Comparative Analysis of Prostate Volume as a Predictor of Outcome in Prostate Artery Embolization

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ABSTRACT

Purpose: To determine the role of prostate volume as a predictor of outcome after prostatic artery embolization (PAE).

Materials and Methods: From January 2012 to September 2014, 78 consecutive patients undergoing PAE were evaluated at baseline and 1, 3, and 6 months. Analysis was performed comparing prostate volume groups (group 1, < 50 cm^3; group 2, 50–80 cm^3; group 3, > 80 cm^3) at baseline and follow-up to assess for differences in outcomes of American Urological Association (AUA) symptom index, quality of life (QOL)–related symptoms, and International Index of Erectile Function (IIEF).

Results: Mean baseline prostate volumes were 37.5 cm^3 in group 1 (n = 16), 65.7 cm^3 in group 2 (n = 26), and 139.4 cm^3 in group 3 (n = 36). There were no significant differences in baseline age, AUA symptom index, QOL, or IIEF between groups. Bilateral embolization was successful in 75 of 78 patients (96%). Two patients underwent unilateral embolization, and treatment failed in one patient as a result of bilateral atherosclerotic occlusion. A significant reduction in AUA symptom index was achieved within groups from baseline to 1, 3, and 6 months (n = 77): in group 1, from 27.2 to 14.0, 12.9, and 15.9, respectively ($P = .002$); in group 2, from 25.6 to 17.1, 16.3, and 13.5, respectively ($P < .0001$); and in group 3, from 26.5 to 15.2, 12.5, and 13.6, respectively ($P < .0001$). There was also a significant improvement in QOL. Comparative analysis demonstrated no statistically significant differences in AUA symptom index, QOL, or IIEF between groups. Two minor complications occurred: groin hematoma and a urinary tract infection.

Conclusions: PAE offers similar clinical benefits to patients with differing gland sizes and may offer a reasonable alternative for poor candidates for urologic surgery.

ABBREVIATIONS

ANOVA = analysis of variance, AUA = American Urological Association, BPH = benign prostatic hyperplasia, DSA = digital subtraction angiography, IIEF = International Index of Erectile Function, PAE = prostatic artery embolization, QOL = quality of life

The current treatment options for benign prostatic hyperplasia (BPH) include watchful waiting, medical therapy, and surgical intervention. However, there are limitations with treatment of prostate glands of varied sizes. Transurethral resection of the prostate is associated with a number of complications, such as urinary tract infection, clot retention, incontinence, and impotence (1). In large gland sizes, specifically > 80 cm^3, longer operative times are required, with increased bleeding and anesthesia-related complications. Transurethral resection of the prostate has also been reported to have failure rates as high as 20% in small-volume prostates (< 50 cm^3), necessitating future surgical revision in more than 5% of patients (2,3). Laser vaporization in small-volume BPH has been associated with a 7% incidence of bladder neck contractures (4,5). Besides surgery, medical therapies such as 5-α reductase inhibitors have been demonstrated to reduce prostate volumes greater than 30 mL, but these effects were not observed in patients with prostate sizes smaller than 30 mL (6).

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More recently, prostatic arterial embolization (PAE) has been shown to be a safe and effective minimally invasive option in the management of BPH (7–9). As the primary proposed mechanism for PAE is prostate volume reduction, it has been suggested that PAE would have limited effectiveness in small-volume BPH, and may also be technically challenging because of a smaller main prostatic artery. Although experience with large-volume BPH has been described recently, there is a lack of comparative data evaluating midsize and small-volume glands (10,11). The purpose of the present study was to evaluate the comparative safety and efficacy of PAE in varying gland sizes.

