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FUNCTIONAL UROLOGY

Endoscopic transvesical adenomectomy of the prostate, a new minimally invasive approach for large benign prostatic hyperplasia. What has our experience taught us?

Luís Vale[1,2,3], Laurent Fossion[1]

[1]*Maxima Medical Centre, Department of Urology, Veldhoven, The Netherlands*
[2]*Centro Hospitalar Universitário São João, Department of Urology, Porto, Portugal*
[3]*Faculty of Medicine, University of Porto, Department of Biomedicine, Porto, Portugal*

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Corresponding author
Luís Manuel Pedrosa do Vale
Centro Hospitalar Universitário São João
Department of Urology
Alameda Prof. Hernâni Monteiro
4200-319 Porto, Portugal
phone: +351 22 551 2100
luismpvale@gmail.com

Introduction Recent technical advances have made new minimally invasive techniques possible to treat large volume (>80 ml) benign prostatic hyperplasia (BPH). The endoscopic transperitoneal adenomectomy of the prostate (ETAP) is a new minimally invasive technique developed in our centre. The aim of this study was to describe the safety, efficacy and to evaluate our learning curve in ETAP.

Material and methods This was a single-centre study that enrolled eighty-eight consecutive patients with large BPH who underwent ETAP. Pre-, per- and postoperative data were prospectively collected. Statistical analysis compared the first 40 patients submitted to ETAP (Group A) with the subsequent 48 patients (Group B).

Results There were no significant differences in the surgical procedure between groups. The median operating time was 94 (80–110) minutes and the estimated blood loss 150 (100–300) ml. There were no perioperative blood transfusions nor any conversions to open approach needed. Median hospital stay was 3 (3–5) days and catheter was removed mainly at day 9 (5–11). The median Qmax improved from 8.0 (6.2–9.9) ml/s to 15.0 (11.5–23.0) ml/s postoperatively and the median International Prostate Symptom Score (IPSS) score decreased from 20 (15–24) to 6 (4–11) after the procedure.

Conclusions ETAP is a secure and feasible minimally invasive technique for treatment of large BPH. The functional outcomes of this technique are consistent and promising.

Key Words: endoscopic transvesical adenomectomy of the prostate ‹› benign prostatic hyperplasia ‹› new minimally invasive surgery

INTRODUCTION

Large volume benign prostatic hyperplasia (BPH) is defined by the European Association of Urology as >80 mL [1]. The gold standard treatment of large BPH is still the open adenomectomy according to Hryntschak/Freyer or Millin, as described in the 50's [2, 3]. Although proved to be an effective treatment, open adenomectomy is associated with significant morbidity [4]. With the recent technological advances, new and minimally invasive techniques have become available. One of the recent introductions was the laser surgery, which is still considered an expensive technique and not widely available [5]. Also, laparoscopic and robotic simple prostatectomy is nowadays performed in some centres. Both techniques are expensive, technically demanding, and time consuming and therefore not widely spread throughout the urological community [5–8]. There is no clear consensus about which of these minimally invasive techniques is the best treatment, mainly due to a lack of long-term results.

The endoscopic transperitoneal adenomectomy of the prostate (ETAP) was developed in our centre. We wanted to develop a new technique with the advantages of minimally invasive surgery, in a familiar anatomy and with the possibility of performing it with standard low-cost laparoscopic instruments. The ETAP technique and the results of the first 40 patients in our centre were presented in 2019 [9]. The goal of this study is to describe the safety and efficacy of the procedure and to evaluate the results of our learning curve for this new minimally invasive technique in order to validate it and promote its widespread use amongst the urological community. For this reason, we compared the results of the first 40 patients who underwent ETAP with the subsequent 48 patients.

