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ORIGINAL ARTICLE

Thulium laser enucleation versus thulium laser resection of the prostate for prevention of bladder neck contracture in a small prostate: a prospective randomized trial

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Abstract

Purpose To compare the safety and efficacy of thulium laser enucleation of the prostate (ThuLEP) versus thulium laser resection of the prostate (TmLRP) in small prostates (≤ 30 g) and to test the validity of ThuLEP for bladder neck contracture (BNC).

Methods A total of 115 patients with benign prostatic hyperplasia (BPH) (prostate size ≤ 30 g) were randomly assigned to ThuLEP ($n = 56$) or TmLRP ($n = 59$). All patients were evaluated preoperatively and at 1, 3, 6, and 12 months after surgery. Baseline characteristics of the patients, perioperative data, postoperative outcomes and complications were assessed.

Results Comparisons of the baseline and perioperative data demonstrated no significant differences between the ThuLEP and TmLRP groups. Significant improvement was noted in the International Prostate Symptom Score, quality of life, maximal urinary flow rate (Q_{max}) and post-void residual volume (PVR) in both groups at the 12-month follow-up, and assessment showed no differences in these parameters between the two groups. The TmLRP group showed a significantly higher rate (13.6%) of BNC than the ThuLEP group (1.8%; $P = 0.045$). There were no significant differences in other complications between the two groups ($P > 0.05$).

Conclusions ThuLEP and TmLRP are both safe and efficient procedures for the treatment of patients with small prostate volume, while ThuLEP can significantly reduce the risk of BNC in patients with a small prostate because the procedure enucleates adenomas without thermal damage to the bladder neck.

Keywords Benign prostatic hyperplasia · Bladder neck contracture · Small prostate · Thulium laser enucleation of the prostate · Thulium laser resection of the prostate

Introduction

BPH is a common disease in ageing males and is the most common cause of lower urinary tract symptoms (LUTS) and benign outlet obstruction (BOO). Although transurethral resection of the prostate (TURP) is still considered the gold standard of surgical treatment [1], new endourologic procedures including various laser prostatectomies have been applied in the clinic because of their low morbidity and high efficiency [2]. As one of the most innovative and accepted lasers, thulium lasers work at a wavelength of two microns in continuous-wave mode and offer more advanced vaporization and haemostatic features than other lasers [3]. Furthermore, thulium lasers are suitable for most kinds of prostatectomies including vaporization, bladder neck incision (BNI), vaporesection and enucleation [4–6].

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The first choice treatment for patients with a small prostate is medical intervention and surgical treatment is an alternative for patients who are refractory to medical therapy. The common surgical procedures include vaporesection, enucleation and BNI. Despite advancements in endourologic therapy, BNC is a common complication that may occur following the surgical treatment of BPH, especially when the weight of the resected gland does not exceed 30 g. Although the exact mechanisms of BNC remain unclear, extensive resection and fulguration of the bladder neck and intraurethral adenomas have been accepted as the main predisposing factors [7].

Recently, laser treatment of BPH through enucleation techniques has been proven to be size independent [8, 9], and we believe that enucleation can accomplish complete anatomical removal of the prostate while maintaining the bladder neck and leaving it undamaged, which can prevent the occurrence of BNC despite the lack of evidence. The aim of this prospective study was to analyse the clinical outcomes of thulium laser enucleation of the prostate (ThuLEP) versus thulium laser resection of the prostate (TmLRP) in patients with a small prostate (≤ 30 g) and to test the validity of ThuLEP for BNC.

Methods

Subjects

In this prospective analysis, all patients presenting with LUTS or BOO due to BPH were assessed at our institution from January 2015 to March 2018. Evaluation of all patients included assessments of International Prostate Symptom Score (IPSS), quality of life (QoL), maximal urinary flow rate (Q_{max}), post-void residual volume (PVR), and digital rectal examination (DRE), transrectal ultrasound, and measurement of prostate specific antigen (PSA) levels.

