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# PROSTATIC DISORDERS ORIGINAL ARTICLE



# Transurethral bipolar plasmakinetic vapo-enucleation of the prostate: Is it safe for patients on chronic oral anticoagulants and/or platelet aggregation inhibitors?

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# **KEYWORDS**

Anticoagulant; BPH; LUTS; PKERP

## **ABBREVIATIONS**

Hb, haemoglobin; HoLEP, holmium laser enucleation of the prostate; INR, international normalised ratio; M-TURP, monopolar TURP; OA, oral anticoagulant; Abstract *Objectives:* To assess the safety and efficacy of bipolar plasmakinetic enucleation and resection of the prostate (PKERP) for the management of benign prostatic hyperplasia (BPH) in patients on oral anticoagulant (OAC) therapy and/ or platelet aggregation inhibitors (PAIs).

**Patients and methods:** In all, 91 patients were recruited and underwent PKERP whilst they were receiving PAIs (aspirin, 56 patients; clopidogrel, three; aspirin and clopidogrel, 11). In all, 15 patients were receiving an OAC drug perioperatively, whilst another six patients were on dual PAIs and OACs. The primary outcomes were the perioperative morbidity and mortality rates. The secondary outcomes were functional outcomes including maximum urinary flow rate ( $Q_{max}$ ), International Prostate Symptoms Score (IPSS), and post-void residual urine volume (PVR).

**Results:** The mean (SD) age of the patients was 65 (5.9) years, preoperative adenoma volume was 80.9 (30.4) mL, and the operative time was 67 (23) min. No patient developed serious perioperative cardiovascular complications. The mean (SD) duration of hospital stay was 1.79 (1) days and the postoperative catheterisation time was 1.14 (0.76) days. The mean (SD) haemoglobin drop was 0.74 (0.61) g/dL, blood transfusion rate was 2.2%, and the clot retention rate was 2.2%. The mean (SD) postoperative  $Q_{max}$  was 18.6 (4.37) mL/s as compared to 7.2 (3.2) mL/

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PAI, platelet aggregation inhibitor; PKERP, plasmakinetic enucleation and resection of the prostate; PVR, post-void residual urine volume; Q<sub>max</sub>, maximum urinary flow rate; ThuVARP, thulium vaporesection of the prostate; ThuVEP, thulium vapoenucleation of the prostate; UI, urinary incontinence; US, ultrasonography

#### Introduction

One of the common problems affecting older men is LUTS, which is related to BPH. The incidence of LUTS increases proportionally with age, approaching 50% by age of 60 years and 90% by the age of  $\geq$ 80 years [1] There are several treatment options available to relieve patients' symptoms and their related morbidity, including: watchful waiting, medications, minimally invasive surgeries, TURP, and open prostatectomy [2]. Although the 'gold standard' for the endoscopic management of BPH is TURP, this approach is associated with high complication rates, especially haemorrhage, which can lead to a prolonged hospital stay and may necessitate blood transfusion [3].

The number of patients requiring oral anticoagulant (OAC) therapy and/or platelet aggregation inhibitors (PAIs) is increasing steadily. Nearly, 30% of patients who may need surgery have cardiovascular diseases and are treated with PAI and/or OAC medications. These patients are at increased risk of haemorrhagic complications, and therefore represent a challenge for urologists [4]. The complications of altering PAI and OAC therapies for surgery are underestimated, and simple stoppage of these medications with no substitution is associated with a high risk of thromboembolic adverse effects [5].

Multiple minimally invasive approaches have been attempted. Minimally invasive laser prostatectomy is commonly used and has several advantages, such as speedy relief from symptoms, quick recovery, as well as reduced postoperative complications. Nevertheless, the cost issue, as well as the steep learning curve of laser prostatectomy restrict its widespread use, and indeed this technique is used in few centres [6].

operatively to 29.5 (10.6) mL postoperatively (P < 0.001). *Conclusion:* Minimally invasive PKERP may be considered as a safe and effective treatment option for managing patients with BPH receiving OAC/PAI drugs.

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In contrast, recently introduced bipolar electrosurgical technology has gained attention worldwide due to its low morbidity and affordability. In addition, bipolar electrosurgical technology achieves similar results to TURP in improving patient's symptoms [7].

