### PANEL DISCUSSION

# Optimizing Prostatic Artery Embolization Outcomes

Experts discuss the impact of the updated American Urological Association guidelines, current evidence and long-term data, patient candidacy, imaging and embolic selection, the reimbursement landscape, establishing referral relationships, and the next phases of clinical research.

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The American Urological Association's (AUA) 2023 guidelines support prostatic artery embolization (PAE). What does this mean for growth, acceptance, and referrals for the procedure in the United States and elsewhere?

**Prof. Bilhim:** I recently coauthored a commentary on this issue with Drs. Justin McWilliams and Sandeep Bagla from the United States. I believe the updated guidelines will have a big impact within the United States to help PAE get reimbursed and thus become

more widely used. Outside the United States, existing guidelines, such as those from the European Association of Urology and NICE (National Institute for Health and Care Excellence), already support PAE for patients with benign prostatic hyperplasia (BPH). This will naturally imply an expected growth in PAE usage within the United States and less growth elsewhere. Referrals will continue to be limited. Just because guidelines recommend PAE does not necessarily mean that urologists will start referring their BPH patients for PAE. Direct patient referrals will continue to be fundamental to help implement and grow PAE practice worldwide. As for acceptance, I believe that this 2023 AUA guideline update will be very relevant. For centers starting a PAE program, it will be important to show hospital administrations that PAE is an accepted treatment modality for BPH patients both in interventional radiology and urology guidelines. As such, opposing urologists will not have scientific reasons to exclude a PAE practice, even if they do not refer patients.

Dr. Fischman: This was a big deal. Prior to the new 2023 guidelines, PAE has been significantly handicapped in terms of private insurance reimbursement and preauthorization for the procedure. Despite very good level 1 evidence and > 10 years of follow-up data for PAE, it was not included in the AUA guidelines in the same way as other minimally invasive treatments. Many operators around the United States recently received a letter from Cigna stating that as of October 2023, PAE was not covered based on the previous AUA guidelines stating that PAE should only be used in the context of a clinical trial. Now that the AUA guidelines have been updated to include PAE with level C evidence, insurance companies should approve preauthorization and reimbursement for most of these cases moving forward, similar to approvals for other minimally invasive surgical therapies (MISTs), including prostatic urethral lift (UroLift, Teleflex) and water vapor thermal therapy (Rezum, Boston Scientific Corporation). However, the caveat is that the new AUA guidelines state that PAE should be performed only by physicians who are specifically trained in this technique.

**Dr. Mouli:** Formal recognition of PAE in the AUA 2023 guidelines recognizes the rigorous data obtained by several groups across the world in treating men with BPH with lower urinary tract symptoms (LUTS). Inclusion in the guidelines also recognizes the significant benefit this therapy offers patients. The AUA guidelines' only caveat to PAE use is that it should be offered by interventional radiologists (IRs) trained in

this procedure. This should support wide adoption in the United States among practicing urologists whose patients have been asking for this therapy for years. Additionally, this will spur more formalized interventional radiology training to master technical aspects of this therapy.

Dr. Piechowiak: As an experienced IR, I believe the inclusion of support for PAE in the AUA 2023 guidelines is a significant milestone for the growth, acceptance, and referrals for this procedure. This endorsement adds credibility and legitimacy to PAE, leading to increased adoption and use. The multidisciplinary approach encouraged by the guidelines fosters collaboration between specialists, resulting in improved patient outcomes. It also increases awareness among physicians and patients, driving demand and expanding availability. Additionally, the acceptance of PAE in the United States will likely influence its adoption globally, leading to increased interest and referrals from physicians and patients worldwide. Overall, this development has a positive impact on the growth of PAE and improves patient care on a global scale.

## How would you summarize the current evidence supporting PAE? Where do we stand with respect to long-term data?

**Dr. Fischman:** We have been doing PAE for > 10 years. If you look through the literature, we have all different types of studies with level 1 evidence, including randomized trials, meta-analyses, sham trials, and long-term follow-up studies, including a publication by Carnevale and colleagues with 10-year follow-up data.<sup>2</sup> There are many subgroup analyses for specific patient populations, as well as studies looking at access technique, radiation dose, different embolics, and all sorts of other technical factors. There is definitely no lack of data when it comes to PAE.

