Thulium laser enucleation versus transurethral resection of the prostate in saline in the management of benign prostatic hyperplasia: experience in a developing country

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Introduction
Transurethral resection of the prostate in saline (TURis) was introduced as an alternative to monopolar resection to reduce its complications. Among all the emerging lasers, thulium has gained high acceptance and become an alternative therapeutic option in prostate enucleation (ThuLEP). Literature on ThuLEP is still limited; to our best knowledge, cost-effectiveness between both techniques in developing countries had not been estimated before.
Patients and methods
This is a prospective, randomized, comparative study comparing two different techniques for treating benign prostatic hyperplasia. Sample size was 40 cases, which were randomly assigned into two groups. Preoperative, operative, and early postoperative data were collected and compared. Patients were followed up for 1 month for evaluating postoperative effectiveness. Running cost was also evaluated for both techniques.
Results
We evaluated 37 patients who completed follow-up and their data were analyzed. ThuLEP was associated with less hemoglobin drop (1.14±0.95) compared with 2.54±1.21 for TURis. Also, the amount of irrigation volume needed was less for ThuLEP. Both show high statistical significance. Weight of the extracted tissue, hospital stay, and catheterization time were statistically significantly better with ThuLEP. Results after 1 month as regards postvoid residual urine, International Prostate Symptom Score, and Qmax improvement were indifferent confirming equal efficacy of both techniques. In the cost analysis, ThuLEP was more cost-effective than TURis.
Conclusion
Both ThuLEP and TURis were safe and effective in the surgical management of benign prostatic hyperplasia. The ThuLEP technique was associated with less hemoglobin drop, less hospital stay, and catheterization time and was more cost-effective than TURis.

Keywords:
benign prostatic hyperplasia, cost-effectiveness, hemoglobin drop, thulium laser enucleation, transurethral resection

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Introduction

Approximately 30% of men aged 50–80 years suffer from moderate-to-severe lower urinary tract symptoms that are significant enough to reduce the patient's quality of life [1].

While monopolar transurethral resection of the prostate (TURP) is still the gold standard to treat benign prostatic hyperplasia (BPH), transurethral resection of the prostate in saline (TURis) was introduced as an alternative to TURP to reduce its complications, using saline as an irrigate, avoiding the possibility of TUR syndrome, claiming better hemostasis than monopolar TURP, with shorter catheterization time, and shorter hospital stay [2].

With the clinical application of new types of laser in surgeries, laser was fully integrated into endoscopic enucleation of the prostatic adenoma from the surgical capsule in a manner similar to open prostatectomy. Among all the emerging laser techniques, the introduction of thulium has gained high acceptance and become another alternative therapeutic option [2].

On the basis of available data, literature on thulium laser enucleation of prostate (ThuLEP) is still limited; to our best knowledge, cost-effectiveness in a developing country had not been estimated before between both techniques. The present study aimed to compare the most recently introduced technique, ThuLEP, with the most safe and widely accepted technique for prostate surgery TURis, and to address the most significant operative and early postoperative outcomes in terms of safety, efficacy, and cost-effectiveness.

Patients and methods

A total of 40 patients were included in our study from the outpatient clinics of our hospital, from January 2019 to February 2020. Patients with lower urinary tract symptoms (LUTS) secondary to BPH with prostatic volume more than 80 ml and had surgical indication based on EAU guidelines were included in our study, whether absolute indications, urinary retention (intractable) and renal insufficiency, or relative indications, failure of medical therapy, recurrent cystitis, and persistent prostatic bleeding, while patients with history of prostate surgery, neurogenic bladder, urethral strictures, and bladder stones were excluded.

After obtaining informed consent, patients were equally and randomly assigned into two different surgical groups. Group 1: 20 patients underwent ThuLEP and group 2: 20 patients underwent TURis. Randomization was done using sealed envelopes that were prepared by the department's ethics committee. Patients were blinded to the type of intervention, as were the data collector and the statistician.

All patients were subjected to the following: history taking and physical examinations including digital rectal examination. Urinalysis, prostate-specific antigen assay, and abdominal ultrasound were done to all patients to evaluate upper urinary tract, postvoid residual, and size of the prostate. Functional measures including the International Prostate Symptom Score (IPSS), Qmax, and postvoid residual volume were recorded before surgery. All these data were included in comparison between the two groups (Table 1).

