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TOPIC PAPER

A prospective multicenter randomized comparison between Holmium Laser Enucleation of the Prostate (HoLEP) and Thulium Laser Enucleation of the Prostate (ThuLEP)

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Abstract

Purpose To compare intra and perioperative parameters between HoLEP and ThuLEP in the treatment of benign prostatic hyperplasia and to evaluate clinical and functional outcomes of the two procedures with a 12-month follow-up.

Methods A prospective randomized study was performed on 236 consecutive patients who underwent ThuLEP ($n=115$), or HoLEP ($n=121$) in three different centers. Intra and perioperative parameters were analyzed: operative time, enucleated tissue weight, irrigation volume, blood loss, catheterization time, hospital stay and complications. Patients were evaluated preoperatively and 3 and 12 months postoperatively with the international prostate symptom score (IPSS), the quality of life (QoL) score, post-void residual volume (PVR), PSA and maximum flow rate (Q_{max}).

Results Preoperative variables in each study arm did not show any significant difference. Compared to HoLEP, ThuLEP showed similar operative time (63.69 vs 71.66 min, $p=0.245$), enucleated tissue weight (48.84 vs 51.13 g, $p=0.321$), catheterization time (1.9 vs 2.0 days, $p=0.450$) and hospital stay (2.2 vs 2.8 days, $p=0.216$), but resulted in less haemoglobin decrease (0.45 vs 2.77 g/dL, $p=0.005$). HoLEP presented a significantly higher number of patients with postoperative acute urinary retention and stress incontinence. No significant differences were found in PSA, Q_{max}, PVR, IPSS and QoL score during follow-up.

Conclusion ThuLEP and HoLEP both relieved lower urinary tract symptoms equally, with high efficacy and safety. ThuLEP detemined reduced blood loss and early postoperative complications. Catheterization time, enucleated tissue, hospital stay, operative time and follow-up parameters did not show any significant difference.

Keywords Benign prostatic hyperplasia · Lower urinary tract symptoms · Endoscopic · Enucleation of the prostate · Endourology · Holmium · Thulium · Laser · HoLEP · ThuLEP

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Introduction

Benign prostatic hyperplasia (BPH) is a common cause of lower urinary tract symptoms (LUTS) in aging men [1]. Approximately 50% of men during the 7th decade and 80% during 9th decade present LUTS. Accepted medical treatments for moderate to severe LUTS are alpha-blockers and 5-alpha-reductase inhibitors, in single, or combination therapy, depending on prostate volume. A surgical approach is required in case of medical treatment failure, recurrent urinary retention, urinary infections, co-existence of bladder stones, or deterioration in kidney function [2]. In the past, the choice between classical surgical treatments mainly depended on prostate size: transurethral incision of the prostate for prostates < 30 cc, mono or bipolar transurethral resection of prostate (TURP), for prostates between 30–80 cc and open prostatectomy (OP) if > 80 cc.

For decades TURP has been the standard of care in the treatment of prostates < 80 cc. The extensive amount of literature confirming its efficacy, with long term follow-up, still makes TURP the most employed surgical treatment for BPH and the treatment of reference when evaluating new techniques. Over the past 3 decades lasers have become increasingly popular amongst urologists in the endoscopic treatment of BPH, trying to find an alternative to TURP, due to its complications, such as bleeding, voiding dysfunction and transurethral resection syndrome (TURS) and to its limitation in treating large prostates [3].

Several different lasers have been developed: neodimium, diode, potassium-titanyl-phosphate (KTP), lithium-triborate (LBO), holmium and thulium. These have different interactions with human tissues, according to their wavelength and output and can be used to perform resection, vaporisation, or enucleation of the prostate depending on the energy source employed.

