Prostatic Artery Embolization in Nonindex Benign Prostatic Hyperplasia Patients: Single-center Outcomes for Urinary Retention and Gross Prostatic Hematuria

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OBJECTIVE To present outcomes for prostatic artery embolization (PAE) to treat urinary retention and gross prostatic hematuria in nonindex benign prostatic hyperplasia patients.

MATERIALS AND METHODS Seventy-five patients undergoing PAE from December 2013 to August 2018 (age = 77.5 ± 8.6, age-adjusted Charlson comorbidity index = 4.6 ± 2.0, prostate volume = 224 mL ± 135 mL) for retention (n = 46) and/or gross prostatic hematuria (n = 55) were retrospectively reviewed. Twenty-six patients had both problems. Urinary retention patients (UR, n = 46, catheterization = 162.4 ± 148.1 days) underwent voiding trials 1-2 months post-PAE, with International Prostate Symptom Score (IPSS), Quality of Life (QoL), and postvoid residual (PVR) recorded at 3, 6, 12, 24, and 36 months. Pre- and post-PAE hematuria-related visits were compared for gross hematuria patients (GH, n = 39), as were transfusion rates for severe hematuria patients requiring bladder irrigation (SH, n = 16). Ninety-day adverse event tabulation used Clavien-Dindo classification.

RESULTS Three months post-PAE, 33/38(87%) UR patients were catheter-free (IPSS = 8.9 ± 5.3, QoL = 1.6 ± 1.7, PVR = 158 mL ± 207 mL). Results were similar at 6 months (catheter-free = 26/28(93%), IPSS = 6.5 ± 4.4, QoL = 1.1 ± 0.9, PVR = 149 mL ± 139 mL), 12 months (catheter-free = 19/20(95%), IPSS = 4.7 ± 4.8, QoL = 0.6 ± 0.9, PVR = 125 mL ± 176 mL), 24 months (catheter-free = 11/12(92%), IPSS = 4.4 ± 3.0, QoL = 0.9 ± 0.8, PVR = 66 mL ± 68 mL), and 36 months (catheter-free = 5/6(83%), IPSS = 5.8 ± 3.8, QoL = 0.8 ± 1.0, PVR =99 mL ± 71 mL). Out of 37, 34(92%) GH patients remained hematuria-free at 483 ± 137 days, with 22 hematuria-related visits pre-PAE vs none post-PAE. Hematuria resolved <48 hours post-PAE in 14/16(87.5%) SH patients, with 36 blood units transfused pre-PAE, 4 units transfused <48 hours post-PAE, and none thereafter. Subsequently, 13/16(81%) remained hematuria-free at 500 ± 501 days; 2/16(13%) required fulguration; 1/16(6%) developed bladder tumor. There were 2 deaths <30 days post-PAE, and 8(11%) Grade-II urinary infections.

CONCLUSION PAE provided safe, effective, and durable treatment for retention and gross hematuria in nonindex benign prostatic hyperplasia patients. UROLOGY 136: 212–217, 2020. © 2019 Elsevier Inc.

Urinary retention (UR) and gross hematuria (GH) resulting from benign prostatic hyperplasia (BPH) can be challenging problems to manage. Among BPH patients suffering from medication-refractory lower urinary tract symptoms (LUTS), 4.9% will progress to retention within 4 years, and 23% of 60-year-old men with mild symptoms will develop retention by age 80.[1,2] Many will progress to chronic urinary retention that can lead to progressive bladder dysfunction and renal impairment. GH in BPH patients can cause clot retention or catheter clogging, and can progress to life-threatening severity requiring intensive care unit admission, continuous bladder irrigation (CBI), and blood transfusion.[3] Both UR and GH patients may need long-term indwelling urinary catheters, with accompanying quality of life detriments and infection risks.