MATERIALS AND METHODS

An institutional review board–approved retrospective chart review of patients who underwent PAE between January 2012 and September 2014 was performed. The study was compliant with the Health Insurance Portability and Accountability Act. Seventy-eight consecutive patients with moderate- or severe-grade symptoms from BPH (Table 1) underwent PAE by four interventional radiologists (with 7–27 y of experience; mean, 15.8 y). Patients were evaluated by a urologist, and prostate-specific antigen (PSA) levels were obtained in all patients. Prostate biopsy was performed if the PSA level was greater than 4 ng/mL, or based on a shared decision with the urology service based on current task force guidelines to exclude prostate cancer. Of note, 20 patients have been described previously (7). Patients were evaluated at baseline and 1, 3, and 6 months with the American Urological Association (AUA) symptom index, including quality of life (QOL)–related symptoms, International Index of Erectile Function (IIEF), and prostate imaging (magnetic resonance [MR] imaging, ultrasonography [US], or computed tomography [CT] at baseline). Prostate volume was calculated by two board-certified radiologists based on the ellipsoid volume formula of length × width × height × 0.52 (Figs 1, 2).

Embolization Technique

Patients received 30 mg intravenous ketorolac (Roche, Basel, Switzerland) and 500 mg oral ciprofloxacin (Bayer, Wayne, New Jersey) immediately before the procedure and a second dose of ketorolac before discharge. Patients were discharged with prescriptions for ciprofloxacin for 5 days after the procedure, ibuprofen 600 mg orally three times daily as needed, and 200 mg phenazopyridine three times daily as needed (Warner Chilcott, Rockaway, New Jersey). No additional analgesic agents were given for pain. The procedure was performed with moderate sedation with midazolam (West-ward, Eatontonwn, New Jersey) and fentanyl (Hospira, Lake Forest, Illinois).

Angiography was performed with a unilateral femoral approach in all patients. Selective hypogastric artery digital subtraction angiography (DSA; Artis zee; Siemens, Forchheim, Germany) was performed in the anteroposterior view and ipsilateral 30° oblique/10° craniocaudal view. Angiography with Visipaque (GE Healthcare, Princeton, New Jersey) was performed in each projection to identify the prostatic arteries (Figs 3, 4). The prostatic arteries were selected with a 2.4-F microcatheter (straight or angled Renegade STC; Boston Scientific, Natick, Massachusetts), and DSA was

Table 1. Baseline Demographics

Group/Measurement	Age (y)	PSA (ng/mL)*	Peak Urine Flow (mL/s)*	AUA	QOL	IIEF
All patients (N = 78)						
Range	48–81	0.36–16.69	2.0–23.3	13–35	1–6	3–30
Mean ± SD	65.2 ± 7.8	4.7 ± 0.5	7.2 ± 0.7	26.3 ± 6.0	4.9 ± 1.1	14.0 ± 6.4
Small volume (n = 16)						
Range	48–75	0.36–2.85	3.0–23.3	19–35	1–6	4–30
Mean ± SD	62.7 ± 8.0	1.0 ± 0.9	10.1 ± 7.4	27.2 ± 5.2	4.6 ± 1.5	15.0 ± 7.3
Medium volume (n = 26)						
Range	50–80	0.7–15.8	2.5–20.0	14–35	3–6	4–25
Mean ± SD	65.5 ± 8.3	4.1 ± 4.0	6.4 ± 4.6	25.6 ± 6.7	4.9 ± 1.1	14.8 ± 6.9
Large volume (n = 36)						
Range	51–81	1.0–16.69	2.0–12.0	13–35	3–6	3–20
Mean ± SD	66.1 ± 7.4	6.7 ± 3.7	6.3 ± 2.6	26.5 ± 5.9	5.0 ± 0.9	12.7 ± 5.5
ANOVA *P* value	.352	< .001	.106	.687	.429	.375

ANOVA = analysis of variance; AUA = American Urologic Association Symptom Index; IIEF = International Index of Erectile Function; QOL = quality of life [due to urinary symptoms]; PSA = prostate-specific antigen; SD = standard deviation.

