BRIEF REPORT

Prostatic Artery Embolization Using Embosphere Microspheres for Prostates Measuring 80–150 cm^3: Early Results from a US Trial

Ari J. Isaacson, MD, Mathew C. Raynor, MD, Hyeon Yu, MD, and Charles T. Burke, MD

ABSTRACT

Between November 2014 and October 2015, 12 patients with prostates measuring 80–150 cm^3 and lower urinary tract symptoms (LUTSs) were enrolled in a prospective single-center US trial to evaluate Embosphere Microspheres for use in prostatic artery embolization (PAE). At 3 months, mean improvements in International Prostate Symptom Score and quality of life score were 18.3 points (range, 5–27) and 3.6 points (range, 1–6), respectively. One-month cystoscopies and anoscopies demonstrated no ischemic injuries. There were no major complications. In this cohort, Embosphere Microspheres, when used for PAE, were safe and effective in reducing LUTSs in the early follow-up period.

ABBREVIATIONS

BPH = benign prostatic hyperplasia, DSA = digital subtraction angiography, FDA = Food and Drug Administration, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptom, PAE = prostatic artery embolization, PSA = prostate-specific antigen, PV = prostate volume, PVR = postvoid residual volume, Q_{max} = peak urine flow rate, QoL = quality of life

Recently, several studies have demonstrated that prostatic artery embolization (PAE) is effective in treating lower urinary tract symptoms (LUTSs) secondary to benign prostatic hyperplasia (BPH) in patients with prostate glands with volumes of 80 cm^3 or more as an alternative to open prostatectomy (1–4). However, the data provided in these reports were collected retrospectively or from trials outside of the United States. The present study adds to this body of evidence by providing early results from a single-center, investigator-initiated, prospective US trial with Food and Drug Administration (FDA) oversight.

From the Departments of Radiology (A.J.I., H.Y., C.T.B.) and Urology (M.C.R.), University of North Carolina, 101 Manning Dr., Chapel Hill, NC 27514. Received November 13, 2015; final revision received January 22, 2016; accepted January 23, 2016. **Address correspondence to** A.J.I.; E-mail: ari_isaacson@med.unc.edu

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A.J.I. serves on the advisory board for BTG (London, United Kingdom). M.C.R. is a paid consultant for Intuitive Surgical (Sunnyvale, California), Teleflex (Wayne, Pennsylvania), and Transenterix (Morrisville, North Carolina). Neither of the other authors has identified a conflict of interest.

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MATERIALS AND METHODS

This study (*ClinicalTrials.gov* identifier NCT02167919) was conducted with an FDA Investigational Device Exemption (G140027/A001) for the use of Embosphere Microspheres (Merit Medical, South Jordan, Utah) for PAE and under the approval of our institutional review board with full Health Insurance Portability and Accountability Act compliance. The approved protocol included a 15-patient sample size. From October 2014 to October 2015, 36 patients with a history of BPH and LUTSs were screened for enrollment. Urodynamic testing was performed if there was a question as to the etiology of the LUTSs. All patients with a serum prostate-specific antigen (PSA) level greater than 2.5 ng/mL and a free PSA fraction less than 25% or a PSA greater than 10 ng/mL underwent biopsy to rule out malignancy. Twelve patients were enrolled, with a mean age of 69 years (range, 65–79 y; Fig 1). Inclusion and exclusion criteria are summarized in Table 1.

International Prostate Symptom Score (IPSS) with quality of life (QoL), International Index of Erectile Function, peak urine flow rate (Q_{max}), and postvoid residual volume (PVR) were assessed at baseline, 1 month, and 3 months. Anoscopy and cystoscopy were