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When retention or hematuria is refractory to conservative management, surgical treatments are considered such as transurethral adenoma resection, fulguration of bleeding tissue, or prostatectomy.[4] Such procedures carry risks of operative blood loss, urinary incontinence, sexual dysfunction, bladder neck contractures, and anesthesia complications.[5] Many patients have glands too large or comorbidities too severe to safely undergo general anesthesia, and thus have few acceptable treatment options. The current American Urological Association guideline for the surgical management of LUTS attributable to BPH is not written to address procedural BPH management in these challenging nonindex patients.[4]

Prostatic artery embolization (PAE) is a minimally invasive angiographic procedure that can safely and effectively treats UR,[6-11] and GH,[12-19] of prostatic origin. Embolization causes irreversible ischemic necrosis, resulting in shrinkage of adenomatous tissue that causes bladder outlet obstruction and GH. PAE is routinely performed in prostate glands with volumes between 80 mL and 250 mL,[20,21] on an outpatient basis under moderate sedation through a small arteriotomy. Accordingly, PAE has potential to help nonindex UR and GH patients with glands larger than 80 mL or patients deemed high risks for general anesthesia. Indeed, the current National Institute for Health and Care Excellence (NICE) guidelines from the United Kingdom support the use of PAE in certain patients.[22]

Although many studies have reported meaningful improvements in UR and GH of prostatic origin after PAE, cohort sizes have been small, few have reported outcomes beyond 1 year,[6,7,12,14,16] and still fewer have focused on nonindex patients. The purpose of this study is to report safety and efficacy outcomes up to 3 years for PAE performed to treat UR or GH in a cohort of nonindex BPH patients.

MATERIALS AND METHODS

Patients

Among 151 patients referred for PAE at a single medical center from December 2013 to August 2018, 46 patients had BPH-related UR and 55 patients had GH of prostatic origin. Between these 2 groups, there was overlap of 26 patients with both problems, for a total of 75 patients included for study. Among the 55 hematuria patients, 16 were embolized urgently for severe hematuria (SH) requiring CBI, while 39 had GH not requiring CBI. Baseline characteristics for all 75 patients and the retention (UR, n = 46) and hematuria (GH or SH, n = 55) subgroups are summarized in Table 1. At the time of embolization, >80% of UR and GH patients were of American Society of Anesthesiology physical status classification level III, while 100% of the SH patients were American Society of Anesthesiology level IV. All patients were referred by urologists after undergoing cystoscopy, and were evaluated by the interventional radiology team. Hematuria patients underwent cross-sectional imaging to exclude other nonprostatic causes of bleeding. For these patients, decisions about proceeding to embolization instead of fulguration or resection were individualized to the referring urologist, but were commonly based on successful institutional experience with PAE. Preprocedure prostate gland volumes (PGV) measured by transabdominal ultrasound or cross-sectional imaging were obtained when possible. For retention patients (duration of retention = 162.4 ± 148.1 days, 57% of patients in acute retention ≤90 days, residual at time of catheter placement 428 ± 243 mL), neither preprocedural International Prostate Symptom Scores (IPSS), Quality of Life (QoL) indices, postvoid residual volumes (PVR) nor peak urinary flow rates were measurable, but IPSS, QoL, and PVR were measured in follow-up for patients who passed voiding trials.[23] For hematuria patients, pre- and postprocedure blood transfusions and urgent hematuria-related healthcare facility visits were quantified. Data were retrospectively reviewed under an Institutional Review Board-approved protocol. This cohort overlaps with others described in separate publications by these authors regarding technical aspects of PAE and the role of PAE in treating LUTS.[21,24]

Table 1. Baseline characteristics for all 75 patients undergoing prostatic artery embolization (PAE), including subgroup characterization of urinary retention patients (UR, n = 46) and all patients with hematuria (n = 55). Hematuria patients were further categorized as having severe hematuria (SH, n = 16) requiring continuous bladder irrigation, and gross hematuria (GH, n = 39) not requiring continuous bladder irrigation.

