




Holmium laser enucleation of the prostate versus thulium laser enucleation of the prostate for the treatment of large-volume prostates > 80 ml: 18-month follow-up results

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Abstract

Purpose To compare the perioperative and functional outcomes of holmium laser enucleation of the prostate (HoLEP) and thulium laser enucleation of the prostate (ThuLEP) for the treatment of large-volume benign prostatic hyperplasia (BPH) (> 80 ml).

Methods A total of 116 consecutive patients with BPH were randomized to be treated surgically with either HoLEP ($n=58$) or ThuLEP ($n=58$), following the classical three-lobe enucleation technique. Follow-up was assessed at 1, 3, 6, 12 and 18 months after surgery.

Results At 18 months, the lower urinary tract symptom index was improved significantly in both groups compared with the baseline values. The operative time (78.4 ± 8.0 vs. 71.4 ± 6.4 min) and enucleation time (61.2 ± 5.4 vs. 56.4 ± 8.4 min) were significantly shorter for ThuLEP compared to HoLEP (both $p < 0.001$). There were no significant differences between the two groups regarding morcellation time, resected weight, hemoglobin decrease, catheter time and hospital stay ($p > 0.05$). The HoLEP and ThuLEP groups had equivalent International Prostate Symptom Scores (3 [3–3] vs. 3 [3–3], $p = 0.776$), quality of life (1 [1–2] vs. 2 [1–2], $p = 0.809$), Qmax (25.3 ± 4.8 ml/s vs. 24.7 ± 4.4 ml/s, $p = 0.470$), postvoid residual urine (PVR) (6.1 [2.6–20.8] vs. 7.7 [3.1–22.8] ml, $p = 0.449$) and PSA (0.84 ± 0.32 vs. 0.90 ± 0.34 ml, $p = 0.309$) at 18 months postoperatively.

Conclusion Both HoLEP and ThuLEP relieve lower urinary tract symptoms in a comparable way with high efficacy and safety. ThuLEP was statistically superior to HoLEP in operation time and enucleation time, although the differences were clinically negligible.

Keywords HoLEP · ThuLEP · Benign prostatic hyperplasia (BPH) · Large-volume prostate · Randomized controlled trial (RCT)

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Introduction

Open prostatectomy (OP) is generally considered the gold standard for benign prostatic hyperplasia (BPH) in large prostates [1]. Despite the overall good long-term results and the low reoperation rates after OP, the high perioperative morbidity associated with this approach stresses the need to find an adequate alternative that can reproduce the same functional results and drastically reduce morbidity [2].

Over the past decades, different laser systems for enucleation of the prostate have been successfully introduced, including holmium laser [3], thulium laser [4], green light laser [5], and diode laser [6]. Holmium laser enucleation of the prostate (HoLEP) has been proven to be a minimally invasive, size-independent method in numerous randomized

controlled trials (RCTs) with excellent long-term results [3] and is recommended by the current guidelines of the European Association of Urology (EAU) in men with substantially enlarged prostates (e.g., > 80 ml) as the first choice [1].

Based on the HoLEP technique, Bach et al. first described the enucleation with the thulium laser, called ThuVEP, in 2009 [7], and Herrmann et al. proposed ThuLEP 1 year later [8]. The main difference between the two lasers is that holmium has a pulsed energy, while thulium emits a continuous laser wave [9]. ThuLEP may have several advantages over the holmium laser, including improved spatial beam quality and more precise tissue incision [10]. ThuLEP has been shown to be the technique that best fits all types of prostatic adenomas, giving optimal outcomes in terms of urinary symptom resolution and preservation of urinary continence and erectile function [11].

Herein, we present this randomized controlled trial to further investigate the possible differences in terms of intra- and postoperative variables, surgical complications, and outcomes of ThuLEP with HoLEP in patients with large-volume prostates (> 80 ml) during a medium-term 18-month follow-up.

