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Efficacy and safety of prostate artery embolization for benign prostatic hyperplasia: an observational study and propensity-matched comparison with transurethral resection of the prostate (the UK-ROPE study)

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Objectives

To assess the efficacy and safety of prostate artery embolization (PAE) for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) and to conduct an indirect comparison of PAE with transurethral resection of the prostate (TURP).

Patients and Methods

As a joint initiative between the British Society of Interventional Radiologists, the British Association of Urological Surgeons and the National Institute for Health and Care Excellence, we conducted the UK Register of Prostate Embolization (UK-ROPE) study, which recruited 305 patients across 17 UK urological/interventional radiology centres, 216 of whom underwent PAE and 89 of whom underwent TURP. The primary outcomes were International Prostate Symptom Score (IPSS) improvement in the PAE group at 12 months post-procedure, and complication data post-PAE. We also aimed to compare IPSS score improvements between the PAE and TURP groups, using non-inferiority analysis on propensity-score-matched patient pairs. The clinical results and urological measurements were performed at clinical sites. IPSS and other questionnaire-based results were mailed by patients directly to the trial unit managing the study. All data were uploaded centrally to the UK-ROPE study database.

Results

The results showed that PAE was clinically effective, producing a median 10-point IPSS improvement from baseline at 12 months post-procedure. PAE did not appear to be as effective as TURP, which produced a median 15-point IPSS score improvement at 12 months post-procedure. These findings are further supported by the propensity score analysis, in which we formed 65 closely matched pairs of patients who underwent PAE and patients who underwent TURP. In terms of IPSS and quality-of-life (QoL) improvement, there was no evidence of PAE being non-inferior to TURP. Patients in the PAE group had a statistically significant improvement in maximum urinary flow rate and prostate volume reduction at 12 months post-procedure. PAE had a reoperation rate of 5% before 12 months and 15% after 12 months (20% total rate), and a low complication rate. Of 216 patients, one had sepsis, one required a blood transfusion, four had local arterial dissection and four had a groin haematoma. Two patients had non-target embolization that presented as self-limiting penile ulcers. Additional patient-reported outcomes, pain levels and return to normal activities were very encouraging for PAE. Seventy-one percent of PAE cases were performed as outpatient or day cases. In contrast, 80% of TURP cases required at least 1 night of hospital stay, and the majority required 2 nights.

Conclusion

Our results indicate that PAE provides a clinically and statistically significant improvement in symptoms and QoL, although some of these improvements were greater in the TURP arm. The safety profile and quicker return to normal activities may be seen as highly beneficial by patients considering PAE as an alternative treatment to TURP, with

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the concomitant advantages of reduced length of hospital stay and need for admission after PAE. PAE is an advanced embolization technique demanding a high level of expertise, and should be performed by experienced interventional radiologists who have been trained and proctored appropriately. The use of cone-beam computed tomography is encouraged to improve operator confidence and minimize non-target embolizations. The place of PAE in the care pathway is between that of drugs and surgery, allowing the clinician to tailor treatment to individual patients' symptoms, requirements and anatomical variation.

Keywords

prostate artery embolization, transurethral resection of the prostate, UK Register of Prostate Embolization, embolization, lower urinary tract symptoms, benign prostatic hyperplasia

Introduction

The standard established UK surgical operation of choice for voiding LUTS presumed secondary to BPH (LUTS/BPH) is TURP [1], and the development of bipolar TURP [2] has led to a substantial reduction in complications, such as transurethral resection (TUR) syndrome and the need for transfusions [3,4]. Several alternative surgical techniques have been developed in recent years, including laser prostatectomy [4] and transurethral prostatic lift implants (Urolift, Neotract Inc., Pleasanton, CA, USA) [5,6]. Greenlight photoselective vaporisation of the prostate and holmium enucleation of the prostate (HoLEP) have favourable 10-year outcome data [4], while medium-term data are available for Urolift [5], but long-term data are still awaited.

Prostate artery embolization (PAE) is an interventional radiological technique involving the injection of small particles directly into the prostatic arteries bilaterally, leading to devascularization of hypervascular nodules. PAE is technically challenging, with studies suggesting technical failure and unilateral embolization rates of 2–5% [7,8].There is also a large variation in prostatic artery anatomy, which, together with potential bowel, bladder and penile anastomoses, can make identification and embolization of the prostatic artery difficult [9,10]. The use of preoperative CT angiography and intra-procedural cone-beam CT (CBCT) has improved the accuracy and safety of the procedure [11].

After initial PAE case studies by Carnevale et al. [8,12], there have been several subsequent studies from around the world. A pilot PAE study performed at University Hospitals Southampton showed similar results to those published by Brazilian and Portuguese groups [13].

A 2014 systematic review by Schreuder et al. [14] looked at nine studies from three international groups (Brazil, Portugal and USA), with a total of 706 patients. The majority of the study designs were rated as poor quality with short follow-up. Results showed improved IPSS, prostate volume and maximum urinary flow rate (Q_{max}), with no deterioration in International Index of Erectile Function (IIEF). A recent meta-analysis included 20 studies, concluding that PAE is a promising alternative for those patients who do not want to undergo or cannot tolerate surgery [15]. Another systematic review presented PAE as effective in the short and medium term, but called for more long-term studies [16].

There have been very few studies comparing PAE with surgical treatments for LUTS/BPH, such as TURP and HoLEP. A randomized controlled trial (RCT) comparing PAE with TURP presented the two techniques as having similar improvement in IPSS, Q_{max} and post-void residual urine volume (PVR) at 12 and 24 months [17]. PAE has been further developed using the 'PErFecTED' technique, in which standard proximal embolization is followed by deep microcatheter placement within the prostate gland and further embolization. Patients treated with PAE using the PErFecTED technique showed much improved outcomes over patients treated with the original technique, and clinical improvements were closer to that seen with TURP for IPSS, quality of life (QoL), prostate volume and Q_{max} [18].

