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Original Article

Prostate artery EmbolisAtion Safety and efficacY: Preliminary and foLlow-Up urodynamic Studies (P-EASY PLUS)

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Objective

To assess the efficacy of prostate artery embolisation (PAE) in the management of obstructive benign prostatic hyperplasia (BPH) by conducting formal urodynamic studies.

Methods

Patients with symptomatic BPH underwent baseline assessments, including urodynamic evaluation, followed by PAE. Follow-up International Prostate Symptom Scores (IPSS), Quality of Life questionnaire (QoL) scores, prostate volume and urodynamic variables were assessed at a mean follow-up of 18 months.

Results

A total of 105 patients underwent PAE, with average final follow-up at 18 months. Prostate volumes reduced by a mean of 30.6% and significant improvements were identified across all IPSS parameters (total IPPS decreased by 55%; $P < 0.001$), QoL scores (improved by 65.9%; $P < 0.001$), maximum urinary flow rate (increased by 5 mL/s; $P < 0.001$), postvoid residual urine volume (decreased by 24%; $P = 0.049$), detrusor pressure (decreased from 65.0 to 48.9 cmH_2O; $P < 0.001$) and bladder obstruction rates. Bladder obstruction decreased from 66.7% to 29.8% of patients following embolisation. Results were found to be positively correlated to the absolute amount of embolic material injected during the embolisation procedure. PAE was well tolerated, with expected post-embolisation symptoms resolving completely after a mean (SD; range) of 7 (±5; 1–28) days. There were no major procedural complications, no reported urinary incontinence, and new retrograde ejaculation occurred in 2%.

Conclusion

In this study, PAE resulted in statistically significant improvements by both subjective and objective measures, including symptom severity, quality of life and urodynamic parameters. Whilst longer-term studies are required, these findings support PAE as a non-surgical option within the treatment algorithm for managing symptomatic, obstructive BPH.

Keywords

benign prostatic hyperplasia, embolisation, LUTS, PAE, urodynamics

Introduction

More than half of men aged 60 years and over have BPH that causes obstructive LUTS [1]. Treatment for this condition typically begins with conservative management, followed by medical therapies, minimally invasive surgical treatments and, ultimately, TURP. Although TURP is considered the surgical 'gold standard' for refractory BPH, it can impact continence and erectile function and cause retrograde ejaculation [2], prompting patients to seek non-surgical alternatives.

Prostate artery embolisation (PAE) is a minimally invasive, non-surgical alternative to long-term medical therapy that has been shown to delay the need for prostate outflow obstruction surgery in both short- and long-term studies

[3–5]. In comparison to TURP, PAE has demonstrated similar reductions in LUTS, with fewer complications and sexual side effects [3,6]. Notably, PAE has shown promising results for larger prostate volumes [7], with embolisation able to be performed safely and effectively on prostates of up to 200–600 mL. Thus, PAE can be used as a second-line option for BPH patients who are refractory to medical therapy, or who are unwilling or unsuitable to undergo more invasive surgical procedures, including open or robot-assisted laparoscopic surgical enucleation of large prostate volumes above 150 mL. There is also growing interest in PAE as a potential first-line treatment choice, with two recent randomised controlled trials demonstrating that PAE results in improved urinary and sexual function outcomes compared to combination medical therapy with alpha blockers and 5α-reductase inhibitors [8,9]. The safety and efficacy of PAE in the short term have previously been reported [10].

Whilst subjective symptomatic relief, improvements in quality of life and reductions in postvoid residual urine volumes are common outcomes, few studies have assessed PAE efficacy with formal urodynamic studies. The primary aim of this prospective study was to evaluate the impact of PAE on objective urodynamic variables. Secondary outcomes were subjective urinary symptom scores and complications after PAE.

Methods

Trial Design and Participants

This was a prospective study designed and conducted by interventional radiologists, urologists, and I-MED Radiology staff at the Wesley Hospital in Brisbane, Australia, from 2019 to 2023. Local ethics approval was obtained (UCH HREC reference number: 1520), and the trial was registered with the Australian New Zealand Clinical Trial Registry (ID: ACTRN12617001201369).

