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Original Article

Thulium Laser Enucleation of The Prostate for Treatment of Benign Prostatic Hyperplasia: A Single Center Experience

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Abstract

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Background: Benign prostatic hyperplasia [BPH] is a prevalent medical condition in older men that leads to symptoms affecting the lower urinary system [LUTS]. Thulium Laser Enucleation of The Prostate [THULEP] seems to be a promising procedure for treatment of BPH with minimal side effects.

Aim of the work: The aim of this study was to evaluate the outcomes of THULEP in patients with benign prostatic hyperplasia.

Patients and methods: A prospective non-controlled study included 30 participants who have failed medical therapy to LUTS attributable to BPH and underwent THULEP. The primary outcome was international prostate symptom scores [IPSS] score at 6 months. Other outcomes included operative time, intraoperative complications, length of hospital stay, changes in the maximum flow rate, post voiding residual [PVR], prostate-specific antigen [PSA] and continence status.

Results: The mean [range] prostate size was 72.3 [40-124] ml, the mean operative duration was 86.40 [48-123] min and the mean enucleation time 73.33 [40-105] min. The improvements in IPSS, Q_{max} , PVR and PSA were significant [$P < 0.001$], with mean values before and after THULEP [IPSS from 25 to 2.5, Q_{max} from 10 ml/sec to 18.1 ml/sec, PVR from 92.5 to 13 ml, PSA from 3 to 1.05, respectively]. Of the 30 patients, 20 [66.6%] were catheter-free on the first day after THULEP; the mean hospital stay was 2.63 days.

Conclusion: The BPH can be completely removed with ThuLEP. The methods combine high effectiveness with negligible negative effects.

Keywords: Prostate; Prostatic Hyperplasia; Laser Coagulation.



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INTRODUCTION

Among older men, benign prostatic hyperplasia [BPH] is a prevalent condition leading to lower urinary tract symptoms [LUTS]^[1]. For years, transurethral resection of the prostate [TURP] and open simple prostatectomy [OSP] have been the standard treatments for prostates under 80 g and between 80 and 100 g, respectively, when Lower urinary tract symptoms [LUTS] are intractable to medicinal therapy and unpleasant enough to merit surgical intervention^[2, 3]. However, both procedures are linked to significant complications, which occur during and after surgery, and related to conditions such as bleeding, blockage of urinary flow, by clots, needing treatment, infections in the urinary system, absorption of fluids, resulting in a condition called transurethral resection syndrome [TUR] syndrome^[4-6]. The last two decades have seen newer, less invasive surgical methods like Prostate artery embolization [PAE]^[7], photo-selective vaporization of the prostate [PVP]^[8] and laser resection therapies. Laser enucleation of the prostate [LEP] has become a popular and widely used less invasive option for surgical treatment of BPH, serving as an alternative to TURP and OSP^[9, 10]. Laser enucleation of the prostate [LEP] can be conducted using various energy sources, with the most widely known being holmium laser enucleation of the prostate [HoLEP]^[11]. The advancement of new technologies has led to the introduction of alternative laser energy sources^[12]. The thulium laser, a newly emerging surgical laser, has gained attention in the medical field along with the development of holmium laser prostatectomy. It possesses unique qualities that make it stand out from other lasers, including negligible bleeding, a high rate of tissue removal while causing minimal heat damage, and precise cutting capabilities^[9, 13]. The outstanding safety and effectiveness of the thulium laser for the treatment of BPH have been shown in several studies from Europe and Asia^[14]. There is no much data published about thulium laser enucleation of the prostate in low-resources countries. So, as a growing center, we will present our effort in studying this procedure.

PATIENTS AND METHODS

From October 2018 to June 2023, symptomatic BPH 30 patients enrolled prospectively in our study. Patients were presented at the outpatient clinic of Al-Azhar University Hospital, New Damietta for BPH-related symptoms.