Today, several bipolar electrosurgical devices are available to minimise the complications of standard monopolar TURP (M-TURP) with concomitant increase/maintenance of durability and effectiveness [8].

The currently available information about the safety of transurethral plasma kinetic prostatectomy for patients on OAC therapy and/or PAIs are scarce, and mostly concern different laser techniques, which are not commonly available in developing countries due to high cost and lack of appliances, such as morcellators, in these countries. Thus, the present study was designed to investigate whether bipolar transurethral plasmakinetic enucleation and resection of the prostate (PKERP) is feasible and safe in patients on chronic OAC therapy and/or PAIs.

## Patients and methods

This is a prospective study carried out in Banha University Hospitals, Banha, Egypt and the study protocol was approved by the Local Ethics Committee. From May 2012 through July 2016, 100 patients with LUTS due to BPH were recruited. Patients fulfilling the inclusion criteria and having none of the clinical exclusion criteria were enrolled into the study after they had signed the informed consent form.

Patients were eligible for the study if they meet the following inclusion criteria: Patients with LUTS due to BPH with a maximum urinary flow rate ( $Q_{max}$ ) of  $\leq 10 \text{ mL/s}$ , severe LUTS/BPH requiring surgical

treatment, or patients with an IPSS > 7 due to BPH. All the enrolled patients were on OAC therapy or PAIs.

Exclusion criteria: Patients with bladder or prostate cancer, bladder diverticula, urethral stricture, active UTI, and neurogenic voiding dysfunction.

Of the 100 patients initially enrolled, 91 patients were available for analysis (Fig. 1).

#### Preoperative assessment of enrolled patients

Preoperative assessment of the patients included: present and past history; IPSS; physical examination; DRE; urine analysis; urine culture and sensitivity (when indicated); renal function assessment (blood urea and serum creatinine); haemoglobin (Hb); coagulation profile [prothrombin time, partial thromboplastine time, prothrombine concentration, and international normalised ratio (INR)]; serum electrolytes; random blood sugar and liver functions; serum PSA; abdominal ultrasonography (US) to assess upper tract lesions; and TRUS to measure residual urine, prostate size, and Q<sub>max</sub>.

#### Management of anticoagulants in perioperative period

Patients on PAIs (aspirin and/or clopidogrel) continued their treatment in the perioperative period, whilst patients on warfarin with or without PAIs were shifted



Fig. 1 Patient flow chart.

to therapeutic dose of low-molecular-weight heparin (40 mg twice daily) if their INR was >2 (only six patients had an INR >2; two patients were on warfarin and four patients were on dual therapy), whilst those with an INR  $\leq$ 2 continued their OAC without bridging.

All patients continued their regular preoperative OAC/PAI drug regimens before they were discharged from hospital.

#### Surgical procedure

The device used for PKERP was a bipolar highfrequency generator (UES-40 SurgMaster; Olympus, Tokyo, Japan). The power output was set at 180 W and 100 W for vaporisation and coagulation modes, respectively. A 26-F continuous flow resectoscope with a separate irrigation channel was used. All patients were operated upon by single experienced surgeon (A.A.).

Normal saline solution (pre-warmed to body temperature) was used as an irrigant for clear vision and to prevent bubbles. A continuous-flow setup was important to ensure clear vision during the procedure.

A three lobe-enucleation technique was used for adenoma enucleation, then resection of the enucleated lobe. This enabled us to obtain biopsies for histopathological assessment. The procedure started with two incisions at the 5 and 7 o'clock positions starting from the bladder neck to the prostatic apex using a mushroom loop. At this point, another incision was made to connect the two previous incisions and deepened to the level of the surgical capsule. Thus, the median lobe was ready for enucleation by pushing it retrogradely from the connecting incision towards the bladder by the top and the loop of the resectoscope, whilst doing so the loop could be intermittently activated for haemostasis or vaporising adhesions, leaving it attached only by a small stalk and then the incompletely enucleated median lobe was resected rapidly by the cutting electrode. The resultant prostatic chips were then removed by the evacuator. The two lateral lobes were dealt with in a similar manner, starting with a 12 o'clock incision from the bladder neck to the prostatic apex using the mushroom loop, then connecting it to the previously made 5 or 7 o'clock incision accordingly, then enucleation and resection of the lateral lobes as previously described for the median lobe. Afterwards, the mushroom loop was used for vaporisation of any shreds present in the resultant prostatic bed and smoothing the surface of the prostatic fossa. During the procedure 20 mg furosemide/h was infused to minimise volume overload and improve urinary flow.

