Case-Control Comparison of Conventional End-Hole versus Balloon-Occlusion Microcatheter Prostatic Artery Embolization for Treatment of Symptomatic Benign Prostatic Hyperplasia

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ABSTRACT

Purpose: To compare procedural metrics and clinical improvement for prostatic artery embolization (PAE) performed with a balloon-occlusion (BO) versus end-hole (EH) microcatheter in patients with benign prostatic hyperplasia.

Materials and Methods: Retrospective review was performed of 129 patients undergoing PAE with 100–300 μm Embosphere microspheres from April 2013 through August 2018. Microcatheter selection was nonrandom, based on prostatic artery anatomy. Five technical failures and 5 microcatheter crossover cases were excluded. BO group (n = 46, age 72.8 y ± 9.0, gland volume 184 mL ± 83, 42% in retention) and EH group (n = 73, age 76.0 y ± 9.0, gland volume 190 mL ± 116, 44% in retention) were compared using procedural metrics (excluding 30 EH learning-curve cases); symptomatic improvement at 3, 6, and 12 months after PAE; voiding trial success; and adverse events (reported used Clavien-Dindo classification).

Results: Procedural and fluoroscopy times were lower in the BO group (n = 46) vs EH group (n = 43) (152.0 min ± 34.0 vs 172.8 min ± 47.9, $P < .02$; 37.8 min ± 12.9 vs 50.3 min ± 18.9, $P < .001$). Collaterals coiled, contrast material used, and injected particle volume were similar for both groups (P = NS). International Prostate Symptom Score improvement was similar for BO group (n = 25) (before PAE 23.5 ± 6.5, 12 months after PAE 7.6 ± 6.8) and EH group (n = 30) (before PAE 20.9 ± 5.9, 12 months after PAE 6.6 ± 5.2) (P = NS). Quality-of-life improvements were also similar (BO: before PAE 4.5 ± 1.2, 12 months after PAE 1.4 ± 0.9; EH: before PAE 4.1 ± 1.0, 12 months after PAE 0.9 ± 0.7), as were 12-month postvoid residual improvements, voiding trial failure rates (EH 12%, BO 8%), and adverse event rates (grade II, III: EH 15%, BO 11%) (P = NS for all).

Conclusions: BO microcatheter use in PAE did not affect injected particle volume, contrast material use, or protective coiling and did not impact symptomatic improvement, postvoid residual improvement, voiding trial success, or adverse events after PAE. Lower procedure and fluoroscopy times with BO microcatheter were likely due to selection bias.

ABBREVIATIONS

BO = balloon-occlusion, BO-L = balloon-occlusion for LUTS, BO-R = balloon-occlusion for retention, CCI = Charlson Comorbidity Index, EH = end-hole, EH-L = end-hole for LUTS, EH-R = end-hole for retention, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptoms, NS = not significant, PAE = prostatic artery embolization, PGV = prostate gland volume, PVR = postvoid residual, QOL = quality of life

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EDITORS' RESEARCH HIGHLIGHTS

- This single-center, single-operator, retrospective analysis from 2013–2018 compared outcomes of prostatic artery embolization (PAE) with balloon-occlusion (BO) microcatheter versus end-hole (EH) microcatheter in 129 patients with benign prostatic hyperplasia.
- There was a selection bias that affected choice of microcatheter type; all patients considered to have a more favorable anatomy for selective catheterization received a BO microcatheter (n = 46), whereas patients with more challenging anatomy received an EH microcatheter (n = 73). This selection bias may have contributed more to the lower procedural and fluoroscopy times observed in the BO group than any actual difference related to the type of microcatheter selected.
- Use of BO microcatheter showed equivalent adverse event rates and symptomatic improvement compared with use of EH microcatheter. Outcomes related to protective coil embolization did not distinguish EH and BO groups.
- The authors suggest that the initial learning curve of PAE is approximately 30 procedures, after which procedural and fluoroscopy times decrease significantly. Adverse events and symptomatic improvement were similar compared with procedures performed after the initial learning curve.

Prostatic artery embolization (PAE), an endovascular procedure for treatment of symptoms related to benign prostatic hyperplasia, can be technically challenging (1–3). Multiple collateral vessels are commonly found to anastomose with arteries supplying the bladder, rectum, and penis. Additionally, variations in arterial anatomy, such as the rectoprostatic trunk (a single branch supplying both the rectum and the prostate) or the accessory internal pudendal artery (supplying both the prostate and the penis) are commonly found (4,5). Furthermore, patients undergoing PAE are older men, often with pelvic arterial atherosclerotic occlusions that can lead to ectopic collateral formation (6). If this arterial anatomy is not safely navigated, nontarget embolization can result in irreversible vascular compromise to other vital pelvic organs.

A balloon-occlusion (BO) microcatheter has the ability to reduce reflux-mediated nontarget embolization with a balloon tip that, when inflated, occludes the selected vessel upstream of the catheter tip. Such a device also has the potential to effect a more thorough embolization by theoretically enabling injection of more embolic particles than would be possible without flow reversal in downstream collateral vessels. Small case series describe safe and effective use of a BO microcatheter in chemoembolization procedures (7–11), with 1 report describing its use for PAE in 12 patients (12). In that study, embolization was performed in all patients using a BO microcatheter, with short-term follow-up demonstrating substantial clinical improvements and minimal adverse events, in line with many larger reported PAE series. However, in that study, multiple embolic agents were used, procedural metrics were not evaluated, and no comparison was made between outcomes achieved with a BO microcatheter and outcomes obtained with a conventional end-hole (EH) microcatheter. The purpose of this study was to determine if using a BO microcatheter offers any benefit in procedural metrics or clinical improvements over an EH microcatheter when used to perform PAE, done uniformly with a single embolic agent.

MATERIALS AND METHODS

Patients

Data for this study were retrospectively collected and reviewed with institutional review board approval. Between April 2013 and August 2018, 129 patients underwent PAE at a single institution with 100–300 μm Embosphere microspheres (Merit Medical Systems, Inc, South Jordan, Utah). Among 129 patients, 75 underwent PAE for lower urinary tract symptoms (LUTS), and 54 had urinary retention with indwelling catheters. Before embolization, all patients were evaluated by urologists and the performing interventional radiologist, with completion of International Prostate Symptom Score (IPSS) and quality-of-life (QOL) questionnaires where appropriate and calculation of Charlson Comorbidity Index (CCI) (13). Postvoid residuals (PVRs) and prostate gland volumes (PGVs) measured by transabdominal ultrasound or cross-sectional imaging were obtained before PAE when possible.

