Techniques in Vascular and Interventional Radiology

Current Debates Regarding Optimal Patient Evaluation and Procedural Technique for Prostatic Artery Embolization

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There are active debates surrounding patient evaluation and procedural techniques of prostate artery embolization. This review evaluates the available evidence on the value of urodynamics, the effect of prostate gland size, the benefits of pre- and intraprocedural cross-sectional imaging, the utility of a balloon-occlusion microcatheter, the differences among embolic particle sizes and types, and the merits of radial versus femoral arterial access.
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Introduction

Prostate artery embolization (PAE) is an emerging minimally invasive procedural therapy for symptomatic benign prostatic hyperplasia (BPH), especially for men with large glands or severe comorbidities which would preclude more invasive surgical procedures. For PAE to gain widespread acceptance, standardization of preoperative evaluation and procedural technique is important to help practitioners new to PAE perform the procedure safely and effectively.

This review summarizes the currently available evidence around 6 infrequently studied aspects of PAE to help answer the following questions: Are urodynamics studies necessary for the workup of a patient before PAE? Should PAE be performed on men with smaller glands? Is pre- or intraprocedural cross-sectional imaging needed? How does use of a balloon occlusion microcatheter affect outcomes after PAE? Do outcomes differ with the size of embolic agent used? Does the route of arterial access, radial or femoral, matter?

Urodynamic Evaluation Prior to PAE

BPH is not the only etiology of lower urinary tract symptoms (LUTS). Urethral stricture, bladder neck contracture, neurologic conditions, overactive bladder, cystitis, prostatitis, bladder stones, prostate cancer, or bladder cancer can all cause LUTS. These must be excluded before embarking on a procedural treatment for BPH. A detailed history and physical exam can narrow the differential, but urodynamic evaluation is often necessary to reduce diagnostic uncertainty and improve patient selection prior to invasive therapy for symptomatic BPH. The aims of urodynamic studies are summarized in Table 1.[1] Noninvasive urodynamic studies include postvoid residual (PVR) measurement and uroflowmetry. Invasive urodynamic studies include cystometry, electromyography, and pressure-flow evaluation. Both noninvasive tests, PVR and uroflowmetry, are easy to perform in the outpatient setting, can add objective data to the evaluation of a patient, and should be routinely obtained prior to invasive therapies for benign prostatic obstruction (BPO; Fig. 1).

Abbreviations: AUR, acute urinary retention; BPH, Benign prostatic hyperplasia; BPO, benign prostatic obstruction; ICS, International Continence Society; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; PA, prostatic artery; PAE, prostate artery embolization; PVA, polyvinyl alcohol particles; PVR, post void residual; Q_{max}, peak flow rate; QoL, quality of life

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Table 1 Basic Aims of Urodynamic Studies in Male Lower Urinary Tract Symptoms

- Reproduce the patient's symptoms during urodynamic testing to obtain objective information to make an accurate diagnosis of primary cause of LUTS
- Distinguish BPO from other causes of LUTS
- Evaluate bladder storage and emptying, which can impact treatment success or complications
- Determine if serious or irreversible damage to upper and lower urinary tract has already occurred or is at risk

Adapted with permission from Gomez C et al.[1]

If the diagnosis of BPO remains equivocal after noninvasive urodynamic tests, a multichannel urodynamic study including cystometry, electromyography, and pressure-flow evaluation can be performed by a urologist by catheterizing and filling the bladder.[1] The concurrent measurement of detrusor pressure and urine flow is the gold-standard for diagnosing LUTS due to BPO. In an attempt to standardize these measurements, the International Continence Society (ICS) synthesized available data into the ICS nomogram (Fig. 2). The ICS nomogram divides men into 3 groups (obstructed, equivocal, and unobstructed) based on their detrusor pressure at maximum flow ($P_{det}Q_{max}$) compared to maximum flow (Q_{max}). Bladder contractility can be divided into 3 groups (strong, normal, and weak) by comparing the same values. These 2 nomograms can be combined to categorize men into one of 9 groups based on their degree of obstruction and contractility (Fig. 2).[2]

Although little evidence is currently available, intuitively, noninvasive and invasive urodynamics should help optimize patient selection prior to PAE, but the impact of urodynamic evaluations prior to PAE has not yet been rigorously studied. In our experience, PVRs greater than about 500 mL are associated with more frequent clinical failures after PAE, as are neurologic comorbidities such as multiple sclerosis or Parkinson's disease, and age >90 years.[3] Such subgroups of patients may benefit from invasive urodynamic evaluation prior to undertaking any procedural treatment. Important parameters for refining patient selection for invasive interventions, including PAE, are summarized in Table 2.