Finally, a TURP-like cavity was obtained, a threeway 20/22-F silicone urethral catheter was inserted for postoperative continuous bladder irrigation with saline until haematuria resolved, then the catheter was removed and the patient observed until he voided satisfactorily and resetting of the stopped anticoagulants if so before discharge.

Catheterisation time, postoperative hospital stay, and any perioperative complications were recorded.

#### Postoperative assessment of patients

Serum electrolytes and Hb were assessed within the first 24 h postoperatively, and follow-up visits were scheduled at 1, 3 and 6 months (and any other time if there were any complications) for IPSS,  $Q_{max}$ , prostate volume, and post-void residual urine volume (PVR) measured by TRUS.

### Study outcomes

The primary outcomes of the study included: operative time, Hb drop, catheterisation time, length of hospital stay, and the perioperative morbidity and mortality rates. The secondary outcomes were functional outcomes including  $Q_{max}$ , IPSS, prostate volume, and PVR.

#### Statistical analysis

We compared measures taken at baseline with those taken 6 months postoperatively. The results are presented as the mean  $\pm$  standard deviation (SD) or median and range. The paired Student's *t*-test or Kruskal–Wallis H test, with a significance level of P < 0.05, was used when appropriate to test our hypothesis that bipolar transurethral PKERP is safe in patients on chronic OACs and/or PAIs. All analysis was performed with Prism 7.0 (GraphPad Software Inc., La Jolla, CA, USA).

#### Results

#### Study patients and baseline characteristics

In all, 100 patients were recruited for this study. Of these patients, only 91 patients fulfilled the inclusion criteria. As shown in Table 1, the mean (SD, range) age of the

patients was 65 (5.9; 50–78) years. The enrolled patients were all using PAI and/or OAC drugs preoperatively. In all, 70 patients were using PAIs (of them 56 patients were on aspirin, three on clopidogrel and 11 were on both drugs) preoperatively. Preoperatively, 15 patients were using the OAC drug warfarin, and six patients were on both PAI and OAC drugs (Table 2).

#### The primary outcomes

All the procedures were performed successfully. All patients recovered uneventfully after the procedure. The mean (SD) preoperative prostate volume was 80.9 (30) mL and PSA level was 3.9 (2.3) ng/mL. The mean (SD) operating time was 66.87 (22.53) min. The mean (SD) postoperative catheter time and hospital stay were 1.14 (0.76) and 1.79 (1) days, respectively (Table 1).

There was no statistically significant change in the serum level of Na<sup>+</sup> after PKERP; the mean (SD) preoperative serum Na<sup>+</sup> level was 139.8 (3.04) mmol/L as compared with 138.2 (3.4) mmol/L postoperatively (Table 1). So clinically, no patient had TUR syndrome, even if the procedure time was >1 h.

There were no significant differences in the assessed parameters between patients receiving PAI alone, OAC alone, or PAI and OAC combined therapy. Therefore, we opted to pool all patients on PAIs, OAC, or dual therapy as one category.

**Table 2** Summary of the perioperative use of PAI/OAC drugs.

	N
Total number of patients	91
Number of patients on PAIs	70
Number of patients on aspirin	56
Number of patients in clopidogrel	3
Number of patients on aspirin and clopidogrel	11
Number of patients on OAC warfarin	15
Number of patients on dual therapy	6