MATERIAL AND METHODS

Patients

Eighty-eight consecutive patients with lower urinary tract symptoms (LUTS) due to BPH larger than 80 ml, measured by transrectal ultrasound of the prostate (TRUS), were included in the study. Prostate cancer was excluded by prostate-specific antigen (PSA) level measurement and digital rectal examination (DRE) and, if necessary, with prostate biopsy. Informed consent was given by all patients after a detailed explanation of the procedure, possible complications, and alternative treatment options. The study protocol was approved by the local ethical committee.

Data

Patients were included from March 2014 to December 2019. Data was collected prospectively regarding pre-, per- and postoperative data and complemented as needed with the electronic patient file. Preoperative data included: age, body mass index (BMI, kg/m^2), prostate volume (ml), PSA (ng/ml), International Prostate Symptom Score (IPSS), Qmax (ml/s), and post-void residual volume (PVR, ml). Perioperative data included: estimated blood loss (ml), operating time (min), complications, and transfusion rate. Postoperative data included: hospital stay (days), catheterization time (days), resected specimen weight (g), Qmax (ml/s), and PVR (ml). The IPSS was assessed preoperatively and 6 months after surgery. Complications were registered using the Clavien-Dindo classification [10]. The statistical analysis was based on the comparison of the first 40 patients who underwent ETAP (Group A) and the subsequent 48 patients who underwent the same procedure (Group B). The qualitative values comparison was performed by the Chi-squared Pearson or Fisher's exact test and the quantitative values by Student's t test. The level of significance was set at $p < 0.05$. All statistical analyses were performed using IBM SPSS Statistics version 24.0 (IBM Corp.).

Technique

All patients were treated in a single-centre general hospital, by a single urologist with extensive laparoscopic experience having performed over 1500 laparoscopic procedures. According to the IDEAL model of surgical innovation and evaluation this study is assigned to a stage 2a [11]. The ETAP surgical procedure was carefully explained step-by-step previously [9]. Firstly, all patients undergo general anesthesia. The patient is positioned in the dorsal decubitus position (Figure 1). A 16 Fr catheter is placed in the bladder and filled with 300 ml of water. A 2 cm midline incision is made below the umbilicus. Through this incision a cystotomy of the bladder dome is performed and a 10 mm camera trocar is placed into the bladder. Both lateral 5 mm balloon trocars are then placed under direct vision in a transcutaneous and transvesical way. The adenomectomy starts with circumferential incision of the bladder mucosa 1 cm distal from the trigonum and ureteral orifices. Placement of ureteral stents to prevent ureteral injury is not routinely performed. The enucleation is then performed. At the apex, the urethra is transected and the adenoma placed in an endobag. Hemostasis of the prostate bed is performed using bipolar coagulation. Finally, a Dufour bladder catheter of 22 Fr is introduced, the endobag is removed and the cystotomy is closed in 2 layers. A drain is placed in the Retzius space through one of the 5 mm ports. The drain is removed at day 1 if no urinary leakage occurs. The catheter is standardly removed after 7–10 days. Bladder irrigation is continued until the urine is clear.

Follow-up

On the first postoperative day, all patients received a blood test: hemoglobin, creatinine, leukocytes, and CRP. After this, patients visited our outpatient clinic at 3 and 6 months. In addition to clinical evaluation, a new IPSS-score and uroflowmetry was also performed.

RESULTS

Between March 2014 and December 2019, a total of 88 patients underwent an ETAP at our institu-

