Perspectives: PEVAR in Practice

Peter R. Nelson, MD, MS, FACS, and Benjamin W. Starnes, MD, FACS, share their insights on the learning curve, benefits, and considerations involved in choosing a percutaneous approach to EVAR.

PEVAR APPLICATIONS

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What are some benefits of the percutaneous approach to endovascular aneurysm repair (PEVAR) that you observe in your daily practice?

Dr. Nelson: The rationale for adopting PEVAR can be seen in its benefits for both patients and surgeons' practices. In terms of the patient experience, there is less pain and less concern for wound infection and other complications related to the incision itself. In our practice and experience, we have seen that procedure and anesthesia times can be shorter, and as a result, delivery of the stent graft is more efficient. We have also seen earlier discharge from the hospital, less pain medicine required, and faster return to normal activity.

Can PEVAR be broadly applied, or is it best targeted toward a specific group of patients?

Dr. Nelson: In the PEVAR clinical trial, certain patient groups were excluded, as is the case with most trials. The indication for bilateral PEVAR that the trial sponsor (Endologix, Inc., Irvine, CA) received from the US Food and Drug Administration reflects the inclusion and exclusion criteria of the trial. In my and others' personal experience, we have been able to apply PEVAR more broadly. For example, morbidly obese patients with BMI > 40 kg/m^2 were not included in the PEVAR trial, but we think this is one group in which PEVAR can potentially be most beneficial. Patients with a lot of soft tissue between their skin and their femoral artery usually require an incision that is much larger and exposure that is much more extensive than with a thinner patient; as a result, they may have a much higher rate of wound infection.

Patients in the PEVAR trial were included based on femoral artery anatomy, such as absence of anterior and circumferential calcification and posterior calcification under 50%. In practice, many experienced operators would still attempt and successfully accomplish EVAR with a percutaneous approach outside of these limits. In my practice, after performing PEVAR for some time, it has really become an "all-comers" approach with very few exceptions. Such exceptions might include patients with heavily, circumferentially calcified access arteries and those who have femoral artery aneurysms (which would likely be addressed surgically anyway).

Single-center series have shown safety in populations that fall just outside the trial inclusion.[1] Future trials should be aimed at further demonstrating the benefit of PEVAR in this expanded population.

With all that being said, when operators are first starting out with the PEVAR technique, it is prudent to be more restrictive in patient selection. Initially exhibiting caution in obese patients or those with evidence of calcification along the femoral and iliac vessels leading to the aneurysm will result in better outcomes as your experience grows.

What differences are there in the clinical course of a patient who undergoes a procedure with surgical cutdown versus one who undergoes a completely percutaneous procedure?

Dr. Nelson: From what we have seen in practice, procedure times are faster, there is less pain (and

therefore less need for pain medicine), and patients are getting out of bed and back to walking sooner. These differences may be subtle rather than dramatic for an individual patient; for example, a PEVAR patient may go home a half-day sooner than one who underwent femoral cutdown based on comfort with activity. But from a greater perspective, these small differences can add up to significant, system-wide advantages for PEVAR. The next thing we should look further into is whether or not PEVAR patients are back to full, unrestricted activity or even work sooner after discharge compared to femoral cutdown patients.

Are there any differences in the stent graft deployment?

Dr. Nelson: A delivery strategy that involves placement of an indwelling procedural sheath prior to delivery of the stent graft is ideal for PEVAR. Having fewer exchanges of large equipment through the femoral arteriotomy reduces the likelihood of disrupting the preclose-placed sutures. If a device is "sheathless," it can certainly be delivered percutaneously, but it will require placement of a secondary sheath in order to "plug the hole" in the femoral artery and maintain access. This needs to be factored into case planning and inventory decisions. With an open cutdown, you can manage the artery with your finger or vascular loops/clamps without another sheath because you have direct control.

Which specific devices were used in the PEVAR trial?

Dr. Nelson: The stent graft used in the PEVAR trial was the IntuiTrak Powerlink device (Endologix, Inc.). Endologix has now released the AFX system, but the trial began before that transition. The ipsilateral profile of the IntuiTrak iteration was 21 F; with the AFX, the sheath is now 17 F and even better suited for percutaneous delivery. The contralateral sheath of the AFX system is 9 F, which is ideal for PEVAR.

On the closure side, there were two devices from Abbott Vascular (Santa Clara, CA)—the Perclose ProGlide and the ProStar XL. Before the trial began, both devices had frequently been used in an off-label manner for some time. Operators had largely adopted one device or the other based on their own exposure and experiences, and both were ultimately included in the trial. There was a 2:1 randomization between percutaneous and standard EVAR to accommodate inclusion of both devices. Based upon the trial results, the Endologix endograft (AFX and Powerlink) and Abbott ProGlide systems have received on-label indication specific for PEVAR.

The data from this trial are pending publication, so we won't ask for specific details on the findings just yet. But, looking back over your experience with PEVAR, is there anything in particular you learned between Patient 1 and Patient 500 that you would like to share?