Table 1         Baseline and perioperative dat	a.				
Characteristics	PAI $(n = 70)$	OAC - warfarin (n = 15)	Dual therapy $(n = 6)$	$P^*$	Overall $(n = 91)$
Age, years, mean (SD)	65.2 (6.1)	65.2 (5.5)	62.7 (5.4)	0.554	65 (5.9)
Prostate size, mL, mean (SD)	83.6 (31.6)	76 (26.1)	61.3 (18.1)	0.163	80.9 (30.4)
PSA level, ng/mL, mean (SD, range)	3.6 (2.4, 1.3–9.5)	4.1 (3.4, 1.5–10)	2.8 (3, 2-8)	0.581	3.7 (2.3)
INR, mean (SD)	1.2 (0.4)	1.9 (0.9)	1.7 (0.75)	< 0.001	1.32 (0.56)
Operative time, min, mean (SD)	69.8 (21.8)	56 (14.1)	60.8 (15.3)	0.06	66.87 (22.53)
Hb drop, g/dL, mean (SD)	0.7 (0.52)	1 (0.8)	0.82 (0.65)	0.092	0.74 (0.61)
Catheterisation time, days, median (range)	1 (0.5–4)	1 (0.5–3)	1.25 (1-4)	0.245	1.14 (0.76)**
Hospital stay, days, median (range)	1.5 (1-5)	1.5 (1-4)	2.75 (1-5)	0.458	1.79 (1)**

\* Statistical comparison of four groups (PAI, OAC warfarin, and dual therapy) was performed using the Kruskal–Wallis H test; P < 0.05 was considered statistically significant.

\*\* Data are presented as mean (SD).

For the Hb level, there was a statistically significant drop in the postoperative Hb concentration as compared to the corresponding preoperative levels. Hb concentrations dropped from a mean (SD, range) of 12.2 (0.9, 10–15.2) g/dL preoperatively to 11.5 (0.8, 8–14.6) g/dL postoperatively (P < 0.05). As indicated in Table 1, the mean (SD) Hb drop was 0.74 (0.61) g/dL. Interestingly, there was no significant difference in Hb drop in patients on PAIs or OAC (Table 1). One patient on dual therapy (PAI + clopidogrel) with a prostate volume of 130 mL, had intraoperative bleeding that necessitated transfusion of 1 unit of blood. The same patient had a secondary haematuria on the fourth postoperative day requiring another unit of blood. Another patient who was on a PAI (clopidogrel), with a baseline prostate volume of 85 mL, had a severe attack of haematuria with clot retention on the seventh postoperative day and was managed by hospitalisation, recatheterisation, manual irrigation with removal of clots and a 1-unit blood transfusion.

Secondary haematuria occurred in three (3.3%) patients at  $\leq 10$  days postoperatively. Transient urinary incontinence (UI), defined as postoperative UI that resolves within 6 months, occurred in six patients (6.6%). Only four patients required management by pelvic floor muscle exercises (Kegel exercises) and/or anti-cholinergic medications (Table 3).

Three patients (3.3%) developed urinary retention. The first patient developed urinary retention on the third postoperative day and required catheter reinsertion; this patient yielded tissue that caused the retention and after evacuation of the bladder the catheter was removed. The second patient had urinary retention a week after hospital discharge and a catheter was re-inserted, as an outpatient procedure, for another 1 week. The patient successfully voided after catheter removal. The third patient presented with clot retention

 Table 3
 Summary of the early and late adverse events associated with their incidence in study subjects.

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2 (2.2) 2 (2.2)	II
2 (2.2)	п
	11
3 (3.3)	II
5 (5.5)	II
8 (8.8)	II
2 (2.2)	II
6 (6.6)	II
1(1.1)	IIIa
0	_
	2 (2.2) 3 (3.3) 5 (5.5) 8 (8.8) 2 (2.2) 6 (6.6) 1(1.1) 0

\* Grading according to the modified Clavien–Dindo classification of complications.

and was managed by hospitalisation, re-catheterisation, manual irrigation with removal of clots, and a 1-unit blood transfusion.

As shown in Table 3, dysuria and irritative symptoms were reported in 13 patients (14.3%). Of these 13 patients, five patients had UTIs, which were documented by urine culture and sensitivity tests, and therefore they were treated accordingly. The other eight patients complained of persistent LUTS for 2 weeks and were treated with NSAIDs and anticholinergic drugs.

Only one patient (1.1%) had urethral stricture during the follow-up period and required only endoscopic guided urethral dilatation.

None of the patients had any thromboembolic adverse events such as: pulmonary embolism, deep venous thrombosis, myocardial infarction or strokes.

