Influence of Early Apical Release on Outcomes in Endoscopic Enucleation of the Prostate: Results From a Multicenter Series of 4392 Patients

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OBJECTIVE To evaluate outcomes after laser endoscopic enucleation of the prostate (EEP) stratified by whether early apical release (EAR) was performed or not.

METHODS We retrospectively reviewed patients with clinical benign prostatic hyperplasia who underwent EEP with holmium or thulium fiber laser in 8 centers (January 2020-January 2022). Exclusion criteria: previous prostate/urethral surgery, prostate cancer, pelvic radiotherapy, concomitant lower urinary tract surgery. One-to-one propensity score-matching was performed between patients with EAR vs no EAR, with covariates including age, prostate volume, diabetes mellitus, hypertension, preoperative indwelling catheter, IPSS, Qmax, enucleation, and laser types. Multivariable logistic regression analyses were performed to evaluate independent predictors of 30-day postoperative complications and urinary incontinence.

RESULTS EAR was performed in 2094 of 4392 included patients. The matched cohort consisted of 787 patients per arm. Total operation time was significantly longer in the EAR group (median 75 vs 67 minutes, P = .004). Early complications were higher in the EAR group (18.6% vs 12.5%, P = .001), while postoperative incontinence rates were similar (14.1% vs 13.1%, P = .61). Multivariable regression analysis showed that 3-lobe enucleation and operation time were significant predictors of postoperative complications; preoperative indwelling catheterization, higher prostate volume, and en-bloc enucleation were associated with higher odds of postoperative incontinence. Limitation: retrospective nature.

CONCLUSION Performing EAR during EEP is associated with a greater incidence of early complications, which was mainly driven by higher rates of postoperative hematuria and perioperative transfusion. The risk of postoperative incontinence and its duration are not affected by EAR. UROLOGY 187: 154–161, 2024.

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Patients with benign prostatic hyperplasia (BPH) and bothersome lower urinary tract symptoms require surgical intervention in 30% of cases despite being on medical therapy.[1] Endoscopic enucleation of the prostate (EEP) was first introduced in 1983 and gained popularity with the introduction of holmium laser (HL) and morcellators.[2] EEP has evolved continuously with technological and technical modifications aimed at improving outcomes.[3]

Postoperative urinary incontinence (UI) is a common complication of any surgical intervention for BPH.[4] Proposed measures to prevent or reduce UI after EEP include bladder neck preservation, avoiding radial strain of the sphincter, careful incision of the mucosa from proximal to distal at the 12 o′clock position, use of sharp energy, and precise low-energy hemostasis near the prostatic apex.[5] More recent techniques such as the en-bloc no-touch approach[6] combined with the early apical release (EAR) technique[7] have demonstrated favorable visualization, quick identification of the surgical capsule and plane dissection, which may offer better sphincter preservation. The influence of EAR when used miscellaneously with other EEP techniques on intra and perioperative outcomes is poorly reported, especially in real-world settings using different energy sources.[8]

We aimed to assess perioperative outcomes of EAR vs no EAR in a global real-world multicenter study of EEP.

MATERIALS AND METHODS

The "Refinement in Endoscopic Anatomical Enucleation of Prostate" (REAP) registry is a retrospective multicenter anonymized pooled database created at understanding how EEP is performed in a real-world setting where different surgeons adopt it to suit their practice based on the available resources.[9] Institutional review board approval was obtained by the leading center (AINU 11/2022) and the remaining centers received approval from their respective institutional boards.