ThuLEP was performed by the two surgeons (A.S., M. H.). On the other hand, TURis was carried out by two other surgeons (M.I., M.A.). All surgeons were experienced in these techniques. Patients were placed in lithotomy position. It was kept in mind that thighs are abducted sufficiently especially during ThuLEP, where the range of motion for the endoscope was larger than when performing TURis.

ThuLEP was performed using the 50–150 W powered MultiPulse Tm+ 1470 Thulium Laser Device (JenaSurgical, Jena, Br?sseler, Germany). A 600 µm end-firing laser fiber was used. The irrigating fluid used was physiological saline (0.9%). A continuous energy was used with a total power of 60 W for cutting and 30 W for coagulating. Morcellation was done using the tissue morcellator with reusable blades (Karl Storz, STORZ MEDICAL AG, Lohstampfestrasse, Tägerwilen, Switzerland).

Enucleation of the prostate was done in a retrograde manner; in seven cases the size of median lobe was large with intravesical protrusion, so we used the three-lobe technique; in 12 cases the two-lobe technique was used, either for small size of the median lobe or if the median lobe was completely fused to one lobe. In one case en-bloc enucleation was done as the prostate was small in size. We did not use the four-lobe technique, as the anterior lobe was not large enough to be enucleated separately in any case.

Hemostasis of the prostatic fossa was done before pushing the lobes to the bladder as the fossa is still stretched by the occupied enucleated lobe. At the end of the procedure, morcellation was done through the nephroscope taking care to avoid injuring the bladder wall. A dual-way 22-Ch silicone urethral catheter was inserted at the end of the procedure.

For the TURis group, a bipolar resection system (Olympus or Karl Storz, Olympus Europa SE & Co. KGWendenstraße, Hamburg) was used. The irrigating fluid used was physiological saline (0.9%). The technique used was similar to the ordinary monopolar TURP.

For all patients, gentle traction was applied on the catheter for 6 h and reapplied in case of bleeding, wash through a dual-way catheter was applied at an average rate of one bag 500 ml physiological saline (0.9%) per hour for the first 24 h unless hematuria requiring a higher rate. All patients were offered hospital discharge after 24 h, as long as the urine is clear. Catheter removal was done 1 day after stabilization of clear urine without wash.

Our primary outcome was the decrease in hemoglobin level calculated after 24 h of surgery. Secondary outcome measures included operative time, volume

Table 1 Demographic and preoperative data

Preoperative	ThuLEP group *N*=20	TURis group *N*=20	Test value	*P* value	Significance
Age					
Mean±SD	68.25±5.34	69.35±5.94	–0.616[a]	0.541	NS
Range	58–80	55–97			
Prostatic volume by abdominal ultrasound (ml)					
Mean±SD	104.45±24.18	106.85±22.44	–0.325[a]	0.747	NS
Range	80–160	80–156			
Hb (g/dl)					
Mean±SD	12.95±1.35	12.72±1.48	0.506[a]	0.616	NS
Range	10.92–16.2	10.63–16.2			
PSA (ng/ml)					
Mean±SD	5.31±2.40	5.57±2.54	–0.324[a]	0.748	NS
Range	2.42–11.2	2.42–11.2			
Of the 40 patients, 15 (37.5%) patients had acquired urinary retention with indwelling catheter, so IPSS, Qmax, and PVR were not calculated for them preoperatively, 7 from the ThuLEP group and 8 from the TURis group					
	N=13	*N*=12			
Preoperative IPSS					
Mean±SD	27.62±3.88	26.58±3.90	0.663[a]	0.514	NS
Range	21–34	21–34			
Qmax preoperative					
Mean±SD	7.46±1.81	7.00±1.95	0.613[a]	0.546	NS
Range	5–10	4–10			
Preoperative postvoid urine residual					
Mean±SD	64.31±17.62	84.08±19.87	0.638[a]	0.515	NS
Range	35–95	45–122			

Hb, hemoglobin; PSA, prostate-specific antigen assay; PVR, post-void residual volume; ThuLEP, therapeutic option in prostate enucleation; TURis, transurethral resection of the prostate in saline. [a]Independent *t* test. *P* value more than 0.05: nonsignificant (NS); *P* value less than 0.05: significant (S); *P* value less than 0.01: highly significant (HS).

extracted, amount of irrigation volume, hospital stay, catheterization time, cost-effectiveness, perioperative complication according to the Clavien–Dindo classification, and postoperative efficacy including postvoid residual urine, IPSS, and maximum flow rate (Qmax) after a 1-month follow-up period.

