Prostatic Arterial Embolization for Benign Prostatic Hyperplasia: Short- and Intermediate-term Results[1]

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Purpose: To evaluate the safety, morbidity, and short- and intermediate-term results of prostatic arterial embolization (PAE) for benign prostatic hyperplasia (BPH) after failure of medical treatment.

Materials and Methods: This prospective study was approved by the institutional review board, and informed consent was obtained from all participants. Men older than 50 years with a diagnosis of BPH and moderate-to-severe lower urinary tract symptoms that were refractory to medical treatment for 6 months were eligible. PAE with nonspherical 80–180-μm (mean, 100-μm) and 180–300-μm (mean, 200-μm) polyvinyl alcohol particles was performed by means of a single femoral approach in most cases. Effectiveness variables of International Prostate Symptom Score (IPSS), quality of life (QOL) score, peak urinary flow, postvoid residual volume, International Index Erectile Function (IIEF) score, prostate volume, and prostate-specific antigen level were assessed for up to 24 months after the procedure. Statistical analysis included the Kaplan-Meier method and random-effects generalized least squares regression with autoregressive disturbance.

Results: Eighty-nine consecutive patients (mean age, 74.1 years) were included. PAE was technically successful in 86 of the 89 patients (97%). Cumulative rates of clinical improvement in these patients were 78% in the 54 patients evaluated at 6 months and 76% in the 29 patients evaluated at 12 months. At 1-month follow-up, IPSS decreased by 10 points, QOL score decreased by 2 points, peak urinary flow increased by 38%, prostate volume decreased by 20%, postvoid residual volume decreased by 30 mL, and IIEF score increased by 0.5 point (all differences were significant at $P < .01$). These changes were sustained throughout the observation period. There was one major complication: Intraluminal necrotic tissue attached to the bladder, which was removed with simple surgery and did not necessitate wall reconstruction.

Conclusion: PAE is a safe and effective procedure, with low morbidity, no sexual dysfunction, and good short- and intermediate-term symptomatic control associated with prostate volume reduction.

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The diagnosis of benign prostatic hyperplasia (BPH) may be based on three findings: microscopic detection of prostatic hyperplasia (benign proliferation of the stroma and epithelium on the basis of pathologic specimens); palpable enlargement of the prostate, as detected with clinical or ultrasonographic (US) examination; or the presence of lower urinary tract symptoms, such as higher urinary frequency (particularly at night, termed "nocturia"), urinary urgency, urinary leaking, and decreased, hesitant, interrupted urinary stream. However, it is the clinical findings, particularly those indicated by the severity of the lower urinary tract symptoms, that affect the management of these cases.

BPH has a high prevalence rate (>50% in men >50 years and >90% by the age of 80 years) (1,2). Age-related vasculopathy has been suggested as the cause of BPH. This theory suggests that there is an association between BPH (with lower urinary tract symptoms and erectile dysfunction) and chronic pelvic pain syndrome and that BPH is a manifestation of an aging vascular disease rather than an etiopathogenic factor.

Treatment with phosphodiesterase inhibitors clearly improves both erectile dysfunction and lower urinary tract symptoms secondary to BPH, which suggests the existence of a pathophysiologic link between the two conditions. The smooth muscle relaxation that occurs with phosphodiesterase inhibitors in prostatic, bladder neck, and erectile tissues is associated with symptom improvement. Possible mechanisms include pelvic atherosclerosis (because pelvic ischemia may lead to smooth muscle loss in the corpora cavernosa and bladder) and reduced nitric oxide levels (nitric oxide is a nonadrenergic, noncholinergic mediator of smooth muscle activity) in the prostate, bladder, and penis.

Medical therapy is a first-line treatment option and is indicated for patients with moderate lower urinary tract symptoms (3,4). Medical therapies for BPH relief include α-adrenergic blockers and 5α-reductase inhibitors. Medical therapy is indicated for patients with moderate lower urinary tract symptoms with no absolute indications for surgery (recurrent urinary retention, recurrent urinary tract infections, renal insufficiency, bladder calculi, and recurrent gross hematuria). Medical therapy, α-adrenergic blockers, and 5α-reductase inhibitors, even when combined with each other, have limited effectiveness in reducing urinary symptoms (5.6–7.4-point improvement in the International Prostate Symptom Score [IPSS]) (3).

Transurethral resection of the prostate (TURP) is the most common surgical treatment for severe symptomatic cases of BPH in which medical therapy has failed. Although spinal anesthesia is used most frequently for TURP, all patients should be suitable for general anesthesia. Blood loss should be considered a frequent complication.

Minimally invasive treatments, including interstitial laser ablation, transurethral microwave treatment, and transurethral needle ablation, were originally conceived in an attempt to offer effectiveness equivalent to that of surgical therapy but without the burden and risk of surgical morbidity (5). Prostatectomy may be performed via the urethra (TURP) if the prostate is smaller than 80–100 g or by means of open surgery if the prostate is larger. Both procedures are associated with a high complication rate. None of the minimally invasive treatments have proved superior to TURP from a cost-versus-benefit standpoint, and TURP remains the standard of effective treatment (6).

Both medical and surgical treatment options for BPH are associated with hospital stay and postoperative pain, sexual dysfunction (retrograde ejaculation), and hemorrhage. Therefore, there is a need for innovative technologies that improve outcomes and minimize patient discomfort and morbidity in the management of BPH (7).