Men with prostate volumes of >35 mL and bothersome LUTS, who were referred for PAE, were screened for inclusion in this study. Patients underwent urodynamic evaluation before recruitment and after PAE. Additionally, patients underwent ultrasound assessments of the renal tracts and prostate volume, and were required to complete the International Prostate Symptom Score (IPSS) and Quality of Life questionnaire (QoL) at both baseline and two follow-up timepoints after PAE (7 and 18 months). Patients who had previously been treated with minimally invasive or surgical treatments for BPH, including TURP, were eligible for this study provided they met the criterion of severe LUTS and obstructive BPH. Although only a few patients had a history of TURP, they were included based on the severity of their current symptoms.

Inclusion and Exclusion Criteria

The study inclusion criteria were as follows: age 45–80 years; BPH with prostate volume >35 mL; medically refractory (>6 months) BPH with bothersome LUTS; unwillingness to continue taking medication for BPH due to side effects, inefficacy, or unsatisfactory outcomes; and unsuitability for, or unwillingness to undergo, surgical prostate resection following consultation with a urological surgeon and interventional radiologist.

Exclusion criteria were: prostate malignancy >Gleason 3 + 3 and requiring active treatment; neurogenic bladder; renal failure eGFR <35 mL/min; severe contrast allergy; history of severe peripheral vascular disease; and urethral or bladder pathology.

PAE Procedure

Patients recruited to this study underwent PAE performed by experienced interventional radiologists (N.B., D.W.) using the techniques previously described [10]. In summary, selective catheterisation of prostate arteries was carried out via the radial artery or brachial artery approach using a 135-cm Bern-tip 4-Fr Navicross® catheter (Terumo, Tokyo, Japan) with a coaxial 1.3-Fr 168-cm Headway Duo® microcatheter (Microvention, Alisa Viejo, CA, USA) and either a 0.036 cm (0.014) Chikai® wire (Asahi, Aichi, Japan) or a 0.041-cm (0.016) Radifocus Guidewire GT® (Terumo, Tokyo, Japan). Diluted 250-μm Embozene® microsphere (Varian, Palo Alto, CA,USA) embolics were injected, followed by intra-arterial Gelfoam (Pfizer, New York, NY, USA) or Spongistan (Ethicon, Raritan, NJ, USA) slurry to further block arterial inflow. Ciprofloxacin oral 500 mg was commenced twice daily for 7 days post-PAE. Other medications prescribed for all patients to take as required during the post-PAE recovery included oxybutynin 5 mg oral twice daily (or 3.9 mg/24 h topical patch), paracetamol 500 mg, a non-steroidal anti-inflammatory and a urinary alkalinizer.

Statistical Analysis

Descriptive data are summarised as mean (SD and range) for continuous variables and frequency (%) for categorical variables. The association between exposure and outcome variables was investigated using mixed effects regression, and effect estimates were reported as mean difference with 95% CIs and *P* values. The same analyses were performed on log-transformed outcomes and effect estimates were reported as percentage difference (95% CI; *P* value). In all models, the study period (pre- and post-treatment) was included as a fixed effect, and models were adjusted for repeated observations in the same participant. Spearman's rank correlation coefficients (denoted by the symbol r_s) were utilised for correlation analysis given the non-normal

distribution of the variables under investigation. Statistical analyses were conducted using Stata statistical software version 13.1 (StataCorp, College Station, TX, USA).

Results

Figure 1 illustrates the recruitment, intervention, and follow-up assessments for this study. Initially, 127 men with bothersome LUTS secondary to BPH who were referred for PAE were screened for potential inclusion in this study. Of these, 22 men were deemed ineligible for participation as they did not meet the study's inclusion criteria. A total of 105 eligible patients were recruited for the study with a median (interquartile range [IQR]; range) age of 69 (9; 48–89) years. All participants completed baseline assessments and underwent technically successful PAE.

