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ORIGINAL ARTICLE

Thulium:YAG VapoEnucleation of the prostate in large glands: a prospective comparison using 70- and 120-W 2-μm lasers

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This study compared the efficacy of 70- and 120-w 2-μm thulium:YAG VapoEnucleation of the prostate (ThuVEP) for patients with benign prostatic obstruction (BPO). A prospective analysis of 84 patients with symptomatic BPO and prostatic enlargement (⩾60 ml) who underwent either 70-w (*n*=44) or 120-w ThuVEP (*n*=40) non-randomly was carried out. Patient demographics and perioperative and 12-month follow-up data were analysed. The mean prostate volume was 79.90±27.49 ml in patients who had received 70-w ThuVEP, which was less than in those who had received 120-w ThuVEP (88.53±25.10; *P*=0.033). The mean enucleation (resected weight/laser time, 2.16±1.21 g min^{-1} *vs.* 1.23±0.60 g min^{-1}; *P*=0.013), operation efficiency (resected weight/total operation time, 0.76±0.35 g min^{-1} *vs.* 0.42±0.27 g min^{-1}; *P*=0.000) and percentage of resected tissue (66.93%±22.79% *vs.* 45.41%±23.33%; *P*=0.000) were higher with 120-w treatment compared to 70-w ThuVEP. One patient (1.2% of total patients) (in the 120-w group) required a blood transfusion postoperatively. Sixty-one patients (73%) were available for review at the 12-month follow-up time point. The quality of life (QoL), International Prostate Symptom Score (IPSS), maximum urinary flow rate (Q_{max}), postvoiding residual urine (PVR) and prostate volume improved significantly after treatment (*P*⩽0.035) and were not significantly different between those treated with the different devices (70- and 120-w). The median prostate volume reduction was 81.70% and 82.19% with 70- and 120-w ThuVEP, respectively. The incidence of complications was low and did not differ between groups treated with the different devices. Two patients (2.4%) (one per group) had a bladder neck contracture at the follow-up. ThuVEP is a safe and efficacious procedure for the treatment of symptomatic BPO. The incidence of complications was low with both devices. The 120-w thulium:YAG device enhances the effectiveness of ThuVEP with regard to the percentage of resected tissue and the enucleation/operation efficiency.
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INTRODUCTION

Transurethral resection of the prostate (TURP) and open prostatectomy (OP) are considered to be the 'gold standard' for the treatment of benign prostatic obstruction (BPO).[1,2] Perioperative complications and morbidities associated with these procedures, such as severe bleeding and the risk of fluid volume absorption, led to the development of more minimally invasive techniques. Holmium laser enucleation of the prostate (HoLEP) appears to be a size-independent method of treating BPO.[3–5] However, the prolonged learning curve for using the HoLEP procedure has hitherto limited its clinical acceptance. Thulium YAG VapoEnucleation of the prostate (ThuVEP) with a 70-w 2-μm thulium:YAG (Tm:YAG) laser has recently been introduced, showing promising results as a size-independent treatment modality of BPO.[6,7] The latest development has been the introduction of a 120-w Tm:YAG laser device. The consequences of ThuVEP using the 120-w device have not been determined. The aim of this prospective study was to compare the efficacy of 70- and 120-w ThuVEP in patients with enlarged prostates and to provide a 12-month follow-up.

MATERIALS AND METHODS

Patients

This study was a prospective analysis of 84 consecutive patients presenting with symptomatic BPO ⩾60 ml undergoing 70- or 120-w ThuVEP non-randomly at our institution. After obtaining institutional review board approval, all patients gave their informed consent prior to their inclusion in the study. The exclusion criteria were a maximum urinary flow rate (Q_{max}) of >15 ml s^{-1}, an international prostate symptom score (IPSS) of <7 points, a urodynamically diagnosed neurogenic bladder, prostate cancer and previous prostatic or urethral surgery. The preoperative assessment included calculation of the prostate volume by transrectal ultrasonography and the post-voiding residual urine (PVR) volume by abdominal ultrasonography, a digital rectal examination, calculation of the IPSS, completion of the quality of life (QoL) questionnaire, a prostate-specific antigen (PSA) assay, a urine analysis and a urine culture. Uroflowmetry was performed in all patients except those in urinary retention.

The patients were discharged after the catheter had been removed and they were able to void adequately, as measured by Q_{max} and PVR.

