Original Article

Comparison of enucleation efficiency of HoLEP with the early apical release 'En Bloc' technique between the learning curve period and after becoming proficient in HoLEP

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Enucleation, HoLEP, En Bloc, learning curve, proficiency

Abstract

Objective: To compare prostate enucleation efficiency using Holmium laser (HoLEP) with the early apical release 'En Bloc' technique between a learning curve and experienced group and to evaluate factors required to ensure proficiency.

Materials and Methods: A retrospective analysis was conducted on 120 patients diagnosed with benign prostatic hyperplasia (BPH) who underwent En Bloc HoLEP with early apical release by a single surgeon (CL) at Thammasat University Hospital between January 2019 and December 2023. The primary outcome was a comparison of enucleation efficiency (EE). EE was calculated by dividing the weight of enucleated prostatic tissue (g) by the enucleation time (min). Secondary outcomes were hematocrit (Hct) change, one-month postoperative maximum urine flow rate (Qmax), International Prostate Symptom Score (IPSS) reduction, catheter time (CT; day), length of hospital stay (LOS; day), morcellation efficiency (ME; calculate by dividing enucleated tissue weight (grams) by the morcellation time) and post-operative stress urinary incontinence (SUI) occurrence. The 120 cases were divided into a learning curve group of 60 cases and an experienced group of 60 cases. Mean EE & ME, post-operative Hct change, IPSS reduction, Qmax, CT, LOS and post-operative SUI were compared.

Results: The median (IQR) prostate weight in the learning curve group vs the experienced group was 66 (50.5-101) g vs 69 (50-95) g. Demographic and clinical data differed significantly between groups. Mean EE was significantly different between the learning curve group vs the experienced group (0.76 g/min vs 0.92 g/min ($p = 0.021$), respectively) after experience of 60 cases. Mean CT and LOS were decreased in the experienced group. Mean ME improved slightly but was not statistically significant.

Conclusion: The number of cases required to become proficient at the early apical released En Bloc technique of HoLEP is 60 cases.

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Introduction

Surgical treatment is considered for treatment of benign prostatic hyperplasia (BPH) when any of the following indications are present: refractory acute urinary retention[1], recurrent gross hematuria[2], recurrent urinary tract infection (UTI), signs of end-stage bladder decompensation (bladder calculi, bladder diverticula) or bilateral hydronephrosis with renal function impairment.[3] The surgical treatment is usually a minimally invasive endoscopic procedure for example transurethral resection of the prostate (TURP). Another option is Holmium laser enucleation of the prostate (HoLEP), which has been shown to have better surgical outcomes than TURP.[4-6]

HoLEP is safe, effective, and independent of prostrate size.[7,8] Previous studies have shown that HoLEP was equally efficient as open prostatectomy and resulted in comparatively lower morbidity, catheterization time, and length of hospital stay (LOS).[7-9] HoLEP provides better visualization, easier identification of prostate surgical capsule location, increased ability to approach the correct plane while dissecting adenoma, and better preservation of the external urethral sphincter.[10]

A study by Riedinger et al.[11] showed that prolonged operative time of transurethral surgery is associated with an increased risk of postoperative complications such as septicemia with or without shock. Extending the duration of the procedure leads to blood loss, deep vein thrombosis, or pulmonary embolism.[12-15] Therefore, to achieve efficacy and safety in terms of reducing operative time for this challenging procedure, only experienced urologists should perform HoLEP, which has a steep learning curve.[16]

A study was carried out in Thailand into the safety and outcome of transurethral anatomical enucleation of prostate (TUAEP) using bipolar energy.[17] However, no prior study has been carried out in prostate enucleation by laser energy. In this study the aim was to determine the number of cases a urologist needs to experience to become proficient at this procedure. To fulfil this aim data was collected regarding HoLEP with early apical release En Bloc technique performed by a single surgeon (CL) at Thammasat University Hospital between January 2019 and December 2023. To our knowledge, this is the first Thai study into the HoLEP learning curve.

