Society of Interventional Radiology Research Reporting Standards for Prostatic Artery Embolization

Andre B. Uflacker, MD, Ziv J Haskal, MD, Mark O. Baerlocher, MD, Shivank S. Bhatia, MD, Francisco C. Carnevale, MD, PhD, Sean R. Dariushnia, MD, Salomao Faintuch, MD, MS, Ron C. Gaba, MD, MS, Jafar Golzarian, MD, Mehran Midia, MD, Boris Nikolic, MD, MBA, Marc R. Sapoval, MD, PhD, and T. Gregory Walker, MD

ABBREVIATIONS

AUA = American Urological Association, BPH = benign prostatic hyperplasia, BPO = benign prostatic obstruction, DRE = digital rectal examination, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptoms, PAE = prostatic artery embolization, PSA = prostate specific antigen, PVR = postvoid residual, Qmax = peak urinary flow, UAE = uterine artery embolization

From the Department of Radiology and Radiological Sciences, Division of Vascular and Interventional Radiology (A.B.U.), Medical University of South Carolina, Charleston, South Carolina; Department of Radiology and Medical Imaging/Interventional Radiology (Z.J.H.), University of Virginia School of Medicine, Charlottesville, Virginia; Department of Radiology (M.O.B.), Royal Victoria Hospital, Barrie, Ontario, Canada; Department of Interventional Radiology (S.B.), University of Miami Miller School of Medicine, Miami, Florida; Department of Interventional Radiology (F.C.C.), University of Sao Paulo Medical School, Sao Paulo, Brazil; Department of Radiology and Imaging Sciences, Division of Interventional Radiology and Image-Guided Medicine (S.R.D.), Emory University School of Medicine, Atlanta, Georgia; Department of Radiology (S.F.), Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts; Department of Radiology (R.C.G.), University of Illinois at Chicago, Chicago, Illinois; Department of Radiology, Division of Interventional Radiology and Vascular Imaging (J.G.), University of Minnesota, Minneapolis, Minnesota; Department of Radiology (M.M.), McMaster University, Joseph Brant Hospital, Burlington, Ontario, Canada; Department of Interventional Radiology (B.N.), Cooley Dickinson Hospital, Massachusetts General Hospital Affiliate, Northampton, Massachusetts; Department of Interventional Vascular and Oncologic Radiology (M.R.S.), Hôpital Européen Georges Pompidou, Paris, France; and Division of Interventional Radiology (T.G.W.), Massachusetts General Hospital, Boston, Massachusetts. Final revision received February 28, 2020; accepted March 2, 2020. **Address correspondence to** A.B.U, c/o Elizabeth Himes, SIR, 3975 Fair Ridge Dr., Suite 400 N, Fairfax, VA 22033; E-mail: andreuflacker@gmail.com

A.B.U. and Z.J.H. share first authorship.

Z.J.H. receives grants from Siemens (Erlangen, Germany), personal fees from W.L. Gore & Associates (Flagstaff, Arizona), Becton Dickinson (Franklin Lakes, New Jersey), Boston Scientific (Marlborough, Massachusetts), and Medtronic (Dublin, Ireland). S.S.B. receives personal fees from Merit Medical (South Jordan, Utah), Terumo (Tokyo, Japan), Embolx (Sunnyvale, California), Mentice (Gothenburg, Sweden), and Siemens. R.C.G. has a research contract with Janssen Research & Development (Raritan, New Jersey). None of the other authors have identified a conflict of interest.

Appendix A can be found by accessing the online version of this article on *www.jvir.org* and clicking on the Supplemental Material tab.

J Vasc Interv Radiol 2020; 31:891–898

https://doi.org/10.1016/j.jvir.2020.03.003

INTRODUCTION

Prostatic artery embolization (PAE) is a promising alternative to traditional surgical options for treatment of lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) (1–50). However, as with any developing area of investigation, there is a need to assemble consistent high-quality data that clarify the role of that therapy and allow for systematic analyses of multiple studies (51).

SCOPE

The objective of this Reporting Standards document is to define a consistent nomenclature and terminology with which investigators can communicate the results of PAE trials to facilitate subsequent comparisons of published techniques, embolic materials, patient populations, and outcomes. The intent is to systematize the reporting of PAE data so that higher levels of evidence can be sought. Reporting Standards are not intended to validate or recommend technical aspects of PAE, but to promote transparent, detailed, and uniform reporting of relevant data. Reporting Standards may also have value in the nontrial setting in highlighting important aspects of clinical care. These recommendations are made in addition to the checklists of items found in the Standards for Reporting of Diagnostic Accuracy Studies Guidelines, Animal Research: Reporting of In Vivo Experiments Guidelines, Strengthening the Reporting of Observational Studies in Epidemiology Statement, and Consolidated Standards of Reporting Trials Guidelines (52–55).

Most PAE studies have been single-arm studies; controlled and comparative trials are needed and are also under way. **Appendix A** of the Enhancing the Quality and Transparency of Health Research Network reporting guidelines (56) describes several shortcomings of contemporary health research reporting in general, some of which can be found in the current PAE literature.

PATIENT SELECTION AND ASSESSMENT BEFORE PAE

Terminology

BPH is a histologic diagnosis that refers to smooth muscle and epithelial cell proliferation within the prostatic transition zone. LUTS include storage and/or voiding symptoms, which may not necessarily be related to BPH. Storage symptoms include frequency and nocturia, while voiding symptoms include difficulty initiating micturition and weak stream. BPH has been described as an etiology of LUTS through direct bladder outlet obstruction

and through increased smooth muscle tone. The American Urological Association (AUA) defines bladder outlet obstruction as obstruction to the bladder outlet from all causes. Several terms have been used to describe LUTS in men, including prostatism, prostate enlargement, BPH, or clinical BPH. Because LUTS may have an etiology unrelated to the prostate, the term "LUTS independent of BPH" has been introduced. LUTS secondary to BPH is a meaningful descriptor of LUTS secondary to prostatic hyperplasia. Alternatively, the term "benign prostatic obstruction" (BPO) can be used when obstruction of the bladder outlet is confirmed by pressure-flow studies or is highly suspected from flow rates in the presence of an enlarged gland.

