Preclosure for PEVAR

This technique can be applied in a majority of AAA patients.

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Since the introduction of endografts in the early 1990s by Volodos and Parodi,[1] the treatment of abdominal aortic aneurysms (AAAs) has shifted dramatically from open surgery to endovascular repair (EVAR). The number of endovascular AAA repairs in the past 10 years in the United States has risen from 5.2% to 74% of total AAA repairs.[2] Key to success in EVAR are the newer-generation devices with smaller profiles and lower rates of secondary intervention and aneurysm-related mortality.[3] With the expansion of indications for endovascular treatment thanks to the availability of fenestrated and branched devices, the rate of open versus EVAR reconstruction is decreasing further.

Standard access for EVAR in most centers is done via bilateral open surgical cutdown of the common femoral artery in the groin. Exposure is done by vertical or oblique skin incision. Although a minor surgical procedure, this cutdown is inherently associated with a low degree of complications, such as groin hematoma, lymphocele, intimal dissection, femoral nerve injury, delayed wound healing, and infection.[4,5] The induced scar tissue can hamper future access to the groin.

By lifting EVAR to a percutaneous level, we can even further reduce the degree of invasiveness of AAA treatment. Percutaneous endovascular aortic aneurysm repair (PEVAR) using the preclose suture technique via femoral artery access has become more popular in recent years. Two commercially available devices are reported in the literature for percutaneous closure of large-sheath access via the common femoral artery (CFA): Perclose ProGlide (Abbott Vascular, Santa Clara, CA) and Prostar XL (Abbott Vascular). Technical success rates of up to 98% are reported in the literature, with improvement over time.[6,7] The ProGlide system seems to have better outcomes than the Prostar,[8] and ProGlide is also the closure device we use as our standard approach for EVAR procedures.

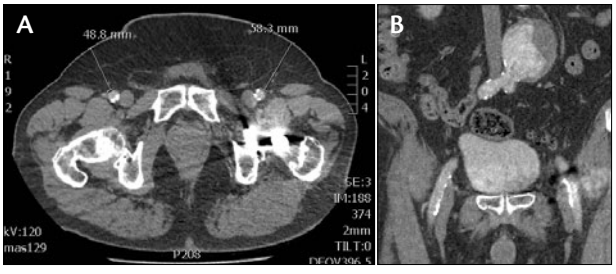

Figure 1. CT angiogram of a 78-year-old man with an infrarenal AAA suitable for EVAR. Transversal (A) and frontal (B) planes show a minor posterior wall calcification of the right CFA and considerably more calcification of the left CFA. PEVAR was performed in this patient, with delivery of the main body of the endograft via the right groin and the contralateral limb via the left groin.

ACCESS CONSIDERATIONS

An evaluation of the CFA should be made on the preoperative CT angiogram (Figure 1). Make sure you have a good, accessible depth, length, and diameter of the CFA. Puncture above the inguinal ligament augments the chance of unidentified retroperitoneal bleeding; puncture below the femoral bifurcation can lead to a vascular complication, such as occlusion.

The degree of calcification is the most critical determinant of technical success.[9-11] Circumferential or anterior wall calcification is an exclusion criterion, as the needles of the closure device will bounce off of the calcium, making percutaneous closure impossible.

Relative contraindications are a small vessel diameter, morbid obesity, and scar tissue.[9,11] Extreme external iliac artery tortuosity could make introducing or reintroducing the ProGlide device difficult and should be taken into consideration as well. Ultrasound-guided puncture can be used for the avoidance of calcified/atheromatous plaques,

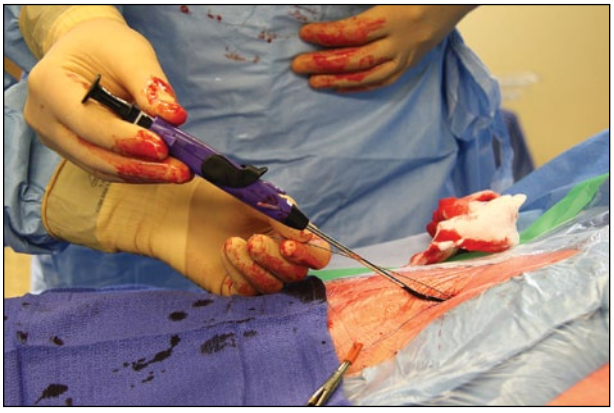

Figure 2. The ProGlide device is advanced over the guidewire in the right groin. Mark the clamp on a pair of sutures of an already-deployed ProGlide device. The second device will be deployed with a 60° rotation in a crosshair configuration from the first device.

for determination of the femoral bifurcation, or in obese patients. This technique could likely prevent possible access problems.[12,13]

STEP-BY-STEP DESCRIPTION OF THE TECHNIQUE

Step 1: Puncturing the CFA

The percutaneous approach is feasible under local anesthesia,[14,15] but in our institution, all EVAR procedures (standard EVAR, fenestrated EVAR [FEVAR], and thoracic EVAR [TEVAR]) are done under epidural or general anesthesia. No matter the level of experience, you can never completely rule out a technical failure of the preclosure technique, and you need to be prepared to do a surgical cutdown, in which case local anesthesia can be a burden. We believe that these percutaneous procedures need to be performed in a surgically equipped room with adequate lighting.