The neodimium laser has been widely abandoned due to its low absoprtion coefficient, which causes deep penetration in tissues and consequently, long lasting postoperative irritative symptoms. The diode lasers, instead, have different wavelengths and therefore, different penetration depths. They can be employed for vaporisation, or enucleation of the prostatic tissue and have proved to be comparable to TURP in relieving LUTS, with good haemostatic capacity, but there are few randomized controlled trials with a long term follow-up. Further studies are needed to assess long term results [4, 5]. Photoselective vaporization of the prostate, using the KTP or LBO lasers (which have a 532 nm wavelength and are absorbed by haemoglobin), has also shown to be similar to TURP in improving micturition and quality of life (QoL). It allows reduced blood loss, complications (such as capsular perforation and TURS), catheterisation time and hospital stay [6]. Its main drawbacks are disuria, re-intervention rate and operating time, but, most importantly, the lack of a pathological specimen for the diagnosis of otherwise undetected prostate cancer.

Laser endoscopic enucleation of the prostate (EEP) techniques, which started with the introduction of the holmium laser and expanded with the advent of the thulium laser, mimick an OP, combining the use of the laser with the tip of the resectoscope to enucleate the prostatic adenoma. These are today the most demanded surgical techniques and compared to vaporizing techniques, they allow retrieval of tissue for pathological analysis. The holmium and thulium lasers have similar wavelengths (2.1 and 2.0 microns respectively) and a high absorption coefficient in water, allowing immediate vaporization of water-containing tissues. The holmium laser works in a pulsed mode and has a penetration depth of 0.4–0.5 mm, whereas the thulium laser has a continous wave output and a 0.25 mm penetration depth. Both lasers can be used for resecting, vaporizing and enucleating the prostatic tissue [4, 5].

Holmium Laser Enucleation of the Prostate (HoLEP) was introduced in 1998 by Gilling et al. [7]. Several studies have shown that it is equivalent to TURP and OP in relieving LUTS and improving QoL, with the advantage of reduced blood loss, complications, catheterisation time, hospital stay and and re-intervention rate. Moreover, it is size indipendent, allowing to treat large prostates [8–11]. The only disadvantage compared to TURP is a longer learning curve [12, 13].

Thulium Laser Enucleation of the Prostate (ThuLEP) was introduced in 2010 by Hermann et al. [14]. It is performed in several urology departments worldwide. Like HoLEP, it has shown excellent efficacy in improving patients' micturition and QoL, with the same advantages over TURP and OP [15–18]. It is also a size indipendent technique, allowing to treat large prostates [19]. This has become an important variable to take into account when choosing which laser system to employ in a urology department, as one laser system could allow to treat prostates of all sizes. Moreover, EAU guidelines reccomend to perform OP for prostates larger than 80 cc only in the absence of an EEP system [20]. An advantage of ThuLEP over HoLEP is its shorter learning curve [21].

Despite being used for several years now, there is still a lack of direct comparisons between these two techniques and the question remains: is one better than the other? To help fill this gap in the literature and trying to give an answer to this question, we decided to perform a multicenter, prospective, randomized study comparing the two procedures.

Materials and methods

After obtaining ethical committee approval (number ASLMI2 237/2014), a multicenter, randomized study was carried out between June 2015 and June 2018. Three different centers were involved: the urology departments of the ASST-Valle Olona, Busto Arsizio Hospital (Busto Arsizio, VA, Italy), of the San Carlo di Nancy Hospital (Rome, Italy) and of the Clinique Saint Augustine (Bordeaux, France).

Patient selection

During the study period, 564 patients suffering from BPH-related LUTS, with indication to undergo surgery, were assessed for eligibility. Inclusion criteria were: IPSS ≥ 8; weak or no response to previous medical treatments; $Q_{max} < 15$ ml/sec; acute urinary retention. Exclusion criteria were: history of prostatic surgery; prostate or bladder cancer suspicion/history; documented/supspected neurogenic bladder; urethral stricture; anticoagulant/antiaggregant therapy; concurrent bladder stones; patients unfit for surgery; failure to sign the informed consent.

278 patients were excluded; 286 patients were finally included and randomly assigned 1:1 to undergo either HoLEP (group A) or ThuLEP (group B) (Fig. 1).