**Dr. Mouli:** Numerous prospective studies have demonstrated short- to mid-term safety and efficacy of PAE across gland sizes. Recently, two of the most experienced groups have published their 10-year experience with PAE, demonstrating long-term safety and efficacy. Carnevale et al presented data on 317 men (mean follow-up, 27 months), reporting International Prostate Symptom Score (IPSS) improvement of 16 points, < 25% LUTS recurrence after PAE, and median time to recurrence of 72 months. No patients reported urinary incontinence or erectile dysfunction.<sup>2</sup> In addition, Bilhim et al published the largest cohort of 1,072 patients, with the longest follow-up data to date.<sup>3</sup> With a mean follow-up of 52 months, patients demonstrated

significant improvement in LUTS and quality of life at last follow-up. An IPSS reduction of 10 points was reported, with < 30% LUTS recurrence at last follow-up and median time to recurrence of approximately 36 months. Additionally, both these studies and numerous others demonstrate significant safety of PAE in comparison to other treatment options, with minor, self-limited adverse events in < 5% of patients.

Dr. Piechowiak: The current evidence supporting PAE is promising and suggests that it is an effective and safe treatment option for BPH, with an average IPSS reduction varying from 11 to 15 points. Numerous studies have shown that PAE can provide significant relief from BPH symptoms, such as urinary frequency and urgency, without the need for surgery. Although the majority of studies have focused on shorter-term outcomes, the available long-term data indicate that PAE maintains its effectiveness in reducing BPH symptoms over time, with a likely long-term durability of 5 to 7 years on average. Furthermore, PAE has demonstrated an excellent safety profile. Complications associated with the procedure are infrequent and typically minor, such as puncture site hematomas, urinary tract infections (UTIs), and temporary urinary retention. Serious complications, such as nontarget complications resulting in significant sequelae, are fortunately quite rare.

Prof. Bilhim: If you compare PAE with the competing existing minimally invasive treatment options for BPH patients, PAE has the most robust and largest evidence base supporting its use. I believe we already have enough evidence when comparing PAE with resective surgical techniques and even with medical therapy. Phase 2 and phase 3 trials have shown that PAE is safe and effective. We now know that symptomatic relief of PAE is comparable with prostatic surgery and higher than medical therapy. Improvement of objective measures such as prostate volume reduction, peak urinary flow improvement, and prostate-specific antigen reduction might be more pronounced with surgery. However, PAE has lower morbidity and lower hospital admission times, with faster and better recovery periods. More importantly, PAE preserves sexual function in both erectile and ejaculatory domains, with better outcomes when compared not only to surgery but also medical therapy.

As for long-term data, we have done our job! In 2022, we published our 10-year follow-up data in > 1,000 BPH patients treated with PAE.<sup>3</sup> This was a huge amount of work and is a cornerstone paper that will help physicians and patients understand the potential benefits of PAE after 1, 5, 8, and 10 years. Let's just hope that all

other PAE centers will be able to replicate these long-term findings—we need more centers with 5- to 10-year data.

## Who are the ideal candidates for PAE, and what do you base your decisions on? What are the known contraindications?

**Dr. Mouli:** With the evolution of tools and techniques for PAE, the ideal candidates for this therapy have also broadened. During its inception, PAE was initially reserved in cases of hematuria from prostatic sources, patients with urinary retention with very large glands, or those not amenable or contraindicated for surgical intervention. Now, the group of eligible patients has broadened to those with confirmed LUTS secondary to BPH after a urologic evaluation. This necessitates exclusion (contraindications) of other sources of LUTS such as neurogenic bladder, urethral strictures, bladder malignancy, or active UTIs or prostatitis.

