ORIGINAL PAPER

FUNCTIONAL UROLOGY

Complications of anatomical endoscopic enucleation of the prostate in real-life practice: What we learnt from the 6,193 patients from the Refinement in Endoscopic Anatomical Enucleation of Prostate registry

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Introduction Anatomical endoscopic enucleation of the prostate (AEEP) is a guideline-recommended treatment for benign prostatic hyperplasia (BPH). We aimed to analyze postoperative complications and outcomes within a large real-world database.

Material and methods The Refinement in Endoscopic Anatomical enucleation of Prostate (REAP) registry includes patients who received AEEP for BPH in 8 centers worldwide from January 2020 to January 2022. Exclusion criteria included previous prostate/urethral surgery, prostate cancer, pelvic radiotherapy, and concomitant lower urinary tract surgery (internal urethrotomy, cystolithotripsy, or transurethral resection of bladder tumor). The primary outcome was postoperative incontinence; secondary outcomes included early complications (<30 days) and late complications (>30 days).

Results We analyzed 6,193 patients; the mean age was 68 years. Thulium laser was used in 37% and high-power holmium laser in 32%. Median operation time was 67min [IQR 50–95 min]. The 2-lobe enucleation technique was utilized in 49%, and en-bloc resection was utilized in 39%. Early postoperative complications included urinary tract infection (4.7%), acute urinary retention (4.1%), post-operative bleeding requiring additional intervention (0.9%), and sepsis requiring intensive care admission (0.1%).

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The incidence of postoperative incontinence was 14.8%, of which 54% were stress incontinence; 84% cases resolved by 3 months. On univariate and multivariate analysis, prostate volume >100 ml was a significant predictor of postoperative incontinence. Late complications such as bulbar urethral stricture, bladder neck sclerosis, and need for redo BPH surgery each occurred in <1% of patients.
Conclusions Analysis of the real-world REAP database shows favorable safety outcomes for AEEP, with a low incidence of serious complications and postoperative incontinence beyond 3 months.

Key Words: benign prostate hyperplasia ‹› anatomical endoscopic enucleation of the prostate ‹› prostate

INTRODUCTION

Anatomical endoscopic enucleation of the prostate (AEEP) is recommended by international guidelines [1, 2] for the surgical management of clinical benign prostate hyperplasia (BPH). When counseling patients on operative outcomes, it is imperative to highlight the pros and cons of any surgery, as AEEP is not devoid of complications even in experienced hands [3, 4]. To optimize laser AEEP procedures, a Delphi consensus statement on a standardized practices has been published, with the aim to improved outcomes and patient satisfaction [5]. Although considered safe, complications still occur and can be attributed to patient selection, instrument, intra-operative technical difficulties [6], surgeons' experience and learning curve [4]. The Refinement in Endoscopic Anatomical enucleation of Prostate (REAP) database [7] was established with the aim of analyzing outcomes from a multicenter real-world experience. Our primary aim is to report and analyze complications from the REAP database, where AEEP is practiced and adapted via various techniques and energy sources according to local expertise and resources.

MATERIAL AND METHODS

Registry design and enrolment protocol

The REAP registry is a retrospective multicenter anonymised database aimed at understanding how enucleation is performed in different parts of the world. Data from this registry is hoped to strengthen results known in the literature, reveal unknown issues and ultimately help to improve the real-world practice of AEEP. 6,193 patients were enrolled in the registry from 12 surgeons, from 8 centers, with at least 200 cases of enucleation experience for each surgeon. This study included adult patients who underwent AEEP for clinical BPH between January 2020 and January 2022. Patients with previous prostate/urethral surgery, prostate cancer, and pelvic radiotherapy were excluded. Patients who underwent concomitant lower urinary tract surgery were also excluded (i.e., internal urethrotomy, cystolithotripsy, or transurethral resection of bladder tumor). If there was a suspicion of prostate cancer, it was ruled out with prostate biopsy before enucleation. Oral anticoagulant agents were switched to low-weight molecular heparin in preparation for surgery and resumed as per each center's discretion. Antibiotic prophylaxis was administered to all patients according to local protocols. Intraoperative, immediate postoperative (within 24 hours), intermediate (within 3 months), and late, more than 3 months and within a year, were also recorded.