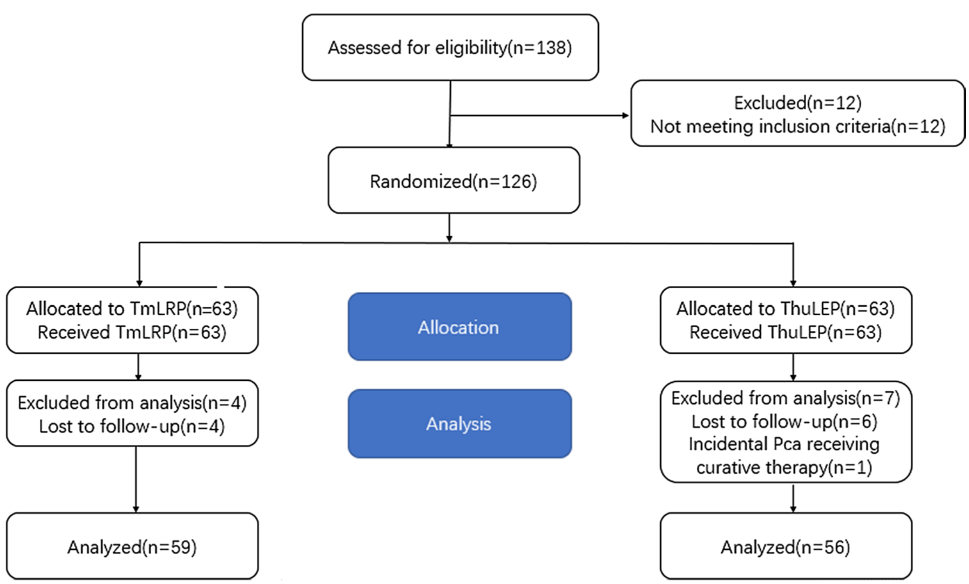
The inclusion criteria were a prostate size ≤ 30 g, IPSS ≥ 8, Q_{max} ≤ 15 mL/s, recurrent urinary retention, persistent gross haematuria from the prostate, recurrent urinary tract infection (UTI) and bladder stones. Patients with neurogenic bladder, prostate cancer or previous transurethral surgery were excluded from the study. All patients provided written informed consent. Approval for the study was granted by the ethics committee of our hospital prior to recruitment.

Randomization and sample size

Randomization was performed by an independent investigator. A total of 126 patients were randomized in a 1:1 fashion by a computer-generated simple randomization chart (Fig. 1). The primary outcome measure was the change in IPSS from baseline at 3 months. Secondary outcome measures were changes in IPSS from baseline at 1, 6, and 12 months, assessment of Q_{max}, QoL, and PVR during the follow-up, operative time, catheterization time, hospitalization time, and complication rate.

The sample size was calculated based on the assumption that improvements in IPSS after ThuLEP would be no different from those after TmLRP. According to the published ThuLEP studies, it was anticipated that 3 months after ThuLEP, IPSS would increase by approximately 14 [10, 11]. For TmLRP, we considered a change in IPSS of 16 [3, 12]. Assuming a standard deviation (SD) of 3 for both of the 3-month changes in IPSS, a sample size of 49 subjects per treatment arm would provide sufficient power to detect this difference as statistically significant ($\beta = 0.10$,

Fig. 1 Flow diagram of the participants through the study



$\alpha = 0.05$). Anticipating a drop-out rate of approximately 10%, 54 patients per group had to be recruited.

Equipment

All laser surgeries were performed by two surgeons who had conducted at least 300 procedures prior to this study. The instruments used were a 120-W continuous-wave Thulium-yttrium aluminium garnet (Tm:YAG) laser and a 26-F continuous flow resectoscope, and laser energy was applied through a reusable 550 nm laser fibre. Physiological saline irrigation was applied throughout the entire procedure.

Surgical procedures

The technique for TmLRP has been previously described in detail [3]. ThuLEP procedures were performed similarly to those reported in a previous article. An inverted-U-shaped incision around the verumontanum was made. The incision was continued until the surgical capsule was identified. Then, we used a resectoscope sheath to push the lobe along the surgical capsule and the laser with a 70-W laser beam was used for haemostasis when a bleeding vessel was encountered and to excise adhesive fibres between the capsule and the lobe. The middle lobe, left lobe and right lobe were dissected off the surgical capsule but were still attached to the bladder neck at 11 o'clock to 1 o'clock. Then, the laser energy was switched to 120 W for incision and vaporization. The attached adenoma was resected into small pieces and extracted with an Ellik evacuator. At the end of the surgery, a 22-Fr three-way Foley catheter was inserted for continuous bladder irrigation with normal saline.