The REAP registry includes data of 6193 patients who underwent EEP for clinical BPH in 8 centers from January 2020 to January 2022. EEP was performed by 12 surgeons with > 200 cases of EEP experience. Of these, 4392 men who underwent thulium or HL enucleation of the prostate had a specification of whether EAR was performed. Patients were divided into two groups; group 1: patients who had EEP without EAR, group 2: patients underwent EEP with EAR. Inclusion criteria were lower urinary tract symptoms with no response to or were worsening despite medical therapy, acute urinary retention, or any other absolute indication for surgery (ie, recurrent urinary tract infection, bilateral hydronephrosis with renal impairment, recurrent hematuria due to BPH). Patients with previous prostate/urethral surgery, prostate cancer, and pelvic radiotherapy were excluded. Patients who underwent concomitant lower urinary tract surgery were also excluded (ie, internal urethrotomy, lithotripsy, or transurethral resection of bladder tumor). If there was any suspicion of prostate cancer prior to EEP, this was ruled out with a prostate biopsy before surgery. Patients taking oral anticoagulants were switched to low-molecular-weight heparin and resumed as per each center's discretion, while single antiplatelet therapy was maintained. Antibiotic prophylaxis was administered to patients according to local protocols. EEP was performed using either high-power HL (120 W VersaPulse, Lumenis Ltd, Yokneam, Israel or Cyber Ho, Quanta System, Varese, Italy) or TFL (TFL U3, IRE-Polus, Russia or 60 W super pulse TFL IPG photonics, Oxford, MA). EAR was defined as dividing the apex of the adenoma from the urinary sphincter with a circumferential incision of the muscosa at the beginning of the operation. Morcellation was performed in all cases after enucleation using different morcellators as available. Enucleation time was calculated from the start of enucleation to the start of morcellation and included time for EAR as well. Surgical time was considered from cystoscopy to catheter placement. Patients were assessed postsurgery according to each center's practice protocols. UI was defined as any urine leakage as reported by patients; this was further categorized according to duration (< 1 month, 1-3 months, and > 3 months) and type (urge, stress, or mixed).

Statistical Analysis

The Shapiro-Wilk test was used to assess data for normality. Continuous variables are reported as medians and interquartile ranges or means and standard deviations, and categorical variables as absolute numbers and percentages. Patient demographics, perioperative parameters, and outcomes were compared between groups using the χ^2 test or Fisher exact test for categorical parameters and the Mann-Whitney *U* test for continuous variables.

Propensity score matching (PSM) was used to reduce confounding in the statistical comparisons and calculated using a logistic regression model, with one-to-one matching for the following variables: age, prostate volume, diabetes mellitus, hypertension, preoperative indwelling catheter, International Prostate Symptom Score (IPSS), peak flow rate (Qmax), enucleation type, and laser used. To guarantee the optimal matching of baseline covariates, the caliper width was started at 0.2[10] and decreased in increments of 0.01 until the absolute standardized mean difference (ASMD) for all covariates was < 0.1,[10,11] which was achieved at a caliper width of 0.07. All baseline variables were described for the PSM cohort similar to the overall cohort.

Outcomes were assessed using the PSM cohort only. The primary outcome was the incidence of early complications, defined as postoperative complications occurring within 30 days (excluding UI). Secondary outcomes included postoperative UI, micturition parameters, and IPSS at 3 and 12-month follow-up, and delayed complications (within 1 year).

Variables that have been suggested to impact early complications[12] and postoperative incontinence[4,5,13] were included in two multivariable models to assess their significance as independent predictors. Predictors are described using OR, 95% CI, and *P*-values. Statistical analyses were performed using R Statistical language, version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria) with $P < .05$ indicating statistical significance.

RESULTS

Among 4392 included patients, EAR was performed in 2094 men. Table 1 shows patient baseline characteristics before and after PSM. Patients in the group 2 were significantly older [median 68 (63-74) vs 67 (61-72) years, ASMD = 0.121], and had larger prostate volume [median 77 (58-100) vs 70 (56-90) mL, ASMD = 0.266]. IPSS, Quality of Life (QoL) score, and postvoid residual (PVR) were significantly higher in group 2, while Qmax and prostate-specific antigen were significantly higher in group 1. Patients with diabetes, cerebrovascular disease, and an indwelling catheter were significantly more prevalent in group 2. There were also significant differences in enucleation type and lasers used.

After PSM, 787 patients per group were well-matched for baseline characteristics, type of laser, and enucleation techniques. There still remained a higher prevalence of ischemic heart disease and cerebrovascular disease in group 1. Baseline QoL, prostate-specific antigen, and PVR (which were not matched for) still differed between the groups.

In the PSM cohort, median surgical time was significantly longer in group 2 [median 75 (60-100) vs 67 (55-98) minutes, $P = .004$] but enucleation time was similar in both groups (Table 2). Mean postoperative catheter dwelling time was significantly shorter in group 1 [1.79 ± 0.90 vs 2.89 ± 1.19 days, $P < .001$].