Table 2 Patient Selection for Invasive Treatment Based on Urodynamic Studies

- Noninvasive testing: $Q_{max} < 10$ mL/s
- Multichannel urodynamic studies
- ICS nomogram: BOOI > 4
- Schafer nomogram: zones 3-6
- Predictors of suboptimal results
- Impaired compliance with DLPP >40 cm H2O is a risk factor for future upper tract damage
- Decreased cystometric capacity can lead to increased urinary frequency
- PAE and other transurethral surgical procedures will not improve bladder compliance, resulting in persistent LUTS, especially storage-related symptoms
- Detrusor overactivity occurs in 45%-50% of men with BOO and persists in 20%-40% of patients after relief of BOO with residual storage-related symptoms after invasive treatment

BOO - bladder outlet obstruction; BOOI - Bladder Outlet Obstruction Index; DLPP - detrusor leak point pressure; ICS - International Continence Society; LUTS - lower urinary tract symptoms; PAE - prostate artery embolization; Q_{max} - maximum flow rate. (Adapted with permission from Gomez C et al.[1])

Gland Volume and Efficacy of PAE

Patients considering a procedural BPH therapy have an increasing number of options from which to choose. Gland size is a key determinant of which procedural therapies are available to a patient with BPH. As gland size increases, many of the minimally invasive therapies become ineffective or more difficult to perform.[4] For this reason, much of the PAE data has been from patients with glands >120 mL who were not necessarily candidates for transurethral therapies.[5] However, many believe that PAE may be equally effective in men with glands 80-120 mL or smaller.

Bagla et al first investigated how gland size affects PAE in 2015 when 78 patients with symptomatic LUTS who underwent PAE were divided into 3 groups based on prostate volume (<50 mL, 50-80 mL, >80 mL) and followed for 6 months for improvements in International Prostate Symptom Score (IPSS).[6] No significant differences in pre-procedure IPSS were observed among groups. At 6 months after PAE, a significant reduction in symptom score was achieved in all 3

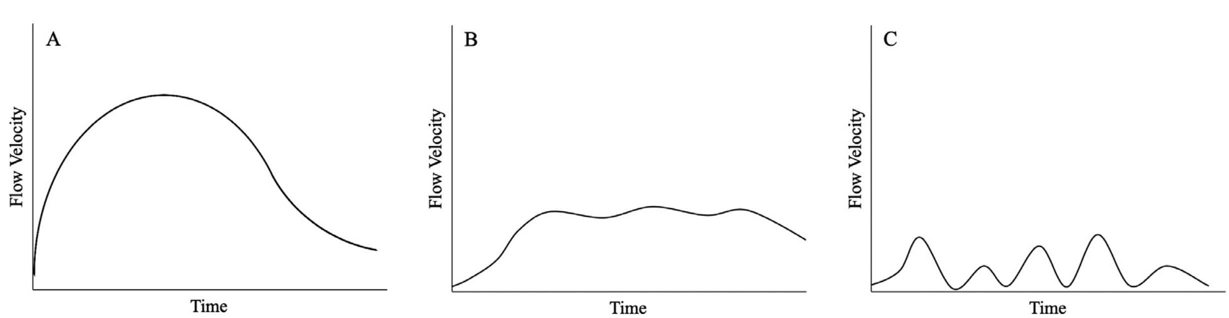

Figure 1 (A) Normal uroflowmetry curve showing a "bell-shaped" curve. (B) Obstructed pattern of uroflowmetry showing a flattened curve, common in BPO. (C) Intermittent flow pattern also common in BPO.

