



Clinical

# Bipolar plasma enucleation of the prostate vs. open prostatectomy in large benign prostatic hyperplasia: a single centre 3-year comparison

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## Abstract

**Background** Aim of our study is to compare the surgery outcomes and safety of button bipolar enucleation of the prostate vs. open prostatectomy in patients with large prostates (> 80 g) in a single-centre cohort study.

**Materials and methods** All patients with lower urinary tract symptoms due to benign prostatic enlargement undergoing button bipolar enucleation of the prostate (B-TUEP) or open prostatectomy (OP) between May 2012 and December 2013 were enrolled in our study. Data on clinical history, physical examination, urinary symptoms, erectile function, uroflowmetry and prostate volume were collected at 0, 1, 3, 6, 12, 24 and 36 months. Early and long-term complications were recorded.

**Results** Overall, 240 patients were enrolled. Out of them 111 patients (46%) performed an OP and 129 patients (54%) performed a B-TUEP. In terms of efficacy, both procedures showed durable results at three years with a reintervention rate of 7.5% in the OP group and 5% in the B-TUEP group. In terms of safety, B-TUEP presented less high-grade complications when compared with OP.

**Conclusions** In our single-centre study, B-TUEP represents a valid alternative to OP with excellent outcomes at three years. Further multicentre studies should confirm our results.

## Introduction

Transurethral resection of the prostate (TURP) is the current standard procedure for men with prostates between 30 and 80 mL. However, in prostates larger than 80 mL, open surgery (i.e., open prostatectomy, OP) or endoscopic enucleations represent the indicated techniques [1]. In places with restricted access to newer technologies, OP remains the standard procedure. OP is the oldest surgical treatment for moderate-to-severe non-neurogenic male Lower Urinary Tract Symptoms (LUTS) and benign prostatic enlargement (BPE) secondary to Benign Prostatic Obstruction (BPO).

OP results in a reduction in LUTS by 63–86% (12.5–23.3 IPSS points), an improvement in the IPSS-QoL score of 60–87%, a mean increase of Qmax of 375% (range:

88–677%; in absolute terms + 16.5–20.2 mL/s) and reduction of PVR by 86–98% [2, 3]. Moreover, its efficacy is maintained even after long-term observation. However, the high morbidity associated with OP represents a major limitation. Perioperative complications include mortality (< 0.25% in contemporary series) and blood transfusion (7–14%) [2, 4]. While, long-term complications are urinary incontinence (10%) and bladder neck stenosis or urethral stricture (~6%) [2, 4].

To overcome the limitations of OP, many endoscopic procedures have been introduced in the past years for the treatment of large prostates. Several studies have demonstrated the role of conventional TURP (cTURP) as an alternative to OP in men with enlarged prostates [5, 6]. However, cTURP is still associated with significant morbidity (postoperative bleeding, blood transfusion requirements and early and late complications such as clot retention, urinary retention, bladder neck stenosis and urethral stricture).

To reduce risks, Hiraoka and Akimoto [7] introduced the concept of enucleation of the prostate. Subsequent studies have suggested that bipolar transurethral

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enucleation and resection of the prostate (TUERP) is a safe and effective treatment for BPH with few complications [8, 9].

Recently, button bipolar enucleation of the prostate (B-TUEP) [10] has been introduced as a safe, effective and durable procedure for the treatment of bladder outlet obstruction (BOO) secondary to BPE [10, 11]. According to the available evidence, B-TUEP has comparable results at 1 year when compared with OP. However, to our knowledge no long-term data comparing B-TUEP to OP is available.

Aim of this study was to evaluate, the long-term (3 years) overall efficacy and safety of B-TUEP vs. OP in patients with large prostates and LUTS.

## Materials and methods

After an internal review board approval, all patients undergoing OP or B-TUEP between May 2010 and December 2013 were included in the study. All patients signed an informed consent and all the procedures were performed in accordance to the Declaration of Helsinki. Any patient with a prior history of prostatic or urethral surgery, urethral stricture, neuro-vesical dysfunction and/or prostate cancer was excluded from the study. Patients with prostate volume < 80 cc were excluded as well. The study is a retrospective analysis of a prospectively maintained database.