*One-way ANOVA results demonstrated significant differences in PSA and peak urine flow between the three prostate volume groups; a Levene test of homogeneity of variance also demonstrated statistical significance for these values. Welch and Brown–Forsythe ANOVA tests were also run for the data. This demonstrates a statistical significance for PSA between prostate volume groups ($P < .001$); however, no statistical significance was observed for peak urine flow with Welch and Brown–Forsythe ANOVA: $P = .106$ and $P = .077$, respectively.

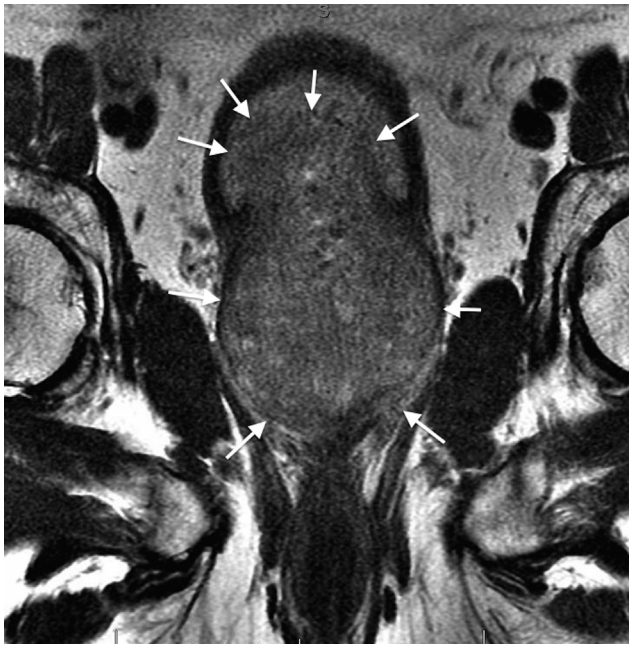

Figure 1. Images from a 72-year-old patient taking finasteride, silodosin, and tamsulosin for BPH with a baseline AUA (QOL) score of 20 (5) and IIEF of 9. Coronal T2-weighted MR image demonstrates large-volume BPH (188 cm^3) with prominent median lobe hypertrophy and intravesical component (arrows) corresponding to angiographic findings.

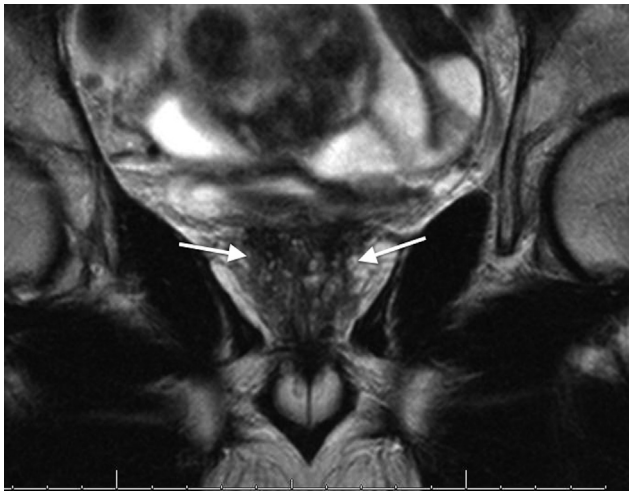

Figure 2. Coronal T2-weighted MR image demonstrates nodular central gland with low signal intensity (arrows) in a 62-year-old patient with small-volume BPH (27.6 cm^3) who was taking finasteride, silodosin, and tamsulosin, with a baseline AUA (QOL) score of 33 (6) and IIEF of 15.