Statistical analysis

Normally distributed continuous variables were expressed as the mean ± standard deviation and they were compared by *t* tests. Non-normally distributed continuous variables are presented as the median and interquartile range, and they were analysed with the Wilcoxon rank-sum test. Categorical data were compared by the χ^2 test or Fisher's exact test. SPSS 16 software was used for the statistical analysis. A *P* value < 0.05 was considered statistically significant.

Results

Table 1 compares the baseline parameters and primary perioperative outcomes between the two groups. There were no significant differences with regard to patient age, prostate volume, IPSS, QoL, Q_{max}, or PVR ($P > 0.05$).

The perioperative data are listed in Table 2. Both procedures required a similar operative time, catheterization time and length of hospitalization. Most prostatic adenomas were vaporized and a small amount of tissue was washed out with an Ellik evacuator. The weight of the extracted tissue was significantly different between the two groups.

Table 1 Comparison of baseline parameters and primary perioperative outcomes between the two groups

Parameters	Group 1 (ThuLEP)	Group 2 (TmLRP)	*P* value
Number of patients	56	59	
Age (years)	69.2 ± 13.4	67.7 ± 9.9	0.363
Prostate volume (g)	26.4 ± 3.5	25.1 ± 4.7	0.097
IPSS	23.5 ± 5.2	22.9 ± 4.9	0.525
QoL	4 (4–5)	4 (4–5)	0.832
Q_{max}	8.1 ± 4.4	8.9 ± 4.3	0.326
PVR (mL)	74.2 ± 79.9	71.8 ± 82.4	0.874

IPSS International Prostate Symptom Score, *QoL* quality of life, Q_{max} maximum urinary flow rate, *PVR* post-void residual urine, *ThuLEP* thulium laser enucleation of the prostate, *TmLRP* thulium laser resection of the prostate

Table 3 and Fig. 2 list the changes in IPSS, QoL scores, Q_{max} and PVR at 1, 3, 6 and 12 months. Significant improvements in all these parameters compared with the baseline values were observed at the 1-year follow-up. However, the differences between both groups were not significant.

Table 4 shows the incidence of complications according to the Clavien–Dindo system during the 1-year follow-up. Only one patient in the ThuLEP group developed BNC (1.8%), while eight patients in the TmLRP group developed BNC (13.6%), and the difference was significant ($P = 0.045$). Five and two patients had urgency urinary incontinence in the ThuLEP and TmLRP groups, respectively, but no patients developed urinary incontinence that was persistent for more than 3 months. The incidences of gross haematuria and febrile UTI were also not different between the two groups and they usually resolved with conservative treatments, such as bladder irrigation and antibiotic therapy. The occurrence of temporary urinary retention was similar between the two groups, with no significant difference and recatheterization was needed when this occurred. There were three (5.1%) patients in the TmLRP group who required prolonged catheterization and antibiotic therapy because capsular perforation occurred intraoperatively. Only one patient in the TmLRP group had urethral stricture that was controlled by outpatient urethral dilation. No other severe complications occurred during the follow-up period.

Table 2 Comparison of perioperative data between the two groups

	Group 1 (ThuLEP)	Group 2 (TmLRP)	*P* value
Operative time (min)	19.8 ± 11.1	17.4 ± 9.2	0.208
Enucleation time (min)	11.7 ± 4.7		
Enucleation/resected tissue weight (g)	4.1 ± 1.9	2.2 ± 1.2	< 0.001
Indwelling catheter time (h)	44.6 ± 16.3	44.2 ± 19.4	0.905
Hb decrease	0.43 ± 0.31	0.47 ± 0.25	0.447
Hospital stay (h)	45.8 ± 16.3	48.7 ± 19.9	0.396