Clinical data including age, BMI, haemoglobin levels, International Prostate Symptom Score (IPSS), QoL score, International Index of Erectile Function (IIEF-5) Questionnaire, prostate-specific antigen (PSA), prostatic volume (PV) and post-void residual were retrospectively collected. PV was measured using transrectal 7.5 MHz ultrasound probe (Bk-Medical), volume was calculated using the ellipsoid formula:  $\pi/6 \times \text{width} \times \text{height} \times \text{depth}$  of the prostate.

Patients with bothersome LUTS were offered surgery if preoperative IPSS  $\geq 12$  points; quality of life (QoL)  $\geq 4$ ; maximal urinary flow rate (Qmax) < 15 mL/s; post-void residual urine volume (PVR) > 50 mL; not responding to medical therapy; and/or not willing to undergo medical therapy. The benefits and harms of surgical treatment vs. other conservative/medical options were extensively discussed with all patients.

All operations were performed by one single expert surgeon (R.G.).

The surgical technique was selected according to the patient's preference after detailed explanation by the surgeon of the procedures, outcomes and complications of each option. B-TUEP equipment was introduced in 2011 in our

centre, therefore most of the patients included after that date chose the endoscopic technique.

## Operative techniques

OP was performed as described by Tubaro and De Nunzio [12]. B-TUEP was also conducted as previously described [10]. The equipment for the plasma enucleation procedure consisted of an Olympus SurgMaster UES-40 bipolar generator, OES-Pro bipolar resectoscope, continuous flow saline irrigation and 'button'-type vapo-resection electrodes (Olympus Europe, Hamburg, Germany). Briefly, regardless of the prostatic anatomy, such as the presence or absence of a medium lobe or asymmetric lateral lobes, we started the procedure with an apical incision with the button laterally to the verumontanum. The apical incision at 5 and 7 o'clock is extended with a latero-lateral movement and a disto-proximal compression of the surgeon on the button. This action of the button creates progressive pedunculation plus tissue vaporization of the adenoma. At this point, we can proceed with a fast, safe and easy resection of the pedunculated structures of the adenoma. All supply vessels were coagulated.

In both groups, the bladder catheter was routinely removed when the urine was bloodless.

## Surgical outcomes

Intraoperative outcomes measured were operative time, weight of the resected prostatic tissue and histological features. Perioperative outcomes were duration of bladder irrigation, time to catheter removal, hospital stay and postoperative haemoglobin levels (on postoperative day 1). During the follow-up, according to our department protocol, patients underwent uroflowmetry, I.P.S.S. score, QoL score, PSA and PVR rate at 1, 3, 6, 12, 18, 24, 30 and 36 months and IIEF-5 Questionnaire score at 3 months. PV was measured with transrectal ultrasound at 6, 12, 24 and 36 months.

## Safety

Perioperative complications were divided into early haematuria with clots following the catheter removal, bleeding requiring surgery to stop bleeding, postoperative acute retention of urine (AUR), extraperitoneal extravasation, reintervention for free bladder fragments and late urinary incontinence and readmission to hospital up to 30 days.

Urethral stricture, BOO, residual adenoma and postoperative acute urinary retention, as well as reintervention rate were also recorded during the follow-up, according to our department protocol.