PAE candidates should have a diagnosis of LUTS secondary to BPH as defined by the AUA 2018 BPH Management Guidelines (57). Complicated LUTS include etiologies and symptoms other than BPH, such as LUTS in the presence of suspicious digital rectal examination (DRE) findings, hematuria, abnormal prostate-specific antigen (PSA) level, pain, infection, palpable bladder, or neurologic disease (57).

Preprocedural Assessment

Studies should report whether history and physical examination (including DRE) were performed. Documentation of medical therapy, including dosages, frequencies, duration of therapy, and medication washout periods, if any, for BPO should be described for every patient. Surgical history, including previous urological and pelvic interventions, should be reported. The use of continuous or intermittent catheterization and the duration of symptoms should be reported. A validated self-administered questionnaire such as the International Prostate Symptom Score (IPSS) or the AUA Symptom Index should be used to subjectively assess symptoms. The quality of life component should be independently reported from those questionnaires. Investigators may consider assessment with other validated questionnaires (such as the Expanded Prostate Cancer Index Composite or the BPH Impact Index). Although other validated questionnaires may be of value, the IPSS and the AUA Symptom Index are recommended for clinical trials (58,59).

A urinalysis to evaluate for hematuria, proteinuria, pyuria, or other pathologic conditions should be obtained as a routine screening laboratory examination before PAE. In 2018, the US Preventive Services Task Force provided a negative, grade-D recommendation for PSA screening for men older than 70 years of age and a grade-C recommendation for PSA-based screening on a case-by-case basis for men aged 55–69 years (60). The decision to screen patients for prostate cancer should be based on DRE findings and on individual patients' clinical indications and risk factors. The AUA recommends that findings suggesting prostate cancer, such as DRE results, prostate biopsy findings, hematuria, or elevated PSA level, indicate referral to a urologist for evaluation before treatment. Investigators should report PSA if obtained. Recommended demographic, anamnestic, and laboratory data are provided in **Table 1**.

Objective Assessment

Objective assessment of patients with LUTS can be performed with a wide variety of invasive or noninvasive means (61–63); the interpretation of these studies is beyond the scope of this document. Noninvasive tests include measurement of peak urinary flow (Qmax) and postvoid residual (PVR). These noninvasive tests are useful in the initial diagnostic assessment and to measure treatment response (57). Invasive tests include filling cystometrography, abdominal leak point pressure, voiding cystometrography, static cystography, pelvic floor electromyography, and voiding cystourethrography, which measure the relative contribution of the individual components of the lower urinary tract (bladder, bladder outlet, and prostate) to LUTS and lower urinary tract function.

Invasive urodynamic testing should be considered when the history and examination findings suggest that LUTS may be multifactorial or nonprostatic. Because the etiology of LUTS can be related to a number of different entities (such as detrusor overactivity, nocturnal polyuria, neurogenic bladder dysfunction, urinary tract infections, or malignancy) known as "complicated LUTS" (57), it is important that men considered for PAE undergo a thorough evaluation of their LUTS, preferably in conjunction with a urologist. The AUA 2018 surgical management guidelines (57) recommend PVR assessment before surgical intervention for LUTS caused by BPH and pressure-flow studies if the diagnosis of obstruction is uncertain. Nevertheless, these measures are routinely reported in high-level urologic trials, and consistent, continued reporting in the PAE literature is strongly suggested (64–70).

Recommended objective data collection details are provided in **Table 1**.

Table 1. Recommended Data Collection

Demographic Data
Age and race
Patient weight and BMI
Score of validated self-administered questionnaire (eg, IPSS, IIEF)
Medical therapies for LUTS/BPH (including washout periods)
Prior nonmedical therapy for LUTS/BPH
Comorbid conditions (including cardiac history, recent surgery, hospitalizations)
History of sexual dysfunction
Presence of acute or chronic urinary retention
Laboratory Data
Urinalysis
PSA (or PSA density), if obtained
Results of prostate biopsies, if obtained
Objective data
Qmax
PVR
Invasive urodynamic testing

BMI = body mass index; IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; PSA = prostate-specific antigen; PVR = postvoid residual; Qmax = peak urinary flow.

Imaging before PAE: Modality, Techniques, and Prostatic Volume

There are no consensus recommendations on the optimal imaging modality that should be used for evaluation before PAE. Investigators have advocated the use of computed tomographic (CT) angiography and magnetic resonance (MR) imaging before PAE for anatomic mapping and prostate volume measurement (17,71,72). Although the AUA 2018 Guidelines (57) suggest that clinicians should consider assessment of prostate volume by imaging, measurement of prostate volume by imaging is logical before PAE, as it may provide a useful outcome parameter that can be analyzed for determination of patient selection, and is routinely reported in urologic BPO studies (64,69).

Baseline prostate volumes can be calculated by using an ellipsoid formula (height × width × length × 0.524) with dimensions acquired on imaging, such as transrectal ultrasound (US), CT angiography, or MR imaging (73). Investigators may alternatively use 3-dimensional volumetric software if the technique for volume measurements is consistently applied and described. Each technique has limitations, such as the variability in measurement with transrectal US and potentially inadequate measurements on CT angiography caused by orthopedic hardware artifact and absence of fat planes between the prostate and pelvic musculature. For imaging performed with CT angiography and MR, protocols should be described as well as the experience of the readers,

Table 2. Imaging Data

CT Angiography Protocol
Imaging system brand and model (including number of slices)
Power settings (kV and mA)
Matrix size, collimation, slice thickness, and pitch
Contrast material used
MR Imaging Technique
Imaging system make and model
Field strength
Use of phased-array coils
Slice thickness, field of view, matrix size
Contrast material utilized

the number of readers, whether readings were blinded, and how disparate interpretations were reconciled. If the identification of the prostatic arteries was performed on preprocedural imaging, these should be reported. Recommended preprocedural imaging data are provided in Table 2.