	Total Patients	Patients in Retention (UR)	All Patients With Hematuria	Severe Hematuria Patients (SH)	Gross Hematuria Patients (GH)
Cohort size	75	46	55	16	39
Mean age	77.5 ± 8.6	78.6 ± 8.5	76.5 ± 8.8	79.8 ± 8.8	75.2 ± 8.5
Mean ACCI	4.6 ± 2.0	4.7 ± 1.9	4.5 ± 2.1	5.8 ± 2.5	3.9 ± 1.6
Mean PGV	224 ± 135 mL	205 ± 97 mL	245 ± 146 mL	326 ± 171 mL	215 ± 125 mL
Pre-PAE procedures	22 (29%)	8 (17%)	16 (29%)	6 (11%)	10 (18%)
Pre-PAE medications					
• 5-α reductase Inhibitor	7 (9%)	4/46 (9%)	4/55 (7%)	1/16 (6%)	3/39 (8%)
• α-Blocker	28 (37%)	17/46 (37%)	20/55 (36%)	4/16 (25%)	16/39 (41%)
• Both	29 (39%)	19/46 (41%)	21/55 (38%)	6/16 (38%)	15/39 (38%)
• None	11 (15%)	6/46 (13%)	10/55 (18%)	5/16 (31%)	5/19 (13%)

ACCI, age-adjusted Charlson comorbidity index; PGV, prostate gland volume.

Procedure

Outpatients were started on antibiotic, anti-inflammatory, antacid, and stool softener medications 2 days before PAE. Inpatients were given the same medications if possible. Any patient with a positive urine culture was given 2-7 days of antibiotic before embolization unless SH prompted urgent intervention. All cases were performed by a single operator using intravenous moderate sedation (midazolam, fentanyl) and ketorolac. A 6-F arterial sheath was introduced into the femoral or radial artery. One of the internal iliac arteries was then selected with a 5-F angiographic catheter, and angiography mapped out the branches of the internal iliac artery (Supplementary Fig. 1A). The prostatic artery was then subselected using an end-hole microcatheter (2.1-F Maestro or 2.4-F SwiftNinja by Merit Medical, South Jordan, UT), or a 2.2-F balloon-occlusion microcatheter (Sniper by Embolx, Sunnyvale, CA). Subselective angiography defined the arterial supply to the prostate and identified nontarget branch vessels (Supplementary Fig. 1B). Subsequently, 200 mcg of nitroglycerin were injected into the prostatic artery, and cone-beam CT was performed to confirm arterial anatomy (GE Advantage Workstation, Release 4.5; GE Healthcare, Chicago, IL) (Supplementary Fig. 1C-D). Any nontarget vessels were bypassed or protectively coil-embolized (Tornado by Cook Medical, Bloomington, IN or Concerto by Medtronic, Minneapolis, MN). The microcatheter was then advanced further into the prostatic artery, and embolization to stasis was performed using 100-300 μm Embosphere particles (Merit Medical Systems, South Jordan, UT). The same procedure was then performed on the opposite side, followed by removal of vascular access and hemostasis at the arteriotomy site. Technical success was defined as bilateral embolization to stasis with 100-300 μm Embosphere particles. No actual source of bleeding was ever identified angiographically in hematuria cases.

Follow-up

Outpatients were observed 2 hours and then discharged home. Inpatients were discharged per their primary medical teams. Postprocedure medications included antibiotic treatment for 14 days, antacid and stool softener for 7 days, phenazopyridine for 5 days, and ibuprofen and solifenacin succinate as needed for pain or bladder spasm, respectively. Hematuria patients undergoing CBI had irrigation rates titrated and voiding trials performed by the Urology service within 2-7 days after PAE. Urinary retention patients had voiding trials performed with their urologists 1 month after PAE. Patients with voiding efficiency ([voided volume/(voided volume + PVR)] × 100) >60%, had catheters removed. Patients who failed initial voiding trials had a second voiding trial arranged 1 month later. Both retention and hematuria patients returned for follow-up with Interventional Radiology at 1, 3, 6, 12, 24, and 36 months after PAE. They also followed-up with their urologists within 6 months after embolization. At each follow-up from 3 months onward, IPSS, QoL, PVR, and PGV were measured. Patients continued taking any BPH medications until their first follow-up. Thereafter, decisions regarding continuation of medications were made depending on symptomatic improvement reported. Adverse events were recorded using Clavien-Dindo classification.[25]