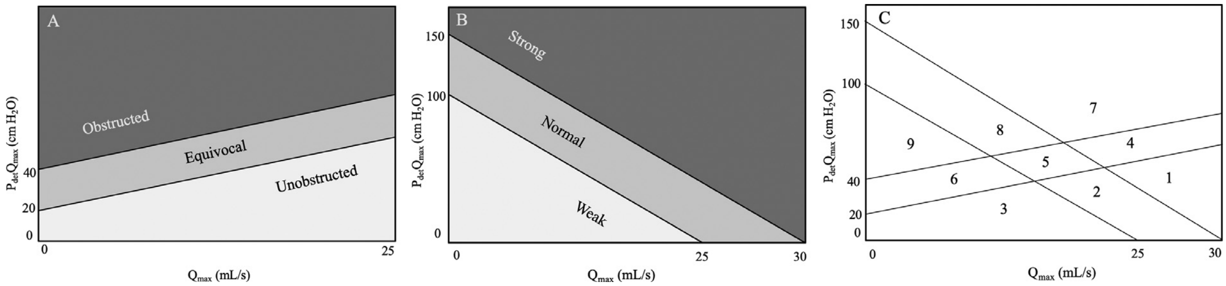

Figure 2 Nomograms. Based on maximum flow rate (Q_{max}) and detrusor pressure at maximum flow ($P_{det}Q_{max}$) during pressure-flow urodynamics, the (A) ICS nomogram divides men into either obstructed, equivocal, or unobstructed and the (B) bladder contractility nomogram categorizes their bladder function as strong, normal, or weak. The (C) composite nomogram categorizes patients into 9 categories; for example, those in category 7 are obstructed but with strong detrusor function.[2]

groups: from 27.2 to 15.9 in the <50 mL group, from 25.6 to 13.5 in the 50-80 mL group, and from 26.5 to 13.6 in the >80 mL group. In 2019, Ayyagari et al reviewed 74 consecutive patients who underwent PAE for LUTS. Linear regression analyses showed baseline gland volume had no significant effect on improvement in IPSS at 3, 6, or 12 months, with overall improvement in IPSS from 22.4 to 7.3 across all patients.[7] However, gland volumes ranged from 50 to 750 mL in this study, with the large majority of glands >120 mL. These studies suggest that PAE may offer equivalent clinical improvement regardless of gland size.

However, other research has suggested that men with larger glands may be more likely to benefit from PAE than men with smaller glands. Wang et al found that men with large glands >80 mL had a significantly better improvement in symptom burden after PAE compared to men with medium-sized glands 50-80 mL in 101 patients. IPSS scores improved by 14 points in the large gland group but only by 10.5 in the small gland group.[8] Abt et al also showed that gland size correlated with symptom improvement after PAE in a post hoc analysis of randomized trial data for 48 patients. In this analysis higher total prostate gland volume was associated with greater improvements in IPSS.[9] The largest dataset that specifically addressed the question of gland size came from the UK Registry of Prostate Artery Embolization (UK-ROPE). The UK-ROPE trial evaluated outcomes in 216 patients from 20 British centers. Data from 203 patients showed that men with larger glands (>80 mL) had a larger IPSS reduction.[10] In a retrospective review of 93 patients who had preprocedural magnetic resonance imagings, de Assis et al found that baseline whole prostate and central gland volume correlated with degree of IPSS improvement. This group went on to demonstrate that the prostate zonal volumetry index (ZVi, defined as ZVi = central gland/whole prostate) also correlated with improvement in symptom score, and that the ZVi at which a better clinical outcome was expected was >0.45.[11] These studies suggest that PAE may offer better outcomes in larger glands, or perhaps more precisely in glands with larger volumes of hyperplastic adenoma.

Preprocedure and Intraprocedural Imaging

PAE is technically challenging, in part because of the small caliber and variable origin of the prostatic arteries (PA). Pre-procedural CT angiograms (CTA) can help plan embolization by identifying the prostatic artery origins,[12] but few studies have addressed their effectiveness. Maclean et al retrospectively reviewed 110 patients who underwent PAE after preprocedural CTAs. They found that CTA was successful in identifying the PA supply 97.3% of the time. CTA demonstrated a sensitivity of 59.0% and a specificity of 94.2% for detecting anastomoses of prostatic vessels.[13] However, without a control arm it is unclear if preoperative CTA impacted any PAE procedural parameters. Contrast-enhanced MR angiography (MRA) has also been investigated as a technique to ease PAE. In a randomized-controlled trial, Zhang et al randomized 100 men to undergo PAE without or with a preoperative MRA. MRA identified the PAs with a sensitivity of 91.5%. Further, they showed that the MRA group had lower procedure times (82.3 vs 123.9 minutes), fluoroscopy times (13.8 vs 28.5 minutes), and radiation doses (329 vs 920 mGy).[14] Intraprocedural cone-beam CT (CBCT) is an alternative to pre-procedure CTA for identifying the PA origins and prostatic anastomoses. Wang et al showed CBCT to be more effective than DSA at identifying the PA origin (94.7% vs 74.5%) and arterial anastomoses (97.0% vs 58.2%), and also provided "essential information," not seen on traditional DSA 60.8% of the time.[15] Desai et al corroborated these findings, showing that CBCT allows for PA identification with improved signal- and contrast-to-noise ratios and with less radiation dose compared to conventional CTA.[16]