Patients were assessed preoperatively with a physical and digital transrectal examination, uroflowmetry to assess flow peak (Q_{max}), transrectal ultrasonography (TRUS) to assess prostate volume, suprapubic ultrasonography to assess post-void residual volume (PVR) and prostate specific antigent (PSA) levels. To assess patients' symptoms and quality of life, two validated questionnaires were employed: the International Prostate Symptom Score (IPSS) and the QoL score. Operative time, irrigation volume, enucleated tissue weight, catheterisation time, hospital stay and haemoglobin drop (on postoperative day^{-1}) were compared. We also performed a 3 and 12-month follow-up, during which IPSS, QoL score, Q_{max}, PSA and PVR were re-evaluated.

22 patients in group A and 28 patients in group B were excluded from the final analysis either because lost to follow-up, or due to discontinued intervention, because of equipment malfunction, in which case TURP was used to finish the procedure.

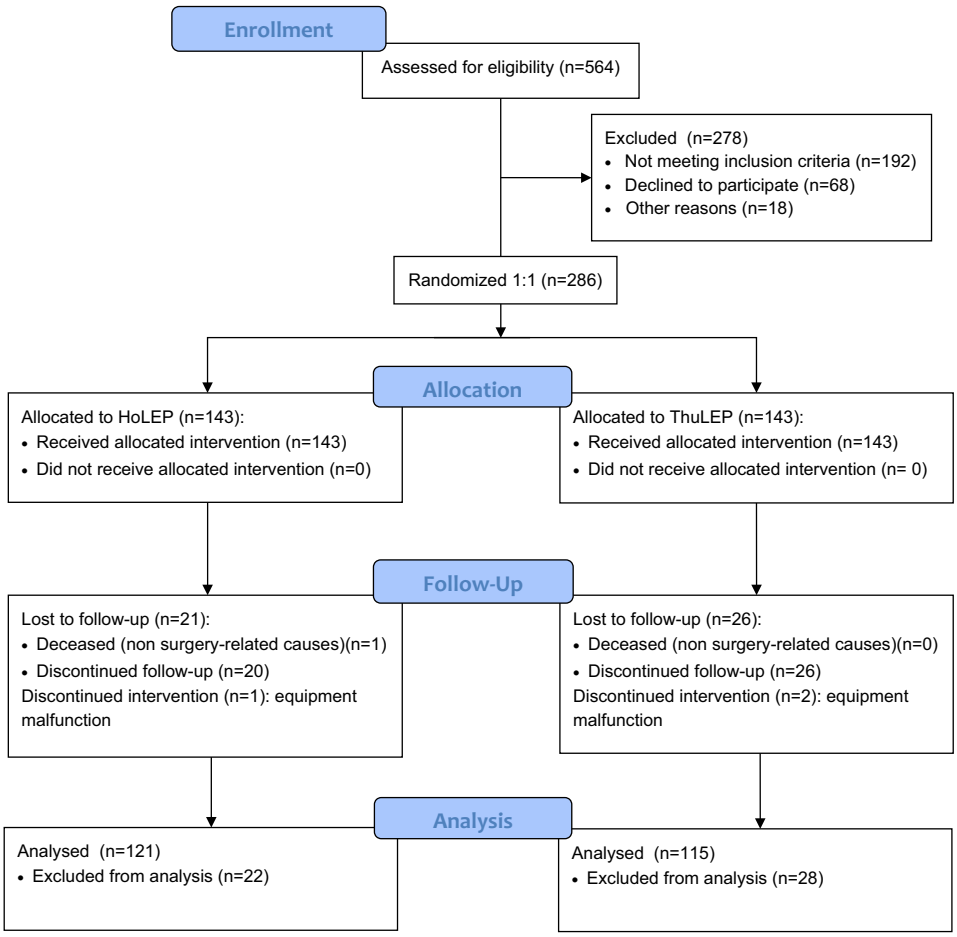

Fig. 1 CONSORT (consolidated standards of reporting trials) flowchart for study participants

HoLEP and ThuLEP: equipment and techniques

The 100 W-Cyber-Ho laser generator (Quanta System, Samarate, Italy), with a 550 µm fiber and a 27 Fr resectoscope sheath were used during the HoLEP procedures. Energy settings were 2 J, 40 Hz for cutting and 0.4 J, 40 Hz for coagulation.