#### The perioperative and postoperative functional outcomes

Functional outcomes were measured by assessing Q<sub>max</sub>, IPSS, change in prostate volume, and PSA levels. As shown in Fig. 2; the preoperative Q<sub>max</sub> significantly increased from a mean (SD) of 7.2 (3.2) to 14.5 (3.9); 17.9 (3.8); and 18.6 (4.37) mL/s at 1, 3 and 6 months postoperatively, respectively ( $P \le 0.05$ ). In addition, there was a marked improvement in the IPSS. The IPSS dropped from a mean (SD) of 24.3 (6.1) preoperatively to 7.9 (2.4); 6.9 (3.1); and 5.7 (2.3) at 1, 3 and 6 months postoperatively, respectively ( $P \le 0.05$ ). Similarly, the mean (SD) PVR at the same postoperative periods was 35.96 (30.3), 26 (25.5), and 24.83 (21.4) mL, respectively, as compared to 195 (225.5) mL preoperatively ( $P \le 0.05$ ).

For the change in prostate volume, the mean (SD) preoperative prostatic volume was 80.9 (30.4) mL as compared with 33.9 (12.8); 32.7 (11.2); and 29.5 (10.6) mL at 1, 3 and 6 postoperatively, respectively ( $P \le 0.05$ ). Accordingly, the PSA level dropped from a mean



**Fig. 2** Preoperative and postoperative Q<sub>max</sub>, IPSS, prostate size, PVR, and PSA level during follow-up.

(SD) of 3.9 (2.3) ng/mL preoperatively to 2.1 (1.2) ng/mL (~47% reduction) at 6 months postoperatively ( $P \le 0.05$ ).

# Discussion

Several minimally invasive surgical procedures are currently available for treating patients with moderate-tosevere LUTS/BPH and its associated morbidity. Thus, clinical practitioners need to select the most appropriate option based on patient's anatomy and the associated morbidity and risk factors [9].

Although M-TURP is an effective endoscopic minimally invasive intervention for LUTS/BPH, this procedure is accompanied with significant adverse events, especially in patients with larger prostates, bleeding tendencies and/or patients receiving OAC/PAI drugs, which are a contraindication for TURP [10].

As BPH commonly afflicts older patients, several cardiovascular and thromboembolic diseases are common co-morbidities associated with BPH in this age group. Thus, a substantial number of patients with BPH receive OAC/PAI drugs for the management of thromboembolic disorders such as: deep vein thrombosis, heart diseases, artificial cardiac valves or patients who have undergone percutaneous cardiac interventions such as angioplasty or stenting [11]. In these patients laser surgery may offer a viable treatment option due to its minimal perioperative morbidity and good functional outcomes and therefore, it is safe in senior patients especially those with high morbidity [12]. Abstention from PAI and/or OAC drugs before surgery for prevention of bleeding remains a matter of controversy. It was found that there was insignificant risk of perioperative morbidity, whilst withdrawal of PAI and/or OAC drugs led to more cardio-cerebro-vascular adverse events during TURP [13,14].

A recent meta-analysis confirmed that bipolar transurethral resection with saline (B-TURP) was as effective as M-TURP, with statistically significant better intraand postoperative safety, hospital stay and reduced post-discharge re-hospitalisation. Lastly, B-TURP is a relatively inexpensive procedure and has a shallow learning curve [15].

Today, PKERP and holmium laser enucleation of the prostate (HoLEP) are amongst the most widely used technologies for managing BPH. These techniques are mostly used for enucleation and may replace conventional resection. The two procedures show comparable or even equal efficacy and safety with minimal sideeffects in comparison with M-TURP. The enucleation technique has many advantages including reduced risk of bleeding, especially in larger glands. In addition, the enucleation technique provides clearer visibility, has a lower capsular perforation rate, and enables faster and complete adenoma removal comparable to open surgery. Moreover, it is not affected by prostate size, does not cause TUR syndrome, and is associated with a decreased rate of recurrence and lower catheter and hospitalisation times [16].

The present study showed that the perioperative blood transfusion rate, postoperative catheterisation time and postoperative hospitalisation time are comparable with the currently practiced interventional treatment for BPH with ongoing OAC therapy [17]. A comparative study between B-PKERP and M-TURP in patients at high risk of bleeding, who were maintained on their treatment, concluded that there is a significant reduction of bleeding complications in favour of B-PKERP with a lower Hb drop, blood clots and haematuria without transfusion [18]. A previous study, which enrolled 26 patients on OACs, reported that no blood transfusions were needed. However, the recatheterisation rate due to clots was 1.2% compared to 3.3% in our present study. On the other hand, the operative time, the catheterisation time and the duration of hospital stay were much lower in our present study as compared to a similar previously published study [19]. The difference in the outcomes of our present study and the previously published study by Kranzbühler et al. [19] could be attributed to several possible reasons. First, the enucleation technique that we use is much more rapid than pure vaporisation that was used by the aforementioned study. In addition, the number of patients enrolled in the study by Kranzbühler et al. [19] was relatively small compared to the relatively large number of patients in our study. Ong et al. [20] observed more bleeding complications in patients who continued their PAIs (16%) than those who stopped it (4%).