Materials and Methods

Patient selection

Data pertinent to patients who were diagnosed with BPH underwent HoLEP with early apical release En Bloc technique between January 2019 and December 2023 were retrospectively reviewed. Prostate volume was measured before the HoLEP procedure by one of the following techniques: transrectal ultrasound, computer scan of the genitourinary system, or MRI of the prostate gland. The research was approved by the Human Research Ethics Committee of Thammasat University (Medicine): 0263/66. The protocol number MTU-EC-SU-0-263/66.

Inclusion criteria

Patients were included if they were diagnosed with BPH with an indication for surgery (refractory urinary retention, recurrent gross hematuria, recurrent UTI, renal deterioration from BPH, bladder diverticulum or bladder calculi from BPH, or BPH with troublesome symptoms) and underwent HoLEP with early apical release En Bloc technique.

Demographic data

Patients' data were collected through the Electronic Patient Health Information System (E-PHIS). The information included age (years), body weight (kg), height (m), preoperative IPSS, preoperative prostate-specific antigen (PSA), preoperative Hct (%), prostate volume (gm), and history of BPH medication use.

Surgical procedure

En Bloc HoLEP with early apical release was performed in each case by a single surgeon. Either general anesthesia or spinal anesthesia was used based on the underlying disease of the patient and expected operative time. Holmium: YAG laser (Lumenis PULSE MOSES TM) 120 W two pedal was used for the procedure. A 550-μm end-firing laser fiber (SLIMLINE TM, Lumenis Inc.) was used. The procedure was performed using the following settings: for cutting, energy of 1.2-1.8 J, frequency of 50-60 Hz, and power of 72-90 W; for coagulating, energy of 1 J, frequency of 20 Hz, and power of 20 W, employing a long pulse energy. A 26 Fr continuous flow resectoscope (Karl Storz and Richard Wolf Shark) with a laser bridge was also used. Two types of morcellators were used to remove the prostatic tissue: the

VersaCut (Lumenis) and the Piranha (Richard Wolf) morcellators. The procedure was carried out using the standard reference technique of Dr. Fernando GS[18] and self-learning from YouTube[19] without a proctor.

Statistical analysis

A suitable sample size was calculated for cases in the learning curve group. In studies by Seki Narihito[20] and Shah HN[21], the mean EE in the learning curve group was 0.75 g/min±0.3 (Mean1±SD), while the expected mean for the experienced group increased by 0.15 to reach 0.9 g/min±0.3 (Mean2±SD). We analyzed optimum sample size using program STATA version 15, with a set type 1 error of 0.05, power of 80%, and assuming SD1 = SD2 = 0.3. The calculated sample size was 60 cases per group, resulting in 120 cases in the study. Patient data was divided into two groups, the learning curve and the experienced group, and comparisons were made between the two groups. The student's t-test was used for normally distributed continuous data [expressed as mean and standard deviation (SD)] and the Wilcoxon Rank Sum test for skewed data [expressed as the median and interquartile range (IQR)]. Fisher's exact test was used for categorical data. Results were categorized as statistically significantly different at $p < 0.05$.

Results

A total of 120 cases were categorized into two groups: 60 cases in the learning curve group and 60 cases in the experienced group. The demographic data is shown in Table 1. The mean (SD) age of patients in the learning curve group was 71.5 (7.3) years, and in the experienced group was 70.7 (6.7) years which were not significantly different. The number of patients was highest in ASA class 2 for both groups. The median preoperative PSA (IQR) in the learning curve group was 4.8 (2.7-9) ng/ml, while in the experienced group, it was 6 (2-11.3) ng/ml, data showing no significant difference. There was no statistically significant difference in the median (IQR) prostate volume of patients in the learning curve group vs the experienced group (66 (50.5-101) vs 69 (50-95) g) ($p = 0.872$).

The mean (SD) preoperative IPSS for the learning curve group vs the experienced group were 24.9 (5.5) vs 25.8 (4.4) respectively. The median (IQR) preoperative Qmax for the learning curve group vs the experienced group were 7.5 (5-10.7) ml/sec vs 8.1 (6.5-12) ml/sec, respectively. The indication for HoLEP in the learning curve group included urinary retention in 26 (43.33%) patients and troublesome symptoms in 26 (43.33%) patients, whereas, in the experienced group, the indications were urinary retention in 30 (50%) patients and troublesome symptoms in 25 (41.67%) patients. Of the preoperative demographic data, only ASA classification ($p = 0.021$), BMI ($p = 0.001$), medication ($p = 0.022$), and preoperative urinary retention ($p = 0.044$), showed statistically significant differences between the two groups.