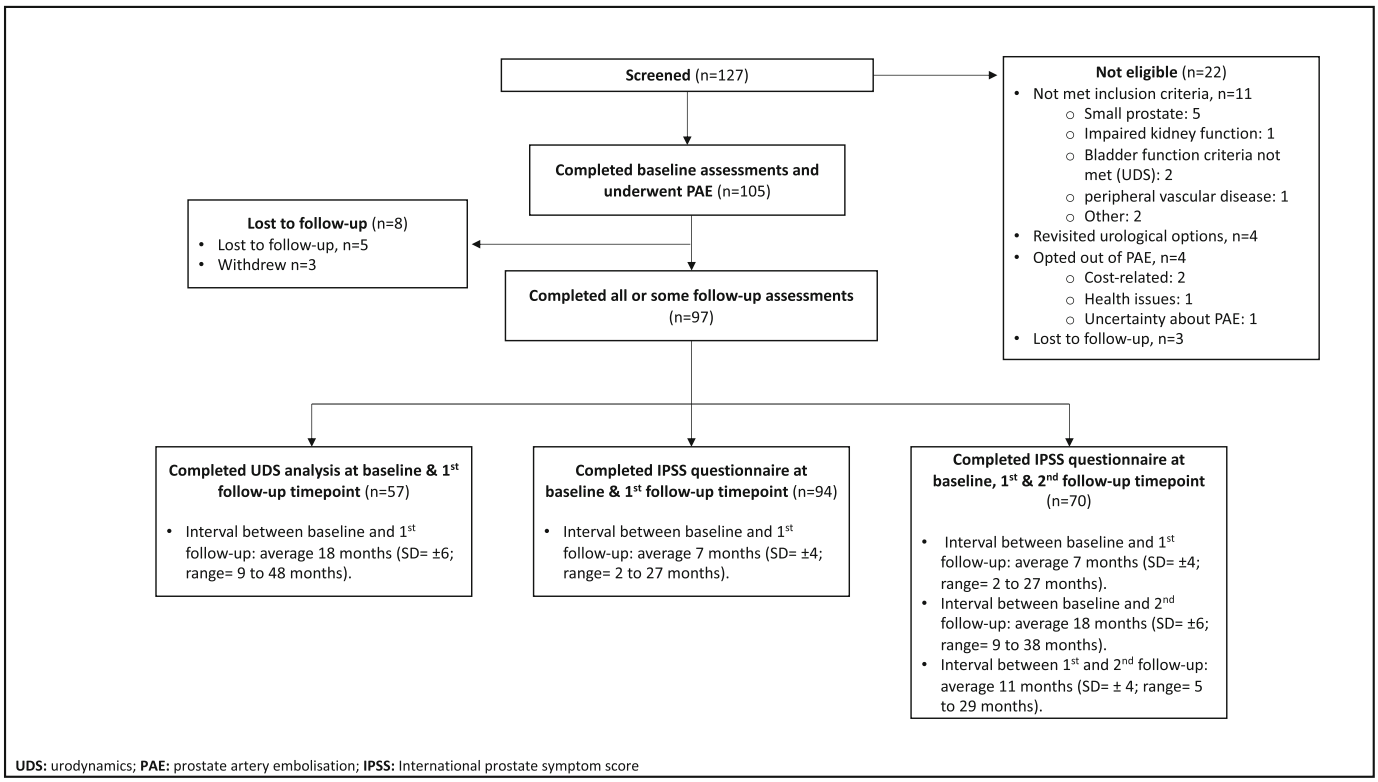
At baseline, the median (IQR; range) prostate volume was 77 (68; 34–237) mL. The median (IQR; range) total IPSS was 22 (9; 3–34), indicating a severe range of symptoms. The median (IQR; range) maximum urinary flow rate (Q_{max}) was 12 (7; 2–29) mL/s on uroflowmetry. The median (IQR; range) QoL score, based on the IPSS QoL assessment, was 4 (2; 0–6), indicating a status of 'mostly dissatisfied' (Table 1). PAE was technically successful in all patients. Bilateral PAE was ultimately achieved in 93/105 patients (88.6%), with eight of these (7.6%) requiring a repeat PAE to achieve bilateral treatment. Unilateral PAE was achieved in the remaining 12 patients (11.4%). PAE procedures used a mean (SD; range) of 46% (±22%; 9%–100%) of a single vial of 250-μm Embozene particles, with a mean (SD; range) fluoroscopy time of 62 (±21; 27–166) min and a mean (SD; range) total procedural time of 153 (±37; 70–255) min. The average radiation dose area product was 234 Gy/cm^2, which converts to an average effective dose of 25.7 mSv per procedure [11].

Table 1 Baseline characteristics of 105 patients who underwent prostate artery embolisation.