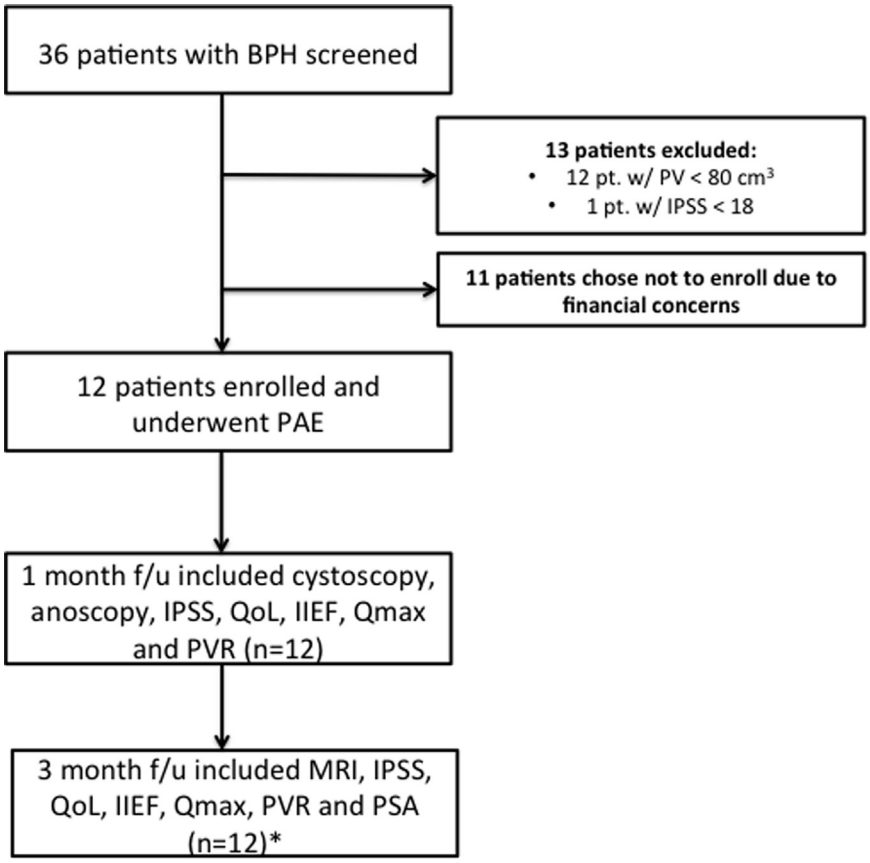

Figure 1. Chart demonstrating patient flow throughout the study. (*PSA, PVR, Q_{max}, and PV were not available for two patients at 3-mo follow-up. IIEF = International Index of Erectile Function.)

Table 1. Inclusion/Exclusion Criteria

Inclusion criteria
Age > 40 y
PV 80–150 cm^3
Previous trial of BPH medication
IPSS ≥ 18
Life expectancy > 1 y
Exclusion criteria
Neurogenic bladder
Acute urinary retention
GFR < 45 mL/min
Confirmed/suspected bladder or prostate malignancy
Recent cystolithiasis or gross hematuria
Urethral stricture or bladder neck contracture
Active urinary tract infection
Previous rectal surgery or rectal disease
Previous pelvic radiation
Uncorrectable coagulopathy
Severe cardiac or pulmonary disease
Uncontrolled diabetes mellitus
Immunosuppression

BPH = benign prostatic hyperplasia; GFR = glomerular filtration rate; IPSS = International Prostate Symptom Score; PV = prostate volume.

performed on all patients at 1 month. Changes in PSA level and prostate volume (PV) were evaluated at 3 months with magnetic resonance (MR) imaging.

Imaging Technique

A computed tomographic (CT) angiogram of the pelvis was used for preprocedural planning and to measure baseline PV. Before preprocedural pelvic CT angiography, patients received 800 μg sublingual nitroglycerin (Wilshire, Atlanta, Georgia) unless they had taken a phosphodiesterase inhibitor in the previous 48 hours. The study was performed on a 64-slice scanner (SOMATOM Sensation 64; Siemens, Munich, Germany) with a 150-mL bolus of iohexol (Omnipaque 350; GE Healthcare, Waukesha, Wisconsin) injected at 4–6 mL/s. Imaging was initiated when a region of interest in the abdominal aorta just proximal to the bifurcation reached a threshold of 300 HU. Additional scanning parameters included 0.6-mm collimator with reconstructions at 2 mm, pitch of 0.9, 0.33-second gantry rotation period, 120 kV, and 180 mA reference with automated modulation along the *z*-axis based on body mass (CARE Dose 4D; Siemens). Delayed images were obtained 4 minutes after initial contrast agent injection with the use of similar imaging parameters but reconstructed in 5-mm slices.