Inclusion criteria for the study were as follows: **1]** Patients who were 50 years of age or older, **2]** Patients with refractory lower urinary tract symptoms [LUTS] caused by benign prostatic hyperplasia [BPH] who did not respond to medical treatment. This includes patients with either: a) International prostate symptom scores [IPSS] greater than 15 and a bother score [quality of life] of 3 or higher [based on IPSS question 8], b) Peak urinary flow rate [Q max] less than 15 ml/sec with a minimum voided volume of 125 ml, **3]** Patients who experienced acute urine retention due to BPH and did not successfully void after receiving medical treatment, **4]** Patients with an estimated transrectal ultrasound [TRUS] prostate volume of 40 ml or larger, and **5]** Patients with an American Society of Anesthesiologists [ASA] score of 3 or lower.

The exclusion criteria include the following: **1]** Patients who have neurological disorders that may impact bladder function, such as stroke or Parkinson's disease, **2]** Patients with an ongoing urinary tract infection that has not yet been treated, **3]** Patients who have had bladder cancer within the past 2 years, and **4]** Patients with known prostate cancer who are identified through a preoperative assessment

involving a digital rectal examination, measurement of prostate specific antigen levels, and transrectal ultrasound imaging along with multiparametric MRI. If needed, prostate biopsies will be performed to further evaluate the presence of cancer.

Ethical consideration: The patients provided written consent for their clinical records to be used in this study. Before conducting the study, we obtained approval from the Institutional Review Board [IRB] at Damietta Faculty of Medicine, Al-Azhar University, Egypt.

Data collection: Prior to the surgery, thorough evaluations of the urinary system were conducted, which involved procedures such as a digital rectal examination, transrectal ultrasound, and an assessment of the International Prostate Symptom Score. The examination also included reviewing the postvoid residual urine and urinary peak flow rate. Additional tests performed included urine analysis, blood tests [including hemoglobin levels], and measuring the serum prostate specific antigen. This measurement was taken before the digital rectal examination and any other procedures performed on the patient. In cases where the PSA values were abnormal or the digital rectal examinations were suspicious, a biopsy of the prostate was conducted using a 12-core needle. Preoperative clinic assessments were done two weeks before surgery, where routine laboratory tests, ECG and full medical evaluation will be performed. Patients with urinary tract infection [UTI] will be treated accordingly preoperatively.

Surgical technique: We used [RevoLix DUO, LISA Laser Products OHG, Katlenburg-Lindau, Germany] 120 W system. Energy Typically 100 W laser is used. Fiber Typically, a 550 µ end-firing thulium laser fiber is used. Morcellator mechanical tissue morcellator [storz with S-PILOT® vacuum control unite and UNIMATE®30 suction pump]. 26 Fr continuous flow resectoscope. Continuous saline irrigates solution set. Enucleation done using Fiber Typically, a 550 µ end-firing thulium laser fiber a 100 W laser is used. All patients offered spinal anesthesia. Initial cystoscopy to assess ureteric orifices and bladder anatomy and prostate anatomy either bilobar or trilobar. Procedure starts by inspection of urinary bladder and ureteric orifice and prostate [figure 1] then incision of the bladder neck [figure 2] and trough creation [figure 3] then we develop the plain [figure 4] followed by apico-lateral dissection [figure 5] and sphincter release [figure 6] then anterior dissection and bladder neck dissection [figure 7] and c-shaped basolateral dissection then detachment of the adenoma [figure 8] a technique called veil sparing THULEP as described by **Elshal et al.**^[15]. At the end of the procedure, the developed TURP-like cavity was inspected after evacuating the bladder and any remaining bleeders were identified and coagulated, the end point was a TURP-like cavity reaching to capsular fibers with tongue like projecting of the veru montanum. A 22 Fr 3-way catheter was inserted with continuous irrigation [with saline] over night until urine is clear. The catheter was routinely removed the next morning provided that it was clear if the urine wasn't clear continuous bladder irrigation was carried out till the urine became clear. When the patient could void adequately [no significant PVR], he was discharged from the hospital for follow up in outpatient clinic with recommendation of oral quinolones for 2 weeks unless other indication. Catheter was prolonged in case of bladder wall injury, capsular violation and failed first trial of voiding [TOV]. Patients with failed 1st TOV were managed conservatively by prolongation of catheterization time for one week [then removed at the outpatient clinic] and medical treatment [antibiotics, anti-inflammatory and anti-edematous treatment].



