 16 months; at the 12th month telephone follow-up no patients complained loss of efficacy and satisfaction, or complications.

4. Discussion

TPLA has shown to be efficient in symptoms relief and urodynamic improvement, and the results were durable at one year. Symptoms relief is well documented by the reduction of IPSS score, statistically significant at one month but even more evident at three and six months. This progressive improvement can be explained by inflammatory effect of lasing and coagulative necrosis, which can partially hinder the beneficial effects immediately after the procedure. The ejaculatory discomfort at 1 month, no longer recorded at successive follow-up, could be a consequence of the inflammatory response as well. For this reason, we included anti-inflammatory and anti-oedemigen therapy after the procedure in our protocol.

In the therapeutic algorithm actually codified, the first line treatment of BPO is medical therapy, preferably an association of alpha-blockers (AB) and inhibitors of 5-alpha reductase enzyme (5ARI). ABs produce a mild symptom relief, without influencing the clinical progression of the disease. 5ARIs show a slow-onset, well documented reduction of the symptoms burden, interfering with clinical evolution of BPO (reduction in symptom progression and indication to surgery), in 4-5 years of follow-up. The combination of both medical options has a synergistic effect, but scanty evidences exist about longer follow-up [11]. Furthermore, worth of attention is that out of clinical trials the discontinuation rate is high, suggesting that in real life the clinical efficacy is less brilliant and the side effects, complications and interaction with other drugs more burdening than expected [12].

On the other side of therapeutic algorithm are invasive options. Laser enucleation overcomes open surgery for big prostates [13], while in case of traditional endoscopic surgery the clinical results of laser vaporization and TURP are very similar and the safety profiles not so different, except for the perioperative management of anticoagulant and antiplatelet drugs [14]. These procedures need general or spinal anaesthesia, can cause anejaculation/retrograde ejaculation, transient or sometimes permanent inconti-

nence (0.5-2% of cases). Moreover, data on sexual side effects are conflicting. Despite this, surgical treatment is mandatory in case of major complications of BPO (high PVR or indwelling catheter, sepsis, hydronephrosis and/or renal insufficiency, bladder damage). Thus, when the medical treatment fails, a thorough counselling of the patient is mandatory, for the aforementioned features of surgery.

The therapeutic efficacy of TPLA, even if tested in a small sample of patients, looks promising if compared to medical therapy and does not entail the heavy load of side effects that surgical options usually do. Notably, the ejaculatory function results improved after TPLA. This is a remarkable evidence, since it is in contrast with the ejaculatory disorders of medical treatment, which can be cause of discontinuation. Even surgery can be burdened by irreversible retrograde ejaculation/anejaculation. TPLA preserves bladder neck, as shown in the surgical technique video, which is the main anatomical structure deputed to the antegrade progression of seminal fluid. Dorschner et coll. have demonstrated the importance of musculus ejaculatorius in the preservation of antegrade ejaculation, and this has raised a plenty of surgical techniques to preserve it [15]. This structure, located distally at the veru montanum, is never addressed by the TPLA, which even justifies the 100% preservation of ejaculation observed in our case series.

The technique shown in the video is essentially similar to a transperineal prostate biopsywhich is a widespread diagnostic procedure. Furthermore, the help of a needle guide and an overlaying grid to US image are determinant tools lowering the difficulty index of the procedure. However, a learning curve still exists, influencing the time of the treatment. The estimated time in our series was 37.2 ± 9.9 min, but the range of the data was 25-60 min. The longest procedures are set among the first cases of our series. Even with these limitations, the operative time and the local anesthesia are those typical of an outpatient treatment.

The present work has the following limitations. Firstly, the absence of a control group did not allow a proper appraisal of the worth of TPLA compared with the other therapeutic options, both medical and surgical. Furthermore, a certain degree of heterogeneity exists among patients in terms of previous medical therapy. Nevertheless, this heterogeneity mirrors the variability of the clinical scenarios that characterize a real life setting and demonstrates that TPLA could be an option for different kinds of patients (men refusing or intolerant to oral drugs, patients with longer history of LUTS in single therapy or men that already experienced the best possible combination, patients unwilling or unfit for surgery). Finally, the small sample size is another drawback of this series.

5. Conclusion

TPLA is a simple, feasible procedure able to produce symptomatic and urodynamic improvements durable at one year. The reduced invasiveness, the outpatient vocation and the peculiar ability to preserve ejaculation candidates the procedure to become an intermediate option between medical treatment and surgery.

Gaetano De Rienzo had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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***Data Sharing Policy*:** Data are available for bona fide researchers who request it from the authors.

CRediT authorship contribution statement

Gaetano De Rienzo: Conceptualization, Methodology, Validation, Investigation, Writing - original draft. **Alfonso Lorusso:** Conceptualization, Investigation, Writing - review & editing. **Paolo Minafra:** Formal analysis, Investigation, Data curation, Writing - original draft, Visualization. **Marcello Zingarelli:** Investigation. **Giuseppe Papapicco:** Visualization. **Giuseppe Lucarelli:** Writing - review & editing. **Michele Battaglia:** Supervision. **Pasquale Ditonno:** Investigation, Writing - review & editing, Supervision, Project administration.

Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at doi:https://doi.org/10.1016/j.eururo.2020.08.018 and via www.europeanurology.com.

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