Patient follow-up and secondary treatment

Patients were assessed post-surgery according to the local standard of care. Follow-up time intervals were at 1, 3, and up to 6 months. Enucleation time was calculated from the start of enucleation to the start of morcellation. Surgical time was considered from cystoscopy to catheter placement. Incontinence was defined as any urine leakage as reported by the patients. Details for histopathology were also obtained. Information on functional outcomes at 3-month or 6-month follow-up and up to 1 year, as available, was requested. The follow-up reflected each participant's center's protocols.

Statistical analysis

All statistical analyses were performed using R Statistical language, version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria), with $p < 0.05$ indicating statistical significance. Continuous variables are reported using medians and interquartile ranges (IQR), while categorical variables as absolute numbers and percentages. Univariable logistic regression analysis (UVA) was performed

to evaluate factors associated with complications and postoperative urinary incontinence. Relevant potentially prognostic variables in UVA were entered into a multivariable model (MVA) to assess their significance as independent predictors. Predictors were described using odds ratios (OR), 95% confidence intervals (CI), and p-values.

Bioethical standards

Institutional review board approval was obtained by the Asian Institute of Nephrology and Urology (AINU 11/2022), and the remaining centers received approval from their respective institutional boards.

RESULTS

6,193 patients, who met the inclusion criteria were included in the final analysis. Table 1 shows patients' baseline characteristics. Median age was 68 years, with 8% of the cohort being >80 years. The majority (40.5%) of patients were ASA 2 score. Preoperative PSA was reported in 5,232 patients with a median value of 4.30 ng/dl [2.40, 7.15]. Only 21.95% of patients were on a preoperative indwelling catheter for acute urinary retention. AEEP was performed in 2,326 (37.8%) patients with a prostate volume larger than >80 ml. Table 2 shows the operative characteristics of the cohort. The most popular energy source was the Holmium laser. Both low-power (2.7%) and high-power holmium lasers (HLs) (31.6%) were used. Thulium fiber laser (TFL) was used in 36.5% of cases. Monopolar electrocautery devices were used in 1.1% of patients.

The most common technique used for enucleation across all gland sizes was the 2-lobe technique in 48.8% of cases with the En-bloc technique being the next preferred approach in 38.6% of patients. 86.2% of the procedures were performed under spinal anesthesia with a median operation time, [IQR] of 67 min [50, 95]. The most used morcellator was Piranha (Richard-Wolf, Germany) (81.4%). Median postoperative catheter time was 2 [1, 3] days. Table 3 shows the postoperative outcomes. The early postoperative complication rate was very low with urinary tract infections as the most commonly reported (4.7%) followed by acute urinary retention within 24 hours of post-operative catheter removal (4.1%). Postoperative bleeding needing additional intervention was only reported in 57 patients (0.9%) and sepsis needing intensive care admission in 9 patients only

Table 1. *Patient baseline characteristics and demographics*

Parameter	
Age, median [IQR]	68 [62, 74]
Age categories, n (%)	
<50	47 (0.76)
50–60	882 (14.3)
60–70	2,676 (43.3)
70–80	2,084 (33.6)
>80	498 (8.0)
Prostate volume (cc), median [IQR]	73 [55, 95]
<30 cc, n (%)	145 (2.4)
30–80 cc, n (%)	3,686 (59.9)
>80 cc, n (%)	2,326 (37.8)
Preoperative IDC for urinary retention, n (%)	1,355 (21.9)
ASA score, n (%)	
1	1,249 (33.8)
2	1,497 (40.5)
3	940 (25.4)
4	14 (0.4)
Preoperative IPSS, median [IQR]	23 [21, 26]
Preoperative QoL, median [IQR]	5.0 [4.0, 5.0]
Preoperative Q_{max}, median [IQR]	8.0 [6.0, 10.5]
Preoperative PVR, median [IQR]	70 [50, 100]
Preoperative PSA, median [IQR]	4.30 [2.40, 7.15]