Cost analysis could be divided into two main categories: the capital cost including the Thulium laser device, morcellator device, and the bipolar electrocautery, and the running cost including laser fiber, bipolar resection loop, irrigation fluids, and hospital stay. In the present study, we aimed to evaluate the running cost of both surgical procedures.

Ethical considerations

The study was approved by the Research Ethics Committee of our university under approval No. FMASU 22/2019. Written consent was obtained from all patients before participation.

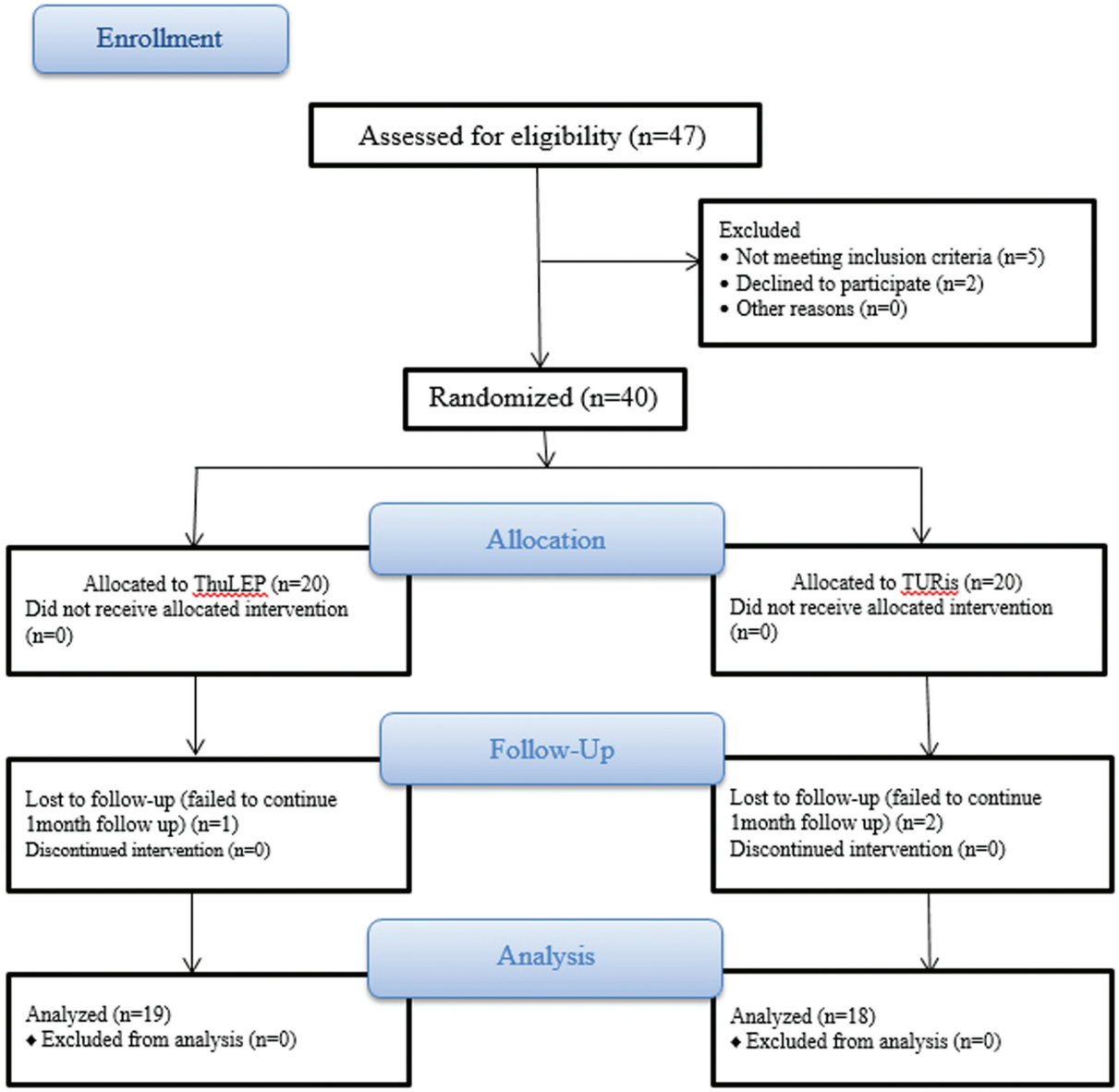
Statistical analysis

Data were collected, revised, coded, and entered into the Statistical Package for Social Sciences (IBM SPSS, 1 New Orchard Road, Armonk, New York, United States), version 23. The distribution of quantitative data was tested by Kolmogorov–Smirnov test of normality. So the quantitative data were presented as mean, SDs, and ranges when parametric while nonparametric were presented as median with the interquartile range. Also, qualitative variables were presented as number and percentages. The comparison between groups regarding qualitative data was done using the χ^2 test and/or Fisher's exact test when the expected count in any cell was found to be less than five. The comparison between two independent groups with quantitative data and parametric distribution was done using the independent *t* test. The comparison between two independent groups with quantitative data and nonparametric distribution was done using the Mann–Whitney test. A *P* value less than 0.05 was considered statistically significant, and less than 0.01 was considered highly significant.

Results

A total number of 19 and 18 patients in groups 1 and 2, respectively, completed a 1-month follow-up, as shown in the consort flowchart (Fig. 1). There was no

Figure 1



Consort flowchart.

difference observed among the two groups as regards demographics and other preoperative data (Table 1).

