The Preclose Technique for AAA Repair

A promising technique for achieving improved outcomes in percutaneous endovascular repair of abdominal aortic aneurysms.

BY ZVONIMIR KRAJCER, MD

Totally percutaneous endovascular abdominal aortic aneurysm repair (PEVAR) using the preclose technique via femoral artery access with local anesthesia and conscious sedation has evolved during the last decade. This technique is used to avoid the complications of surgical common femoral artery (CFA) repair and the use of general anesthesia.[1]

VASCULAR CLOSURE DEVICES FOR CFA REPAIR

There are two commercially available devices that have been tried extensively for CFA percutaneous repair during endovascular abdominal aortic aneurysm repair (EVAR) procedures: the Prostar XL (Abbott Vascular, Santa Clara, CA) and Perclose ProGlide (Abbott Vascular). The Prostar XL has been commercially available in the European Union since 1994 and in the United States since 1998. Prostar XL is approved for closure of up to 10 F, and the 6-F ProGlide can be used for up to 8-F CFA access sites. Neither device is approved in the United States in a preclose fashion for large-bore CFA access sites. However, in the European Union, Prostar XL is approved for use in the preclose fashion for up to 24-F access sites. The Prostar XL suture-mediated closure device is designed to deliver four 3-0 braided nonabsorbable polyester sutures. Two green and two white sutures are delivered in a diagonal pattern by using four nitinol needles, which are directed through the anterior arterial wall from inside out. The needles and sutures are advanced through the barrel of the delivery system and are removed from the back end of the Prostar XL housing using hemostats. Each needle is then cut from the suture, the closure device is partially withdrawn from the artery, and the suture ends are retrieved. The sutures can then be tied in a conventional sliding knot technique.

The ProGlide device consists of a monofilament suture and two stainless steel needles that capture the sutures during deployment. This device has a pretied sliding knot housed in the device, which offers easier closure and a shorter learning curve to gain expertise.

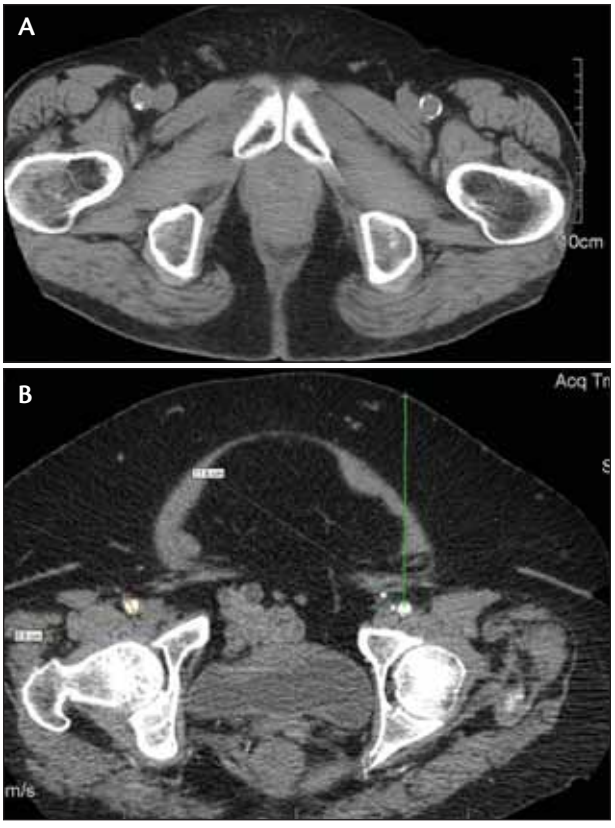

Figure 1. CT image of the femoral artery access site (A). Extensive femoral artery calcification, especially circumferential, contraindicates percutaneous access and repair. CT image of the femoral artery access site reveals severe obesity and 11-cm distance from the skin to the femoral artery (B).