The 200 W-Cyber-TM laser generator (Quanta System, Samarate, Italy), with an 800 µm fiber and a 27 Fr resectoscope sheath were used during ThuLEP procedures. Energy settings were 120 Watts for cutting and 35 W for coagulation.

Morcellation was performed with the Piranha morcellator (Richard Wolf, Knittlingen, Germany).

All procedures were performed by one surgeon per center, with a previous experience of at least 500 cases (GB, JBR and PB), who carried out both HoLEP and ThuLEP procedures in each center.

Each procedure started with a preliminary cistoscopy, then, a three lobe enucleating technique was performed for both HoLEP and ThuLEP, similarly to previously described techniques [7, 14].

Statistical analysis

Simple Block Randomization was obtained with the Adaptative Randomization software (University of Texas) to reach a good number balance between the two groups. To achieve good allocation concealment a centralized service to rule all the participating centers was used. To avoid any outcome bias, participants blinding was ensured for all the hospitalization (they did not know which laser was used for their enucleation) and data were never analyzed by one of the operating surgeons.

Statistical analysis was carried out to assess patients data and outcomes. All of the reported p values were obtained with the two-sided exact method at the conventional 5% significance level. Data were analyzed with the April 2016 by R software v.3.2.3 (R Foundation for Statistical Computing, Vienna, Austria), according to previously published guidelines for the reporting of statistics [22]. We calculated the sample size with a confidence level of 95% and a confidence interval of 5%.

Results

236 patients were finally analyzed: 121 were assigned to group A and 115 to group B. Demographic characteristics and pre-operative parameters of the patients are summarized in Table 1. No significant preoperative differences were found between the two groups.

HoLEP and ThuLEP presented similar operative time, enucleated tissue weight, catheterization time, irrigation volume and hospital stay. Whereas, haemoglobin drop was significantly lower in the ThuLEP group (Table 2).

Overall complications in the two groups during follow-up are listed in Table 3: a higher number of patients in group A required blood transfusions, presented acute urinary retention (AUR) after catheter removal and stress incontinence; there was one case of bladder injury during HoLEP, which occured during morcellation.

At 3 and 12 months follow-up, the procedures did not demonstrate significant differences in terms of Q_{max}, PVR, IPSS, PSA and QoL score (Table 4).

Discussion

HoLEP and ThuLEP are the two most employed laser EEP techniques in the treatment of BPH. A consistent body of literature has proved that they are both safe and effective alternatives to TURP and OP and allow reduced complications and morbidity [23, 24].

The physical properties of the holmium and thulium lasers make them both ideal for incising, vaporizing and coagulating the prostatic tissue. The holmium laser has a 2.1 microns wavelength and a high absorption coefficient

Table 1 Demographic and preoperative clinical features

	Group A (HoLEP)	Group B (ThuLEP)	p value
Patients no.	121	115	0.45
Age (years) (mean ± SD)	69.5 ± 15.54	67.1 ± 17.83	0.12
Preoperative prostate volume (ml) (mean ± SD)	86.3 ± 46.7	90.2 ± 42.7	0.17
PSA (ng/ml) (mean ± SD)	2.9 ± 5.25	3.2 ± 4.14	0.31
Preoperative Haemoglobin (g/dl) (mean ± SD)	14.1 ± 3.98	13.9 ± 5.13	0.09
IPSS (mean ± SD)	17.9 ± 6.95	18.2 ± 7.31	0.16
Q_{max} (ml/sec) (mean ± SD)	8.2 ± 6.71	7.9 ± 8.05	0.15
PVR (ml) (mean ± SD)	90.4 ± 120.44	115.5 ± 130.54	0.24

PSA prostate specific antigen, *IPSS* international prostate symptom score; Q_{max} maximum flow rate; *QoL* quality of life score, *PVR* post-void residual volume