At the beginning of the procedure, the patient is prepared, and the lower abdomen and groins are draped in a sterile surgical fashion. After localization of the appropriate puncture site (depending on the appropriate anatomical landmarks, preoperative CT scan, and ultrasonography), a skin incision (vertical/oblique) of 1 to 2 cm is made, and the anterior wall of the CFA is punctured at a 45° angle. Side or posterior wall punctures should be avoided because this will lead to technical failure of the closure device. If thought necessary, appropriate puncture can be documented with ultrasound or angiographically in an oblique projection.[8]

A 0.035-inch guidewire is engaged, and the dilator of a 6-F sheath is used for predilatation of the subcutaneous tissue and vessel wall. In obese patients or patients with scarred tissue, it may be necessary to bluntly dissect the subcutaneous tissue with a small clamp.

Step 2: Preclose by Deployment of the ProGlide Devices

The ProGlide device is a 6-F, suture-mediated closure system. Therefore, it must be deployed before a large-profile sheath is inserted (hence the term preclose); otherwise, the needles of the device will not be engaged through the vessel wall, and vessel closure will not be possible.

The ProGlide device is advanced over the guidewire (Figure 2), and when it is in adequate position, blood return is observed. The footplate is deployed by raising the lever and is then retracted to the vessel wall. Two needles are deployed through the sheath and through the vessel wall to the footplate by depressing the plunger. The needles and suture are engaged, and the suture is withdrawn through the proximal portion of the device by withdrawing the plunger. The device is then removed. Using excessive force to advance the device should be avoided, as this can damage the vessel wall or dislocate a calcified plaque.

The preclose technique using ProGlide requires two devices in the ipsilateral groin (introduction of the main body of the endograft; sheath size > 14 F) and one device in the contralateral groin (sheath size < 14 F). In the ipsilateral groin, the needles of the first ProGlide are deployed 30° medially from the midline (or at 2 o'clock), and the needles of the second device are deployed at 30° laterally from the midline (at 10 o'clock, or a 60° angle difference between the two ProGlides). The pretied knot and sutures of both devices are secured with a separate covered clamp. A 6-F introducer sheath is advanced over the guidewire. On the contralateral side, only one ProGlide is deployed. This preclose procedure of the two groins will take 5 to 10 minutes in experienced hands, and then the EVAR procedure can begin (Figure 3).

Sometimes there is a little bit of oozing of blood around a small sheath. This can be controlled by upsizing the sheath or pulling on the longer rail suture (blue) so that the knot

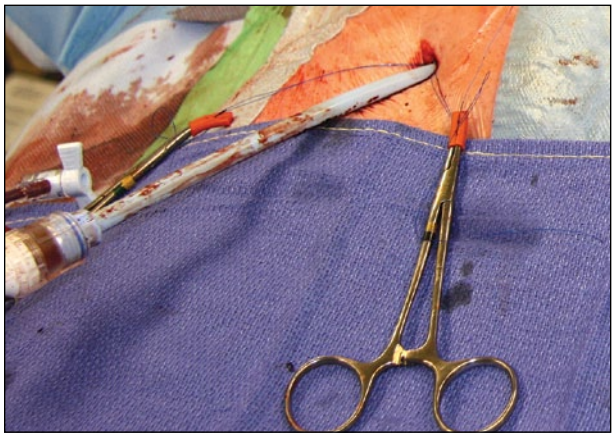

Figure 3. Sutures of both ProGlide devices are secured with clamps, and an 18-F introducer is in place for introduction of the main body.

Figure 4. Finishing the closure procedure at the right groin. The second slipknot is advanced to the vessel wall with the knot pusher. The guidewire has already been removed, as good hemostasis has been achieved.

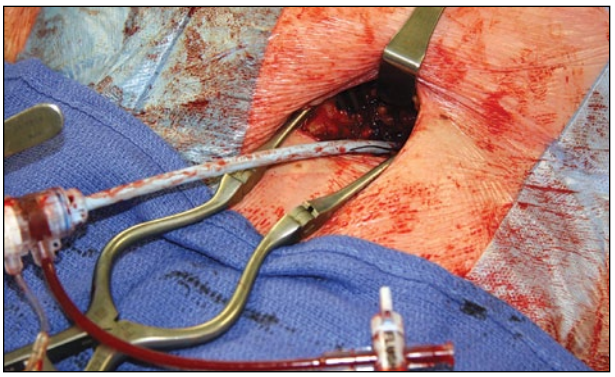

Figure 5. Contralateral (left) groin of the same patient: access for the delivery of the contralateral limb through a 12-F sheath. At the beginning of the procedure, the advancement of the plunger of the ProGlide device was difficult, and the needles and sutures could not be engaged/withdrawn. A second device was used for preclosure. At the end of the EVAR procedure, hemostasis could not be achieved, and the sheath was reinserted over the guidewire, which was still in place. A surgical cutdown was performed.

will be tighter. Avoid pulling on the shorter, non-rail suture (white), because this will block the knot.