Variable	Intention to treat		Per protocol	
	n	Median (IQR); range	*n*	Median (IQR); range
Age of participants	105	69 (9); 48–89	97	69 (9); 52–86
Prostate volume, mL	105	77 (68); 34–237	97	78 (66); 35–237
IPSS total score*	101	22 (9); 3–34	96	22 (9); 3–34
QoL score*	100	4 (2); 0–6	95	5 (2); 0–6
Q_{max} (uroflow test)†	104	12 (7); 2–29	97	12 (8); 2–29

*IQR, interquartile range; QoL, Quality of Life questionnaire; Q_{max}, maximum urinary flow rate; *Not all participants completed every survey question. †Due to a malfunction of the uroflow meter on the assessment day, uroflow data were unavailable for one patient.*

Fig. 1 Study flowchart. PAE, prostate artery embolisation; UDS, urodynamic study.



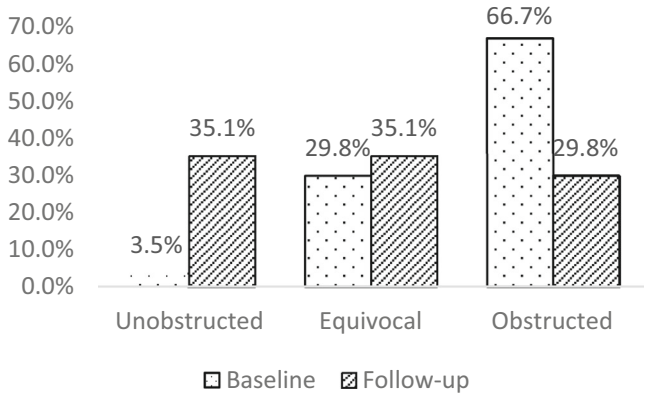
There were no available follow-up data for 8/105 patients. The reasons for this were as follows: five patients (4.8%) were lost to follow-up and three patients (2.8%) withdrew due to perceived lack of efficacy. The remaining 97 patients completed all or part of the follow-up assessments. The per-protocol analysis of these follow-up assessments focused on two primary areas: Urodynamic assessment and IPSS questionnaire analysis.

Urodynamic Assessment Outcomes

Of the 97 patients who attended for follow-up, 40 (41.2%) did not undergo repeat urodynamic studies for various reasons, including travel restrictions, refusal to undergo invasive testing and reluctance to travel long distances. The other 57 patients (58.8%) completed follow-up urodynamic assessments at a mean (SD; range) 18 (±6; 9–48) months post-PAE. At baseline (pre-PAE) these patients had a mean (SD; range) Q_{max} of 8.3 (±4.5; 2–20) mL/s, a total void volume of 352 (113.9; 115–665) mL, a post-void residual urine volume (PVR) of 91.2 (±68.2; 0–280) mL, and a detrusor pressure at maximum flow rate ($pdet_{Qmax}$) of 65 (±31.5; 23–191) cmH_2O (Table 2). Following PAE, significant urodynamic improvements were observed across all parameters during follow-up assessments (Table 2): Q_{max} increased from 8.3 to 13.3 mL/s ($P < 0.001$), PVR decreased from 91.2 to 69.1 mL ($P = 0.049$), and $pdet_{Qmax}$ decreased from 65.0 to 48.9 cmH_2O ($P < 0.001$).

Baseline urodynamic studies for this cohort revealed obstructed urodynamics in 38/57 patients (66.7%) or equivocal findings for 17/57 patients (29.8%; Fig. 2). Of these 57 patients, two (3.5%) had unobstructed bladders at baseline; however, the decision was made to proceed with PAE under the study protocol due to the severity of symptoms attributed to prostatomegaly after urologist consultations. Follow-up urodynamic studies showed that the number of unobstructed patients had reduced to 20/57 (35.1%), while 20/57 (35.1%) had equivocal findings and 17/57 (29.8%) remained obstructed. The proportion of patients with obstructed bladders more than halved after PAE, with 70.2% of the cohort demonstrating either unobstructed or equivocal urodynamics on follow-up (Fig. 2).

Fig. 2 Changes in overall urodynamic bladder status pre- and post-prostate artery embolisation, for patients who underwent both preliminary and follow-up urodynamic studies ($n = 57$), per protocol.



IPSS, QoL and Prostate Volume Outcomes

Of 97 patients, 94 (96.9%) completed first follow-up IPSS assessments at a mean (SD; range) of 7 (±4; 2–27) months post-PAE procedure. Significant improvements (P value <0.001) were identified across all assessed parameters (Table S1).

