

Prostate artery Embolisation Assessment of Safety and feasibility (P-EASY): a potential alternative to long-term medical therapy for benign prostate hyperplasia

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Objectives

To assess the safety, short-term efficacy and early functional results of prostate artery embolisation (PAE), an emerging minimally invasive treatment for symptomatic benign prostate hyperplasia (BPH).

Patients and methods

In all, 51 men with BPH (prostate size >40 mL) causing moderate–severe lower urinary tract symptoms, who had either failed or ceased medical therapy and had declined or were considered unsuitable for surgical intervention, were recruited to this study. All men underwent baseline clinical assessment, PAE, and 3-month follow-up. The primary endpoints of this study were safety and feasibility. Safety was measured by the incidence of post-PAE adverse events and feasibility was defined by technical success. Secondary endpoints were changes in the International Prostate Symptom Score (IPSS) and quality of life (QoL) score at 3 months after PAE.

Results

There were no serious adverse events and all procedures were technically successful. For non-

catheterised patients, improvement in IPSS and QoL was reported in 95.1% of cases ($P < 0.001$). The mean reductions in IPSS and QoL were 18.8 points (80.7%) ($P < 0.001$) and 3.8 points (80.6%) ($P < 0.001$), respectively. Of the 30 non-indwelling-catheter-dependent men on medical therapy, 23 men were able to completely cease all medications, with all but one of the remaining men reporting significant improvements in IPSS and QoL score.

Conclusion

PAE is a technically feasible and safe procedure, with excellent short-term efficacy. High rates of patient satisfaction were achieved in this study, along with significant reductions in prostate symptoms and improvements in QoL. PAE may be an alternative to long-term use of medical therapy for symptoms due to BPH.

Keywords

benign prostate hyperplasia, prostate artery embolisation, minimally invasive, #UroBPH

Introduction

BPH is a common cause of LUTS [1]. BPH often presents as a range of LUTS that can include: nocturia, urgency, hesitancy, weak or interrupted urinary stream, and post-urination dribble [2]. Age is the greatest risk factor for BPH-related LUTS with an incidence of 33.6% in Australian men aged 60–69 years, increasing to 46% between the ages of 70 and 80 years [3]. For men with moderate–severe LUTS, a significantly decreased quality of life (QoL) is often reported [1].

The primary goals of BPH therapy are to reduce LUTS, improve QoL, and prevent disease progression. Standard treatment pathways involve sequential step-up medical

therapy before consideration of surgical intervention, usually TURP [4]. TURP remains the long-term ‘gold standard’ treatment for BPH, with established durability exceeding 10 years and superior improvements in maximum urinary flow rate (Q_{max}) compared to other surgical interventions [5].

Prostate artery embolisation (PAE) is an emerging minimally invasive treatment for symptomatic BPH. PAE is an interventional radiology procedure that involves blocking the prostate arteries with microspheres to atrophy and soften the central gland, thereby relieving pressure on the urethra and bladder.

PAE was initially used to treat intractable prostatic bleeding [6]. Early cases demonstrated resolution of haematuria after

selective embolisation of the prostatic arteries, along with incidental clinical improvement in LUTS and reductions in prostate volumes of up to 62% at 12-month follow-up [7]. Further animal studies showed that PAE was effective at reducing prostate volume without compromising erectile or sexual function [8,9].

Human studies have since confirmed that PAE is a safe procedure with demonstrable improvements in LUTS, QoL, prostate volume, and Q_{max} associated with a decreased post-void residual urine volume (PVR) [10–15]. Clinical success rates, defined by the capacity of PAE to reduce patient LUTS and restore QoL, have consistently been reported at ~90% after 12 months with rates of serious complications of <0.3% [11,13–15]. The largest cohort published to date comprised 630 patients with clinical success in 81.9% at 3 years and 76.1% at 6.5 years [13].

Interventional radiologists who treat prostate enlargement must possess not only high-level procedural skills but also develop broad clinical knowledge of BPH, LUTS and its treatment. Because of the complex treatments that exist for BPH, it is appropriate that urologists remain the primary health provider responsible for decisions on management of BPH. Further, radiologists and urologists need to be accountable and responsible for scrutiny and interpretation of data collection for studies that are aimed at improving patient outcomes, particularly in research partnerships with co-specialties [16]. Therefore, in collaboration between urologists and radiologists the Prostate artery Embolisation Assessment of Safety and feasibility (P-EASY) study was commenced in 2015 to assess the safety and feasibility of PAE. It also evaluated patient QoL, satisfaction, and functional improvements at 3 months after PAE.