**Table 1** Baseline characteristics of both groups

	Open prostatectomy	B-TUEP	<i>p</i>
Patients	111/240 (46%)	129/240 (54%)	
Age (years)	73.68 ± 6.77	73.05 ± 7.48	0.985
Hb (g/dl)	13.74 ± 1.17	13.57 ± 1.88	0.725
BMI (kg/m <sup>2</sup> )	27.81 ± 2.8	28.09 ± 2.63	0.689
I.P.S.S.	23.54 ± 5.77	23.15 ± 5.65	0.356
Qmax (ml/s)	7.37 ± 4.15	7.07 ± 3.78	0.568
QoL	2.21 ± 0.73	2.39 ± 0.70	0.856
PVR (ml)	85 ± 26.01	85.29 ± 26.13	0.625
TRUS (cc)	97.62 ± 12.21	94.80 ± 14.99	0.854
I.I.E.F.-5	17.65 ± 4.66	17.50 ± 4.67	0.503
PSA (ng/ml)	7.32 ± 4.1	6.25 ± 3.44	0.854

Data are presented as mean ± standard deviation

*IPSS* International Prostate Symptom Score, *BMI* body mass index, *Qmax* maximum flow rate, *PVR* post-voided residual volume, *IIEF* International Index of Erectile Function, *PSA* prostate-specific antigen, *QoL* quality of life, *B-TUEP* bipolar transurethral enucleation of the prostate

## Statistical analysis

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA). Continuous variables are presented as mean ± standard deviation and were compared using the Mann–Whitney test. Categorical data (percentages) were compared using the Chi-square test or Fisher’s exact probability test. Differences from baseline were evaluated using the Wilcoxon test. *P*-values < 0.05 were considered statistically significant.

## Results

Overall 240 patients were enrolled, 111 patients (46%) underwent OP and 129 patients (54%) underwent B-TUEP. There were no statistically significant differences in baseline characteristics between the two groups (Table 1).

### Intra and perioperative results

Intraoperative and perioperative data are described in Table 2. Overall, the volume of tissue retrieved and postoperative Hb were similar in both groups ( $p > 0.05$ ). The OP procedure required significantly shorter operative time than the B-TUEP procedure, with a weighted mean difference (WMD) of – 41.5 min ( $p < 0.05$ ). Conversely, postoperative bladder irrigation time (WMD – 27.5 h,  $p < 0.05$ ), catheterization time (WMD – 38.14 h,  $p < 0.05$ ) and hospital stay (WMD – 16.82 h,  $p < 0.05$ ) were significantly shorter in the B-TUEP group than in the OP group ( $p < 0.05$ ).

## Early and late complications

Perioperative complications are shown in Table 3. Dysuria was the most common Clavien–Dindo Grade I complication in the B-TUEP group (49.1%, WMD – 39.9,  $p < 0.05$ ) and urinary urge incontinence up to 30 days in the OP group (14.1%, WMD – 12.5%,  $p < 0.05$ ), however at 30 days, all patients resolved the incontinence (Table 3). In the sub-analysis of complications according to Clavien–Dindo Grade, in the Grade II complications, the results favoured the B-TUEP group (postoperative acute urinary retention, WMD – 50%,  $p < 0.05$  and blood transfusion requirement, WMD – 45%,  $p < 0.05$ ) than the OP group.

For Grade III complications, the trend favoured the B-TUEP group (capsular perforation, WMD – 33.3%,  $p < 0.05$  and reintervention for free bladder fragments, WMD – 100%,  $p < 0.05$ ) over the OP group, which showed a more statistically significant rate only in points, requiring surgery due to bleeding (WMD – 40%,  $p < 0.05$ ). There were no grade IV and V complications.

## Functional outcomes

Overall, both treatments resulted in statistically significant improvements in urinary symptoms, quality of life, erectile function, PSA value and PV and PVR rates at each postoperative assessment ( $p < 0.05$ ).

During the follow-up period, at each time point, there were no significant differences in terms of the Qmax score, QoL score, IIEF-5 Questionnaire score, PSA and PV between the groups (Table 4). However, in the B-TUEP group, we observed significantly lower IPSS and PVR scores at 12, 24 and 36 months when compared with the OP group ( $p < 0.05$ ).

## Follow-up

Overall, 211/240 (87.9%) patients completed the three years follow-up period. During the follow-up period, 11 patients were diagnosed with cancer, 14 patients needed a reintervention and 4 patients died of non-urolological conditions. Reintervention rate was 7.5% in the OP group (two cases of bladder neck contracture, five cases of residual adenoma and two urethral strictures) and 5% in the B-TUEP group (four BNC and two urethral strictures).