ASA – American Society of Anesthesiologists; IDC – indwelling catheter; IQR – interquartile range; IPSS – International Prostate Symptom Score; Q_{max} – maximum flow rate; QoL – quality of life; LWMH – low-weight molecular heparin; PSA – prostate-specific antigen; PVR – post-voiding residual urine

Table 2. *Operative characteristics*

Parameter	
Energy source for enucleation, n (%)	
Low power Holmium (up to 30 W)	166 (2.7)
High Power Holmium (>30 W)	1,954 (31.6)
Holmium laser with MOSES technology	176 (2.8)
Thulium fiber laser	2,262 (36.5)
Thulium-YAG laser	676 (10.9)
Bipolar electrocautery	391 (6.3)
Monopolar electrocautery	70 (1.1)
Holmium laser with virtual basket	498 (8.0)
Enucleation type, n (%)	
3 lobes	775 (12.5)
2 lobes	3,021 (48.8)
En bloc	2,390 (38.6)
Early apical release, n (%)	2,898 (46.8)
Spinal anesthesia, n (%)	5340 (86.2)
Operation time, median [IQR]	67 [50, 95]
Enucleation time, median [IQR]	50 [35, 77]
Morcellation time, median [IQR]	20 [10, 40]
Morcellator events, n (%)	
Malfunction	10 (0.16)
Minor bladder injury	40 (0.65)
Major bladder injury	1 (0.02)
Fragment retrieval issues	1 (0.02)
Day surgery, n (%)	49 (0.8)
Postoperative catheter time (days), median [IQR]	2.0 [1.0, 3.0]

BPH – benign prostatic hyperplasia; IQR – interquartile range

(0.1%). 3-month follow-up visit showed decreased IPSS, with improvement in micturition parameters and QoL. These improvements were sustained one year after surgery (Table 3). Stress urinary incontinence was the most frequently reported type, affecting 53.9% of patients with incontinence. After three months, it persisted in 16.2% of the cohort. 25.5% of the patients were put on postoperative Kegel exercises to cope with postoperative urinary incontinence. The all-cause 30-day readmission rate was only seen in 3% of the cohort. Over the 1-year follow-up, only 8 patients (1.4%) had a surgical re-intervention for management of residual adenoma. Table 4 shows that when analyzed for prostate size, the incidence of post-operative incontinence was more significant if the prostate volume was larger than 100mls, with no statistical difference in duration of incontinence or delayed complications such as urethral stricture or redo BPH surgery within a year. On further subgroup analysis (Table 5), enucleation type did not have any impact on the incidence of postoperative incontinence but rather the duration of incontinence and need for Kegel exercise.

Table 3. *Early and late post-operative complications, and symptoms and micturition parameters at follow-up*