Patients and methods

Patient work-up

The patient inclusion criteria are outlined in Table 1. All patients were referred by urologists or directly from GPs. All men referred by a GP required a urological review to confirm

their suitability for enrolment in this study. Urological evaluation included: urinary tract ultrasonography, PSA level measurement, urine microscopy, prostate multiparametric 3-T MRI to screen for malignancy, and uroflow studies. Men with suspected prostate cancer, normal uroflow studies or a prostate volume of <40 mL were excluded from this study. Men had either failed or were unable to tolerate medical therapy. After consultation with a urologist, a TURP or other endoscopic urological procedure, including greenlight laser or UroLift® (Neotract Inc., Pleasanton, CA, USA) procedures, were either declined by the patients or considered high risk due to medical comorbidities, physician concerns regarding cessation of anticoagulants in the event of intraoperative or postoperative bleeding, or for technical reasons such as a very large prostate.

Interventional radiologist evaluation included a CT angiogram of the pelvis to assess prostate artery anatomy and extent of any atherosclerotic disease. Prostate volumes were assessed by CT scan measurements using the formula: height × width × depth × 0.53. MRI and ultrasonography measurements corroborated these results. Patients were also required to complete the IPSS questionnaire. The IPSS is a validated urological tool for assessing symptom severity, and is derived from an eight-question assessment of patient LUTS and QoL.

PAE procedure

PAE procedures were performed between November 2015 and February 2017 by two experienced interventional radiologists, with extensive experience in embolisation procedures, and who had completed local and overseas training courses in PAE, including proctoring by experienced PAE operators.

Patients received ciprofloxacin before (500 mg, i.v.) and after the procedure for 7 days (400 mg twice daily, oral). Paracetamol (1 g, i.v.), heparin (5000 units, intra-arterial) and glyceryl trinitrate (100 µg, intra-arterial) were administered at the beginning of the procedure. Repeat doses of glyceryl trinitrate were given if required for vasodilation, up to a maximum dose of 400 µg throughout the procedure. A 100 mg diclofenac suppository was administered after the procedure, and a second NSAID (400 mg ibuprofen, oral) was recommended every 8 h as required, for up to 7 days.

PAE procedures were performed with a right femoral, left brachial, or left radial artery approach, using 4- or 5-F sheaths or slender sheaths (Terumo Medical Corporation, Somerset, NJ, USA). A 5-F 125-cm Impulse (Merit Medical, South Jordan, UT, USA), 4-F 120-cm Cobra Glidcath (Terumo), 4-F 150-cm Navicross (Terumo) or RIM shaped catheters were combined with either 150- or 180-cm glidewires (Terumo) to access the internal iliac arteries,

Table 1 Inclusion and exclusion criteria for the P-EASY trial.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Patients diagnosed by a urologist with BPH causing LUTS • Enlarged prostate >40 mL • Medically refractory LUTS, or patient not tolerating medication • Moderate–severe LUTS (IPSS >8) • Q_{max} <12 mL/s • Patient declines or unsuitable/high-risk for TURP 	<ul style="list-style-type: none"> • Prostate malignancy • Neurogenic bladder/other cause of LUTS • Severe peripheral vascular disease • Severe contrast allergy • Severe renal impairment (eGFR <30 mL/min/1.73 m²)

eGFR, estimated GFR.

depending on the approach used. A 2.0-F 150-cm Progreat (Terumo), 1.7-F 150-cm SL-10 (Stryker, Kalamazoo, MI, USA) or 1.3-F 167-cm Headway Duo were used to selectively catheterise the prostate arteries over microwires, either 0.041 cm (0.016 ") Radifocus Guidewire GT (Terumo) or 0.036 cm (0.014 ") Synchro Soft (Stryker). Angiographic navigation software (Syngo 3D Roadmap; Siemens, Berlin, Germany) guided selective catheterisation of the pelvic arteries without the need for contrast injection or additional acquisitions. After selective catheterisation of the prostate arteries and positioning of the microcatheter tip within the distal prostate artery, an on-table cone-beam CT scan using hand-injected 1–2 mL contrast (Ultravist 300; Bayer, Leverkusen, Germany) in a 3 mL Medallion syringe (Merit Medical) was performed and reviewed in three planes to assess for non-prostatic enhancement. Once the operators were confident that no off-target enhancement was evident, a single pre-loaded syringe of 250 μ m Embozene[®] particles (Boston Scientific, Marlborough, MA, USA) was prepared with serial dilution in contrast to a concentration of 1/16 (6.25%) of the initial concentration. Embolisation was then performed by slowly injecting the diluted particles until complete stasis of the prostate artery had been achieved.