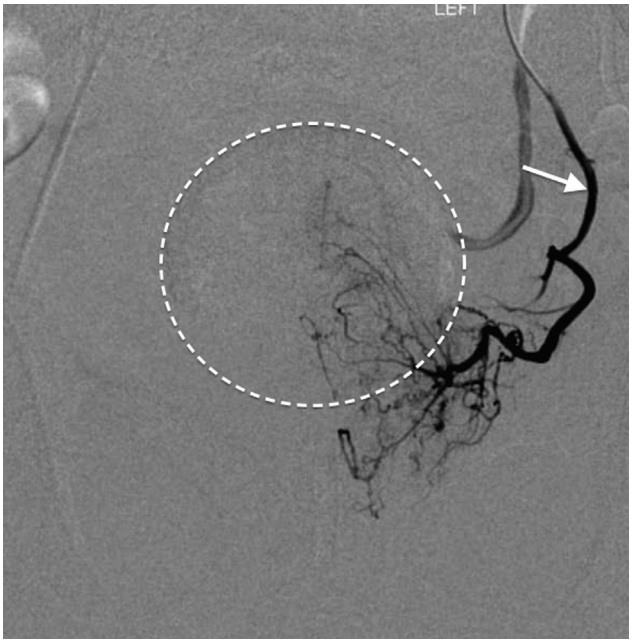

Figure 3. DSA image with microcatheter (arrow) in the left prostatic artery demonstrates large-volume BPH with hypervascularity and protrusion into the bladder (circle). AUA (QOL) score at 3 months was 11 (1).

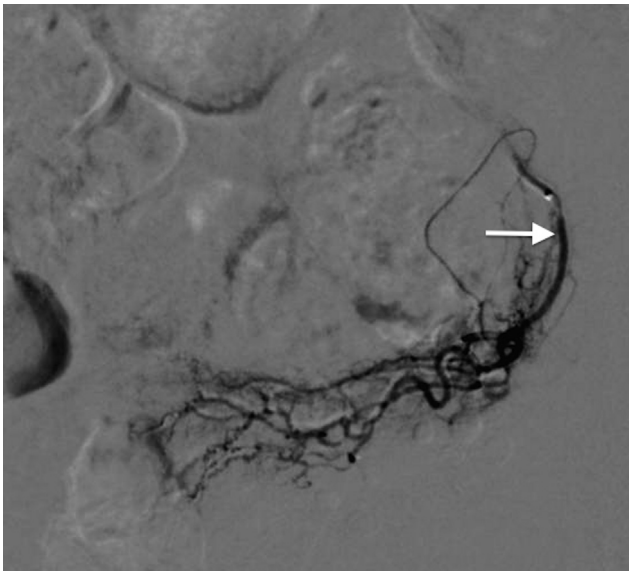

Figure 4. DSA of left prostatic artery in a patient with small-volume BPH depicts a smaller-sized prostatic artery (arrow) with perfusion of the left hemiprostate. The AUA (QOL) score at 3 months was 18 (3).

again performed in the anteroposterior projection. Cone-beam CT was performed with a 4–6-second delay after hand injection of 2–3 cm^3 iodinated contrast medium to evaluate for sites of nontarget embolization (Figs 5, 6). The imaging sequence used an 8-second rotational scan of 208° at 26° rotation per second with image acquisition every 0.5° with a source power of 125 kVp, resulting in a total of 417 matrix images of 512 × 512 voxels each. Embolization of the left prostatic artery was performed first with spherical embolic agents (100–400-μm Embozene; CeloNova, San Antonio, Texas) to an endpoint of at least near-stasis. A gelatin sponge slurry (Gelfoam; Pharmacia and Upjohn, Kalamazoo, Michigan) was used as an adjunct to achieve complete stasis of the proximal prostatic artery in 31 of 77 patients. The same technique was then used to perform embolization of the right prostatic artery. A closure device (StarClose SE; Abbott Laboratories, Abbott Park, Illinois) was used in