Operative data are shown in Table 2. The mean (SD) EE of the learning curve group vs the experienced group was significantly different, 0.76 (0.38) g/min vs 0.92 (0.36) g/min respectively, ($p=0.021$). The median amounts of enucleated prostatic tissue in the learning curve group vs the experienced group were 44 (31-63) g vs 51.5 (30-71.5) g, respectively ($p = 0.171$). The median (IQR) morcellation times for the learning curve group vs the experienced group were 15 (10-26) min vs 11.5 (7-20) min, respectively ($p = 0.137$). The mean (SD) of morcellation efficiency in the learning curve group and the experienced group were 3.76 (3.1) g/min and 4.89 (2.81) g/min, respectively ($p = 0.05$).

The mean (SD) of catheterization time in the learning curve group and the experienced group were 3 (2.3) days and 2 (0.4) days, respectively ($p=0.0003$). The mean (SD) of LOS in the learning curve group and the experienced group were 4 (2.1) days and 3 (0.48) days, respectively ($p = 0.0008$).

Table 2 shows the perioperative complications. The rates of high-grade complications (Clavien Dindo Classification (CDC) grade 3-4) showed no difference between the two groups. Other complications included bladder mucosal injury in 3 cases (2 cases in the learning curve group needed open cystotomy to repair), blood transfusion in 2 cases (both in the learning curve group), and severe UTI sepsis in 2 cases. Unfortunately, the rate of urethral catheter reinsertion was not collected in this study.

Post-operative data

Table 3 shows the mean (SD) improvement of Qmax in the learning curve group vs the experienced group, 17.8 (10.8) ml/sec vs 19.6 (11.4) ml/

Table 1. Preoperative demographic data

Variables	First 60 cases	Last 60 cases	P-value
Age, year, mean (SD)	71.5 (7.3)	70.7 (6.7)	0.540
ASA classification n (%)			0.021
1	2 (3.33)	1 (1.67)	
2	39 (65.00)	52 (86.67)	
3	19 (31.67)	7 (11.67)	
BMI, kg/m^2 (SD)	25.46 (4.74)	22.86 (3.71)	0.001
Previous BPH medication n (%)			0.022
None	4 (6.67)	4 (6.67)	
Alpha-blocker	10 (16.67)	23 (38.33)	
Combination	46 (76.67)	33 (55.00)	
Indication for surgery n (%)			0.805
Urinary retention	26 (43.33)	30 (50.00)	
Bothersome	26 (43.33)	25 (41.67)	
Hematuria	3 (5.00)	3 (5.00)	
UTI	1 (1.67)	0	
Renal deterioration	3 (5.00)	1 (1.67)	
Bladder stone	1 (1.67)	1 (1.67)	
Prostate volume, g, median (IQR)	66 (50.5-101)	69 (50-95)	0.872
Pre-op IPSS, mean (SD)	24.9 (5.5)	25.8 (4.4)	0.346
Pre-op Hct, %, mean (SD)	39.6 (4.5)	38.6 (4.1)	0.198
Pre-op urinary retention, n (%)	23 (38.33)	34 (56.67)	0.044
Pre-op Qmax, ml/sec, median (IQR)	7.5 (5-10.7)	8.1 (6.5-12)	0.285
Pre-op PVR, ml, median (IQR)	52 (42-100)	68 (35-145)	0.698
Pre-op PSA, ng/ml, median (IQR)	4.8 (2.7-9)	6 (2-11.3)	0.728

SD = standard deviation, BMI = body mass index, BPH = benign prostatic hyperplasia, n = number, IQR = interquartile range, g = grams, Pre-op IPSS = preoperative International Prostate Symptom Score, Pre-op Hct = preoperative hematocrit, Pre-op Qmax = preoperative maximum urine flow rate, Pre-op PVR = preoperative postvoid residual urine, Pre-op PSA = preoperative prostate specific antigen, UTI = urinary tract infection