It is clear from the current evidence base that comparative studies and studies with longer follow-up are required to establish the clinical effectiveness and safety of PAE and its role in the treatment pathway for LUTS/BPH. We therefore undertook a registry-based observational study to examine the efficacy and safety of this technique with 12 months' follow-up, and also to compare these findings with a propensity-matched cohort of patients undergoing TURP.

Patients and Methods

The British Society of Interventional Radiologists and the BAUS co-funded the online UK Register of Prostate Embolization (UK-ROPE), which was built and hosted by Dendrite Clinical Systems Ltd. The National Institute for Health and Care Excellence (NICE) approved funding of an independent academic unit to run the registry through a competitive tender, which was won by the Cardiff and Vale UHB/Cardiff University based unit, Cedar. Cook Medical (Europe) provided a Research Grant to enable the participating centres to cover NHS costs for the PAE procedure where it was not possible to fund these from existing commissioning pathways.

The UK-ROPE study protocol was reviewed by the sponsor, Cardiff and Vale UHB and the Research Ethics Committee Northeast-Sunderland (REC reference 14-NE-0128) under proportionate review. The UK-ROPE study is listed on clinicaltrials.gov with the reference number NCT02434575.

Nineteen UK recruitment centres were approved by the steering committee for training and proctoring in PAE. Four of these were trained and proctored by the PAE team from Lisbon, Portugal. The remaining UK centres were then trained by the interventional radiologists at University Hospitals Southampton. All centres agreed to enter patient data to the UK-ROPE, and were expected to enter consecutive TURP cases in order to build the indirect comparator arm. Dr Hacking, from Southampton took on the role as clinical lead and provided ongoing support for all UK sites. Participating sites and clinicians are detailed in Appendix 1.

Objectives

One of the primary objectives of the present study was to assess the efficacy of PAE using IPSS by comparing baseline variables with those at 12 months post-procedure. We aimed to detect a minimum clinically important difference in IPSS of 3 units (this margin was decided by the steering committee) in patients in the PAE group over 12 months. At a significance level of 0.05 and a power of 90%, a minimum of 117 patients needed to be recruited in the PAE arm of the study. In addition, we aimed to identify complications arising from PAE up to 12 months post-procedure.

A secondary objective was to compare the treatment effect of PAE with that of TURP, using IPSS score at 12 months post-procedure. A non-inferiority approach was chosen. PAE would be classed as non-inferior to TURP if the difference (PAE–TURP) was no worse than 3 IPSS points. A propensity score method was used to create matched pairs of patients in the PAE and patients in the TURP group, which were then used in the final analysis. At a power of 90% and a significance level of 0.05, we calculated that 150 patients per arm (PAE and TURP) should be sufficient for this objective. Descriptive statistics for IPSS, IIEF, prostate volume and urinary flow studies for PAE, TURP and HoLEP, 12 months post-procedure, are also presented.

Patient Inclusion Criteria

Patient suitability for PAE was covered during the training and proctoring offered by the Portuguese or Southampton interventional radiologists, to ensure quality control of the interventional radiologist arm of the study. Patients were considered for inclusion in the study if they were men with LUTS who had consented to undergo PAE, TURP, open prostatectomy or HoLEP in one of the UK-ROPE collaborating centres, were able to read, write and understand English, and were capable of giving informed written consent. Each potential participant was provided with a questionnaire pack with a unique code. This contained consent forms and questionnaires, to be completed pre-procedurally. Questionnaires were mailed directly to the trial management unit (Cedar).

Once patients had consented to take part in the study, the clinicians and local research team performed the procedure and entered baseline data onto UK-ROPE using the unique identifier. Cedar then uploaded the questionnaire data by matching the unique code. All follow-up questionnaires were handled by Cedar and mailed directly to patients. If patients did not respond within 10 days, a 'reminder pack' was sent out, with identical questionnaires. This process shown in Fig. 1.

Follow-up was performed at 1, 3, 6 and 12 months, when questionnaires were mailed to all patients, including IPSS, IIEF and patient-reported complication domains. At 3 and 12 months, additional clinical follow-up was performed at participating sites. This involved flow studies such as Q_{max}, and a prostate volume study required for patients in the PAE group only. The rationale for this was that patients in the TURP group were to be treated using UK standard practice, for both preoperative assessment and follow-up. There was no blinding (either clinician or participant) in this single-arm observational study.

Statistical Analysis

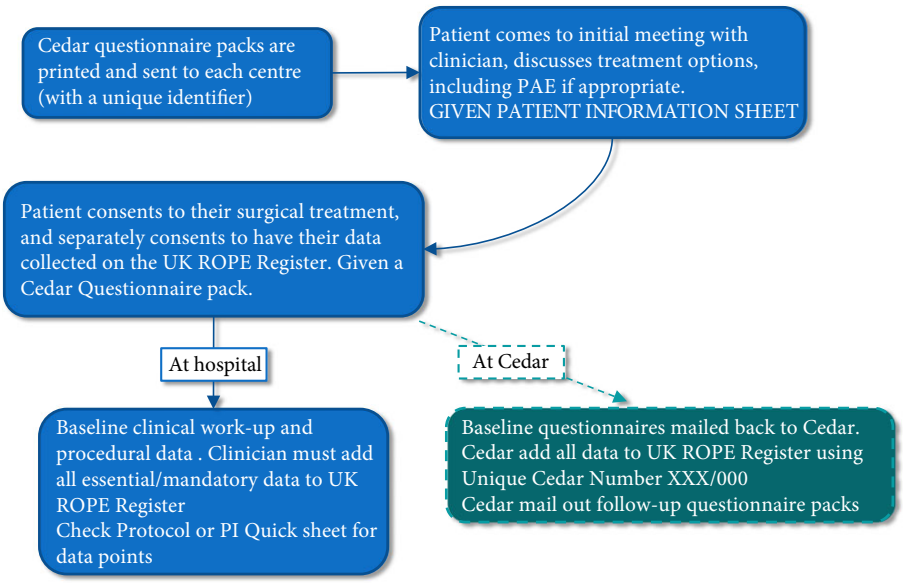
Basic statistical analysis was performed using IBM SPSS v21. Univariate within-group analysis was performed on all quantifiable urological measurements: IPSS, IPSS QoL, IIEF, prostate volume, Q_{max} and PVR. All tests were carried out on the changes from baseline to 12-month follow-up. Analysis was carried out using the paired *t*-test or, if the data were not normally distributed, using the Wilcoxon signed rank test. *P* values <0.05 were taken to indicate statistical significance.