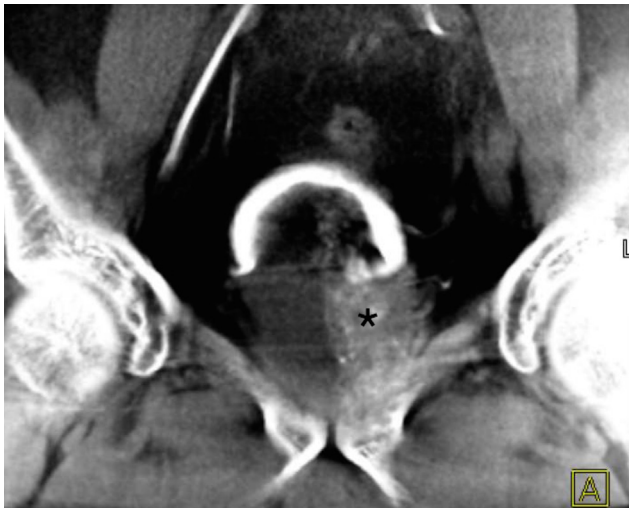

Figure 5. Cone-beam CT image obtained after contrast medium injection in the left prostatic artery depicts glandular perfusion (asterisk), including the large intravesical component. No sites of potential nontarget embolization are identified.

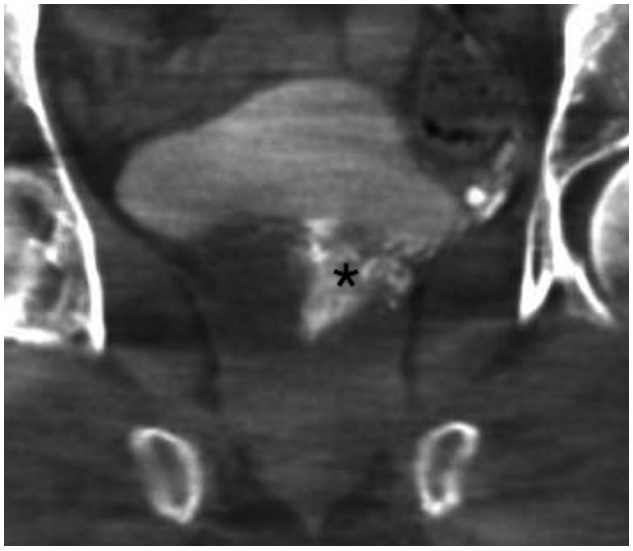

Figure 6. Cone-beam CT after left prostatic artery injection shows enhancement of the left hemiprostate (asterisk) corresponding to angiography and MR imaging findings.

all patients. The embolization was considered technically successful if bilateral embolization was performed. Clinical success was defined as a greater than 3-point improvement in AUA symptom score at follow-up intervals, catheter independence in patients with urinary retention, or cessation of medication (12). Complications were categorized as major or minor (13).

Statistical Analysis

Patients were separated into three groups: group 1 (prostate volume < 50 cm^3), group 2 (volume 50–80 cm^3), and group 3 (volume > 80 cm^3). An analysis of variance (ANOVA) was used to evaluate demographic data (age, PSA level, urine flow rate) as well as baseline AUA score, QOL, and IIEF. Within-group changes in individual patient AUA score, QOL, and IIEF from baseline to 1, 3, and 6 months were analyzed by paired t tests. Between-group analyses of the same time points were performed by ANOVA. AUA symptom and QOL scores at each time point were normally distributed (Shapiro–Wilk W test); therefore, a parametric statistical technique was used to produce the reported P values, with $P \leq .05$ used to indicate significance. Symptom scores and QOL scores are reported as means with 95% confidence intervals. AUA symptom score reduction $\geq$ 3 points was considered to indicate clinical success. All analyses were conducted by using SPSS Statistics software (version 22.0, 2013; IBM, Armonk, New York).

