

20 Years of PEVAR, 20 Questions With Zvonimir Krajcer, MD, FACC

One of the pioneers in percutaneous endovascular aneurysm repair shares thoughts on the early days of the procedure, how it has evolved over 2 decades, and what may come next.



What factors led early enthusiasts of percutaneous endovascular aneurysm repair (PEVAR) away from the traditional surgical cut-down, toward a totally percutaneous approach?

It was Dr. Juan Parodi's seminal work and introduction of EVAR in 1990 that stimulated me to search for a less-invasive way to perform EVAR. We knew that the patients with abdominal aortic aneurysms and comorbid conditions were at high risk for complications with the use of general anesthesia and surgical femoral artery repair. Thus, out of necessity, we initiated the PEVAR procedure in high-risk patients in June 1996 by using a totally percutaneous approach and local anesthesia.

Were benefits immediately seen in terms of reduced procedure time, hospital stay, and wound complications, or did these findings emerge gradually?

We saw immediate benefits in all our patients by avoiding many of the side effects of general anesthesia and complications encountered after surgical femoral artery access and repair. Almost from the beginning, we implemented a protocol wherein all PEVAR procedures were performed in the cardiac catheterization laboratory, and post-PEVAR care was given on the interventional floor rather than in the more costly operating room and intensive care unit. The patients were allowed to eat 1 hour after the procedure and ambulate within 6 hours. Most of them were discharged from the hospital 24 hours after the procedure. We defined this as a "fast-track" PEVAR protocol.

In your opinion, what did PEVAR's emergence mean for patient candidacy?

This approach offered a great majority of our patients a less-risky procedure with good outcomes, lower incidence of complications, and speedier recovery.

Where do we stand in terms of proven results shown in studies and clinical trials, and which areas still require further study?

I am very appreciative that several EVAR device manufacturers saw the significant benefits that this approach offered to our patients in our early PEVAR results and publications. Later on, many investigators published information that also revealed encouraging results. However, there were still many nonbelievers, and it was obvious that the PEVAR results had to be validated in a randomized multicenter trial. We helped initiate Endologix's PEVAR trial to validate our and other investigators' preliminary results with this approach. The PEVAR trial results were published in the *Journal of Vascular Surgery* in 2014 (see article by Nelson et al in recommended reading list) and revealed that the incidence of vascular complications 30 days after the procedure was lower with PEVAR than with surgical femoral artery access and repair. However, this study was not powered to evaluate the benefits of local anesthesia during PEVAR.

The recently completed LIFE (Least Invasive Fast-Track EVAR) registry (also sponsored by Endologix, Inc.) proved that PEVAR with local anesthesia offers significant benefits, including reduced length of hospital stay and a lower incidence of complications than general anesthesia and surgical femoral artery access and repair. The midterm results of this study will be published in the

next few months, and the final results will be presented at VIVA 2016. I do not believe that there is a need for any other study to validate the benefits of PEVAR.

What is the most common complication specifically related to PEVAR, and how is it best handled?

The most common complication of PEVAR is suboptimal femoral artery hemostasis, which occurs in 4% to 6% of cases. However, most if not all of the access site complications can be avoided by proper patient selection, meticulous access technique, and increased operator expertise. The majority of access site complications can be treated with endovascular techniques—surgical intervention is rarely needed. It should be noted, however, that the availability of surgical backup and blood transfusion is required in case of emergencies.

What did PEVAR face in terms of early skepticism or detraction?

At the beginning, a lot of operators were intimidated by this approach, as there was a significant learning curve required with the use of the first suture-mediated closure device (SMCD) on the market. However, the introduction of the “preclose” technique has made it easier to perform PEVAR with a significantly shorter learning curve. Also, a lot of surgical operators were not used to performing these procedures with local anesthesia and conscious sedation. We have been working enthusiastically to train many operators in the PEVAR technique and show them the benefits of this approach. We have personally trained more than 1,000 physicians on the PEVAR technique at various courses at our institution. However, at this time, the use of SMCDs is not reimbursable, whereas surgical femoral artery repair is reimbursable.

Although acceptance for PEVAR continues to rise, what are the remaining barriers to more widespread adoption?

We live in the era of rising hospital expenditures, and for this reason, cost-saving measures are important. Current-generation SMCDs are somewhat costly and, as previously mentioned, are not reimbursable. Efforts need to be made to allow reimbursement for percutaneous femoral artery repair, as this approach is rapidly becoming the standard of care for large-bore sheath use. Although current SMCDs offer satisfactory results when used by experienced operators, they have to be used in a modified or so-called preclose fashion. There is definitively a need for dedicated percutaneous closure devices for large-bore access sites. Several devices are currently being evaluated outside of the United States for this

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application, and a trial studying the Manta large-bore vascular closure device (Essential Medical, Inc.) will begin soon in the United States.

Where can interested operators learn the technique in a hands-on fashion?

There are many observational courses available nationwide by several EVAR device manufacturers. We also offer these courses on a monthly basis at the Texas Heart Institute in Houston, Texas.

Which facet of the technique has evolved the most over the last 20 years?

We have performed more than 2,000 PEVAR procedures and used over 6,000 SMCDs for large-bore access. There are multiple details that help us to achieve safe access site repair. The most important of these include proper CT analysis of the access site to determine the patient's suitability for the use of a SMCD. Patients with extensive anterior wall calcifications are not good candidates for PEVAR. The second most important detail is the use of ultrasound while gaining access with a micro-puncture kit. We always perform access site angiography to decide if the location of the access site is appropriate for PEVAR.