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The patients were invited for a follow-up visit 12 months after the surgery, and the following measures were examined: transrectal ultrasonography, Q_{max}, PVR, IPSS and QoL. If the patients had not responded to mailed invitations, a structured telephone interview was performed. The patients were asked about their reasons for not responding to the mailed invitations, the occurrence of complications and operative interventions.

Surgical procedure

ThuVEP was performed by two experienced surgeons to minimize the effects of the learning curve on the surgical outcome. ThuVEP was conducted using the 70- or 120-w 2 μm continuous-wave Tm:YAG laser (RevoLix; LISA Laser products, Katlenburg, Germany) as the energy source. The laser energy was delivered through a 550-μm optical-core, bare-ended, reusable laser fibre (RigiFib; LISA Laser products). The procedure was performed using a 26 F continuous-flow laser resectoscope in combination with a mechanical tissue morcellator (Piranha; TUR-Set Richard Wolf, Knittlingen, Germany). All interventions were carried out using normal saline as the irrigation fluid. Spinal anaesthesia was performed in most patients, except in those with a decline in spinal anaesthesia, with coagulopathy, or in whom regional anaesthesia failed, for whom general anaesthesia was used. The technique of ThuVEP has previously been reported in detail.[6] The foley catheter was routinely removed 48 h after ThuVEP. Blood loss was estimated by comparing the haemoglobin (Hb) value 1 day before surgery with the corresponding value on the first postoperative day. The enucleated tissue was histopathologically analysed in all patients.

Statistical analysis

Statistical analysis was performed using the SPSS version 11.5.1 (SPSS Inc., Chicago, IL, USA) for Windows. Patient data are expressed as mean±s.d. or as median with interquartile ranges. Differences between 70- and 120-w ThuVEP were assessed using the Mann–Whitney *U* test, and improvements in the assessed parameters in each group were calculated using the paired *t*-test. Categorical variables were compared using the *Chi*-squared test. $P<0.05$ was considered to be statistically significant.

RESULTS

Table 1 lists the baseline characteristics of both groups. The mean prostate volume was 79.90±27.49 ml in the 70-w group, which was lower than in the 120-w ThuVEP group (88.53±25.10; $P=0.033$). PVR was higher in the 120-w ThuVEP group (254.69±172.89 ml) than in the 70-w ThuVEP group (110.00±55.98 ml) ($P=0.000$).

Table 2 lists the perioperative data. The enucleation efficiency (weight/laser time, 2.16±1.21 g min^{-1} *vs.* 1.23±0.60 g min^{-1}; $P=0.013$), operation efficiency (weight/total operation time, 0.76±0.35 g min^{-1} *vs.* 0.42±0.27 g min^{-1}; $P=0.000$), resected weight (58.90±22.55 g *vs.* 38.34±25.48 g; $P=0.000$) and percentage of resected tissue (66.93±22.79% *vs.* 45.41±23.33%; $P=0.000$) were higher with 120-w ThuVEP than with 70-w ThuVEP. The mean Hb decrease was higher with 120-w ThuVEP than with 70-w ThuVEP (1.83±1.81 g dl^{-1} *vs.* 0.75±1.01 g dl^{-1}; $P=0.004$).

Two patients died during the follow-up, and 18 patients did not respond to mailed invitations. These patients were contacted by telephone and were asked to provide reasons for their non-response. The most common reasons for non-response were that the patients had moved abroad or were unwilling to participate in the follow-up. Three patients with incidental prostate cancer were excluded from further analysis. Sixty-one patients (73%) were available for review at the 12-month follow-up. At the follow-up, there was a highly significant improvement in IPSS, QoL, Q_{max}, PVR and prostate volume in comparison to the preoperative assessment in each group, with no differences being observed between the groups at the follow-up (**Table 3**). The median (interquartile range) prostate volume reduction was 81.70% (51.04%–88.44%) and 82.19% (80.31%–87.45%) in the 70- and 120-w ThuVEP groups, respectively, at the follow-up ($P=0.509$).