Table 2 Peri-operative findings

	Group A (HoLEP)	Group B (ThuLEP)	*p* value
Operative time (minutes) (mean ± SD)	71.66 ± 38.70	63.69 ± 41.44	0.245
Haemoglobin decrease on postoperative day^{-1} (g/dl) (mean ± SD)	2.77 ± 1.23	0.45 ± 1.78	**0.005**
Catheterization time (days) (mean ± SD)	2.0 ± 3.55	1.9 ± 2.81	0.45
Continuous irrigation volume (l) (mean ± SD)	33.2 ± 24.78	29.4 ± 24.22	0.234
Enucleated tissue weight (g) (mean ± SD)	51.13 ± 23.14	48.84 ± 18.23	0.321
Hospital stay (days) (mean ± SD)	2.8 ± 3.89	2.2 ± 4.05	0.316

The bold underlines the statistical significance evidence

Table 3 Postoperative complications

	Group A (no patients, %)	Group B (no patients, %)	*p* value
Blood transfusions	8 (6.6)	2 (1.7)	**0.03**
Post-voidal urinary retention	13 (10.7)	7 (6.1)	**0.04**
Stress incontinence	9 (7.4)	2 (1.7)	**0.03**
Urge incontinence	10 (8.2)	8 (6.9)	0.2
Urethral stricture	1 (0.8)	1 (0.8)	0.4
Bladder injury	1 (0.8)	0 (0)	0.8

Group A HoLEP, *Group B* ThuLEP

The bold underlines the statistical significance evidence

Table 4 Follow-up variables

	Group A (HoLEP)	Group B (ThuLEP)	*p* value
Q_{max} (ml/sec) (mean ± SD)			
3rd month	20.76 ± 9.78	25.87 ± 11.09	0.12
12th month	19.43 ± 12.56	26.12 ± 7.76	0.08
PVR (ml) (mean ± SD)			
3rd month	45.3 ± 25.16	50.9 ± 30.46	0.07
12th month	31.9 ± 20.35	42.1 ± 18.99	0.11
IPSS (mean ± SD)			
3rd month	6.12 ± 3.75	5.45 ± 6.88	0.16
12th month	7.34 ± 5.43	6.81 ± 4.92	0.21
QoL (mean ± SD)			
3rd month	44.2 ± 13.22	40.9 ± 15.22	0.13
12th month	45.6 ± 11.59	43.6 ± 12.49	0.17
PSA (ng/ml) (mean ± SD)			
3rd month	1.6 ± 2.13	1.1 ± 2.37	0.15
12th month	1.7 ± 2.45	1.3 ± 2.41	0.12

PSA prostate specific antigen, *IPSS* ınternational prostate symptom score, Q_{max} maximum flow rate, *QoL* quality of life score, *PVR* Post-void residual volume

in water, which allows immediate vaporization of water containing tissues and a shallow penetration in the prostatic tissue (0.4–0.5 mm). Dissipated heat ensures coagulation of small to intermediate-sized blood vessels, up to 2–3 mm. Its pulsed wave output is responsible for its tearing effect on the prostatic tissue and makes it also ideal for urinary stones lithotripsy. The thulium laser works in a continous manner, which allows a smoother and more precise cut; it has a slightly shorter wavelength (2.0 microns) and an even higher absorption coefficient in water, improving vaporization, haemostasis and reducing the penetration depth in the prostatic tissue to 0.25 mm [4, 5].

HoLEP and ThuLEP are both reccomended by EAU guidelines [20] and are employed in many urology departments worldwide. Despite being used for 22 and 10 years respectively, few direct comparative trials between the two have been performed and choosing one or the other laser system for a urology department can be challenging, as it is unclear if one is superior to the other.