Data Analysis

Clinical outcomes for retention patients (Group UR, n = 46) and hematuria patients (gross hematuria, Group GH, n = 39; severe hematuria, Group SH, n = 16) were evaluated separately on an intention to treat basis. Adverse events were evaluated for all 75 patients combined, also on an intention-to-treat basis. Statistical analysis was performed using R (The R Foundation for Statistical Computing, Version 3.3.2, 2016). For comparisons among postprocedure QoL and IPSS scores, paired analysis with Wilcoxon signed rank tests were performed. For comparisons of PVR to baseline, paired 2-tailed Student's t tests were used. For all statistical analyses, P values <0.05 were considered statistically significant.

RESULTS

Urinary Retention Outcomes

Technical success was achieved in 45/46 (98%) UR patients (mean procedure time = 186.9 ± 54.8 minutes, mean fluoroscopy time = 55.2 ± 23.4 minutes). The single technical failure occurred because the patient's prostatic arteries were too small and tortuous to select with an angiographic microcatheter. This patient and 2 patients who declined postembolization voiding trials were included in adverse event analysis but excluded from outcomes analysis, and further managed by their urologists with continued indwelling catheters.

Due to rolling accumulation of cases and unrelated deaths of elderly patients, decreasing numbers of UR patients were available for follow-up at each advancing time point. Follow-up data for 3-, 6-, 12-, 24-, and 36-month time-points for the 43 UR patients studied are depicted in Figures 1 and 2. At 1 month, 31/43 patients presented for voiding trials, and 27/31 (87%) of these patients had catheters successfully removed. Out of 43 patients, 11 had not yet presented for voiding trials owing to logistical challenges, and there was 1 unrelated death. Of the remaining 11 patients, over the second postprocedure month 10 presented for voiding trials and there was a second unrelated death. At 3 months, 34/41 (83%) patients eligible for follow-up were catheter-free. This proportion was maintained through 24 months after PAE, and at 36 months 75% of patients remained catheter-free (Fig. 1). Furthermore, IPSS, QoL, and PVR values consistent with low symptom burden and low retention volume were

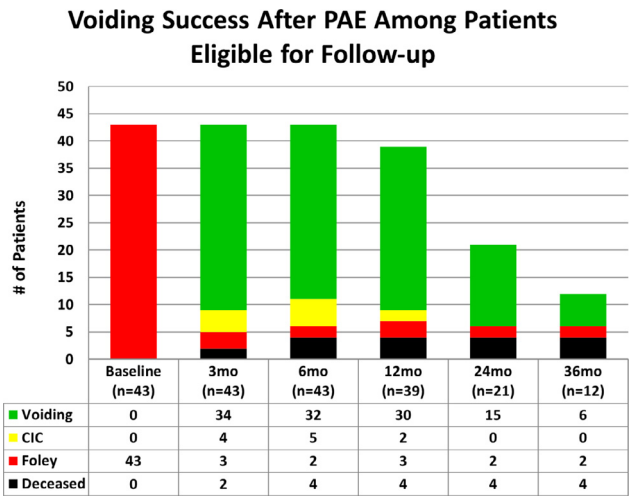

Figure 1. Patients remaining free of a urinary catheter among those eligible for follow-up from 3 months after PAE through 36 months of follow-up. The number of patients eligible for follow-up decreases with each time point due to ongoing maturation of the patient cohort. Deceased patients (black bars) are excluded from the total of follow-up eligible patients at each time point. (Color version available online.)