Procedure

A single operator with 8 years of experience (R.A.) performed all PAE procedures. After a 6-F vascular sheath was introduced into the femoral artery, one of the internal iliac arteries was selected with a 5-F angiographic catheter (CONTRA 2 catheter [Boston Scientific, Marlborough, Massachusetts] or Roberts uterine catheter [Cook Medical, Inc, Bloomington, Indiana]). Digital subtraction angiography was then performed in an ipsilateral oblique position to define branches of the anterior division of the internal iliac artery. The prostatic artery was then selected with either a 2.1-F or 2.4-F EH microcatheter (Maestro [Merit Medical, Inc], SwiftNINJA [Merit Medical, Inc], or Renegade STC [Boston Scientific]) (EH group) or a 2.2-F Sniper BO microcatheter (Embolx, Inc, Sunnyvale, California) (BO group), using a 0.016-inch Fathom guide wire (Boston Scientific). Use of the BO microcatheter was not randomized. The BO microcatheter was selected for use in any femoral access case in which the operator deemed the patient's prostatic arterial origins amenable to accommodating the Sniper's straight 2.2-F microcatheter tip. An EH microcatheter was selected in cases with tortuous prostatic arterial origins deemed too curved to accommodate the Sniper's straight tip.

After prostatic artery selection, digital subtraction angiography was again performed to delineate arterial supply to

the prostate gland and to detect any branch vessels supplying nontarget tissues. Subsequently, 200 μg nitroglycerin was injected into the prostatic artery, followed by cone-beam computed tomography (GE Healthcare, Chicago, Illinois) to confirm arterial anatomy and to obtain a PGV. If any arteries supplying nontarget tissues were encountered that could not be bypassed or excluded by a BO microcatheter (Fig 1), they were selected and protective coil embolization with microcoils (Concerto detachable coils [Medtronic, Minneapolis, Minneapolis] or Tornado pushable coils [Cook Medical, Inc]) was performed (14). Regardless of microcatheter selection, collateral vessel coiling was limited to situations when the operator did not believe embolization could otherwise be safely performed. Collaterals were not coiled for the purpose of enabling a more pressurized injection of particles into the prostate.

The microcatheter was then advanced deeper into the prostatic artery for embolization with 100–300 μm Embosphere microspheres. Each vial containing 2 mL of particles and 7 mL of saline (after decanting 1 mL to clear air bubbles) was mixed with 11 mL of iohexol (Omnipaque-300; GE Healthcare, Marlborough, Massachusetts) to yield a total volume of 20 mL for each vial of particles. If using an EH microcatheter, embolization was performed to stasis with any nontarget reflux of particles avoided. The catheter was then cleared of embolic particles by slow intermittent injection under fluoroscopic monitoring. If the BO microcatheter was used, the balloon was first inflated with 50% contrast under fluoroscopic control, and contrast material was injected into the vessel to confirm upstream balloon occlusion (Fig 2a–d). Embolization with 100–300 μm Embosphere microspheres then proceeded until persistent stasis was seen in the prostatic vessels after the balloon was deflated. The catheter was then cleared of embolic particles by slow intermittent injection under fluoroscopic control. After all embolizations, follow-up digital subtraction angiography was performed to assess for stasis within the selected prostatic artery and to confirm patency of any adjacent nontarget arteries. Embolization was then carried out on the contralateral side using the same technique. The procedure was concluded, and hemostasis was achieved with a 6-F Angio-Seal device (Terumo Medical Corporation, Somerset, New Jersey). For each case, the fluoroscopy time, procedure time, contrast material used, number of collateral vessels coiled, number of vials of embolic particles used, and volume of embolic agent injected normalized to PGV (number of vials of particles injected per 100 mL of PGV) were recorded. Additional radiation exposure data, such as cumulative dose and dose area product, were unavailable because of the lack of a data storage mechanism in the imaging workstation software.

Follow-up

Outpatients were observed for 2 hours and then discharged home. Inpatients were discharged per their admitting service. Patients returned for follow-up with Interventional Radiology 1, 3, 6, and 12 months after PAE and yearly thereafter, completing IPSS and QOL assessments each time. Voiding trials with the referring urologists were arranged at 4 weeks (and for patients who failed, a second trial at 8 weeks was arranged). PVR and PGV measurements were obtained at 3 months and thereafter. Patients were also seen by their urologist within 6 months after PAE. The decision to discontinue benign prostatic hyperplasia medications was made based on the degree of symptomatic improvement reported. Adverse events within 90 days were tabulated at 1-month or 3-month follow-up visits according to the Clavien-Dindo classification (15). Dysuria, urgency, and frequency up to 1 week after PAE were considered normal symptoms. Prostate specific antigen levels, sexual function scores, and urinary flow rates were not able to be routinely obtained.

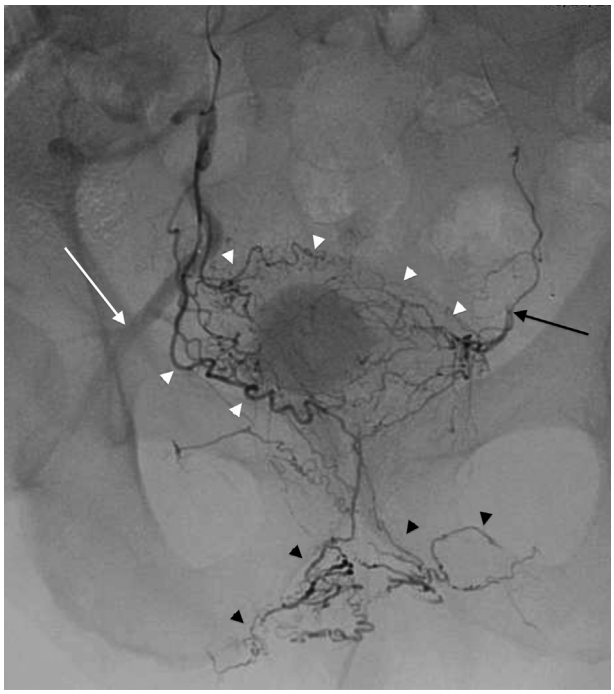


Figure 1. Angiogram showing superselective contrast injection into the left inferior vesical artery (black arrow). Collateralization was seen to branches of the bilateral internal pudendal arteries (black arrowheads) and right inferior vesical and bilateral superior vesical arteries (white arrowheads), with contrast spillover into the right inferior gluteal artery (white arrow). The bladder was decompressed around a Foley catheter balloon filled with contrast material.