Prostatic arterial embolization (PAE) for BPH has been shown to be a safe and effective method of inducing prostatic volume reduction in animals and humans (8–10). Mauro (11) reported that treatment of BPH with PAE might be the next developmental step after uterine artery embolization to treat fibroids. This statement was based on the therapeutic parallel between PAE and uterine artery embolization because embolization leads to ischemia and organ shrinkage with both procedures. Short-term studies on BPH have shown that PAE is a safe and effective procedure that improves lower urinary tract symptoms related to BPH and is associated with a decrease in prostate volume (12,13). Intermediate-term

Advance in Knowledge

- Prostatic arterial embolization (PAE) for symptomatic benign prostatic hyperplasia (BPH) is a safe procedure, with low morbidity and no loss of sexual function, resulting in an estimated 10-point decrease in International Prostate Symptom Score and a 20% reduction in prostate volume that were sustained after 12 months.

Implication for Patient Care

- PAE may be a conservative alternative for the treatment of BPH in symptomatic patients.

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Abbreviations:
BPH = benign prostatic hyperplasia
CI = confidence interval
IIEF = International Index of Erectile Function
IPSS = International Prostate Symptom Score
PAE = prostatic arterial embolization
PSA = prostate-specific antigen
QOL = quality of life
TURP = transurethral resection of the prostate

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Conflicts of interest are listed at the end of this article.

results of PAE for BPH have been reported in a few studies on the basis of small case series.

We investigated the short- and intermediate-term results and morbidity of PAE as an alternative treatment option for BPH-associated symptoms while preserving sexual function. The objective of this study was to prospectively evaluate the safety, morbidity, and short- and intermediate-term results of PAE for BPH after failure of medical treatment.

Materials and Methods

Study Population and Preprocedural Evaluation

This prospective study was approved by the institutional review board, and informed consent was obtained from all participants. From March 2009 to April 2011, all patients with symptomatic BPH that was refractory to medical treatment for at least 6 months and with a clinical indication for surgery were evaluated for PAE and included in this study.

The medical therapy was consistent among the study patients, with one α-1-adrenergic receptor antagonist administered once daily (10 mg of alfuzosin hydrochloride [Ratiopharm, Ulm, Germany]; 4 mg of doxazosin mesylate [Cardura Gits; Pfizer, Lisbon, Portugal]; or 0.4 mg of tamsulosin hydrochloride [Ratiopharm]).

Inclusion criteria included men older than 50 years with a diagnosis of BPH and moderate-to-severe lower urinary tract symptoms refractory to medical treatment for at least 6 months (IPSS >18, quality of life [QOL] score >3, peak urinary flow <12 mL/sec, and/or presence of acute urinary retention), a prostate larger than 40 g, and sexual dysfunction or acceptance of the risk of developing sexual dysfunction after treatment.

Exclusion criteria were malignancy and advanced atherosclerosis or tortuosity of the iliac arteries (on the basis of visual evaluation by the interventional radiologists of pelvic computed tomographic [CT] angiograms or magnetic resonance [MR] angiograms obtained before PAE). Prostatic biopsy was performed in all patients suspected of having prostatic malignancy because of a prostate-specific antigen (PSA) level of more than 4 μg/L or the presence of focal lesions at transrectal US or MR imaging.

All patients were informed about the embolization technique, and the experimental nature of the procedure was clearly indicated. The patients were allowed to choose freely among PAE, TURP (open surgery), or laser surgery if the prostate volume was smaller than 80 mL and between PAE and open surgery if the prostate volume was larger than 80 mL.

Preprocedural imaging.—In the first 15 patients, pelvic MR angiography was performed with a 1.5-T system (Achieva; Philips, Eindhoven, the Netherlands) before PAE to evaluate the pelvic vessels for tortuosity and atherosclerotic changes of the iliac arteries. In the remaining patients, pelvic CT angiography was performed with a 16–detector row spiral scanner (LightSpeed; GE Medical Systems, Milwaukee, Wis). Initially, preprocedural imaging planning was performed with MR imaging to evaluate the pelvic and prostate arteries. However, MR imaging failed to have enough resolution to allow confident identification of the prostatic arteries, which was achieved with CT angiography.

Our CT angiography protocol included power settings of 100–120 kV and 200–300 mA, a matrix of 512 × 512 pixels, a collimation of 16 × 1.25 mm (section thickness, 0.5 mm), and a pitch of 1.3. Iodinated contrast material (150 mL at a concentration of 350 mg/mL iodine) was injected at a rate of 4 mL/sec by using bolus triggering in the abdominal aorta (above the renal arteries). Postprocessing was performed by using maximum intensity projections and volume rendering with three-dimensional reconstructions.

The prostate diameters were measured visually with transrectal US in sagittal, axial, and transverse planes. Volumes were assessed by using the ellipsoid formula $\pi/6 \times$ (transverse diameter × anteroposterior diameter × sagittal diameter). One author (V.V.S., with 8 years of experience) performed all transrectal US examinations, and another (T.B., with 7 years of experience) performed all MR examinations by using these measurement techniques and volume formulas before and after PAE to avoid interobserver variability.

Embolization technique.—Patients stopped taking all prostatic medications 1 week before embolization, if possible. After undergoing successful PAE, all prostatic medications were taken during the entire follow-up period if there was consistent clinical improvement. Patients started taking an acid-suppressing drug once daily (20 mg of omeprazole [Bluepharma, Coimbra, Portugal]), an anti-inflammatory medication twice daily (1000 mg of naproxen [Naprosyn; Roche, Paris, France), and an antibiotic twice daily (500-mg dose of levofloxacin [Ciprofloxacin; Jaba, Santiago de Besteiros, Portugal]) 2 days before the procedure and continued for 10 days after PAE. On the day of PAE, the patients were given 20 mg of omeprazole, 1000 mg of naproxen, and 500 mg of levofloxacin in the morning before PAE and 1000 mg of naproxen and 500 mg of levofloxacin 8 hours after PAE.