PREPROCEDURAL IMAGING

Preprocedural imaging is essential to determine the suitability of patients for PEVAR and should include

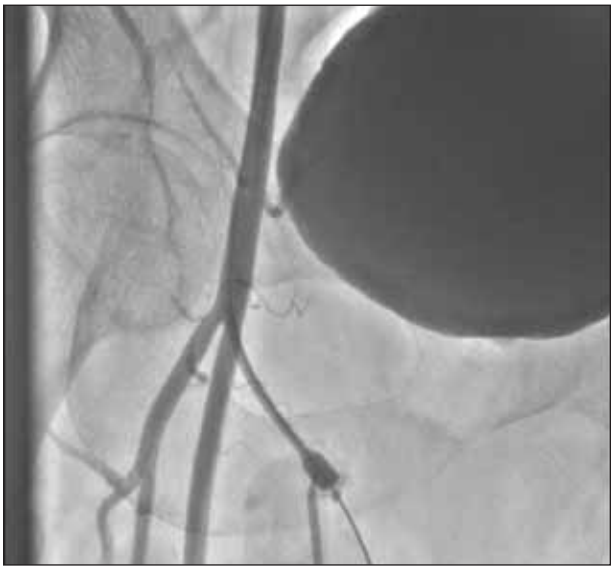

Figure 2. Femoral artery angiogram in a right anterior oblique view showing the access site. Such an image enables the clinician to determine the feasibility of percutaneous CFA repair.

duplex ultrasonography and spiral computed tomographic (CT) angiography of the CFAs. The femoral artery access sites should be inspected for calcification, distance from the skin to the CFA, and the vessel diameter (Figure 1). Extensive anterior wall CFA calcification might not allow deployment of the Prostar XL or ProGlide needles and sutures and is considered a contraindication to PEVAR. Other contraindications to PEVAR include < 7-mm CFA diameter, morbid obesity, coagulopathy, CFA aneurysm, excessive scarring at the arterial access site, and arterial conduits.

PERCUTANEOUS FEMORAL ARTERY ACCESS FOR PEVAR

The patient is prepared, and the abdomen and both groins are draped in a sterile surgical fashion. Through a 22-gauge needle, the subcutaneous entry tracks of both inguinal areas are generously infiltrated with 20 mL of 1% lidocaine to provide local anesthesia for the femoral access sites.

To obtain optimal CFA access, arterial entry is usually achieved with a 21-gauge micropuncture kit needle. Angiography can be performed through this needle to identify the site of arterial entry. If the arterial entry is too high or too low, the micropuncture needle is removed, and another attempt is made in a more appropriate location. Anything other than anterior arterial wall entry, or "side stick," is a contraindication for using the preclose technique because it will frequently lead to suboptimal arterial repair. A Doppler needle and

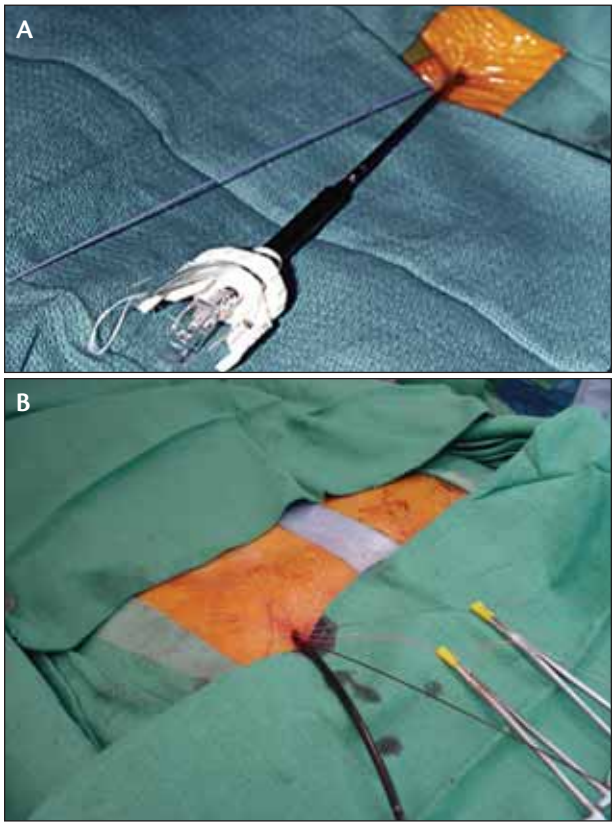

Figure 3. The preclose technique for EVAR. A 10-F Prostar XL is advanced in a monorail fashion over a 0.035-inch wire into the CFA, and the needles are deployed (A). Two green and two white sutures are secured with hemostats (B). The Prostar XL device is then removed over the wire.

duplex ultrasound guidance should be used for patients in whom CFA access is difficult. This is particularly important in obese patients. Once bilateral CFA access is obtained, a femoral artery angiogram is obtained in a 30° anterior oblique view to appropriately visualize the exact site of entry and to determine the feasibility of PEVAR (Figure 2). A 6-F sheath is then introduced over the wire into the CFA. The incision above the CFA access sites is widened with a scalpel to 1 cm, and the subcutaneous tissues are bluntly dissected with a hemostat. Then, 3,000 units of heparin is administered intravenously.