The main limitations of the studies comparing HoLEP and ThuLEP are the heterogeneous study designs, the different techniques employed, the different energy and frequency settings of the lasers and the different machines and fibres employed. Moreover, one of the issues when comparing HoLEP with thulium laser enucleation, is that there are two slightly different techniques for thulium enucleation: ThuVEP [25] and ThuLEP [14]. These are almost indistinguishable: the former uses the laser applied in a continous mode to separate the adenoma from the capsule, whereas the latter combines the use of the laser with the tip of the resectoscope to enucleate the adenoma (similarly to HoLEP). This dualism can generate confusion, but to simplify things, considering the similarity of the two, they are often considered together as thulium enucleation of the prostate (ThuEP) techniques.

The first study comparing HoLEP and ThuLEP was performed in 2012 by Zhang et al. [26], who performed a single center randomized study, involving 133 patients, with an 18-month follow-up. The two procedures, though, differed from classical HoLEP [7] and ThuLEP [14]: enucleation was followed by removal of the prostatic adenoma with an electrocautery resection. Moreover, only prostates of maximum 80 cc were considered. Despite these limitations, both procedures proved to be equally effective in relieving LUTS and resulted in similar catheterisation time and enucleated

prostate volumes, but ThuLEP showed longer operative time and reduced blood loss.

In 2018 Pirola et al. [27] published a two center, retrospective, non-randomized, matched-pair analysis comparing HoLEP and ThuLEP, performed according to their original techniques [7, 14]. Two groups of 117 patients each were taken into consideration and large prostates were considered. Both procedures proved to be safe and effective in improving LUTS and QoL and similarly to Zhang et al. [26], ThuLEP resulted in reduced blood loss. In contrast, enucleating time and total operative time were shorter with ThuLEP and PSA drop at 12 months was significantly higher in the HoLEP group, possibly indicating a more effective removal of prostatic tissue.

A prospective randomized trial, performed by Becker et al. [19], comparing HoLEP and ThuVEP, involving 94 patients, with a 6-month follow-up, instead, showed that both techniques were equally effective in improving subjective symptoms and voiding parameters, with no significant differences between the two.

To summarize these heterogeneous results from the scarse existing comparitive trials, Xiao et al. [28] performed a systematic review and meta-analysis of studies comparing HoLEP and ThuEP techniques, including the studies mentioned above. 5 studies and 1,010 patients, were analysed. The improvement in Q_{max}, PVR and QoL score were comparable between HoLEP and ThuEP. However, Q_{max} was found to be significantly higher and PVR significantly lower after 1 month in patients treated with ThuEP. IPSS was significantly higher after HoLEP at 1 year follow-up, indicating a possible better symptom resolution with ThuEP. Enucleating time and peri-operative haemoglobin drop also favoured ThuEP. No significant differences in complications were found in the two groups. Authors conclude that both techniques are effective in improving micturition and QoL, with a low complication rate, but ThuEP might contain several advantages over HoLEP with regard to enucleation time and efficacy, blood loss and early micturition improvement.

In order to contribute to the literature we performed a multicenter prospective randomized study comparing HoLEP and ThuLEP, including a large number of patients, 121 of which underwent HoLEP and 115 of which underwent ThuLEP (performed according to their classical techniques [7, 14]). Preoperative parameters of the patients were similar in the two groups and no significant differences were found (Table 1). We evaluated intra and perioperative parameters: no significant differences were found regarding enucleated tissue weight, catheterization time, irrigation volume and hospital stay.

In contrast with the studies performed by Pirola [27] and Zhang [26] and similarly to the results presented by Becker [19], we found no significant differences in total operative time between the two procedures (Table 2). Whereas, similarly to Pirola [27] and Zhang [26], haemoglobin drop and transfusions were significantly lower in the ThuLEP group (Table 2 and 3).

During follow-up, no differences in Q_{max}, IPSS, PVR and QoL score were registered, showing that both techniques were equivalent in improving urinary flow and resolution of LUTS. No significant differences were found in enucleated tissue weight and PSA levels at 12 months after surgery, indicating equivalent removal of prostatic tissue with both techniques (Table 4).