The ThuLEP procedure showed a mean hemoglobin drop of 1.14±0.95 g/dl compared with 2.54±1.21 g/dl in the TURis procedure, with a high statistical significance. The irrigation volume (in l) calculated from patients' files on discharge was found higher in the TURis group than the ThuLEP group with *P* value less than 0.001, as shown in Table 2.

The hospital stay and catheterization time (in days) were found to be higher in the TURis group than the ThuLEP group with a *P* value of 0.032 and 0.022, respectively, which is statistically significant. The table also showed that there was no statistically significant difference found between the ThuLEP group and the TURis group regarding operative time with a *P* value of 0.113.

The postoperative efficacy parameters were evaluated in both groups after 1 month of the operations, as shown in Table 3. There was no statistically significant difference between both groups, although a highly statistically significant difference was documented in both groups in comparison with their preoperative parameters.

Operative and postoperative complications are shown in Table 4 according to the Clavien–Dindo classification. The most common complications of prostate surgery are urinary retention (mostly related to postoperative pain), clot retention (as the prostate gland is highly vascular), and stress incontinence (due

Table 2 Operative and early postoperative outcomes

	ThuLEP group *N*=20	TURis group *N*=20	Test value	*P* value	Significance
Operative time (min)					
Mean±SD	91.30±20.42	80.95±19.96	1.621[a]	0.113	NS
Range	60–120	55–120			
Hemoglobin drop (g/dl)					
Mean±SD	1.14±0.95	2.54±1.21	–3.436[b]	<0.001	HS
Range	0.2–3.45	0.24–4.55			
Extracted tissue (g)					
Mean±SD	81.4±23.29	59.45±20.32	2.129	0.042	S
Range	40–129	35–110			
Irrigation volume (l)					
Mean±SD	24.80±6.34	34.05±7.64	–4.167[a]	<0.001	HS
Range	15–40	25–49			
Hospital stay (days)					
Mean±SD	1.55±0.83	2.25±1.16	–2.143[b]	0.032	S
Range	1–4	1–5			
Catheterization time (days)					
Mean±SD	2.30±1.30	3.45 ±1.88	–2.292[b]	0.022	S
Range	1–6	1–7			

ThuLEP, therapeutic option in prostate enucleation; TURis, transurethral resection of the prostate in saline. *χ^2 test. [a]Independent *t* test. [b]Mann–Whitney test.

