CLINICAL STUDY

Medium- and Long-Term Outcome of Prostate Artery Embolization for Patients with Benign Prostatic Hyperplasia: Results in 630 Patients

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ABSTRACT

Purpose: To confirm that prostatic artery embolization (PAE) has a positive medium- and long-term effect in symptomatic benign prostatic hyperplasia (BPH).

Materials and Methods: Between March 2009 and October 2014, 630 consecutive patients with BPH and moderate-to-severe lower urinary tract symptoms refractory to medical therapy for at least 6 months or who refused any medical therapy underwent PAE. Outcome parameters were evaluated at baseline; 1, 3, and 6 months; every 6 months between 1 and 3 years; and yearly thereafter up to 6.5 years.

Results: Mean patient age was 65.1 years ± 8.0 (range, 40–89 y). There were 12 (1.9%) technical failures. Bilateral PAE was performed in 572 (92.6%) patients and unilateral PAE was performed in 46 (7.4%) patients. The cumulative clinical success rates at medium- and long-term follow-up were 81.9% (95% confidence interval [CI], 78.3%–84.9%) and 76.3% (95% CI, 68.6%–82.4%). There was a statistically significant ($P < .0001$) change from baseline to last observed value in all clinical parameters: International Prostate Symptom Score (IPSS), quality-of-life (QOL), prostate volume, prostate-specific antigen, urinary maximal flow rate, postvoid residual, and International Index of Erectile Function. There were 2 major complications without sequelae.

Conclusions: PAE had a positive effect on IPSS, QOL, and all objective outcomes in symptomatic BPH. The medium- (1–3 y) and long-term (> 3–6.5 y) clinical success rates were 81.9% and 76.3%, with no urinary incontinence or sexual dysfunction reported.

ABBREVIATIONS

AUR = acute urinary retention, BPH = benign prostatic hyperplasia, CI = confidence interval, DSA = Digital subtraction angiography, IIEF = International Index of Erectile Function, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptoms, PAE = prostate artery embolization, PSA = prostate-specific antigen, PV = prostate volume, PVA = polyvinyl alcohol particles, PVR = postvoid residual volume, Qmax = maximal flow rate, QOL = quality of life

Benign prostatic hyperplasia (BPH) is the most frequent benign tumor in men and is present in > 50% of men ≥ 60 years old (1). The incidence increases with age, and all men can develop BPH if they live long enough (2). BPH clinically manifests with lower urinary tract symptoms (LUTS), including frequency, nocturia, urgency, hesitancy, decreased and interrupted stream, and incomplete bladder emptying. All these symptoms have a significant impact on daily life and sleep patterns (3). Medical and surgical therapies for BPH may be associated with major complications, including sexual dysfunction (4–9). To reduce the morbidity of therapy for BPH, a new

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procedure with good results and a lower rate of adverse events is needed; one such procedure is prostatic artery embolization (PAE). A few patients may not improve; however, their condition does not worsen or result in severe adverse events. PAE is a minimally invasive therapy that has been shown to be safe and effective for LUTS associated with BPH, resulting in good short-term and medium-term outcomes, a decrease in prostate volume (PV), and significant clinical improvement (10–15). Nonspherical polyvinyl alcohol (PVA) particles have been the most commonly used embolic agent for PAE (14–28). The aim of this retrospective cohort study was to confirm that PAE has a positive effect on all objective outcomes in symptomatic BPH between 2 and 6.5 years of follow-up.

MATERIALS AND METHODS

Study Population

This single-center, retrospective cohort study was approved by the institutional review board. Eligible patients had been informed regarding the embolization procedure through a schematic drawing, and all provided informed consent. From March 2009 to October 2014, 630 consecutive patients underwent PAE for the relief of BPH symptoms (ie, moderate-to-severe LUTS). Of 630 patients, 429 had been refractory to medical therapy for at least 6 months, 120 had previously refused any medical or surgical therapy, 67 had presented with acute urinary retention (AUR), and 14 had undergone surgery 1–12 years before PAE. A second PAE was required in 58 patients. The short-term and medium-term results of the first 255 patients in this series have been previously published (16–18).