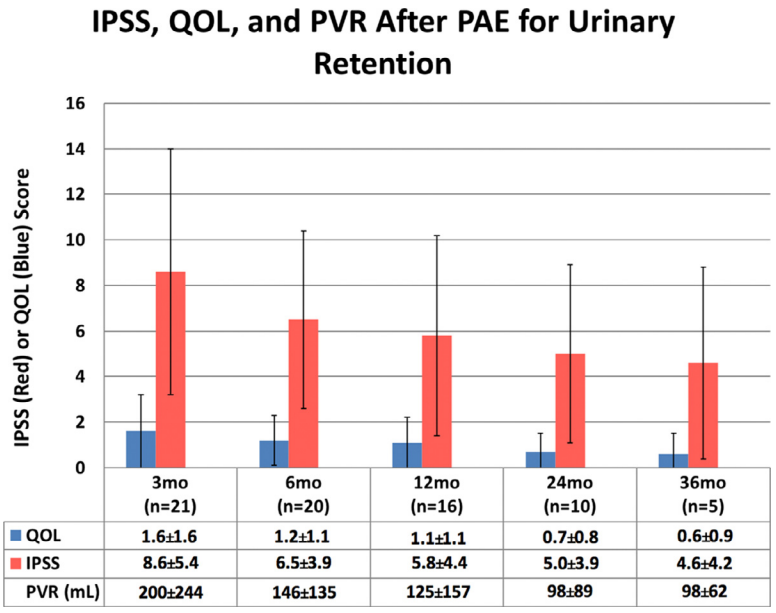

Figure 2. International Prostate Symptom Score (IPSS) and Quality of Life Score (QoL) stability over time in patients with resolved urinary retention after PAE (data reported as means with standard deviations). (Color version available online.)

sustained through 36 months after PAE (Fig. 2). For all patients who passed voiding trials, catheters were removed on average 40 ± 33.6 days after PAE (given the protocol of initial voiding trial planned 30 days after PAE). Of the 42 patients taking BPH medications before PAE, 22/36 (61%) of patients with available follow-up had discontinued BPH medications and remained off of them at latest follow-up (mean = 337 ± 382 days).

Urinary Retention Nonresponders

Of the 4/31 (13%) UR patients who failed initial voiding trials at 1-month post-PAE, 2 patients of ages 86.3 and 70.6 years went on to pass subsequent voiding trials at 2 months. The 2 patients who never passed voiding trials were 91.3 and 91.9 years old. By 3-month follow-up, 4 additional patients had failed voiding trials and were performing self-catheterization while another patient who was 98 years old failed voiding and had to revert to a catheter. Hence, the average age at time of PAE for those who failed voiding trials afterward was 93.7 years, with average ACCI of 5.7. These patients were offered suprapubic catheters per their referring urologists. One UR patient had recurrent obstructive symptoms 3 months after PAE from autoenucleated prostate gland tissue requiring transurethral removal. Another UR patient underwent limited resection of symptomatic sloughing necrotic prostate tissue 14 months after PAE. Both had return of satisfactory voiding function after resection. No other episodes of new urinary retention were reported up to the time of submission.

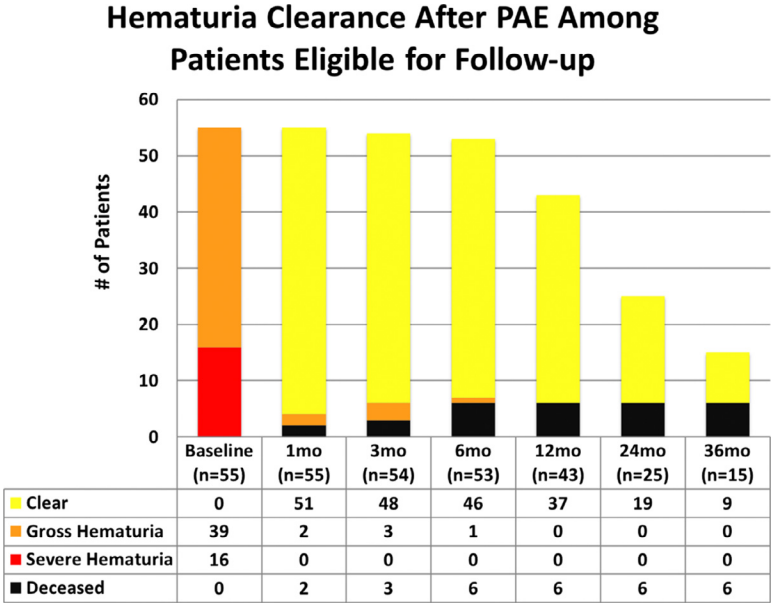

Figure 3. Patients remaining free of gross hematuria among those eligible for follow-up from 3 months after PAE through 3 years of follow-up. Two GH patients passed away within 30 days of PAE before follow-up could be obtained, and thus were excluded from analysis. GH, gross hematuria; PAE, prostatic artery embolization. (Color version available online.)