RESULTS

Of the 78 patients in whom embolization was attempted, embolization was considered technically successful (ie, bilateral embolization) in 75 patients; two unilateral embolizations were related to atherosclerosis and severe tortuosity. One complete technical failure was secondary to severe bilateral atherosclerotic occlusion of the prostatic arteries. Baseline volumes for small- (group 1; n = 16), medium- (group 2; n = 26), and large-volume (group 3; n = 36) prostate groups were 37.5 cm^3 (range, 25.9–48 cm^3), 65.7 cm^3 (range, 52–79.5; cm^3), and 139.4 cm^3 (range, 80–274 cm^3), respectively. There were no significant differences in age (mean, 65.2 y; $P = .352$), baseline AUA score (mean, 26.3; $P = .687$), QOL (mean, 4.9; $P = .429$), or IIEF (mean, 14; $P = .277$) between groups. Initial one-way ANOVA also demonstrated significant differences between the three groups in mean PSA level ($P < .001$; group 1, 1.0; group 2, 4.1; group 3, 6.7) and mean peak urine flow rate ($P < .023$; group 1, 10.1 cm^3/s; group 2, 6.4 cm^3/s; group 3, 6.3 cm^3/s). Further investigation with a Levene test of homogeneity showed significant differences for PSA level and peak urine flow rate. Therefore, a Welch ANOVA was performed, which also demonstrated a significant difference between PSA values among each volume group ($P < .001$). However, there was no significant difference in peak urine flow rate between volume groups ($P = .106$).

At the time of this analysis, not all patients were eligible for all follow-up intervals: 68 of 78 eligible patients were followed up at 1 month, 58 of 78 were followed up at 3 months, and 44 of 75 were followed up at 6 months. Of the 16 patients in the small-volume cohort, 14 of 16 eligible patients were followed up at 1 month, 13 of 16 were followed up at 3 months, and 11 of 15 were followed up at 6 months. Of the 26 patients in the medium-volume cohort, 21 of 26 eligible patients were followed up at 1 month, 17 of 26 were followed up at 3 months, and 14 of 25 were followed up at 6 months. Of the 36 patients in the large-volume cohort, 31 of 36 eligible patients were followed up at 1 month, 28 of 36 were followed up at 3 months, and 19 of 35 were followed up at 6 months (**Table 2**).

Table 2. Follow-up for Patients Who Were Eligible at Each Time of Analysis

Interval/Group	Total	Small Volume	Medium Volume	Large Volume
Baseline				
No. of pts.	78	16	26	36
1 Month				
No. eligible	78	16	26	36
No. followed up	66 (84.62)	14 (87.50)	21 (80.77)	31 (86.11)
3 Months				
No. eligible	78	16	26	36
No. followed up	58 (74.36)	13 (81.25)	17 (65.38)	28 (77.78)
6 Months				
No. eligible	75	15	25	35
No. followed up	44 (58.67)	11 (73.33)	14 (56.00)	19 (54.29)

Note–Values in parentheses are percentages.

Table 3. Small Prostate Volume: Within-Group Analysis

Interval/Measurement	AUA	QOL	IIEF
1 Month			
No. of pts.	14	14	12
Mean ± SD	14.00 ± 6.37	2.79 ± 1.31	14.75 ± 8.00
95% CI	10.32–17.68	2.03–3.54	9.67–19.83
P value	< .0001	.005	.95
3 Months			
No. of pts.	13	13	8
Mean ± SD	11.92 ± 6.10	2.69 ± 1.70	17.38 ± 4.87
95% CI	8.24–15.60	1.66–3.72	13.31–21.44
P value	< .0001	.004	.844
6 Months			
No. of pts.	11	10	7
Mean ± SD	15.91 ± 9.12	2.70 ± 1.77	17.57 ± 6.58
95% CI	9.79–22.03	1.44–3.96	11.49–23.66
P value	.002	.01	.902

AUA = American Urologic Association Symptom Index; CI = confidence interval; IIEF = International Index of Erectile Function; QOL = quality of life [due to urinary symptoms]; SD = standard deviation.