Figure [1]: Inspection

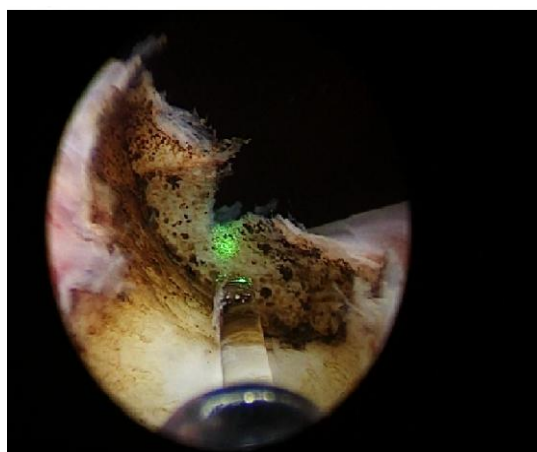


Figure [2]: Incision of bladder neck



Figure [3]: Trough creation



Figure [4]: Plain development



Figure [5]: Apico-lateral dissection



Figure [6]: Sphincter identification



Figure [7]: Bladder neck dissection

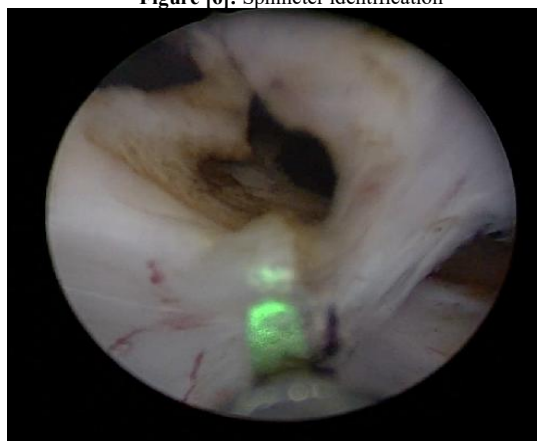


Figure [8]: Adenoma detachment

Assessment

Intraoperative assessment:

1] Estimation of the operative time [started from onset of enucleation till time of insertion of urethral catheter], 2] Enucleation time, 3] Morcellation time and 4] Recording of any intraoperative complications.

Postoperative assessment:

1] Estimation of hemoglobin value in the first postoperative day, 2] Estimation of duration required for postoperative irrigation and its amount, 3] Time required for catheter removal, 4] PVR at discharge, 5] Hospital stay, 6] Continence status at discharge, and 7] Recording of any postoperative complication according to Clavien-Dindo classification.

Follow up:

The patients were followed up in outpatient clinic after 2 weeks, 4 and 6 months postoperative. Each visit included assessment of 1] Continence state: Postoperative urinary incontinence was defined as the complaint of any involuntary leakage of urine. Continence status was reported every visit and pad test was performed for those with persistent incontinence lasting till 6 months visit to assess severity or degree of incontinence. Then different treatment options were offered such as: PFMT [pelvic floor muscle training], behavioral therapy [patient education, double and timed voiding, moderation of fluid intake and avoid bladder irritants], medications [antimuscarinics]; 2] IPSS score; 3] Urine analysis and culture if needed; 4] PSA; 5] Uroflowmetry; 6] Estimation of post micturition residual urine by pelvic Ultrasound

Outcome measures

The primary outcomes: The primary endpoint is IPSS score at 6 months among preoperatively catheterized and non-catheterized patients.