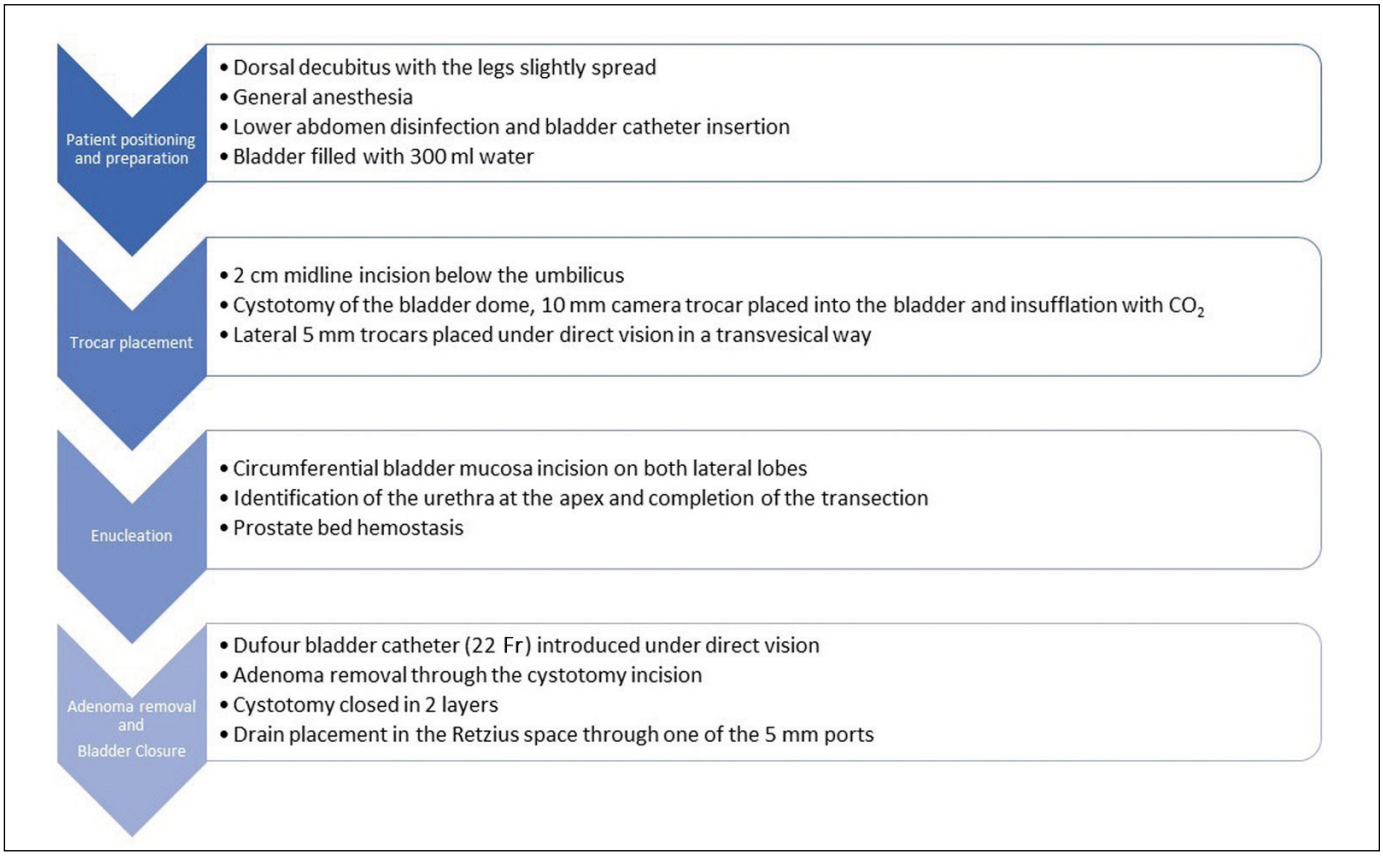

Figure 1. *Iterative steps of endoscopic transvesical adenomectomy of the prostate technique.*

tion. To assess the impact of surgical experience on the outcomes, we divided our population into 2 groups. In Group A were included the first 40 patients who underwent ETAP and in Group B were included the subsequent 48 patients who underwent the same procedure.