Inclusion and Exclusion Criteria

Clearly defined inclusion and exclusion criteria must be consistently applied and described in investigations of PAE. All studies should document inclusion and exclusion criteria. Prospective trials should report and maintain the inclusion and exclusion criteria, the number of excluded patients, and reasons for exclusion in screening logs. The definitions of inclusion and exclusion criteria should be included if they are subject to variable interpretation.

REPORTING OF PAE

PAE can be performed in an inpatient or outpatient setting, which should be reported. Investigators should report specific angiographic equipment brand and model and whether cone-beam CT was available and used. Table 3 lists data that should be collected during PAE procedures. Table 4 lists recommendations for reporting data.

INTRAPROCEDURAL TECHNIQUE

PAE requires experience with pelvic angiography, complex and variant anatomy, and facility with microcatheter use in 1–3-mm–diameter blood vessels. The described arterial anatomy should follow standard anatomic terminology. Examples of acceptable descriptions of the male pelvic arterial anatomy have been provided (71,74–76).

Descriptions of angiographic findings should be precise and include the position of the catheter injected and the visualized arteries of interest. A number of investigators have reported their preferred techniques for PAE; however, the comparative clinical impact of these methods have had limited study (72,77,78).

Reports have also assessed particle size versus outcome, catheter position during embolization, clinical efficacy of unilateral versus bilateral embolization, and role of cone-beam CT during PAE (8,9,75,79,80).

Given that the optimal technique of PAE is still being elucidated, studies reporting specific and varying techniques are anticipated to remain an important and active area of research. The reported rate of PAE-related major complications is $< 1\%$ (46,81). As nontarget embolization is a notable potential risk, measures used to mitigate it should be described. Investigators should include the use of cone-beam CT, 3-dimensional road mapping, coil embolization, and any other strategies for reducing risks of nontarget embolization if used (including type, number, and size of embolization coils, as well as exact anatomic position of deployment) (82). Anastomotic pathways such as the accessory pudendal artery, the middle rectal artery, and accessory obturator arteries may bear mention (74,76,83,84). Recommended intraprocedural data collection is provided in Table 3.

Table 3. Periprocedural Data

Recommended Periprocedural Data during PAE
Use (or nonuse) of a Foley catheter for bladder decompression
Visual analog scale of pain
Administration of sedation
Administration of antibiotics
Use of pharmacologic adjuncts such as vasodilators
Technical Details of PAE
Operator training and specialty, including years of practice
Number of PAE procedures performed at investigator's institution
Access site (radial, femoral, uni- or bilaterality, use of US guidance)
Sheath size
Catheter and microcatheter system, including shape and caliber, if standardized
Guide wires and microwire
Means of hemostasis (manual compression or closure device)
Angiographic equipment brand and model
Angiographic injection technique (manual vs powered injection) and parameters
Cone-beam CT injection rate, contrast dilution, volume
Cone-beam CT rotational scan time, degrees per second, frequency of image acquisition, source power, matrix size, and number of images
Technical Details of Embolic Agents Used in PAE
Embolic material(s), including size and brand
Volume of embolic solution
Angiographic endpoint of embolization
Catheter positions during embolization
Embolization injection technique

PAE = prostatic artery embolization.

REPORTING OF RADIATION EXPOSURE

Quality improvement guidelines for recording patient radiation exposure have been published by the Society of Interventional Radiology (SIR) (85), and these guidelines should be considered by investigators of PAE. Radiation exposure is a concern in PAE, and prolonged fluoroscopy times (as long as 72 min) with a resulting skin burn have been reported (86). Radiation exposure should be provided as dose–area product (DAP) in Grays times centimeters square ($Gy \cdot cm^2$). Mean area kerma and peak skin dose should also be reported in Grays if available. Fluoroscopy time can be included, but it alone does not account for dose, as patient body mass index, frame rates, and magnification are important determinants of the radiation exposure. Radiation related to CT angiography should also be reported where applicable.

OUTCOMES: TECHNICAL SUCCESS, PROCEDURAL ENDPOINTS, AND CLINICAL SUCCESS

The angiographic endpoints for PAE have not been defined in an objective manner; this remains a question to be answered by future study. Further, agent-specific embolization endpoints may emerge, as observed in the uterine artery embolization (UAE) literature (87).

Table 4. Recommendations for Reporting Standards

Criterion	Required	Highly Recommended	Recommended
Preprocedural data			
Patient population			
Age, race	X		
Patient weight		X	
BMI		X	
Score of self-administered questionnaire	X		
Medical therapy for LUTS	X		
Washout periods	X		
Prior surgical therapy for LUTS	X		
Comorbidities	X		
Study Design			
Inclusion criteria	X		
Exclusion criteria	X		
Primary endpoint(s)	X		
Secondary endpoint(s)	X		
Laboratory data			
Urinalysis	X		
PSA		X	
Results of prostate biopsies		X	
Objective data			
Qmax	X		
PVR	X		
Invasive urodynamic testing (if performed)	X		
Imaging			
CT angiography protocol			
Imaging system make and model			X
Power settings			X
Matrix size, collimation, slice thickness, pitch			X
Contrast material			X
MR imaging technique			
Imaging system make and model			X
Field strength			X
Use of phased array coils			X
Sequences used			X
Slice thickness, field of view, matrix size			X
Contrast material			X
Procedural data			
Use or nonuse of Foley catheter		X	
Visual analog pain scale		X	
Administration of sedation		X	
Administration of antibiotics		X	
Use of pharmacologic adjuncts		X	
Technical details of PAE	X		
Operator training and specialty	X		
No. of cases performed at investigator's institution	X		
Access site			X
Sheath size			X
Catheter and microcatheter system (shape and size)		X	
Guide wire and microwires			X
Means of hemostasis			X
Embolic material(s) used	X		
Angiographic equipment make and model	X		
Catheter position during injection	X		

continued

Table 4. Recommendations for Reporting Standards *(continued)*

Criterion	Required	Highly Recommended	Recommended
Injection technique	X		
Cone-beam CT injection rate, dilution, volume	X		
Cone-beam CT rotational scan time, degrees per second, frequency of image acquisition, source power, matrix size, number of images	X		
Angiographic endpoint	X		
Uni- or bilaterality of embolization	X		
Clear definition of technical success	X		
Radiation exposure			
Dose–area product	X		
Skin entry dose			X
Fluoroscopy time			X
Postprocedure data			
Complications	X		
Clinical success	X		
Follow-up data			
Follow-up duration	X		
Study dropout rate	X		
Qmax	X		
Scores of validated questionnaires			
Clinical and imaging follow-up schedule	X		

BMI = body mass index; LUTS = lower urinary tract symptoms; PAE = prostatic artery embolization; PSA = prostate-specific antigen; PVR = postvoid residual; Qmax = peak urinary flow.