Table 3 Follow-up data for up to 12 months in the two groups

	Perioperative	Postoperative				
		1 month	3 months	6 months	12 months	*P*2 value
IPSS						
ThuLEP	23.5 ± 5.2	8.2 ± 4.5	6.5 ± 4.3	6.6 ± 4.1	6.9 ± 3.7	< 0.001
TmLRP	22.9 ± 4.9	7.2 ± 4.3	6.7 ± 4.1	6.8 ± 3.9	7.1 ± 3.8	< 0.001
*P*1 value	0.525	0.226	0.799	0.789	0.776	
QoL						
ThuLEP	4 (4–5)	2 (2–3)	2 (1–3)	2 (1–3)	2 (1–2)	< 0.001
TmLRP	4 (4–5)	2 (2–3)	2 (1–3)	2 (1–2)	2 (1–2)	< 0.001
*P*1 value	0.832	0.396	0.452	0.668	0.813	
Q_{max}						
ThuLEP	8.1 ± 4.4	24.4 ± 11.7	25.7 ± 10.1	25.4 ± 8.3	25.1 ± 7.2	< 0.001
TmLRP	8.9 ± 4.3	23.6 ± 12.2	25.0 ± 9.4	24.8 ± 9.3	24.3 ± 8.1	< 0.001
*P*1 value	0.326	0.721	0.701	0.716	0.577	
PVR						
ThuLEP	74.2 ± 79.9	22.3 ± 24.4	21.8 ± 20.2	20.1 ± 21.2	20.7 ± 23.4	< 0.001
TmLRP	71.8 ± 82.4	24.7 ± 21.8	24.0 ± 19.8	21.8 ± 24.5	22.1 ± 24.2	< 0.001
*P*1 value	0.874	0.579	0.557	0.692	0.753	

*P*1 value for intergroup comparison

*P*2 value for the comparison between baseline and postoperative

Discussion

The thulium laser has become one of the most widely accepted lasers in urology since it was introduced in 2005 [13]. This relatively new continuous-wave laser can perform efficient resection and vaporization and provide maximum haemostasis and coagulation. The safety and efficacy of TmLRP, which was initially applied to treat BPH in 2005, have been demonstrated for any prostate size in many clinical trials. Recently, the enucleation technique has become increasingly popular because it provides complete dissection of prostate adenomas from the prostatic capsule. ThuLEP was first introduced as a clinical application in 2009, and it offered anatomical removal of the transition zone with encouraging clinical results similar to holmium laser enucleation of the prostate (HoLEP) [4].

Many urologists do not use the enucleation technique because it is a technically difficult procedure with a steep learning curve. The enucleation technique requires blunt dissection with the beak of a resectoscope between the adenoma and the capsule, but the layer of the enucleated capsule plane is hard to identify, especially in small prostate glands [14]. Recently, the transurethral enucleation approach has been proven to be size independent [15]. Ehab et al. stated that HoLEP was a safe and effective procedure for patients with a small prostate in 2009 and another review of ThuLEP demonstrated favourable results in all prostatic sizes in 2015 [11, 16].

Prostate size is closely related to operative time and many perioperative morbidities and it is a major factor to consider when deciding on a treatment option for BPH. Although TmLRP and ThuLEP are both proven to be size-independent techniques [3, 12, 17], we believe that different surgical procedures can result in different postoperative morbidities and complications, especially for patients with a small prostate. Urologists might hesitate to perform surgery on patients with a small prostate due to the possibility of decreased procedure efficacy and worse clinical