Table 4 lists the adverse events in the 70- and 120-w groups. There were no statistical differences in the incidence of complications between patients treated with the different laser devices. None of the patients in the 70-w group received blood transfusions postoperatively, whereas one in the 120-w group did. Immediate recatheterisation was necessary in three patients, owing to inadequate micturition (70-w (2), 120-w (1)) within 1 week of surgery (3.6%). In one of these patients, micturition normalized successfully after the extraction of the foley catheter 2 days later; cystoscopy revealed a residual adenoma at the apex of the prostate fossa in the other two patients. At the 12-month follow-up time point, bladder neck contractures (BNCs) had developed in 2.3% and 2.5% of the patients in the 70-w and 120-w ThuVEP groups, respectively (**Table 4**). BNCs were successfully treated with the Tm:YAG laser using the technique that was previously reported.[8] Notably, none of the patients developed urethral strictures during the follow-up period.

The cumulative incidence of urinary tract infections at the 12-month follow-up was 9.1% in the 70-w ThuVEP group and 10% in

Table 1 Baseline characteristics of 70- and 120-w ThuVEP groups[a]

	70-w ThuVEP	*120-w ThuVEP*	P *value*
No. of patients	44	40	
Age (year)[b]	70.66±8.62 (46–87)	69.50±6.15 (55–82)	0.375
PSA (ng ml^{-1})[b]	10.68±11.05 (1.23–42.00)	7.98±7.30 (0.51–44.25)	0.973
Prostate volume (ml)	79.90±27.49 (60–167)	88.53±25.10 (60–170)	0.033
IPSS[b]	17.77±7.43 (7–28)	17.60±8.53 (7–30)	0.751
QoL[b]	4.71±1.07 (2–6)	3.80±1.37 (1–6)	0.063
Q_{max}[b] (ml s^{-1})	8.18±3.15 (4.7–14.0)	8.44±3.86 (1.3–14.4)	0.816
PVR (ml)	110.00±55.98 (10–200)	254.69±172.89 (20–700)	0.000
Preoperative urinary retention (%)	31.81	32.50	NS

Abbreviations: IPSS, International Prostate Symptom Score; NS, not significant; PSA, prostate-specific antigen; PVR, postvoiding residual urine; Q_{max}, maximum urinary flow rate; QoL, quality of life; ThuVEP, Tm:YAG VapoEnucleation of the prostate.

[a] The data are mean±s.d. (range). Differences between 70- and 120-w ThuVEP were assessed using the Mann–Whitney *U* test. Categorical variables were compared using the *Chi*-square test.

[b] No statistical differences between 70- and 120-w ThuVEP.

Table 2 Perioperative data of 70- and 120-w ThuVEP groups[a]

	70-w ThuVEP	*120-w ThuVEP*	P *value*
No. of patients	44	40	
Laser energy (kJ)	175.46±161.95 (67.80–989.03)	225.3±101.22 (14.65–424.16)	0.001
Laser energy/laser time (kJ min^{-1})	4.30±1.18 (3.40–10.41)	6.33±1.96 (0.67–7.31)	0.000
Total operation time (min)	90.74±25.99 (57–145)	81.86±27.14 (40–165)	0.108
Total laser time (min)	38.07±15.24 (16–95)	33.00±16.47 (13–73)	0.069
Enucleation efficiency[b] (g min^{-1})	1.23±0.60 (0.27–3.07)	2.16±1.21 (0.27–5.00)	0.013
Operation efficiency[c] (g min^{-1})	0.42±0.27 (0.02–1.00)	0.76±0.35 (0.19–1.69)	0.000
Resected weight (g)	38.34±25.48 (10–110)	58.90±22.55 (14–110)	0.000
Percentage of resected tissue[d] (%)	45.41±23.33 (3–97)	66.93±22.79 (23–122)	0.000
Haemoglobin decrease (g dl^{-1})	0.75±1.01 (−1.5–3.0)	1.83±1.81 (−1.5–6.7)	0.004
Catheter time (days)	2.25±1.00 (1–6)	2.35±0.89 (2–6)	0.824

Abbreviation: ThuVEP, Tm:YAG VapoEnucleation of the prostate.
[a] The data are mean±s.d. (range). Differences between 70- and 120-w ThuVEP were assessed using the Mann–Whitney *U* test. $P<0.05$ was considered to be statistically significant.
[b] Enucleation efficiency: weight/laser time.
[c] Operation efficiency: weight/total operation time.
[d] Percentage of resected tissue: resected weight/preoperative prostate volume.

the 120-w ThuVEP group, respectively. Two patients had an episode of epididymitis (2.4%) after 120-w ThuVEP.