ORIGINAL CFA PRECLOSE TECHNIQUE WITH PROSTAR XL

In 1999, we described the use of a Prostar XL percutaneous suture device in a preclose fashion for percutaneous closure of femoral artery access sites during EVAR.[2] The outside diameters of stent graft delivery systems previously ranged from 20 to 27 F for the main

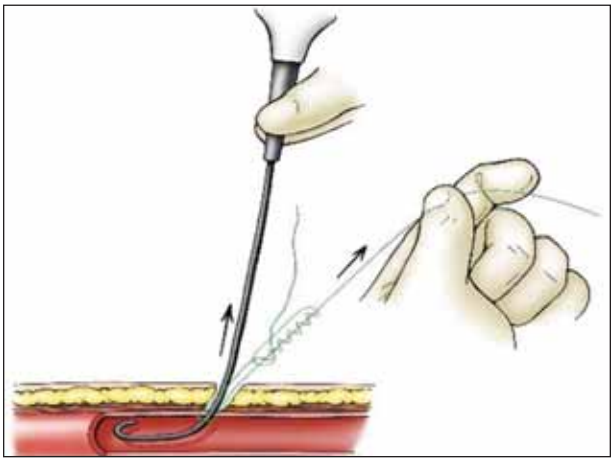

Figure 4. The sliding knot technique is used to complete the procedure. The Prostar XL is used to tie the sutures.

body and from 9 to 18 F for the contralateral iliac limb. Because of the large profile of these sheaths and delivery devices for EVAR, most of the investigators practicing the preclose technique originally used two Prostar XL devices during PEVAR. To perform total PEVAR with the 10-F Prostar XL device, the sutures are deployed before the large-bore sheath is inserted by using a preclose technique (Figure 3A).

Our original preclose technique consisted of using two Prostar XL devices for 16-F and larger-bore sheaths and one Prostar XL device for 12- to 14-F sheaths. When using two Prostar XL devices, the second 10-F Prostar XL device is deployed after it is rotated 60° in relation to the first device. The preclose technique requires that two white and two green sutures are left untied and are secured with hemostats until the stent graft is deployed (Figure 3B). Once the Prostar XL sutures are delivered to both CFAs, additional heparin is given to maintain an activated clotting time of 200 to 225 seconds. The CFA is then progressively dilated with 14-, 16-, and 18-F hydrophilic vessel dilators (Cook Medical, Bloomington, IN) before the endograft delivery system or appropriate size sheath is placed. After satisfactory completion of the procedure, the subcutaneous tissues surrounding both CFA sheath entry sites are infiltrated with 10 mL of 1% lidocaine with epinephrine (1:100,000). A 0.035-inch super-stiff hydrophilic wire (Glidewire, Terumo Interventional Systems, Inc., Somerset, NJ) is then introduced through the sheath and advanced into the abdominal aorta. A matching-diameter dilator (Cook Medical) is then introduced over the wire into the sheath. The dilator allows better transition between the sheath and the guidewire during removal of the sheath and better advancement of the sliding knot to the arteriotomy.