Terms such as "near-stasis" and "total stasis" have been used (72,77). Technical success can be described on a per-side, per-artery, or per-gland basis, and investigators should have clear definitions of technical success. When reporting angiographic endpoints, authors should consider catheter position during embolization, number of prostatic arteries identified and how many were treated, and description of the desired angiographic endpoint. Authors should describe whether complete stasis was observed and at which level embolization was achieved. If less than complete stasis was performed, authors should describe if there was still perfusion to the gland after embolization, or if forward flow was still demonstrable on the postembolization arteriograms. When applicable, authors may include reasons for inability to catheterize the prostatic artery, such as atherosclerosis, dissection, spasm, or thrombosis of the target vessel (85).

Clinical success should be based on subjective data from validated questionnaires and/or from objective measurements such as uroflowmetry, which can also serve as primary endpoints for clinical investigations. Clinical success can be defined using benchmarks found in the urologic literature, such as an improvement in IPSS of > 25% (65,88). IPSS can be reported as an absolute reduction, percent reduction, or statistical reduction compared with baseline. It is possible that treatment outcome may be linked to the extent of necrosis, similar to what has been observed in UAE, or to decrease in prostatic volume (89). Investigators studying the relationship between prostatic volume and outcomes should report volumes measured with consistent techniques. As with embolotherapy for interventional oncology and UAE, imaging endpoints such as gland size and percent necrosis should be reported, as these may correlate with clinical outcomes (90,91). Imaging follow-up intervals and protocols should be defined prospectively and reported.

Prospective studies should describe the intended follow-up intervals and patient adherence, with these on an intent–to–follow up basis, as missed appointments can lead to under- or overreporting of adverse events or outcomes, ie, loss to follow-up bias. Retrospective studies should report actual numbers of patients in each follow-up interval. Follow-up intervals can be modeled on urologic controlled trials of BPH, with visits at 1, 3, 6, 12, 24, and 48 months or longer (64,69). Follow-up visits should include, at a minimum, an IPSS/Sexual Health Inventory for Men score, medication review, and physical examination and review of systems to be considered a complete follow-up visit.

Adverse Events

All major and minor procedural adverse events should be classified according to SIR criteria (**Appendix A** [available online on the article's Supplemental Material page at *www.jvir.org*]) (92). Examples of procedure-related adverse events are provided in **Table 5**. Complications and deaths within 30 days of the procedure should be reported as procedure-related; subsequent adverse events should be adjudicated for relationship to PAE. Common postprocedure events, possibly considered "postembolization syndrome," may include dysuria, fever, pelvic pain, hematuria, hematospermia, and rectalgia, which should be recorded when present. Routine discharge medications, such as analgesic agents, α-1 blockers, laxatives, corticosteroids, or antipyretic agents, should be noted, although use beyond that expected for postprocedural analgesia should not be reported as an adverse event. Additional treatments of these symptoms beyond routine discharge medications, prolonged or repeat hospitalization, and secondary interventions (eg catheterization for acute urinary retention) can be reported as adverse events. Examples of complications include angiographic complications (eg, vessel dissection, contrast-induced nephropathy), pelvic infection, sexual dysfunction, passage of tissue requiring intervention, nontarget embolization (eg, penis, bowel, bladder, buttock, nerves), postembolization syndrome requiring escalation of care or > 48-hour admission, radiation injuries, adverse drug reaction, and pulmonary embolism. Findings from endoscopic studies performed after PAE, such as anoscopy or cystoscopy, should be reported if obtained.

CONCLUSIONS AND SUMMARY

Although sufficient evidence on PAE does exist and has allowed SIR to publish a multisociety consensus position statement (93,94), further high-quality studies (with a focus on noninferiority) would improve the evidence base in support of this procedure (1). Adherence to reporting standards for PAE research would decrease the number of publications not providing estimates of variability, such as standard deviation or standard error, which would allow meta-analysis, without imputing data (52,55,56).

Table 5. Complications List

Patient Death or Unexpected Pregnancy Abortion
Perioperative death
Life-Threatening or Disabling Event
Contrast-induced nephropathy requiring permanent dialysis
Pelvic necrosis requiring surgery
Penile necrosis requiring surgery
Infertility
Nerve injury
Permanent erectile dysfunction
Severe Adverse Event
Life-threatening hemorrhage
Contrast reactions: anaphylaxis
Contrast-induced nephropathy requiring dialysis
Bladder ischemia requiring cystectomy
Radiation injury requiring surgery
Moderate Adverse Event
Severe urinary tract infection
Hemorrhage requiring transfusion
Bladder injury requiring surgery
Penile necrosis not requiring surgical repair
Prostatic abscess
Contrast reactions: hypotension
Self-limited contrast-induced nephropathy
Mild Adverse Event
Transient ischemic rectitis
Bladder ischemia
Acute transient urinary retention
Mild urinary tract infection
Femoral artery pseudoaneurysm
Passage of tissue
Inguinal hematoma
Arterial dissection without ischemic consequences
Radiation dermatitis
Contrast reactions: hives
Rectalgia and/or dysuria
Transient hematuria
Transient hematospermia
Transient rectorrhagia
Balanitis
Retrograde ejaculation
Postembolization syndrome
Diarrhea

Meta-analyses are also limited by the longitudinal drop-off of patient populations during studies. Therefore, heterogeneous patient populations are being compared at each study time point. To improve systematic reviews or meta-analyses, investigators are encouraged to share individual-level data by direct collaborations or through public data repositories. As with any developing area of clinical research, the evolution from feasibility to larger-scale studies requires comparisons to established therapies with increasing rigor and prospective study (95). As PAE indications expand to oncologic applications, other criteria such as oncologic endpoints would merit reporting. These reporting standards are provided as a guide to encourage greater consistency and systematization of future PAE research.