Use of Balloon Occlusion in PAE

Use of balloon-occlusion microcatheters has been theorized to make PAE easier for the operator, safer for the patient, and possibly improve outcomes. When inflated, the balloon-occlusion device theoretically prevents reflux of particles into nontarget arteries, and may also reverse blood flow through prostatic anastomoses away from nontarget organs by lowering the effective blood pressure in the organ.[17]

A small series of 12 patients who safely underwent PAE with a balloon-occlusion microcatheter was first described in 2018 by Isaacson et al.[17] In a 2019 retrospective nonrandomized case-control series of 129 patients, Ayyagari et al found procedure time and fluoroscopy time to be lower when a balloon-occlusion microcatheter was used, however there was probably a selection bias against use of the balloon-occlusion microcatheter in more technically challenging cases. Postprocedure outcomes including IPSS, PVR, or voiding trial success were not different between groups, nor was there any significant difference in the rates of adverse events found between groups.[18] In corroboration of these findings, a 2019 randomized controlled trial by Bilhim et al failed to show any improvement in procedural metrics or post-clinical outcomes between balloon-occlusion and end-hole microcatheter groups, although the trial did suggest there was a safety benefit to the balloon-occlusion microcatheter. In the 89 patients randomized to PAE with either an end-hole or balloon-occlusion microcatheter, only patients who had conventional PAE suffered penile skin lesions ($n = 3$) or rectal bleeding ($n = 2$), suggesting that the balloon-occlusion microcatheter may be effective at reducing nontarget embolization.[19]

Type and Size of Embolic Particles

The goal of PAE is to cause ischemia and necrosis of obstructive prostatic adenomatous tissue. Smaller particles have been shown to cause a greater degree of ischemia than larger particles.[20] For example, in hepatic tumor embolization, small particles are generally accepted to be superior at creating tumor ischemia than larger particles, with 70-150 μm particles as the accepted standard.[21] However, in PAE there is not yet a consensus about the appropriate size for embolic particles. Although smaller particles should theoretically cause more ischemia and subsequent necrosis, many authors cite concerns for smaller particles leading to higher incidences of nontarget embolization. Furthermore, prostate necrosis can lead to auto-enucleation and sloughing of necrotic tissue. This may be functionally equivalent to TURP, and has been dubbed "endovascular resection of the prostate."[22] Such necrosis can result in the need for adjunctive cystoscopic resection of the necrotic tissue, subjecting a patient to similar morbidities associated with TURP, such as retrograde ejaculation. One benefit of PAE is that it can improve symptoms without the trauma of resection. Finding a balance in PAE between the desired degree of ischemia and the risks of necrosis and nontarget embolization is an active area investigation.

In 2013 Bilhim et al randomized 80 patients to undergo PAE with either 100 μm or 200 μm PVA particles. Although there was a trend toward greater decrease in IPSS and QOL in the group embolized with the larger particles, no significant differences in outcomes were observed.[23] A recent study by Goncalves et al compared outcomes after PAE with 100-300 μm or 300-500 μm tris-acryl gelatin microspheres in 30 patients. Again, there was no difference in symptom or quality of life improvements. However, although the difference was not significant, there was a trend toward more adverse events in the group embolized with the smaller 100-300 μm microspheres, leading the authors to conclude that larger particles might be safer.[24] Torres et al randomized patients to different sized microspheres (group A 100-300 μm, group B 300-500 μm, or group C 300-500 μm followed by 100-300 μm). IPSS improvements were robust, but not significantly different among groups. This trial did demonstrate a significant difference in rate of minor adverse events of 86.0% in group A, but only 41.3% in group B, and 58.3% in group C.[25] Other authors have reported low adverse event rates despite using smaller 100-300 μm microspheres. In a retrospective review of 58 patients who underwent PAE using 100-300 μm microspheres, Ayyagari et al reported a minor adverse event rate of just 31% and IPSS improvements from 22.4 at baseline to 7.3 at 12 months.[7] The UK-ROPE trial also evaluated outcomes with different embolics, and found that embolization with small spherical particles performed best in reducing prostate volume, reducing IPSS, and improving peak flow rate (Q_{max}). A targeted ANOVA analysis suggested that variation in embolic agents used could explain the variability in data for prostate volume reduction and Q_{max} improvement, but not for IPSS reduction.[10] Although the UK-ROPE trial suggests that spherical particles outperform nonspherical particles, few additional well-designed studies specifically address this question.