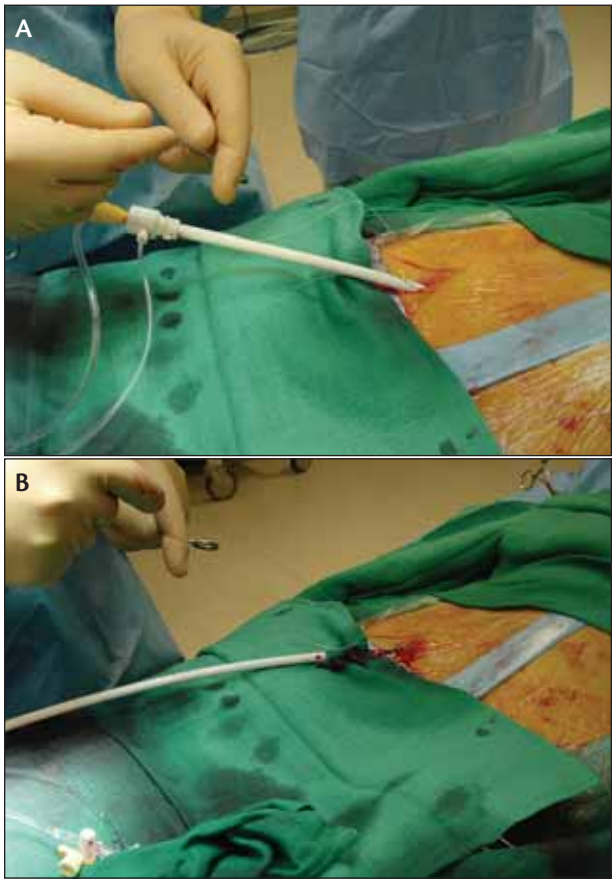

Figure 5. The sliding knot is advanced through the subcutaneous track to the CFA access site (A). The sheath and dilator are removed, leaving the 0.035-inch hydrophilic guidewire in the CFA (B). With a knot pusher, sutures are advanced and further secured to the CFA. The 0.035-inch hydrophilic wire is removed once satisfactory hemostasis has been obtained.

The Prostar XL sutures are then generously soaked in heparinized saline. Two green sutures are tied using the sliding knot technique; the same process is also used for the two white sutures (Figure 4). This is achieved by holding the rail end of the suture while making five loops around the rail with a nonrail end of the suture and sliding the nonrail end through a loop. After the green and white suture rails are secured with hemostats, the sheath can be gradually removed while holding the hemostats with both rail sutures (Figure 5A). The sheath and dilator should be slowly pulled out of the CFA while the 0.035-inch hydrophilic guidewire remains in the CFA (Figure 5B). By pulling on the rails of each suture, the sliding knots are advanced through the subcutaneous tract to the CFA access site. Once adequate hemostasis is achieved, the 0.035-inch hydrophilic guide wire is removed, and a Prostar XL knot pusher (Abbott

Vascular) is used to further advance and tighten the knots at the CFA entry site.

After satisfactory hemostasis is achieved, the sutures are cut, the 1-cm incision is closed with a single subcuticular stitch, and Steri-Strips (3M, St. Paul, MN) are placed on the skin and over the incision (Figure 6). Both CFA entry sites are covered with a sterile, nonadhering pad and clear dressing. The patient remains on bed rest with 30° head elevation for 4 to 6 hours, after which they are allowed to ambulate under observation. Patients are usually discharged from the hospital the next day.

CURRENT PRECLOSE TECHNIQUE WITH PROSTAR XL

For the last 7 years, at our institution, only one 10-F Prostar XL has been used for all sheath sizes. This technique is simpler, faster, and equally effective in achieving hemostasis as the original technique with two Prostar XL devices. Currently, some of the commercially available EVAR devices can be introduced via a percutaneous femoral artery approach (AneuRx Expedient [Medtronic, Inc., Minneapolis, MN], Talent [Medtronic, Inc.], Endurant [Medtronic, Inc.], and Powerlink [Endologix, Inc., Irvine, CA]), whereas others are introduced into the femoral artery via proprietary sheaths (Zenith [Cook Medical] and Excluder [Gore & Associates, Flagstaff, AZ]). Our experience, and the experience of other investigators using Prostar XL in preclose fashion, revealed equally good results as with ProGlide. The preclose technique with the ProGlide requires the use of at least two devices for any sheath sizes larger than 10 F, whereas one Prostar XL device is sufficient for repair of access sizes up to 24 F. In our experience, almost all patients with adequate-diameter CFAs are candidates for PEVAR. Proper evaluation with duplex ultrasound to access the CFA and to avoid anterior wall calcification has increased our population of candidates for PEVAR. In morbidly obese patients, access and preclose can be achieved by compressing the adipose tissue at the access site or by slightly enlarging the incision to be able to advance the 10-F Prostar XL deeper into the subcutaneous tissue. Access sites with extensive scarring from previous surgery or intervention are approached with more aggressive blunt dissection with the hemostat or scissors. In our experience using the previously mentioned techniques, 97% of EVAR patients are considered suitable candidates for the preclose technique with the Prostar XL device.