ACKNOWLEDGMENTS

The authors thank Emil I. Cohen, MD, Joseph J. Gemmete, MD, Neil J. Halin, DO, Thomas B. Kinney, MD, MSME, Brian J. Schiro, MD, James E. Silberzweig, MD, and David S. Wang, MD, for their review of the manuscript.

REFERENCES

1. Abt D, Hechelhammer L, Mullhaupt G, et al. Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial. Br Med J 2018; 361:k2338.
2. Abt D, Mullhaupt G, Mordasini L, et al. Outcome prediction of prostatic artery embolization: post hoc analysis of a randomized, open-label, non-inferiority trial. BJU Int 2019; 124:134–144.
3. Antunes AA, Carnevale FC, da Motta Leal Filho JM, et al. Clinical, laboratorial, and urodynamic findings of prostatic artery embolization for the treatment of urinary retention related to benign prostatic hyperplasia. A prospective single-center pilot study. Cardiovasc Intervent Radiol 2013; 36:978–986.
4. Bagla S, Martin CP, van Breda A, et al. Early results from a United States trial of prostatic artery embolization in the treatment of benign prostatic hyperplasia. J Vasc Interv Radiol 2014; 25:47–52.
5. Bagla S, Smirniotopoulos JB, Orlando JC, van Breda A, Vadlamudi V. Comparative analysis of prostate volume as a predictor of outcome in prostate artery embolization. J Vasc Interv Radiol 2015; 26:1832–1838.
6. Bhatia S, Sinha VK, Harward S, Gomez C, Kava BR, Parekh DJ. Prostate artery embolization in patients with prostate volumes of 80 ml or more: a single-institution retrospective experience of 93 patients. J Vasc Interv Radiol 2018; 29:1392–1398.
7. Bhatia S, Sinha VK, Kava BR, et al. Efficacy of prostatic artery embolization for catheter-dependent patients with large prostate sizes and high co-morbidity scores. J Vasc Interv Radiol 2018; 29:78–84.e1.
8. Bilhim T, Pisco J, Campos Pinheiro L, et al. Does polyvinyl alcohol particle size change the outcome of prostatic arterial embolization for benign prostatic hyperplasia? Results from a single-center randomized prospective study. J Vasc Interv Radiol 2013; 24:1595–1602.e1.
9. Bilhim T, Pisco J, Rio Tinto H, et al. Unilateral versus bilateral prostatic arterial embolization for lower urinary tract symptoms in patients with prostate enlargement. Cardiovasc Intervent Radiol 2013; 36:403–411.
10. Brown AD, Stella SF, Simons ME. Minimally invasive treatment for benign prostatic hyperplasia: economic evaluation from a standardized hospital case costing system. Cardiovasc Intervent Radiol 2019; 42:520–527.
11. Cardarelli-Leite L, de Assis AM, Moreira AM, et al. Impact of 5-alpha-reductase inhibitors use at the time of prostatic artery embolization for treatment of benign prostatic obstruction. J Vasc Interv Radiol 2019; 30:228–232.
12. Carnevale FC, Antunes AA, da Motta Leal Filho JM, et al. Prostatic artery embolization as a primary treatment for benign prostatic hyperplasia: preliminary results in two patients. Cardiovasc Intervent Radiol 2010; 33:355–361.
13. Carnevale FC, da Motta-Leal-Filho JM, Antunes AA, et al. Midterm follow-up after prostate embolization in two patients with benign prostatic hyperplasia. Cardiovasc Intervent Radiol 2011; 34:1330–1333.
14. Carnevale FC, da Motta-Leal-Filho JM, Antunes AA, et al. Quality of life and clinical symptom improvement support prostatic artery embolization for patients with acute urinary retention caused by benign prostatic hyperplasia. J Vasc Interv Radiol 2013; 24:535–542.
15. Carnevale FC, Iscaife A, Yoshinaga EM, Moreira AM, Antunes AA, Srougi M. Transurethral resection of the prostate (TURP) versus original and PErFecTED prostate artery embolization (PAE) due to benign prostatic hyperplasia (BPH): preliminary results of a single center, prospective, urodynamic-controlled analysis. Cardiovasc Intervent Radiol 2016; 39:44–52.
16. Carnevale FC, Moreira AM, Harward SH, et al. Recurrence of lower urinary tract symptoms following prostate artery embolization for benign hyperplasia: single center experience comparing two techniques. Cardiovasc Intervent Radiol 2017; 40:366–374.
17. de Assis AM, Maciel MS, Moreira AM, et al. Prostate zonal volumetry as a predictor of clinical outcomes for prostate artery embolization. Cardiovasc Intervent Radiol 2017; 40:245–251.

