CLINICAL STUDY

Meta-Analysis of Prostatic Artery Embolization for Benign Prostatic Hyperplasia

Andre Uflacker, MD, Ziv J Haskal, MD, Tiago Bilhim, MD, James Patrie, MS, Timothy Huber, MD, and João Martins Pisco, MD

ABSTRACT

Purpose: To perform meta-analysis of available data on prostatic artery embolization (PAE).

Materials and Methods: Meta-analysis was conducted on articles published between November 2009 and December 2015. Peer-reviewed studies with > 5 patients and standard deviations and/or individual-level data on one or more of the following outcomes were included: prostate volume (PV), peak flow rate (Qmax), postvoid residual (PVR), International Prostate Symptom Score (IPSS), quality of life (QOL) score, International Index of Erectile Function (IIEF) score, and prostate-specific antigen (PSA) level. A random-effects meta-analysis was performed on the outcomes at 1, 3, 6, and 12 mo after PAE compared with baseline values, with a $P < .05$ decision rule as the null hypothesis rejection criterion.

Results: Nineteen of 268 studies were included in data collection, with 6 included in the meta-analysis. At 12 mo, PV decreased by 31.31 cm^3 ($P < .001$), PSA remained unchanged ($P = .248$), PVR decreased by 85.54 mL ($P < .001$), Qmax increased by 5.39 mL/s ($P < .001$), IPSS improved by 20.39 points ($P < .001$), QOL score improved by −2.49 points ($P < .001$), and IIEF was unchanged ($P = 1.0$). There were a total of 218 adverse events (AEs) among 662 patients (32.93%), with 216 being Society of Interventional Radiology class A/B (99%). The most common complications were rectalgia/dysuria (n = 60; 9.0%) and acute urinary retention (n = 52; 7.8%). No class D/E complications were reported.

Conclusions: PAE provided improvement in Qmax, PVR, IPSS, and QOL endpoints at 12 mo, with a low incidence of serious AEs (0.3%), although minor AEs were common (32.93%). There was no adverse effect on erectile function.

ABBREVIATIONS

AE = adverse event, BPH = benign prostatic hyperplasia, IIEF = International Index of Erectile Function, IPSS = International Prostate Symptom Score, NCBI = National Center for Biotechnology Information, PAE = prostatic artery embolization, PRISMA = Preferred Reporting Items for Systematic Review and Meta-Analysis, PSA = prostate-specific antigen, PV = prostate volume, PVA = polyvinyl alcohol, PVR = postvoid residual, Qmax = peak flow rate, QOL = quality of life

Prostatic artery embolization (PAE) is emerging as a viable nonsurgical treatment for lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH) (1,2). Multiple uncontrolled studies (3–18) have reported safety and efficacy results, and one randomized trial compared it versus transurethral resection of the prostate (12). These studies suggest that PAE is a potential alternative to surgical therapies, but with a different and potentially favorable adverse-effect profile.

Naturally, prospective controlled multicenter trials will be required for large-scale validation. In the interim, careful analyses of existing studies may provide guidance for current practice and future investigations. Systematic and narrative reviews have been published (2,19,20). However, they have been limited in a number of ways, including reporting of redundant data across multiple

From the Department of Radiology and Medical Imaging, Division of Vascular and Interventional Radiology (A.U., Z.J.H., T.H.), and Department of Public Health Sciences (J.P.), University of Virginia, 1215 Lee St., Charlottesville, VA 22908; and Interventional Radiology Department (T.B., J.M.P.), Saint Louis Hospital, Lisbon, Portugal. Received May 7, 2016; final revision received August 2, 2016; accepted August 5, 2016. **Address correspondence to** Z.J.H.; E-mail: haskaljvir@gmail.com

Z.J.H. receives personal fees from Bard Peripheral Vascular (Tempe, Arizona), W.L. Gore and Associates (Flagstaff, Arizona), Penumbra (Alameda, California), Medtronic (Dublin, Ireland), and Cook (Bloomington, Indiana). None of the other authors have identified a conflict of interest.

Appendix A, Tables E1–E5, and Figures E1–E5 are available online at *www.jvir.org*.