Gross Hematuria Outcomes

Technical success was achieved in 55/55 (100%) hematuria patients (mean procedure time = 187.4 ± 61.8 minutes, mean fluoroscopy time = 49.9 ± 22.6 minutes). As above, due to rolling accumulation of cases and unrelated deaths of elderly patients, decreasing numbers of GH and SH patients were available for follow-up at each advancing time point. Among the 16 SH patients treated, 36 units of blood were transfused prior to PAE. After PAE only 4 units were transfused, all within 48 hours of PAE in 3 patients whose hemoglobin levels had stabilized but were still undesirably low. Out of 16 SH patients, 14 (87.5%) had hematuria resolve and CBI stopped within 48 hours after PAE. Five of these patients had previously been on anticoagulation therapy and 1 patient had been on dual antiplatelet therapy, and all were able to resume these medications after PAE. Thirteen of these patients remained free of GH at latest follow-up (mean = 500 ± 501 days) (Fig. 3), while 1 SH patient developed GH 165 days after PAE due to recurrent bladder tumor. Out of 16 SH patients, 2 (12.5%) had initial cessation of hematuria, but then recurred at 52 and 60 days after PAE. One was on dual antiplatelet therapy. Both underwent successful fulguration of bleeding prostatic tissue, with marked decrease in gland volume noted at cystoscopy.

Among the 39 GH patients, there were 22 urgent healthcare facility visits for hematuria prior to PAE, although no patients received transfusions. Of the 37 GH patients eligible for follow-up, 34 (92%) remained free of GH with no further hematuria-related visits as of latest follow-up (mean = 483 ± 137 days) (Fig. 3). Four of these patients had been on anticoagulation and 1 had been on dual antiplatelet medications that were successfully resumed after PAE. For the 3 GH patients with recurrent hematuria after PAE, no further urgent visits, transfusions, or interventions occurred. One of these patients was found to have bladder calculus on cystoscopy. The other 2 were on anticoagulation for stroke. Two patients died <30 days after PAE, before follow-up could be obtained.

Thus, among all GH and SH patients eligible for follow-up after PAE, at 1 month 51/53 (96%) patients were free of GH, with 48/51 (94%) clear at 3 months and 46/47 (98%) clear at 6 months. Thereafter, 100% of patients were clear at 12 months (n = 37), 24 months (n = 19), and 36 months (n = 9) after PAE (Fig. 3).

Adverse Events

All 75 patients were analyzed together regarding adverse events. Two deaths occurred <30 days after PAE. One of these patients was an immunocompromised stage-IV cancer patient who developed fungemia during an inpatient hospital stay, which progressed to sepsis and multiorgan failure. The second patient died from a cardiopulmonary complication of unrelated warfarin toxicity, presumed to be a fatal pulmonary embolism although no autopsy was performed. Both deaths were deemed unrelated to PAE. Eight Grade-II catheter-associated urinary infections requiring antibiotic treatment occurred over a total of 1577 patient-catheter days, counted from day after embolization to day of catheter removal, giving a catheter-associated urinary infection rate of 5.1 per 1000 patient-catheter days. There were 10 Grade-I events including dysuria >1 week (n = 4), self-limited contrast nephropathy (n = 2), access site ecchymosis (n = 2), urinary retention requiring a catheter <1 week (n = 1), and delirium from anticholinergic medication (n = 1).