The first 15 patients in the study were admitted to hospital for precautionary overnight observation after the procedure. Subsequent procedures were conducted as day cases, with patients discharged after 4–6 h of observation. Indwelling urinary catheters (IDCs) were initially used in seven patients, as a precaution against development of acute urinary retention secondary to prostate inflammation. However, this practice was discontinued, as the clinical risk of acute urinary obstruction was considered low and the IDC exacerbated patient discomfort and dysuria.

Patient follow-up and study endpoints

An internal post-PAE questionnaire was developed to assess procedural side-effects and pain (scale of 0–10), as well as patient satisfaction in relation to the duration of the procedure, duration of admission, and overall clinical improvements (Fig. 1). Follow-up questionnaires (IPSS and post-PAE questionnaires) were administered at 1, 2, and 4 weeks, and 3 months after PAE. Prostate volume, PVR and Q_{\max} were re-assessed at 3 months. The IPSS and QoL scores were also recorded, if possible, at 12 months after PAE.

The primary endpoints of this study were safety and feasibility at 3 months after PAE. Safety was measured by the incidence of post-procedure adverse events. Adverse events were scored using the Clavien–Dindo classification of postoperative complications [17]. Feasibility was defined as technical success, meaning complete embolisation of the arteries to at least one side of the prostate.

The secondary endpoint of this study analysed the reduction in the IPSS and QoL score at 3 months after PAE, using paired *t*-tests.

Ethics approval

The study was approved by the Uniting Care Health Human Research Ethics Committee (reference, 1520). Informed consent was obtained from all participants.

Results

In all, 55 patients were referred for enrolment in this study, and 51 underwent PAE procedures between November 2015 and February 2017. Three patients were excluded during evaluation due to the presence of bladder calculi (one) or incidental findings of prostate malignancy (two), and one patient withdrew before treatment. The mean (median, range) patient age was 67.8 (67, 55–95) years, with a mean (median, range) prostate volume of 113 (97.5, 40–290) mL. The IPSS was in the 'severe' range, with a mean (median, range) score of 23.1 (23, 10–30) for non-catheterised men. Indications for inclusion were LUTS (40 patients), intractable haematuria with LUTS (one), and catheter-dependent urinary retention (10). One patient had persistent LUTS despite two previous surgical UroLift procedures. All other patients had no previous surgical interventions for the relief of LUTS before PAE.

Safety and efficacy (primary endpoints)

In all, 47 men had bilateral embolisations, and four had unilateral embolisations. Four men underwent repeat procedures; two because of initial unilateral embolisations due to tortuous arteries; one because of a complete failure to respond clinically at 3 months after PAE; and one because of a delayed recurrence of previously intractable haematuria 7 months after PAE.

All post-PAE side-effects were classified as Clavien–Dindo grade I. Puncture site haematomas were reported in six men (11.8%), which were managed with ice packs and all completely resolved within 4 weeks. Other post-procedure side-effects included dysuria (84.3%), perineal/perianal pain (25.5%), transient increased urinary frequency (54.9%), transient haematuria (11.8%), haemospermia (11.8%), low-grade fever or night sweats (9.8%), and nausea (2.0%). Five men (9.8%) described dry or reduced ejaculate volume after PAE. Four of these cases were new and returned to normal levels by 6 months after PAE. The remaining case was a pre-existing side-effect of medication and did not resolve completely during the follow-up period. Two unexpected Clavien–Dindo grade I events occurred: one case of mild, unilateral medial gluteal irritation, and one case of transient

Fig. 1 The P-EASY post-PAE questionnaire to assess procedural side-effects, pain, and satisfaction.PEASY Study – Follow-up Lower Urinary Tract Symptoms Questionnaire

1. Full name: _____

2. Date of birth: _____

3. Today's date: _____ Date of prostate treatment: _____

4. Have you had your catheter removed since your treatment? Yes / No

If yes, when was your catheter removed? (DD/MM/YY) _____

Did you have any urinary incontinence or retention? Yes / No

5. Did you return to normal daily activities after your treatment? Yes / No

If yes, how long after your treatment did it take? If no, why?