Before the procedure, every patient was evaluated at baseline for the degree of LUTS using the International Prostate Symptom Score (IPSS), the quality of life (QOL) questions in IPSS, and the International Index of Erectile Function (IIEF) questionnaire. The following parameters were evaluated: PV measured using transrectal ultrasound in all patients and using magnetic resonance imaging in 87 patients, prostate-specific antigen (PSA), and urinary maximal flow rate (Qmax) and postvoid residual (PVR) volume in patients who did not have AUR. Prostate biopsy was performed whenever a suspicious focal lesion was detected on transrectal ultrasound, magnetic resonance imaging, or digital rectal examination or when the PSA was > 4 mg/mL. Computed tomography (CT) angiography was performed before the procedure in all patients, as previously described, to study the iliac and prostatic arteries (20). An interventional and diagnostic radiologist with 10 years of experience interpreted all CT angiography images. Based on CT angiography data, the patients were informed regarding the anticipated difficulty of the procedure and probability of technical and clinical success.

Patients were administered an acid-suppressing drug (omeprazole 20 mg once daily [Pantoprazole; Bluepharma, Coimbra, Portugal]), an antiinflammatory (naproxen 1,000 mg twice daily [Naprosyn; Roche, Basel, Switzerland]), and an antibiotic (ciprofloxacin 750 mg twice daily [Ciprofloxacina Jaba; Porto Salvo, Portugal]) for 2 days before and 7 days after PAE. On the day of PAE, medications were administered during breakfast and dinner 8 hours after the procedure. During embolization, an antihistamine (hydroxyzine 25 mg [Atarax; Paço de Arcos, Portugal]) was orally administered, and an analgesic (metamizole 2 g [Nolotil; Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany]) and an antiinflammatory (ketorolac trometh-amine 30 mg [Toradol; Roche]) were intravenously administered (16–18).

The inclusion criteria were age > 40 years, a diagnosis of BPH with moderate-to-severe LUTS (IPSS ≥ 18 and QOL ≥ 3), Qmax ≤ 12 mL/s or AUR, refractoriness to medical or other treatment for at least 6 months, PV > 30 mL, and acceptance of the risk of developing sexual dysfunction after treatment (16–18). Patients with PV < 30 mL were included if the urodynamic study showed infravesical obstruction. Urodynamic studies were performed in cases of possible infravesical obstruction or bladder dysfunction or neurogenic bladder, particularly if the Qmax was > 15 mL/s. Exclusion criteria included malignancy, advanced atherosclerosis and tortuosity of the iliac and/or prostatic arteries on CT angiography, secondary renal insufficiency (eg, secondary to prostatic obstruction), large bladder diverticula or stones, neurogenic bladder, detrusor failure, active urinary tract infection, and unregulated and uncontrollable coagulation parameters (16–18).

Procedures

Procedures were performed on an outpatient basis. PAE was performed under local anesthesia by a unilateral approach whenever possible, usually through the right femoral artery. A 5-F 11-cm or 23-cm sheath (Terumo, Tokyo, Japan) was introduced into the right femoral artery. A Roberts uterine catheter (Cook, Inc, Bloomington, Indiana) and a 0.035-inch hydrophilic guide wire (Terumo) were used for catheterization of the left internal iliac artery and its anterior division (16–18). However, if the iliac arteries were very tortuous, a bilateral femoral approach was used. For bilateral cases, a Rösch inferior mesenteric catheter (Cook, Inc) was introduced into the ipsilateral internal iliac artery. Digital subtraction angiography (DSA) of the anterior division of the internal iliac arteries was performed with ipsilateral anterior oblique (35°) with cranial tilt (−10%) views. For selective catheterization of the prostatic arteries, a Progreat 2.7 or Progreat 2.0 microcatheter