Patients and methods

Study design and enrollment

After receiving institutional review board approval, from March 2016 to September 2017, a total of 116 consecutive patients (Fig. 1) who suffered from BPH-related obstructed voiding symptoms with prostate volume > 80 ml, as determined by transrectal ultrasound (TRUS), were considered eligible for surgical treatment and enrolled in this RCT. Inclusion criteria were maximum urinary flow rate (Q_{max}) \leq 15 ml/s, International Prostate Symptom Score (IPSS) \geq 12, urodynamic obstruction without detrusor dysfunction and no response to pharmacologic therapy. The exclusion criteria were neurogenic bladder, findings suspicious for prostate cancer or urethral strictures, and poor tolerance for surgery. The study was approved by our ethics committee, and informed consent was obtained from all patients.

Randomization and preoperative assessments

The patients were randomized to be treated surgically with either HoLEP ($n=58$) or ThuLEP ($n=58$) by a computer-based prospective random sequence generator in a 1:1 ratio. Preoperative assessment included a physical examination with digital rectal examination (DRE), prostate-specific antigen (PSA), prostate volume by TRUS, uroflowmetry, postvoid residual urine (PVR) and by scoring of subjective symptoms with the IPSS and quality of life (QOL) questionnaires.

Interventions

The high-power pulsed 100-W VersaPulse holmium laser unit (Lumenis, Santa Clara, CA) was used for the HoLEP procedure, with an energy setting of 90 W for cutting and 20 W for coagulation. The thulium:YAG laser unit (Vela[®] XL, Boston Scientific, Ratingen, Germany) was used for the ThuLEP, with an energy setting of 120 W for cutting and 60 W for coagulation. A 26-F continuous-flow laser resectoscope (Karl Storz, Tuttlingen, Germany) in combination with a mechanical tissue morcellator (R. Wolf, Piranha[™], Knittlingen, Germany) was used in both procedures.

All procedures were performed by two surgeons who had performed more than 300 HoLEP and 200 ThuLEP procedures both. Enucleation of the prostate using holmium:YAG and thulium:YAG is similar, and the three-lobe technique was usually performed in cases of large prostates. Following the initial depiction by Gilling [12] for HoLEP and Herrmann [8] for ThuLEP, enucleation was performed.

In brief, two incisions of the median lobe deep into the plane of the surgical capsule were progressively made at the 5- and 7-o'clock positions. Then the median lobe was enucleated following the margin of the prostatic capsule toward the verumontanum. Subsequently, an upper incision at 12 o'clock separated the lateral lobes, which were enucleated by joining the lower and upper resection planes of the lateral lobes. All enucleation was carried out while maintaining the sight of the surgical capsule. The enucleation was performed by bluntly exposing the plane of the adenoma and separating it from the capsule by means of laser energy. Physiological saline solution as irrigation fluid was used throughout the entire procedure. Morcellation was performed after completing the enucleation by means of a long nephroscope. A double inflow maintains safe bladder distension, avoiding injuries to the bladder wall. Following surgery, all patients had a Foley catheter with continuous bladder irrigation.

Data collection and follow-up

Perioperative data included the total operative time, enucleation time, morcellation time, resected weight, hemoglobin decrease, catheter time and hospital stay. All patients were reassessed 1, 3, 6, 12, and 18 months after surgery by IPSS, QoL, Q_{max} , PVR, and PSA. Perioperative and postoperative complications were reported according to the modified Clavien–Dindo system [13, 14].