Patients were admitted to the hospital on the day of the procedure. During embolization, analgesic (2 g of metamizol [Nolotil; Boehringer Ingelheim, Ingelheim, Germany]) and anti-inflammatory (30 mg of ketorolac trometamine [Toradol, Roche]) drugs were given intravenously. Embolization was performed with local anesthesia by using a unilateral approach, usually in the right femoral artery. A 5-F cobra or Roberts Uterine Catheter (Cook, Bloomington, Ind) was introduced into the right femoral artery to catheterize the left hypogastric artery and its anterior division. Angiography of the anterior division of the hypogastric artery was performed in the ipsilateral oblique plane to visualize the anatomy of the prostatic arteries. The prostatic vessels were selectively catheterized with a 3-F coaxial microcatheter (Progreat; Terumo, Tokyo, Japan) if catheterization was not possible with the regular catheter. Another angiography procedure

Figure 1

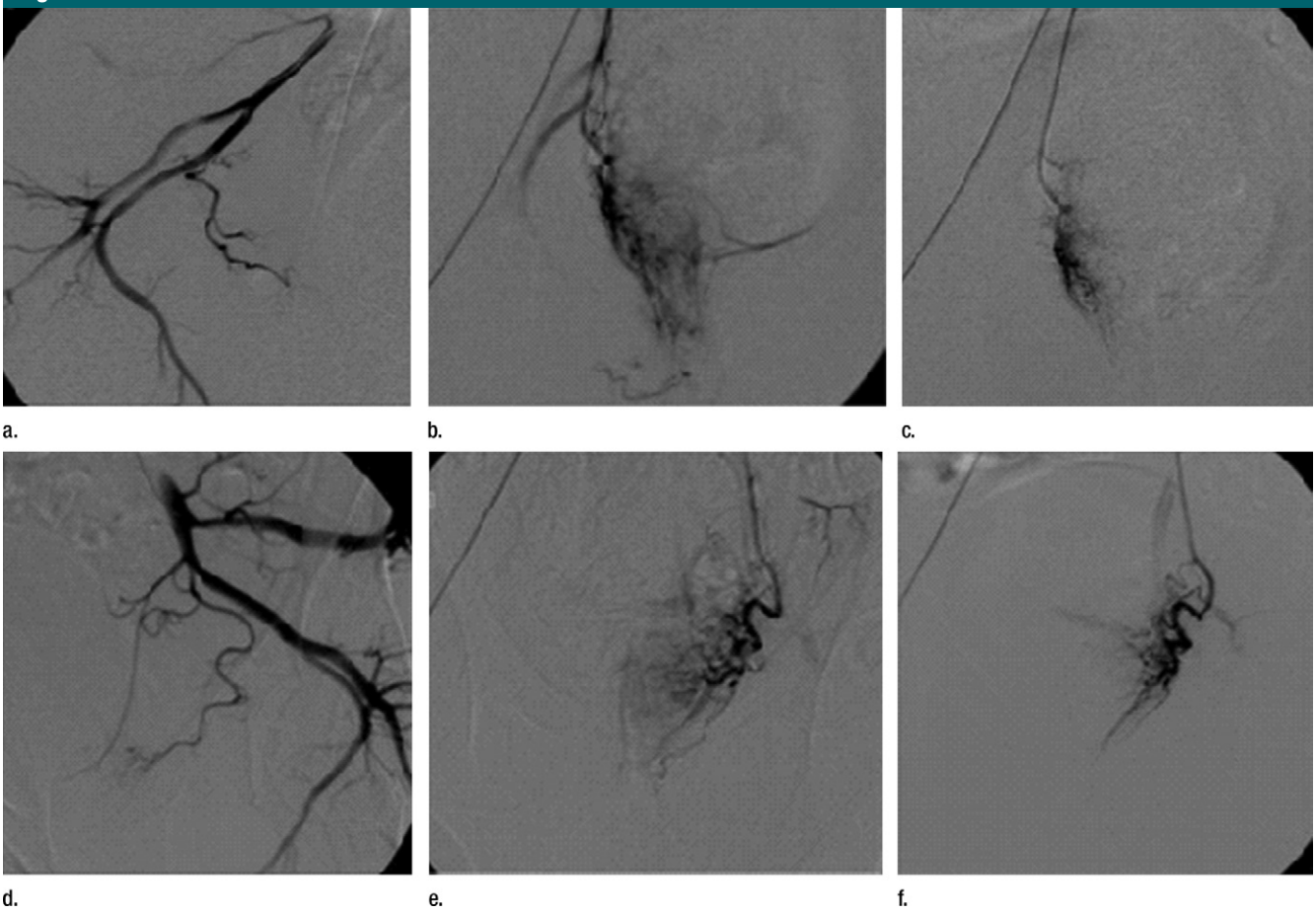

Figure 1: Angiograms in 68-year-old man with BPH and urinary retention, which necessitated an indwelling bladder catheter of 3 months. **(a)** Oblique view of anterior division of right hypogastric artery. **(b, c)** Images of right prostatic artery before (**b**) and after (**c**) PAE. **(d)** Oblique view of anterior division of left hypogastric artery. **(e,f)** Images of left prostatic artery before (**e**) and after (**f**) PAE.

was performed to confirm the position of the catheter in the ostium of the prostatic artery before embolization.

The first 14 patients underwent embolization with use of nonspherical 200-μm (range, 180–300-μm) polyvinyl alcohol particles (Cook). The remaining patients underwent embolization with use of 100-μm particles (range, 80–180 μm). The end point chosen for embolization was slow flow or "near stasis" in the prostatic vessels, with interruption of the arterial flow and prostatic gland opacification (Fig 1). When embolization of the left prostatic arteries was complete, the Waltman curve was formed on the cobra catheter and the right prostatic arteries were embolized in the same manner. The PAE procedure time was measured from the start of femoral puncture access to the removal of the catheter after PAE. Fluoroscopy time was also recorded.