Cohort Selection

The flowchart in Figure 3 illustrates the patient inclusion and exclusion criteria and cohort formation process for this study. To correct for learning curve effects on the analysis of procedural metrics between the EH microcatheter (EH group) and the BO microcatheter (BO group), the first 30 PAE cases (none of which used the BO microcatheter) were excluded. This was based on regression analysis demonstrating these initial 30 learning curve PAE cases required substantially more procedure time (261.5 min ± 42.7 vs 161.4 min ± 42.0) and fluoroscopy time (68.5 min

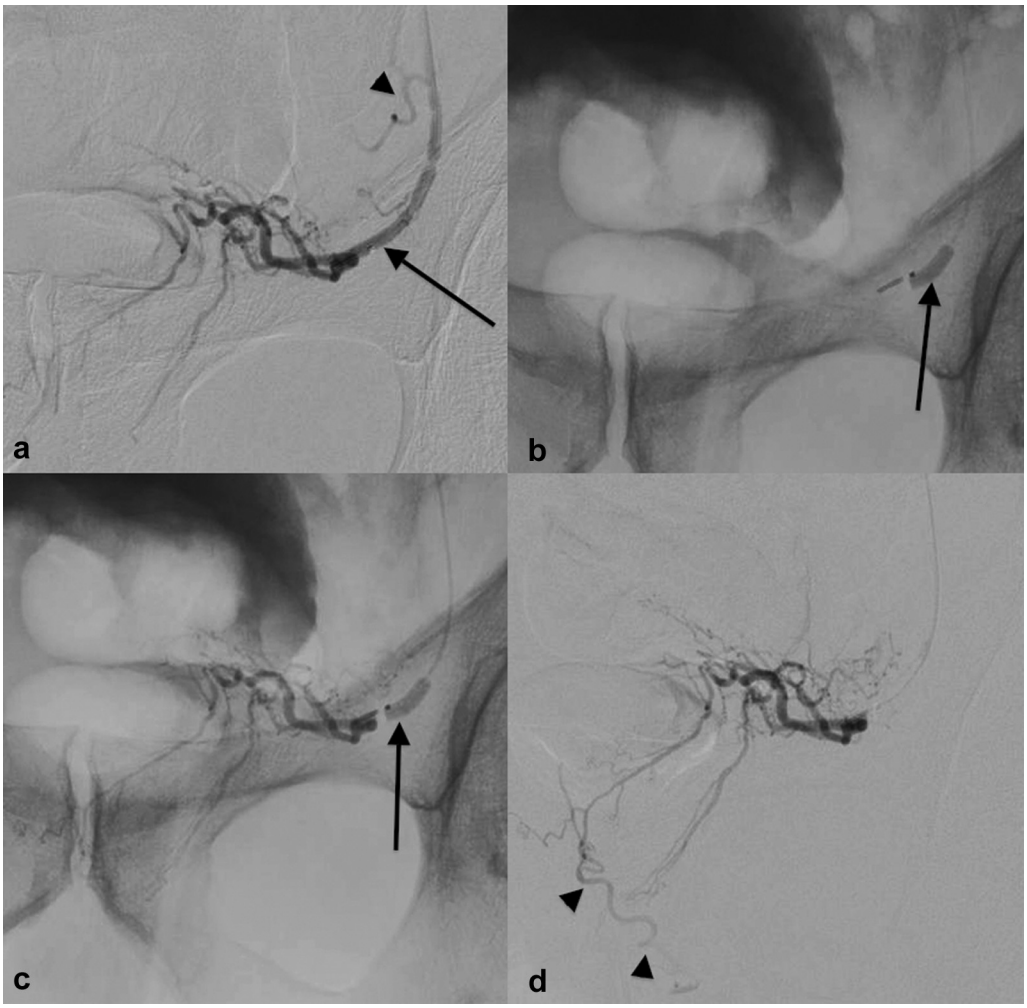


Figure 2. **(a)** Digital subtraction angiography with BO microcatheter tip (arrow) situated in the left prostatic artery, with balloon deflated. Contrast material filled prostatic vessels and refluxed back into a left vesical branch (arrowhead). **(b)** Unsubtracted image showing the microcatheter balloon inflated (arrow). **(c)** Unsubtracted angiographic image with microcatheter balloon inflated (arrow), demonstrating prevention of reflux upstream from the balloon. **(d)** Digital subtraction angiography of the same injection revealed forward flow into collaterals connecting to the right internal pudendal artery previously not seen without the balloon inflated (arrowheads).

± 21.1 vs 43.5 min ± 17.0) than the subsequent 99 cases (Fig 4a, b). Table 1 lists characteristics of the excluded learning curve patients compared with the remainder of the cohort used for the study. The 2 groups did not differ in any studied patient characteristic before PAE except that the learning curve group had significantly higher PGVs. Among the subsequent non–learning curve cases, technical failures in which either unilateral embolization or no embolization was performed (n = 5) were excluded from all analyses, as were technically successful crossover procedures in which the prostatic artery on one side was treated with a BO microcatheter, but the other prostatic artery was not (n = 5). Therefore, 89 patients were included for analysis of the impact of the BO microcatheter on procedural metrics of PAE, with 43 patients treated with an EH microcatheter (EH group) and 46 patients treated with the BO microcatheter (BO group).

For analysis of the impact of the BO microcatheter on clinical outcomes after PAE, the 30 learning curve patients were included (Fig 3). Of the original 129 patients, exclusion of the 5 technical failures and 5 crossover patients yielded a cohort of 119 patients for this analysis. Baseline characteristics for these 119 patients (EH group, n = 73; BO group, n = 46) are summarized in Table 2, with no significant differences seen between the 2 groups. Twelve patients with bladder pathology (Parkinsonian neurogenic bladder, n = 4; recurrent bladder cancer, n = 3; bladder stone, n = 5), 4 patients with prostate cancer, and 10 patients with dementia preventing quantitative follow-up were excluded. This yielded a cohort of 93 patients for clinical outcomes analysis (EH group, n = 55; BO group, n = 38). Within the EH and BO groups, subgroups were created for patients who underwent PAE to treat LUTS, EH-L (n = 30) and BO-L (n = 25) and patients who had retention, EH-R (n = 25) and BO-R (n = 13).

Image Processing and Statistical Analysis

Multiplanar images were reformatted from source cone-beam computed tomography procedural images (GE Advantage Workstation, Release 4.5; GE Healthcare). Segmented volumetric measurements of PGV were