DISCUSSION

Tm:YAG vaporesection of the prostate (ThuVaRP) was introduced recently for the treatment of BPO and has been shown to be safe and effective in men with small- and medium-sized prostates.[9–12] Wider application of ThuVaRP, to larger prostates, is limited, owing to the prolonged operation time that would be required for this procedure.[9,11] ThuVEP was developed to solve this problem. ThuVEP is based upon the HoLEP technique, in which the entirety of the median and lateral lobes are anatomically dissected from the surgical pseudocapsule using a retrograde approach and are mechanically morcellated in the bladder.[6,13] Beginning with a TURP-like retrograde ThuVaRP, the progression to a faster and even more efficient retrograde ThuVEP technique might overcome the learning curve for the procedure.[14] Bach *et al.*[15] recently analysed the ablation capacities of the 70- and 120-w Tm:YAG devices in an *ex vivo* model. They found higher tissue vaporisation rates with the 120-w Tm:YAG device than with the 70-w device, despite comparable bleeding rates and tissue penetration. The consequences of ThuVEP using the 120-w device have not been examined to date. Owing to the greater ablation by the 120-w device, this laser might provide a more effective ThuVEP than the 70-w device.

With this series, we provide 12-month follow-up data for patients treated with 70- and 120-w ThuVEP, and we show significant relief of

Table 3 Baseline and follow-up data of 70- and 120-w ThuVEP groups[a]

	Baseline	*Discharge*	*12-month follow-up*	*Baseline* vs. *follow-up* P *value*
IPSS				
70-w ThuVEP	17.77±7.43 (7–28)	NA	4.88±2.99 (1–12)	0.012
120-w ThuVEP	17.60±8.53 (7–30)		4.73±3.40 (1–14)	0.001
P value	0.751		0.588	
QoL				
70-w ThuVEP	4.71±1.07 (2–6)	NA	1.32±1.14 (0–5)	0.000
120-w ThuVEP	3.80±1.37 (1–6)		1.50±0.86 (0–3)	0.008
P value	0.063		0.259	
Q_{max} (ml s^{-1})				
70-w ThuVEP	8.18±3.15 (4.7–14.0)	19.40±12.44 (9.0–47.5)	23.80±8.76 (7.4–41.2)	0.000
120-w ThuVEP	8.44±3.86 (1.3–14.4)	20.99±12.82 (9–50)	22.93±19.35 (14.1–59.2)	0.000
P value	0.816	0.387	0.283	
PVR (ml)				
70-w ThuVEP	110.00±55.98 (10–200)	18.70±20.01 (0–100)	25.83±26.73 (0–90)	0.035
120-w ThuVEP	254.69±172.89 (20–700)	29.13±35.52 (0–200)	18.35±33.4 (0–150)	0.000
P value	0.000	0.133	0.091	
Prostate volume (ml)				
70-w ThuVEP	79.90±27.49 (60–167)	NA	20.35±13.73 (4.3–52.0)	0.000
120-w ThuVEP	88.53±25.10 (60–170)		14.73±12.80 (7.6–33.0)	0.000
P value	0.033		0.395	

Abbreviations: IPSS, International Prostate Symptom Score; NA, not analysed; PVR, postvoiding residual urine; Q_{max}, maximum urinary flow rate; QoL, quality of life; ThuVEP, Tm:YAG VapoEnucleation of the prostate.
[a] The data are mean±s.d. (range). Differences between 70- and 120-w ThuVEP were assessed using the Mann–Whitney *U* test, and improvements in the assessed parameters in each group were calculated using the paired *t*-test.

Table 4 Incidence of complications after 70- and 120-w ThuVEP with mechanical morcellation, as well as previously reported incidences after HoLEP, OP and TURP, given as a percentage and/or range