## Discussion

The present study compares two effective procedures in the treatment of large adenomas in patients with LUTS due to BPE. Our study confirms, as previous experiences, that B-TUEP is a valid alternative to OP with great outcomes

**Table 2** Peri and postoperative characteristics in both groups

	Open prostatectomy	B-TUEP	<i>p</i>
Surgery time (min)	55.54 ± 4.36	97.02 ± 25.90	0.001
Volume of tissue retrieve (g)	60.25 ± 16.9	59.36 ± 17.45	0.876
Postoperative Hb (g/dl)	10.08 ± 1.51	10.99 ± 1.27	0.245
Bladder irrigation (h)	67.37 ± 11.37	40.22 ± 15.22	0.001
Catheterization time (h)	98.91 ± 12.68	60.77 ± 16.18	0.001
Hospital stay (h)	116 ± 11.18	99.18 ± 13.51	0.001

Data are presented as mean ± standard deviation

**Table 3** Complications according to the Clavien classification system

Complications	Open prostatectomy	B-TUEP	<i>p</i>
Clavien I	<b>25 (23)</b>	<b>11 (9)</b>	<b>0.002</b>
Haematuria with clots following catheter removal (%)	8 (6.6)	2 (1.66)	0.276
RUA after catheter removal (%)	11 (9.1)	5 (4.1)	0.050
Extraperitoneal extravasation (%)	6 (5)	4 (3.33)	0.526
Urinary incontinence up to 30 days (%)	7 (5.83)	2 (1.66)	0.045
Clavien II (%)	<b>11 (9.9)</b>	<b>4 (3)</b>	<b>0.029</b>
Bleeding requiring blood transfusions (%)	11(9.9)	5 (3)	0.029
Clavien IIIa (%)	<b>5 (5)</b>	<b>6 (5)</b>	<b>0.956</b>
Reintervention for bleeding (%)	5 (4.1)	2 (1.66)	0.175
Reintervention for free bladder fragments (%)	0 (0)	4 (3.33)	0.001
Clavien IIIb (%)	<b>9 (8)</b>	<b>6 (5%)</b>	<b>0.261</b>
Bladder neck contracture (%)	2 (2)	4 (3)	0.520
Urethral stenosis (%)	2 (2)	2 (2)	0.879
Residual adenoma (%)	5 (5)	0 (0)	0.001
Clavien IV (%)	<b>0 (0)</b>	<b>0 (0)</b>	<b>0.999</b>
Clavien V (%)	<b>2 (2)</b>	<b>2 (2)</b>	<b>0.879</b>
Death of urological causes (%)	<b>0 (0)</b>	<b>0 (0)</b>	<b>0.999</b>
Death of non-urological causes (%)	<b>2 (2)</b>	<b>2 (2)</b>	<b>0.879</b>

at 12 months [10, 13]. Moreover, for the first time, we report comparable outcomes at 36 months when comparing both procedures.

The goal of prostate surgery for BPH is to remove the obstructing tissue while minimizing damage to surrounding structures with as little discomfort to the patient as possible. According to the latest EAU guidelines in prostates larger than 80 cc, surgeons can choose between OP, B-TUEP or holmium laser enucleation of the prostate [1].

Notwithstanding the excellent long-term results of OP, the procedure is still associated with a high morbidity rate, including mortality (<0.25%), blood transfusion (7–14%), urinary incontinence (±10%) and bladder neck stenosis or urethral strictures (6%) (3–4). For these reasons, during the past years endoscopic procedures have slowly replaced OP.