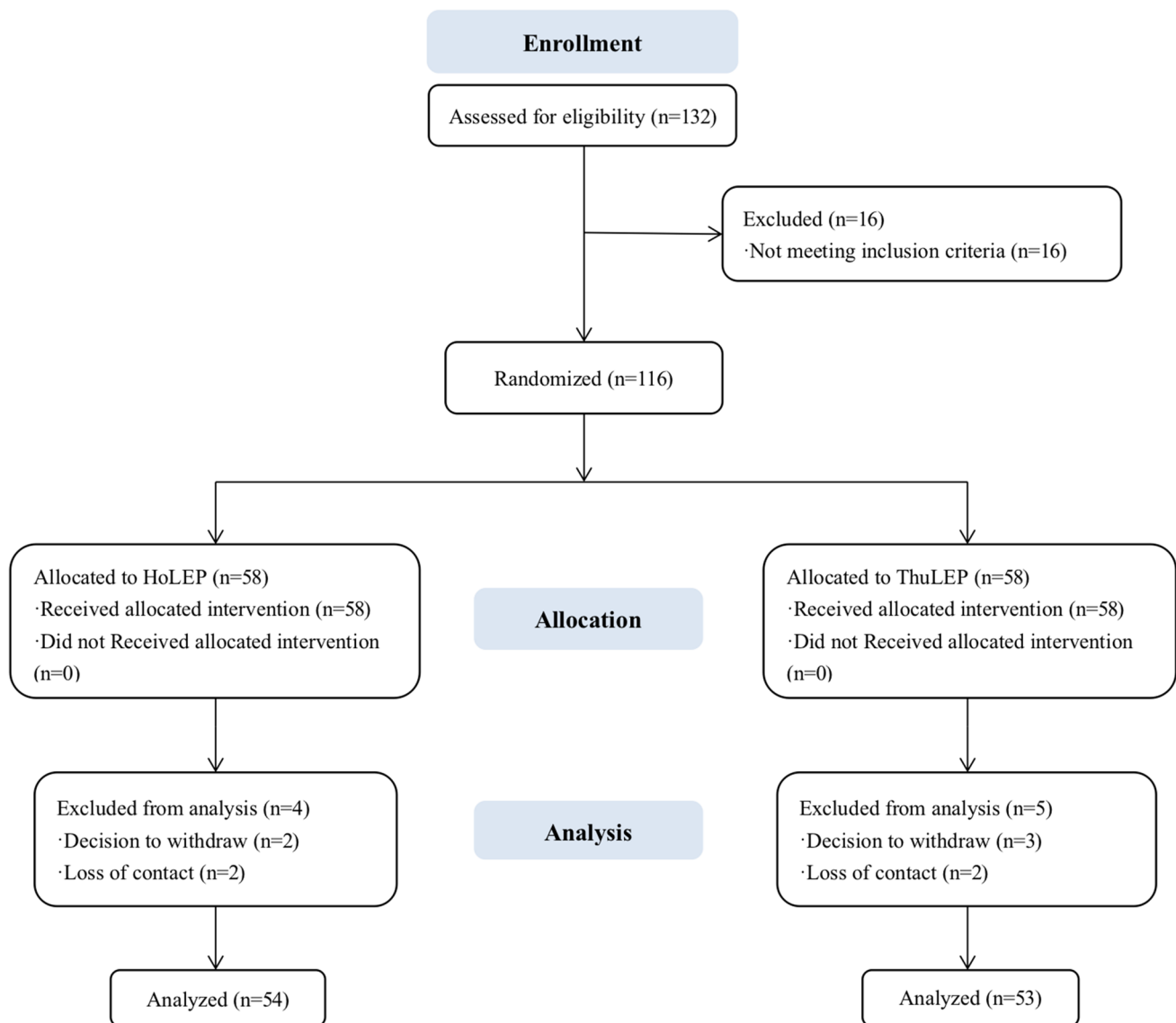


Fig. 1 CONSORT (consolidated standards of reporting trials) flowchart for study participants

Statistical analysis

The primary endpoint of the study was Q_{\max} (ml/s) at 1 year postoperatively. The sample size was calculated for the detection of statistically significant differences. The calculation assumed that the relevant difference in Q_{\max} would be 3 (SD = 5.5) ml/s. With $\alpha = 0.05$ and a power of 80% ($\beta = 0.20$), a sample size of 53 patients per group was calculated. Assuming a 10% loss to follow-up over 1 year, we enrolled 58 patients in each group.

The secondary endpoints included Q_{\max} at other time points after surgery, operative time, resected weight, hemoglobin decrease, catheter time and hospital stay.

Postoperative variables included IPSS, QOL, PVR and PSA.

Statistical analysis was performed using SPSS 23 (IBM Corp, Armonk, NY, USA). Parametric continuous variables are expressed as mean \pm standard deviation and were compared with the independent-sample t test. Nonparametric continuous variables are expressed as median and interquartile range and were analyzed with the Mann–Whitney U test or Wilcoxon matched-pairs signed rank test. Categorical variables were compared with the Chi-square test or Fisher's exact probability test. For all statistical comparisons, a p value ≤ 0.05 was considered statistically significant.