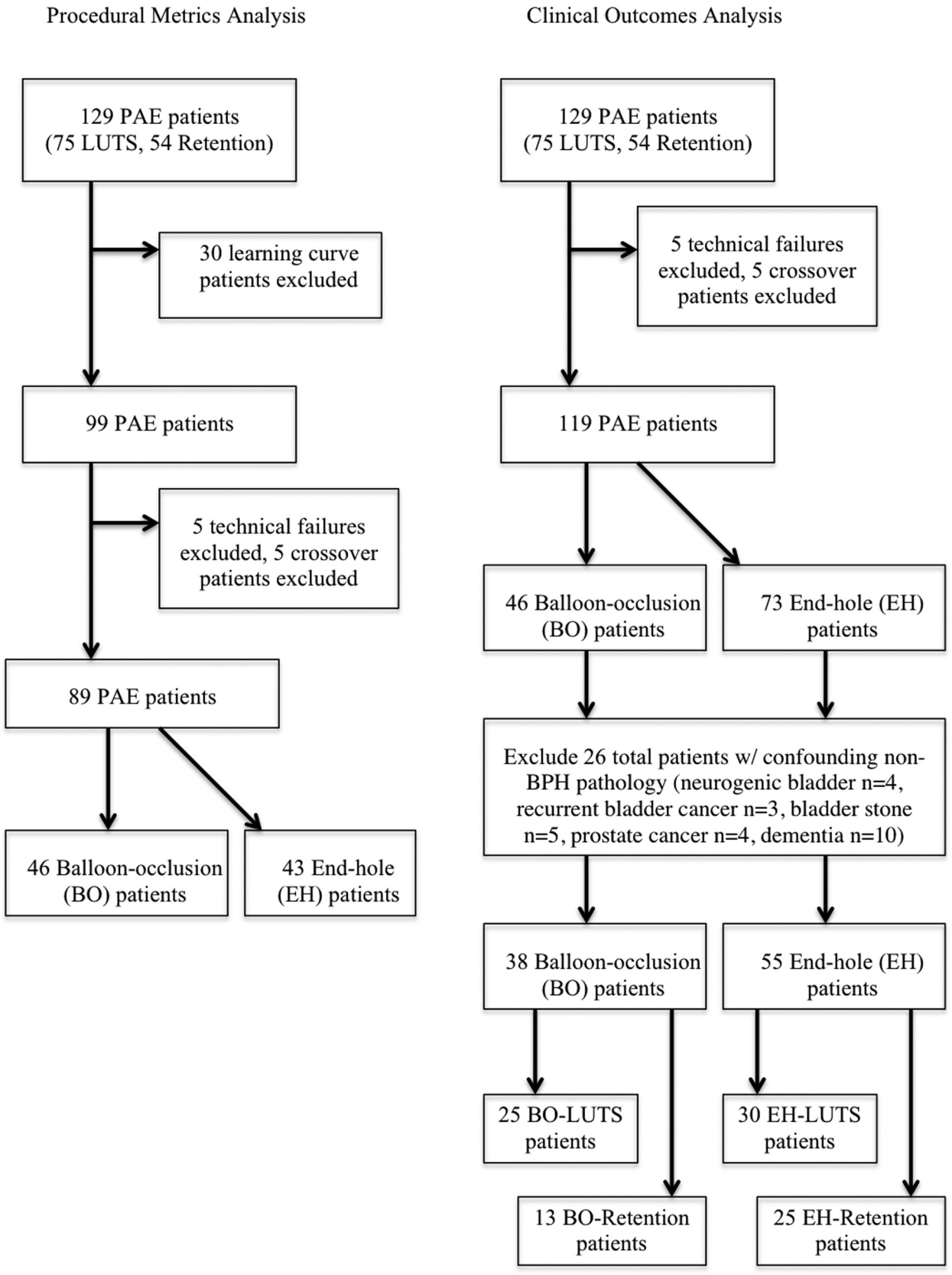


Figure 3. Flowchart depicting the patient inclusion and exclusion criteria and cohort formation process for both the procedural metrics analysis and the clinical outcomes analysis.

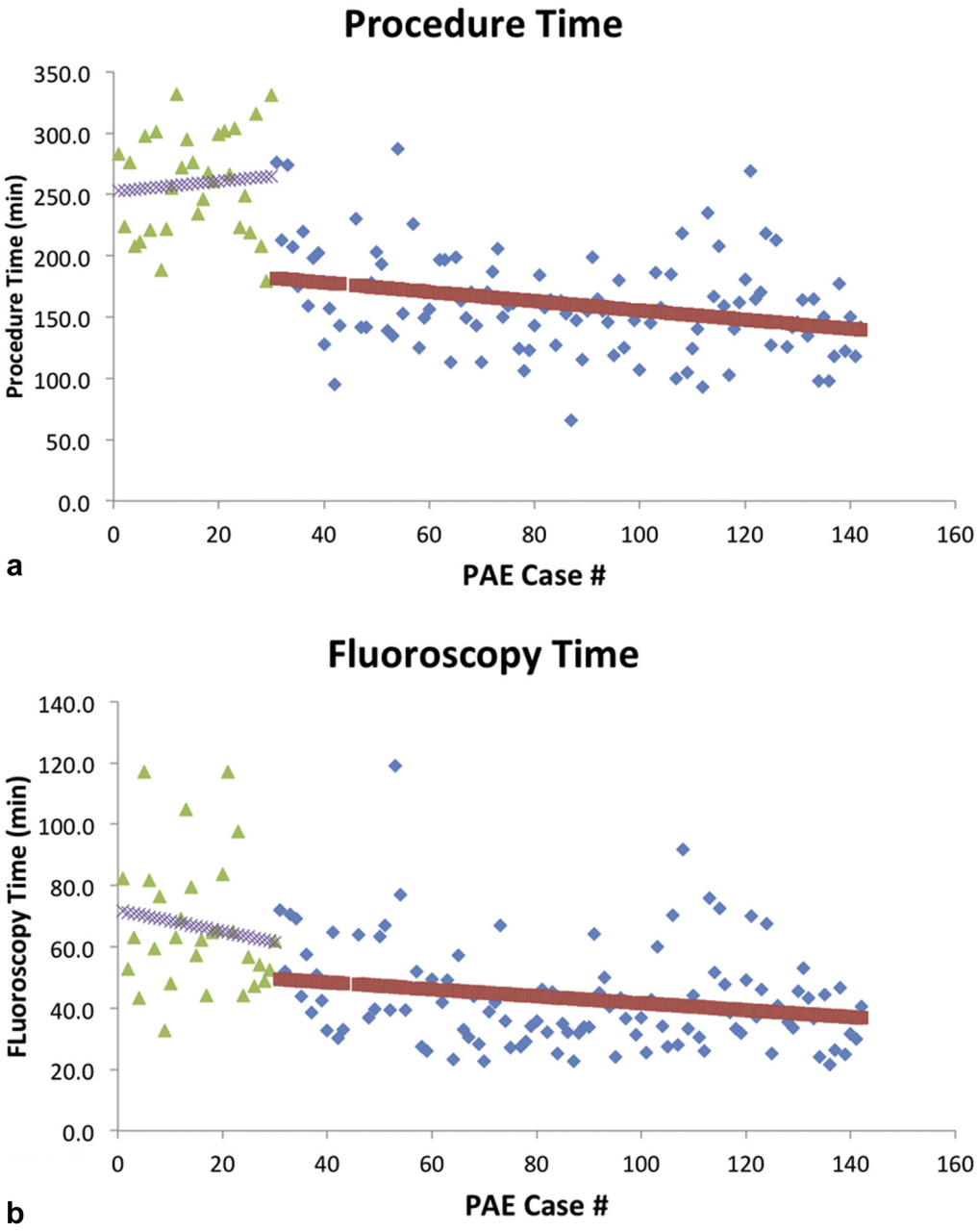


Figure 4. Procedure times **(a)** and fluoroscopy times **(b)** for all 124 PAE cases included for study, plotted in sequential case order. Values for both parameters were found to be higher for the first 30 cases.

calculated using regions of interest drawn around prostate tissue on axial images. Statistical analysis was performed using R Version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria) and Excel 2016 (Microsoft Corporation, Redmond, Washington). Two-tailed Student *t* tests compared baseline characteristics before PAE between groups (age, PGV) and procedural metrics between groups (procedure time, fluoroscopy time, contrast material used, particle vials used, and volume of embolization particles deposited). Wilcoxon signed rank tests were used to compare CCI and number of collateral vessels coiled and to compare IPSS and QOL score with baseline values and between the BO and EH groups. For comparison of the proportion of patients with LUTS in each group, Fisher exact test was used. For comparisons of PGV and PVR with baseline values and between groups, 2-tailed Student *t* tests were used. Nonlinear regression was used to evaluate temporal trends in procedure time and fluoroscopy time in all procedures for the purpose of defining which patients to exclude from analysis on the basis of learning curve effects. Adverse event rates between BO and EH groups were compared using χ^2 test. For all analyses, $P < .05$ was considered statistically significant.