Secondary outcomes:

- Operative: prostate morphology by cystoscopy, operative time, irrigation fluids and intraoperative complications.
- Early postoperative period: change in hemoglobin, duration of catheterization time, length of hospital stay and morbidity.
- During follow up visits [till 6 months]: Changes in the maximum flow rate, PSA, post voided residual urine, retreatment rate, continence status.

Statistical analysis:

The statistical analysis was performed using the IBM-SPSS program version 21. The variables were described using measures of

frequency, percentages, averages [mean, median], and measures of dispersion [standard deviation, range, interquartile range]. Inferential statistics, such as t-tests, ANOVA, and chi-square tests, were used to determine the representativeness of the study samples and investigate any differences in the variables based on demographic characteristics. Friedman Two-way analysis Test with post pairwise comparison and Wilcoxon Signed Rank test were used to detect the repeated measures differences among the study groups. Learning curve with equation was done to detect the rate of reduction of the duration of the procedure time using Excel software [office 2016 computer package]. Alpha was set to 0.05

RESULTS

The mean age of the retention group is slightly lower than the non-retention group, but the difference is not statistically significant [$p=0.489$]. Similarly, there were no significant differences between the two groups in terms of residency, BMI, diabetes mellitus, hypertension, and smoking history, as indicated by the p-values above 0.05 [table 1].

In table [2], IPSS, PVR, Q max, and hemoglobin levels are recorded. The catheter-dependent group had significantly lower hemoglobin levels [mean $\pm$ SD: 13.9 ± 0.2 vs. 14.6 ± 0.4 , $p=0.002$] compared to the non-retention group. However, there were no significant differences in PSA levels between the two groups [mean $\pm$ SD: 3.58 ± 1.7 vs. 3.01 ± 1.2 , $p=0.259$].

There was no difference between the two groups regarding, operative time, prostate morphology, and none of the patients developed TUR syndrome. There were no significant differences between the catheter-dependent and non-catheter-dependent groups for any of the operative parameters, as indicated by the p-values above 0.05. Specifically, the frequency and percentage of patients with bilobar and trilobar prostate morphology were not significantly different between the two groups [$p=0.090$].

Additionally, there were no significant differences between catheter-dependent and non-catheter-dependent groups for catheterization time [mean $\pm$ SD: 2.00 ± 2.4 vs. 2.42 ± 2.2 , $p=0.692$], length of hospital stay [mean $\pm$ SD: 3.17 ± 3.3 vs. 2.50 ± 2.4 , $p=0.584$], procedure time [mean $\pm$ SD: 91.81 ± 7.1 vs. 85.0 ± 20.8 , $p=0.468$], Enucleation time [mean $\pm$ SD: 78.67 ± 15.1 vs. 72.0 ± 17.9 , $p=0.409$]. The table shows that the mean catheterization time was 2.33 ± 2.2 days, the mean length of hospital stay was 2.63 ± 2.6 days, the mean procedure time was 86.40 ± 20.0 minutes, the mean enucleation time was 73.33 ± 17.3 minutes, the mean morcellation time was 13.07 ± 3.6 minutes.

Regarding IPSS score, there was rapid improvement from 27.7 ± 0.99 preoperatively to 2.79 ± 1.10 after 2 weeks [$P, < 0.001$]. Patients continued to show slight improvements over the 6-months follow up. Regarding Q-Max, patients showed marked improvement after 2 weeks, which persisted over follow up duration [table 4].

There was gradual improvement of PVR and PSA over the period of follow up with statistically significant difference [table 5].