Table 1 Baseline characteristics

Variables	HoLEP group	ThuLEP group	<i>P</i> value
Patient no.	58	58	–
Age (years) ^a	71.8 ± 3.9	72.7 ± 3.1	0.171
Prostate volume (ml) ^a	93.0 ± 7.2	91.8 ± 6.9	0.369
PSA (ng/ml) ^a	5.09 ± 1.49	4.96 ± 1.40	0.629
Qmax (ml/s) ^a	7.1 ± 2.8	6.6 ± 2.3	0.368
PVR (ml) ^a	172.7 ± 39.4	165.5 ± 46.2	0.367
IPSS ^a	23.9 ± 3.9	22.8 ± 3.7	0.126
QoL ^b	5 (4–6)	5 (4–6)	0.646

Mean ± standard deviation. Median (IQR)

PSA total serum prostate-specific antigen, Qmax maximum urinary flow rate, PVR postvoid residual urine, IPSS International Prostate Symptom Score, QoL quality of life

^aNormally distributed variable data analyzed with independent-sample *t* test

^bNon-normally distributed variable data analyzed with the Mann–Whitney *U* test

Table 2 Perioperative data

Variables	HoLEP group	ThuLEP group	<i>P</i> value
Operative time (min) ^a	78.4 ± 8.0	71.4 ± 6.4	< 0.001
Enucleation time (min) ^a	61.2 ± 5.4	56.4 ± 8.4	< 0.001
Morcellation time (min) ^b	15 (14–16)	14 (13–15.25)	0.071
Resected weight (g) ^a	65.0 ± 7.6	66.5 ± 5.8	0.230
Hemoglobin decrease (g/dl) ^b	0.8 (0.6–1.0)	0.7 (0.6–1.0)	0.154
Catheter time (days) ^b	2 (2–3)	2 (2–3)	0.694
Hospital stay (days) ^b	2 (2–3)	2 (2–3)	0.501

Mean ± standard deviation. Median (IQR)

^aNormally distributed variable data analyzed with independent-sample *t* test

^bNon-normally distributed variable data analyzed with the Mann–Whitney *U* test

Results

Baseline characteristics

Table 1 lists the baseline characteristics of the patients. There were no statistically significant differences in baseline characteristics between the HoLEP (*n* = 58) and ThuLEP groups (*n* = 58).

Perioperative results

Table 2 lists perioperative data. The operation was successful for all patients. The operative time (78.4 ± 8.0 vs. 71.4 ± 6.4 min) and enucleation time (61.2 ± 5.4 vs.

56.4 ± 8.4 min) were significantly longer for HoLEP compared to ThuLEP (both *p* < 0.001). There were no significant differences between the two groups regarding morcellation time, resected weight, hemoglobin decrease, catheter time or hospital stay.

Follow-up results

Table 3 lists the changes in IPSS, QoL, Qmax, PVR and PSA in 1, 3, 6, 12 and 18 months after the operation. There were no statistically significant differences between the two groups with respect to follow-up data (*p* > 0.05). Of the 116 patients, 107 completed the 18-month follow-up: 54 of 58 in the HoLEP group and 53 of 58 in the ThuLEP group. The reasons for dropouts were decision to withdraw by five patients and loss of contact by four patients.

Complications

Table 4 lists detailed information on all complications and treatment modalities. Slight postoperative hematuria was observed in three (5.2%) patients in the HoLEP group and one (1.7%) patient in the ThuLEP group, who all received prolonged bladder irrigation. After catheter removal, only one patient in the HoLEP group needed recatheterization because of urinary retention, while five (8.6%) patients in the HoLEP group and two (3.4%) patients in the ThuLEP group developed a self-limiting transient incontinence. Bladder mucosal injury was observed in four (6.9%) patients in the HoLEP group and one (1.7%) patient in the ThuLEP group. During the first 3 months of follow-up, four patients (one in the HoLEP group and three in the ThuLEP group) complained of urinary tract infection, but this resolved with sensitive antibiotics. In total, there was no significant difference in the first 3-month side effect rate between the HoLEP and ThuLEP groups (*p* = 0.147).