Table 2. Operative data

Variables	First 60 cases	Last 60 cases	P-value
Enucleation efficiency, g/min, mean (SD)	0.76 (0.38)	0.92 (0.36)	0.021
Enucleation tissue, gm, median (IQR)	44 (31-63)	51.5 (30-71.5)	0.171
Morcellation time, min, median (IQR)	15 (10-26)	11.5 (7-20)	0.137
Morcellation efficiency, g/min, mean (SD)	3.76 (3.10)	4.89 (2.80)	0.050
Hct changed, %, mean (IQR)	1.15 (0.10-2.45)	0.70 (0-2.80)	0.647
Catheter time (day), mean (SD)	3 (2.3)	2 (0.4)	0.0003
Length of hospital stay (day), mean (SD)	4 (2.1)	3 (0.48)	0.0008
CDC, n (%)			0.385
I	26 (43.33)	30 (50)	
II	8 (13.33)	5 (8.33)	
III	4 (6.67)	4 (6.67)	
IIIa	2 (3.33)	4 (6.67)	
IIIb	2 (3.33)	0 (0.00)	
IV	0 (0.00)	2 (3.33)	
IVa	0 (0.00)	0 (0.00)	
IVb	0 (0.00)	2 (3.33)	

SD = standard deviation, n = number, IQR = interquartile range, g = grams, Hct = hematocrit, CDC = Clavien Dindo Classification

Table 3. Post-operative outcomes at 1-month follow-up

Variables	First 60 cases	Last 60 cases	P-value
Improved Qmax, ml/sec, mean (SD)	17.8 (10.8)	19.6 (11.4)	0.363
IPSS reduction, mean (SD)	19.6 (6.2)	19.3 (4.4)	0.786
Post-op SUI, n (%)	9 (15.00)	14 (23.33)	0.354
Post-op hematuria, n (%)	10 (16.67)	5 (8.33)	0.269

SD = standard deviation, Qmax = maximum urine flow rate, n = number, IPSS = International Prostate Symptom Score, Post-op SUI = post-operative stress urinary incontinence, Post-op hematuria = post-operative hematuria

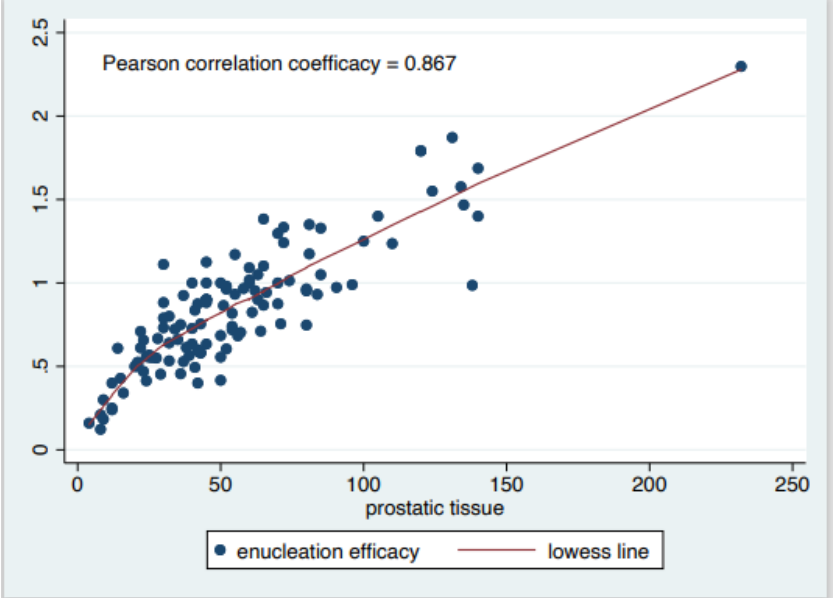

Figure 1. Enucleation efficiency and enucleated prostatic tissue.

sec, respectively. The difference was not significant (p = 0.363). The mean (SD) IPSS reductions in the learning curve group vs the experienced group were 19.6 (6.2) vs 19.3 (4.4), respectively with no statistically significant difference (p = 0.786). Postoperative SUI at 1-month follow-up in the learning curve group vs the experienced group, were 9 (15%) patients vs 14 (23.3%) patients, with no statistically significant difference (p = 0.354). Postoperative hematuria at 1-month follow-up in the learning curve group vs the experienced group were 10 (16.67%) patients vs 5 (8.33%) patients, which was not significantly different (p = 0.269).