6. Do you have any prostate / treatment related pain? Yes / No
Please rate on a scale of 1 – 10 (1 = minimal, 10 = severe)

1	2	3	4	5	6	7	8	9	10
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How long have you had prostate / treatment related pain?

7. Have you had complications / symptoms since your prostate treatment?

Blood in urine?	Yes / No
Blood in semen?	Yes / No
Dry orgasm?	Yes / No
Fever?	Yes / No
Nausea?	Yes / No
Other?	_____

8. Overall, how satisfied are you with your prostate treatment?

Length of procedure	Satisfied	Neutral	Dissatisfied
Procedure side-effects	Satisfied	Neutral	Dissatisfied
Duration of hospital admission	Satisfied	Neutral	Dissatisfied
Relief of symptoms/Quality of life	Satisfied	Neutral	Dissatisfied

rectal haemorrhagic spotting. Both resolved completely without the need for further treatment and were presumed to represent minor off-target embolisation via collaterals.

Post-procedural pain showed complete resolution at a mean of 7.9 days after PAE. The mean (range) pain severity was 4.8/10 (0–10/10) at 1 week after PAE, and 1.1/10 (0–7/10) at

2 weeks. Two men had mild pain beyond 2 weeks, which resolved completely by 4 weeks after PAE.

IPSS and QoL improvements (secondary endpoints)

For non-catheterised men, a reduction in the IPSS of >50% or a reduction in QoL score of >2 points was reported in 95.1% of cases ($P < 0.001$). The IPSS in these patients reduced by a mean of 18.8 points ($P < 0.001$), from 23.1 to 4.3 points (range 0–23) at 3 months (Table 2, Fig. 2). The QoL scores reduced by a mean of 3.8 points ($P < 0.001$), from 4.7 to 0.9 (range 0–5) at 3 months. Follow-up data were available at 12 months for 19 men, and the mean IPSS and QoL scores had risen slightly to 7.3 points (IPSS range 0–17) and 1.7 points (QoL range 0–5), respectively ($P = 0.001$). Five out of the 51 men underwent uncomplicated TURP procedures within 18 months of PAE.

Additional findings

In the 10 men who presented with catheter-dependent urinary retention and refused or were not considered suitable for surgical intervention, seven (70%) had a successful trial-of-void after catheter removal by 6-weeks post-PAE (range 2–6 weeks).

The mean (median, range) rate of nocturia reduced from 3.1 (3.5, 1–5) episodes/night to 1.0 (1.0, 0–4) episodes/night after PAE ($P < 0.001$). The majority of men (71.8%) reported rising ≤ 1 time per night to urinate after the PAE procedure.

Prostate volumes decreased by a mean of 37 mL, representing a reduction of 32.3% ($P < 0.001$) (Fig. 3). The PVR reduced by 25.9% from a mean of 159 to 117 mL (range 6–700, median 77.5 mL) ($P = 0.018$). The Q_{\max} values increased by a mean of 2.1 to 11.1 mL/s (range 3.8–28.2, median 13.7 mL/s) at 3 months after PAE, representing an improvement of 23.5% ($P = 0.035$).

Medical therapy for LUTS, which included α -blockers and 5 α -reductase inhibitors, was ceased completely within 3 months of PAE by 24 of the 31 men (77.4%) who had been taking medication. The IPSS for those men who remained on some form of medication for their LUTS after PAE still

showed significant improvements after PAE, with a mean 14-point drop in IPSS, a 2.3 point improvement in QoL, a 25% reduction in prostate volume, and decreased nocturia from 2.7 to 0.9 episodes/night.

Procedural time decreased from a mean of 200 min for the first five cases to 120 min for the last five cases. Radiation doses also decreased, falling from a mean of 3.2 Gy total skin dose for the first five cases to 0.8 Gy for the final five cases (equivalent to three CT IVUs). All cases involved image acquisition of the pelvis in multiple C-arm positions and no deterministic skin effects were observed for any patient at follow-up. Dose reductions were aided by increased operator proficiency and utilisation of angiographic navigation software.

Discussion

The wide variation in patient samples between PAE studies, paucity of high level evidence, and the broad definition of success, remain an issue that detracts from the body of evidence on PAE and must be overcome before solid conclusions can be drawn on this procedure [18].

The significant reduction in LUTS and improved QoL seen in the present study highlight the potential role of PAE in the treatment of BPH in men not considered suitable for surgical treatment or who fail to respond to medical therapy. It is acknowledged that some men on anticoagulants may undergo a successful surgical procedure with greenlight laser without ceasing anticoagulants [19]; however, the men in our present cohort were considered at high risk by their physicians if anticoagulants needed to be ceased in the postoperative period for unexpected bleeding.