As displayed in Table 1, there were no major significant differences in the baseline population characteristics between Group A and Group B. The median age of the whole study cohort was 70 (65–75) years, with a median BMI of 26.7 (24.8–29.3) and an American Society of Anesthesiologists (ASA) comorbidity score of 2. Group B patients were more commonly catheterized preoperatively relative to patients from Group A (54% vs. 25%; p = 0.006, respectively). We observed a tendency towards patients with greater PVR and greater prostate volumes in Group B. In the whole cohort, preoperative median PVR was 237 (88–500) ml and the TRUS estimation of prostate volume showed a median volume of 112 (95–150) ml. 66 patients (75%) received 5α-reductase inhibitor therapy preoperatively.

With regards to the surgical procedure itself (Table 2) there were no significant differences between the two groups. The median operating time was 94 (80–110) minutes and the estimated blood loss 150 (100–300) ml. There were no perioperative transfusions or conversions needed. The catheter was removed mainly at day 9 (5–11) in both groups. There was a tendency towards earlier discharge in Group B patients with a median of 3 (2–4) days of hospital staying compared to 4 (3–6) days in Group A patients. The mean volume of the enucleated prostate adenoma was 83 (64–110) grams in the pathology report.

The functional outcomes are displayed in Table 3. There were no significant differences between the two groups. After removal of the catheter, only 3 patients experienced urinary retention, but at the 90-day re-evaluation all of them were spontaneously voiding and without need for any surgical intervention. The median Qmax improved from 8.0 (6.2–9.9) ml/s preoperatively to 15.0 (11.5–23.0) ml/s postoperatively in the entire cohort. Also, the median IPSS score decreased from 20 (15–24) before the procedure to 6 (4–11) after the procedure.

All complications were registered according to the Clavien-Dindo classification. Intraoperatively, in Group A we observed seven (18%) cases of a small perforation in the prostate-capsule and in 1 (3%)

Table 1. *Baseline population characteristics*

Variable	Median (P25–P75) or n (%)			P value (A–B)
	A	B	All	
Age (years)	71 (66–76)	68 (63–74)	70 (65–75)	0.13
Body mass index (kg/m^2)	26.5 (24.3–30.0)	27.1 (24.9–29.0)	26.7 (24.8–29.3)	0.78
Anticoagulation	13 (33%)	23 (48%)	36 (41%)	0.14*
5-ARI	28 (70%)	38 (79%)	66 (75%)	0.32*
ASA	2 (2–2)	2 (2–2)	2 (2–2)	0.5*
Prostate volume (ml)	105 (94–135)	117 (98–166)	112 (95–150)	0.09
PSA (ng/ml)	5.7 (4.4–9.7)	6.8 (3.8–14.0)	6.2 (3.9–12.0)	0.17
IPSS	21 (17–25)	18 (14–25)	20 (15–24)	0.44
Urinary retention (n)	23 (57.5%)	29 (60.4%)	52 (59.1%)	0.8*
Qmax (ml/s)	7.9 (6.2–9.8)	8.5 (6.2–10.2)	8.0 (6.2–9.9)	0.69
PVR (ml)	146 (48–370)	350 (140–600)	237 (88–500)	0.08
QoL	4 (3–5)	5 (3–5)	4 (3–5)	0.35
Preoperative transurethral catheter	10 (25%)	26 (54%)	36	0.006*

ARI – alpha-reductase inhibitors; ASA – American Society of Anesthesiologists; PSA – prostate-specific antigen; IPSS – International Prostate Symptom Score; PVR – post-void residual volume; QoL – quality of life; A – First 40 patients submitted to ETAP; B – The last 48 patients submitted to ETAP; Independent T-test; *Chi-square Pearson

Table 2. *Perioperative data*

Variable	Median (P25–P75) or n (%)			P value (A–B)
	A	B	All	
Conversion to open (n)	0 (0%)	0 (0%)	0 (0%)	–
Blood loss (ml)	100 (50–300)	150 (100–300)	150 (100–300)	0.79
Operation time (min)	96 (82–110)	93 (78–111)	94 (80–110)	0.34
Hospital stay (days)	4 (3–6)	3 (2–4)	3(3–5)	0.06
Days with catheter	9 (6–13)	9 (4–10)	9 (5–11)	0.12
Prostate volume (g)	82 (65–100)	90 (63–114)	83 (64–110)	0.22