A significantly higher proportion of patients experienced early complications in EAR compared to no EAR group (18.6% vs 12.5%, $P = .001$). Of the individual component complications, postoperative hematuria needing prolonged irrigation was significantly more prevalent in group 2 (8.0% vs 4.8%, $P = .014$), as was that of perioperative blood transfusion (2.2% vs 0%, $P < .001$). The incidence of additional surgical intervention for hemostasis (Clavien grade 3) was similar in both groups ($P = .54$). The 30-day all-cause readmission rate did not differ between the groups (1.8% in no-EAR vs 3.5% in the EAR group, $P = .07$). No difference was noted in late complications within a 1-year follow-up (urethral strictures, bladder neck contracture, and reoperation for BPH).

Postoperative incontinence rate (urge, stress, and mixed) was low and similar between the two groups (13.1% in group 1 vs 14.1% in group 2, $P = .67$). Most patients with incontinence had resolution of this complication by 3 months; past this time point, incontinence only affected 7.6% in group 1% and 5.4% in group 2.

At 3- and 12-month follow-up visits there was a significant decrease in PVR, IPSS, and QoL item scores, and an increase of Q-max from baseline in both groups but the median rate of decrease in IPSS, improvement in QoL and Q-max were significantly higher in group 1 over 12 months (Table 3).

Multivariable regression analysis of matched populations showed that 3-lobe enucleation (OR 5.10, 95% CI 1.43-20.49, $P = .01$) and operation time (OR 1.06, 95% CI 1.01-1.12, $P = .023$) were significantly associated with higher odds of postoperative complications (Table 4). Multivariable regression analysis of matched populations showed that preoperative IDC (OR 1.76, 95% CI 1.06-2.81, $P = .022$), prostate volume (OR 1.01, 95% CI 1.00-1.04, $P = .007$), and en bloc enucleation (OR 1.68, 95% CI 1.21-2.32, $P = .002$) were significantly associated with higher odds of postoperative UI (Table 4).

DISCUSSION

Conventionally, transurethral resection of the prostate has been the gold standard for BPH intervention. EEP is now debated as the new gold standard, and holds a standard recommendation in international guidelines as a size-independent intervention.[14,15]

In the past decade, the quest to improve procedural outcomes and ease of learning the procedure has mostly focused on understanding sphincter anatomy, gland shape and size, and various laser energy sources.[2] Recent modifications in EEP surgery such as the evolution from classic 3-lobe to 2-lobe to en-bloc technique have been shown to improve almost all perioperative outcomes.[16] In our study, the median operative time was statistically significantly longer in group 2. As a real-world international study, operative setups may be heterogeneous in factors such as procurement and handling of instruments, nursing and anesthesia support, and overall theater efficiency.[17] Additionally, given that EAR is commonly done in combination with 2 or 3-lobe techniques, this is congruent with prior literature reporting longer operative time compared to en-bloc enucleation.[18] Conversely, the similarity in actual enucleation time between both groups suggests that adding EAR to non-enbloc approaches does not necessarily affect enucleation time in the hands of experienced surgeons; this has also been described in a recent meta-analysis.[19]

Saitta et al proposed that combining en-bloc enucleation with EAR shortens overall operative time, since dissection of the prostatic adenoma is performed as a single tissue mass with optimized visualization of the dissection plane.[7] Tuccio et al similarly reported a reduction in mean enucleation time with en-bloc enucleation plus EAR and proposed that reducing the amount of energy delivered to the fossa over 3-lobe

Table 1. Patients' baseline characteristics in unmatched and matched cohorts.