18. de Assis AM, Moreira AM, Carnevale FC. Angiographic findings during repeat prostatic artery embolization. J Vasc Interv Radiol 2019; 30:645–651.
19. de Assis AM, Moreira AM, Carnevale FC, et al. Effects of prostatic artery embolization on the dynamic component of benign prostate hyperplasia as assessed by ultrasound elastography: a pilot series. Cardiovasc Intervent Radiol 2019; 42:1001–1007.
20. de Assis AM, Moreira AM, de Paula Rodrigues VC, et al. Prostatic artery embolization for treatment of benign prostatic hyperplasia in patients with prostates > 90 g: a prospective single-center study. J Vasc Interv Radiol 2015; 26:87–93.
21. du Pisanie J, Abumoussa A, Donovan K, Stewart J, Bagla S, Isaacson A. Predictors of prostatic artery embolization technical outcomes: patient and procedural factors. J Vasc Interv Radiol 2019; 30:233–240.
22. Feng S, Tian Y, Liu W, et al. Prostatic arterial embolization treating moderate-to-severe lower urinary tract symptoms related to benign prostate hyperplasia: a meta-analysis. Cardiovasc Intervent Radiol 2017; 40:22–32.
23. Gao YA, Huang Y, Zhang R, et al. Benign prostatic hyperplasia: prostatic arterial embolization versus transurethral resection of the prostate–a prospective, randomized, and controlled clinical trial. Radiology 2014; 270: 920–928.
24. Grosso M, Balderi A, Arno M, et al. Prostatic artery embolization in benign prostatic hyperplasia: preliminary results in 13 patients. Radiol Med 2015; 120. 361–358.
25. Hwang JH, Park SW, Chang IS, et al. Comparison of nonspherical polyvinyl alcohol particles and microspheres for prostatic arterial embolization in patients with benign prostatic hyperplasia. Biomed Res Int 2017; 2017: 8732351.
26. Kenny AG, Pellerin O, Amouyal G, et al. Prostate artery embolization in patients with acute urinary retention. Am J Med 2019; 132:e786–e790.
27. Klow NE, Grotta OJ, Bay D, et al. Outcome after prostatic artery embolization in patients with symptomatic benign prostatic hyperplasia. Acta Radiol 2019; 60:1175–1180.
28. Kurbatov D, Russo GI, Lepetukhin A, et al. Prostatic artery embolization for prostate volume greater than 80cm3: results from a single-center prospective study. Urology 2014; 84:400–404.
29. Li Q, Duan F, Wang MQ, Zhang GD, Yuan K. Prostatic arterial embolization with small sized particles for the treatment of lower urinary tract symptoms due to large benign prostatic hyperplasia: preliminary results. Chin Med J (Engl) 2015; 128:2072–2077.
30. Malling B, Roder MA, Brasso K, Forman J, Taudorf M, Lönn L. Prostate artery embolisation for benign prostatic hyperplasia: a systematic review and meta-analysis. Eur Radiol 2019; 29:287–298.
31. Mullhaupt G, Hechelhammer L, Engeler DS, et al. In-hospital cost analysis of prostatic artery embolization compared with transurethral resection of the prostate: post hoc analysis of a randomized controlled trial. BJU Int 2019; 123:1055–1060.
32. Pisco J, Campos Pinheiro L, Bilhim T, et al. Prostatic arterial embolization for benign prostatic hyperplasia: short- and intermediate-term results. Radiology 2013; 266:668–677, Erratum in Radiology 2013; 268:929.
33. Pisco JM, Bilhim T, Pinheiro LC, et al. Medium- and long-term outcome of prostate artery embolization for patients with benign prostatic hyperplasia: results in 630 patients. J Vasc Interv Radiol 2016; 27:1115–1122.
34. Pisco JM, Pinheiro LC, Bilhim T, Duarte M, Mendes JR, Oliveira AG. Prostatic arterial embolization to treat benign prostatic hyperplasia. J Vasc Interv Radiol 2011; 22:11–19.
35. Pisco JM, Rio Tinto H, Campos Pinheiro L, et al. Embolisation of prostatic arteries as treatment of moderate to severe lower urinary symptoms (LUTS) secondary to benign hyperplasia: results of short- and mid-term follow-up. Eur Radiol 2013; 23:2561–2572.
36. Pyo JS, Cho WJ. Systematic review and meta-analysis of prostatic artery embolisation for lower urinary tract symptoms related to benign prostatic hyperplasia. Clin Radiol 2017; 72:16–22.
37. Ray AF, Powell J, Speakman MJ, et al. Efficacy and safety of prostate artery embolization for benign prostatic hyperplasia: an observational study and propensity-matched comparison with transurethral resection of the prostate (the UK-ROPE study). BJU Int 2018; 122:270–282.
38. Russo GI, Kurbatov D, Sansalone S, et al. Prostatic arterial embolization vs open prostatectomy: a 1-year matched-pair analysis of functional outcomes and morbidities. Urology 2015; 86:343–348.
39. Salem R, Hairston J, Hohlastos E, et al. Prostate artery embolization for lower urinary tract symptoms secondary to benign prostatic hyperplasia: results from a prospective FDA-approved investigational device exemption study. Urology 2018; 120:205–210.
40. Shim SR, Kanhai KJ, Ko YM, Kim JH. Efficacy and safety of prostatic arterial embolization: systematic review with meta-analysis and meta-regression. J Urol 2017; 197:465–479.
41. Singhal S, Sebastian B, Madhurkar R, Uthappa MC. Prostate artery embolisation: an initial experience from an Indian perspective. Pol J Radiol 2018; 83:e554–e559.
42. Smith C, Craig P, Taleb S, Young S, Golzarian J. Comparison of traditional and emerging surgical therapies for lower urinary tract symptoms in men: a review. Cardiovasc Intervent Radiol 2017; 40:1176–1184.
43. Stewart JK, Isaacson AJ. Clinical outcomes following prostatic artery embolization in patients with bladder diverticula. J Vasc Interv Radiol 2019; 30:1633–1635.
44. Tapping CR, Boardman P. Prostatic artery embolization (PAE) in catheter-dependent patients with large prostatic (BPH) glands (>90 cc): early intervention essential. Acta Radiol 2019; 60:1562–1565.
45. Torres D, Costa NV, Pisco J, Pinheiro LC, Oliveira AG, Bilhim T. Prostatic artery embolization for benign prostatic hyperplasia: prospective randomized trial of 100-300 µm versus 300-500 µm versus 100- to 300-µm + 300- to 500-µm Embospheres. J Vasc Interv Radiol 2019; 30:638–644.
46. Uflacker A, Haskal ZJ, Bilhim T, Patrie J, Huber T, Pisco JM. Meta-analysis of prostatic artery embolization for benign prostatic hyperplasia. J Vasc Interv Radiol 2016; 27:1686–1697.e8.
47. Wang M, Guo L, Duan F, et al. Prostatic arterial embolization for the treatment of lower urinary tract symptoms as a result of large benign prostatic hyperplasia: a prospective single-center investigation. Int J Urol 2015; 22:766–772.
48. Wang MQ, Guo LP, Zhang GD, et al. Prostatic arterial embolization for the treatment of lower urinary tract symptoms due to large (>80 mL) benign prostatic hyperplasia: results of midterm follow-up from Chinese population. BMC Urol 2015; 15:33.
49. Wang MQ, Zhang JL, Xin HN, et al. Comparison of clinical outcomes of prostatic artery embolization with 50-mum plus 100-mum polyvinyl alcohol (PVA) Particles versus 100-µm PVA particles alone: a prospective randomized trial. J Vasc Interv Radiol 2018; 29:1694–1702.
50. Wang XY, Zong HT, Zhang Y. Efficacy and safety of prostate artery embolization on lower urinary tract symptoms related to benign prostatic hyperplasia: a systematic review and meta-analysis. Clin Interv Aging 2016; 11:1609–1622.
51. Golzarian J, Antunes AA, Bilhim T, et al. Prostatic artery embolization to treat lower urinary tract symptoms related to benign prostatic hyperplasia and bleeding in patients with prostate cancer: proceedings from a multidisciplinary research consensus panel. J Vasc Interv Radiol 2014; 25:665–674.
52. Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 1996; 276: 637–639.
53. Cohen JF, Korevaar DA, Altman DG, et al. STARD 2015 guidelines for reporting diagnostic accuracy studies: explanation and elaboration. BMJ Open 2016; 6:e012799.
54. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG. Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research. PLoS Biol 2010; 8, e1000412.
55. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol 2008; 61:344–349.
56. Simera I, Moher D, Hirst A, Hoey J, Schulz KF, Altman DG. Transparent and accurate reporting increases reliability, utility, and impact of your research: reporting guidelines and the EQUATOR Network. BMC Med 2010; 8:24.
57. Foster HE, Barry MJ, Dahm P, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline. J Urol 2018; 200:612–619.
58. Barry MJ, Fowler FJ Jr, O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. J Urol 1992; 148:1549–1557.
59. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the expanded prostate cancer index composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. Urology 2000; 56:899–905.
60. US Preventive Services Task Force, Grossman DC, Curry SJ, Bibbins-Domingo K, et al. Screening for prostate cancer: US Preventive Services Task Force Recommendation Statement. JAMA 2018; 319:1901–1913.
61. Lenherr SM, Clemens JQ. Urodynamics: with a focus on appropriate indications. Urol Clin North Am 2013; 40:545–557.
62. Mehdizadeh JL, Leach GE. Role of invasive urodynamic testing in benign prostatic hyperplasia and male lower urinary tract symptoms. Urol Clin North Am 2009; 36:431–441.v.