Early complications, n (%) (24 hours to 30 days)	
Acute urinary retention within 24 hours (Clavien 2)	252 (4.1)
Postoperative bleeding needing surgical control or additional hemostasis (Clavien 3)	57 (0.9)
Urinary tract infection (Clavien 2)	289 (4.7)
Sepsis needing ICU (Clavien 4)	9 (0.1)
Postoperative incontinence, n (%) within 3 months	916 (14.8)
Urge	296 (29.5)
Stress	541 (53.9)
Mixed	167 (16.6)
Postoperative incontinence	916 (14.8)
Duration <1 month	407 (44.4)
Urge	179
Stress/mixed	228
Duration 1–3 months	252 (27.5)
Urge	69
Stress/mixed	166
Duration >3 months	127 (13.8)
Urge	48
Stress/mixed	78
Kegel exercise needed, n (%)	609 (25.5)
30-day readmission, n (%) (any cause)	138 (3.0)
Late complications, n (%)	61 (11.0)
Bulbar urethral stricture requiring dilatation alone as an outpatient:	
Urethral stricture requiring urethrotomy under anesthesia	20 (3.6)
Bladder neck sclerosis requiring transurethral incision	45 (8.1)
Redo BPH surgery within 1 year	8 (1.4)
3-month follow-up	
IPSS, median [IQR]	6.0 [4.0, 8.0]
QoL, median [IQR]	2.0 [1.0, 2.0]
Q_{max}, median [IQR]	21.3 [18.0, 25.2]
PVR, median [IQR]	16 [10, 30]
12-month follow-up	
IPSS, median [IQR]	5.0 [3.0, 7.0]
QoL, median [IQR]	1.0 [1.0, 2.0]
Q_{max}, median [IQR]	22.0 [18.0, 27.0]
PVR, median [IQR]	15 [0, 31]

BPH – benign prostatic hyperplasia; ICU – intensive care unit; IPSS – International Prostate Symptom Score; Q_{max} – maximum flow rate; QoL – quality of life; PVR – post-voiding residual urine

DISCUSSION

Primarily, AEEP can be described in two main steps: 1) enucleation of prostatic adenoma (any energy modality) and 2) intravesical morcellation [8]. When first described in 1998 by Gilling and Fraundorfer, holmium laser resection of the prostate (HoLRP) was reported to be inferior to transurethral resection of the prostate (TURP) with respect to operative time, as there were limitations with morcellation, thereby limiting widespread acceptance [9]. Despite the advent of the electromechanical/power

Table 4. *Analysis of post-operative complications grouped by prostate volume*

	All	Prostate volume <100 (n = 4,753)	Prostate volume >100 (n = 1,404)	p
Postoperative incontinence, n (%)	916 (14.8)	682 (14.3)	232 (16.5)	0.049
Urge	296 (29.5)	216 (28.9)	80 (31.4)	
Stress	541 (53.9)	418 (56.0)	123 (48.2)	
Mixed	167 (16.6)	113 (15.1)	52 (20.4)	
Duration of incontinence for those affected, n (%)				0.148
1–3 months	252 (32.1)	193 (33.9)	59 (27.4)	
>3 months	127 (16.2)	93 (16.3)	33 (15.3)	
Kegel exercise needed, n (%)	609 (25.5)	443 (23.0)	165 (36.1)	<0.001
30-day readmission, n (%)	138 (3.0)	113 (3.2)	24 (2.4)	0.254
Delayed complications, n (%)				
Bulbar urethral stricture requiring dilatation alone as outpatient	61 (11.0)	45 (0.9)	16 (1.1)	0.626
Urethral stricture requiring urethrotomy under anesthesia:	20 (3.6)	17 (0.4)	3 (0.2)	0.571
Bladder neck sclerosis requiring transurethral incision	45 (8.1)	30 (0.6)	13 (0.9)	0.326
Redo BPH surgery within 1 year:	8 (1.4)	6 (0.1)	2 (0.1)	>0.99

BPH – benign prostatic hyperplasia

morcellator in 1993 being utilized in other surgical domains, it still remained unsuitable for transurethral surgery [10, 11]. Only with the innovation of the first enucleation morcellator design [8, 12] and its use in prostate surgery did AEEP catalyze a paradigm shift. Henceforth, several morcellators have been developed with improvements in their efficacy and efficiency but with their own drawbacks too [13].

