CLINICAL STUDY

Early Results from a United States Trial of Prostatic Artery Embolization in the Treatment of Benign Prostatic Hyperplasia

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ABSTRACT

Purpose: To report early findings from a prospective United States clinical trial to evaluate the efficacy and safety of prostatic artery embolization (PAE) for benign prostatic hyperplasia (BPH).

Materials and Methods: From January 2012 to March 2013, 72 patients were screened and 20 patients underwent treatment. Patients were evaluated at baseline and selected intervals (1, 3, and 6 mo) for the following efficacy variables: American Urological Association (AUA) symptom score, quality of life (QOL)–related symptoms, International Index of Erectile Function score, peak urine flow rate, and prostate volume (on magnetic resonance imaging at 6 mo). Complications were monitored and reported per Society of Interventional Radiology guidelines.

Results: Embolization was technically successful in 18 of 20 patients (90%); bilateral PAE was successful in 18 of 19 (95%). Unsuccessful embolizations were secondary to atherosclerotic occlusion of prostatic arteries. Clinical success was seen in 95% of patients (19 of 20) at 1 month, with average AUA symptom score improvements of 10.8 points at 1 month ($P < .0001$), 12.1 points at 3 months ($P = .0003$), and 9.8 points at 6 months ($P = .06$). QOL improved at 1 month (1.9 points; $P = .0002$), 3 months (1.9 points; $P = .003$), and 6 months (2.6 points; $P = .007$). Sexual function improved by 34% at 1 month ($P = .11$), 5% at 3 months ($P = .72$), and 16% at 6 months ($P = .19$). Prostate volume at 6 months had decreased 18% (n = 5; $P = .05$). No minor or major complications were reported.

Conclusions: Early results from this clinical trial indicate that PAE offers a safe and efficacious treatment option for men with BPH.

ABBREVIATIONS

AUA = American Urological Association, BPH = benign prostatic hyperplasia, IIEF = International Index of Erectile Function, PAE = prostatic artery embolization, QOL = quality of life, TURP = transurethral resection of the prostate

Benign prostatic hyperplasia (BPH) affects more than 15 million men in the United States, with an annual health care cost of more than $3 billion (1,2). By 60 years of age, the prevalence of BPH is greater than 50%, and, by 85 years of age, the prevalence is as high as 90% (3). BPH significantly alters quality of life (QOL), interferes with normal daily activities and sleep patterns, and manifests primarily with lower urinary tract symptoms, which consist of urinary frequency and urgency, nocturia, decreased and intermittent force of stream, and the sensation of incomplete bladder emptying. Complications of longstanding BPH include urinary calculi, infection, neurogenic bladder, and complete bladder outlet obstruction.

Therapeutic options for patients with mild or moderate-grade symptoms include watchful waiting and medical or surgical therapy. Although long-term medical

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therapy can be effective, it is limited by significant side effects such as dizziness, orthostatic hypotension, erectile dysfunction, and decreased libido. Often, medical therapy cannot be maintained for long periods of time because of compliance, cost, significant drug interactions, and, ultimately, lack of efficacy.

Investigators (4,5) have been seeking less invasive and durable therapies for BPH-related symptoms; one of the newest approaches has been prostatic artery embolization (PAE). Pisco et al (6) initially studied PAE in 15 human patients in Portugal, demonstrating technical success in 14 (92%), with good short-term clinical results and minimal adverse effects. PAE was shown to provide improvement in urinary flow rates, prostate volume, and QOL. In a follow-up study (7), Pisco et al demonstrated technical success rates of 97% with PAE, with 86 of 89 patients treated. Short- and intermediate-terms results were also impressive, with patients who received smaller embolic particles (mean 100-μm and 200-μm polyvinyl alcohol) exhibiting longer-term symptom improvement. In a study of 255 patients treated over a 36-month period (8), Pisco et al showed cumulative clinical success rates of 81.9%, 80.7%, 77.9%, 75.2%, 72.0%, 72.0%, 72.0%, and 72.0% at 1, 3, 6, 12, 18, 24, 30, and 36 months, respectively.