A – First 40 patients submitted to ETAP; B – The last 48 patients submitted to ETAP

Table 3. *Functional outcomes*

Variable	Median (P25–P75) or n (%)			P value (A–B)
	A	B	All	
Urinary retention (n)	0 (0%)	3 (6%)	3 (3%)	0.25†
Qmax (ml/s)	16.1 (12.6–23.3)	13.0 (9.6–23.0)	15.0 (11.5–23.0)	0.28
PVR (ml)	40 (0–88)	66 (0–103)	50 (0–100)	0.11
IPSS	9 (6–11)	6 (4–12)	6 (4–11)	0.77

IPSS – International Prostate Symptom Score; PVR – post-void residual volume; A – First 40 patients submitted to ETAP; B – The last 48 patients submitted to ETAP; † Fisher's exact test

case a small bladder defect occurred, all corrected with a V-lock suture. These patients did not have any problems in the postoperative follow-up. In Group B there was a bladder perforation which was treated conservatively.

Postoperative complications are displayed in Table 4. Two patients suffered from wound complications, all treated successfully with antibiotics. A further 16 of the 88 (18%) patients suffered from urinary tract infection after catheter removal and required antibiotics. Two (2%) of these patients developed urosepsis and were readmitted for intravenous treatment.

We observed an increased rate of stress urinary incontinence in the immediate post-operative period of Group B patients compared to Group A (29% vs. 18%; p = 0.003, respectively). All of them were

Table 4. *Complications*

Grade		Complications	N < 90 days				N > 90 days			
			A	B	All	P value (A–B)	A	B	All	P value (A–B)
Low-grade	Grade I	Stress incontinence	7 (17.5%)	14 (29%)	21 (24%)	0.003*	3 (5%)	10 (20.8%)	13 (15%)	0.08*
		Wound infection	–	2 (4%)	2 (2%)	0.50†	–	–	–	–
	Grade II	Urinary tract infection	8 (20%)	8 (17%)	16 (18%)	0.10†	2 (5%)	2 (4%)	4 (5%)	1†
		Hematuria after discharge	4 (10%)	3 (6%)	7 (8%)	1†	–	–	–	–
		Urge LUTS	–	1 (2%)	1 (1%)	0.17†	4 (10%)	2 (4%)	6 (7%)	0.41†
		Urinary retention	–	3 (6%)	3 (3%)	0.25†	1 (2.5%)	2 (4%)	3 (3%)	1†
High-grade	Grade III	Hematuria and need for TUR-coagulation	2 (5%)	4 (8%)	6 (7%)	0.69†	–	–	–	–
		Bladder neck obstruction	–	–	–	–	3 (7.5%)	–	3 (3.4%)	0.04†
		Recto-vesical fistula		–	–	–	1 (2.5%)	1 (2.3%)	2 (2.3%)	1†
	Grade IV	Hematuria, TUR-coagulation, TUR-syndrome with ICU-admission and partial glans necrosis	1 (2.5%)	–	1 (1%)	–	–	–	–	–

ICU – intensive care unit; LUTS – lower urinary tract symptoms; TUR – transurethral resection; A – First 40 patients submitted to ETAP; B – The last 48 patients submitted to ETAP; * Chi-square Pearson; † Fisher's exact test

referred for pelvic floor training, with clinical improval. In fact, 90 days after the surgical procedure, this difference was not significant. A total of 5 patients (6%) suffered from persisting urinary incontinence. Three patients from Group A (8%) required a bladder neck incision due to bladder neck sclerosis while in Group B there were no interventions due to this complication (p = 0.04). Two patients (2%) suffered from a rectovesical fistula and were referred to a high-volume academic centre for fistula repair.

