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ORIGINAL PAPER

Does Holmium laser enucleation of the prostate (HoLEP) still have a steep learning curve? Our experience of 100 consecutive cases from Turkey

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Summary *Aim: The aim of our study is to examine the learning curve of HoLEP and to discuss our results in the light of the literature.*
Methods: 100 patients who had LUTS resistant to medical treatment and complicated BPH to whom HoLEP procedure had been administered regardless of the size of the prostate in the last 1 year were analysed retrospectively. To evaluate the learning curve, the patients were classified into 4 main groups of 25 consecutively operated patients beginning from the first case.
The 4 main groups were divided into 2 subgroups including patients who had prostate volume below or above 80 grams.
Results: The mean age of the 100 patients who had HoLEP was 64.5 years. The mean prostate volume was 99.1 cc (45-281 cc). When those with prostate smaller than 80 g are examined, Enucleation efficiency was 0.76 g/min (0.46-0.97 g/min) and Morcellation efficiency was 3.07 g/min (3.34-4 g/min). When those with prostates larger than 80 g are examined, Enucleation efficiency was 0.89 g/min (0.66-1.04 g/min) and Morcellation efficiency was 4.01 g/min (3.93-4.25 g/min). These two parameters were statistically and significantly different in all the 4 groups ($p < 0.05$).
Conclusions: HoLEP still has a steep learning curve. It is necessary to reach the number of cases of 25-50 to reach fundamental experience.

KEY WORDS: *HoLEP; Learning curve; LUTS; Enucleation efficiency; Morcellation efficiency.*

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INTRODUCTION

Holmium laser resection of the prostate (HoLEP) was first described by Gilling et al. in 1995 and after a few years, this technique was standardized as HoLEP (1). The classical well-known gold standards for the surgical treatment of *benign prostate hyperplasia* (BPH) have been OP and *transurethral resection of the prostate* (TURP) depending on prostate size (2). HoLEP has been shown in studies to have several advantages compared to *transurethral resection of the prostate* (TURP), including shorter hospital stay, reduced bleeding complications and absence of TURP-syndrome (3). Furthermore, functional outcomes of HoLEP have been stated to be at least as good as after TURP, and comparable to those obtained with *open prostatectomy* (OP) for larger prostates (3, 4). HoLEP is one of the most commonly used *endoscopic enucleation of prostate* (EEP) intervention that is recommended by the *European Association of Urology* (EAU) and *American Urological Association* (AUA) as a minimal invasive treatment method regarding patients with BPH independently from prostate sizes (but especially prostates with volume greater than 80 ml) (5, 6). HoLEP is thus often considered as a "*new gold standard*" by several Authors, However, in many centers, HoLEP has not yet replaced TURP and OP (7) because HoLEP is considered as a more difficult and lengthy procedure and learning curve has been pointed out as a limitation for a high diffusion of this surgical technique already described 15 years ago (8, 9). Therefore, the prolonged learning curve has slowed acceptance of the procedure in the urological community (10). There is some literature about the learning curve of HoLEP (10, 11), but this is the first learning curve analysis in Turkey. The aim of our study is to examine the learning curve of this surgery and to discuss our results in the light of the literature.

MATERIAL AND METHOD

Study design and patients

After our study had been approved by the Ministry of Health and the local ethics committee, patients to whom HoLEP procedure was administered between March 2019 and May 2020 were analysed retrospectively. Patients who had LUTS (lower urinary tract symptom) resistant to medical treatment and complicated BPH to whom HoLEP procedure had been administered regardless of the size of the prostate in *Adana City Hospital Urology Clinic* in previous approximately 1 year were analysed retrospectively. The first HoLEP case was performed in March 2019.
The surgeon who had great experience in endoscopic surgery, started to perform HoLEP after watching videos, reading available published articles, and being an observer in 10 cases with a mentor in an external centre. No counsellor accompanied the surgeon during the cases. HoLEP operation was performed by the same urologist on 100 patients. Informed consent was obtained from all participants. All patients were evaluated preoperatively with serum *prostate specific antigen* (PSA), *haemoglobin* (Hb), *transrectal ultrasound* (TRUS), *digital rectal examination* (DRE), urinalysis and *International Prostate Symptom*

No conflict of interest declared.