Multivariate analysis was performed in R version 3.3.2 (2016-10-31). We applied a combination of multiple imputation and propensity-matched pairing in the comparative between-group analysis. Propensity matching was based on a logistic regression model, and yielded 65 matched pairs. The background variables used for matching were: age at procedure; length of time with LUTS; baseline IPSS; IPSS QoL; IIEF; Q_{max}; and PVR. We used a non-inferiority test to compare PAE with TURP, with an *a priori* margin of 3 IPSS points. For QoL, we used a non-inferiority margin of 1 IPSS QoL point.

Results

Patients were recruited between July 2014 and January 2016. Data were collected on a total of 305 cases, of which 216

Fig. 1 UK ROPE Study recruitment and data entry flow diagram. XXX is the site code, 000 represents the unique patient number.



were PAE and 89 were TURP (45 monopolar TURPs and 44 bipolar TURPs). Monopolar and bipolar TURP cases were combined into one treatment type, 'TURP', as they provide very similar functional outcomes [3,4]. The flow of patients through the study at each timepoint is shown in Fig. 2.

The registry also collected data on 13 HoLEP cases, but these are not included in the present study; because there were very few cases, we focused on TURP as the main comparator for the present paper. No open prostatectomy cases were recruited. Long-term indwelling catheters were not used routinely for PAE procedures in the present study as this is not standard practice in the UK. Indwelling catheters were removed at the end of the PAE procedure. PAE was performed on some men with existing indwelling catheters and these would typically be removed 2 weeks after the procedure.

The mean (SD) duration of the PAE procedures (defined as time in and out of the operating room, not 'skin to knife') was 144 (51) min; these data were not collected during TURP procedures. The median (IQR) radiation screening time was 38 (28–49) min and the median (IQR) dose area product was 17 892 (11 301–30 905) cGy.cm^2 with a median (IQR) skin dose of 1 368 (823–2 317) mGy.

Baseline characteristics and statistical comparisons for all patients are shown in Table 1.

Descriptive Statistics for Key Urological Measurements

Table 2 shows the unadjusted descriptive data for the quantifiable urological variables. Patients in the PAE group showed improvements of ~10 points in IPSS, and 2.6 points in IPSS QoL measurement. TURP appears to deliver greater improvements than PAE in each of these fields (~15 points and 3.4 points, respectively). IIEF was stable in both procedures. Prostate volume measurement data were not available for TURP cases in this pragmatic study, as described in the Methods section.

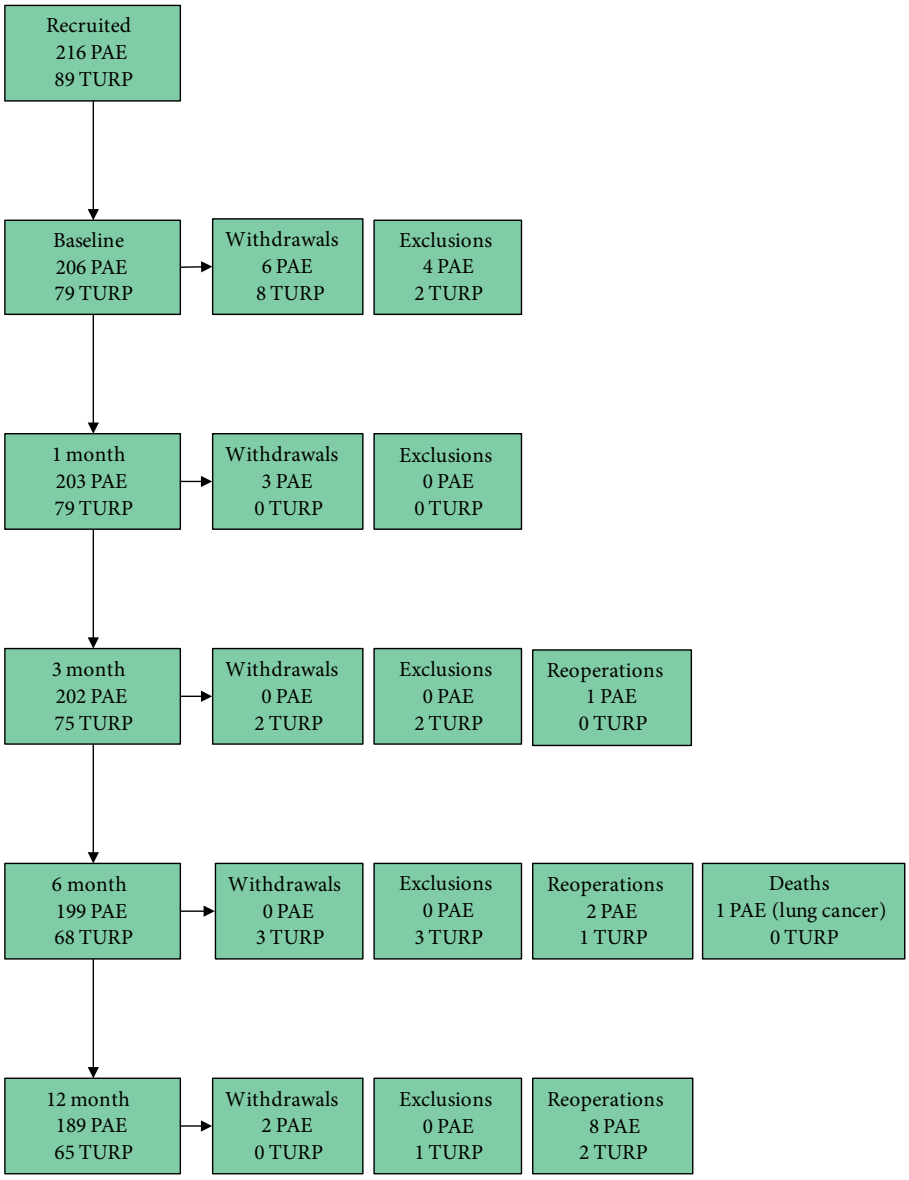
The results in Table 2 are descriptive only and not comparative between groups because of confounding that cannot be excluded in an observational study. Comparative analyses of our main secondary outcome, the IPSS and QoL comparison between PAE and TURP, are presented in the multivariate analysis on propensity-matched PAE and TURP patient pairs, as this analysis takes into account the differences in baseline characteristics between these groups.