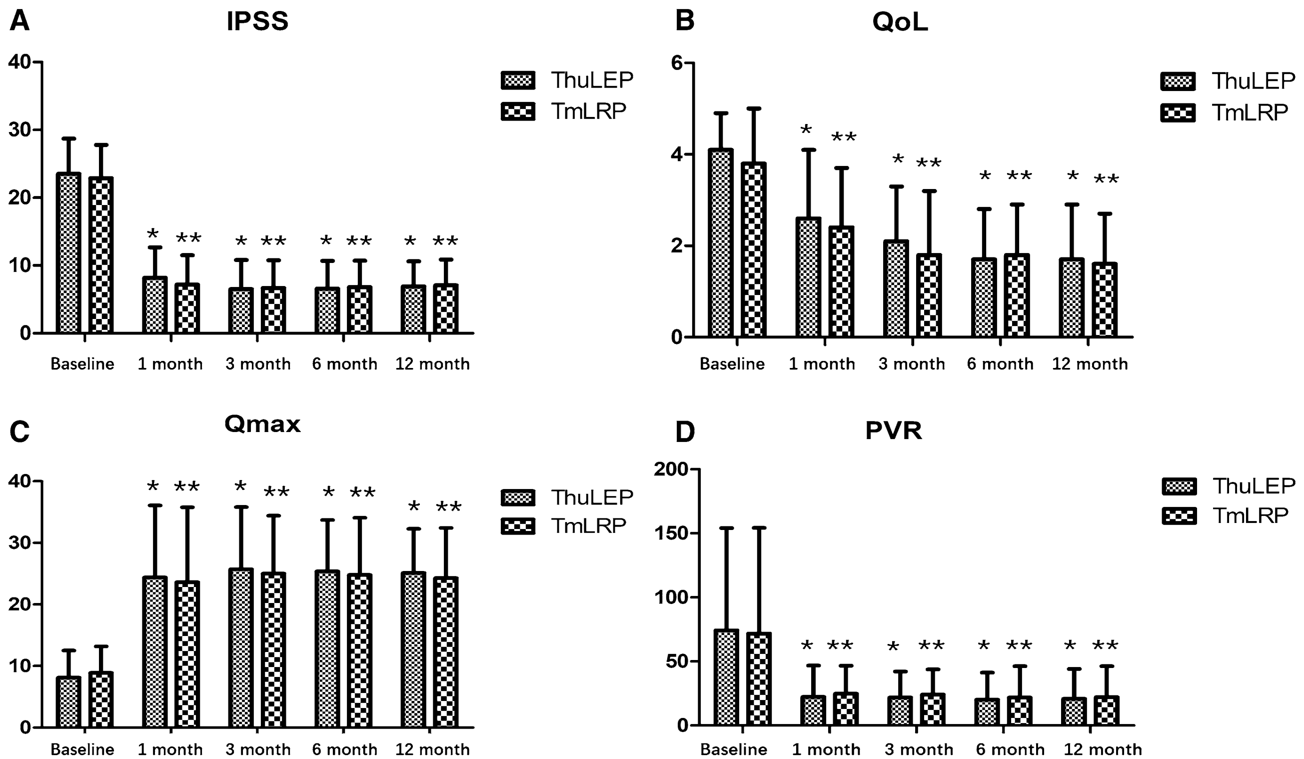


Fig. 2 Follow-up data for up to 12 months in the two groups. **a** IPSS, **b** QoL, **c** Q_{max} and **d** PVR. *$P < 0.05$ and **$P < 0.05$ compared with baseline values

Table 4 Adverse events in the two groups

	ThuLEP	TmLRP	*P* value
Clavien–Dindo grade 1 complications			
Gross haematuria	4 (7.1%)	5 (8.5%)	0.394
Transient urge incontinence	5 (8.9%)	2 (3.4%)	0.394
Temporary urinary retention	3 (5.4%)	4 (6.8%)	0.943
Clavien–Dindo grade 2 complications			
Capsular perforation	0 (0)	3 (5.1%)	0.261
Febrile urinary tract infection (temperature > 38.5)	4 (7.1%)	5 (8.5%)	0.935
Clavien–Dindo grade 3a complications			
Bladder neck construction	1 (1.8%)	8 (13.6%)	0.045
Urethral stricture	0 (0)	1 (1.7%)	0.979

outcomes, and some studies have reported a strong correlation between a small prostate and BNC [18].

BNC is a well-known but poorly evaluated complication of prostate surgery. Although conventional transurethral resection of the prostate has resulted in BNC rates between 1 and 12.3% [19], Chiu reported that the incidence of BNC in patients with a small prostate (less than 20 g) was up to 16% [20]. Once BNC has occurred, it can be a difficult and challenging clinical problem for urologists due to its high rate of recurrence. Refractory BNC often requires repeated surgical treatment, but the symptoms of BOO relapse in a very short time.