In our experience, B-TUEP showed several advantages when compared to OP. Bladder irrigation time (40.22 ± 15.22 h vs. 67.37 ± 11.37 h, *p* < 0.05), catheterization period (60.77 ± 16.18 h vs. 98.91 ± 12.68 h, *p* < 0.05) and hospital stay (99.18 ± 13.51 h vs. 116 ± 11.18 h, *p* < 0.05) were

significantly better in the B-TUEP group when compared with the OP group. Our results are in line with the available evidence comparing these two procedures and confirm the validity of our results [13–15]. Moreover, both procedures were comparable in terms of medium and long-term outcomes with over 90% of the patients having a successful outcome at three years.

In terms of safety, the B-TUEP group presented some advantages when compared with the OP group. B-TUEP was characterized by a reduced blood transfusion rate (9 vs. 15, *p* < 0.05), reduced postoperative re-catheterization rate (9.1% vs. 4.1%, *p* < 0.05) and a reduced reintervention endoscopic rate due to postoperative bleeding (1.66% vs. 4.1%, *p* < 0.05) when compared with OP. These good results in terms of safety are in line with other endoscopic procedures as B-PEP [13] and HoLEP [16].

Consequently, the shorter postoperative recovery, otherwise one of the main goals of the newly introduced BPH therapeutic approaches, seemed to be within the reach of the plasma enucleation procedure.

**Table 4** Functional outcomes after OP and B-TUEP

	OP group	B-TUEP group	<i>p</i>
<i>IPSS</i>			
1 month	6.04 ± 3.79	5.8 ± 3.41	0.882
3 months	4.70 ± 3.06	4.35 ± 3.1	0.326
6 months	4.23 ± 1.56	3.06 ± 1.29	0.001
12 months	4.0 ± 1.41	2.68 ± 0.98	0.001
24 months	4.02 ± 0.62	2.66 ± 1.01	0.001
36 months	4.06 ± 1.43	2.62 ± 0.78	0.001
<i>QoL</i>			
1 month	4.23 ± 1.15	4.02 ± 1.11	0.856
3 months	4.34 ± 1.05	4.23 ± 1.15	0.754
6 months	5.06 ± 0.81	5.06 ± 0.86	0.956
12 months	5.24 ± 0.54	5.25 ± 0.63	0.965
24 months	5.30 ± 0.62	5.10 ± 0.67	0.754
36 months	5.26 ± 0.53	5.26 ± 0.63	0.954
<i>Qmax</i>			
1 month	17.4 ± 6.25	17.41 ± 5.75	0.854
3 months	22.11 ± 7.19	20.7 ± 7.36	0.756
6 months	22.56 ± 6.79	21.7 ± 7.22	0.564
12 months	23.08 ± 6.82	23.14 ± 7.25	0.832
24 months	22.14 ± 7.0	22.18 ± 7.13	0.778
36 months	22.21 ± 7.39	22.88 ± 7.04	0.856
<i>PVR</i>			
1 month	28.8 ± 17.86	35.2 ± 23.86	0.754
3 months	28.2 ± 17.02	28.2 ± 17.06	0.954
6 months	22.9 ± 11.17	17.75 ± 9.86	0.365
12 months	23.24 ± 11.26	18.6 ± 9.86	0.105
24 months	22.69 ± 10.2	18.8 ± 9.86	0.111
36 months	25.69 ± 10.5	17.8 ± 8.28	0.062
<i>PV</i>			
6 months	49.09 ± 9.16	48.29 ± 9.38	0.856
12 months	48.13 ± 8.20	47.4 ± 9.47	0.732
24 months	48.39 ± 9.11	46.4 ± 12.2	0.835
36 months	48.44 ± 9.16	46.14 ± 12.13	0.656
<i>PSA</i>			
6 months	2.33 ± 0.66	2.38 ± 0.74	0.856
12 months	2.34 ± 0.67	2.39 ± 0.76	0.855
24 months	2.30 ± 0.62	2.56 ± 0.56	0.801
36 months	2.31 ± 0.61	2.37 ± 0.73	0.798