Table 3 shows the 12-month improvement from baseline for each of the urological variables, where both baseline and 12-month data were completed. Significance values are within-group, and presented for improvement from baseline only. PAE and TURP provided significant improvements in almost all of these measurements at 12 months post-procedure. IIEF scores remained unchanged post-procedurally for both PAE and TURP.

Non-Inferiority Analysis of Matched Pairs for IPSS and IPSS Quality of Life

Results were taken from 10 pooled complete datasets, produced using multiple imputation. Sixty-five matched pairs of patients in the PAE and patients in the TURP group were produced using propensity score analysis, and then subjected to non-inferiority testing.

Fig. 2 Flow of patients through the study over the 12-month follow-up period. PAE, prostate artery embolization.



At our *a priori* non-inferiority margin of 3.0 IPSS points, there was no evidence of non-inferiority of PAE to TURP. This is consistent with our unadjusted data in Tables 6 and 7: TURP provided better improvements in IPSS than PAE at 12 months post-procedure. After performing sensitivity analyses with margins of 4.0 and 2.0 IPSS points, these conclusions remained unchanged.

With IPSS QoL, at a non-inferiority margin of 1 point (enough to take a patient from one QoL classification to the next), there was again no evidence of non-inferiority of PAE compared with TURP; however, in our sensitivity analyses, a margin of 1.25 points produced a significant *P* value, which was evidence that PAE was non-inferior to TURP at this margin. This margin was probably too large, however, for a small scale of only 6 points. At a smaller margin of 0.75 QoL points, there was no evidence of non-inferiority of PAE to TURP. These results are summarized in Tables 4 and 5.

Reoperation Rates

The reported reoperation rate up to 12 months post-procedure for PAE was 11/216 (5.1%). An additional 32 patients (14.8%) were reported as having, or awaiting, a reoperation outside of our 12-month follow-up period. Three of these patients received only unilateral embolization and nine had median lobe enlargement. Four had small prostate

Table 1 Baseline clinical characteristics of patients included in the UK-ROPE study.

Characteristic	PAE *N* = 216 (100%)	TURP *N* = 89 (100%)
Patient age, years		
Mean (SD)	66 (7.4)	70 (7.5)
Median (IQR)	67 (61.0–71.0)	70 (65.6–77.0)
Comparison, PAE vs TURP	Significantly different (P = 0.000, Mann–Whitney U-test)	
IPSS (possible range 0–35)		
n (%)	181 (83.8)	38 (42.7)
Mean (SD)	21.3 (6.7)	21.63 (5.8)
Median (IQR)	22.00 (17.0–26.0)	22.0 (17.0–26.0)
Comparison, PAE vs TURP	Not significantly different (P = 0.926, Mann–Whitney U-test)	
IPSS QoL (possible range 0–6)		
n (%)	189 (87.5)	48 (53.9)
Mean (SD)	4.6 (1.1)	4.9 (1.1)
Median (IQR)	5.00 (4.0–5.0)	5.00 (4.0–6.0)
Comparison, PAE vs TURP	Not significantly different (P =0.076, Mann–Whitney U-test)	
IIEF (possible range 5–25)		
n (%)	164 (75.9)	36 (40.4)
Mean (SD)	14.4 (7.0)	14.4 (6.7)
Median (IQR)	15.0 (8.0–21.0)	15.0 (7.5–19.0)
Comparison, PAE vs TURP	Not significantly different (P = 0.906, Mann–Whitney U-test)	
Prostate volume, mL		
n (%)	209 (96.8)	28 (31.5)
Mean (SD)	101.2 (57.1)	65.6 (31.5)
Median (IQR)	89.00 (59.5–125.0)	58.5 (50.0–80.0)
Comparison, PAE vs TURP	Significantly different (P = 0.000, Mann–Whitney U-test)	
Q_{max}, mL/s		
n (%)	133 (61.6)	40 (44.9)
Mean (SD)	8.8 (4.718)	10.36 (6.3)
Median (IQR)	8.0 (5.0–11.0)	10.0 (7.0–13.0)
Comparison, PAE vs TURP	Not significantly different (P = 0.095, Mann–Whitney U-test)	
Residual void volume, mL		
n (%)	125 (57.9)	46 (51.7)
Mean (SD)	161.6 (136.4)	263.6 (202.4)
Median (IQR)	130.0 (69.5–218.5)	204.0 (99.0–403.0)
Comparison, PAE vs TURP	Significantly different (P = 0.004, Mann–Whitney U-test)	

IIEF, International Index of Erectile Function; IQR, interquartile range; PAE, prostate artery embolization; Q_{max}, maximum urinary flow rate; QoL, quality of life.

volumes, with two of these additionally having a high bladder neck. The remaining cases had late clinical failure with no clear cause identified. The total reoperation rate for PAE cases was 43 (19.9%). Table 6 shows these overall reoperation rates, across all procedural groups.

Length of Stay

Post-procedure length of stay was recorded for 171 patients (79.2%) in the PAE group and 75 patients in the TURP group. The majority of patients in the PAE group underwent their operation as an outpatient or day case (71.3% of cases, median = 0.0 days), compared with patients in the TURP group, who stayed in hospital for either 1 (30.7%) or 2 (49.3%) days post-procedure, with a median of 2.0 days. The length of stay for the TURP group was significantly longer than for the PAE group (P = 0.000, Mann–Whitney U-test).