Recently, Yee et al. [21] reported that PAIs are a risk factor for secondary haemorrhage after bipolar surgery of the prostate. They reported that the rate of secondary haematuria necessitating hospitalisation was as high as 7.9%, the mean duration of hospital stay was 2.6 days, and the average catheterisation time was 2 days.

Numerous published studies on HoLEP in anticoagulated patients have reported a high safety profile. In a recent study by El Tayeb et al. [22], the transfusion rate was 3.5% for anticoagulated patients as compared with 1.6%, for non-anticoagulated patients (P = 0.128). They also reported that 1.9% of their patients required evacuation of blood clots, the catheterisation time was 28 h, whilst hospital stay was 30 h. Indeed, these data are similar to our present results. Similarly, another study reported that no patient required blood transfusion and 8% of the patients was readmitted because of haematuria and the duration of indwelling postoperative catheterisation was twice as long as in our present study (2.6 days) [23]. In another earlier HoLEP study, including 83 patients receiving anticoagulant treatment, the authors found that the blood transfusion rate was 8.4%, secondary clot retention rate was 3.6%, catheterisation time and hospital stay were 2.2 and 2.5 days, respectively [24]. These values are greater than the corresponding values in our present study.

When comparing our present results with that of Bishop et al. [25], who studied 52 patients who underwent HoLEP on antithrombotic therapy, there are some different results as their transfusion rate was 7.7% and hospital stay was 2 days.

In a comparative study, it was concluded that both thulium vapoenucleation of the prostate (ThuVEP) and thulium vaporesection of the prostate (ThuVARP) are safe and effective in management of high risk men on OAC drugs [26]. The study had 26 patients in each group and the transfusion and clot retention rates were both 3.9% and the postoperative catheter removal was 2 days after ThuVEP compared with 1 day only after ThuVARP [26]. Lastly, а retrospective nonrandomised multi-centric study utilised 180-W XPS-Greenlight laser for the same category of patients and none of the patients required a blood transfusion despite the recorded rate of difficult bleeding during the procedure being 4.9% [27]. In addition, 13.5% of cases were converted to conventional TURP, catheter duration was 2 days and hospital stay was 4 days, which are twice as long as the corresponding values in our present study.

For other postoperative morbidities, we did not record any cardio- or cerebro-vascular accidents perioperatively. None of our present patients needed reoperation for residual adenoma, only one patient (1.1%) had a urethral stricture, which was managed by endoscopic guided dilatation only. In all, 6.6% of the patients had transient postoperative UI and 5.5% of them were confirmed to have UTIs. Elzayat et al. [24] reported a 1.2% myocardial infarction rate, the UI rate was 6%, whilst the UTI rate was 3.6%, a result which is relatively similar to ours. Another study reported a 2% incidence of thromboembolic events [20]. A more recent study confirmed that cardiovascular complications may be as much as 28% [17]. In a study that used a pure bipolar plasma vaporization technique, the UTI rate was very high (36%) as compared to our present findings [19]. This may be due to extensive use of coagulation during the procedure, which can cause an excessive devitalised prostatic bed. This group also the reported a urethral stricture rate of 4% [19].

Finally, with respect to the functional outcomes, the present study confirmed that PKERP can substantially improve patients' LUTS/BPH. This improvement is manifested in form of excellent reduction in IPSS and PVR, and increase in  $Q_{max}$ . In addition, the improvement of the functional outcomes was maintained throughout the whole follow-up period, which is similar to other published data [19,20,26–29].

#### Conclusion

PKERP can be considered as a safe and effective minimally treatment option for BPH in high-risk patients who are on OAC/PAI drugs.

#### **Conflict of interest**

None.

#### Source of funding

None.

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