Score (IPSS). *Uroflowmetry* (UFM) was done and *post-void residual urine* (PVR) was measured by ultrasound.
The patients who had high PSA were operated one month after prostate biopsy under transrectal ultrasound guidance. The drugs of patients who were receiving antiplatelet and anticoagulant treatment were discontinued 12 hours before the operation and they were replaced with low molecular weight heparin. Enucleation time and morcellation time were recorded perioperatively and the weight of the removed tissue was measured. Patients with IPSS ≥ 8, maximum urine flow rate (Q_{max}) ≤ 15 mL/h, and PVR ≥ 50 mL were included in the study. On the other hand, the patients with urethral stricture, neurogenic component, prostate cancer and bladder cancer were excluded from the study. The patients were classified into 4 main groups of 25 consecutively cases beginning from the first case to determine the learning curve. Group A consisted of the first 25 patients, group B consisted of the second 25 patients, group C consisted of the third 25 patients, and group D consisted of the fourth 25 patients. The 4 main groups were divided into 2 subgroups as the patients who had prostate volume below or above 80 grams. The two subgroups were statistically compared within themselves.

Surgical technique

Upon the anaesthetist's preference, the operations were performed under general anaesthesia and spinal anaesthesia. 120W Holmium: yttrium-aluminium-garnet (*Versa Pulse Power Suite, Lumenis, Yokneam Israel*), resectoscope, morcellator and display screen appropriate for 26 F HoLEP (*Richard Wolf GmbH, Knittlingen, Germany*) were used during the surgery. After the surgery was completed, all tissues were examined histologically.
A 22 F 3-way catheter was used in the patients and washing with continuous saline was performed until haematuria ceased.
Control hemogram was checked at the first postoperative day.
The patient was discharged from the hospital after the catheter was removed and micturition was performed after the end of haematuria of the patient.

Postoperative follow-up

IPSS, UFM, PVR, and *quality of life* (QoL) were checked during follow-up at 1st, 3rd, and 6th month postoperatively, and serum PSA and postoperative TRUS measurements were performed at 3rd month. Postoperative complications were graded using the Clavien-Dindo classification (12). Continence status and *post micturition symptoms* (PMS) were evaluated according to the standards which are recommended by the *International Continence Society* (ICS) (13).

Statistical evaluation

SPSS (*Statistical Package for the Social Sciences*) 23.0 (*IBM, Armonk, NY*) package program was used for statistical analysis of the data. Categorical measurements were reported as numbers and percentages, and continuous measurements as mean and standard deviation (median and minimum-maximum where needed). Shapiro-Wilk test was used to determine whether the parameters in the study showed a normal distribution or not. The Kruskal Wallis test was used in the analysis of more than two groups. Bonferroni method, which is one of the Post Hoc analysis methods, was used to determine the source of the difference between the groups. Statistical significance level was taken as 0.05 in all tests.

Results

The mean age of 100 patients who had HoLEP was 64.5 years. The mean prostate volume was 99.1 cc (45-281

Table 1.
Patient demographics and perioperative results.

	< 80 G				> 80 G			
	Group A n 12	**Group B n 10**	**Group C n 12**	**Group D n 11**	**Group A n 13**	**Group B n 15**	**Group C n 13**	**Group D n 14**
Mean age (years)	68.1	63.5	61.6	65.2	64.3	65.4	61.6	66.4
P				.101				.232
Mean PSA (ng/ml)	3.6	2.4	3	2.8	9.8	8.35	7.8	9.02
P				.851				.977
Mean prostate volume (ml)	64	63.1	59.7	65	131.3	116.5	143.8	125.7
P				.741				.522
Enucleation time (min)	103.3	60.5	54.1	48.2	156.9	108.6	125.7	93.5
P				< .001				.001
Post hoc p				A-B; p < .001 A-C; p < .001 A-D; p < .001				A-B; p = .005 A-D; p < .001
Morcellation time (min)	14.3	13	11.6	11.8	26.7	26.3	28.6	23.9
P				< .001				.168
Post hoc p				A-C; p < .001 A-D; p < .001 B-D; p = .005				
Amount of removed tissue (gr)	47.8	48.5	46.2	47.2	105	100.6	119	97.5
P	.874	.654						
Enucleation efficiency (g/min)	0.46	0.8	0.85	0.97	0.66	0.92	0.94	1.04
P				< .001				< .001
Post hoc p				B-A; p < .001 C-A; p < .001 D-A; p < .001 D-B; p = .043				B-A; p = .003 C-A; p = .002 D-A; p < .001
Morcellation efficiency (g/min)	3.34	3.73	3.98	4	3.93	3.82	4.25	4.07
P				< .001				0.040
Post hoc p				C-A; p = .003 D-A; p < .001 D-B; p = .003				C-B; p = .026
Loss of haematocrit	4.2	3.7	3.5	2.5	5.8	4.7	4.1	3.5
P				.615				.907
Length of hospitalization (day)	2.08	2.2	1.7	1.8	3.5	2.7	2.61	2.14
P				.275				.333
Length of removing (hour)	34.8	30.2	27.8	25.6	62.6	45.3	43.6	31.8
P				.037				.024
Post hoc p				A-D; p = .044				A-D; p = .012