Table [1]: Demographic and medical history of the study patients

Variables		Catheter dependent 6 [16.7%]	Non-Catheter dependent 24 [66.7%]	Total 30 [100%]	P value
Age [Years]	Mean $\pm$ SD	64.1 $\pm$ 7.54	65.8 $\pm$ 4.72	65.53 $\pm$ 5.29	0.489
	Range	55 – 72	53 – 74	53 – 74	
Residence	Urban	2 [53.8%]	11 [46.2%]	13 [43.3%]	0.580
	Rural	4 [52.9%]	13 [47.1%]	17 [56.7%]	
BMI [kg/m ²], mean $\pm$ SD		25.8 $\pm$ 1.53	26.5 $\pm$ 1.35	26.38 $\pm$ 1.39	0.330
Diabetes mellitus	Yes	1 [16.9%]	7 [29.2%]	8 [26.7%]	0.536
	No	5 [83.3%]	17 [70.8%]	22 [73.3%]	
Hypertension	Yes	3 [50.0%]	10 [41.7%]	13 [43.3%]	0.713
	No	3 [50.0%]	14 [48.3%]	17 [43.3%]	
Smoking	Yes	4 [66.7%]	11 [45.8%]	12 [40%]	0.361
	No	2 [33.3%]	16 [44.2%]	18 [40%]	

Table [2]: Pre-operative data of the study patients

Variables		Catheter-dependent 6 [16.7%]	Non-catheter-dependent 24 [66.7%]	Total 30 [100%]	P value
IPSS, mean $\pm$ SD		NA	24.7 $\pm$ 0.9		
PVR [ml], mean $\pm$ SD		NA	103.7 $\pm$ 24.2		
Qmax [mL/s], mean $\pm$ SD		NA	10.8 $\pm$ 1.9		
PSA [ng/mL], mean $\pm$ SD		3.58 $\pm$ 1.7	3.01 $\pm$ 1.2	3.1 $\pm$ 1.3	0.259
Hemoglobin[g/dL], mean $\pm$ SD		13.9 $\pm$ 0.2	14.6 $\pm$ 0.4	14.4 $\pm$ 0.5	0.002
Prostate Volume [mL] [TRUS]	Mean $\pm$ SD	76.3 $\pm$ 16.0	71.3 $\pm$ 22.8	72.37 $\pm$ 21.4	0.621
	Range	44-87	42-124		

Table [3]: Operative data of the study patients

Variables		Catheter-dependent 6 [16.7%]	Non catheter-dependent 24 [66.7%]	Total 30 [100%]	P value
Prostate Morphology	Bilobar	3 [50.0%]	20 [83.3%]	23 [76.7%]	0.090
	Trilobar	3 [50.0%]	4 [16.7%]	7 [23.3%]	
Catheterization time [days]					
Mean $\pm$ SD		2.00 $\pm$ 2.4	2.42 $\pm$ 2.2	2.33 $\pm$ 2.2	0.692
Length of hospital stay					
Mean $\pm$ SD		3.17 $\pm$ 3.3	2.50 $\pm$ 2.4	2.63 $\pm$ 2.6	0.584
Procedure time [min]					
Mean $\pm$ SD		91.81 $\pm$ 7.1	85.0 $\pm$ 20.8	86.40 $\pm$ 20.0	0.468
Enucleation Time [min]					
Mean $\pm$ SD		78.67 $\pm$ 15.1	72.0 $\pm$ 17.9	73.33 $\pm$ 17.3	0.409
Morcellation Time [min]					
Mean $\pm$ SD		13.1 $\pm$ 3.6	13.0 $\pm$ 3.4	13.07 $\pm$ 3.6	0.941
Energy used [Joule]					
Mean $\pm$ SD		64.6 $\pm$ 5.4	55.7 $\pm$ 12.3	57.53 $\pm$ 11.7	0.098
Retrieved prostate Weight					
Mean $\pm$ SD		36.1 $\pm$ 10.1	34.4 $\pm$ 12.1	34.80 $\pm$ 11.6	0.753
Morcellation efficiency					
Mean $\pm$ SD		2.9 $\pm$ 1.2	2.6 $\pm$ 0.7	2.74 $\pm$ 0.8	0.577
Enucleation efficiency					
Mean $\pm$ SD		0.47 $\pm$ 0.1	0.48 $\pm$ 0.1	0.48 $\pm$ 0.1	0.841