	70-w ThuVEP n *(%)*	*120-w ThuVEP* n *(%)*	*Total ThuVEP*[b] n *(%)*	*HoLEP*[e] *(%)*	*OP*[e] *(%)*	*TURP*[e] *(%)*
No. of patients	44	40	84			
Early complications						
Death/myocardial infarction/pulmonary embolism[a]	—	—	—			
Intraoperative blood transfusions	—	—	—			
Postoperative blood transfusions	—	1 (2.5)	1 (1.2)	0–1.9[3–5,16–20,23–25]	1–32[2,16,26,27,29,30]	0–22[1,17–20,28]
TURS	—	—	—	—	—	0–5[1,17–20,28]
Transient irritative urinary symptoms	8 (18.2)	9 (22.5)	17 (20.2)	0–44[16–20,25]	7.46–38.60[16,26]	0–38.6[17–20]
Transient stress incontinence	2 (4.5)	1 (2.5)	3 (3.6)	0–7.1[5,16,20,22,25]	2.50–5.97[16,26,27,29,30]	0–40[1,17–20]
Recatheterisation	1 (2.3)	2 (5)	3 (3.6)	0.4–17.0[5,16,19,20,25]	3.3–5.1[16,29]	0–13.3[1,17–20]
Haemorrhage requiring coagulation	1 (2.3)	1 (2.5)	2[c] (2.4)	0–6[16–20,25]	1.1–3.7[26,27,29]	0–14.3[1,17,18,20]
Residual adenoma at the apex of prostate fossa	1 (2.3)	1 (2.5)	2 (2.4)	0–3.3[16–18,20]	0–1.1[26,27,29,30]	0–3.3[18,20]
Clot retention	1 (2.3)	1 (2.5)	2 (2.4)	0–3.6[20,23–25]	0–11.6[16,26,27,[f] 29]	0–39[20]
Incomplete morcellation	—	2 (5)	2[d] (2.4)	0–3.7[23,25]	—	—
Overall immediate re-operation rate	2 (4.5)	4 (10)	6 (7.2)	0–5[5,16–18,20,23,24]	0.5–3.7[26,27,29,30]	2.2–5.6[1,17,18,28]
Complications at 12-month follow-up						
Cumulative rate of UTI	4 (9.1)	4 (10)	8 (9.52)	0–6[5,19,20,22,24,25]	5.1–12.9 [26,27]/[g]8.6[29]	0–25[1,19,20,28]
Epididymitis	—	2 (5)	2 (2.4)	0.6–0.7[22,25]	4[30]	[h]0–4[1]
Persistent irritative urinary symptoms	3 (6.8)	1 (2.5)	4 (4.76)	0–10.8[16,17,20,25]	0–8.5[16,26,29]	0–3.3[17,19]
Persistent urge/stress incontinence	—	—	—	0–5.4[16,17]/ 0–3.3[5,16–20,24]	0–8.5[2,16,26,29,30]/ 0–20[2,16,26,27,29]	0–3.3[1,17–19]/ 0–2.2[1,17–20]
Bladder neck contracture/urethral stricture	1(2.3)	1(2.5)	2(2.4)	1.4–6.4[3,4,16–18]	3.3–5.7[3,16,29]	2.2–7.4[17,18]

Abbreviations: HoLEP, holmium laser enucleation of the prostate; OP, open prostatectomy;ThuVEP, Tm:YAG VapoEnucleation of the prostate; TURP, transurethral resection of the prostate; TURS, transurethral resection syndrome; UTI, urinary tract infection; —, none.

[a] Within the first 30 days postoperatively.

[b] No statistical differences between 70- and 120-w ThuVEP.

[c] Re-operation due to haemorrhage with clot retention.

[d] Procedure abandoned and completed 48 h later.

[e] For clarity, *n* is not shown, as the studies cited included pooled results from meta-analyses.

[f] Information given as severe bleeding.

[g] Sepsis.

[h] Epididymitis/urinary tract infection.

obstructive symptoms in patients with symptomatic BPO of $\geqslant$60 ml. The improvements in voiding (Q_{max}, PVR) and symptom parameters (IPSS, QoL) did not differ between the 70-w and 120-w ThuVEP groups and were comparable to those after HoLEP,[3–5,16–19] TURP,[17–20] or OP.[3,16] The median prostate volume reduction at the 12-month follow-up time point after 70-w ThuVEP (81.7%) and 120-w ThuVEP (82.19%) confirms the complete removal of the prostatic adenoma, which is comparable to the results achieved with HoLEP.[5,21–23] In addition, the prostate volume was at least 80 g in 37 of the patients in this series. One might therefore conclude that ThuVEP is an effective, size-independent treatment modality for patients with symptomatic BPO, although the durability of symptom relief should be confirmed with a longer follow-up.