Within the observation periods of 12 months and 18 months, the complications included urethral stricture and bladder-neck contracture, which required internal urethrotomy or bladder-neck incisions. However, no significant differences were observed between the two groups.

Using the modified Clavien classification system (Table 5), minor complications requiring slight treatment occurred in 14 (24.1%) patients in the HoLEP group (Clavien 1: 22.4%; Clavien 2: 1.7%) and 7 (12.1%) patients in the ThuLEP group (Clavien 1: 6.9%; Clavien 2: 5.2%). Major complications requiring interventions occurred in two (3.4%) patients in the HoLEP group (Clavien 3a: 0; Clavien 3b: 3.4%) and two (3.4%) patients in the ThuLEP group (Clavien 3a: 0; Clavien 3b: 3.4%). No life-threatening complications occurred. There was no significant difference between the two groups in the occurrence of Clavien grade 1–3b complications.

Table 3 Follow-up data

Variables	1 month	3 months	6 months	12 months	18 months
Patient no.					
HoLEP	58	58	57	55	54
ThuLEP	58	58	58	56	53
IPSS ^a					
HoLEP	7 (6–7)	4 (3.75–5)	3 (3–4)	3 (2–3)	3 (3–3)
ThuLEP	6 (6–7.25)	3 (3–5)	3 (2.75–4)	3 (2–4)	3 (3–3)
<i>P</i> value	0.629	0.177	0.986	0.400	0.776
QoL ^a					
HoLEP	3 (2–3)	2 (1–2.25)	1 (1–2)	1 (1–2)	1 (1–2)
ThuLEP	2 (1–3)	2 (1–2)	1 (1–2)	1 (1–2)	2 (1–2)
<i>P</i> value	0.077	0.217	0.476	0.484	0.809
Qmax (ml/s) ^b					
HoLEP	22.8±4.1	24.8±4.7	26.0±4.5	26.6±4.9	25.3±4.8
ThuLEP	23.3±3.8	25.2±4.4	25.3±4.7	25.5±4.5	24.7±4.4
<i>P</i> value	0.513	0.683	0.446	0.197	0.470
PVR (ml) ^a					
HoLEP	15.9 (6.9–27.1)	12.1 (4.8–27.0)	9.3 (4.1–24.8)	6.5 (2.9–18.3)	6.1 (2.6–20.8)
ThuLEP	15.0 (7.1–33.2)	14.7 (7.0–31.8)	8.2 (3.5–26.7)	7.5 (3.8–21.3)	7.7 (3.1–22.8)
<i>P</i> value	0.718	0.193	0.763	0.341	0.449
PSA (ng/ml) ^b					
HoLEP	1.44±0.35	0.86±0.38	0.62±0.31	0.58±0.32	0.84±0.32
ThuLEP	1.40±0.38	0.81±0.34	0.57±0.30	0.65±0.33	0.90±0.34
<i>P</i> value	0.634	0.440	0.413	0.213	0.309

Mean ± standard deviation. Median (IQR)

IPSS International Prostate Symptom Score, QOL quality of life, Qmax maximum urinary flow rate, PVR postvoid residual urine, PSA total serum prostate-specific antigen

^aNon-normally distributed variable data analyzed with the Mann–Whitney *U* test

^bNormally distributed variable data analyzed with independent-sample *t* test

Table 4 Short- to medium-term complications of the two groups

Complication	Treatment	HoLEP, <i>n</i> (%)	ThuLEP, <i>n</i> (%)	<i>P</i> value
Early postoperative complications, from 0- to 3-month follow-up				
Postoperative hematuria	Bladder irrigation	3 (5.2)	1 (1.7)	0.618
Transient incontinence	Functional training	5 (8.6)	2 (3.4)	0.438
Urinary retention	Recatheterization	1 (1.7)	0	–
Bladder mucosal injury	No treatment	4 (6.9)	1 (1.7)	0.364
Urinary tract infection	Antibiotics	1 (1.7)	3 (5.2)	0.618
Total ^a		14 (24.1)	7 (12.1)	0.147
12-Month follow-up complications				
Urethral stricture	Internal urethrotomy	1 (1.7)	0	–
Total		1 (1.7)	0	–
18-Month follow-up complications				
Urethral stricture	Internal urethrotomy	0	1 (1.7)	–
Bladder-neck contracture	Bladder-neck incisions	1 (1.7)	1 (1.7)	1.000
Total		1 (1.7)	2 (3.4)	1.000