How have closure methods changed since the original procedure?

Originally, in 1996, we used the Prostar XL device (Abbott Vascular), and then the Perclose ProGlide device (Abbott Vascular) became available in 2004. In our experience, both devices work well; however, we prefer the use of Prostar XL for large-bore sheaths > 16 F. One Prostar XL works very well for access sites up to 24 F, whereas at least two ProGlide devices are necessary for large-bore access > 18 F.

What technologic advancements in closure devices would you most like to see for even better results?

In the near future, there will be several dedicated closure devices available for large-bore femoral artery

closure both outside of and in the United States. One of them is the previously mentioned Manta device, and we are glad to be participating in the US Food and Drug Administration investigational device exemption trial in the near future. This device has shown excellent results in the European study.

How has the learning curve for PEVAR changed since the early days?

With the introduction of ProGlide, the learning curve has been shortened. It is recommended that those who use SMCDs familiarize themselves with the technical details and select the best possible cases at the beginning of their experience with PEVAR. It should be mandatory that they observe several cases and receive proper training from the device manufacturers prior to introduction of PEVAR at their institution.

With all of the patient comfort aspects associated with this approach, do you find that patients seek this procedure out specifically? In other words, how well known is this option in the public/patient realm?

A great majority of my EVAR patients are referred to me because of their comorbid conditions. These patients and the referring physicians are well aware of the benefits of less-invasive EVAR. This technique has been well publicized on the web, in several publications, and at vascular and endovascular meetings.

The degree of access site calcification, vessel diameter, presence of scar tissue, as well as the patient's body mass index, are all critical factors in the success of the procedure. Do you feel these are "contraindications" for which patients should be excluded from this approach, or are there ways to overcome these challenges, at least in some cases?

All of the mentioned access site problems add to the complexity of the procedure. Operators who are just embarking on the PEVAR procedure should follow the above contraindications. However, at our institution, we consider many of them more as challenges rather than absolute contraindications to PEVAR. Over the last 2 decades, we have learned how to overcome some of these obstacles and how to avoid and treat complications with endovascular approaches.

When should an operator bail out to a femoral cutdown approach?

The most common causes for a surgical bailout include suboptimal hemostasis due to failure of an

SMCD, severe access site stenosis, vessel perforation, vessel laceration, and vessel avulsion.

In what ways can the specific aortic anatomy of the patient make a difference in whether PEVAR is a good choice for treatment?

Patients who have very challenging aortic anatomy that will require a prolonged procedure, such as chimneys or fenestrated grafts, might not be good candidates for PEVAR. Also, patients who are uncooperative or have severe lower extremity ischemia might also not be good candidates for PEVAR with local anesthesia and conscious sedation.

What are your protocols for postprocedure access site management?

My protocol for postprocedural access site management is the same as any other endovascular procedure via the femoral approach. The patients normally eat within a few hours after the procedure and ambulate after 4 hours. In general, we do not use sandbags unless there is access site bleeding or hematoma. After PEVAR, we start all of our patients on 75 mg of clopidogrel and 81 mg of aspirin for 1 month.

Does this approach afford economic benefits to the hospital/health care system?

In the recently completed LIFE study, we were able to show that completion of the fast-track EVAR protocol was associated with a potential perioperative cost savings of \$5,300 due to reduced procedural time and length of hospital stay compared to national benchmarks of hospitals performing EVAR.

The preliminary data from the LIFE study demonstrate improvement in procedure time and length of hospital stay as compared to the nationwide benchmark of hospitals performing EVAR (see the first article in the recommended reading list for more information). Additional variables to be collected include costs related to anesthesia, access method, and 30-day EVAR reinterventions.

What are five must-read articles for those interested in PEVAR?

I will do you one better. Here is a list of my top six recommended articles:

- Al-Khatib WK, Zayed MA, Harris EJ, et al. Selective use of percutaneous endovascular aneurysm repair in women leads to fewer groin complications. *Ann Vasc Surg.* 2012;26:476–482.
- Bechara CF, Barshes NR, Pisimisis G, et al. Predicting the learning curve and failures of total

percutaneous endovascular aortic aneurysm repair. *J Vasc Surg*. 2013;57:72–76.

- Georgiadis GS, Antoniou GA, Papaioakim M, et al. A meta-analysis of outcome after percutaneous endovascular aortic aneurysm repair using different size sheaths or endograft delivery systems. *J Endovasc Ther*. 2011;18:445–459.
- Hass PC, Krajcer Z, Dietrich EB. Closure of large percutaneous access sites using the Prostar XL percutaneous vascular surgery device. *J Endovasc Surg*. 1999;6:168–170.
- Krajcer Z, Strickman N, Mortazavi A, Dougherty K. Single-center experience of percutaneous abdominal aortic aneurysm repair with local anesthesia and conscious sedation: technique and results. *J Cardiovasc Surg (Torino)*. 2012;53:695–706.
- Nelson PR, Krajcer Z, Kansal N, et al. A multi-center, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). *J Vasc Surg*. 2014;59:1181–1193.

What do you see as the next level for EVAR to transcend?

The new generation of endografts will be more durable, lower profile, easier to use, and more applicable in challenging anatomy. ■

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