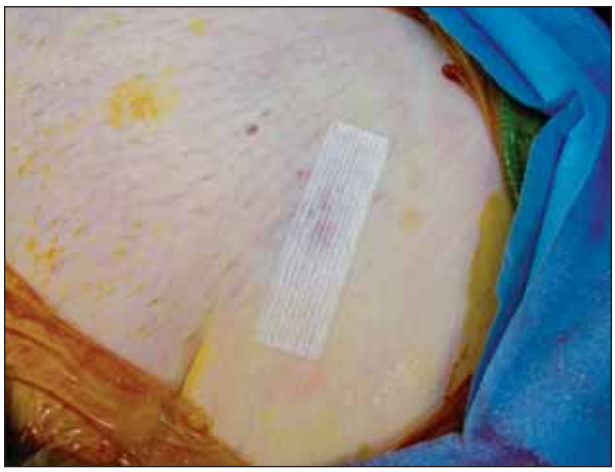

Figure 6. The Prostar XL sutures are then cut, and a Steri-Strip is applied to the CFA access site. A nonadhering pad and clear dressing are placed over these strips.

RESULTS WITH THE PRECLOSE TECHNIQUE USING THE PROSTAR XL

Haas et al[2] published the first United States clinical feasibility report of PEVAR with the Prostar XL device in 1999. Since then, several investigators have described the feasibility and safety of PEVAR in prospective and

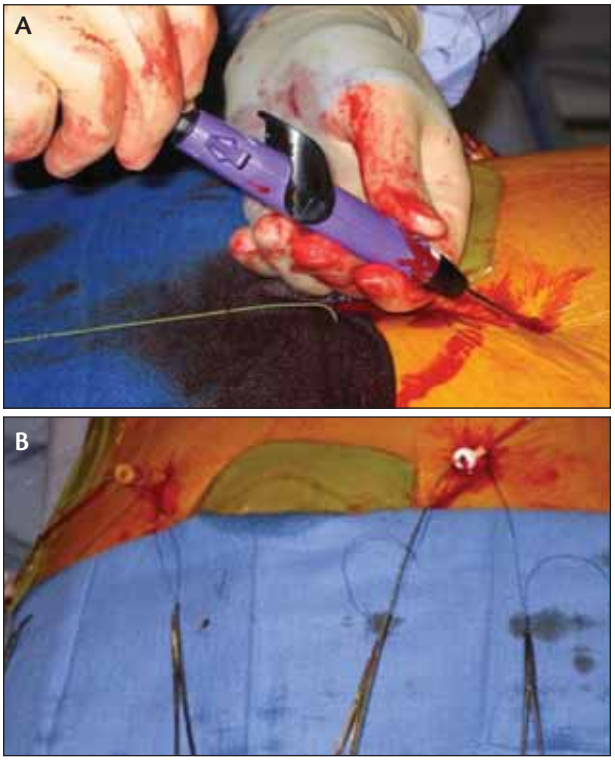

Figure 7. The deployment technique of the first ProGlide device, which is advanced over 0.035-inch guidewire (A). After the guidewire is removed, the ProGlide is advanced until the pulsatile bleeding from the side port occurs. The device is then rotated 30º medially, and the sutures are deployed. The second ProGlide device is then deployed at a 60º angle from the first device. An image of a preclose technique using ProGlide after the needles of two ProGlide devices are removed, and the pretied knots and the sutures of both devices are secured with hemostats (B).

retrospective single-center studies. Several single-center observational studies revealed that the technical success rates range between 63% and 92%.[3-10] Among these reports, percutaneous failure and conversion to surgical femoral artery repair were primarily related to inadequate hemostasis. These reports also indicated that physician experience and preprocedural CT scan assessment of the iliofemoral vessels are considered important in assessing the presence of severe calcification and tortuosity.

We have previously reported procedural outcomes in two nonrandomized, observational reports.[3-5] In the first report, technical success was achieved in 136 of 144 patients (94%). In the second report, the comparison between bilateral PEVAR and a surgical femoral artery repair with general anesthesia in 96 patients revealed a technical success rate of 93% for the preclose technique. This study, which used a 22-F sheath, also revealed a significant reduction in the procedure time (105 ± 21 min vs 171 ± 33 min; $P < .0001$) and estimated blood loss (91 ± 50 mL vs 383 ± 410 mL; $P < .0001$) with PEVAR versus surgical repair, respectively. No blood transfusions or postprocedure groin complications occurred in this study.

Morasch et al also published a retrospective study of their experience with PEVAR and reported significant reduction in procedure time (139 vs 169 min; $P = .002$) and anesthesia time (201 vs 225 min; $P = .008$); however, estimated blood loss was similar.[6]

Torsello et al published the only prospective, randomized study of PEVAR versus surgical femoral artery repair, which involved 30 patients.[7] Compared to open femoral artery repair, PEVAR patients had significantly reduced procedure time (87 ± 27 min vs 108 ± 39 min; $P < .05$) and time to ambulation. However, the authors suggest that obesity is an important risk factor for PEVAR and conclude that their study supports the relative benefits of PEVAR in a controlled environment with an experienced operator.