Table 3 Postoperative efficacy after 1 month

IPSS	Preoperative	1 month postoperative	*P* value	Significance
ThuLEP group				
Mean±SD	27.62±3.88	7.95±2.19	<0.001	HS
Range	21–34	4–12		
TURis group				
Mean±SD	26.58±3.90	7.35± 2.28	<0.001	HS
Range	21–34	4–12		
P value	0.514	NS	0.892	NS
Qmax				
ThuLEP group				
Mean±SD	7.46±1.81	16.05±2.53	<0.001	HS
Range	5–10	13–20		
TURis group				
Mean±SD	7.00±1.95	15.0±2.93	<0.001	HS
Range	4–10	11–20		
P value	0.546	NS	0.733	NS
Postvoid residual urine volume				
ThuLEP group				
Mean±SD	64.31±17.62	25.45±8.91	<0.001	HS
Range	35–95	12–45		
TURis group				
Mean±SD	84.08±19.87	24.50±9.29	<0.001	HS
Range	45–122	12–55		
P value	0.515	NS	0.743	NS

IPSS, International Prostate Symptom Score; ThuLEP, therapeutic option in prostate enucleation; TURis, transurethral resection of the prostate in saline. *P* value more than 0.05: nonsignificant (NS); *P* value less than 0.05: significant (S); *P* value less than 0.01: highly significant (HS).

to decreased resistance to urine flow newly adapted after prostate removal). If retention reoccurred after catheter removal, ultrasound is done to evaluate the presence of clot retention, in case of clot retention bladder wash is done in the ward by a three-way silicone catheter and the catheter is left for another 3 days.

The overall morbidity was higher in the TURis group but not statistically significant.

Table 4 Operative and postoperative complications according to Clavien–Dindo classification

Grades	ThuLEP group [*n* (%)] *N*=20	TURis group [*n* (%)] *N*=20	Test value	*P* value	Significance
Grade I					
Clot retention					
No	18 (90.0)	17 (85.0)	0.229*	0.633	NS
Yes	2 (10.0)	3 (15.0)			
Postcatheter removal AUR and recatheterization					
No	18 (90.0)	16 (80.0)	0.784	0.375	NS
Yes	2 (10.0)	4 (20.0)			
Grade II					
Blood transfusion					
No	19 (95.0)	17 (85.0)	1.111*	0.292	NS
Yes	1 (5.0)	3 (15.0)			
Capsule perforation					
No	20 (100.0)	19 (95.0)	1.026	0.311	NS
Yes	0	1 (5.0)			
Stress incontinence					
No	18 (90.0)	18 (90.0)	0.000*	1.000	NS
Yes	2 (10.0)	2 (10.0)			
Urge incontinence					
No	17 (85.0)	18 (90.0)	0.229*	0.633	NS
Yes	3 (15.0)	2 (10.0)			
Grade IIIa					
Intraprotenial collection required pigtail drainage					
No	20 (100.0)	19 (95.0)	1.026	0.311	NS
Yes	0	1 (5.0)			
Grade IV					
Acute myocardial infarction requiring admission to the ICU					
No	20 (100.0)	20 (100.0)	NA	NA	NA
Yes	0	0			
Grade V					
Death					
No	20 (100.0)	20 (100.0)	NA	NA	NA
Yes	0	0			
Overall morbidity					
%	7.1	11.4	1.526	0.216	NS

ThuLEP, therapeutic option in prostate enucleation; TURis, transurethral resection of the prostate in saline. *χ^2 test. [a]Independent *t* test. [b]Mann–Whitney test.

Table 5 Running cost

Cost in EGP	ThuLEP (average price/case)	TURis (average price/case)
LASER fiber (1 fiber =14 370)	1597	1750
Bipolar loop (1 loop=1750)	1 fiber per 9 cases	1 loop per 1 case
Irrigation fluids (1 l=35)	868	1190
Hospital stay (1 day=1200)	1860	2700
Total/case in EGP	4325	5640
Ratio	1	1.3

ThuLEP, therapeutic option in prostate enucleation; TURis, transurethral resection of the prostate in saline.

As shown in Table 5, we evaluated the running cost in the present study. Regarding laser fibers, each fiber was used for approximately nine patients. Regarding bipolar loops, one loop was used for each case. Irrigation fluid consumption was calculated by the price of 1 l multiplied by the mean consumption of fluids. The hospital stay was evaluated by the price of one night multiplied by the mean hospital stay. From our analysis, the cost analysis ratio per case between ThuLEP and TURis was 1 : 1.3, respectively.