Table 4. Medium Prostate Volume: Within-Group Analysis

Interval/Measurement	AUA	QOL	IIEF
1 Month			
No. of pts.	21	21	17
Mean ± SD	17.14 ± 8.50	3.14 ± 1.53	14.41 ± 6.64
95% CI	13.27–21.01	2.45–3.84	11.00–17.83
P value	< .0001	< .0001	.882
3 Months			
No. of pts.	17	16	12
Mean ± SD	16.29 ± 9.45	3.00 ± 1.79	17.33 ± 6.32
95% CI	11.43–21.15	2.05–3.95	13.32–21.35
P value	.001	.002	.101
6 Months			
No. of pts.	14	13	11
Mean ± SD	13.50 ± 7.24	2.08 ± 1.38	16.91 ± 6.61
95% CI	9.32–17.68	1.24–2.91	12.47–21.35
P value	< .0001	< .0001	.373

AUA = American Urologic Association Symptom Index; CI = confidence interval; IIEF = International Index of Erectile Function; QOL = quality of life [due to urinary symptoms]; SD = standard deviation.

Within-group paired *t* test analysis demonstrated a significant reduction in AUA scores in all groups from baseline to 1, 3, and 6 months (n = 77). Group 1 (Table 3) had a reduction from a baseline mean of 27.2 to 14.00 at 1 month (n = 14; $P < .0001$), 11.92 at 3 months (n = 13; $P < .0001$), and 15.91 at 6 months (n = 11; $P = .002$). Group 2 (Table 4) had a reduction of AUA from a baseline mean of 25.6 to 17.14 at 1 month (n = 21; $P < .0001$), 16.29 at 3 months (n = 17; $P = .001$), and 13.5 at 6 months (n = 14; $P < .001$). Group 3 (Table 5) had a reduction in AUA from a baseline mean of 26.5 to 15.23 at 1 month (n = 31; $P < .0001$), 12.54 at 3 months (n = 28; $P < .0001$), and 13.58 at 6 months (n = 19; $P < .0001$).

Additionally, there was a significant improvement in QOL from baseline to 1, 3, and 6 months in all cohorts (Tables 3–5). Group 1 had a reduction from a baseline score of 4.6 to 2.79 at 1 month (n = 14; $P = .005$), 2.69 at 3 months (n = 13; $P = .004$), and 2.70 at 6 months (n = 10; $P = .01$). Group 2 had a reduction from a baseline score of 4.9 to 3.14 at 1 month (n = 21; $P < .0001$), 3.00 at 3 months (n = 16; $P = .002$), and 2.08 at 6 months (n = 13, $P < .0001$). Group 3 had a reduction from a baseline score of 5.0 to 2.28 at 1 month (n = 29; $P < .0001$), 2.11 at 3 months (n = 28, $P < .0001$), and 2.00 at 6 months (n = 16; $P < .0001$). In addition, there was no significant change in IIEF scores for patients at 1-, 3-, and 6-month follow-up. Between-group analysis demonstrated no significant difference in outcomes between groups 1, 2, and 3 at all time intervals for AUA score, QOL score, and IIEF (Table 6).

Clinical success, as measured by a reduction in patient AUA score by 3 or more points, was achieved in 100% of patients in the small-volume group with appropriate

follow-up at 1 month, in 91.7% of such patients at 3 months, and in 100% of such patients at 6 months. In the medium-volume group, 89.5% of patients had clinical success at 1 month, along with 68.6% at 3 months and 77.8% at 6 months. Finally, the large-volume group had 88.5% clinical success at 1 month, 94.7% success at 3 months, and 90% success at 6 months.

Table 5. Large Prostate Volume: Within-Group Analysis

Interval/Measurement	AUA	QOL	IIEF
1 Month			
No. of pts.	31	29	18
Mean ± SD	15.23 ± 8.39	2.28 ± 1.46	13.15 ± 8.26
95% CI	12.15–18.30	1.72–2.83	9.28–17.02
P value	< .0001	< .0001	.456
3 Months			
No. of pts.	28	28	14
Mean ± SD	12.54 ± 6.41	2.11 ± 1.45	17.00 ± 8.60
95% CI	10.05–15.02	1.55–2.67	12.03–21.97
P value	< .0001	< .0001	.167
6 Months			
No. of pts.	19	16	9
Mean ± SD	13.58 ± 6.57	2.00 ± 1.75	16.39 ± 8.80
95% CI	10.41–16.74	1.07–2.93	9.90–22.43
P value	< .0001	< .0001	.397

AUA = American Urologic Association Symptom Index; CI = confidence interval; IIEF = International Index of Erectile Function; QOL = quality of life [due to urinary symptoms]; SD = standard deviation.