Postprocedural follow-up.—Baseline data were obtained before PAE (Table 1). All patients were evaluated by means of clinical observation, with measurement of the IPSS (scale of 0 [best] to 35 [worst]), QOL score (scale of 0 [delighted] to 6 [terrible]), sexual function (International Index of Erectile Function [IIEF] score of 0–30), peak urinary flow and postvoid residual volume (with use of uroflowmetry), and PSA level. Prostate volume was calculated in all patients before embolization and 1, 3, and every 6 months after with transrectal US (14,15) (Fig 2).

Table 1

Baseline Values of Effectiveness Parameters

Variable	Value*
IPSS	23.0 ± 7.61
QOL score	4.07 ± 0.92
IIEF score	18.3 ± 8.73
Peak urinary flow (mL/sec)	8.68 ± 4.24
Prostate volume (mL)	85.3 ± 43.5
Postvoid residual volume (mL)	102.2 ± 90.9
PSA level (μg/L)	6.37 ±6.87

* Data are means ± standard deviations.

MR imaging was used to measure prostate volume before and after PAE in only the first 15 patients (Fig 3).

Clinical and imaging examinations were performed before PAE and 1, 3, and every 6 months after the procedure.

A procedure was considered technically successful if selective prostatic arterial catheterization and embolization was achieved on at least one pelvic side.

Pain assessment was performed during and 6–8 hours after PAE by means of verbal and written questionnaires involving the use of a visual analog scale. Patients were asked to rate their pain severity on a scale of 0 (no pain) to 10 (worst pain possible).

Symptoms of postembolization syndrome, including pain and fever, were not considered complications unless pain and/or fever resulted in prolonged hospitalization or repeat hospital admission. Postprocedural fever was also considered a complication when a detailed history, physical examination, and laboratory evaluation served to confirm a specific cause. Complications were categorized as complications of angiography (related to puncture site, contrast material, or radiation injury), pelvic infection, ischemic complications, sexual dysfunction, nonprostatic embolization, adverse drug reactions, pulmonary embolism, or "other." Complications were considered minor if they could be addressed with ambulatory medical treatment and major if they resulted in prolonged hospitalization, repeat hospital admission, and/or the need for surgery. Possible ischemic, infectious, or puncture site complications were evaluated by means of clinical and physical examination with pain assessment on the day after PAE and weekly during the following month. Further imaging or laboratory studies were conducted when a complication was suspected.

Cases of persistent severe symptoms (decrease in IPSS of ≤25%, IPSS ≥18, decrease of QOL score by ≤1, and QOL score ≥4) and/or peak urinary flow increase of less than 2.5 mL and a peak urinary flow of up to 7 mL/sec after PAE were considered clinical failures. Clinical improvement was defined as improving symptoms, with reduction of IPSS of at least 25% of the total score, IPSS lower than 15, reduction of QOL score by at least 1, QOL score of up to 3, increase of peak urinary flow by at least 2.5 mL/sec, and peak urinary flow of at least 7 mL/sec (16).