Table 1. Patient Characteristics and Procedural Details for Initial 30 PAE Learning Curve Cases Compared with Subsequent 89 PAE Study Cases

Baseline Characteristic before PAE	Learning Curve Cases (n = 30)	Study Cases (n = 89)	*P* Value
Age, y	76.5 ± 8.4	74.5 ± 9.5	NS
CCI	4.2 ± 1.7	4.1 ± 2.1	NS
PGV, mL	256 ± 167	175 ± 88	< .001
LUTS patients, %	43% (13/30)	61% (54/89)	NS
IPSS, LUTS patients only	23.7 ± 5.9	21.3 ± 6.2	NS
QOL, LUTS patients only	4.4 ± 1.0	4.3 ± 1.1	NS
PVR, LUTS patients only, mL	218 ± 144	171 ± 154	NS

Note–Values are reported as mean ± SD. Five technical failures and 5 microcatheter crossover cases were excluded. There were no significant differences between the 2 groups apart from PGV, which was significantly larger in the learning curve patients.
CCI = Charlson Comorbidity Index; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; NS = not significant; PAE = prostatic artery embolization; PGV = prostate gland volume; PVR = postvoid residual; QOL = quality of life.

Table 2. Baseline Characteristics for All 119 Cohort Patients in EH and BO Groups for Whom Clinical Outcomes Were Studied

Characteristic	EH (n = 73)	BO (n = 46)	*P* Value
Age, y	76.0 ± 9.0	72.8 ± 9.0	NS
CCI	4.3 ± 2.1	3.8 ± 2.1	NS
PGV, mL	190 ± 116	184 ± 83	NS
LUTS patients, %	56% (38/73)	58% (30/46)	NS
IPSS, LUTS patients only	20.4 ± 5.8	23.0 ± 6.4	NS
QOL, LUTS patients only	4.2 ± 1.0	4.5 ± 1.1	NS
PVR, LUTS patients only, mL	144 ± 119	212 ± 173	NS

Note–Values are reported as mean ± SD. No significant differences between the 2 groups were observed.
BO = balloon-occlusion; CCI = Charlson Comorbidity Index; EH = end-hole; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; NS = not significant; PGV = prostate gland volume; PVR = postvoid residual; QOL = quality of life.

RESULTS

Procedural Metrics

For the 89 patients in whom procedural metrics were analyzed, both procedure and fluoroscopy times were plotted separately for BO cases and EH cases, with regression analysis showing no differential learning curve effects between the 2 groups for either parameter (Fig 5a, b) (*P* = not significant [NS] for both). Table 3 displays values for the procedural metrics studied in the EH and BO groups. The mean number of collaterals coiled, mean contrast volume used, mean number of embolization particle vials used, and mean normalized particle volume injected did not differ significantly between the 2 groups (*P* = NS for all). Mean procedure time of 152.0 minutes ± 34.0 for the BO group was significantly lower than mean procedure time of 172.8 minutes ± 47.9 for the EH group (*P* < .02). Mean fluoroscopy time of 37.8 minutes ± 12.9 for the BO group was significantly lower than mean fluoroscopy time of 50.3 minutes ± 18.9 for the EH group (*P* < .001).

LUTS Clinical Outcomes

Of the 93 patients for whom clinical outcomes were analyzed, 55 patients underwent PAE to treat LUTS. Patients with LUTS treated using an EH microcatheter (EH-L, n = 30) had a mean age 72.7 years ± 9.0, mean CCI 3.5 ± 1.6, and mean PGV 187 mL ± 132. Patients with LUTS treated using the BO microcatheter (BO-L, n = 25) had a mean age 71.3 years ± 7.9, mean CCI 3.2 ± 1.4, and mean PGV 169 mL ± 75. None of these values were significantly different between the 2 groups (*P* = NS for all).

Mean IPSS values in the EH-L group before PAE and at 3, 6, and 12 months after PAE (Table 4) were plotted against corresponding mean IPSS values in the BO-L group (Fig 6a). Both groups demonstrated clinically substantial and statistically significant decreases in IPSS at 3 months that were sustained through 12 months, with no significant differences between groups at any time point (*P* = NS for all). Similarly, mean QOL scores in the EH-L group over time (Table 4) were plotted against corresponding mean QOL scores in the BO-L group (Fig 6b). Again, both groups demonstrated clinically substantial and statistically significant decreases in QOL at 3 months that were sustained through 12 months, with no significant differences between groups at any time point (*P* = NS for all). The same trend held true for PVR. The EH-L group mean PVRs before PAE and at 3, 6, and 12 months (Table 4) were plotted against corresponding mean PVRs in the BO-L group (Fig 6c). Both groups demonstrated improved PVRs at 3 months that were sustained through 12 months, with no significant differences between groups at any time point (*P* = NS for all).

Clinical nonresponses, defined as IPSS > 12 at 3 months or increase in IPSS to > 12 at any point, were too infrequent to evaluate for differences between BO and EH groups. In the EH-L group, 1 patient had initial relief after PAE, but then symptoms worsened over the next year and his urologist diagnosed overactive bladder. In the BO-L group, 1 patient had initial relief, but then symptoms returned over 3–6 months, with no cause identified.