**Prof. Bilhim:** There is a lot of literature on this topic. Our experience was analyzed with a large cohort of 400 patients and published in *Radiology* in 2016.<sup>4</sup> What we learned is that small (< 30 cm<sup>3</sup>) prostates may not respond well to PAE; however, bigger does not mean better. Even though some studies have shown that larger prostates do better after PAE than smaller prostates, we do not have that impression based on our patient data. Patients with acute urinary retention do well after PAE. Highly symptomatic patients (IPSS > 30 points) may be left with residual LUTS after PAE and therefore may not be ideal candidates. Older patients (aged > 70 years) performed worse than younger patients.

My main contraindications are patients with prostate cancer, as PAE may alleviate LUTS but does not effectively treat cancer; patients with UTI, especially those with bladder catheters as they may be prone to infectious complications after PAE; patients without LUTS seeking PAE to improve their sexual function; and patients with very high postvoid residual urine (> 300 mL), such as diabetic patients or patients with neurologic diseases, as this might be due to hypocontractile bladder and thus will not respond to PAE (urodynamic studies are mandatory in these situations). On the same line, patients with incontinence, especially overflow incontinence, are also very problematic to manage. I tend to avoid patients aged > 80 years, where the likelihood of bladder dysfunction, atherosclerosis, and misinterpretation of expected outcomes may render PAE a failure.

I try to advise patients about the pros and cons of the different treatment options for BPH and let them decide. In the end, it is always a matter of probabilities of clinical success, which might be higher or lower based on baseline parameters and patient expectations.

**Dr. Fischman:** This is a great question, and I think the answer will change depending on who you ask. In my opinion, the best patients are those with severe IPSS, low flow rates (Qmax), moderately elevated postvoid residual volume, and normal bladder function. In addition to that, larger prostates tend to respond better than smaller prostates in my experience. Even patients with larger median lobes do reasonably well with embolization as compared to other MISTs. Patients with bleeding of prostate origin also do very well with embolization. Catheterdependent patients with normal bladder function will have success most of the time; we've seen an 80% to 85% catheter-free rate after embolization in these patients at around 4 weeks. I don't know if I have any absolute contraindications, but patients with bladder dysfunction, arterial occlusions, mild IPSS, and very small prostates (< 40 g) are not good candidates for PAE.

Dr. Piechowiak: I would categorize patients into "resective" and "nonresective" procedures when considering options for therapy in BPH patients. For resective procedures, such as transurethral resection of the prostate (TURP), holmium enucleation of the prostate, or open prostatectomy, patients with significantly enlarged prostates or severe urinary symptoms may be ideal candidates. These patients often have poor bladder function and may require extensive tissue removal to relieve their symptoms. On the other hand, for nonresective procedures like PAE, patients with preserved bladder function and moderate to severe urinary symptoms are strong candidates. These patients typically have an enlarged prostate but still maintain good bladder function. PAE and other MISTs offer a less invasive alternative to traditional surgical options, with potentially fewer complications and a quicker recovery time.

When making decisions about the suitability of PAE for a patient, I consider various factors such as patient age, overall health status, prostate size, morphology, severity of symptoms, and preference for a less invasive procedure. It is important to have a thorough discussion with the patient to understand their goals and expectations before recommending PAE.

Although PAE is a safe and effective procedure, there are known contraindications that should be considered. Patients with significant prostate cancer, active UTI, stage 4 chronic kidney disease, or severe allergies to the contrast agents used in PAE may not be ideal candidates. Each patient's case should be evaluated individually to determine the most appropriate treatment option.

#### What are the key characteristics you look for in an embolic? How has this changed, and what future innovations are you hoping for?

**Dr. Piechowiak:** First, consistency in outcomes is crucial. The embolic should consistently achieve the desired effect, whether it is occluding blood vessels, blocking the blood flow to a tumor, or treating an aneurysm. Consistency ensures that the procedure is predictable and reproducible, leading to successful patient outcomes.

Deliverability is another important characteristic. The embolic should be easy to deliver through a catheter into the targeted blood vessel. It should have good flow characteristics, allowing for precise and controlled delivery. This ensures that the embolic reaches the intended site without causing any complications or embolizing unintended vessels. Safety is paramount in any interventional procedure. The embolic material should have a proven safety profile, minimizing the risk of adverse events. It should be biocompatible, nontoxic, and nonallergenic.