A total of 70/97 patients (72.2%) went on to complete additional IPSS follow-up at a mean (SD; range) of 18 (±6; 9–38) months post-PAE. Among these 70 patients, significant improvements in IPSS and QoL scores were maintained. At the first follow-up, the total IPSS score decreased by an average of 14 points (95% CI −16 to −12), representing a 63.8% improvement. This improvement was sustained at the second follow-up, with a mean decrease of 12 (56.4% reduction) points (95% CI −14 to −11) from baseline. The mean (SD; range) subjective QoL scores relating to urinary symptoms at baseline were 4.4 (±1.2; 0–6), indicating a status of 'mostly dissatisfied'. At the first post-PAE follow-up, the mean QoL score had improved to 1.2, indicating a 'pleased' response (mean difference −3.2, 95% CI −3.5 to −2.8; $P < 0.001$). This improvement persisted to the second follow-up, with a mean QoL score of 1.4 (mean difference = −2.9, 95% CI −3.3 to −2.6; $P < 0.001$). In addition to symptomatic improvements, there was a significant reduction in prostate

Table 2 Pre- and post-prostate artery embolisation urodynamic outcomes ($n = 57$).

Parameters	Baseline	First follow-up	Baseline vs first follow-up	
	Mean (SD); range	Mean (SD); range	Mean difference (95% CI)	*P* value
Q_{max}, mL/s	8.3 (4.5); 2–20	13.3 (7.7); 3–44.8	+5.0 (3.0 to 6.9)	<0.001
Total void volume, mL	352.0 (113.9); 115–665	380.1 (114.9); 130–688	+28.4 (5.3 to 51.4)	0.016
PVR, mL	91.2 (68.2); 0–280	69.1 (66.1); 0–250	−20.9 (−41.7 to −0.12)	0.049
$pdet_{Qmax}$, cmH_2O	65.0 (31.5); 23–191	48.9 (26.3); 6–120	−16.1 (−24.4 to −7.8)	<0.001

$pdet_{Qmax}$, detrusor pressure at maximum flow rate; PVR, postvoid residual urine volume; Q_{max}, maximum urinary flow rate.

volume following PAE. At the first follow-up, the mean prostate volume had decreased by 28.1%, or 25 mL (95% CI −30 to −20), and by the second follow-up, it had decreased from baseline by 30.1%, or 28 mL (95% CI −33 to −23), with both reductions being statistically significant ($P < 0.001$).

There was a significant correlation between the absolute amount of embolic material used during the PAE procedures and improvements in both total IPSS ($r_s = -0.245$; $P = 0.04$) and QoL scores ($r_s = -0.271$; $P = 0.02$) at the second follow-up timepoint, independent of the baseline prostate volume. In addition, reductions in prostate volume significantly correlated to improvements in both IPSS ($r_s = 0.320$; $P = 0.009$) and QoL scores ($r_s = 0.330$; $P = 0.007$) at this follow-up timepoint. However, there was no significant correlation between the starting prostate volume and these outcome measures ($P = 0.34$ and $P = 0.07$, respectively), suggesting that initial prostate volume was less predictive of improvements in symptom scores and QoL following PAE than the total amount of embolic material injected.

Post-PAE Side Effects and Satisfaction Outcomes

Patient-reported side effects and satisfaction outcomes collected within 4 weeks post-PAE are summarised in Table 3. The median (IQR; range) time until the resolution of expected post-PAE pain/discomfort was 6 (6; 1–28) days. Post-embolisation urinary frequency/urgency (84%) and dysuria (75%) were the most common temporary symptoms, while new dry ejaculation was the least reported side effect (2.1%). PAE was well tolerated, with the majority of patients reporting satisfaction with procedure length (97%), side effects (80%), duration of hospital admission (94%), overall relief of symptoms and improvement in QoL score (87%). There were no episodes of incontinence reported post-PAE.