63. Nitti VW. Pressure flow urodynamic studies: the gold standard for diagnosing bladder outlet obstruction. Rev Urol 2005; 7(suppl 6):S14–S21.
64. Cornu JN, Ahyai S, Bachmann A, et al. A systematic review and meta-analysis of functional outcomes and complications following transurethral procedures for lower urinary tract symptoms resulting from benign prostatic obstruction: an update. Eur Urol 2015; 67:1066–1096.
65. Homma Y, Kawabe K, Tsukamoto T, et al. Estimate criteria for efficacy of treatment in benign prostatic hyperplasia. Int J Urol 1996; 3:267–273.
66. Jiang YL, Qian LJ. Transurethral resection of the prostate versus prostatic artery embolization in the treatment of benign prostatic hyperplasia: a meta-analysis. BMC Urol 2019; 19:11.
67. Lepor H. Landmark studies impacting the medical management of benign prostatic hyperplasia. Rev Urol 2003; 5(suppl 5):S28–S35.
68. McConnell JD, Roehrborn CG, Bautista OM, et al; Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med 2003; 349: 2387–2398.
69. Omar MI, Lam TB, Alexander CE, et al. Systematic review and meta-analysis of the clinical effectiveness of bipolar compared with monopolar transurethral resection of the prostate (TURP). BJU Int 2014; 113:24–35.
70. Thomas JA, Tubaro A, Barber N, et al. A multicenter randomized non-inferiority trial comparing GreenLight-XPS laser vaporization of the prostate and transurethral resection of the prostate for the treatment of benign prostatic obstruction: two-yr outcomes of the GOLIATH Study. Eur Urol 2016; 69:94–102.
71. Bilhim T, Pisco JM, Rio Tinto H, et al. Prostatic arterial supply: anatomic and imaging findings relevant for selective arterial embolization. J Vasc Interv Radiol 2012; 23:1403–1415.
72. Martins Pisco J, Pereira J, Rio Tinto H, Fernandes L, Bilhim T. How to perform prostatic arterial embolization. Tech Vasc Interv Radiol 2012; 15: 286–289.
73. Eri LM, Thomassen H, Brennhovd B, Håheim LL. Accuracy and repeatability of prostate volume measurements by transrectal ultrasound. Prostate Cancer Prostatic Dis 2002; 5:273–278.
74. Bilhim T, Tinto HR, Fernandes L, Martins Pisco J. Radiological anatomy of prostatic arteries. Tech Vasc Interv Radiol 2012; 15:276–285.
75. Desai H, Yu H, Ohana E, Gunnell ET, Kim J, Isaacson A. Comparative analysis of cone-beam CT angiogram and conventional CT angiogram for prostatic artery identification prior to embolization. J Vasc Interv Radiol 2018; 29:229–232.
76. Garcia-Monaco R, Garategui L, Kizilevsky N, Peralta O, Rodriguez P, Palacios-Jaraquemada J. Human cadaveric specimen study of the prostatic arterial anatomy: implications for arterial embolization. J Vasc Interv Radiol 2014; 25:315–322.
77. Carnevale FC, Antunes AA. Prostatic artery embolization for enlarged prostates due to benign prostatic hyperplasia. How I do it. Cardiovasc Intervent Radiol 2013; 36:1452–1463.
78. Carnevale FC, Moreira AM, Antunes AA. The "PErFecTED technique": proximal embolization first, then embolize distal for benign prostatic hyperplasia. Cardiovasc Intervent Radiol 2014; 37:1602–1605.
79. Bagla S, Rholl KS, Sterling KM, et al. Utility of cone-beam CT imaging in prostatic artery embolization. J Vasc Interv Radiol 2013; 24:1603–1607.
80. Goncalves OM, Carnevale FC, Moreira AM, Antunes AA, Rodrigues VC, Srougi M. Comparative study using 100-300 versus 300-500 μm microspheres for symptomatic patients due to enlarged-BPH prostates. Cardiovasc Intervent Radiol 2016; 39:1372–1378.
81. Cizman Z, Isaacson A, Burke C. Short- to midterm safety and efficacy of prostatic artery embolization: a systematic review. J Vasc Interv Radiol 2016; 27:1487–1493.e1.
82. Isaacson AJ, Bhalakia N, Burke CT. Coil embolization to redirect embolic flow during prostatic artery embolization. J Vasc Interv Radiol 2015; 26: 768–770.
83. Bilhim T, Pereira JA, Tinto HR, et al. Middle rectal artery: myth or reality? Retrospective study with CT angiography and digital subtraction angiography. Surg Radiol Anat 2013; 35:517–522.
84. Bilhim T, Pisco J, Pinheiro LC, Rio Tinto H, Fernandes L, Pereira JA. The role of accessory obturator arteries in prostatic arterial embolization. J Vasc Interv Radiol 2014; 25:875–879.
85. Miller DL, Balter S, Dixon RG, Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures. J Vasc Interv Radiol 2012; 23:11–18.
86. Laborda A, De Assis AM, Ioakeim I, Sánchez-Ballestín M, Carnevale FC, De Gregorio MA. Radiodermitis after prostatic artery embolization: case report and review of the literature. Cardiovasc Intervent Radiol 2015; 38: 755–759.
87. Shlansky-Goldberg RD, Rosen MA, Mondschein JI, Stavropoulos SW, Trerotola SO, Diaz-Cartelle J. Comparison of polyvinyl alcohol microspheres and tris-acryl gelatin microspheres for uterine fibroid embolization: results of a single-center randomized study. J Vasc Interv Radiol 2014; 25:823–832.
88. Chuang FP, Lee SS, Wu ST, et al. Change in International Prostate Symptom Score after transurethral prostatectomy in Taiwanese men with benign prostate hyperplasia: use of these changes to predict the outcome. Arch Androl 2003; 49:129–137.
89. Pelage JP, Guaou NG, Jha RC, Ascher SM, Spies JB. Uterine fibroid tumors: long-term MR imaging outcome after embolization. Radiology 2004; 230:803–809.
90. Katsumori T, Kasahara T, Kin Y, Nozaki T. Infarction of uterine fibroids after embolization: relationship between postprocedural enhanced MRI findings and long-term clinical outcomes. Cardiovasc Intervent Radiol 2008; 31:66–72.
91. Lencioni R, Llovet JM. Modified RECIST (mRECIST) assessment for hepatocellular carcinoma. Semin Liver Dis 2010; 30:52–60.
92. Khalilzadeh O, Baerlocher MO, Shyn PB, et al. Proposal of a new adverse event classification by the Society of Interventional Radiology Standards of Practice Committee. J Vasc Interv Radiol 2017; 28:1432–1437.e3.
93. McWilliams JP, Bilhim TA, Carnevale FC, et al. Society of Interventional Radiology multisociety consensus position statement on prostatic artery embolization for treatment of lower urinary tract symptoms attributed to benign prostatic hyperplasia: from the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Societe Francaise de Radiologie, and the British Society of Interventional Radiology. Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology. J Vasc Interv Radiol 2019; 30:627–637.e1.
94. McWilliams JP, Kuo MD, Rose SC, et al; Society of Interventional Radiology. Society of Interventional Radiology position statement: prostate artery embolization for treatment of benign disease of the prostate. J Vasc Interv Radiol 2014; 25:1349–1351.
95. Haskal ZJ. Time to purposefully plan ahead: a call for quality in research. J Vasc Interv Radiol 2016; 27:615–617.

