CLINICAL STUDY

Short- to Midterm Safety and Efficacy of Prostatic Artery Embolization: A Systematic Review

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ABSTRACT

Purpose: To review the available safety and efficacy data for prostatic artery embolization (PAE) in the treatment of benign prostatic hyperplasia (BPH).

Materials and Methods: PubMed was searched for publications that included PAE for the treatment of BPH through May 2015. Two independent reviewers determined the appropriateness for inclusion of each article and compiled data by using pooled weighted means and standard deviations.

Results: The literature search identified 161 articles, of which 7 studies, with a total of 562 patients, met all inclusion/exclusion criteria. PAEs were performed bilaterally in 85% of patients, unilaterally in 12%, and unsuccessfully in 3%. International Prostate Symptom Score decreased from 24.51 ± 6.12 at baseline to 10.42 ± 5.39 at 6 months. Quality of life score decreased from 4.76 ± 0.98 at baseline to 2.51 ± 1.13 at 6 months. Peak urinary flow rate increased from 8.41 mL/s ± 2.63 at baseline to 15.44 mL/s ± 5.64 at 6 months. Postvoid residual measurement decreased from 105.94 mL ± 76.77 at baseline to 39.57 mL ± 15 at 6 months. Prostate-specific antigen level decreased from 4.79 ng/mL ± 5.42 at baseline to 3.16 ng/mL ± 1.5 at 6 months. None of these parameters showed clinically significant changes from 6 months to 12 months. Total prostate volume decreased from 96.56 cm3 ± 35.47 at baseline to 46.73 cm3 ± 20.51 at 12 months. There were 200 minor complications and 1 major complication.

Conclusions: PAE improves lower urinary tract symptoms caused by BPH, with a favorable short- to midterm safety profile.

ABBREVIATIONS

BPH = benign prostatic hyperplasia, IPSS = International Prostate Symptom Score, IRB = institutional review board, LUTS = lower urinary tract symptom, MeSH = Medical Subject Headings, PAE = prostatic artery embolization, PSA = prostate-specific antigen, PVR = postvoid residual, Qmax = peak urinary flow, QOL = quality of life, SD = standard deviation, TURP = transurethral resection of the prostate, UTI = urinary tract infection

Recent evidence suggests that prostatic artery embolization (PAE) is no longer only an emergency treatment for prostatic hemorrhage, but rather a viable option for the treatment of lower urinary tract symptoms (LUTSs) secondary to benign prostatic hyperplasia (BPH). Multiple single-arm studies testing the safety and efficacy of PAE for the treatment of LUTSs secondary to BPH published during the past several years support PAE as an alternative to standard surgical therapy. However, randomized controlled data comparing PAE versus transurethral resection of the prostate (TURP), the current standard of care, are limited, with only one such published study currently available to our awareness (1). The next best methodology to describe the safety and efficacy of PAE is to critically evaluate the current data allowing for pooled analysis. Here, by extracting

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Table E1 is available online at www.jvir.org.

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outcomes and follow-up intervals common to all included studies and attempting to exclude overlapping data, we provide a summary of efficacy metrics and adverse events following PAE.

MATERIALS AND METHODS

This systematic review was performed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines (2). The review protocol was not registered in advance. This study was found to be exempt from review by the institutional review board (IRB). A search of PubMed was performed by using the Boolean search string "embolization" (Medical Subject Headings [MeSH] terms) AND "prostate" (MeSH terms) OR "embolization" (title/abstract) AND "prostate" (title/abstract) for studies published as recently as May 2015.

Two independent reviewers selected all potentially relevant articles based on titles and abstracts. Inclusion criteria included original research focusing on PAE as a treatment of LUTSs in the setting of BPH, study population greater than three patients, English as the primary language, and at least 6 months of follow-up data. Review articles, letters, comments, and conference abstracts were excluded. When a single research group authored multiple articles, only the study with the largest sample population size was included to avoid the use of duplicate data (3). Manual search of the bibliographies revealed one missed study that fulfilled the inclusion criteria. This led to the creation of an additional Boolean search string: "embolisation" (MeSH terms) AND "prostate" (MeSH terms) OR "embolisation" (title/abstract) AND "prostate" (title/abstract). These results were then evaluated based on the aforementioned criteria.

Attempts to construct a meta-analysis were not successful because of the large variation in study design, patient dropout, lack of standardized inclusion/exclusion criteria, procedural variability, and incomplete standard deviations (SDs). For these reasons, a systematic review was constructed. Pooled weighted means were calculated by the technique previously described by Schreuder et al (4), and pooled weighted SDs were calculated by using Excel 2011 (Microsoft, Redmond, Washington). Sample size was chosen as the weighing factor for SDs and means. When comparing data between baseline and follow-up outcomes, pooled weighed means and SDs were used.

Data were extracted from the included studies in a standardized manner by two authors by using a prepared worksheet. If disagreements arose, a third author served to mediate a consensus of opinions among the authors. Extracted data were divided into three categories: study design, study quality, and patient outcomes. Study design characteristics included study type, data collection, period of recruitment, IRB approval, conflict of interest, and payment source.

Study quality, or risk of bias, was based on the Quality Assessment of Diagnostic Accuracy Studies 2 tool (5) and the Strengthening the Reporting of Observational Studies in Epidemiology checklist (6,7). These guidelines served to divide the study quality assessments into four categories: methods, results, discussion, and other. These categories were then further subdivided into obtainable data points as follows: the methods category included subdivisions for study design, inclusion/exclusion criteria, bias discussion, procedure description, informed consent, IRB approval, and sample size calculations; results included subdivisions for number of participants in each follow-up period, reasons for nonparticipation, outcomes, dropout rate greater than 20%, and descriptive data; discussion subdivisions included limitations and generalizability; and subdivisions in the other category included conflict of interest and funding.

A binary point system was constructed to establish study quality by using each of the aforementioned domains. The scoring system is presented in full in **Table E1** (available online at *www.jvir.org*). The maximum score that could be obtained was 16 points. Studies were considered to be of good quality when they scored 13 or more points. A poor-quality study scored 8 points or fewer, and a moderate-quality study met 9–12 of the listed criteria.

When study quality had been established, data on technical and clinical outcomes were extracted. Clinical outcomes included baseline and follow-up data on International Prostate Symptom Score (IPSS), quality of life (QOL) score, total prostate volume (TPV), peak urine flow (Qmax), prostate-specific antigen (PSA) level, International Index of Erectile Function (IIEF)–5 score, and postvoid residual (PVR). Data were extracted by using a standardized worksheet that included number of patients, SD, and mean. Detrusor pressure was not included in the pooled analysis because it was not recorded in the majority of studies. The clinical outcomes data (IPSS, QOL score, Qmax, TPV, PSA level, IIEF score, and PVR) were extracted as means and SDs from tables or charts. If nominal values were stated in figures or graphs, they were also extracted. If means were written as a percentage and baseline data were available, the means were calculated. There were no attempts to contact the initial investigators and obtain original data.

Technical data gathered included complications, technical success rate, clinical failure rates, and time to discharge. In the present systematic review, technical success was defined as bilateral PAE. Complications from the procedure were also extracted and classified into major and minor categories in accordance with the Society of Interventional Radiology (SIR) criteria (8). Technical failure rates and times to discharge were available for all included studies. Clinical failure rates