Our present study cohort had significant LUTS or urinary retention despite medical therapy. As a minimally invasive treatment option with few side-effects, the results of our present study indicate that PAE may eventually be incorporated into treatment algorithms for BPH and considered as an alternative to long-term medical therapy of LUTS. Importantly, PAE preserves all future surgical treatment options for BPH. In multiple overseas studies, small numbers of patients with recurrent LUTS after PAE have

Table 2 Summary of outcomes for the P-EASY participants.

Variable	Mean (range) values before PAE	Mean (range) values at 3 months after PAE	Mean % change	P
Prostate volume, mL	113 (40–290)	77 (25–185)	–32.3	<0.001
IPSS	23.1 (10–30)	4.3 (0–23)	–80.7	<0.001
QoL score	4.7 (2–6)	0.9 (0–5)	–80.6	<0.001
Q_{\max} , mL/s	9.0 (3.3–18.3)	11.1 (3.8–28.2)	+23.5	0.035
PVR, mL	159 (9–700)	117 (6–700)	–25.9	0.018
Nocturia, episodes/night	3.1 (1–5)	1.0 (0–4)	–66.7	<0.001

Fig. 2 The mean IPSS (a) and QoL scores (b) of P-EASY participants measured at baseline and post-PAE follow-up time points of 1, 2, and 4 weeks, and 3 months, with standard error bars shown.

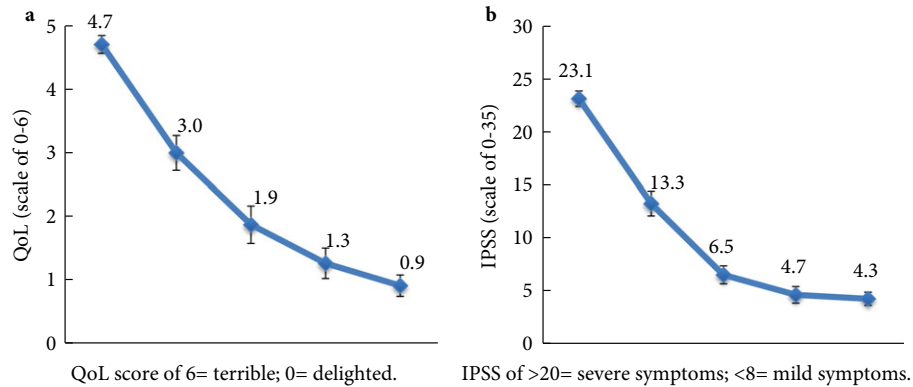
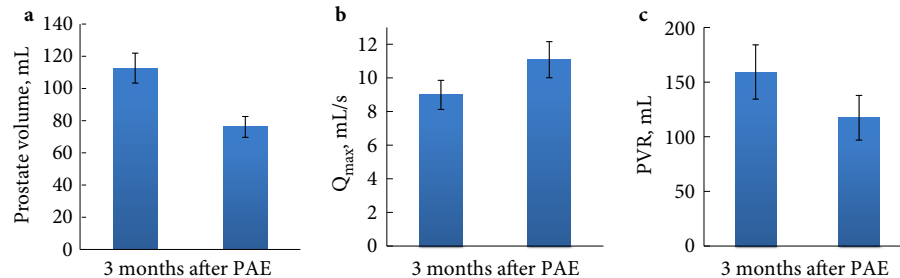


Fig. 3 The mean prostate volume (a), Q_{max} (b) and PVR (c) of P-EASY participants measured at baseline and at conclusion of the trial at 3 months after PAE. Standard error bars shown.



been treated successfully with either a repeat PAE or TURP [13,20].

PAE has some advantages to existing treatments for BPH. PAE offers early improvement of urinary symptoms, usually within 2 weeks for non-catheter-dependent men, with very low rates of complications. The procedure can be performed as a day-case without general anaesthetic, and there is no routine requirement for inserting an IDC. Post-PAE side-effects, whilst common, are typically minor and resolve within 1–2 weeks. These side-effects are attributed to transient post-embolic inflammation of the prostate and urethra. The mean time to side-effect resolution for the present study was 7.9 days, with a mean pain score of <5/10 in the first week after PAE. PAE is not associated with incontinence or erectile dysfunction and retrograde ejaculation is uncommon. Furthermore, studies have shown that PAE may improve erectile function for some men, most likely by allowing for the withdrawal of medical therapy [12,13].