With respect to hematuria and retention, a separate analysis by Ayyagari et al of PAE to treat 46 men with urinary retention and 55 men with gross hematuria of prostatic origin demonstrated excellent results after embolization with 100-300 μm microspheres. 87% of the retention patients were catheter-free by 3 months post-embolization, and 92% of the hematuria patients remained hematuria-free for an average of 483 days post-procedure. Again, adverse events were relatively low; 24% of patients suffered minor adverse events.[3]

Radial Versus Femoral Access

Left radial access is a widely used alternative to femoral access in PAE and has shown equivalent results in multiple case series. Isaacson et al first reported the feasibility of transradial access for PAE, describing a 100% technical success in 19 patients.[26] Bhatia et al then retrospectively compared cohorts of patients who underwent PAE with radial access and femoral access. Two femoral access cohorts of 32 patients each (initial learning curve and subsequent cases) were compared to a single cohort of 32 radial access patients. Technical success was 93.8% in the transradial group and 90.6%-96.6% in the femoral access groups. Mean procedure time and mean fluoroscopy time were significantly less in the radial access group when compared to the 2 femoral access groups. Access site complications and overall adverse events were not different among groups.[27] However, it should be noted that continuing learning curve effects may have partially accounted for some of these differences.

A disadvantage of radial access is the theoretical risk of stroke brought about by traversing the aortic arch. While no literature has specifically addressed this risk in PAE, the risk of a cerebrovascular accident resulting from radial access for percutaneous coronary intervention (PCI) has been reported to be exceedingly low. In one study comparing 124,616 radial PCIs with 223,476 femoral PCIs, in which the proximal aorta was crossed in both groups, each cohort had a neurologic complication rate of just 0.11%.[28] In PAE, much less manipulation of catheters occurs in the aortic arch, and thus the neurologic complication rate would be expected to be exceedingly low. Indeed, multiple meta-analyses have not named stroke as a risk of PAE, although these include patients who underwent PAE both via femoral and radial access.[29-31] Another risk specific to radial access is radial artery occlusion or spasm. In noncoronary interventions these risks have been demonstrated to be exceedingly low. In a retrospective analysis of 946 patients who underwent 1531 transradial procedures including chemoembolization, yttrium-90 mapping/infusion, renal/visceral interventions, and uterine artery embolization among others, there were just 11 radial artery occlusions and 6 radial artery spasms.[32] Finally, a more practical disadvantage of radial access for PAE is the need for longer catheters to reach the prostate, an issue which can be exacerbated by tortuous aortas and common iliac arteries. For example, steerable catheters are currently only available in lengths of 125 cm. This can be evaluated beforehand with cross-sectional imaging of the abdomen.

Radial access has considerable advantages from a patient satisfaction perspective, in that patients can ambulate immediately after the procedure, and they can avoid the albeit small risk of femoral access complications (primarily unsightly ecchymoses). Overall, both femoral and radial access for PAE have yielded comparable results with minor advantages or disadvantages to each. Ultimately, the best determination of which technique to use probably lies with operator, as the best overall outcomes and patient satisfaction will result when the operator performs PAE in their comfort zone.

Conclusions

1. Noninvasive urodynamics (PVR and uroflowmetry) are simple to perform in the outpatient setting, offer objective measurements of voiding, and should be routinely performed prior to embolization and in follow-up. Invasive urodynamics (multichannel cystometry, electromyography, and pressure-flow studies) are an optional part of the evaluation of patients when the diagnosis of BPO is equivocal.
2. The best results after PAE can be expected for glands >80 mL, but the advantage is small, and any patient with LUTS can expect likely benefit from PAE regardless of gland size. Thus, patients should not be excluded from PAE due to smaller gland size, although they need to be properly informed about the existing data, as well as about other transurethral surgical options available to them.
3. Pre-procedural CTA or MRA prior to PAE is not necessary for a successful procedure, but may aid in identifying the origins of the prostatic arteries, decrease procedure/fluoroscopy time, and decrease radiation dose to the patient and operator. These benefits should be balanced against the increased burden and cost associated with extra tests.
4. Limited data regarding use of a balloon-occlusion microcatheter for PAE suggest a possible improvement in adverse advents. Therefore, the use of a balloon occlusion catheter during PAE is advised on a case-by-case basis.
5. Outcomes after embolization with small and spherical particles appear to be superior to large and nonspherical particles. The most data exist for tris-acryl gelatin microspheres, with data available for 100-300 μm or 300-500 μm particles. The smaller 100-300 μm particles are theorized to have more adverse events, although this has not yet been borne out in clinical studies.
6. Both radial and femoral access for PAE are safe and feasible, and likely yield equivalent outcomes. Although radial access may improve procedure and fluoroscopy times for an experienced operator, it can be technically challenging. Therefore, the choice of radial or femoral access should remain at the discretion of the operator.

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