Table [4]: IPSS and Q-MAX scores comparison of preoperative and postoperative data between the studied groups

Variables	Pre-operative		After 2 weeks	After 4 Months	After 6 Months	P value*
IPSS scores	Non-Catheter Dependent					
	Mean $\pm$ SD	24.7 $\pm$ 0.99	2.79 $\pm$ 1.10 ^a	2.71 $\pm$ 0.62 ^b	2.67 $\pm$ 1.23 ^c	0.002
Q-MAX scores	Non-Catheter Dependent					
	Mean $\pm$ SD	10.85 $\pm$ 1.96	29.05 $\pm$ 3.73 ^a	18.45 $\pm$ 2.06 ^b	18.65 $\pm$ 5.95 ^c	0.001

* ANOVA with post hoc Tukey, ** Independent t test, ^a significant pre-operative and After 2 weeks, ^b significant pre-operative and After 4 months, ^c significant pre-operative and After 6 months

Table [5]: PVR, PSA and Prostate Volume scores comparison of preoperative and postoperative data between the studied groups

Variables		Pre-operative	After 2 weeks	After 4 Months	After 6 Months	P value*
PVR [ml]	Non-Catheter Dependent					
	Mean ± SD	24.29 ± 4.95	12.46 ± 2.54 ^a	10.30 ± 2.10 ^b	9.57 ± 1.95 ^c	0.004
PSA [ng/mL]	Catheter Dependent					
	Mean ± SD	3.58 ± 1.75	-----	1.55 ± 0.65 ^b	1.33 ± 0.61 ^c	0.000
	Non-Catheter Dependent					
	Mean ± SD	3.01 ± 1.24	-----	1.21 ± 0.48 ^b	0.94 ± 0.22 ^c	0.004
	P value**	0.359	-----	0.160	0.073	

* ANOVA with post hoc Tukey, ** Independent t test, ^a significant pre-operative and After 2 weeks, ^b significant pre-operative and After 4 months, ^c significant pre-operative and After 6 months

DISCUSSION

Over the past ten years, the holmium laser enucleation of the prostate [HoLEP] and the thulium laser enucleation of the prostate [ThuLEP] have become increasingly popular methods for treating prostate issues, with similar levels of success ^[16]. The Thu: YAG laser operates by emitting a continuous wave of energy with a wavelength that is near 2.0 mm, which is the peak wavelength for water absorption. This makes it effective for vaporizing and cutting purposes. ThuLEP was introduced by **Herrmann et al.** ^[17] in 2010 as a progression of thulium laser vapo-enucleation of the prostate [ThuVEP] described by **Bach et al.** ^[18] in 2009.

Regarding baseline data of the studied group, the current study showed that the mean age was 65.53 ± 5.29 years. The current study showed that the mean operative time was 109.3 min and mean enucleation duration was 64.53 min with morcellation duration was 47.1 min, while mean catheter time was 1.4 days and mean hospital stay ranges from 1 to 7 days.

The current study was further supported by **Petov et al.** ^[19] who analyzed the outcome of ThuLEP on 1328 patients with mean age of 66.9 – 7.5 years. The study revealed that the duration of the surgical procedure ranged from 70.5 to 31.3 minutes, with a variation between 25 and 248 minutes. Likewise, the amount of tissue that was removed varied from 69.6 to 33.6 grams, with a range of 20 to 255 grams. The average length of time for catheterization and hospitalization was between 1.7 and 0.8 days, with a range of 1 to 3 days and 3.7 to 1.0 days, respectively, with a range of 3 to 5 days for hospitalization.

The operative time varied from study to another depending on the size of the tumor of the studied patients, surgeon experience and the used instrumentations. Also, the hospital stay depends on the rate of complications incidence and patient age.

A recent analysis found a significant difference in the time it takes to remove the prostate using the ThuEP and HoLEP techniques. The ThuEP technique was found to be faster. Many studies have also reported that the ThuEP technique is highly effective in removing the prostate ^[12].