Figure 2

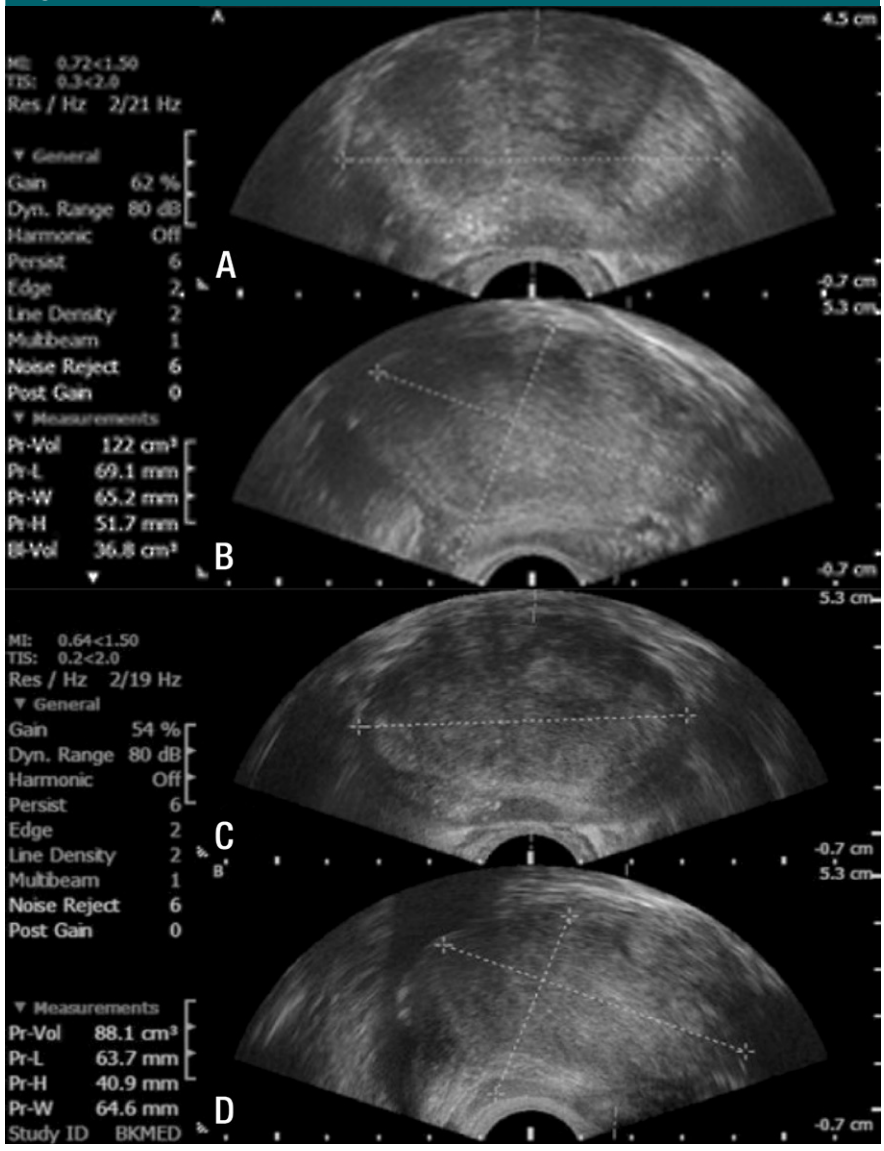

Figure 2: US scans in 71-year-old man with BPH treated with tamsulosin hydrochloride for 4 years. Prostate US was performed with rectal approach. *A, B,* US scans obtained before embolization. Prostate volume was 122 mL. *C, D,* US scans obtained 1 week later, after embolization. Prostate volume was 88.1 mL, a reduction of 28%.

Statistical Analysis

Response variables (IPSS, QOL score, peak urinary flow, postvoid residual volume, PSA level, prostate volume, and IIEF score) were analyzed with random-effects generalized least squares regression with an autoregressive error structure (17). Prostate volume, peak urinary flow, and PSA level were logarithmically transformed to obtain a normal distribution. Observation time was entered in the model as a categorical variable. There was weak correlation between response variables, with the only significant correlations between QOL score and IPSS (Spearman rank correlation, r = 0.44),

Figure 3

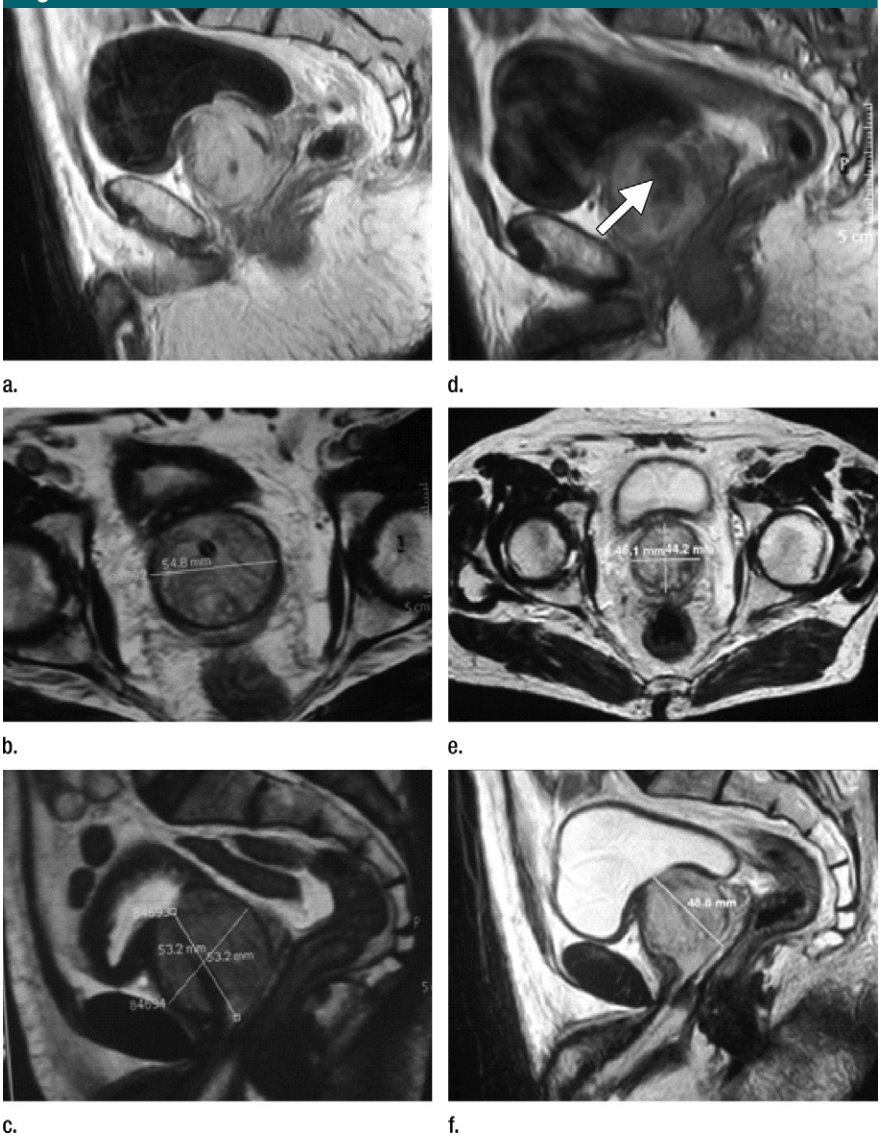

Figure 3: MR images in 76-year-old man with BPH. Patient had undergone medical treatment for 6 years. Peak urinary flow was 5.2 mL/sec. Images were obtained **(a–c)** before and **(d–f)** 3 months after PAE. Prostate volume was 81.1 mL (53.2 × 53.2 × 54.8 mm) before PAE and 53 mL (46.1 × 44.2 × 48.8 mm) 3 months after PAE, a reduction of 35%. Note central gland nonenhancement (arrow in **d**) with intravenous contrast material owing to ischemia.

PSA level and prostate volume ($r = 0.47$), and PSA level and peak urinary flow ($r = -0.30$). No adjustment for multiplicity was done. Rates of clinical improvement over time were analyzed with the Kaplan-Meier method to account for incomplete follow-up times. Results are reported for short-term (≤6 months after PAE) and intermediate-term (12–24 months after PAE) follow-up. Software (Stata, release 12; Stata, College Station, Tex) was used for all analyses. $P < .05$ was indicative of a statistically significant difference.