In terms of changes, there have been significant advancements in embolic materials over the years, from the traditional options like coils and particles to now liquid embolics such as glue or Onyx (Medtronic) that may offer differences in control or penetration. These innovations have improved the precision and effectiveness of certain embolization procedures but are not yet proven in PAE to be more effective or safe.

Looking toward the future, I hope for further advancements in embolic materials. One area of interest is the development of targeted embolization agents that can selectively occlude specific blood vessels while sparing adjacent healthy tissues. This would allow for more precise and tailored treatments, minimizing the potential for complications. Another potential could be easily retrievable or resorbable if needed, providing an option for reversibility in case of complications or if the treatment needs to be modified. Additionally, the further development of resorbable embolic materials may be beneficial. These materials would gradually degrade over time, eliminating the need for retrieval procedures and reducing the long-term risks associated with permanent embolic agents. With ongoing advancements and future innovations, I am optimistic about the potential for even better embolic options that will further enhance patient care in interventional radiology.

**Dr. Mouli:** A variety of embolic particles are available for PAE, but there is no consensus on the ideal agent currently. The most robust data in terms of safety and efficacy comes from utilization of 300–500-μm spherical calibrated particles, which are agents of choice in

numerous randomized controlled trials of PAE versus TURP, sham, and medical management. From a risks/benefits standpoint, these agents offer the best outcomes in terms of efficacy while still maintaining the advantageous safety profile of PAE over other transurethral therapies. Smaller particles (100–300  $\mu m$ ) have been explored, and while offering a similar symptomatic benefit as larger particles (similar IPSS reduction), the trade-off appears to be more adverse events likely due to nontarget embolization.

That is not to say that the ideal embolic agent has already been determined. We know from cadaveric studies that the diameter of intraprostatic arterial branches feeding BPH tissues range from 50 to 300  $\mu$ m. As we edge closer to the lower limit with smaller agents, there is increased likelihood of deposition of embolic material in the rich collateral network of the pelvis—arteries to the bladder, colon, and penis. An ideal embolic would need to penetrate this range of arterial sizes, without traversing the collateral network into other organs. Newer agents that offer clear visualization and limited distal penetration may meet this requirement.

**Dr. Fischman:** We have learned quite a bit over the years in terms of particle size as it relates to response and potential adverse events. Much of the data suggests that small particles probably don't work that much better than larger particles. Smaller particles typically range between 100 and 300 μm and larger particles between 300 and 500 μm. That being said, we see more necrosis on follow-up imaging with smaller particles, and this comes with a cost, as smaller particles typically will cause more postprocedure symptomatology as well as potentially higher risk of nontarget embolization. At my institution, we are investigating using novel liquid embolic agents including N-butyl-cyanoacrylate (NBCA) to get faster occlusion rates, lower radiation doses, and similar clinical results. Stay tuned for results from this study.

Prof. Bilhim: First, the embolic needs to be safe and easy to use. Second, it needs to induce consistent LUTS improvement, prostate volume reduction, and peak urinary flow rate improvement, ideally with low revascularization rates (but this is not routinely measurable). We compared the most frequently used particles for PAE in our paper on long-term outcomes and concluded that nonspherical polyvinyl alcohol (PVA) particles, Embosphere microspheres (Merit Medical Systems, Inc.), Embozene microspheres (Varian Medical Systems), and Bead Block (Boston Scientific Corporation) performed equally well.³ Based on our results, we concluded that 300–500-μm microspheres should be used for PAE

(lower might be dangerous), whereas PVA particles can be used in the 100-300- $\mu m$  range. NBCA has been introduced in the last couple of years and looks to be as safe and effective as particles, with the potential to reduce revascularization. We need more comparative studies to determine if NBCA is better than particles for PAE.