Data are presented as mean ± standard deviation

*IPSS* International Prostate Symptom Score, *BMI* body mass index, *Qmax* maximum flow rate, *PVR* post-voided residual volume, *IIEF* International Index of Erectile Function, *PSA* prostate-specific antigen, *QoL* quality of life, *B-TUEP* bipolar transurethral enucleation of the prostate

During the initial evaluation period, at 12 months, OP and B-TUEP showed excellent functional outcomes in terms of Qmax, QoL, IPSS score and PVR. Although there is some statistically significant differences between the

groups in terms of the IPSS score ( $2.68 \pm 0.98$  vs.  $4.0 \pm 1.41$ ,  $p < 0.05$ ) and PVR ( $18.6 \pm 9.86$  ml vs.  $23.24 \pm 11.26$  ml,  $p < 0.05$ ), these differences cannot be considered clinically significant. In this regard, Geavlete et al. [13], in their randomized clinical trial comparing B-TUEP and OP with a 12-month follow-up, showed similar functional outcomes and confirm our experience.

Both procedures showed a statistically significant reduction in PSA levels and PV up to 36 months. The elevated PSA level seen in BPH patients is believed to be due to hyperplasia of the transition zone. Hence, if resection of the adenoma is complete, the PSA level should return to normal range (i.e., below 4 ng/mL) [17]. Therefore, the reduction in mean PSA values in the B-TUEP group indicated that adenoma resection was complete. The lower PSA level and higher peak urinary flow can be considered as surrogate markers of complete adenoma removal [7]. Moreover, in this regard, the TRUS evaluation of the postoperative prostate volume decrease was similar between B-TUEP and OP, confirming once more the effective tissue removal of the procedures.

We observed a significant increase in the incidence of post-surgery complications in the OP group (two cTUIP for BOO, five cTURP for residual adenoma and two cases of internal urethrotomy due to urethral stenosis) when compared with the B-TUEP group (four cTUIP for BOO and two cases of internal urethrotomy due to urethral stenosis). The results are in line with the available evidence on HoLEP [3] and bipolar electrosurgical enucleation of the prostate (BEEP) [18]. Therefore, the present study adds further evidence to the better long-term outcomes of endoscopic enucleation techniques.

B-TUEP represents a novel technique, which can be considered a valid alternative to open prostatectomy with lower morbidity as shown by the present paper. B-TUEP technique has been extensively discussed in a previous study by our group [11]. It is important to discuss technical issues as well as advantages and disadvantages of both techniques. B-TUEP can be considered an easy technique especially for surgeons already trained in endoscopy, although no studies are available on the learning curve; we believe that an experienced endoscopic surgeon may take 15–20 procedures to perform a good B-TUEP. Important pitfalls in the technique include first of all the identification of the capsule by the verumontanum accessing the avascular plane. This phase is similar to the identification of the right plane in open surgery, and probably the most important phase of both procedures. Once the surgeon has identified the right plane, the button enables, with a 180 degrees proximo-distal semi-circular movement, an easy detachment of the adenoma on the avascular plane. In open surgery, the surgeon has no visibility of the capsule plane while detaching the adenoma. This procedure depends

exclusively on the sensibility of the surgeon and is probably much more challenging than endoscopic detachment. Once the adenoma is detached the surgeon can either proceed to the resection of this avascular tissue (which is obviously faster) with a loop or detach the adenoma and proceed to morcellation. As discussed in our previous paper, the speed of resection is directly related to the endoscopical expertise of the surgeon. However, tissue morcellation is a valid alternative to resection of the partially detached adenoma. If the surgeon wants to proceed with resection of the adenoma, it is important to keep a distance from the bladder neck so that the adenoma is kept in the prostatic loggia and to avoid damages to the bladder neck. This phase in open surgery is probably faster considering that the adenoma is removed entirely, however the surgeon needs to close the capsule, the bladder and the abdomen, which is as time consuming as resection/morcellation. Probably the B-TUEP technique could be improved by enhancing the resistance of the button, considering the pressure which is needed to perform the procedure. In summary, when comparing both procedures, B-TUEP is probably a cheaper procedure, with lower morbidity, good haemostatic control and probably has a shorter learning curve when compared with open prostatectomy. From a technical point of view, it is important to identify the right plane by the verumontanum, perform meticulous haemostasis of the perforating arteries and keep a good distance from the bladder neck to ensure its integrity during the resection of the avascular adenoma.