Results

During the enrollment period, 296 patients met the inclusion criteria. Of these 296 patients, 152 opted for TURP (open surgery), 36 opted for laser surgery, and 108 opted for PAE. Nineteen candidates for PAE were excluded: nine because of malignancy and 10 because of advanced atherosclerosis and tortuosity of the iliac and prostatic arteries.

The 89 patients included in this study ranged in age from 52 to 85 years (mean, 74.1 years), and the duration of medical therapy in this group ranged from 6 months to 14 years (mean, 3.5 years). One patient had undergone two TURP procedures 14 and 10 years previously and open prostatectomy 8 years previously, three patients had undergone TURP several years before, and 16 patients had bladder catheters in place at the time of study inclusion owing to acute urinary retention.

PAE was technically successful in 86 of the 89 treated patients (97%). In three patients (3%), the procedure was impossible to complete because of tortuosity and atherosclerotic changes of the iliac arteries; surgery was performed in these cases. These three patients were excluded from effectiveness analysis. PAE was bilateral in 79 of the 86 patients (technical success rate for bilateral PAE, 92%) and unilateral in seven patients (8%) because of tortuosity and atherosclerotic changes of the iliac arteries. CT angiography showed small prostatic arteries with atherosclerotic changes in five patients, and these findings were explained to the patients. Despite these changes, the patients wanted to be treated with PAE. A bilateral femoral approach was used in these patients.

The PAE procedure lasted 25–185 minutes (mean, 86 minutes), and the fluoroscopy time was 7–63 minutes (mean, 27 minutes). Only one vial of 180–300-μm polyvinyl alcohol particles was used in each of the first 14 patients. A vial of 80–100-μm particles was used in the remaining patients.

During the procedure, the degree of pain ranged from 0 to 10 (mean, 1.7). However, 68 of the 86 patients (79%) did not feel any pain. Only one patient felt very severe pain (score, 10) during embolization, and this patient later

Table 2

Cumulative Probability of Clinical Improvement over Time

Month of Follow-up	No. of Patients	No. of Treatment Failures	Percentage of Patients Demonstrating Clinical Improvement	95% CI (%)
1	86	10	88	79.5, 93.6
3	71	3	85	75.0, 90.8
6	54	4	78	67.3, 86.1
12	29	1	76	63.4, 84.3
18	13	3	58	37.1, 74.4
24	6	0	58	37.1, 74.4

developed a small area of bladder wall ischemia.

Sixteen patients had urinary retention (with vesical catheters) at the time of their procedure. Twelve of these patients had urinary tract infections, as proved with urine cultures obtained at baseline. The vesical catheters were removed 5–20 days after the procedure, and the patients started to urinate without difficulty.

Seventy-eight of the 86 patients (91%) were discharged from the hospital 6–8 hours after the procedure (as outpatients). The remaining eight patients were discharged the following morning, 18 hours after the procedure (as inpatients).

At short-term follow-up, 86 patients were evaluated at 1 month, 71 at 3 months, and 54 at 6 months. At intermediate-term follow-up, 29 patients were evaluated at 12 months, 13 at 18 months, and six at 24 months. The median follow-up time was 6 months (mean, 8 months). Baseline values of the effectiveness parameters are presented in Table 1.

Of the 86 patients evaluated for efficacy, the proportion of patients with short-term clinical improvement at 1, 3, and 6 months was, respectively, 88% (71 of 81 patients), 95% (54 of 57 patients), and 88% (29 of 33 patients). The Kaplan-Meier estimates of the cumulative probability of clinical improvement were 88% at 1 month, 85% at 3 months, and 78% at 6 months (Table 2).

At 3 months, there were 13 short-term clinical failures. Eight failures occurred soon after the procedure and did not improve at all after PAE. All clinical failures involved the same symptoms after PAE (IPSS remained higher than 20, with a QOL score of ≥4) as those that occurred before the procedure. In three cases, there was no clinical success despite a significant reduction in prostate volume. In five of the early failures, only unilateral embolization could be performed. In three failures, the embolization was incomplete because of advanced atherosclerosis. In four of the early failures, preprocedural CT angiography did not show the advanced atherosclerotic changes. Three of the seven patients who underwent unilateral embolization were diabetic. Two weeks after embolization, PAE was performed successfully in the nonembolized prostatic artery in two of seven patients with unilateral embolization by means of a different femoral approach. As a result, the bladder catheters in these two patients with urinary retention were removed, and the patients could urinate easily. Therefore, the number of patients with short-term clinical failure decreased from 13 to 11.

The remaining seven patients with short-term clinical failure underwent embolization bilaterally without technical difficulties, and their condition improved after embolization. The IPSS, QOL, and peak urinary flow values deteriorated 1–3 months after embolization. However, in two patients, the prostate volume continued to decrease.

At intermediate-term follow-up, the proportion of patients with clinical improvement at 12, 18, and 24 months was, respectively, 93% (14 of 15 patients), 67% (six of nine patients), and 100% (one of one patient). The Kaplan-Meier estimates of the cumulative probability of clinical improvement were 76% at 12 months (95% confidence interval [CI]: 63.4%, 83.4%) and 58% at both 12 and 24 months (95% CI: 37.1%, 74.4%) (Table 2). Three patients with clinical failure at 18 months had acute urinary retention, and a bladder catheter was placed. Two of the patients improved after repeat PAE, and the bladder catheter was removed. The third patient underwent open prostatectomy because of advanced atherosclerosis.

Table 3 and Figures 4 and 5 show the point estimates and 95% CIs of the change from baseline in the effectiveness variables. There was a significant decrease in IPSS ($P < .0001$), QOL score ($P < .0001$), prostate volume ($P < .0001$), postvoid residual volume ($P = .002$), and PSA level ($P < .0001$) and a significant increase in peak urinary flow ($P < .0001$) and IIEF score ($P = .003$). The IIEF scores improved in 31 patients and remained stable in the remaining patients.