	Unmatched Cohort			Matched Cohort		
	Group 1 No EAR (N = 2298)	Group 2 EAR (N = 2094)	ASMD	Group 1 No EAR (N = 787)	Group 2 EAR (N = 787)	ASMD
Age, median [IQR]	67 [61,72]	68 [63,74]	**0.121**	67 [61,71]	67 [62,72]	0.022
Prostate volume (cc), median [IQR]	70 [56,90]	77 [58,100]	**0.266**	80 [60,93]	77 [59,100]	0.074
Preoperative IDC, n (%)	203 (8.8)	812 (38.8)	**0.751**	45 (5.7)	65 (8.3)	0.100
Diabetes mellitus, n (%)	196 (9.9)	430 (29.2)	**0.502**	136 (17.3)	141 (17.9)	0.017
Hypertension, n (%)	1046 (52.9)	913 (62.0)	**0.185**	479 (60.9)	487 (61.9)	0.021
Ischemic heart disease, n (%)	152 (34.5)	342 (23.2)	**0.250**	77 (43.3)	146 (18.6)	**0.555**
Cerebrovascular disease, n (%)	61 (13.7)	170 (11.5)	0.066	29 (16.1)	96 (12.2)	**0.112**
Preoperative IPSS, median [IQR]	22 [21,25]	24 [19,27]	**0.121**	22 [21,24]	24 [19,28]	0.068
Preoperative QoL, median [IQR]	4.0 [3.0, 5.0]	5.0 [5.0, 6.0]	**0.956**	4.0 [3.0, 5.0]	5.0 [5.0, 6.0]	**0.878**
Preoperative Qmax, median [IQR]	8.6 [7.1, 11.3]	7.0 [5.0, 9.6]	**0.617**	7.8 [6.4, 9.0]	7.50 [5.1, 9.8]	0.043
Preoperative PVR, median [IQR]	70 [60,90]	89 [40,236]	**0.671**	70 [60,90]	70 [15,157]	**0.224**
Preoperative PSA, median [IQR]	4.3 [2.6, 6.3]	4.0 [2.3, 8.0]	**0.237**	4.4 [2.7, 6.2]	3.91 [2.3, 7.0]	**0.299**
Enucleation type, n (%)			**0.767**			0.055
3-lobe	314 (13.7)	174 (8.3)		45 (5.7)	54 (6.9)	
2-lobe	1570 (68.3)	827 (39.5)		565 (71.8)	567 (72.0)	
En bloc	414 (18.0)	1093 (52.2)		177 (22.5)	166 (21.1)	
Laser used, n (%)			**0.604**			0.006
Holmium laser	798 (34.7)	1332 (63.6)		238 (30.2)	236 (30.0)	
Thulium fiber laser	1500 (65.3)	762 (36.4)		549 (69.8)	551 (70.0)	

ASMD, absolute standardized mean difference; EAR, early apical release; IDC, indwelling catheter; IPSS, International Prostate Symptom Score; IQR, interquartile range; PSA, prostate-specific antigen; PVR, postvoid residual urine volume in mL; Qmax, peak flow rate in mL per second; QoL, Quality of Life score.
Variables in which ASMD > 0.1 are highlighted in bold.

Table 2. Intraoperative and postoperative outcomes in unmatched and matched cohorts.

	Group 1 No EAR (N = 787)	Group 2 EAR (N = 787)	*P*
Spinal anesthesia, n (%)	777 (98.7)	638 (81.1)	**< .001**
Operation time, median [IQR]	67 [55,98]	75 [60,100]	**.004**
Enucleation time, median [IQR]	55 [35,76]	55 [40,80]	.52
Morcellation time, median [IQR]	20 [11,35]	21 [15,35]	**.002**
All postoperative complications within 30 d, n (%)	98 (12.5)	146 (18.6)	**.001**
Acute urinary retention (Clavien 2)	20 (2.5)	20 (2.5)	> .99
Postoperative hematuria requiring prolonged irrigation (Clavien 2)	38 (4.8)	63 (8.0)	**.014**
Urinary tract infection (Clavien 2)	28 (3.6)	37 (4.7)	.31
Postoperative bleeding needing hemostasis (Clavien 3)	4 (0.5)	7 (0.9)	.54
Perioperative transfusion	0	17 (2.2)	**< .001**
Ureteral orifice injury needing a stent (Clavien 3)	4 (0.5)	0 (0.0)	.13
Sepsis (Clavien 4)	0	0	-
Postoperative catheter time (d), mean [SD]	1.79 (0.90)	2.89 (1.19)	**< .001**
Postoperative incontinence, n (%)	103 (13.1)	111 (14.1)	.61
Urge	18 (26.9)	56 (32.6)	
Stress	35 (52.2)	83 (48.3)	
Mixed	14 (20.9)	33 (19.2)	
Duration of incontinence for those affected, n (%)			.54
< 1 mo	**32 (48.5)**	**63 (56.8)**	
Urge	14 (43.8)	33 (52.4)	
Stress	14 (43.8)	10 (15.9)	
Mixed	4 (12.5)	20 (31.7)	
1-3 mo	**29 (43.9)**	**42 (37.8)**	
Urge	3 (12.5)	20 (47.6)	
Stress	13 (54.2)	11 (26.2)	
Mixed	8 (33.3)	11 (26.2)	
> 3 mo	**5 (7.6)**	**6 (5.4)**	
Urge	1 (20.0)	3 (50.0)	
Stress	2 (40.0)	1 (16.7)	
Mixed	1 (20.0)	2 (33.3)	
30-d all-cause readmission, n (%)	14 (1.8)	19 (3.5)	.07
Delayed complications, n (%)			
Urethral stricture requiring dilation	12 (1.5)	4 (0.5)	.08
Urethral stricture requiring urethrotomy	1 (0.1)	1 (0.1)	> .99
Bladder neck contracture requiring transurethral incision	10 (1.3)	3 (0.4)	.09
Redo surgery for BPH	0 (0.0)	1 (0.1)	> .99