### What is the optimal imaging modality for PAE? Is there still a need for cone-beam CT (CBCT)?

**Prof. Bilhim:** Before PAE, I prefer MR with angioMR, which allows precise evaluation of the prostate, bladder, and pelvic vasculature. This requires 3T scanners and dedicated vascular protocols to allow accurate delineation of prostatic artery anatomy. In my opinion, there is and there will always be room for CBCT during PAE. CBCT has lower radiation exposure rates than two-dimensional (2D) digital subtraction angiographic (DSA) runs, and it doesn't make sense to perform DSA instead of CBCT. CBCT also allows use of dedicated software for prostatic artery identification and vascular guidance with three-dimensional/2D fusion imaging. CBCT gives you so much more information than DSA, with less radiation and time.

**Dr. Piechowiak:** In my opinion, CBCT is not considered necessary for PAE when the IR has a strong understanding of prostatic and pelvic anatomy and can perform real-time imaging using conventional angiography. With a thorough knowledge of the anatomy, collaterals, and flow dynamics, the IR can effectively delineate the target vessels and perform the embolization procedure without the need for CBCT. However, it is important to note that the optimal imaging modality for PAE may vary depending on the individual patient's anatomy and the IR's expertise. My preferred modality is solely fluoroscopy (and ultrasound for access) for PAE.

**Dr. Fischman:** A good fixed fluoroscopy unit is obviously the most ideal setup. However, many office-based labs are using high-quality C-arms, which can offer excellent image quality at a lower cost. CBCT is something that is very helpful when performing PAE. When operators first learn the PAE technique, CBCT is great for confirmation and problem solving. At this point in my experience, I use CBCT very sparingly, if at all, but I used to use it regularly. To answer the question: Do I think CBCT is absolutely necessary? No. Is it useful when first starting out? Absolutely.

**Dr. Mouli:** PAE remains a challenging procedure, requiring experience and extensive training to develop catheterization dexterity and understanding of male

pelvic arterial anatomy. This is further compounded by variability in prostatic artery origins and pelvic arterial collaterals. The primary advantage of PAE over other transurethral therapies lies not in its efficacy but rather its safety and minimally invasive nature. As such, thorough identification of prostatic arterial supply and prevention of nontarget embolization remain critical to its widespread adoption. Given its technically demanding nature and steep learning curve, use of only DSA may be insufficient to identify prostatic supply and collateral vessels, especially early in one's experience. CBCT is valuable in identifying prostatic supply and excluding extraprostatic perfusion. Thus, while CBCT is most beneficial early in one's experience, it remains a critical problem-solving tool to confirm prostatic and exclude extraprostatic perfusion in select cases. For PAE to be considered alongside medical management and/or transurethral therapies, it needs to be performed effectively while keeping adverse event rates due to nontarget embolization near zero. CBCT for identifying soft tissues, target vessels, and anastomoses remains a critical tool to meet this goal.

#### What is the current reimbursement landscape? How often do you encounter insurance denials, and how do you manage these?

**Dr. Piechowiak:** I frequently encounter insurance denials in my practice, but we have developed effective strategies to manage these denials. One of our primary approaches is engaging in peer-to-peer reviews and appeals with insurance companies. By presenting the medical necessity and benefits of the procedures we perform, we often succeed in overturning denials and obtaining reimbursement for our services. When it comes to procedures like PAE in particular, we find that insurance companies often lack guidelines that include it as a reasonable treatment option. In these cases, we advocate for the inclusion of PAE in their guidelines. We emphasize that PAE can be a cost-effective alternative to surgical interventions, with potentially lower risks and comparable or even superior outcomes. By presenting evidence-based data and engaging in discussions with insurance companies, we aim to change their perspective and encourage them to consider PAE as a viable treatment option for their subscribers.

**Dr. Mouli:** Thankfully, the reimbursement landscape is shifting, perhaps in part due to the updated AUA 2023 guidelines. Denials are managed with an appeal, with or without a peer-to-peer discussion, in an attempt to update the insurance providers with the latest data and guideline documents.