With repeated-measures regression, the IPSS showed a positive association with QOL score ($P < .001$) and a negative association with peak urinary flow ($P < .001$) and possibly IIEF score ($P = .07$) but not with postvoid residual volume ($P = .16$), PSA level ($P = .94$), or prostate volume ($P = .21$).

Complications

A number of minor complications occurred. Sixteen of the 86 patients (19%) had urinary tract infections after embolization that were treated with antibiotics, and there was transient hematuria in nine of the 86 patients (10%) and transient hemospermia that disappeared spontaneously without any treatment in six (7%). Balanoprostatitis occurred in two of the 86 patients (2%) and inguinal hematoma in six (7%). Twelve of the 16 urinary infections occurred in patients with a bladder catheter and were already present before PAE, as proved by means of urine culture. Two patients had acute urinary retention after PAE, and a temporary bladder catheter was placed for a couple of hours.

There was one major complication: One patient developed bladder wall ischemia, which involved a small area (1.5 cm^2) of bladder wall on the right side of the base without involvement of the ureteral or urethral orifices (this same patient had severe intraprocedural pain). This resulted in intraluminal necrotic tissue. The patient underwent surgery to remove the intraluminal necrotic tissue that was attached to the bladder wall. There was no bladder wall rupture or fistula. There was no need for any bladder wall reconstruction.

Discussion

Our study showed that PAE is clinically effective, even in symptomatic patients with a very large prostate gland that typically necessitates open prostatectomy. In this prospective noncomparative study, PAE was performed in 86 patients with BPH with an estimated short-term clinical success rate of 78% at 6-month follow-up (95% CI: 67.3%, 86.1%). Intermediate-term rates of clinical improvement were harder to estimate because of the small number of patients followed up for more than 12 months, producing estimates with wide CIs (95% CI at 18 and 24 months: 37.1%, 74.4%). The patients showed significant clinical improvement despite discontinuation of prostatic medication.

At 12-month follow-up, the IPSS decreased by 13.1 points, the QOL score decreased by 2.14 points, the peak urinary flow increased by 47.1%, the IIEF score improved by 3.27 points, the prostate volume decreased by 22.5%, and the PSA level decreased by 26.8%. These results are better than those obtained with medical therapies (3,4,14,17–19).

With our procedure, the clinical improvement in IPSS is similar to that with other minimally invasive techniques (eg, transurethral microwave treatment and transurethral needle ablation) and is slightly less than that obtained with TURP (20,21). The improvement of the peak urinary flow is less than that with the other surgical techniques. However, the other techniques have less improvement in symptom scores, a greater

Table 3

Change from Baseline over Time for Response Variables

Variable and Month of Follow-up	No. of Patients	Change from Baseline	95% CI (%)	*P* Value
IPSS				<.0001
1	79	−10.4	−9.1, −11.6	
3	70	−12.0	−10.2, −13.8	
6	50	−12.2	−10.0, −14.4	
12	28	−13.1	−10.3, −15.8	
18	12	−12.1	−8.3, −15.8	
24	4	−12.9	−6.5, −19.2	
QOL score				<.0001
1	79	−1.71	−1.47, −1.95	
3	70	−1.95	−1.62, −2.28	
6	51	−2.05	−1.66, −2.44	
12	28	−2.14	−1.65, −2.65	
18	12	−2.00	−1.34, −2.66	
24	4	−2.13	−0.99, −3.26	
Q_{max} (% change)				<.0001
1	79	38.1	28.5, 48.4	
3	69	47.3	32.7, 63.4	
6	49	46.4	28.6, 66.7	
12	24	47.1	23.0, 75.9	
18	11	36.1	8.9, 70.2	
24	3	42.9	−2.0, 108.3	
PVR (mL)				.002
1	76	−29.9	−46.2, −13.5	
3	60	−39.7	−63.3, −16.1	
6	48	−39.7	−67.3, −12.1	
12	22	−41.6	−79.1, −4.1	
18	12	−31.6	−76.1, 13.0	
24	6	28.2	−37.1, 93.5	
PV (% change)				<.0001
1	81	−20.6	−23.3, −17.8	
3	69	−24.0	−28.2, −20.0	
6	55	−25.1	−30.5, −19.2	
12	29	−22.5	−30.5, −13.6	
18	13	−18.4	−29.3, −5.9	
24	7	−11.0	−27.1, −8.7	
PSA level (% change)				<.0001
1	78	−29.2	−37.5, −19.9	
3	69	−38.6	−48.3, −27.0	
6	53	−32.1	−44.7, −16.7	
12	28	−26.8	−43.9, −4.5	
18	12	−25.4	−47.2, 5.4	
24	4	−20.2	−53.9, 38.2	
IIEF score				.003
1	77	0.49	−0.40, 1.39	
3	67	0.95	−0.36, 2.26	
6	49	1.08	−0.52, 2.69	
12	23	3.27	1.01, 5.54	
18	11	3.95	1.18, 6.73	
24	4	8.30	3.60, 13.0	

Note.—PV = prostate volume, PVR = postvoid residual volume, Q_{max} = peak urinary flow.