BPH, benign prostatic hyperplasia; EAR, early apical release; IQR, interquartile range; SD, standard deviation. Bold value stands for significant pa value.

Table 3. Change in measurements from baseline at 3 and 12 months in the matched cohort.

	Group 1 No EAR (N = 787)	Group 2 EAR (N = 787)	*P*
3 mo			
IPSS, median [IQR]	17 [14,19]	17 [13,22]	**.001**
QoL, median [IQR]	2.0 [2.0, 3,0]	4.0 [3.0, 4.0]	**< .001**
Qmax, median [IQR]	13 [11,15]	14 [8.1, 18]	.704
PVR, median [IQR]	60 [40,75]	53 [− 4.3, 130] 72 (68)	.070
12 mo			
IPSS, median [IQR]	18 [16,20]	16 [12,21]	**< .001**
QoL, median [IQR]	3.0 [2.0, 4.0] 3.0 (1.2)	4.0 [3.0, 4.0]	**.002**
Qmax, median [IQR]	17 [21,22]	13 [8.2, 17]	**< .001**
PVR, median [IQR]	60 [40,80]	31 [− 7.0, 119]	.572

EAR, early apical release; IPSS, International Prostate Symptom Score; IQR, interquartile range; PVR, postvoid residual urine volume in mL; Qmax, peak flow rate in mL per second; QoL, Quality of Life score.
IPSS, QoL, and PVR are calculated as a decrease from baseline, while Qmax is calculated as an increase from baseline. Bold value stands for significant pa value.

Table 4. Multivariable analysis of predictive factors of early complications and postoperative incontinence in the matched cohorts.

	Early Complications			Postoperative Incontinence		
	OR	95%CI	*P*	OR	95%CI	*P*
Early apical release	0.76	0.25-2.43	.63	1.09	0.82-1.46	.56
Enucleation type (vs 2-lobe)						
3-lobe	5.10	1.43-20.49	**.01**	1.21	0.64-2.12	.53
En bloc	2.31	0.63-9.33	.21	1.68	1.21-2.32	**.002**
Prostate volume	1.01	0.99-1.01	.14	1.01	1.00-1.04	**.007**
Age	1.00	0.95-1.07	.87	1.00	0.98-1.019	.96
Preoperative IDC	1.49	0.9-2.37	.11	1.76	1.06-2.81	**.022**
Operation time	1.06	1.01-1.12	**.023**	1.01	0.99-1.005	.38

IDC, indwelling catheter.

Bold value stands for statistically significant value.

enucleation, EAR reduced stress UI rate.[20] EAR technique consists of the preservation of external sphincter mucosa, detaching it from the striated sphincter through a complete apex-sphincter demarcation. Muscular and elastic tissue located in the distal third of the prostatic urethra might play an important role in sustaining continence and injury to this segment may contribute to stress UI following EEP despite the striated sphincter activity is not the only factor responsible for continence in men.[21,22] EAR may prevent excessive stretching of the sphincter during subsequent dissection movements with the scope, preserving the distal prostatic urethra and reducing the likelihood of postoperative stress incontinence.[7] In our study, although rate and duration of overall UI was not notably different between both groups, a numerically lower proportion had stress UI in the EAR group.