P < 0.05; Kruskal Wallis test. Post Hoc Bonferroni analysis; PSA: prostate-specific antigen. The efficiency of each procedure was calculated as weight of removed tissue in g/min.

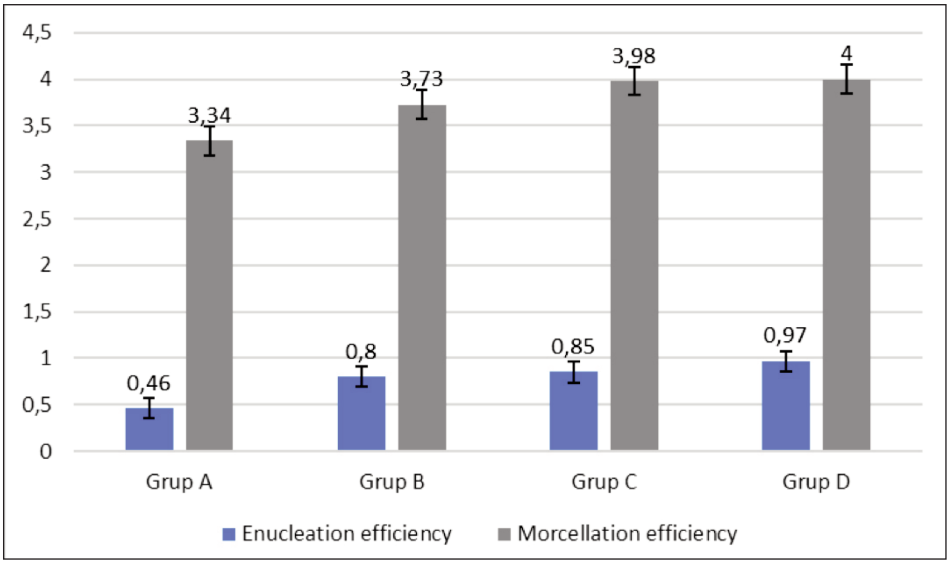

Figure 1.
The difference between Enucleation efficiency ve Morcellation efficiency in 4 Groups at < 80 g prostate volume.

** Enucleation efficiency [weight of enucleated tissue/lasing time (g/min)) and morcellation efficiency (weight of enucleated tissue/morcellation time (g/min)].*

cc). Patients with prostate smaller than 80 g were 45% of all patients. When these patients were considered, it is seen that there was no significant difference ($p > 0.05$) between mean age ($p = .101$), PSA ($p = .851$), prostate volume ($p = .741$), hematocrit loss ($p=.615$), and hospital stay ($p = .275$) of the patients in four groups (A, B, C, D). Enucleation time and morcellation time were statistically different between the groups ($p < .05$). The two most important parameters of the learning curve,
Enucleation efficiency and Morcellation efficiency were 0.76 g/min (0.46-0.97 g/min) and 3.07 g/min (3.34-4 g/min), respectively. These two parameters were statistically and significantly different in all 4 groups ($p < .05$).
Catheter removal time was also statistically different between the groups ($p < .05$) (Table 1 and Figure 1).
The patients with prostates larger than 80 g were 55% of all patients. When these patients were considered, it was seen that there was no significant difference ($p > .05$) with respect of mean age ($p = .232$), PSA ($p = .977$), prostate volume ($p = .522$), morcellation time ($p = .168$), amount of tissue removed ($p = 0.654$), hematocrit loss ($p = .907$), and length of hospital stay (days) ($p = .333$) between patients of four groups (A, B, C, D). Enucleation efficiency was 0.89 g/min (0.66-1.04 g/min) and Morcellation efficiency was 4.01 g/min (3.93-4.25 g/min). There was a statistically significant difference between the groups in terms of enucleation time, enucleation efficiency and morcellation efficiency ($p < .05$). Therefore, when all groups were considered, it was seen that the Enucleation efficiency and Morcellation efficiency were the highest in cases from 25^{th} to 50^{th}, although there was a further improvement even in the cases from 75^{th} to 100^{th} (Table 1 and Figure 2).
Clavien grade 1 and grade 2 complications were observed in 19 cases in group A, in 16 cases in group B, in 5 case in group C and in 4 cases in group D. The most common complication was capsular perforation and it was seen in 16 (16%) patients. In the first 25 cases, 10 capsule perforations occurred although they were usually minimal. Clavien Grade 3 complication was seen in 9 cases in