Discussion

Few studies pointed out comparable outcomes in both ThuLEP and TURis in the management of BPH [3]. We carried out the present study to evaluate both techniques with hemoglobin drop as our primary end point. According to our knowledge, we are the first to address the cost analysis of both techniques in a developing country.

As regards the technique, in the ThuLEP group enucleation was performed using the two-lobe, three-lobe, or en-bloc techniques according to the configuration of the prostate, and this was similar to the techniques used by Enikeev *et al.* [4], but not similar to the technique used by Hou *et al.* [5], who started by removing the median lobe at first in all cases: the three-lobe technique.

For ThuLEP, we used the 600 µm end-firing laser fiber and a power of 60 W for cutting and a power of 30 W for coagulating, which was in accordance with Enikeev *et al.* [4], but not in accordance with Bozzinia *et al.* [3], that used an 800 µm end-firing laser fiber with 120 W for cutting and 40 W for coagulation and Carmignani *et al.* [6], who used an 800 µm end-firing laser fiber with a total power of 150 W.

The difference in power adjustment may be related to using different types of fibers; using larger fiber requires more power. Moreover, using lower power settings with ThuLEP is concomitant with the idea that laser enucleation is a laser-assisted technique, unlike resection which requires higher energy.

Our data on early postoperative outcomes underlined limited hemoglobin drop in most cases, confirming excellent hemostasis with ThuLEP. This was also confirmed by other literature revealing that ThuLEP resulted in significantly lower blood loss and transfusion rates than TURis (0.45±1.23 vs. 2.83 ±1.78 and 0 vs. 3, respectively) [3].

The less bleeding during ThuLEP was not only for the coagulative necrosis done by the laser effect, but also for the enucleation technique itself; attacking the prostatic vessels once at the periphery, unlike during resection at which the same vessel is attacked many times at every level of resection [7]. Also, the fact that thulium laser operates in continuous wave mode is an important feature, which allows for excellent hemostasis as well as precise and shallow incisions [8].

As regards the time of enucleation and morcellation for cases of ThuLEP shown in Table 6, the mean was 59.9 ±27.42 and 32.95±19.96 min, respectively, and when compared with the results of Enikeev *et al.* [4]; 49.0 ±18.4 and 26.6±11.5 min, respectively. It can be noticed that enucleation accounts to about two-thirds of the total operative time.

Table 6 Enucleation versus morcellation time for therapeutic option in prostate enucleation group

Split operative time (min)	Enucleation time *N*=20	Morcellation time *N*=20
Mean±SD	59.9±27.42	32.95±19.96
Range	35–70	22–45

As regards total operative time, the shorter time of operation for TURis (80.9±19.9 min) compared with ThuLEP (91.3±20.4 min) was most probably related to time of morcellation done after enucleation in cases of ThuLEP; still this is not statistically significant. This finding was like the results collected by Bozzinia *et al.* [3] comparing the operative time for both techniques with a *P* value of 0.123. The total operative time (including enucleation and morcellation time) calculated by Carmignani *et al.* [6] ranged from 70 ±40 to 85±50, by Enikeev *et al.* [4] it was 71.6±31.3 and by Raber *et al.* [9] it was (63.7±20.5). This was slightly shorter when compared with our results, which may be attributed to a larger number of cases and cumulative experiences as this technique is still novel in our area.

The weight of extracted tissues was larger with ThuLEP. This finding was concomitant with Bozzinia *et al.* [3], and this can be related to the more radicalism of the enucleation technique compared with the resection technique. As regards overall use of irrigation fluids, there was high statistically significant difference in favor of ThuLEP. This was in accordance with Enikeev *et al.* [4]. This is related to the fact that patients who did ThuLEP need much less wash in the postoperative period.

There was a clear advantage for the ThuLEP group over the TURis group considering hospital stay and catheterization time and was statistically significant. In our results regarding ThuLEP, the mean of catheterization time was 2.30±1.30 that was longer when compared with Bozzinia *et al.* [3] 1.3±2.55, with Carmignani *et al.* [6] it was 1.22±0.7 and with Enikeev *et al.* [4] it was 1.3±0.5. This is because, in our study catheter removal was done 1 day after stabilization of clear urine without wash, which was usually in the second day of discharge in the outpatient clinic.