We registered a small amount of complications after both procedures (Table 3), showing that both techniques are equally safe, but there was a significantly higher number of patients with AUR and postoperative stress incontinence after HoLEP. These results are similar to those of another comparative study, which focused on large prostates, performed by Zhang et al. [29]. Only 1 case of bladder injury was registered in the HoLEP group, but this occured during the morcellating phase and 1 case per group of post-operative urethral stricture.

The higher number of patients with AUR and stress incontinence in group A could be related to the different effect of the two lasers on the prostatic tissue: the holmium laser, with its pulsed output, ruptures the tissue and more traction with the tip of the resectoscope is needed to separate the adenoma from the capsule, whereas the thulium laser, with its continous wave output, allows a more precise and clean cut, reducing mechanical stress. Moreover, the holmium laser penetrates deeper into the prostatic tissue compared to the thulium laser (0.4 vs 0.25 nm). These features of the holmium laser could be the cause of increased stress, inflammation and edema in proximity of the external urinary sfincter, explaining the higher rate of AUR and stress incontinence.

Reduced haemoglobin drop and blood transfusions after ThuLEP, that were registered in our study, confirm the better haemostatic capacity of the thulium laser, which seems to be the most consistent result in the literature [24, 26, 27]. This is due to its continous wave output and to its shorter wavelength, which make the thulium laser ideal to perform haemostasis.

Considering the volume of the prostates included in our study (mean values of 86.3 ± 46.7 cc in group A and 90.2 ± 42.7 cc in group B) our results confirm that both techniques can be employed safely and effectively even in patients with large prostates, as previously stated by Zhang et al. [29].

The main limit of this study is that we did not consider parameters such as enucleating time and enucleated tissue per minute, which could have been useful to verify if there were any differences in enucleation speed and efficacy. Despite the absence of these parameters overall operative time was similar with both techniques.

Our results confirm that HoLEP and ThuLEP are two valid alternatives in the treatment of BPH. They achieve equivalent improvement of subjective symptoms, QoL and voiding parameters and equivalent removal of prostatic tissue. Both can be employed safely in the treatment of almost any prostate size, reason for which, at least one of the two should be employed in every urology department, not having to resort to old-fashioned procedures, such as OP, burdened by excessive morbidity.

Similarly to Xiao et al. [28], our findings are slightly in favour of ThuLEP, which determined reduced haemoglobin drop and early post-operative complications. The better haemostatic capacity of the thulium laser is already well documented throughout the literature and our early postoperative complications seem to be in line with the most recent comparison between the two techniques [29]. ThuLEP is probabily preferable for inexperienced urologists, as it has a shorter learning curve [21] and thanks to its excellent vaporizing effect it is more forgiving. The holmium laser, instead, is well established in the treatment of urinary stones, making it an excellent option if treating BPH and urinary stones, with one laser only, is the department's goal. Therefore, the choice between one or the other procedure should be based on the surgeons' experience, surgical demands in each center and obviously personal preference.

Conclusions

ThuLEP and HoLEP both improved IPSS, QoL, Q_{max}, PVR and PSA equally, with stable results after 12 months. Both techniques determined equivalent removal of prostatic tissue, with a low complication rate. No differences were found in terms of catheterization time, irrigation volume and hospital stay. Nevertheless, ThuLEP determined reduced blood loss and necessity of blood transfusions, confirming a better haemostatic capacity of the thulium laser. Moreover, early post-operative complications such as acute urinary retention and stress incontinence favoured ThuLEP. Further studies comparing HoLEP and ThuLEP with long term follow-up are needed to confirm these results.

Author contributions Protocol/project development: BG, BL, BU, BP, BC, CA, MS, RB, RJB. Data collection or management: BG, BL, BP, MM, RJB, SMC, TBA. Data analysis: MM, PAL, SMC, TBA. Manuscript writing/editing: BG, BL, TBA. Execution of surgical procedures: BG, BP, RJB. Supervision: BG, BU, BC, CA, MS, MA, PAL, RB.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest or any known competing financial interests.

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by our local ethical commitee.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication All patients gave their consent for the publication of this article.

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