In our series, minor bladder injury, which was classified as Clavien-Dindo 1 (CD1), defined as injury that does not preclude further morcellation or requiring further intervention, was only seen in 40 cases (0.65%). Perhaps this can be attributed to the experience of the surgeons who are well-versed with issues pertaining to improper morcellation. One patient (0.02%) with a gland more than 80 ml had a CD3 bladder injury at morcellation, necessitating a suprapubic catheter placement and prolonged catheterization when using the drill-cut morcellator. Ibrahim et al also reported a similar complication [13]. A need to utilize different devices (e.g., monopolar loop, cystoscopic forceps, grasper) to retrieve small fragments of adenoma can occur commonly [13]. We had only 1 reported case where there was a significant challenge in removing the enucleation tissue at morcellation, necessitating open removal via the suprapubic route. The retrospective design of this study could have a bias of many cases performed at these centers, where morcellation-specific complications were either underreported or not recorded.

Often, urinary incontinence is interchangeably reported as a complication or a measure of functional outcome when patients are counselled, and it depends on several factors. Continence in men depends on a complex mechanism where the external (striated) sphincter's activity is not the sole factor responsible. Indeed, urinary continence can still be preserved even when the striated sphincter is paralyzed [14]. It is proposed that the muscular and elastic tissue located in the distal third of the prostatic urethra might have a crucial role in sustaining continence [15]. Damage to this specific segment of the urethra could potentially contribute to SUI following surgery for BPH. Consequently, the preservation of the distal prostatic urethra seems to play an important role in maintaining continence after EEP, as demonstrated by the application of the early apical release technique [16].

In our study, larger prostates of >100 cc was significantly associated with postoperative incontinence (Table 4). A possible hypothesis could be due to the common finding of a wide prostatic fossa after EEP, due to the more complete adenoma removal compared with transurethral resection of the prostate. Indeed, transition zone prostate volume was found to be associated with a 5-fold of persistent SUI after holmium laser enucleation of the prostate [17]. Moreover, a large prostatic fossa can lead to the entrapping of urine and leakage not only with stress maneuvers but also after detrusor contractions correlated to the change in bladder response to filling as a result of distorted feedback from the prostatic fossa itself [18]. This could also explain why there was a proportion of patients who complained of mixed urinary incontinence (MUI) and a higher number who needed Kegel exercises for a longer duration (Table 4).

Press et al. [19] showed no differences in continence rates at 3 months, 6 months, and 1 year after surgery in a series of 95 men undergoing either en-bloc

Table 5. *Analysis of post-operative complications grouped by enucleation technique*

	All	2 lobe (n = 3,021)	3 lobe (n = 775)	En-bloc (n = 2,390)	p
Postoperative incontinence, n (%)	916 (14.8)	468 (15.5)	93 (12.0)	355 (14.9)	0.051
Urge	296 (29.5)	110 (21.6)	37 (24.2)	149 (44.5)	
Stress	541 (53.9)	327 (64.2)	104 (68.0)	103 (30.7)	
Mixed	167 (16.6)	72 (14.1)	12 (7.8)	83 (24.8)	
Duration of incontinence for those affected, n (%)					<0.001
1–3 months	252 (32.1)	146 (39.4)	17 (18.9)	89 (27.4)	
>3 months	127 (16.2)	67 (18.1)	16 (17.8)	44 (13.5)	
Kegel exercise needed, n (%)	609 (25.5)	378 (22.3)	37 (71.2)	194 (30.3)	<0.001
30-day readmission, n (%)	138 (3.0)	67 (2.4)	15 (2.8)	56 (4.5)	0.001
Delayed complications, n (%)					
Bulbar urethral stricture requiring dilatation alone as an outpatient	61 (11.0)	39 (1.3)	7 (0.9)	15 (0.6)	0.048
Urethral stricture requiring urethrotomy under anesthesia	20 (3.6)	5 (0.2)	3 (0.4)	12 (0.5)	0.091
Bladder neck sclerosis requiring transurethral incision	45 (8.1)	21 (0.7)	10 (1.3)	14 (0.6)	0.128
Redo BPH surgery within 1 year	8 (1.4)	4 (0.1)	2 (0.3)	2 (0.1)	0.501

BPH – benign prostatic hyperplasia

holmium laser enucleation of the prostate with early apical release (EAR) or standard approach. In our study, the type of enucleation technique did not affect the incidence of postoperative incontinence but rather the duration of incontinence and need for Kegel exercise (Table 5). To our knowledge, the use of EAR is for the first time being reported alongside the 2- and 3-lobe techniques. Understandably, this is done to try and minimize post-op incontinence, a simple reflection of how evidence-based practice is adopted in experience-based practice in real-life settings.