Starnes et al more recently reported on the use of Prostar XL with the use of intraoperative ultrasound guidance to achieve successful PEVAR access.[8] Successful closure in their studies was achieved in 94% of access sites. They concluded that PEVAR can be performed in all patients, excluding only severe occlusive or aneurysmal disease of the common femoral arteries.

PRECLOSE TECHNIQUE WITH PROGLIDE

Because of the preformed knot, monofilament suture, and the more common use of the ProGlide device after interventional procedures, deploying the needles and sutures of a percutaneous closure device without tying the knots and advancing the knots to the arteriotomy until the completion of the EVAR procedure is now more commonly used for the preclose technique. The preclose technique using ProGlide requires the use of two devices for sheath sizes larger than 10 F (Figure 7A). Some of the investigators advocate the use of three ProGlide devices for sheaths larger than 22 F. The technique consists of deploying the needles of the first ProGlide device 30º medially or laterally from the midline. The second ProGlide needles are then deployed at a 60º angle from the first device, and the pretied knot and sutures of both devices are then secured with hemostats (Figure 7B). This technique is repeated for each CFA access site. The rails of both ProGlides are then pulled at the end of the procedure, as described in the Prostar XL technique, and the sliding knots are gradually advanced to the arteriotomy to achieve

hemostasis. It is important for the guidewire to remain in the artery until satisfactory hemostasis is achieved.

RESULTS WITH THE PRECLOSE TECHNIQUE USING PROGLIDE

Lee and colleagues reported their experience in a retrospective review of 209 patients who underwent EVAR. There were 101 PEVAR patients and 108 surgical femoral artery repair patients between 2004 and 2006 using commercially available devices.[9] They report that their technical success was similar among the two groups (89% vs 91%). The access-related complications were associated with obesity, device malfunction, severe calcific disease, or technical error; however, procedure time was significantly shorter in the PEVAR group (115 vs 128 min; $P < .001$).

TREATMENT OF SUBOPTIMAL HEMOSTASIS

If there is evidence of suboptimal hemostasis at the arterial access site, Thrombi-Gel (Vascular Solutions, Inc., Minneapolis, MN) can be packed into the subcutaneous tract, and manual compression should be performed for 5 to 10 minutes to achieve hemostasis. The effect of heparin is reversed with protamine in cases of access site bleeding. In cases of minor bleeding or hematoma, a 2.26-kg sandbag is placed on each entry site for 4 hours.

In cases of suboptimal hemostasis, after reversing the effect of heparin with protamine and the local application of Thrombi-Gel, a FemoStop (St. Jude Medical, Inc., St. Paul, MN) compression assist device can be applied to the access site at 40 mm Hg for 2 to 4 hours. In case of suboptimal hemostasis, another ProGlide or Prostar XL device can be advanced and deployed over the wire. When the previously described measures fail and the guidewire is still in the femoral artery, a dilator and a sheath of appropriate size can be reintroduced to control the bleeding. This is followed by surgical CFA repair with local anesthesia and conscious sedation. If the guidewire has been removed and the bleeding continues, direct manual compression can be maintained over the CFA until surgical exposure and repair is achieved.

CONCLUSION

Current evidence indicates that the primary benefit of PEVAR is the reduction in surgical wound complications, associated morbidity, and patient discomfort. In addition, PEVAR offers an alternative treatment, which is of significant importance to patients with comorbidities that are recognized risk factors for general anesthesia. However, several investigators caution that PEVAR is highly dependent on appropriate patient selection. Preprocedural CT is mandatory to evaluate iliofemoral artery diameters, vessel tortuosity, and severity of arterial calcification. We also caution that physician experience with both EVAR and percutaneous techniques are essential to good procedural outcomes. The immediate availability of an operating room and a vascular surgery team is of importance in the event of procedural complications regardless of physician specialty, experience, or skill. The US Food and Drug Administration–approved multicenter, prospective, randomized PEVAR trial, a study to evaluate access-related complications and clinical utility outcomes among patients undergoing EVAR via a percutaneous approach compared to a cutdown vascular access approach, is currently underway in the United States.[10] We hope that this trial will validate the benefits of PEVAR techniques, particularly for patients in whom general anesthesia poses a high risk. ■

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