Immediate Clinician-Observed Complications

Three patients had sepsis (one in the PAE group [0.5%] and two in the TURP group [2.2%]). Four patients in the PAE group (1.9%) had local arterial dissection, limiting prostate artery cannulation and therefore embolization, but with no clinical sequelae (Table 7). Four patients in the PAE group (1.9%) had a groin haematoma. One of these also required a blood transfusion as a result of arterial closure device failure. There were two minor non-target embolizations in the PAE group (0.9%). These were two episodes of small penile ulcers caused by embolic particles inadvertently entering anastomotic connections, resulting in temporary discoloration and ulceration. These episodes had a self-limiting course and resolved in both patients within 6 weeks with only simple analgesics (Table 7). No cases of TUR syndrome were reported in the TURP group.

Patient-Reported Complications

At each questionnaire follow-up point, patients were asked to report any complications or adverse events experienced post-procedurally. These included haematuria, haematospermia, urinary incontinence, urinary infection and retrograde ejaculation. Results are shown in Table 8.

These data show that haematuria and haematospermia were the most common complications, and that haematuria was lower in the PAE (18.6%) compared with the TURP group (63.9%).

Haematospermia, however, was more commonly reported by patients in the PAE group (reported by 12.6% of these patients). Reported retrograde ejaculation rates were lower in the PAE group (24.1%), at approximately half the rate reported by patients in the TURP group (47.5%).

Patients were asked to mark their postoperative pain on a visual analogue scale from 0 to 10, where 0 was no pain, and 10 was the worst pain imaginable. Overall, the majority of patients reported very low immediate postoperative pain levels for both PAE and TURP. Forty-seven percent of patients in both the PAE (51/108) and TURP (18/43) groups reported no immediate post-procedural pain, and the majority of patients in both groups (82.4% of PAEs and 95.3% of TURPs) reported immediate post-procedural pain scores of ≤3. Pain scores remained low throughout follow-up, but are lower on average with PAE than with TURP.

Patients were also asked to report when they were able to return to normal activities. Patients in the PAE group reported a significantly shorter median return to normal

Table 2 Descriptive statistics for quantifiable urological measurements.

	PAE		TURP	
	n	Mean (Median)	*n*	Mean (Median)
IPSS				
Baseline	181	21.3 (22.0)	38	21.6 (22.0)
1 month	136	10.5 (10.0)	33	11.5 (12.0)
3 months	159	9.6 (8.5)	45	9.8 (5.0)
6 months	133	10.1 (9.0)	31	8.00 (4.0)
12 months	132	10.0 (9.0)	29	7.2 (5.0)
Difference, baseline to 12 months	117	−10.9 (−10.0)	21	−15.2 (−15.0)
IPSS QoL				
Baseline	189	4.6 (5.0)	48	4.9 (5.0)
1 month	139	2.3 (2.0)	36	2.4 (2.0)
3 months	160	1.9 (2.0)	46	1.9 (1.0)
6 months	135	2.1 (2.0)	35	1.9 (1.0)
12 months	133	2.00 (2.0)	31	1.5 (1.0)
Difference, baseline to 12 months	126	−2.6 (−3.0)	26	−3.4 (−4.0)
IIEF score				
Baseline	164	14.4 (15.0)	36	14.4 (15.0)
1 month	106	15.7 (17.5)	15	15.4 (18.0)
3 months	126	16.2 (18.0)	28	15.6 (16.0)
6 months	100	17.0 (19.0)	20	19.2 (20.0)
12 months	102	16.3 (19.0)	20	14.8 (13.5)
Difference, baseline to 12 months	94	1.0 (0.0)	15	−0.2 (0.0)
Q_{max}, mL/s				
Baseline	132	8.8 (8.0)	39	10.4 (10.0)
3 months	115	13.6 (12.0)	21	20.8 (19.0)
12 months	106	14.1 (13.5)	13	22.3 (20.0)
Difference, baseline to 12 months	78	4.4 (3.0)	10	8.6 (7.5)
Prostate volume, mL				
Baseline	209	101.2 (89.0)	28	65.6 (58.5)
3 months	192	72.1 (60.0)	3	58.7 (49.0)
12 months	166	72.8 (58.0)	0	
Difference, baseline to 12 months	165	−28.6 (−25.0)	0	Not measured
PVR, mL				
Baseline	125	161.6 (130.0)	46	263.6 (204.0)
3 months	110	126.2 (97.0)	20	88.8 (56.5)
12 months	101	129.6 (120.0)	13	80.6 (48.0)
Difference, baseline to 12 months	70	−40.4 (−15.0)	12	−78.1 (−48.5)

IIEF, International Index of Erectile Function; PAE, prostate artery embolization; PVR, post-void residual urine volume; Q_{max}, maximum urinary flow rate; QoL, quality of life.

activities (in days) when compared to TURP (PAE 5.0 vs TURP 14.0; $P = 0.000$, Mann–Whitney *U*-test).

Discussion

The treatment of LUTS/BPH has changed markedly over the past 20–30 years, with the shift towards medical therapy also supported by increased management in primary care. To date, patients who reach the point of requiring an interventional procedure have typically been offered TURP, and more recently, laser prostatectomy, such as HoLEP; therefore, it is an exciting development that embolization of the gland can lead to reduced volume without recourse to surgical removal of tissue. This may follow the embolization of symptomatic uterine fibroids, which is now a well-established alternative to more invasive surgical interventions, with favourable 5-year results [19]. In this paper we describe the results of a large multicentre observational study of UK patients across 17 centres, which show that PAE is an efficacious procedure for LUTS/BPH, with a favourable safety profile. Our results are in accord with evidence from randomized trials from the last 3–5 years. Together, the findings can inform future clinical practice and policy guidance on the treatment of LUTS/BPH.