As regards hospital stay, our mean was 1.55±0.83 that was comparable with Bozzinia *et al.* [3] which was 1.7 ±2.73, but less when compared with Carmignani *et al.* [6] 2.0±1.7, with Enikeev *et al.* [4] it was 3.4±0.6. This is related to the fact that in our study all patients were offered hospital discharge after 24 h, as long as the urine is clear, and they were instructed for continuing wash at home if the color of urine was changed, which led to a shorter hospital stay.

On the basis of these results, the ThuLEP procedure could be applied as a 1-day surgery, as mentioned in the literature for other types of laser enucleation [10].

The overall morbidity was higher in the TURis group than the ThuLEP group (11.4 vs. 7.1%, respectively) but was not statistically significant. According to Clavien–Dindo classification (Table 4) we did not record any grade IIIB, IV, or V complications. Postcatheter removal acute urinary retention was the most frequent complication, occurred in the ThuLEP group (10%) and in the TURis group (20%). This was in concurrent with the findings of Jones *et al.* [11] and Chang *et al.* [12], with a rate of 9.6%.

There was a higher need for blood transfusion with TURis but not statistically evident, as three cases needed blood transfusion; two patients received one bag of full blood and one patient received two bags as capsule perforation had occurred. As regards patients in the ThuLEP group, only one patient received one bag. This was mostly related to a low preoperative hemoglobin of 10.9 g/dl. Little need for blood transfusion with the ThuLEP was in accordance with the literature [3,4,12].

There were four patients who had been on oral antiplatelet, who were shifted to prophylactic doses of subcutaneous low molecular heparin for 5 days till the day before surgery, but relation between previous antiplatelet therapy and the need of blood transfusion was not noticed in either groups.

Surgical capsule perforation did not occur with any one of our patients of ThuLEP. This was compatible with that stated by Herrmann *et al.* [13] that blunt dissection of adenoma over its capsule not only ensures proper capsule visualization during enucleation maneuvers but also minimizes perforation risk.

Two patients from each group developed stress incontinence. Three patients in the ThuLEP group and two patients in the TURis group developed postoperative urge incontinence. Stress and urge incontinence were not statistically significant between both groups and disappeared within 1 month by using anticholinergics and pelvic floor exercises.

Intraprotenial collection requiring pigtail drainage was evaluated as Clavien grade IIIa, for being a complication that required an intervention performed under local anesthesia. This occurred once in the TURis group, confirmed by abdominal ultrasound and managed by applying ultrasound-guided intraabdominal pigtail drainage for 3 days and wash was stopped. The site of perforation was not detected in later cystogram and catheter was left for 1 week.

In the literature bladder wall injury during morcellation has been reported in up to 5.5% of cases, when a mechanical tissue morcellator was employed [14]. During our work this was not reported in any case as bladder wall injury was avoided by allowing irrigation through both the inflow of the nephroscope and the outflow of the sheath, keeping the bladder full, retracting morcellator to the bladder neck and keeping good vision during the whole time of morcellation.

In terms of postoperative efficacy parameters, both groups showed comparable results with no statistically significant difference, with a significant improvement in the preoperative values for both procedures confirming safety and efficacy of ThuLEP. This was well-matched with literature [4,6,12].

Running cost was compared between the two groups in the present study. We considered the devices to be part of the hospital's assets, and each device could be used in other surgeries. After exclusion of the capital cost, ThuLEP procedure was considered to be cheaper than TURis. This was consequent when evaluating other types of laser enucleation done by Higazy *et al.* [15] and Elshal *et al.* [16]. The latter concluded that in high-volume hospitals and 2 years after adopting the technique, laser enucleation of prostate equally costs the hospital as transvesical open prostatectomy and significant hospital cost savings are expected in subsequent cases.

The present study had a limitation in evaluating the learning curve of the ThuLEP technique. Also, a long follow-up could not be carried out to assess long-term outcomes.

Conclusions

From the present study, both ThuLEP and TURis are safe and effective in the surgical management of large BPH. The ThuLEP technique was associated with less hemoglobin drop, less hospital stay and catheterization time, and was more cost-effective than TURis.

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Conflicts of interest

There are no conflicts of interest.

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