Data analyzed with the Fisher's exact probability test

^aData analyzed with the Chi-square test

Table 5 Complications in the two groups using the Clavien–Dindo classification

Complications	HoLEP, <i>n</i> (%)	ThuLEP, <i>n</i> (%)	<i>P</i> value
Clavien grade 1 ^a	13 (22.4)	4 (6.9)	0.033
Clavien grade 2 ^a	1 (1.7)	3 (5.2)	0.618
Clavien grade 3a ^a	0	0	–
Clavien grade 3b ^a	2 (3.4)	2 (3.4)	1.000
Clavien grade 4	0	0	–
Total ^b	16 (27.5)	9 (15.5)	0.175

^aData analyzed with the Fisher's exact probability test

^bData analyzed with the Chi-square test

Discussion

Laser enucleation of the prostate has developed as an efficient and minimally invasive method that may provide similar outcomes compared with TURP and OP [15]. Introduction of the holmium laser represented a turning point in minimally invasive laser therapy for BPH [16]. Newly emerging ThuLEP also showed comparable results to HoLEP, with the same efficacy and safety. Complications associated with these two techniques recorded within the intra- and perioperative period were mostly minor [17]. While long-term safety and efficiency for even large-volume prostates have been noted for HoLEP [2], evidence is still pending on the safety and efficiency of ThuLEP. Only Becker et al. recently reported the 48-month durability of ThuLEP for large-volume prostate [18]. Herein, we report the results of a RCT comparing ThuLEP with HoLEP in patients with large-volume prostates (> 80 ml) during an 18-month follow-up.

In our study, we observed a significant difference in operation time, which favored the ThuLEP technique. The difference in the energy setting might be a reasonable explanation. The HoLEP procedure was performed with an energy setting of 90 W for cutting and 20 W for coagulation. The ThuLEP procedure was performed with an energy setting of 120 W for cutting and 60 W for coagulation. A higher energy setting may result in faster enucleation speed and less operation time [19, 20]. The physical properties of the thulium laser may also play an important role. On the one hand, the wavelength of the thulium laser is closer to the water absorption peak compared with holmium laser, and water is the main absorbing substance, which comprises about two-thirds of the prostate, thus resulting in a high energy absorption rate and tissue vaporization even during enucleation [8, 21]. On the other hand, compared with the pulsed mode of the holmium:YAG laser, the continuous-wave mode of the thulium:YAG laser might provide a faster enucleation [22].

Several studies have reported that the overall PSA reduction could be a marker of complete removal of the adenoma

[23, 24]. In our study, the mean decrease in PSA after HoLEP and ThuLEP at 18 months was 83.5 and 81.9%, respectively, which might be higher than the data reported in the literature [18, 25]. The more obvious PSA reduction in our study can be explained in part by the larger prostate size. In the study from Zhang and his colleagues [23], a mean PSA reduction of 71.3% and 77.2% was obtained in four HoLEP patients and five ThuLEP patients with a prostate 70 ml, while another two patients with a prostate 35 ml had a 24.2% and 26.1% PSA reduction. In the present study, all patients had a prostate over 80 ml, which might explain the result of PSA reduction.

HoLEP and ThuLEP are similarly associated with a high risk of postoperative ejaculatory dysfunction, especially retrograde ejaculation, which was an inevitable sequel of enucleation prostatectomy if the verumontanum was not spared [11, 26]. A recent study from Briganti and his colleagues reported that retrograde ejaculation was the major adverse event of men undergoing HoLEP, and the incidence of retrograde ejaculation was up to 78.3% [27]. Another study from Carmignani et al. reported that of the sexually active patients, 47.3% experienced retrograde ejaculation after ThuLEP [28]. However, in the present study, we failed to use the IIEF-5 questionnaire and calculate the rate of retrograde ejaculation during the follow-up. Because the patients in our center are elderly (ages 63–85 years), almost none participate in sexual activity. Most elderly Chinese men are sexually conservative and consider that the loss of libido and erectile function are natural consequences of aging. Thus, they seldom consult with a doctor about this embarrassing situation, although it is sometimes morbid and could be treated.