Although 94% of patients reported satisfaction with the initial urodynamic procedure at baseline, 40 patients (41.2%) declined to undergo invasive urodynamic follow-up testing. A sub-analysis of the changes in IPSS, QoL score and prostate volume for the group of patients who did not undergo follow-up urodynamic studies was not significantly different from those who did undergo urodynamic studies. The average IPSS score for these patients decreased by 56.8% (13 points) at the first follow-up and by 60.9% (15 points) at the second follow-up from baseline. The average QoL score for patients who did not undergo urodynamic studies improved from 4.6 at baseline to 1.8 at the first follow-up and to 1.6 at the second follow-up. The prostate volume was on average reduced by 29.3% (average = −26.3 mL) at the first follow-up and by 30.5% (average = −27.4 mL) at the second follow-up compared to baseline, which is nearly identical to those who did undergo follow-up urodynamic studies (data not presented in Tables). These results are consistent with the overall findings presented in Table 4 and Table S1.

Discussion

Prostate artery embolisation has emerged as a viable non-surgical treatment option for obstructive BPH that is included in several national clinical guidelines and consensus statements [12–14]. By incorporating formal urodynamic assessments, the current study adds to the growing evidence supporting the effectiveness of PAE in providing non-surgical relief from urinary obstruction and symptomatic improvement from BPH. PAE resulted in significant improvements in patient-reported IPSS and QoL assessments and a decrease in prostate volumes consistent with earlier studies. However, the current study provides objective urodynamic confirmation of improvements at a longer-term average follow-up of 18 months post-treatment.

Table 3 Post-prostate artery embolisation (PAE) prostate volume, IPSS and Quality of Life questionnaire outcomes: a comparison at two follow-up points with pre-PAE ($n = 70$).

Parameter	Baseline	First follow-up	Second follow-up	First follow-up vs baseline		Second follow-up vs baseline		Second vs first follow-up	
	Mean (±SD); range	Mean (±SD); range	Mean (±SD); range	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value
Prostate volume, mL	91.4 (43.4); 35–237	65.7 (30.3); 21–215	63.9 (30.2); 20–195	−25 (−30 to −20)	**<0.001**	−28 (−33 to −23)	**<0.001**	−3.1 (−8.2 to 2.0)	0.230
IPSS questionnaire scores									
Incomplete emptying	3.4 (1.6); 0–5	1.0 (1.3); 0–5	1.4 (1.4); 0–5	−2.4 (−2.8 to −2.0)	**<0.001**	−2.0 (−2.4 to −1.6)	**<0.001**	0.4 (−0.0 to 0.8)	0.054
Frequency	3.6 (1.3); 0–5	1.5 (1.2); 0–4	1.7 (1.3); 0–5	−2.1 (−2.5 to −1.7)	**<0.001**	−1.9 (−2.2 to −1.5)	**<0.001**	0.2 (−0.1 to 0.6)	0.239
Intermittency	3.1 (1.6); 0–5	0.9 (1.3); 0–5	1.3 (1.5); 0–5	−2.2 (−2.6 to −1.8)	**<0.001**	−1.8 (−2.2 to −1.4)	**<0.001**	0.4 (−0.0 to 0.8)	0.056
Urgency	3.0 (1.6); 0–5	1.1 (1.3); 0–5	1.4 (1.4); 0–5	−1.9 (−2.3 to −1.4)	**<0.001**	−1.5 (−2.0 to −1.1)	**<0.001**	0.3 (−0.1 to 0.8)	0.138
Weak stream	3.7 (1.4); 0–5	1.2 (1.3); 0–5	1.5 (1.4); 0–5	−2.4 (−2.8 to −2.1)	**<0.001**	−2.2 (−2.6 to −1.8)	**<0.001**	0.2 (−0.2 to 0.6)	0.253
Straining	2.1 (1.7); 0–5	0.5 (0.8) 0–3	0.5 (0.9); 0–4	−1.6 (−2.0 to −1.2)	**<0.001**	−1.6 (−2.0 to −1.2)	**<0.001**	−0.03 (−0.4 to 0.3)	0.875
Nocturia	3.0 (1.2); 0–5	1.7 (1.1); 0–4	1.7 (1.1); 0–5	−1.3 (−1.6 to −1.0)	**<0.001**	−1.3 (−1.5 to −1.0)	**<0.001**	0.03 (−0.3 to 0.3)	0.846
IPSS total score	21.8 (6.9); 3–34	7.9 (5.7); 0–28	9.5 (6.2); 0–25	−14 (−16 to −12)	**<0.001**	−12 (−14 to −11)	**<0.001**	1.6 (−0.2 to 3.3)	0.081
QoL score	4.4 (1.2); 0–6	1.2 (1.2); 0–5	1.4 (1.2); 0–4	−3.2 (−3.5 to −2.8)	**<0.001**	−2.9 (−3.3 to −2.6)	**<0.001**	0.2 (−0.1 to 0.6)	0.245

Bold indicates significant P value. QoL, Quality of Life questionnaire.