This is likely due to two factors: firstly, the thulium laser has a wavelength that closely matches the peak absorption of water, which makes up a large portion of the prostate. This results in a high rate of energy absorption and quick tissue vaporization. Secondly, the continuous wave mode of the thulium laser may allow for faster removal compared to the pulsed mode of the holmium laser ^[20].

The comparison of preoperative and postoperative data of the studied patients showed that there was a significant reduction in prostate volume, PSA, IPSS, QoL, IIEF-5, VAS, PVR and hemoglobin while there is a significant increase in Q_{max} postoperative.

Our results agreed with **Raber et al.** ^[21] who revealed that during the 1-month follow-up after surgery, 99% of the patients experienced spontaneous voiding and showed significant improvements in IPSS, QoL score, maximum urinary flow rate [Q_{max}], and PVR. ThuLEP had a significant impact on IPSS and QoL score, with improvements seen, as well as an increase in Q_{max} and a decrease in PVR. There was a noticeable decrease in Hb levels between preoperative and pre-discharge measurements. After 12 months, the PSA level, IPSS, QoL score, Q_{max} , and PVR remained similar to the immediate postoperative results.

Furthermore, **Chang et al.** ^[22] aimed to evaluate the outcomes of thulium laser enucleation of the prostate [ThuLEP]. 125 patients with glands larger than 80 mL were included in the study. The average age of the participants was 71.85 ± 8.89 years. The IPSS [International Prostate Symptom Score] before surgery was 27.09, which decreased to 7.35 after surgery. The postoperative prostate-specific antigen [PSA] levels were reduced by 85.59% compared to the preoperative levels. The estimated size of the prostate was reduced by 74.17% after surgery.

In theory, ThuLEP relies more on using blunt dissection compared to ThuVEP, which primarily relies on the cutting ability of the laser. However, in actual practice, a combination of both systems is typically used, making it difficult to make a clear discrepancy between them ^[10]. The advantage of having cutting ability is that it can be useful in cases where it is difficult to access the enucleation plane, as the removal of an organ anatomically is not always required. On the other hand, HoLEP is typically seen as a more anatomical approach because the laser's energy tends to follow the easiest path, which is usually the space between the adenoma and the surgical capsule ^[12].

The current study showed that the postoperative complications rate was 6.7%. Our results were comparable with **Vartak and Raghuvanshi** ^[23] reported that the most common adverse event in high-risk patients subjected to ThuLEP was arrhythmias, which were not harmful, occurring in 16 cases [14.6%]. The second most common adverse event was a decrease in blood pressure that required noradrenaline or mephentine in 11 cases [10%], followed by early left ventricular failure treated with diuretics in 7 cases [6.4%].

Compared to HoLEP techniques **Bozzini et al.** ^[16] showed that both ThuLEP and HoLEP provided equal relief for lower urinary tract symptoms, with high effectiveness and safety. ThuLEP resulted in less blood loss and fewer early postoperative complications. There was no significant difference in catheterization time, enucleated tissue, hospital stay, operative time, and follow-up parameters between the two methods.

Thus, it is assumed that the thulium laser's wavelength could potentially provide better coagulation and effective control over blood loss during surgery when compared to the holmium laser ^[24]. Consequently, literature showed that ThuLEP was associated with the best functional outcome and least adverse events.

The study's limitations consist of a limited number of participants, no control group, and being conducted in a single center.

Conclusion:

ThuLEP represents a safe, effective surgical option in patients with symptomatic BPH producing significant reduction in prostate volume, PSA, IPSS, QoL, IIEF-5, VAS and PVR, while there is a significant increase in Q_{max} postoperative. Furthermore, ThuLEP offers the advantage of decreased bleeding complications and the possibility to treat patients with bleeding disorders or on anti-coagulation therapy. Further comparative studies with larger sample size and longer follow-up are needed to confirm our results and to identify risk factors of adverse events.

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