Appendix A. Adverse Event Classification (92)

Part A: Adverse Event Description

Descriptive narrative of adverse event (including sedation and anesthesia) and severity characterization. This part is suitable for scientific use (presentations, publications, etc) as well as for adverse event reviews within a practice, practice group, facility, or specialty

1. Mild adverse event: no therapy or nominal (nonsubstantial) therapy (postprocedural imaging performed and fails to show manifestation of adverse event); near-miss (eg, wrong site of patient prepared, recognized and corrected before procedure, wrong patient information entered for procedure)
2. Moderate adverse event: moderate escalation of care, requiring substantial treatment, eg, intervention (description of intervention and result of intervention) under conscious sedation, blood product administration, extremely prolonged outpatient observation, or overnight admission postoutpatient procedure not typical for the procedure (excludes admission or hospital days unrelated to adverse event)
3. Severe adverse event: marked escalation of care, ie, hospital admission or prolongation of existing hospital admission for $>$ 24 h hospital admission that is atypical for the procedure, inpatient transfer from regular floor/telemetry to intensive care unit or complex intervention performed requiring general anesthesia in previously nonintubated patient (generally excludes pediatrics or in circumstances where general anesthesia would primarily be used in lieu of conscious sedation, eg, in mentally challenged or severely uncooperative patients)
4. Life-threatening or disabling event, eg, cardiopulmonary arrest, shock, organ failure, unanticipated dialysis, paralysis, loss of limb or organ
5. Patient death or unexpected pregnancy abortion

Note–the SIR Adverse Event Severity Scale is intended to approximate the surgical Clavien–Dindo scale and the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) scale. The SIR scale is tailored toward the procedures and adverse events encountered in interventional radiology practices. The grading of interventional oncology adverse events can selectively incorporate relevant adverse event grading definitions published in the current CTCAE for oncological interventions, which may be particularly relevant in the context of research publications. All adverse events occurring within 30 d of a procedure should be included in the adverse event description and analysis, regardless of causality, in the interest of objectivity. The adverse event scale itself does not assess operator performance. Modifier: M = multiple adverse events, each of which is counted and evaluated separately if possible.