Clavien 1 grade complications were significantly different between the two groups. Of note, transient incontinence and bladder mucosal injury mainly accounted for this difference. The main factor in the occurrence of transient incontinence was the total operation time. A longer operation time seemed to cause postoperative transient incontinence more often, as well as delays in the recovery from this complication [29]. We consider that a long operation time is associated with urethral sphincter damage due to its compression, stretching, and tearing by the resectoscope during the operation. In the present study, the operative time was significantly longer for HoLEP compared to ThuLEP ($p < 0.05$). Bladder mucosal injury is often associated with the use of mechanical morcellation. Although all patients underwent continuous double bladder irrigation to maintain safe bladder distension during the operation, bladder mucosal injury was not avoided successfully in every patient. We attributed this finding to a technical problem. In the future, we will consider improving the operation technique to avoid injuries to the bladder wall.

ThuLEP is characterized by blunt mechanical enucleation of the adenoma [8], while ThuLEP exploits tissue

vaporization to achieve prostate incision and enucleation [17]. One main advantage of ThuLEP is that tissue specimens could be reserved for pathologic examination, which avoids the risk of missing an opportunity for prostate cancer diagnosis. However, in the present study, no prostate cancer was found, nor did histopathological examination produce a high rate of malignancies. On the one hand, most prostate cancers are present in peripheral zones, and transurethral prostatectomy is executed in the transitional zone. On the other hand, to avoid the small risk of not identifying a clinically significant prostate cancer, patients were given adequate preoperative examinations even biopsy, and prostate cancer was strictly and carefully excluded in our trial.

Both HoLEP and ThuLEP ensure complete adenoma removal similar to OP, ensuring excellent and long-term functional results and a low recurrence rate [8, 16]. However, there are still some differences. HoLEP is an energy-based enucleating transurethral procedure where the plane is created by application of energy [21]. The pulsed nature of holmium:YAG includes a “scar-free” feature on the prostatic surface and makes the plane of enucleation easy to develop and follow, providing superior visibility with precise incision and dissection [23]. Moreover, patients undergoing surgical deobstruction for BPH frequently require management of concomitant pathological conditions such as bladder stones or stricture ablation, and the pulsed nature of the holmium laser allows it to be utilized for stone fragmentation as well as soft tissue applications. From a technical standpoint, HoLEP is a more versatile endoscopic tool compared with ThuLEP [25]. ThuLEP is a blunt dissection following the plane over prostatic capsule that is entitled anatomical enucleation. It is an excellent energy source for anatomical enucleation as it provides a clear and bloodless incision through prostatic tissue necessary in the initial steps of the operation when incision at 5 and 7 o’clock of bladder neck is performed. In addition, it has a narrow penetration depth protecting pericapsular tissue from unnecessary energy exposure [20]. It also offers maximum hemostasis necessary for punctual coagulation of penetrating capsular vessels during enucleation [8]. Due to the reduced surface of coagulation, ThuLEP is believed to lead to significantly less irritative symptoms than HoLEP.

This article does have limitations. The sample size was relatively small, and the study was performed in a single center; thus, multicenter and large-scale studies are warranted to further confirm the efficacy and safety of ThuLEP. Moreover, the follow-up time was not long enough, even though the results seem promising. Extended follow-up outcomes are needed to determine the exact role of ThuLEP for the surgical management of large-volume prostate. Finally, erectile and sexual functions need to be compared after these two surgeries. This issue needs to be addressed in further studies.

Conclusion

This RCT confirms that both HoLEP and ThuLEP are comparable treatment modalities in terms of perioperative complications and functional outcome parameters for large prostates (> 80 ml) during an 18-month follow-up period. However, to draw final conclusions, an extended follow-up is needed to assess the true long-term durability.

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Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

Ethical approval All procedures performed in studies involving human participants/or animals 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. Institutional Review Board approval for this study was obtained from the Ethical Committee of Xiangya Hospital Central South University on 31 January 2016.

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

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