While the en-bloc technique has had other innovations reported in single-center series,[23,24] to our knowledge, our study is the first to report the influence of EAR in a large multicenter real-world cohort when combined with en bloc, 2 and 3 lobe techniques and contemporary lasers. We hypothesize that as surgeons are well versed with 2 or 3 or en bloc techniques and there is good awareness about the benefits of the EAR, our cohort has adopted this into their technique.

Different enucleation technique studies have variably reported rates of postoperative incontinence. Gong et al reported on a modified enucleation technique using the HL, in which transient stress UI occurred only in 3 out of 189 consecutive patients who all showed spontaneous resolution within 3 months of surgery.[25] Minagawa et al demonstrated a modification of the en bloc technique which omits median lobe enucleation reporting a 3% incidence rate of postoperative UI at 3 months.[26] A recent meta-analysis comparing transurethral resection of the prostate, ablation, and enucleation techniques showed that even though all techniques had an impact on all forms of incontinence, most instances were transient with no difference between the procedures, except for transient mixed UI which was higher after enucleation.[4]

In our multivariate analysis, prostate volume was a significant predictive factor associated with higher odds of having incontinence. Similarly, Rucker et al and Li et al demonstrated that prostate weight was a significant predictor for postoperative stress incontinence.[18,27] A larger prostate volume equates to longer operative time and potentially longer duration of trauma to the inner longitudinal layer around the apical gland and external sphincter, thereby accounting for a higher incidence of postoperative incontinence.[28] Shigemura et al reported that the surgeon's experience was the significant contributing factor to reducing operative times and this directly translated to reduced UI.[29] In our study, data was acquired only from high-volume surgeons with large experience in EEP. Therefore, the refined ability to perform EEP may explain why EAR does not significantly affect UI rates. However, it is well established that complications in EEP do occur even in experienced hands with 14.8% incidence during the hospital stay and 14% possibility within 1 month of discharge.[30] Clavien grade ≥2 complications were observed in 18 cases and were more common for patients with an indwelling catheter at baseline.[30] These findings corroborate closely well with our study. While group 2 in our series had significantly longer postoperative catheter duration, this could much more likely be linked to the significantly higher rates of postoperative bleeding seen in the EAR arm. We acknowledge that the lack of other details on antiplatelet and anticoagulation use prevents a more detailed explanation of the higher bleeding manifestations in the EAR arm. Nonetheless, 30-day readmission rates and 1-year complications did not differ significantly. Hence, from a long-term standpoint, addition of EAR to any EEP technique remains a safe and feasible option.

We acknowledge the limitations of laser settings, anticoagulation choices, operative theater variabilities, and the retrospective nature of this study that lends bias to inferences drawn. Yet, this is the first-ever attempt at reporting the use of EAR with different techniques in EEP and an effort to understand what major issues are to be expected outside of a randomized clinical trial despite all these inherent biases in real-world practice. PSM helps minimize selection bias and adjusted for the bias inherent to the different baseline patient characteristics such that we could collect data on the prostate volume, type of approach, energy source utilized, and complications. Our multicenter real-world experience reflects how evidence from past practices is adopted, modified, and yielded to achieve actual outcomes. The addition of EAR to all forms of EEP is one such example of its ever-evolving nature, and this could provide the base for future randomized studies.

CONCLUSION

To our knowledge, this is the first multicenter real-world comprehensive analysis reporting the adoption of EAR with different types of EEP using holmium and thulium lasers. EAR, despite a higher rate of postoperative complications seen in this study, remains a feasible technique when combined with any enucleation technique when performed by experienced surgeons. We could not conclusively show that EAR alone improves UI outcomes, and a randomized study may offer better insights.

Declaration of Competing Interest

Fernando Gómez Sancha is a paid consultant for Quanta system and Lumenis. Dean Elterman is a paid consultant/investigator for Boston Scientific, Procept Biorobotics, Olympus, Urotronic, Prodeon, and Zenflow. Thomas R.W. Herrmann is a paid consultant for, has received honoraria from, and is involved in research collaboration with Karl Storz. The remaining authors declare no conflict of interest.

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