In terms of our primary study focus, the IPSS, we did not find evidence that PAE was non-inferior to TURP, but still clinically significant with a mean drop of 10 IPSS points at 12 months post-procedure. We observed a median 12-month post-PAE IPSS of 9.0 (mean of 10.0), which is similar to that reported for 'original PAE' patients in the randomized study by Carnevale 2015 [18], with a mean 12-month IPSS of 12.8 [18].

Our median 12-month IPSS improvement from baseline was −10.0 (mean −10.9), which is lower than the mean figure of −16.4 points presented in a recent systematic review by Pyo and Cho [16], across seven randomized studies. There may be a number of reasons for this. Firstly, the mean baseline IPSS

Table 3 Within-group improvement from baseline at 12 months, with significance testing.

Measurement	Median improvement from baseline at 12 months *n* of patients completing baseline and 12-month follow-up *P* value improvement from baseline	
	PAE	TURP
IPSS	−10.0 *n* = 117 *P* = 0.000	−15.0 *n* = 21 *P* = 0.000
IPSS QoL	−3.0 *n* = 126 *P* = 0.000	−4.0 *n* = 26 *P* = 0.000
IIEF	0.0 *n* = 94 *P* = 0.19	0.0 *n* = 15 *P* = 0.903
Q_{max}, mL/s	+3.0 *n* = 78 *P* = 0.000	+7.5 *n* = 10 *P* = 0.022
Prostate volume, mL	−25.0 (−27.8%) *n* = 165 *P* = 0.000	N/A *n* = 0 *P* = N/A
PVR, mL	−15.0 *n* = 70 *P* = 0.071	−48.5 *n* = 12 *P* = 0.059

IIEF, International Index of Erectile Function; PAE, prostate artery embolization; PVR, post-void residual urine volume; Q_{max}, maximum urinary flow rate; QoL, quality of life.

Table 4 Non-inferiority testing with regard to IPSS.

Non-inferiority margin (IPSS points)	Mean difference, PAE–TURP	*T*-statistic	*P*	Notes
3.0 4.0 2.0	−2.386 SE = 1.575	0.390 1.024 −0.245	0.697 0.305 0.807	Reject null hypothesis: no evidence that PAE is non-inferior to TURP

PAE, prostate artery embolization.

of the patients included in the review was 24.5, which gives scope for a larger improvement than in the UK-ROPE study, where the mean baseline IPSS was 21.3. Additionally, the review included the 21-point improvement in the Carnevale 2015 [18] 'PErFecTED' cohort, and our study contains mostly PAE according to the original technique, which produces less dramatic IPSS improvements.

In terms of IPSS QoL in the present study, the patients in the PAE group experienced a mean improvement of −2.5 (median −3.0) points, taking them from 'Unhappy' (score of 5) to 'Mostly satisfied' (score of 2). This is consistent with the −2.8 point improvement presented in the aforementioned recent systematic review [16].

Other quantifiable urological findings differ somewhat from those presented by recent systematic reviews. The Q_{max} and

Table 5 Non-inferiority testing with regard to IPSS quality of life.

Non-inferiority margin (IPSS QoL points)	Mean difference, PAE–TURP	*T*-statistic	*P*	Notes
1.0	−0.480 SE = 0.318	1.635	0.102	Reject null hypothesis
1.25*		2.421	0.015	Accept null hypothesis: PAE non-inferior to TURP
0.75		0.849	0.849	Reject null hypothesis

*PAE, prostate artery embolization; QoL, quality of life. *We deem this non-inferiority margin too large for a narrow 6-point QoL scale.*

Table 6 Overall reoperation rates for each procedure up to 12-month follow-up.

Initial procedure failed	Within 12 months, *n* (%)	After 12 months, *n* (%)	Total, *n* (%)
PAE	11 (5.1)	32 (14.8)	43 (19.9)
TURP	3 (3.4)	1 (1.1)	5 (5.6)

PAE, prostate artery embolization.

Table 7 Complication and grade for patients treated with prostate artery embolization.

Description	Number of patients	Clavien–Dindo grade	Treatment
Sepsis	1	II	Antibiotics
Local arterial dissection	4	I	No treatment
Groin haematoma	3	I	No treatment
	1	II	Transfusion
Penile ulcer (non-target embolization)	2	I	Analgesics

PVR findings were both much smaller improvements than those reported by Pyo and Cho [16]. This may be attributable to our pragmatic study design; it can be reasonably assumed that the incorporated RCTs would have had very tightly controlled inclusion and exclusion criteria, so patients under a certain baseline Q_{max}, or over a certain baseline PVR, would not have been eligible for the RCTs. This was not the case for the UK-ROPE study, where each clinical team was expected to make a clinical judgement on the suitability of a patient for PAE without strict inclusion and exclusion criteria, as they would do if PAE were a freely-available procedure in a real-world setting.

In the UK-ROPE study, we observed a 28% reduction in prostate volume in the PAE cohort. This was similar to the 29% reported by Pyo and Cho [16], and the 19% reported for original PAE by Carnevale et al. [18]. In that study, there was also a 24.5% volume reduction in the PErFecTED PAE cohort, which was similar to the findings in the present UK-ROPE study.

Table 8 Patient-reported complications at any time post-procedure (% of total return rate).

	Haematuria, *n* (%)	Haematospermia, *n* (%)	Incontinence, *n* (%)	Urinary infection, *n* (%)	Retrograde ejaculation, *n* (%)
PAE (199 returns)	37 (18.6)	25 (12.6)	2 (1.0)	10 (5.0)	48 (24.1)
TURP (61 returns)	39 (63.9)	1 (1.6)	2 (3.3)	1 (1.6)	29 (47.5)

PAE, prostate artery embolization.