Table 4 Post-prostate artery embolisation patient-reported side effects and satisfaction outcomes.

Variable	*n*	Outcomes	
Side effects		**Median (IQR); range**	**Frequency, %**
Pain/discomfort scale following PAE (scale: 0–10)	81*	7 (3); 0–10	–
No. of days postoperatively that the pain was experienced by patients	78*	6 (6); 1–28	–
Increased frequency/urgency	81*	–	84
Painful urination	81*	–	75
Pain/discomfort in rectal area	81*	–	52
Pain in prostate region	81*	–	49
Pain in penile tip	81*	–	26
Blood in urine	81*	–	25
Blood in semen	81*	–	17
Fever	81*	–	11
Nausea	81*	–	7
New dry ejaculation	81*	–	2
Medication		**Ceased, %**	**N/A, %**	**Continued, %**
	78*	28	47	25
Patient satisfaction outcomes		**Satisfied, %**	**Neutral, %**	**Dissatisfied, %**
Length of procedure	79*	97	3	0
Procedure side effects	81*	80	11	9
Duration of hospital admission	81*	94	3	3
Relief of symptoms/ improvement in QoL score	78*	87	10	3
Urodynamic procedure	78*	94	3	3

*IQR, interquartile range; N/A, not available; PAE, prostate artery embolization; QoL, Quality of Life questionnaire. *Not all participants completed every survey question.*

Few studies investigating PAE efficacy have incorporated invasive urodynamic studies to formally quantify urinary obstruction and bladder contractility post-PAE, despite these being used to assess the clinical impact of a wide range of other BPH treatments [15–17]. Whilst PVR and Q_{max} are easy clinic-based surrogates, formal assessment of urodynamics is the gold standard for assessing bladder function and outflow obstruction. Importantly, the urodynamic outcomes in this study parallel the non-invasive results in both this study and prior publications [9].

Durable and significant reductions in mean prostate volume were demonstrated at both the first (−25 mL, 28% reduction) and second (−28 cc, 30% reduction) follow-up time points. The baseline prostate volumes for these patients ranged between 35 and 237 mL, while the final follow-up prostate volumes ranged from 20 mL to 195 mL. Baseline prostate volume is an important consideration in deciding on the treatment option for BPH. Although no upper size limit has been established for PAE, and studies have shown its safety in larger prostates >100 mL [18], guidelines generally remain conservative. Techniques such as open or robot-assisted laparoscopic enucleation prostatectomy are generally recommended for larger prostates. Recently, other techniques, such as holmium laser enucleation of the prostate (HoLEP), a size-independent procedure, have been added to the treatment options for BPH [19], but have been associated with increased rates of early and late-stage complications, such as urge incontinence [20,21]. PAE as a preoperative technique to downstage prostate volume, in both benign and malignant settings, has also been performed successfully at our institution.

Mixed findings have been reported in the literature regarding correlations between baseline prostate volume and PAE outcomes. For example, Maclean et al. [20] found a significant association between initial prostate volume and post-PAE clinical improvements (change in IPSS). In contrast, Bagla et al. [22] reported that the intermediate-term clinical success of PAE was independent of prostate volume. In the current study, while significant changes in prostate volume, IPSS and QoL scores significantly correlated with the amount of embolic material injected ($P = 0.04$ and $P = 0.02$, respectively), there was no significant association between the changes in these variables and the baseline prostate volume ($P = 0.34$ and $P = 0.07$, respectively) at the second follow-up timepoint. This suggests that the initial prostate volume may be less influential in determining the clinical success of a PAE, and that a positive outcome may be more dependent on the total amount of embolic material injected, which in this study was a mean of 47% of a single vial of 250-μm Embozene particles.