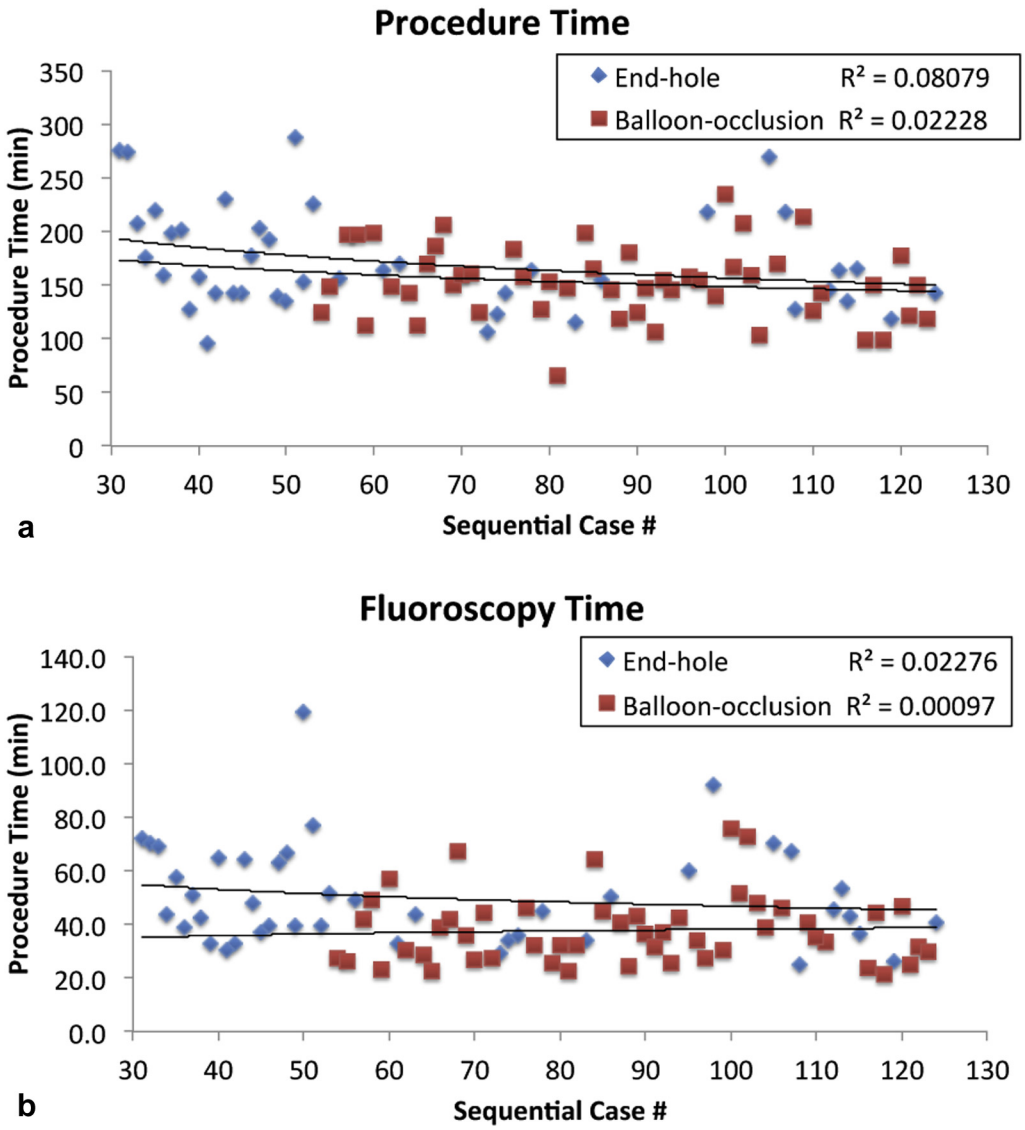


Figure 5. Procedure times **(a)** and fluoroscopy times **(b)** for BO cases (red) and EH cases (blue). No differential learning curve effects were seen between the 2 groups for either parameter.

Table 3. Procedural Metrics Studied in EH and BO Groups

Metric	EH (n = 43)	BO (n = 46)	*P* Value
Collateral vessels coiled	0.6 ± 0.6	0.7 ± 0.9	NS
Contrast volume used, mL	150 ± 46	138 ± 30	NS
No. particle vials used	0.73 ± 0.31	0.78 ± 0.29	NS
Normalized particle volume injected, no. vials/100 mL gland volume	0.53 ± 0.29	0.47 ± 0.18	NS
Procedure time, min	172.8 ± 47.9	152.0 ± 34.0	< .02
Fluoroscopy time, min	50.3 ± 18.9	37.8 ± 12.9	< .001

Note–Values are reported as mean ± SD. Only procedure time and fluoroscopy time were found to be significantly different between the 2 groups.
BO = balloon-occlusion; EH = end-hole; NS = not significant.

Retention Clinical Outcomes

Of the 93 patients with clinical outcomes analyzed, 38 patients underwent PAE for treatment of urinary retention. Patients with retention treated using an EH microcatheter (EH-R, n = 25) had a mean age 77.5 years ± 8.1, mean CCI 4.4 ± 1.5, and mean PGV 210 mL ± 110. Of these patients, 21 (84%) passed voiding trials within 4–8 weeks after PAE and were voiding well with QOL score ≤ 2 and PVR of 143 mL ± 171 at most recent follow-up. Three (12%) patients in the EH-R group failed voiding trials, and 1 patient died within 1 month after PAE from an unrelated cardiac event. Patients with retention treated using the BO microcatheter (BO-R, n = 13) had a mean age 76.8 years ± 8.8, mean CCI 5.1 ± 2.7, and mean PGV 212 mL ± 79. Of these patients, 12 (92%) passed voiding

Table 4. Clinical Outcomes through 12 Months of Follow-up for 55 Patients with LUTS Who Underwent Technically Successful PAE and Have Follow-up Available

Clinical Outcome	No. EH-L Patients	EH-L Mean ± SD	EH-L Mean Improvement	No. BO-L Patients	BO-L Mean ± SD	BO-L Mean Improvement	*P* Value
IPSS							
Baseline	30	20.9 ± 5.9	—	25	23.5 ± 6.5	—	NS
3 mo	18	6.0 ± 5.6	↓71%	17	6.4 ± 4.6	↓73%	NS
6 mo	23	6.0 ± 3.4	↓71%	17	6.7 ± 4.7	↓71%	NS
12 mo	20	6.6 ± 5.2	↓68%	8	7.6 ± 6.8	↓68%	NS
QOL							
Baseline	30	4.1 ± 1.0	—	25	4.5 ± 1.2	—	NS
3 mo	18	1.1 ± 1.2	↓73%	17	1.2 ± 1.2	↓73%	NS
6 mo	22	1.1 ± 1.0	↓73%	17	1.2 ± 1.3	↓73%	NS
12 mo	19	0.9 ± 0.7	↓78%	8	1.4 ± 0.9	↓69%	NS
PVR, mL							
Baseline	22	142 ± 122	—	18	221 ± 173	—	NS
3 mo	10	69 ±3 9	↓51%	15	62 ± 63	↓72%	NS
6 mo	19	53 ± 54	↓63%	17	67 ± 92	↓70%	NS
12 mo	20	56 ± 51	↓60%	6	91 ± 162	↓59%	NS

Note–No significant differences between BO-L and EH-L groups were observed at any time point for any parameter.
BO-L = balloon-occlusion for LUTS; EH-L = end-hole for LUTS; IPSS = International Prostate Symptom Score; NS = not significant; PVR = postvoid residual; QOL = quality of life.

trials within 4–8 weeks after PAE and were voiding well with QOL score $\leq$ 2 and PVR of 202 mL ± 275 at most recent follow-up. One (12%) patient in the BO-R group failed his voiding trial. There were no differences in voiding trial success rate or PVR between the 2 groups (P = NS).