Two minor complications occurred: a self-limited groin hematoma that did not require intervention and a urinary tract infection that was treated with oral antibiotic agents (13). There were no major complications in the study.

DISCUSSION

The results of the present study demonstrate that PAE presents a safe and effective minimally invasive alternative for treatment of BPH for small-, medium-, and large-volume prostates. Patients in each group had statistically significant improvements of AUA and QOL scores at 1, 3, and 6 months of follow-up. Additionally, there was no statistically significant difference between follow-up AUA, QOL, and IIEF scores, indicating that the intermediate-term success of the procedure is not dependent on the size of the prostate.

Recently, two published studies of PAE in large-volume BPH (10,11) have demonstrated success. Our experience demonstrates similar clinical success rates, with the addition of comparative gland sizes at the same center. Previous studies have not evaluated small-volume glands as a separate cohort. De Assis et al (11) reported lower symptom scores following PAE in large glands than reported by Kurbatov et al (10) and in the present experience. However, their cohort (11) started at a baseline level 6 points lower than the other two studies. Compared with the overall PAE literature, the present study is representative of this experience, as described in a recent review article (14).

Table 6. Between-Groups ANOVA of PAE at Baseline, 1 Month, 3 Months, and 6 Months

Interval/Measurement	AUA	QOL	IIEF
Baseline			
Small-volume mean	27.19 (n = 16)	4.60 (n = 16)	15.00 (n = 16)
Medium-volume mean	25.58 (n = 26)	4.85 (n = 26)	14.79 (n = 26)
Large-volume mean	26.50 (n = 36)	5.03 (n = 36)	12.71 (n = 36)
P value	.69	.43	.38
1 Month			
Small-volume mean	14.00 (n = 14)	2.79 (n = 14)	14.75 (n = 12)
Medium-volume mean	17.14 (n = 21)	3.14 (n = 21)	14.41 (n = 17)
Large-volume mean	15.23 (n = 31)	2.28 (n = 29)	13.15 (n = 18)
P value	.50	.12	.82
3 Months			
Small-volume mean	11.92 (n = 13)	2.69 (n = 13)	17.38 (n = 8)
Medium-volume mean	16.29 (n = 17)	3.00 (n = 16)	17.33 (n = 12)
Large-volume mean	12.54 (n = 28)	2.11 (n = 28)	17.00 (n = 14)
P value	.18	.31	.31
6 Months			
Small-volume mean	15.91 (n = 11)	2.70 (n = 10)	17.57 (n = 7)
Medium-volume mean	13.50 (n = 14)	2.08 (n = 13)	16.91 (n = 11)
Large-volume mean	13.58 (n = 19)	2.00 (n = 16)	16.39 (n = 9)
P value	.66	.95	.91

ANOVA = analysis of variance; AUA = American Urologic Association Symptom Index; IIEF = International Index of Erectile Function; PAE = prostatic artery embolization; QOL = quality of life [due to urinary symptoms].

The present study is not without limitations. These include the lack of long-term follow-up, as not all patients had reached the 6-month follow-up point at the time of data collection, in addition to loss to follow-up and lack of randomization to other therapies. In addition, the small number of patients treated limits the ability to make larger generalizations and allows for potential for results to be related to chance. In addition, the experience of the department performing the procedure as a whole may positively influence the likelihood of technical success when performing the technically challenging embolization of smaller-sized prostatic arteries. Finally, volume calculations were performed on various imaging modalities, which may result in differing degrees of accuracy.

In conclusion, the present study demonstrates that PAE is a safe and effective procedure with consistent results in patients with varying gland sizes. This is of particular importance in clinical decision making when offering therapy for patients with gland sizes that would put them at increased risk with traditional transurethral therapy.

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