Fig. 1. Scatter plots of operative data of HoLEP early apical release En Bloc technique. The plots show a correlation between enucleation efficiency and the weight of enucleated prostatic tissue. Larger prostate tissue resulted in a higher enucleation efficiency in comparison to smaller prostate tissue.

Fig. 2. shows the scatter plots of the operative data of HoLEP early apical release En Bloc technique. The plots demonstrated that the improvement of enucleation efficiency increased with the number of cases. The mean EE of the learning curve group was 0.76 g/min (0.38), and the mean of the experienced group was 0.92 g/min (0.36), which was an improvement of 0.16 g/min (p = 0.021).

Discussion

Several studies have demonstrated the advantages of anatomical endoscopic enucleation of the prostate (AEEP) using techniques such as laser or bipolar energy. These have been reported as being especially successful in the treatment of large gland prostate, which is consistent with our data (Fig. 1). However, HoLEP is one of the most challenging procedures in endourology, and due to the steep learning curve, its use has been limited. Without formal instruction, the steepness

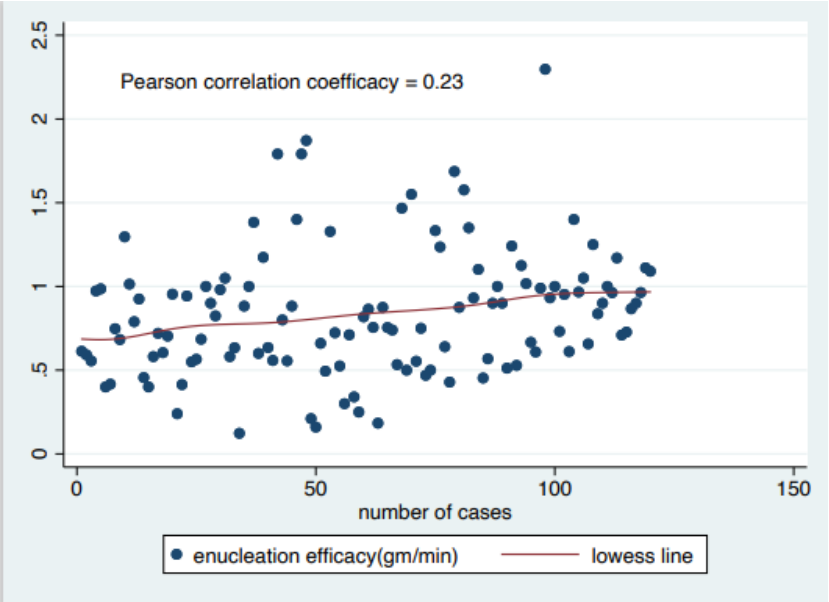

Figure 2. Learning curve parameters: enucleation efficiency and number of cases

of the learning curve is particularly difficult.[22,23]

To date many studies have demonstrated a number of procedures used to achieve the level of proficiency necessary for successful surgery. In the case of the standard three-lobe incisional technique, the novice needs to carry out 20 cases with an experienced instructor and 40-50 in the case of the self-teaching model.[24-27] However, the En Bloc technique is more challenging, proficient requiring at least 30-50 and 100 cases, with or without a proctor.[28,29] However, the En Bloc technique is becoming a more popular option because it saves operative time and is more efficient in enucleating adenoma while using less laser energy, causing lower post-operative complications.[30-32]

Within our study, the operative data revealed a significant improvement in the mean EE of the experienced group compared to the learning group, with an increase of 0.15 g/min (from 0.76 to 0.92), a statistically significant difference ($p = 0.021$). High levels of success occurring after operating in 60 consecutive cases. Catheter time (CT) and LOS were also significantly shorter in the experienced group. This data suggests that a suitable number of procedures required for passing the learning curve in this technique is at least 60 cases, based on the improvement in EE, CT, and LOS in this study. Other studies carried out around the world also support this finding. [22,24,33]

Even three decades after the introduction of HoLEP there is still no consensus with regard to a standard value of mean EE as a cutoff point for gaining expertise. Another factor in the assessment during the learning curve is the stability of skills. Most studies in the multi-incisional technique demonstrate a constant surgical performance state as it reaches a plateau of EE.[24,26,27] Unfortunately, however, our results show a different pattern as a slightly rising trend.