**Dr. Fischman:** In patients aged > 65 years who have Medicare, reimbursement is standard and not an issue. As I mentioned previously, up until September 2023, the AUA guidelines really had a negative impact on reimbursement and insurance denials for private carriers. Many times, we would get denials and do peer-to-peer appeals with medical directors of many of the insurance companies. These would sometimes get approved and many times would not. There are other complicated appeal pathways that can be performed, but they require a fair amount of time and can be very frustrating. Now that the guidelines have changed, I think we will have a much easier time getting reimbursement preauthorization approvals. It may take some time for the guidelines to be updated within insurance carrier algorithms, but I am optimistic that this will lead to more patients being able to be treated in the coming years.

Prof. Bilhim: This will naturally vary based on country, hospital/clinic, and individual insurance contracts. In Portugal, insurance agreements for PAE are usually handled by the private hospitals. For us, PAE has been reimbursed for many years, with main insurance contractors in Portugal supporting it. When PAE gets denied, it is usually related to an individual health insurance contract that does not support invasive treatments of the prostate (PAE or any other). In this case, the patient would need to cover all expenses on their own, and unfortunately, it is not rare to see patients who do not have an insurance contract that covers PAE. Portugal has a strong tradition of a national health care system that is free for everyone, dating back to 1979. Many Portuguese people (especially those who are older) are used to having medicine for free and do not have private health insurances. Thus, they either seek PAE treatment in a public hospital or need to cover the expense on their own. Nowadays, national health care systems are collapsing, and patients are adhering more and more to private health insurances.

### What are your dos and don'ts for establishing referral relationships and reaching patients?

**Dr. Fischman:** First, relationships with local urologists are key. Many urologists see the benefit of PAE in many of their patients, but still, I don't think we should rely on urologists to refer patients. All IRs who want to have a busy PAE practice should be able to evaluate and treat patients with BPH from start to finish. This includes managing and prescribing BPH medications, performing in-office uroflowometry and bladder volumes, setting up appropriate imaging including CT and MRI, referring patients for biopsies and cystoscopy, and

seeing patients in follow-up at appropriate intervals. If you are not dedicated to taking care of these patients from start to finish, I don't think you will have a successful PAE practice.

Another great source of referral is direct from primary care doctors. If they understand that you can take care of these patients from start to finish, they will be much more likely to refer patients to you. My office staff knows that when a patient calls to inquire about PAE, they send me a message with the patient information. I call every patient before bringing them into the office to say hello and get a quick 1-minute background of why they are requesting a consultation. I also give them a heads-up that we may set up preoperative imaging so we can get everything done all in 1 day when they come in for their first office visit. I personally think this builds tremendous rapport with the patients, and they really appreciate the personal contact.

**Prof. Bilhim:** Interventional radiology is a developing medical specialty with growing clinical skills. As such, most IRs are not used to having direct patient referrals and may feel uneasy about performing a procedure that was not requested by a referring physician. I understand this, and it is just a matter of getting used to it, being clinically prepared (as most are already technically well prepared), and having good sense and clinical judgment. Embolization is not for everyone. IRs must develop clinical skills that will help them decide when PAE is indicated, but most importantly, when it's not.

Some dos:

- Do it! We need more interventional radiology centers offering minimally invasive treatments to enhance patient care.
- Master all the clinical needs to offer specific interventional radiology procedures, not only the technical requirements.
- Team up with the right people and find partnering specialty colleagues who will help offer multidisciplinary management and grow your referrals.
- Adopt promotional skills to enhance visibility of your work in the medical and global social community.
   Some don'ts:
- Do not embark on performing PAE when you do not have the motivation, time, expertise, money, or institutional support.
- Avoid starting with very complex, "bad" cases, as they may be used against you.
- Do not try to do everything on your own—performing a PAE in the angio suite is only 5% of what's required to boost a PAE practice; you will need time and the right people to help you manage all the steps.

**Dr. Piechowiak:** Building referral relationships and reaching patients requires a thorough understanding of the treatment options available for various conditions. In the case of BPH, it is essential to have a solid foundation of knowledge about the disease, its management, and the evidence supporting different treatment approaches. One of the most important "dos" for establishing referral relationships with urologists is to invest time in educating yourself about BPH treatment options. This includes staying updated on the latest research, attending relevant conferences, and engaging in discussions with other medical professionals. By becoming a subject matter expert in BPH, you will demonstrate your dedication to providing the best possible care for patients.