In the wide panorama of enucleation of the prostate, it is important to comment on robotic simple prostatectomy (RASP) that has shown excellent outcomes and morbidity profile, improving the limitations of the open technique [19]. A recent review by Vince et al. [20] evaluated the available evidence on robotic simple prostatectomy; according to their results, most of the evidence is retrospective with few comparative studies and almost no prospective trials. The evidence suggest that RASP seems to be attractive when compared with open simple prostatectomy as it can offer less blood loss and shorter hospital stay. However, its advantages over transurethral enucleation techniques, such as HoLEP, remain unclear. As stated by the latest EAU guidelines, given the low level of the available evidence, we can just consider RASP as a feasible procedure in patients with large prostates.

It is also important to underline the significance of Holmium enucleation of the prostate in the treatment of large adenomas. In the past years, its role has been clearly defined as a valid alternative to OP with excellent short- and long-term outcomes [21, 22]. Moreover, HoLEP is superior in terms of blood loss, catheterization and hospitalization time when compared with OP [21, 22]. However, the main limitation of HoLEP is the relevant endoscopic skills needed to perform the procedure, and according to the available

evidence the experience of the surgeon is the most important factor affecting the complication rate.

The management of large prostate offers now a wide range of alternatives including endoscopic, open and minimally invasive approaches. The guidelines standing to the available evidence can just be recommended as gold standards to open prostatectomy and HoLEP. However, we believe that the emerging evidence will give a role in the upcoming years to the new endoscopic enucleation techniques as well as to the minimally invasive approaches.

The present study presents some limitations. Firstly, the retrospective fashion of the study is a major limitation; however, to overcome this, we set up a prospectively maintained database, which was thereafter analyzed retrospectively. Moreover, the lack of randomization could be another limitation; however, no significant differences between the groups are present and therefore this bias was probably minimized. Another important limitation of our study is the presence of selection bias. In our centre B-TUEP equipment was introduced in 2011, therefore most of the patients underwent OP before that date. After 2011 most of the patients with large prostates selected the endoscopic technique; we did not need to account for learning curves, as the single surgeon who performed all the operations (R. G) was already adequately (more than 300 procedures performed) trained in another centre. Lastly, this is a single-centre study with a single surgeon; our results depend on the enrolled population and cannot be extended to other populations. We agree that more than one study is necessary to prove a hypothesis. Notwithstanding all these limitations, the present study is the largest cohort and the only available evidence regarding OP and B-TUEP outcomes and safety at three years.

In this study, B-TUEP and OP showed excellent functional outcomes at three years. We showed that B-TUEP has early and intermediate efficacy and safety equivalent to OP in the treatment of large prostates.

**Authors contributions** Authors have made a substantial contribution to the following: RG: research design, acquisition, analysis and interpretation of data, drafted the paper and approved the submitted and final versions. BCG: research design, acquisition of data, revised the paper critically and approved the submitted and final versions. GM: research design, analysis of data, revised the paper critically and approved the submitted and final versions. GT: research design, analysis of data, revised the paper critically and approved the submitted and final versions. LA: research design, interpretation of data, revised the paper critically and approved the submitted and final versions. PT: research design, acquisition analysis, interpretation of data, drafted the paper or approved the submitted and final versions. GR: research design, acquisition of data, revised the paper critically and approved the submitted and final versions. CF: research design, acquisition of data, revised the paper critically and approved the submitted and final versions. PA: research design, analysis and interpretation of data, drafted the paper and approved the submitted and final versions. GV: research design, analysis, interpretation of data, drafted the paper and approved the submitted and final versions. RL: research design,

acquisition analysis, interpretation of data, drafted the paper or approved the submitted and final versions.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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