Alternative Technique for BO Microcatheter Implementation

Notably, there were PAE procedures in this cohort that could not have been performed safely without the BO microcatheter owing to challenging arterial anatomic configurations. For example, in 1 case, the prostatic arteries on both sides had origins from the internal obturator arteries but were too small and tortuous to be selected with a microcatheter. Bilateral protective coiling of the internal obturator arteries was deemed unsafe because they were supplying by collateralization most of the pelvic tissues that the occluded internal pudendal arteries had originally supplied (**Fig 7a**). The BO microcatheter was used in a fashion analogous to protective coiling. On each side, the balloon was inflated to occlude the obturator artery lumen just downstream from the prostatic artery origin (**Fig 7b**). The tip of the outer 5-F catheter was then advanced over the microcatheter shaft to a point just upstream from the prostatic artery origin. Embolic particles were then injected through the lumen of the 5-F catheter, around the microcatheter shaft, and forward into the prostatic artery. Just before the point of stasis, the 5-F catheter was cleared of all particles before deflating the microcatheter balloon.

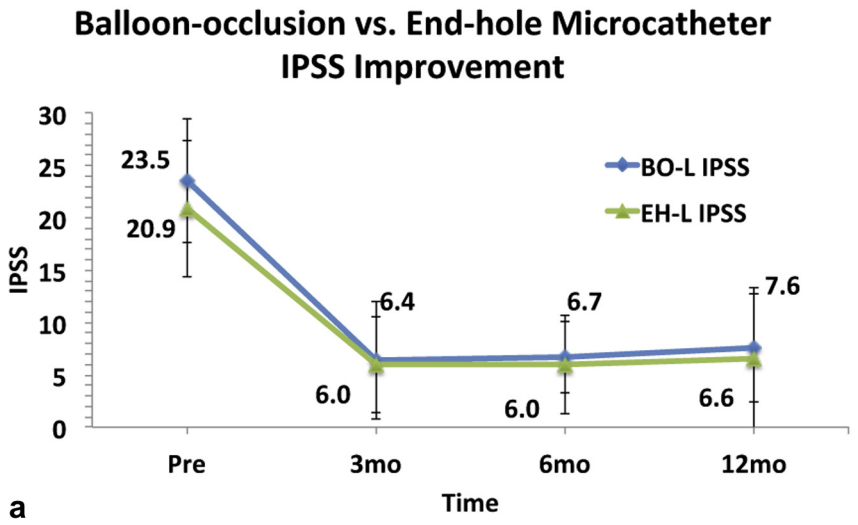
Follow-up Compliance and Adverse Events

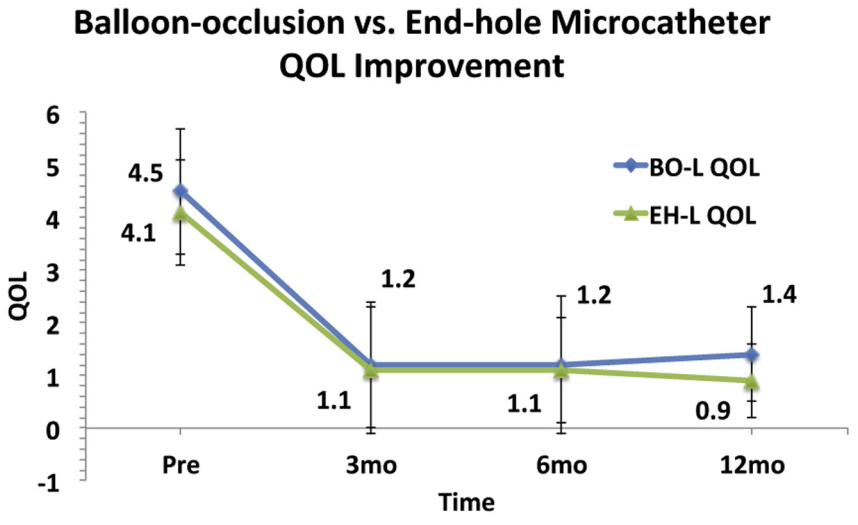
Although not all patients returned for every follow-up visit, at the time of submission 91% of patients had returned for their most recent eligible follow-up visit, with 66% of patients in the EH group and 68% of patients in the BO group remaining off of all benign prostatic hyperplasia medications. Dementia in some of the patients with retention (n = 10) prevented meaningful comparison of symptom improvement data between BO-R and EH-R groups.

Adverse events in the BO and EH groups (including the 30 learning curve patients) are summarized in **Table 5**. There were 9 (16%) self-limited grade I events in the EH group compared with 13 (34%) in the BO group. There were 7 (13%) grade II events in the EH group compared with 3 (8%) in the BO group, and all were urinary tract infections that resolved with outpatient oral antibiotic treatment. Regarding grade III events, 1 patient experienced autoenucleation of the prostate gland that required cystoscopic removal of free-floating tissue. In the BO group, 1 patient had persistent pelvic pain prompting cystoscopic removal of necrotic prostatic tissue 8 months after PAE, although this did not completely improve his pain. There were no statistically significant differences in frequencies of adverse events between EH and BO groups (P = NS).

DISCUSSION

Nontarget embolization and resulting vascular compromise of surrounding pelvic organs is a serious potential risk associated with the PAE procedure, posing a technical challenge to even the most experienced operator (4). A





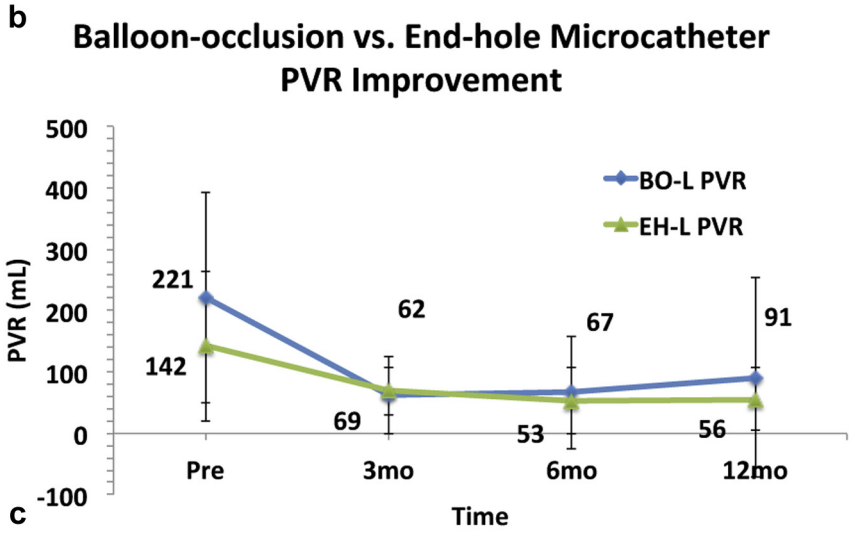


Figure 6. Improvement in IPSS **(a)**, QOL **(b)**, and PVR **(c)** after PAE over 12 months compared with baseline values before PAE. No significant differences were observed between BO-L and EH-L groups for any of these parameters at any time point.