Six of the 88 patients (7%) suffered from persisting severe hematuria postoperatively and required an endoscopic revision and transurethral coagulation in the operating room. Seven (8%) patients had a prolonged hospital stay due to hematuria or suffered from bleeding after discharge needing readmission for continuous irrigation of the bladder. Only two patients required blood transfusions in our series.

One (3%) patient suffered a severe complication. He underwent an endoscopic revision because of persisting hematuria. After this procedure he developed TURP-syndrome, requiring admission to the intensive care unit. The patient then presented necrosis of part of the glans penis, most likely due to continuous traction of the bladder catheter and penile edema, which was managed with debridement and skin grafting.

DISCUSSION

In the last years, surgical options for BPH have progressed with new technologies arising and refinements of established options. Simple adenomectomy of the prostate and Holmium laser enucleation of prostate (HoLEP) are nowadays the surgical treatment options recommended for patients with BPH due to large prostate gland [12]. HoLEP has demonstrated efficacy and safety superior to that of traditional open prostatectomy. However, its high learning curve has limited its widespread acceptance and utility, thus simple prostatectomy is still the most disseminated procedure [13, 14, 15]. However, simple prostatectomy is associated with some cons such as bleeding, long hospital stay, and catheterization time [16]. To overcome these disadvantages, a new minimally invasive technique was developed in our centre, the ETAP. Using standard laparoscopic instruments, and so with a low-cost profile, this procedure has a similar approach as the open prostatectomy described by Hryntschak. It has the advantage of clear vision, good vascular control, and the whole prostate is available for pathology analysis. The easy learning curve for surgeons already performing laparoscopy is another advantage of this technique. The main benefit of this transvesical approach is the direct access to the bladder with less surgical trauma. It does not require Trendelenburg positioning and there is no peritoneal violation or tissue dissection, and therefore no risk of injury to adjacent organs or tissue. The insufflation of the bladder also provides tamponade of venous channels reducing intraoperative bleeding, which often occurs in open surgery. The final benefit of the transvesical approach is the excellent exposure of the prostatic capsule after the enucleation, which is helpful in creating adequate hemostasis.

In the present study, we show that ETAP procedure was successfully performed in 88 patients, without

Table 5. *Surgical outcomes of different procedures for bladder outlet obstruction due to large prostatic adenoma*

Study	Year	Procedure	n	Specimen weight (g)	Operation time (min)	Blood loss	Transfusion rate (n)	Hospital stay (days)	Catheter days (days)	Early incontinence
ETAP	2020	Laparoscopic	88	83	94	150 ml	2 (2.3%)	3	9	24%
Serretta et al. [19]	2002	Open	1804	(75)*	.	.	148 (8.2%)	7	5	3.7%
Gratzke et al. [1]	2007	Open	902	84.8	80.8	.	7.5%	11.9	.	.
Naspro et al. [20]	2006	Open	39	87.9	58	3.15 g/dl	7 (17.9%)	5.4	4.1	41.1%
Porpiglia et al. [21]	2006	Laparoscopic Open	20 20	69.5 88.1	107.3 95.5	412 ml 688 ml	2 (10%) 3 (15%)	7.8 7.0	6.3 5.6	.
McCullough et al. [22]	2009	Laparoscopic Open	96 184	(111.3)* (117.2)*	95.1 54.7	350 ml 400 ml	15.8% 10.2%	6.3 7.7	5.2 6.4	.
Sorokin et al. [23]	2017	Robotic Open	59 59	82.9 91.8	161.4 93.0	339 ml 587 ml	2% 4%	1.5 2.6	5.7 3.1	1.7% 1.7%
Pokorny et al. [24]	2015	Robotic	67	84	97	200 ml	1.5%	4	3	3
Autorino et al. [25]	2015	Robotic Laparoscopic	487 843	75	155 95	200 ml 280 ml	3.5%	2 4	7 4	0,8% 0.1%
Garzon et al. [27]	2016	Robotic Laparoscopic	79 82	68.5 76.3	162.3 161.2	390 ml 331 ml	6.3% 9.8%	. .	9.1 11.9	15.2% 13.5%
Umari et al. [14]	2017	Robotic HoLEP	81 45	89 112	105 105	. .	1.2% 0%	4 2	3 2	8.9% 1.2%
Elmansy et al. [27]	2011	HoLEP	949	(81)*	96	.	4 (0.4%)	.	.	4.9%
Elkoushy et al. [28]	2015	HoLEP	1216	94.8	108	2.2 g/dl	1.2%	1.3	1.4	.
Jhanwar et al. [29]	2017	HoLEP	72	48.5	90	0.47 g/dl	0 (0%)	1.8	1.3	2.8%