The enucleation (resected weight/laser time), operation efficiency (weight/total operation time) and percentage of resected tissue (resected weight/preoperative prostate volume) in patients who received 70- or 120-w ThuVEP in our study are comparable to those reported by Elzayat *et al.*[24] in a large HoLEP series (552 patients) who had a mean prostate volume of 83.7 g. In our study, 120-w ThuVEP demonstrated a higher enucleation, operation efficiency and percentage of resected tissue compared with 70-w ThuVEP. The differences in these parameters might be attributable to the preoperative prostate volumes in the 70- and 120-w groups (79.9 ml *vs.* 88.53 ml). During HoLEP, in smaller fibrotic prostates, the surgical capsule is often less distinct, and the plane of dissection is more difficult than in larger glands in which the greater degree of peripheral compression tends to create a more easily identifiable plane.[25] This property might be one reason for the greater observed vaporisation in the 70-w ThuVEP, although the mean prostate volume was >75 ml in both groups. At the follow-up, the prostate volume was, however, not different between the 70- and 120-w ThuVEP groups.

Intraoperative and postoperative complications occurred at similar low rates in the 70- and 120-w groups. **Table 4** lists the complications of ThuVEP in comparison with recent HoLEP, TURP and OP series.[1–3,16–20,22–30] In particular, the transfusion rate was low in this study (1.2%), even though the mean Hb decrease was higher with 120-w than with 70-w ThuVEP (1.83 g dl^{-1} *vs.* 0.75 g dl^{-1}). The laser enucleation of larger glands leads to a large surface area of the prostate fossa. Therefore, the risk of haemodilution as a result of fluid absorption might be elevated. The preoperative prostate volume, intraoperative duration of irrigation, total amount of irrigation fluid used, and weight of resected prostatic tissue directly influence the amount of fluid absorption during HoLEP.[31] Therefore, the differences in the Hb decrease might be attributable to the preoperative prostate volumes in the 70- and 120-w groups (79.9 ml *vs.* 88.53 ml). In HoLEP, the mean Hb loss has been shown to range from 1.6 to 2.12 g dl^{-1},[16,21,22] in patients with mean prostate sizes ranging from 107.1 to 170.2 g,[16,21,22] respectively. The transfusion rates were 0%[16,22] and 0.8%,[21] respectively, in the HoLEP series. In contrast, the mean Hb decrease was 0.9 g dl^{-1} after HoLEP in patients with a mean prostate size of 126 g, although 1.3% of the patients required blood transfusions.[5] The Hb decreases and transfusion rates after 70- and

120-w ThuVEP of larger glands are therefore comparable to those for HoLEP and lower than those for OP or TURP.[1–3,16–20,22–30]

None of the patients required a re-intervention because of BPO during the follow-up. At the 12-month follow-up, BNCs requiring surgical treatment appeared in 2.3% and 2.5% of the patients after 70- and 120-w ThuVEP, respectively, which is comparable to the HoLEP, TURP and OP series (**Table 4**).[1–3,16–20,22–30] Although the 120-w procedure used more laser power, none of the patients in the 120-w ThuVEP group developed an urethral stricture during the follow-up, in keeping with the results obtained with 70-w ThuVEP,[6,7] HoLEP, TURP and OP (**Table 4**). Finally, it should be emphasized that the overall incidence of complications in this ThuVEP series was low and in line with other minimally invasive procedures. The incidence of complications did not increase when using the 120-w Tm:YAG device compared with the 70-w device.

In conclusion, ThuVEP is a safe and efficacious procedure for the treatment of symptomatic BPO. The 120-w Tm:YAG device enhances the effectiveness of ThuVEP with regard to enucleation and overall operation efficiency compared with the 70-w Tm:YAG device. The incidence of complications in patients who received 70- or 120-w ThuVEP was low. Prospective randomized trials are required to compare ThuVEP with HoLEP, TURP, or OP and to investigate the durability of symptom relief by longer follow-ups.

AUTHOR CONTRIBUTIONS

CN, TB, TRWH and AJG conceived and designed the study. CN and TB collected the data. TB and AJG performed the surgical procedures, while CN carried out follow-up studies. CN and TB performed statistical analyses. CN wrote the manuscript. All authors revised the manuscript for intellectual content and approved the final version.

COMPETING FINANCIAL INTERESTS

The authors declare that they have no competing financial interests.

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