Many factors have been stated to be correlated with a high risk of BNC; the most important of these is excessive resection of the bladder neck in patients with small adenomas, which leads to a hypertrophic scar caused by excessive heat [7]. Other factors including unmanaged preoperative infection, unsuitable diameters of resectoscope and postoperative catheterization, etc., may contribute to BNC [21]. Based on the abovementioned mechanism, we hypothesized that BNC can be prevented if the prostate is enucleated while avoiding damage to the bladder neck. Limited studies have compared TmLRP and ThuLEP in patients with a small prostate volume [22–24], and high-quality evidence to support our hypothesis is lacking. Hence, in this prospective study, we compared the safety and efficacy of ThuLEP with TmLRP in patients with a small prostate (less than 30 g) and highlighted the differences in the incidence of BNC.

During an observation period of 12 months, both groups showed significant relief of obstructive symptoms based on the provided 1-year follow-up data, and there were no statistically significant differences between the two groups in terms of IPSS, QoL, Q_{max}, and PVR at 1, 3, 6, and 12-month postoperative follow-up assessments. Our data also showed similar perioperative parameters with no significant differences between the two groups. We found no differences between the two groups concerning complications except for BNC. Patients in the TmLRP group (13.6%) showed a much higher rate of BNC than those in the ThuLEP group (1.8%), and this finding was statistically significant ($P=0.045$). The incidence of transient urgency urinary incontinence in the ThuLEP group was slightly higher than that in the TmLRP group, which could have been caused by blunt trauma to the external sphincter from the dissection of the sheath [25]. Three patients in the TmLRP had capsular perforation during surgery, while no patients in the ThuLEP group has this complication. Bach et al. reported that surgical capsule perforation can be generally avoided during ThuLEP as blunt dissection of the adenoma over its capsule not only minimizes this risk but also ensures proper capsule visualization during the enucleation [4].

From our series, we found that ThuLEP was suitable for small prostates and the incidence rate of BNC was very low. We believe that our data have proven our hypothesis. Unlike TmLRP, in which the adenoma and the bladder neck are directly vaporized with laser energy, the ThuLEP procedure does not produce significant coagulation or concerning burn marks. Most importantly, damage to the bladder neck can be avoided. Although the postoperative urinary tract through the bladder neck is not very wide, the follow-up results showed significant improvement in micturition symptoms. In our opinion, the procedure of blunt enucleation of the prostate with the beak of a resectoscope can avoid impairment in the adenoma caused by laser energy and keep the bladder neck intact, which further reduces scar formation of the wound and decreases the incidence of BNC. Some other studies have also reported similar results, although they did not place emphasis on BNC. A comparison of photoselective vaporization of the prostate (PVP) versus HoLEP reported by Christopher et al. demonstrated that patients in the PVP group (6%) showed a higher rate of BNC than those in the HoLEP group (1%). The technique for PVP that they used was vaporization of the adenoma including the bladder neck [26]. Another 18-month follow-up study performed by Zhang et al. demonstrated no BNC in both ThuLEP ($n=71$) and HoLEP groups ($n=62$) [27].

The present study had some limitations. BNC is a relatively rare complication and the small sample size limits the power of our study. The number of patients with BPH with a prostate size less than 30 g did not exceed 120 patients, and we also had to exclude the subjects that did not meet the inclusion criteria. Another limitation was the short postoperative follow-up period. BNC may develop in a slow process, and although half of patients with the BNC can be diagnosed within 6 months, some patients may gradually develop BNC over the course of 3 years. Thus, the incidence of BNC may have been underestimated in our study.

Conclusions

ThuLEP and TmLRP can relieve LUTS and BOO equally with high efficacy and safety in patients with a prostate size less than 30 g. We believe that the enucleation technique may have more advantages for preventing BNC than resection for patients with a small prostate. Additional studies with large sample sizes are needed to confirm our findings.

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Author contributions QS and WG: project development, data collection or management, data analysis, manuscript writing/editing. DC and XW: data analysis. FZ, YR and BH: data collection or management. BH, SX and YJ: project development.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All patients gave written informed consent. Approval for the study was granted by the Ethics Committee of our hospital prior to recruitment. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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