Figure 4

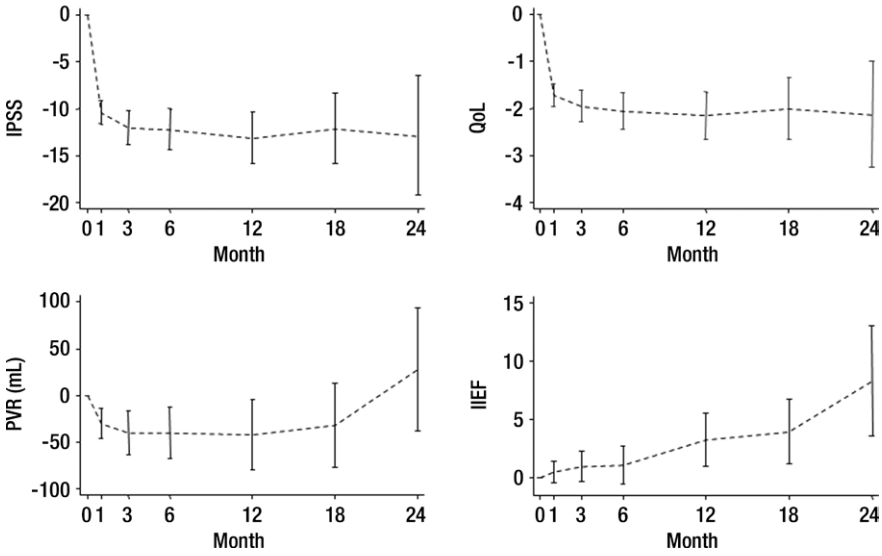

Figure 4: Graphs show changes in IPSS, QOL score, postvoid residual volume *(PVR)*, and IIEF score after PAE. Vertical bars indicate point estimates and 95% CIs.

Figure 5

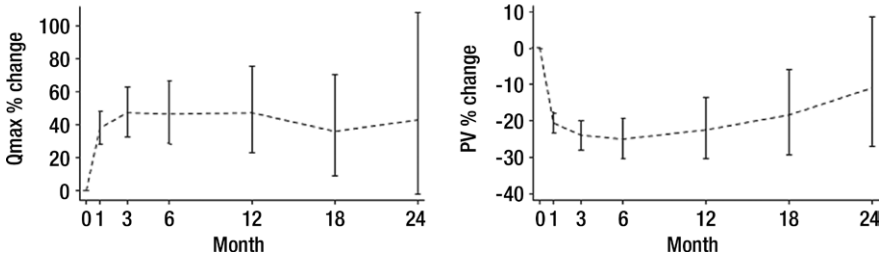

Figure 5: Graphs show percentage change in peak urinary flow *(Qmax)* and prostate volume *(PV)* after PAE. Vertical bars indicate point estimates and 95% CIs.

risk of continued catheterization and repeat surgery, and poorer durability of symptomatic benefit. Up to 25% of all patients initially treated with less-invasive procedures end up undergoing TURP within 2 years because of insufficient therapeutic response (14). Patients treated with TURP have a mean decrease in IPSS of 70.6% and a mean increase in peak urinary flow of 125% (22). For transurethral needle ablation of the prostate, the IPSS improves by 11.8 points and peak urinary flow improves by 6.6 mL/sec (16).

With refined technique and knowledge of the male vascular pelvic structures (23,24), PAE may be performed safely, with minimal morbidity and without associated mortality. The minimally invasive nature of the technique, performed with local anesthesia in an outpatient setting, is a major advantage.

Open surgical prostatectomy is considered the standard of reference for prostates larger than 80–100 g, whereas TURP is considered the standard of reference for prostates smaller than 60–100 g (18). Both treatment options are associated with significant morbidity and complication rates (up to 20%), and complications include urinary tract infection, strictures, postoperative pain, urinary incontinence, urinary retention, and sexual dysfunction (19). Open prostatectomy has a mortality rate lower than 1%, but morbidity includes hemorrhage, myocardial infarction, pulmonary embolism, and cardiovascular accidents (7). Bladder neck contracture occurs in less than 2% of patients, retrograde ejaculation in more than 80%, and impotence in 15%–20% (25,26). The postoperative hospital stay ranges from 5 to 7 days.

TURP has a mortality rate of approximately 0.2%–0.4% for elective procedures, and patients need a catheter for 48 hours and a hospital stay of 5 days. Early postoperative problems include blood transfusion (2.4%), return to the surgical theater for bleeding (2.0%), sepsis (8.0%), and transurethral resection syndrome (absorption of glycine solution with hyponatremia in <1%) (14). Long-term complications include urethral stricture (1%–29%), bladder neck contracture (5%), impotence (5%–10%), retrograde ejaculation (50%), and urinary incontinence (2%–17%) (25,26). Another important feature of open prostatectomy and TURP is that 25%–33% of patients are dissatisfied with the outcome of surgery and the procedure is considered a clinical failure (27).

In our study, there was poor correlation between the degree of prostatic volume reduction and the clinical outcome. These results may imply that prostatic volume reduction might not be the only mechanism involved in symptom improvement after PAE, as it is also noted that there is a weak correlation between prostate size and lower urinary tract symptoms. The clinical success cannot be predicted on the basis of prostate volume reduction alone. Patients who undergo the same amount of prostatic volume change may have different clinical outcomes. Even with a careful selection of the patients and use of good embolization technique, the results are at times unpredictable on the basis of prostatic volume changes. Therefore, before undergoing the procedure, patients should be informed of the possible unpredictability of the results, despite the quality of the embolization results, and notified that the short-term clinical failure rate is approximately 30%.

An improvement in sexual function noted in 31 of our 86 patients (36%) might be explained by the discontinuation of the prostatic medication after PAE because those medications may have an effect on sexual function.

Our study has some limitations. Only six patients underwent 24-month follow-up, and the study was not comparative or randomized. This is an early experience with a new therapeutic procedure, and there are likely to be more unknown factors that affect the results of PAE.

Although the preliminary results look promising, further long-term multicenter studies and prospective randomized trials to compare PAE and the remaining surgical options are needed to validate these findings and define the future role of PAE in the management of BPH.

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