This is also why perhaps the heterogeneity of our data from surgeons' own preferences compounds the analysis to make resolute conclusions. In a recent meta-analysis, Castellani et al. [20] reported that the incidence of transient MUI is often multifactorial and significantly higher after enucleation vis-à-vis other transurethral interventions (OR 3.26, 95% CI: 1.51–7.05, p = 0.003). We reported a cumulative 16.6% incidence (Table 1), and this was significantly associated with prostate volume >100 ml (Table 4) and en bloc enucleation (Table 5). We could not ascertain any other factors that might be related to energy used for AEEP.

Kuo et al. [21] reported in their series of 206 patients following HoLEP, a 2.4% incidence of urethral strictures and 3.9% for bladder neck contracture. Shat et al. [22] documented an incidence of urethral stricture at 4.3% and bladder neck contracture of 0.28%, with a higher rate of stricture in prostate of large volumes. In a meta-analysis [23], the pooled incidence of bladder neck stenosis was highest at 1.3% after TURP, 0.66% after enucleation and 1.2% after ablation.

In a systematic review and meta-analysis of RCTs of AEEP utilizing various lasers, Pang et al. [24] did not identify any significant differences with regards to the incidence of urinary retention, urinary incontinence, bladder neck contracture, and urethral stricture. Based on prostate size and technique, we found that the incidence of urethral strictures that could be easily managed by simple dilation was marginally higher in those who had the two-lobe technique, with no correlation to large size. Perhaps miniaturization as described in the Minimally invasive Laser Enucleation of the Prostate (MiLEP) using Slim (22Ch) and Ultra Slim (18.5Ch) HoLEP technique might indeed prevent these in future [25]. This is the largest and only multicenter global registry created by contributions from highly experienced surgeons that attempts to understand in depth the nuances of performing AEEP in real-world practice, including complications. Our study has several limitations, including its retrospective design and the absence of long-term follow-up on incontinence rates. Additionally, we did not have data on any subsequent surgical treatments for incontinence. We acknowledge that postoperative patient management was not standardized, but we realized from data received that in real-world practice outside of a clinical trial, there is no uniformity in follow-up AEEP, and perhaps this is an area of focus for future studies. We feel that a standardized reporting of complications is needed for a structured follow-up, and this may perhaps help in training as well. By having a large database, we were able to reflect on almost all complications reported in literature in single or smaller series, and indeed, EEP seems to be very safe irrespective of energy and technique. We hypothesize that complications may occur by virtue of technical inexperience or depending on the dynamic interaction relative to gland size. Finally, the findings of our study, being based on data from high-volume centers, may have limitations when it comes to generalizing the results to centers with less experience or lower patient volumes. It is indeed well established that experience is an important variable in minimizing complications of AEEP [26].

CONCLUSIONS

Analysis of complications from the REAP database shows that AEEP is indeed a safe procedure with a low incidence of serious complications irrespective of the type of technique or energy used. Urinary incontinence, which depends on enucleation proper and bladder injury, a sequela of improper morcellation, are the two main concerns. While the risk of complications may increase with enucleation of glands larger than 100 ml, this is observed even among highly experienced surgeons, all of whom had completed at least 200 cases prior to inclusion in the study. Patients must be appropriately counseled as these complications can negatively impact quality of life in the immediate postoperative period.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

The study was approved by the Institutional Review Board of the leading center (approval number: AINU 11/2022), and the remaining centers received approval from their respective institutional boards.

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