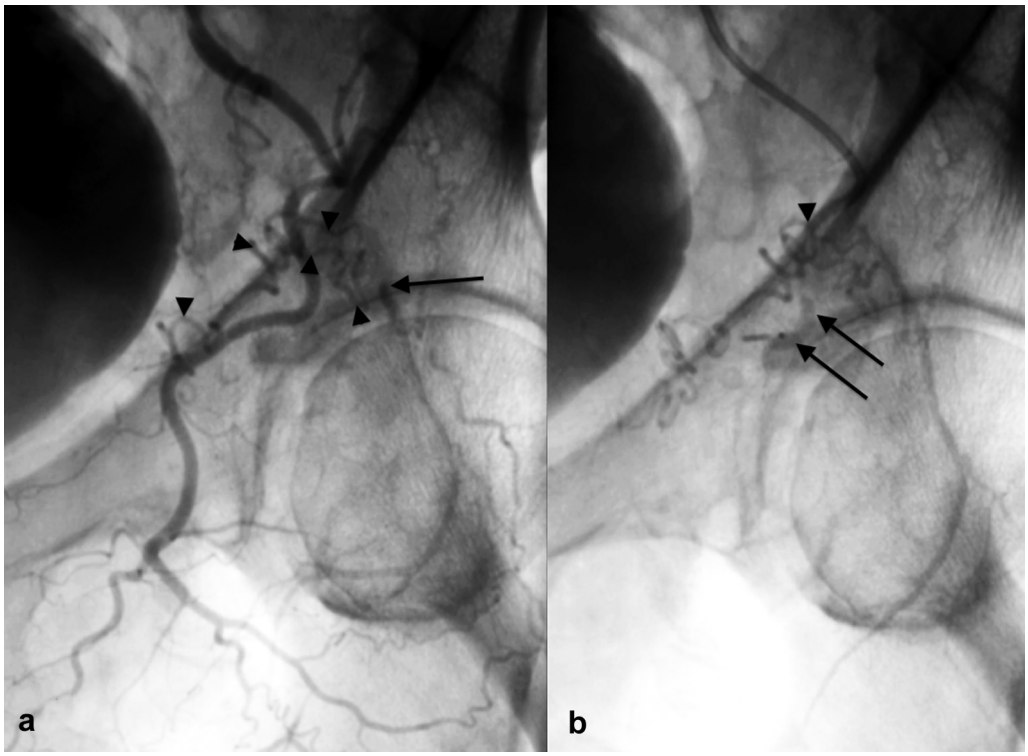


Figure 7. Case example of PAE using a BO microcatheter to exclude and protect downstream blood vessels when prostatic artery selection was not possible. **(a)** Angiogram showed the left internal obturator artery to be collaterally supplying much of the pelvis because of chronic atherosclerotic occlusion of the left internal pudendal artery (black arrow). The left prostate was supplied by a small tortuous branch emanating from the left internal obturator artery that could not be cannulated with a microcatheter (black arrowheads). **(b)** After downstream obturator artery occlusion with the microcatheter balloon (black arrows), the surrounding 5-F catheter was coaxially advanced down over the microcatheter shaft, with its tip situated just upstream to the prostatic artery origin (black arrowhead). Embolization was then performed through the 5-F catheter. The diminutive reconstituted left internal pudendal artery in this angiogram was not seen to opacify during injection of particles.

Table 5. Rates of Clavien-Dindo Grade I, II, and III Adverse Events for EH and BO Groups after PAE

Adverse Event	EH (n = 55)	BO (n = 38)
Clavien-Dindo grade I		
Dysuria >1 wk/>2 wk	2 (3.6%)/1 (1.8%)	5 (13.1%)/1 (2.6%)
Hematuria	2 (3.6%)	1 (2.6%)
Hematospermia	1 (1.8%)	1 (2.6%)
Rectal bleeding	0	1 (2.6%)
Acute urinary retention, <2 wk	1 (3.3% of LUTS)	2 (8% of LUTS)
Delirium	1 (1.8%)	0
Access site ecchymosis	1 (1.8%)	1 (2.6%)
Acute kidney injury, self-limited	0	1 (2.6%)
Total	9 (16%)	13 (34%)
Clavien-Dindo grade II		
UTI requiring antibiotics	1 (3.3% of LUTS)	1 (4% of LUTS)
Catheter-associated UTI	6 (24% of retention)	2 (15% of retention)
Total	7 (13%)	3 (8%)
Clavien-Dindo grade IIIb		
Transurethral resection of necrotic prostate tissue	1 (1.8%)	1 (2.6%)

BO = balloon-occlusion; EH = end-hole; LUTS = lower urinary tract symptoms; PAE = prostatic artery embolization; UTI = urinary tract infection.

balloon-tipped microcatheter that provides upstream occlusion of a vessel selected for embolization would seem useful in PAE to prevent retrograde reflux of embolic particles. Balloon occlusion of dominant arterial inflow could also improve safety by causing reversal of blood flow within downstream collateral vessels (12). Such a dynamic would

seem to further confine particles to the targeted prostate tissue. Beyond improved safety, if using a BO microcatheter were to also result in improved particle delivery within the prostate gland by these mechanisms, enhanced tissue necrosis with improved gland shrinkage might deliver a better clinical outcome.

However, in this study, use of a BO microcatheter was found to have no effect on any technical aspect of the PAE procedure apart from procedure time and fluoroscopy time. It was not shown to have any impact on amount of contrast material used or number of collateral vessels protectively coiled, and it was not associated with any difference in the amount of embolic particles delivered. Clinically, use of a BO microcatheter was not shown to have any impact on improvement from baseline after PAE in IPSS, QOL, or PVR through 12 months of follow-up for patients with LUTS. Voiding trial success rate for urinary retention patients was also not impacted by use of a BO microcatheter. Furthermore, there was no apparent microcatheter-specific difference in the rates of adverse events seen in this series. Overall, the improvements in IPSS, QOL, and PVR and the voiding trial success rates observed in this study after PAE were similar to those reported in other PAE studies (1,2,16,17).

As mentioned, use of a BO microcatheter was associated with lower procedure times and fluoroscopy times, although this was likely due to selection bias. The allocation of cases to the BO group was not randomized, but based on the authors' real-time assessment of whether the straight tip of the Sniper microcatheter could be navigated into the origins of the prostatic arteries. The decreased procedure and fluoroscopy times seen in the BO cases could be due to a tendency to select the BO catheter in less angiographically challenging cases. However, these time differences may also have been in part due to the prevention of reflux commonly afforded by the occlusion balloon during embolization, allowing for more time-efficient particle injection without an apparent effect on safety or efficacy.

The main limitation of this study is its retrospective design, with nonrandomized assignment of cases to the BO and EH groups. Other limitations include the unavailability of procedural radiation dose information and quantitative urine flow and sexual function measurements before and after PAE. Overall, the analysis of clinical outcomes in this study must be interpreted cautiously, as it is a product of a single operator's individual technique and judgment.

In conclusion, this study did not show BO microcatheter use to offer any technical benefits, decreased adverse events, or demonstrable impacts on improvement in clinical outcomes after PAE. However, its potential utility as a means to enhance the safety of the PAE procedure merits further study, especially for more technically challenging cases.

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