Regarding the primary endpoint of the present study, the absence of major adverse events reflects the focus on safety and quality control in our unit and the safety of this procedure. The evaluation and protocol for performing PAE

is meticulous, requiring in-depth understanding of the anatomical variability of the prostatic blood supply. Identifying and isolating the prostate arteries and collateral vessels within the pelvis is critical to avoiding off-target embolisation. Overall, post-PAE side-effects compare favourably to those reported in TURP cohorts and to the recognised side-effects of LUTS medications [21–23].

The lack of long-term, randomised data is the current limitation of PAE. In our present study, the mean IPSS at 12 months was 7.3, up from 4.3 at 3 months and ~10% of patients had proceeded to a TURP. A large cohort study of 1000 patients, presented in 2017, showed rates of clinical success of up to 78% between 6 and 10 years [24], but more studies are needed to validate this. It is unlikely that the durability of a single PAE will consistently match the long-term relief of LUTS or improvement in Q_{max} and PVR that most men achieve from a TURP; although, PAE can be successfully repeated in men who experience early symptom recurrence [24]. In the randomised controlled trial of 114 men by Gao et al. [20], TURP had superior post-treatment improvements in IPSS, QoL and Q_{max} at 3 months compared to PAE. In the non-randomised multicentre UK Register of Prostate Embolisation (UK-ROPE) study, PAE effectiveness

was assessed by the improvement in IPSS at 12 months, and was compared to IPSS improvements after TURP [25]. Similar to our present results, the 216 men in the PAE group showed improvement in IPSS by ~10 points and IPSS QoL scores by 2.6 points. PAE showed significant improvement in Q_{\max} and reduction of prostate volume at 12 months and was not non-inferior to TURP in terms of IPSS improvement [25]. However in the Abt et al. [26] randomised open label non-inferiority trial of 103 men, PAE was less effective than TURP for the change in Q_{\max} (5.19 vs 15.34 mL/s), PVR (-86.36 vs -199.98 mL), and decreased detrusor pressure at Q_{\max} (-17.17 vs -41.07 cmH₂O).

Further research is currently underway investigating the role of PAE as a first-line treatment for BPH [27,28]. While research to date has focused on comparing the outcomes of PAE and TURP, it may be more appropriate to consider PAE as an alternate first-line treatment option against medical therapy. There were additional outcomes within our present cohort that further demonstrate the clinical utility of PAE. Before PAE, 30 men had bothersome LUTS despite persisting with medical therapy. Of the 30 men on α -blockers, 5 α -reductase inhibitors or a combination of drugs at the time of their enrolment in the present study, 24 men (77.4%) were able to cease medications completely after PAE. This has the potential to improve QoL by removing the side-effects of medical therapy. Even those men who remained on medications after PAE had significant improvements in IPSS and QoL. Reported improvements in LUTS from medical therapies are significantly less than those achieved by PAE [22]. Furthermore, α -blockers and 5 α -reductase inhibitors are associated with a range of undesirable side-effects associated with a decrease in sexual function and QoL [23]. PAE as a first-line alternative treatment instead of medical therapy in a select group of men, especially with medical co-morbidity and large prostate volumes, may avert the need for surgical intervention in some men.

Conclusion

PAE is a technically feasible and safe procedure, with encouraging short-term efficacy. Recent guidance from the National Institute for Health and Care Excellence (NICE) supports the use of PAE for BPH in appropriate clinical situations when urologists and radiologists work together [29], as was the case in our present study. High rates of patient satisfaction were achieved in the present study, along with significant reductions in LUTS and improvements in QoL. These results hold promise for men looking for a minimally invasive option to manage LUTS. Additional studies are underway at our institution to provide further evidence on the durability of PAE, including the effect of PAE on bladder function (urodynamics) [30] and the suitability of PAE as a first-line alternative to medical therapy [28]. We believe PAE is a low-risk potential alternative for

men who wish to avoid medical therapy for LUTS, or who develop bothersome side-effects from medical therapies.

Conflict of Interest

Dr Brown has received research grants from Terumo Medical and Boston Scientific, outside the work described here. No other authors have conflicts of interest to declare.

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Abbreviations: IDC, indwelling urinary catheter; PAE, prostate artery embolisation; P-EASY, Prostate artery Embolisation Assessment of Safety and feasibility; PVR, post-void residual urine volume; Q_{max} , maximum urinary flow rate; QoL, quality of life.