

Prostatic Artery Embolization for Benign Prostatic Hyperplasia

Sandeep Bagla, MD, discusses data, tools, training, and what is on the horizon for this procedure.



How would you summarize the clinical trial experience and results to date in prostatic artery embolization (PAE)? Where are we in terms of collecting key data, and what are the research milestones on the horizon?

Dr. Bagla: There have been a number of studies both in the United States and overseas that have looked at the safety and effectiveness of PAE in the treatment of benign prostatic hyperplasia (BPH). These have included retrospective, prospective, and randomized study designs. Research to date has demonstrated an excellent safety profile with very favorable clinical outcomes from PAE. When compared with standard treatments such as transurethral resection of the prostate, clinical improvement is also comparable.

Future milestones will include results from prospective United States studies that evaluate the safety of specific devices for use in PAE. This may lead to labeling changes for certain products and allow more widespread adoption and insurance coverage. Other studies on the horizon will include the cost effectiveness of PAE, parameters that predict favorable or poor outcomes, and potentially comparison of PAE to a placebo treatment.

In your experience treating patients throughout your own PAE trial and in discussing your colleagues' data and experiences, what are some critical lessons you have learned in proper patient selection?

Dr. Bagla: We have learned that the clinical evaluation of a patient with lower urinary tract symptoms is complex, and there are many overlapping syndromes. A detailed history and evaluation of the patient can allow for proper patient selection to ensure that we are tar-

geting symptoms from BPH and not another process, such as bladder instability or an overactive bladder.

Which questions are most pressing in terms of patient candidacy?

Dr. Bagla: It is critical to focus on key exclusion criteria, such as prostate cancer, history of neurogenic bladder, or advanced kidney dysfunction. Risk factors for vascular disease should also be assessed, as this may render a patient a poor candidate if the prostatic arteries are occluded or stenotic.

What are some of the unique challenges of prostatic artery and neighboring vessel anatomy? What don't we know about it?

Dr. Bagla: Unique challenges of the anatomy of the male pelvic arteries include severe tortuosity, small vessel size, and a rich collateral network. We have not traditionally spent much time evaluating this area aside from cases of trauma embolization. However, the growth of PAE has allowed for a renewed and detailed investigation of the anatomy. In particular, recognizing the collateral pathways and how they impact the safety of the patient and comfort of the intervencionist while performing embolization is critical.

How would you summarize the importance of cone-beam computed tomography (CBCT) in PAE? In what ways is it particularly useful in this evaluation/procedure?

Dr. Bagla: CBCT is an important problem-solving tool that undoubtedly improves the safety of PAE. It allows for the identification of sites of nontarget embolization, which is key to improving safety. It may depict collateral circulation or variant anatomy, and it

Highlight From SIR 2015: Favorable Results in PAE for BPH

At SIR 2015 in Atlanta, Georgia, Dr. Bagla presented results from a study showing the effectiveness of PAE in the setting of BPH.

Authors: J.B. Smirniotopoulos, MD; J.C. Orlando, MD; S. Bagla, MD

Patients: 78

Duration: January 2011 to July 2014

Analysis Groups by Enlarged Prostate Size: < 50 cm³; 50–80 cm³; > 80 cm³

Follow-Up: 1, 3, and 6 months

Technical Success: 96% (75/78)

Key Findings:

- Statistically significant improvement in symptoms and quality of life in all groups
- No difference in outcomes between groups
- Minor complications: groin hematoma (1), urinary tract infection (1)

Conclusion: "PAE appears to offer similar positive clinical benefits to 6 months in patients with varying gland size. Future study aimed at comparing recurrence rates and procedural differences is warranted."

can also allow for procedural planning, including overlay or fusion with CT angiography imaging.

What are the ideal characteristics of embolic options and delivery devices in this setting?

Dr. Bagla: Well-calibrated embolic agents are essential, because a reliable size is needed to ensure that operators are selecting and administering agents with confidence. Agents must be able to be administered through small, flexible microcatheters and preshaped/angled catheters that allow for navigation into the small distal target vasculature.

The delivery devices should also allow for excellent imaging ability and power-injector-compatible injections.

Have you identified any key unmet needs, technologically?

Dr. Bagla: With any novel procedure, there are always advancements in technology that are needed to grow with the maturity of the procedure itself. In

PAE, these will include more sophisticated embolic agents that can allow for real-time imaging and therefore potentially predict patient outcomes and safety. Navigational tools and manipulable catheters such as endovascular robotics may play a large role in the future of PAE.

What specific operator training and skill sets are needed?

Dr. Bagla: Interventional radiologists are well suited for PAE because of their knowledge of the space and advanced microcatheter skills. Training for the procedure and clinical evaluation of the patient should include well-organized proctoring programs, too. Operators should be skilled in the use of a variety of microcatheters and microwires, as well as selection and use of embolic agents. A proper understanding of the pelvic arterial anatomy is also critical, and the performance and evaluation of CBCT imaging is needed.

How would you describe potential complications one might encounter in PAE, based on trials and anecdotal experiences to date?

Dr. Bagla: One might encounter complications related to the arteriography, embolization, or postoperative clinical course. Close clinical follow-up is needed to evaluate all of these.

What factors are believed to contribute to late symptom recurrence in PAE cases?

Dr. Bagla: It is not known at this time what causes late recurrence. This is an area of ongoing investigation.

What is currently known regarding any potential effects on fertility?

Dr. Bagla: There are no known effects at this time. The prostate does produce fluid that supports the function of the sperm, but the effect of PAE on fertility is not known. Men have, however, successfully fathered children after PAE.

How long must the follow-up period be in order to further the validation of this technique?

Dr. Bagla: At least 2 years, as data from other studies are usually benchmarked at this time to evaluate for recurrence rates.

What would you like to see from the next trials in this field?

Dr. Bagla: Future trials should focus on the factors that predict better outcomes, including particle size selection and potentially preoperative imaging. Other

trials should focus on comparison to current minimally invasive urological options.

Do you envision a potential role for PAE in prostate cancer therapy?

Dr. Bagla: I do believe that because prostate cancer is hypervascular like BPH, embolization may have a role in the future. This may include downstaging patients with extracapsular spread or use in the treatment of patients with high risk for retention after brachytherapy. It may also be interesting to study PAE as a substitute for radiotherapy, which unfortunately has significant side effects both in the short and long term.

What advice would you offer on how to effectively approach urology colleagues, present this option, and collaborate on patient care?

Dr. Bagla: Patients are at the center of our mission, and we have put the focus here. We should work closely with urology colleagues to show them that we are not trying to eliminate their role in BPH and that we can offer a hand in managing complex cases. This can include small- or large-volume BPH or patients at a younger age with high reliance on sexual function or urinary function.

Ultimately, patients deserve to hear all options for therapy. ■

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RECOMMENDED READING

The Role of Prostatic Arterial Embolization in Patients with Benign Prostatic Hyperplasia: A Systematic Review

Schreuder SM, Scholtens AE, Reekers JA, Bipat S. Cardiovasc Interv Radiol. 2014;37:1198–1219.

Unilateral Versus Bilateral Prostatic Arterial Embolization for Lower Urinary Tract Symptoms in Patients with Prostate Enlargement

Tiago Bilhim T, Pisco J, Rio Tinto H, et al. Cardiovasc Interv Radiol. 2013;36:403–411.

Utility of Cone-Beam CT Imaging in Prostatic Artery Embolization

Bagla S, Rholl KS, Sterling KM, et al. J Vasc Interv Radiol. 2013;24:1603–1607.