Dr. Nelson: With any new procedure or technology, not exceeding the threshold of your comfort level is important. With PEVAR specifically, a key element in the learning curve for me was establishing a degree of comfort in assessing the success of the closure procedure after deployment of the stent graft. Early on, I had a quicker tendency to convert to an open cutdown if I noted residual bleeding.

When beginning the procedure using the ProGlide device, two sutures are sequentially deployed at opposite angles, creating a crosshair-like configuration in the femoral artery, and then set aside. Correct placement at the beginning is critical to success at the end, so a compulsory approach to placing the sutures is warranted. After successful delivery and deployment of the stent graft, the preplaced sutures are cinched down in the same sequence upon removal of the delivery sheaths. Early in my experience, if there was any degree of bleeding, I often made a cutdown to fix the femoral artery because I assumed the sutures had not held. Many times, however, I opened the access to find that the sutures had largely held, and there was perhaps just a small residual hole that was not severe. Now, it is rare for me to cutdown. If there is residual bleeding following suture knotting, I leave the wire in, preserving the option to place another closure device if necessary. The cost of these devices is something we consider, so I will usually first slide a 7-F dilator up on the wire; if it goes right in, I know I have a hole that warrants closing with an additional device. If the 7-F dilator gets stuck at the level of the knots, I know the hole is smaller, and I'm usually comfortable removing everything, reversing the anticoagulation, and holding manual pressure. I always close the larger ipsilateral side first, so I still have the option of going up and over from the contralateral 9-F sheath to perform angiography and potentially address any problems. You then close the contralateral side. These strategies have been uniformly effective.

Having said that, if there is a lot of bleeding, and it is likely that the sutures pulled out, or if you are not happy with the perfusion to the extremity and suspect a problem at the femoral level, do not try to rationalize these cardinal signs—it is fairly obvious that a cutdown and arterial repair is necessary. Like most new minimally invasive techniques, it is important to

be committed to the approach but recognize failure and address it promptly and definitively. A short learning curve exists to develop this level of comfort with PEVAR. For those interested in getting started with or expanding their use of PEVAR, Endologix is offering a training program to teach the technique that was used in the trial and to discuss the trial results, patient selection, and troubleshooting in complicated cases.

1. Smith ST, Timaran CH, Valentine RJ, et al. Percutaneous access for endovascular abdominal aortic aneurysm repair: can selection criteria be expanded? Ann Vasc Surg. 2009;23:621-626.

TRAINING AND PRACTICE MANAGEMENT

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In your experience as the co-chair of a focused training program for PEVAR, how important is this training in achieving successful outcomes with this procedure? Does it help to shorten the learning curve?

Dr. Starnes: I believe this training is essential for anyone who seeks to successfully and safely convert their EVAR practice to a completely percutaneous one. The training program we have put together definitely shortens the learning curve by providing intense review of troubleshooting techniques and providing one-on-one training with hands-on device deployment. The Endologix PEVAR course has consistently been rated by attendees as the best training environment they have seen.

Is the program tailored differently for operators of various experience levels?

Dr. Starnes: Not really; it is an expectation that participants in this course have basic endovascular skills and are facile with EVAR. Someone without basic endovascular skills will likely derive no benefit from this intensive training.

How does PEVAR training benefit a vascular surgeon over other interventionists who don't perform open surgery?

Dr. Starnes: I believe that this course expands the knowledge base of percutaneous access and closure for surgically trained and non–surgically trained interventionists. Most of the vascular surgeons that we have trained have been impressed overall at how this technique has the potential to improve patient outcomes and shorten operative times. Most non–surgically trained interventionists have expressed to me that they now know exactly when to get a surgeon involved in a case due to difficult access.

What has been the effect of offering PEVAR at your hospital's vascular program?

Dr. Starnes: That's a hard question to answer because we have been doing this for more than a decade. We attempt just about everything using a totally percutaneous approach—EVAR, FEVAR, REVAR, TEVAR—it doesn't matter. I know the cutdown rate at our institution for a failed closure hovers around 5% or one out of every 20 access sites. When most of these patients have access in both femoral arteries, that means that one in 10 patients will require cutdown on one side. I believe that PEVAR has improved our patient outcomes overall and decreased complication rates, especially for patients who are morbidly obese and have had prior femoral surgical exposure.

Have any analyses been done regarding the cost efficiency of PEVAR versus using a cutdown approach?

Dr. Starnes: Experience to date suggests reduction in procedure and anesthesia time and showed a trend toward shorter hospitalizations. All of this conceivably translates into real cost savings and offsets the cost of the closure devices. We discuss these issues during the training course.

Is your preprocedure discussion with the patient any different with PEVAR?

Dr. Starnes: No, I tell my patients that if the sutures don't work, we do what would be the default anyway—widen the incision a little bit to directly repair the artery. Honestly, patients are not really concerned about this. They just want their aneurysm fixed!

Have patients exhibited a preference when presented with the available options?

Dr. Starnes: When patients understand the alternatives, they uniformly choose the less-invasive technique. I don't even offer surgical cutdown as a first option; I only use it if it is needed as a backup. ■