Prostate artery embolization is an advanced embolization technique demanding a high level of expertise. After training and proctoring there is a learning curve of 10–20 cases. During the early stages of an operator's experience, higher screening times and skin radiation doses are seen, but these typically improve after an interventional radiologist has performed ~10 cases. The higher doses tend to be associated with older equipment or CBCT. While CBCT increases both dose area product and skin doses, the skin exposure is spread over a wide area, and not concentrated on one spot. Furthermore, the use of CBCT increases operator confidence and reduces the risk of non-target embolization. Operators followed local radiation safety procedures and monitoring requirements. The operator radiation doses were not recorded in the UK-ROPE study.

Tumour necrosis after embolization is well described in hepatocellular cancer, RCC and fibroids. Histologically, hyaline necrosis is seen after fibroid embolization in women undergoing hysterectomy. Radiologically it is seen as non-enhancing tissue on post-contrast CT or especially MRI. The MRI protocols were carefully designed to show not only the dimensions of the prostate, but also the presence or absence of areas of devascularization indicating 'necrosis'. The natural history of this necrosis is that it shrinks month by month and does not regrow. We classified the necrosis as confluent, patchy, asymmetrical and symmetrical, as the belief is that confluent bilateral necrosis would have a better overall shrinkage and lower regrowth rate. It is difficult to see these changes by 12 months and longer-term follow-up will be required.

The necrosis does not commonly 'discharge', but shrinks where it is. The reason is likely to be that we do not cause necrosis or tissue infarction of the urethra and therefore the non-infected necrotic tissue shrinks where it is. Parallels can be drawn after fibroid embolization. The deeper intra-mural and subserosal fibroids shrink where they are, although submucosal and particulary intra-cavity fibroids can slough into the uterine cavity and 'discharge' through the vagina.

The PAE technique has a low complication rate. In our embolization cohort, we had one patient with sepsis, four had local arterial dissection and one required a blood transfusion. Four patients had groin haematoma. Two patients had minor (Clavien–Dindo grade 1), small penile ulcers caused by embolic particles inadvertently entering anastomotic connections. To avoid the risk of non-target embolization, all interventional radiologists underwent formal training at an established centre and had additional on-site training by one of four proctors (two from Lisbon, and two from Southampton). Significant anastomoses were seen in many patients. Digital subtraction angiography as well as cone-beam three-dimensional angiography was used to analyse these carefully on each side in every patient. No cases of rectal or bladder necrosis were recorded. Unlike traditional prostate surgery there is minimal blood loss after PAE, therefore, anaemia, clotting disorders and anticoagulant therapy are not contraindications for PAE.

The complication numbers were low for a 200-patient cohort. In the TURP cohort of 89 patients none of the more serious complications that are often associated with TURP, such as TUR syndrome or blood transfusion, were observed. These complications carry a 1.4% and 4.1% risk in TURP [4], respectively, making them very unlikely in our 89-patient cohort.

Patient-reported complications were favourable for PAE, particularly compared with the surgical alternatives; a similar level of immediate postoperative pain was observed for PAE and TURP. Throughout follow-up, patients in the PAE group reported lower pain on average. Haematuria rates were lower for PAE than for TURP. The reported PAE retrograde ejaculation rate was approximately half that reported by our patients in the TURP group; however, it should be noted that these TURP rates were lower than those found in the literature (~60–65% with TURP [4]). This may be attributable to the sensitive nature of patients reporting retrograde ejaculation by questionnaire. Many of the patients reporting retrograde ejaculation after PAE admitted experiencing this since starting medication months or years before their PAE, so the real difference is likely to be even greater than we have shown in the present study.

We gathered additional sexual function data using the IIEF questionnaire. Our results indicate that, at 12 months post-PAE, there was a very small increase in IIEF score. Pyo and Cho [16] provide a description of four studies: two with significant post-PAE increases in IIEF, and two presenting no negative change. Our results do not challenge this general consensus, which is that PAE does not negatively affect sexual function. This may be of interest for patients who wish to avoid the potential sexual function issues often associated

with TURP; however, our data do not support the assumption that TURP significantly influences IIEF score. This is in agreement with the Cornu systematic review, which concludes that the IIEF score is stable after TURP. It appears that some patients in the TURP group see improvements in IIEF, others worsen, and some experience no change, giving rise to no overall significant change on average in the full patient cohort [4].

It may also be of interest to compare PAE with the UroLift implant, as this presents another emerging, less invasive alternative to transurethral surgical options. Our findings in the UK-ROPE study are very similar to those presented in a recent meta-analysis, which reported the following improvements at 12-months post-Urolift treatment: an IPSS improvement of −10.5 points, a QoL improvement of −2.3 points, a clinically non-significant +0.8 point improvement in IIEF score, a +3.5-mL/s improvement in Q_{max}, and a small improvement in PVR of −5.7 mL [5]. That study also presented economic data in which day-case Urolift treatment was cost-saving compared with inpatient TURP and HoLEP. Length of postoperative stay after Urolift was a key driver of the economic model, with a mean length of stay of 0.25 days. Our findings in the UK-ROPE study show that 71.3% of PAE cases were either performed as outpatient or day case procedures, with a similar mean length of stay of 0.33 days (median 0.0 days), and therefore has the potential for cost savings once implemented. A full economic study would need to be performed to explore this potential fully.

The UK-ROPE study shows that pragmatic, real-world observational research can be complementary to more strictly controlled, randomized trial evidence on new procedures. A large number of patients were recruited, and a greater number of PAE cases were enrolled than was originally planned. We faced some challenges in this study, including specific difficulties in recruiting patients in the TURP group. A limitation of the study was the non-response rate of patients to the questionnaires. We used a mail-based questionnaire system to collect IPSS data from our patients, such as that in patient-reported outcome measure (PROM) studies. Our PAE cohort had an overall IPSS response of 74%, which is very acceptable for a PROM-type study. The overall TURP and HoLEP response were 48% and 55%, respectively; putting them more in line with English PROM study return rates for groin hernia and varicose veins procedures [20]. Furthermore, it should be noted that analysis of our full data against those of Southampton, our lead site (which had a questionnaire response rate of ~95%) indicates that the return rate does not substantially change our findings.