When speaking with urologists, it is crucial to showcase your in-depth understanding of BPH treatment options and how they fit into the overall management of the condition. This might involve discussing the pros and cons of different approaches, potential outcomes for patients, and any evidence supporting the effectiveness of specific interventions. By demonstrating your knowledge and expertise, you will gain urologists' respect and trust, increasing the likelihood of collaboration and patient referrals.

On the other hand, it is important to avoid making assumptions or oversimplifying the complexities of BPH management. Urologists are subject matter experts in this field, and they expect IRs to have a diligent understanding of the disease and its treatment options. Therefore, it is a "don't" to approach urologists without having thoroughly evaluated the evidence and details surrounding BPH management. Failing to do so may hinder the establishment of strong referral relationships and limit collaboration opportunities.

**Dr. Mouli:** Before considering PAE, patients need to have seen a urologist with the appropriate BPH/LUTS workup. This works best if partnered with a urology team that can handle intake and workup. Eventually, PAE patients might need general urologic care after PAE, which is where this relationship can be beneficial. IRs can offer assistance in more complex cases for which the AUA guidelines do not provide guidance, including nonindex patients: those with urinary retention and now catheter-dependent, patients with medical comorbidities, gross hematuria from a prostatic source, or large glands not amenable to resection.

Regarding reaching patients, this is a very savvy patient population. Once diagnosed with BPH/LUTS, they will explore all their treatment options, whether or not they are offered by their local urologist. For men with BPH/LUTS, the relationship with the urologist is not necessarily long term; they might only see them

due to a new problem/urinary issue, and as such, they are often open to seeing any physician who can solve this new issue. To this end, education of patients and other providers about PAE as well as visibility of a PAE program are critical to reaching patients.

## What are the next phases of clinical research? What are the most pressing unanswered questions?

**Dr. Mouli:** Several experienced groups have demonstrated that PAE is both safe and effective for the treatment of LUTS secondary to BPH. However, PAE remains a technically demanding procedure that requires advanced microcatheter skills as well as thorough understanding of pelvic vascular anatomy. The next phase of advancement of this therapy lies in democratizing this procedure for all eligible patients. This requires research into formalizing PAE training such that a systematic standardized approach to treating these patients is used. This will permit technical and clinical results to be reproducible everywhere.

**Prof. Bilhim:** The next phase will be comparing PAE with other MISTs, as well as using artificial intelligence to help guide the best treatment options for patients with BPH/LUTS and minimize the rate of nonresponders after PAE.

**Dr. Piechowiak:** The next phases of clinical research in the field of PAE should focus on investigating its role in prostate cancer treatment. Although PAE is primarily used for BPH, there is emerging evidence suggesting its potential benefits in prostate cancer management. One pressing unanswered question is whether PAE can be used as an adjuvant therapy to radiation or other surgical treatments for prostate cancer. Studies have shown that PAE can effectively reduce prostate volume and improve LUTS, which may be beneficial in combination with other therapies. Further research is needed to determine the optimal timing, dosage, and patient selection for combining PAE with existing prostate cancer treatments.

Another area of research interest is exploring how to reduce gland size further through PAE. By achieving greater glandular shrinkage, we may potentially increase the durability of the treatment and improve long-term outcomes. Investigating different embolic agents, optimizing the embolization technique, and evaluating the impact of multiple PAE sessions on gland size reduction could be valuable areas of future research.

Dr. Fischman: I think that we are just scratching the surface with what we can do with prostate embolization. I don't think we know what the right embolic agent is or what would be considered the ideal embolic agent. I have a very active interest in understanding the role of liquid embolics in these procedures. I think that our focus moving forward should be on how to optimize and standardize our technique, which should include faster procedure times, lower radiation doses, and lower recurrence rates. Given that recurrence rates at around 5 or 6 years can be approximately 20%, there is a lot of room for improvement. There is also some exciting research coming out of Dr. Mouli's group at Northwestern investigating the role of yttrium-90 radioembolization in patients with prostate cancer. The next few years are going to be very exciting.

#### Disclosures

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