J Vasc Interv Radiol ▮▮▮▮; ▮:▮▮▮–▮▮▮

http://dx.doi.org/10.1016/j.jvir.2016.08.004

studies (2). To address this, we undertook a meta-analysis of fully published studies, free of overlapping patients, using subject-level data and repeat analyses where possible.

MATERIALS AND METHODS

This study was granted exemption from review by the institutional review board and was compliant with all aspects of the Health Insurance Portability and Accountability Act. A systematic review and meta-analysis was conducted in adherence to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (21). A full text review of each included article was conducted, and the data were recorded in an Excel (Microsoft, Redmond, Washington) spreadsheet by two separate reviewers.

Search Strategy

A search of the Medline and National Center for Biotechnology Information (NCBI) databases was made from November 2009 until October 2015. For the Medline search, terms included ("embolization" [Medical Subject Headings terms/title/abstract] OR "embolisation" [Medical Subject Headings terms/title/abstract]) AND ("prostatic" [title/abstract] OR "prostate" [title/abstract]). For the NCBI database, search terms were ("prostatic artery" AND "embolization"), ("prostatic artery" AND "embolisation"), ("benign prostatic hyperplasia" AND "embolization"), and ("benign prostatic hyperplasia" AND "embolisation"). The searches were conducted by two investigators in the study (A.U., T.H.) who reviewed all relevant articles based on titles and abstracts after combining results and removing duplicates.

Study Selection Criteria

Criteria for inclusion were fully published, English-language, original manuscripts reporting PAE for treatment of lower urinary tract symptoms in more than five patients with BPH. Commentaries, non–peer-reviewed data, conference abstracts, reviews, letters, and case reports were excluded. Case reports of complications were included solely for analysis of adverse events. Redundant patient data were excluded based on the recruitment period for each study for authoring investigators who had published multiple studies. In such cases, studies with the largest set of patients were chosen for inclusion. Included studies were required to report at least one of the following clinical outcomes: prostate volume (PV), peak flow rate (Qmax), postvoid residual (PVR), International Prostate Symptom Score (IPSS), quality of life (QOL) score, International Index of Erectile Function (IIEF) score, and prostate-specific antigen (PSA) level.

For this statistical analysis, the standard deviations and/or anonymized individual-level patient data were requested from the authors of all manuscripts in which said data were unreported. These requests were made by repeated, confirmed email to corresponding authors before undertaking the analyses, with a 4-week deadline for reply. Thereafter, only studies that included individual-level patient data and/or standard deviation values for quantitative and qualitative clinical outcomes were included in the meta-analysis. The authors chose to not impute data from studies that did not meet these criteria.

Data Extraction

Study characteristics and risk of bias. Recorded data included recruitment periods, inclusion and exclusion criteria, follow-up duration, mean follow-up, previous medical therapy, defined outcome measure recording, study design characteristics (eg, cohort, randomized controlled trial, or retrospective review). Acknowledged interdisciplinary specialist involvement (eg, interventional radiologists and urologists), and medical ethics committee approvals were noted. The risk of bias was calculated based on PRISMA guidelines and previous reports (2,19,21). This scoring system consisted of a rating of 0 to 11; good-quality studies received 9–11 points, moderate-quality studies 6–8 points, and poor-quality studies 5 points or fewer. The 2009 PRISMA checklist is included in **Appendix A** (available online at *www.jvir.org*).

Embolization procedure. The specific procedural details recorded including the specialty of the physician performing the embolization procedure, uni- or bilaterality of treatment, as well as embolization materials and size. Reported complications included in the series and case reports were tabulated in an electronic spreadsheet and categorized into Society of Interventional Radiology (SIR) classes (22). The percentage of cases with each complication was calculated.

Patient characteristics. Inclusion and exclusion criteria, number of patients recruited, number of patients treated, and number of patients included in statistical analysis were collected. Patient ages, quantitative clinical values at baseline (PV, PSA, Qmax, PVR), and qualitative clinical values at baseline (QOL score, IIEF score, IPSS) were recorded.

Statistical Methods

Selection of meta-analysis construct. The random-effects meta-analysis construct was selected a priori. This decision was made based on the fact that the meta-analyses data were extracted from a variety of studies in