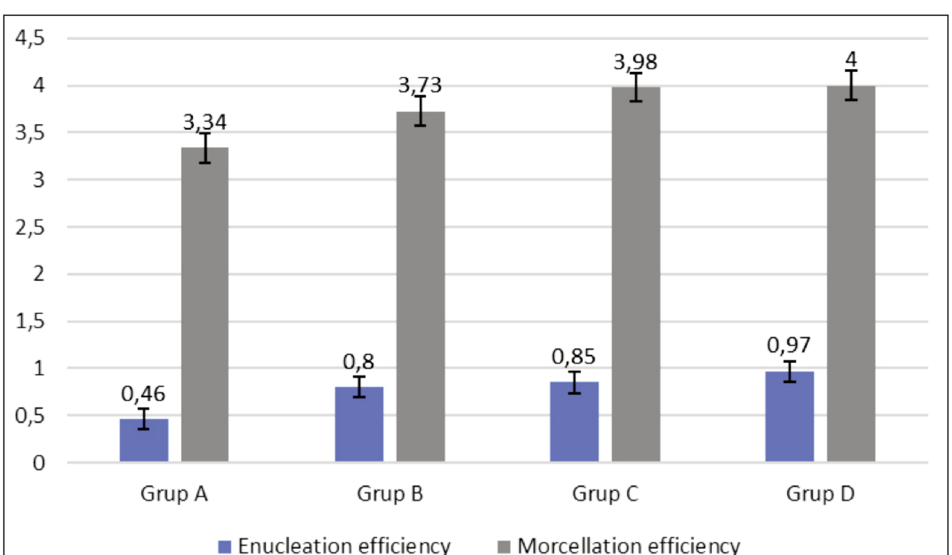

Figure 2.
The difference between Enucleation efficiency ve Morcellation efficiency in Group D at > 80 g prostate volume.

** Enucleation efficiency [weight of enucleated tissue/lasing time (g/min)) and morcellation efficiency (weight of*

Table 2.
Intraoperative and postoperative complications.

	< 80 g				> 80 g			
	Group A		Group B		Group C		Group D	
	< 80 g	> 80 g	< 80 g	> 80 g	< 80 g	> 80 g	< 80 g	> 80 g
Capsule perforation (Clavien 1)	3	7	1	4	-	1	-	-
Returning to TURP or OP (Clavien 3)	-	3	-	-	-	-	-	-
Not being able to proceed to Morcellation due to bleeding (Clavien 3)	1	2	-	-	-	1	-	-
Leaving the case into the second session (Clavien 3)	-	2	-	1	-	-	-	-
Bladder injury (Clavien 1)	1	-	-	1	-	-	-	1
Ureteral orifice injury (Clavien 1)	-	-	-	2	-	-	-	-
Blood transfussion (Clavien 2)	-	-	-	-	-	-	-	-
Re-catheterization (Clavien 1)	-	-	-	2	-	-	-	-
Urinary system infection (Clavien 2)	-	-	-	1	-	-	-	1
Early period stress incontinence (Clavien 1)	3	5	2	4	2	2	1	2
Late period urinary incontinence (Clavien 2-3)	-	-	-	-	-	-	-	-
Urethral stricture (Clavien 3)	1	-	-	1	-	1	-	-

group A, two in group B, and two in group C, and none in group D. No Clavien Grade 4 or 5 complications were seen in any group. Complication rates were found to be very low and stable between 50th and 75th case, while Grade 3, 4 and 5 complications were not seen between 75th and 100th case (Table 2).