In conclusion, the UK-ROPE study adds to the growing body of evidence that indicates that PAE is a safe and efficacious procedure, providing clinically significant improvements in IPSS score over a 12-month follow-up period. Comparative analysis showed that, while PAE was efficacious, it was not non-inferior to TURP in IPSS improvement, as indicated in the raw unadjusted data and propensity-matched patient pair analysis; however, PAE may offer other benefits to patients such as shorter hospital stay, faster return to normal activities, and reduction in some adverse effects. In the right type of patient, there is little to be lost by trying PAE, as it is safe, with minimal complications and a modest failure rate. Whilst it may not be a true replacement for TURP, it offers an option for a large cohort of patients with unmet needs who are positioned on the care pathway between medication and surgery.

Although the UK-ROPE study is not an RCT, it is the first multicentre UK-based study on PAE, and should be considered complementary to the international RCTs that have emerged since 2013. Our findings are largely in agreement with those in recently available RCTs, whilst recruiting a more varied patient group. We recommend that cost-effectiveness studies are now needed in order to evaluate the economic benefits of PAE in standard practice.

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Conflict of Interest

This study received a Research Grant from Cook Medical to fund PAE cases, as well as grants from British Society of Interventional Radiologists and BAUS for the setup of the online register.

Dr Ray, Dr Longford, Mr DasGupta, Dr Bryant, Dr Modi, Mr Dyer, Mr Harris and Prof. Carolan-Rees declare that they have no conflicts of interest. Prof. Powell works part-time as a Consultant Clinical Adviser to the Interventional Procedures Programme at NICE. NICE funded an independent academic unit (the Cardiff and Vale UHB/Cardiff University based unit, Cedar) to run the ROPE registry through a competitive tender. Mr Speakman was President of BAUS 2014–2016. Dr Hacking holds a Consultant Contract with Boston Scientific and has held contracts over the last 2 years with Terumo, Cook Medical and Celonova.

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Appendix 1

List of Centres and Lead Clinicians

The following centres took part in this study and submitted data to the UK ROPE register (lead clinicians are also named):

Southampton

- Dr N Hacking, Consultant Radiologist
- Dr T Bryant, Consultant Radiologist
- Dr S Modi, Consultant Radiologist
- Mr J Dyer, Consultant Urological Surgeon
- Nr M Harris, Consultant Urological Surgeon

Aintree University Hospital NHS Foundation Trust, UK

- Dr Pradesh Kumar, Consultant Radiologist
- Dr Elizabeth O'Grady, Consultant Radiologist
- Mr Andrew Baird, Consultant Urological Surgeon

Belfast Health and Social Care Trust, UK

- Dr Richard Lindsay, Consultant Radiologist
- Mr Ajay Pahuja, Consultant Urological Surgeon
- Mr Ali Thwaini, Consultant Urological Surgeon

Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust, UK

- Dr Clare Bent, Consultant Radiologist
- Mr Kevin Turner, Consultant Urological Surgeon

Colchester Hospital University NHS Foundation Trust, UK

- Dr Arun Sebastian, Consultant Radiologist
- Mr Gerald Rix, Consultant Urological Surgeon

Royal Cornwall Hospitals NHS Trust, UK

- Dr John Hancock, Consultant Radiologist
- Mr Christopher Blake Consultant Urological Surgeon

University Hospitals Coventry and Warwickshire NHS Trust, UK

- Dr James Harding, Consultant Radiologist
- Dr Manpreet Dhillon, Consultant Radiologist
- Mr Mr Rajagopalan Sriram, Consultant Urological Surgeon
- Mr Iain Wharton Consultant Urological Surgeon

Frimley Health NHS Foundation Trust, UK

- Dr Jeremy Taylor, Consultant Diagnostic and Interventional Radiologist
- Mr Simon Bott, Consultant Urological Surgeon

NHS Greater Glasgow and Clyde, UK

- Dr Sivanathan Chandramohan, Consultant Radiologist
- Mr Gordon, Hendry Consultant Urological Surgeon

Hull and East Yorkshire Hospitals NHS Trust, Hull, UK

- Dr Graham Robinson, Consultant Radiologist
- Mr Nick Smith, Consultant Urological Surgeon

Guys & St Thomas' NHS Foundation Trust, UK

- Mr Rick Popert, Consultant Urological Surgeon
- Dr Tarun Sabharwal, Consultant Radiologist

Imperial College Healthcare NHS Trust, UK

- Dr Nicholas Burfitt, Interventional Radiology Consultant
- Mr R DasGupta, Consultant Urological Surgeon

East Kent Hospitals University NHS Foundation Trust, Canterbury, UK

- Dr Neelan Das, Consultant Radiologist
- Mr Nitin Shrotri, Consultant Urological Surgeon

Central Manchester University Hospitals NHS Foundation Trust, UK

- Dr Anantha-Krishnan Ganapathy Consultant Radiologist
- Mr Daniel Burke, Consultant Urological Surgeon

Newcastle Upon Tyne Hospitals NHS Foundation Trust, UK

- Mr Toby Page, Consultant Urological Surgeon
- Dr Philip Haslam, Consultant Radiologist

University Hospitals of North Midlands NHS Trust, UK

- Dr David Wells, Consultant Radiologist
- Mr Lyndon Gommersall

Oxford Health NHS Foundation Trust, UK

- Dr Charles Ross Tapping, Consultant Radiologist
- Mr Jeremy Crew, Consultant Urological Surgeon

Plymouth Hospitals NHS Trust, UK

- Dr Philip Coates, Consultant Radiologist
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Abbreviations: CBCT, cone-beam CT; HoLEP, holmium enucleation of the prostate; IIEF, International Index of Erectile Function; IQR, interquartile range; LUTS/BPH, LUTS secondary to BPH; NICE, National Institute for Health and Care Excellence; PAE, prostate artery embolization; PROM, patient-reported outcome measure; PVR, post-void residual urine volume; Q_{max}, maximum urinary flow rate; QoL, quality of life; RCT, randomized controlled trial; TUR, transurethral resection; UK-ROPE, UK Register of Prostate Embolization.