Transient increases in urinary frequency, urinary urgency and dysuria are expected post-embolisation symptoms, and these were the most commonly reported temporary symptoms after PAE in this study. Whilst sexual adverse effects are known to be a common side effect of TURP, sexual side effects, such as new dry ejaculation, were the least frequently reported symptom after PAE in this study, reported in only in 2/81 patients (2%) who completed the side effects section of the post-PAE questionnaire. A recent systematic review and meta-analysis has also identified a lower risk of erectile and ejaculatory disorders compared to TURP or open simple enucleative prostatectomy [23]. Transient haematuria after PAE occurred in 25% of patients, however, these all resolved spontaneously and did not require bladder irrigation or catheterisation to resolve. Unlike surgical techniques [24], PAE can be performed without ceasing anticoagulation, and techniques such as radial artery access may allow minimally

invasive treatments such as PAE without needing to cease anticoagulation in patients at high risk for thromboembolism.

The rapid resolution of post-PAE side effects, within 7 days, combined with the low incidence of retrograde ejaculation and no episodes of urinary incontinence, suggests that PAE could be a preferred option for men to consider prior to long-term medical therapy [8,9] or surgical treatments, such as TURP [13]. Overall, patients in this study reported high satisfaction levels after PAE, including procedure duration, length of hospitalisation, symptom relief and side effects. These positive outcomes, along with significant urodynamic improvements in bladder function and urinary symptom scores, support the use of PAE as an effective treatment option for BPH.

The most common surgical procedure for treatment of patients with obstructive LUTS is still TURP. The revision rate for TURP at 5-year follow-up is only 10.3%, similar to transurethral incision of the prostate (13.6%) and photo-selective vaporisation of the prostate (11.6%) [25]. While PAE and TURP may have similar efficacy for relieving LUTS and improving QoL scores [26], PAE is known to be associated with earlier symptom recurrence, and longer-term follow-up is required after PAE. A different clinical perspective would be to compare the outcomes of PAE patients to those of patients treated with medical therapy. A recent randomised controlled trial identified that PAE was more effective than combined medical therapy at reducing urodynamic urinary obstruction, decreasing prostate volume and improving LUTS in patients with BPH who had not previously been treated [9].

The absence of standardised questionnaires, such as the International Index of Erectile Function (IIEF), for recording potential sexual dysfunction limits the ability for comparisons to be made to other studies. However, this choice was informed by prior experiences, where use of the IIEF resulted in low compliance, as many participants were reluctant or found it uncomfortable to answer. Instead, qualitative patient self-reported sexual questionnaires of erectile and ejaculate change were used for this study to record outcomes. While this approach achieved good compliance and captured relevant outcomes, it lacks the standardisation of established tools and may impact comparability with other studies.

Another limitation of this study is the number of patients who were lost to urodynamic follow-up; 41% of participants (40/97) did not undergo follow-up urodynamic testing. The specific reasons were not recorded in this study, however, they included a mix of random and non-random factors. General feedback indicated several contributing factors to patients refusing follow-up, including travel restrictions due to the COVID-19 pandemic that prevented patients from attending scheduled follow-up appointments, refusal to undergo repeat invasive urodynamic testing, and a reluctance to travel long distances to complete follow-up once effective treatment had been administered. Although non-invasive follow-up involving IPSS, QoL scores, ultrasound assessment and uroflowmetry was performed in many of these patients to maximise the internal validity of results, and those results in the non-urodynamic follow-up assessment group were found to be similar to those who did undergo urodynamic assessment at their follow-up, the high rate of non-urodynamic follow-up assessment may have introduced an effect bias. Future studies incorporating urodynamic follow-up assessments are planned to maximise retention and minimise losses to follow-up.

In conclusion, PAE significantly improved bladder function as assessed by formal urodynamic studies, reduced IPSS; improved QoL scores, and had no significant durable side effects. Urodynamic studies demonstrated a significant reduction in the rate of bladder obstruction after PAE. This study contributes unique, functional urodynamic objective data supporting the use of PAE in the non-surgical management of obstructive LUTS caused by BPH.

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Disclosure of Interests

The authors have no disclosures.

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Abbreviations: IIEF, International Index of Erectile Function; IQR, interquartile range; PAE, prostate artery embolisation; $pdet_{Qmax}$, detrusor pressure at maximum flow rate; PVR, postvoid residual urine volume; Q_{max}, maximum urinary flow rate; QoL, Quality of Life questionnaire.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Pre- and post-PAE outcomes at the first follow-up timepoint (n = 94), IPSS questionnaires completed on average 7 months post-PAE (SD = ±4; range = 2–27 months).