Discussion

When HoLEP technique is compared with TURP and OP, it can be observed that it has superior haemostatic characteristics, lower morbidity and more efficiency. Furthermore, global costs of HoLEP are comparable to those of TURP and proved to be a strong competitor of OP. On the other hand, the most important disadvantage of the HoLEP technique is that it is difficult to learn it. A significantly longer adaptation time is required especially for novice surgeons when compared to TURP. It requires considerable experience to determine the surgical border between prostate adenoma and prostate capsule particularly for HoLEP. It is assumed that such a good method is still not globally adopted as the gold standard treatment and it is seen as an alternative to TURP and open prostatectomy according to the guidelines, because it is difficult to learn and has complications occurring during the learning curve (14-16).

Both intraoperative and postoperative data are important for evaluating the learning curve of HoLEP. The indicators of surgical activity are enucleation efficiency (weight of enucleated tissue/lasing time) and morcellation efficiency (weight of enucleated tissue/morcellation time). These two indicators of operative efficiency have been used in various previous learning curve studies as a primary outcome measure (10, 11). In a systematic review which went over 24 studies, it was reported that only 4 Authors of these 24 studies did not provide any recommendations about the number of cases which was required to complete the learning curve of HoLEP. Besides, it was recommended in the 20 studies that the number of cases ranged between 20 and 60 (20-30 most commonly). In addition, it was determined that the number of cases was less than 20 in only 2 studies (17). *Shah et al.* found out in their prospective series that the operator became a master at HoLEP after an average of 20 cases. However, this study was limited to small prostates. It was reported that additional learning is required to pass on to large prostate volume from small prostate volume (10). *Seki et al.* found the mean enucleation efficiency to be 0.29 and 0.75 gm/m in the first 10 and the last 10 cases of a total of 70 cases, respectively (11). Similarly, *Placer et al.* divided their series of 125 cases into subgroups of 25 consecutive patients each, showing that the efficiency of enucleation and morcellation increased with the number of procedures (9). *Brunckhurst et al.* reported a steep increase in performance in the first 20-30 cases and a plateau occurring following the first 50-60 cases but they added that there were improvements and variability in efficiency even after 150 cases (18). Moreover, *Du et al.* showed that enucleation efficiency increases with years of experience and is most encountered in men with a large prostate > 100 g (19). *Bae J et al.* showed in their study with 161 cases, that the enucleation efficiency increased significantly after a minimum of 30 cases (20). *Jeong et al.* found that enucleation efficiency increased in the first 50 cases and there was a strong linear correlation with total prostate volume.

Perioperative clinical variables, including enucleation time, morcellation time, enucleation ratio (enucleation weight/transitional zone volume), enucleation efficacy (enucleated weight/enucleation time), enucleation ratio efficacy (enucleation ratio/enucleation time), and early complication rate were analysed. They evaluated the enucleation ratio efficacy by dividing the enucleation ratio (enucleation weight/transitional zone volume) by enucleation time. They suggested that this new parameter might remove the confounding effect of prostate size resulting from enucleation efficiency. This parameter became stable after 25 cases, and the authors interpreted that this number was also consistent with the surgeon's confidence in performing HoLEP (21). Similarly, *Kim et al.* proposed the enucleation time-energy efficacy, defined as enucleated weight/enucleation time/consumed energy. In their studies, this parameter continued to improve after 30 cases and it become stable between 60th and 70th cases (22). *Elzayat et al.* reported that best enucleation efficiency was reached after about 20-30 cases (8). In both two subgroups in our study, enucleation efficiency displayed a statistically significant steep curve after the first 25 cases and enucleation efficiency increased in parallel with case experience in line with the literature.

Morcellation efficiency is also an important indicthator for the learning curve. Learning morcellation is relatively easier than learning enucleation. However, it has been reported in some publications that morcellation causes serious morbidities such as bladder injury at a rate of 18% (23-10) although it seems easier (23-10).