The purpose of the present study is to report early findings from a prospective physician-initiated United States clinical trial to evaluate the efficacy and safety of PAE in the treatment of BPH.

MATERIALS AND METHODS

From January 2012 to March 2013, 72 patients were screened at a single center for eligibility to participate, with 20 patients (mean age, 66.6 y; range, 57–81 y) enrolled thus far in the trial. Institutional review board approved enrollment is for between 30 and 45 patients, and is ongoing. Patients were excluded for the following reasons: elected alternate surgical therapy (n = 3), diagnosed with non–BPH-related symptoms (n = 5), chose watchful waiting (n = 10), prostate cancer (n = 1), declined embolization procedure (n = 17), or did not complete preprocedure tests (n = 16). All patients enrolled in this institutional review board–approved trial signed written informed consent, and the study was compliant with the Health Insurance Portability and Accountability Act. The primary outcome of this study is to measure the reduction in lower urinary tract symptoms from baseline to 1, 3, 6, and 12 months in men undergoing PAE. The inclusion criteria were age greater than 50 years, lower urinary tract symptoms believed to be secondary to bladder outlet obstruction from BPH, AUA symptom score of at least 8, and the ability to give informed consent. Exclusion criteria included bleeding diathesis, renal insufficiency (creatinine level > 1.6 mg/dL), neurologic disease believed to affect the bladder or history of neurogenic or chronically decompensated bladder, known prostate cancer, active bladder cancer (≤ 2 y), prostate-specific antigen level greater than 4.0 ng/dL (unless biopsy findings were negative or biopsy was declined), and acute urinary retention.

Efficacy variables of AUA symptom score, QOL, International Index of Erectile Function (IIEF) score, peak urine flow rate, and prostate volume on magnetic resonance (MR) imaging were assessed at baseline and at 6 months following the procedure (Table). AUA score, QOL, IIEF score, and adverse event monitoring were performed at all visits, including 1, 3, and 6 months. Follow-up is planned at 12 and 24 months as well. All patients were evaluated by a urologist and offered other therapeutic options. Patients were allowed to choose between PAE and other available therapies, including transurethral resection of the prostate (TURP), photoselective vaporization, and transurethral microwave therapy.

Embolization Technique

Patients received 30 mg ketorolac (Roche, Basel, Switzerland) and 500 mg ciprofloxacin (Bayer, Wayne, New Jersey) immediately before the procedure, with a second dose before discharge. Ciprofloxacin was prescribed for 3 days postprocedurally, along with oral ibuprofen 600 mg and 200 mg phenazopyridine (Warner Chilcott, Rockaway, New Jersey) three times daily. No additional analgesic agents were given for pain. The procedure was performed with moderate sedation, with patients receiving midazolam (West-ward, Eatontonwn, New Jersey) and fentanyl (Hospira, Lake Forest, Illinois).

Table. Baseline Efficacy Values per Treatment Cohort

	1 Mo (n = 19)		3 Mo (n = 13)		6 Mo (n = 5)	
Variable	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range
Age (y)	66.5 ± 6.84	57–81	68.9 ± 6.58	61–81	71.0 ± 6.28	63–80
AUA symptom score	24.1 ± 5.25	14–35	24.1 ± 4.59	14–30	21.8 ± 5.02	14–28
QOL score	5.79 ± 1.08	4–7	5.61 ± 1.12	4–7	5.80 ± 1.10	5–7
IIEF score	13.4 ± 6.90	3–30	13.0 ± 7.75	3–30	11.2 ± 7.40	6–24
Prostate volume (cm^3)	82.7 ± 62.0	28–274	66.4 ± 38.1	28–177	56.7 ± 18.1	28–76
Peak urine flow (mL/s)	8.64 ± 4.40	4–23	9.26 ± 4.87	4–23	7.40 ± 2.30	4–10

AUA = American Urological Association, IIEF = International Index of Erectile Function, QOL = quality of life.