In Fig. 2: a gradual proportional increase in EE can be seen in parallel to the cases experienced. This figure is often seen in publications describing the development of the En Bloc learning curve.[28,29] The result of Wenk et al.[29] reveals a slight but steady improvement of EE even after 500 surgical cases, results still not reaching the plateau. To attempt to explain this, we hypothesize that it is challenging to master the En Bloc technique. The enucleation state begins with one incision to seek the space between the adenoma and the surgical capsule, then dissection progresses toward the bladder neck. The most challenging step is finding a good plane and effectively lasering tissue with proper hemostasis. As the surgical field is limited, the perspective and orientation of anatomy is more complicated than in standard incisional techniques, especially without a mentor.

When surgeons gain experience by carrying out increased numbers of consecutive cases in this En Bloc technique, especially with the large prostate volume, this will facilitate reduced enucleation time. This increased familiarity with the procedure might affect gradual improvement in EE (enucleation efficiency) (g/min). This data is

consistent with results from a study by Tamalunas et al.[31] As previously mentioned, HoLEP has a steep learning curve, requiring surgical experience for the best operative outcomes, reduced operative time, minimal perioperative blood loss, and minimal perioperative complications.[34] Self-learning may need more cases to achieve efficiency than in the professional guidance process.[20,21]

The morcellation efficiency in the experienced group improved from 3.76 (3.1) g/min to 4.89 (2.81) g/min, but the results did not quite achieve statistical significance (p = 0.05). In our study, the first 30 cases used the VersaCut morcellator before switching to the Piranha morcellator (oscillating function), which is a more efficient device. This could also have affected the data.[35]

The postoperative data demonstrate no statistically significant differences between the two groups in the case of Qmax improvement (p = 0.363), IPSS reduction (p = 0.786), post-operative SUI (p = 0.354), or post-operative hematuria (p = 0.269). This is consistent with the results of a study by Ito TT.[36] A possible cause of greater post-operative SUI in the experienced group than in the learning curve group is the operative technique. The surgeon removed the tissue around the prostate apex totally to decrease the adenoma recurrence rate, which is a different technique to that used initially, aiming to leave tissue at the apical area because of concerns about incontinence. However, the outcomes documented in this study were at 1-month follow-up. At the 6-month follow-up, the patients had normal continence, which is similar to other studies.[37]

Overall the peri-operative complications in this study were minor, the majority occurring in the learning curve period, the incidence being comparable with another study from high-volume centers.[23] Serious post-operative complications, such as severe bladder mucosal injury (CDC IIIb) caused by a morcellator, occurred in 2 cases in the learning curve group. Those patients underwent open cystotomy for adenoma removal and bladder repair to ensure the patient's safety. Another morbidity was severe UTI sepsis (CDC IVb). These complications may have resulted from prolonged catheterization, which is a risk factor for UTI and poor health.[38]

A limitation of this retrospective study was the limited number of cases and that only a single surgeon performed the procedure, hence all procedures were managed without supervision. The experience of one urologist might not enable the generalization of the findings. Also, this study was based on data from 120 patients which was divided exactly into two groups. This data could potentially yield more detailed findings if it was examined as a continuous data set as the proficiency of the surgeon would assumedly improve along the linear period.

In this case the surgeon had passed proficiency in Bipolar Enucleation of Prostate (BiPoLEP), which might affect the initial phase of the learning group and limit the transferability of the findings to a novice in this technique. Future prospective studies should recruit more cases and follow up longer to provide more reliable results.

Conclusion

This study determined that because of the steep learning curve, urologists require experience of 60 cases to become proficient in Holmium laser enucleation of the prostate with the early apical release En Bloc technique. It is essential that urologists who wish to carry out this procedure should gain the necessary surgical experience.

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Conflict of Interest

The authors declare no conflict of interest.

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