ETAP – endoscopic transperitoneal adenomectomy of the prostate; HoLEP – Holmium laser enucleation of the prostate; * pre-operative transrectal ultrasound of the prostate measurement

conversion to open approach. There were no severe complications during surgery. Postoperatively patients remained an average of 3 days in the hospital and had urethral catheter for 9 days, which is comparable to most treatment options (Table 5). We observed that with experience, there was a tendency towards performing the ETAP surgery in patients with larger prostate size and an earlier hospital discharge. We could hypothesize that it affects the continence rates, but in fact, at 90-day re-evaluation, there was no significant differences between the groups.

Retrospective studies comparing open techniques with laparoscopic or endoscopic techniques show the common advantages of minimally invasive surgery; less blood loss, shorter hospitalization, less days with catheter, less urinary tract infections, and similar percentages of postoperative hematuria are seen in the laparoscopic series (Table 5).

In our series, postoperatively 6 patients had bleeding, which required transurethral coagulation. Two patients required blood transfusions as mentioned above, resulting in a transfusion rate of 2% in our study. This is much lower than the average 7–18% transfusion rate in the open adenomectomy (Table 5). With longer follow-up, 3 patients required a bladder neck incision due to bladder neck obstruction; this is comparable to the number occurring in the open adenomectomy [17]. There were no urine-leakage complications or abdominal sepsis. Two patients developed a vesicorectal fistula and were referred to an academic hospital for operative correction. Ultracision has a quick and efficient sealing effect. However, the use of high-frequency electrosurgical energy has a known risk of deep thermal injury that the surgeon must be aware every time he or she uses this instrument.

Nine patients suffered from incontinence after the procedure. Seven of them showed improvement after standard pelvic floor muscle physiotherapy.

The ETAP procedure shows good functional outcomes with a significant decrease in the IPSS-score (-14 points) and an increase in Qmax (+7 ml/s). All the patients who had urinary retention preoperatively were able to void spontaneously after surgery. These numbers are comparable to open surgery and HoLEP [4, 15, 18]. One of the major concerns with HoLEP is the higher incidence of urge LUTS and pollakiuria which is bothersome in more than 20% of the treated population [16]. These kinds of symptoms tend to decrease with time, however data on the real impact of hyperactive syndrome complications on patient satisfaction rate is scarce. In our series, only 7% of the population complains of urge LUTS which is a positive result.

This study has few limitations. It is a single-centre, single-surgeon study. There is no control group, therefore comparative analysis versus other treatment options is lacking. Also, the ETAP procedure was performed by a very experienced surgeon. The learning curve of this technique needs to be evaluated by someone less experienced. In the future, a prospective multicenter randomized controlled trial is necessary to further evaluate the technique. Furthermore, with the increasing variability of treatments available, patient reported outcomes such as quality of life and satisfaction rates questionnaires are essential in a future evaluation.

CONCLUSIONS

This study suggests ETAP as a safe and technically feasible alternative to open surgery in the surgical treatment of large BPH. The functional outcomes of this technique are also consistent and promising. A prospective, multicentric comparison with other surgical approaches in a larger group of patients and a longer follow-up is necessary to determine its definitive place in the treatment of large BPH.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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