DISCUSSION

In this study, PAE provided safe, effective, and durable treatment for urinary retention and gross hematuria caused by BPH, in patients who were poor surgical candidates either because of large gland size or high risks of undergoing general anesthesia. Eighty-three percent of urinary retention patients had successful voiding trials after PAE, with low subjective symptom burden and PVR seen within 3 months and maintained through 3 years. 87.5% of SH patients experienced hemostasis within 2 days after embolization and with lasting resolution, while 92% of GH patients experienced sustained resolution of their hematuria within 2 days. Transfusions and hematuria-related urgent visits were nonexistent beyond 2 days after PAE. These results were achieved in patients with mean age of 77.5 ± 8.6 years, mean PGV of 224 ± 135 mL, and mean ACCI of 4.6 ± 2.0.

Among the retention patients studied, 61% had discontinued their BPH medications at latest follow-up. However, several patients who improved enough to discontinue their medications were advised to remain on them by their urologists so long as they were not experiencing negative side effects. PVRs overall were 125 ± 176 mL at 1 year and 66 ± 68mL at 2 years after PAE. Retention patients who remained catheter free maintained a voiding efficiency of ≥60% and/or had IPSS ≤7, QoL ≤2 with no evidence of urinary infections or hydronephrosis. Insufficient data were available from this cohort to reliably report postembolization reduction in PGV. However, data reported elsewhere from our larger PAE cohort (including nonretention patients from this study) who had similarly large PGVs and underwent PAE with the same technique, demonstrated a PGV reduction >40%, sustained beyond 1 year.[21]

These urinary retention results are similar to those from other studies with smaller cohorts.[6-11] Carnevale et al reported a 91% catheter removal rate in 11 men with prostate volumes 30-90 mL after PAE.[6] Pisco et al produced similar results in 34 patients with acute urinary retention.[7] Among others, Bhatia et al reported 86.7% catheter removal in 30 patients[10]. These results were similar from smaller to larger glands up to 550 mL.[20] Likewise, the hematuria results reported in the current study were similar to previously published reports of smaller cohorts with shorter term follow-up.[12-19] However, patients in many of those studies would be considered index BPH patients by gland volume, and few of those studies delineated the severity of comorbidities in their cohorts,[8,10,19] or reported follow-up beyond 12 months.[6,7]

No lasting negative side effects were reported by patients in this study. Adverse events were few, with frequencies comparable to other PAE studies and favorable compared to transurethral procedures.[5,26] They primarily consisted of catheter-related urinary infections prior to catheter removal, a problem to which patients with indwelling catheters are already prone. The frequency of catheter-associated urinary infections per number of days catheterized in this cohort was 5.1 per 1000 catheter days. For comparison, medical and surgical inpatients have been reported to have 1.4 urinary infections per 1000 catheter days, in the setting of continuous nursing care with reliable catheter maintenance.[27] Patients residing at rehabilitation facilities with

lower level care have been reported to experience 2.9-3.2 infections per 1000 catheter days.[27] The large majority of patients in the current study were outpatients with chronic indwelling catheters and minimal medical assistance.

This study's retrospective single-arm design is its main limitation. Furthermore, the urinary retention patients in this study by definition did not have updated pre-embolization IPSS, QoL, PVR, or flow rate measurements or urodynamic studies available for comparison to post-treatment values. Also, quantitative measurements of urine flow after embolization were not performed. Additionally, sexual function before and after PAE was not assessed. As mean gland volumes in this study were over 200 mL, these results may not generalize to smaller glands. Furthermore, these results are from a single center.

CONCLUSION

Patients referred for PAE in this study were nonindex BPH patients with urinary retention or gross prostatic hematuria who failed conservative therapy, and had prostate glands too large or comorbidities too severe for standard-of-care surgical procedures. PAE offered these patients successful procedural treatment when they otherwise had few acceptable options. While PAE in these patients did not necessarily offer results equivalent to what index BPH patients might experience after gold-standard transurethral resection procedures, the results of this study support the appropriateness of PAE as a safe, effective, and durable treatment option for nonindex BPH patients with urinary retention or gross hematuria.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.11.003.

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