Brunckhurst et al. showed that morcellation increased its efficiency after 40-60 cases (18). *Soto et al.* reported that morcellation efficiency increased statistically after the 50^{th} case without mentor (24). In our study, morcellation efficiency increased significantly especially after the first 25 cases. It was seen that morcellation performance developed as the case experience increased. However, enucleation efficiency and morcellation efficiency require similar number of cases although morcellation is easier to learn than enucleation (25 cases). We explain this situation as the fact that haematuria, which occurs as a result of poor enucleation in the first 25 cases, affects the image quality, and the surgeon wants to work slowly and in a controlled manner as he fears of bladder injury during morcellation.

Perioperative complications can also be a reference for the learning curve. Capsular perforation and superficial bladder mucosal injury have been shown to be the most common complications in the intraoperative period. The most comprehensive study on this subject was conducted by *Kendidra et al.* The complications of 280 patients were evaluated and it was reported that the most common perioperative complication was capsular perforation with 9.6% and the second most common perioperative complication was superficial bladder mucosal injury and ureter orifice injury (10). Accordingly, it is important to recognize the capsule in this operation both in terms of facilitating enucleation and being able to control bleeding more easily. It should be kept in mind by the surgeon that the prostate capsule in small prostates is not clearly separated and the prostate capsule has too many vascular networks in large prostates. In our study, we did not experience any capsule perforation in 10 patients (40%) in group A, 5 patients (20%) in group B, 1 patient (4%) in group C and none in group D. Perforations were minimal except for 3 patients in the first group and the catheter was kept for one more day in these patients. It was returned to open surgery during the operation (Clavien 3) in 3 patients because of large perforation area and the catheter was kept longer. We assumed that having such high capsule perforation rate especially in the first cases resulted from the lack of a mentor during learning. One of the perioperative complications is returning to TURP or OP. In their series of 146 cases, *Kobayashi et al.* reported that it was returned to TURP in only 12 cases in their series of 146 cases, and the main reason for this was capsular perforation or uncontrolled bleeding (25).

However, it was reported in the study of *Bapat et al.* that it was returned to standard TURP in the first 13 cases (26). On the contrary to these two studies, Jeong et al. reported that it was not returned to TURP in any of the cases despite having no mentoring (21). In our study, it was returned to TURP/OP during the operation in 3 cases which had prostate volume of > 80 g in the first 25 cases.

Postoperative complications can also affect the learning curve. Especially *stress urinary incontinence* (SUI) is one of the postoperative complications that surgeons feel more anxious. Urologists feel serious stress and the learning curve is prolonged due to the fear of causing a sphincteric insufficiency to the patient, due to sphincteric injury in case of long duration procedure, as well as excessive stretching of the anterior of the external sphincter during enucleation of the prostate at 12 o'clock and thermal injury due to use of laser near the sphincter. *Placer et al.* found that transient urinary incontinence, persistent stress urinary incontinence (lasting longer than 6 months), and storage symptoms were observed more commonly in the first 50 cases (9). *Lerner et al.* evaluated stress urinary incontinence (SUI) at 3 months in the early postoperative period during a single surgeon's learning curve and found out that SUI was more common when time intervals between the cases were longer (27). *Shigemura et al.* found that the experience with at least 20 cases significantly affected urinary incontinence (28).

In another study, patients with enucleated prostate volume > 50 g and blood loss > 2.5 g/dL were associated with SUI (26). *Kim et al.* found that 11% of the patients had urge incontinence after the urethral catheters were removed after surgery (22). In our study, 8 (32%) of the first 25 cases had SUI in the first 3 months, and trend continued at a diminishing pace after 25 cases. None of SUI stayed permanent and all the cases returned to normal within 3 months.

In this study, we compared the results of 100 consecutive cases of a single surgeon without a mentor with the literature. Our results were comparable with the literature in terms of learning curve, perioperative and postoperative outcomes, as well as functional outcomes and continence status. Our study has also some limitations. It reflects the results of only one centre and includes a limited number of patients. Another limitation is that it presents the experience of a single surgeon, so the results could be not reproducible by another surgeon with similar experience.

In conclusion, this is the first study which focused on the learning curve in Turkey, to the best of our knowledge. The HoLEP technique still has a steep learning curve, and we predict that a surgeon should perform between 25-50 cases to reach the necessary experience. In addition, we believe a surgeon could cope with HoLEP technique without a mentor or simulation-based training.

Conclusions

HoLEP still has a steep learning curve. It is necessary to reach a number of cases of 25-50 to reach fundamental experience. Moreover, it can be coped with HoLEP without having a mentor.

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