Step 3: Seal the Arteriotomy Site at the End of the EVAR Procedure

Before beginning the arterial closure, remove any clotted blood next to the skin incision and on the sutures with excessive use of saline. Consider repreparation of the skin insertion site and a change of gloves, especially in the case of a prolonged EVAR procedure or if compromise of sterile technique is suspected.

The large-size sheath is withdrawn, keeping the guidewire in place. Manual compression is exerted, and the slipknot is advanced to the arteriotomy site using a knot pusher to seal the arteriotomy site (Figure 4). On the ipsilateral side, the two slipknots (two pairs of sutures) are closed one after the other; on the contralateral site, there is only one slipknot. Always keep the guidewire in place until acceptable hemostasis is achieved. In case of suboptimal hemostasis, another ProGlide device can be advanced and deployed over the wire.

When the sheaths in both groins are removed, heparin can be reversed at operator discretion by giving protamine.[16] If immediate hemostasis has been achieved, no compression bandage is given. Early ambulation is possible, but in our practice, patients stay in their hospital bed until the next day on a nonstrict basis.

If there is still some oozing or minor bleeding, manual compression is exerted for 10 minutes or longer until the bleeding has stopped. A compression bandage can be applied. Be patient and do not decide prematurely to have a surgical cutdown.

As long as there is access through the guidewire, the sheath can be reintroduced, so that in case of technical failure with considerable bleeding, a surgical cutdown can be done in a more relaxed fashion without the need of temporary manual compression (Figure 5).

POSSIBLE COMPLICATIONS

Device-Specific Complications: Technical Failure

- Failure to deploy needles because of calcification: try to redirect a new ProGlide (turn clockwise); if this is not possible, a surgical cutdown is needed.
- Failure to approximate the arteriotomy (sutures not deployed in the artery, sutures cut out, or an inability to advance the knot): use an extra device.
- Arterial split or tear at the site of device entry (usually in calcified arteries; characterized by bleeding at start of procedure with requirement of a larger sheath): a cutdown is often the only solution if the tear is too big.

Vessel-Related Complications

- Bleeding, false aneurysms: these occur because of insufficient closure.
- Arterial thrombosis or occlusion, dislocation of atherosclerotic plaque, or arterial dissection: these are not necessarily related to the use of the closure device, but are sometimes inherently caused by trauma of the vessel wall due to large-profile sheaths in combination with diseased iliac and femoral arteries and will also be encountered in open EVAR.

CONCLUSION

Nelson et al concluded in their recent report of a multicenter, randomized, controlled trial that PEVAR using the

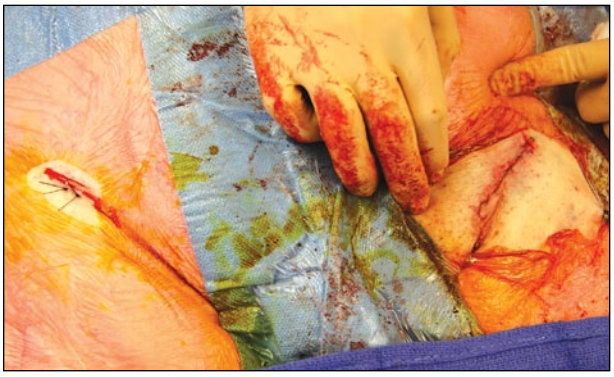

Figure 6. End of the procedure: successful percutaneous approach in the right groin (access via an 18-F sheath, main body); failed preclose technique due to calcification leading to a surgical cutdown in the left groin (access via a 12-F sheath, contralateral limb).

ProGlide closure device is safe and effective, with minimal access-related complications, and is noninferior to standard open femoral exposure.[8]

It is in that way we should approach this technique. We apply PEVAR for the majority of our patients, not because surgical cutdown causes many problems (complication rates are reported in literature at 5%–15%),[4,5] but because the percutaneous approach reduces operation time, blood loss, wound complications, and length of hospital stay.[7,8,17] In our hospital, patients who have not experienced complications leave the day after PEVAR, but only 2 days after open surgical EVAR. Some authors even advocate PEVAR as an outpatient procedure.[14,15,18] Moreover, future access in the groin will be in almost virgin territory because of the minimal reaction to prolene. Cosmetics and patient satisfaction are increased (Figure 6).

TIPS FOR SUCCESS

- Assess the common femoral artery. Beware of anterior wall calcification, and choose the right spot to puncture the artery.
- When anticipating a difficult puncture (due to obesity, high femoral bifurcation, small diameter, or calcification), use ultrasound guidance. Check the site of puncture with angiography if in doubt (oblique view for side/posterior wall punctures).
- Keep access at the moment of closure! Always leave a guidewire in place until acceptable hemostasis is achieved.
- Be patient to achieve good hemostasis, but be prepared for surgical cutdown.

Complications can be minimized by careful patient selection, but more than 90% of patients are suitable for PEVAR.[8,13,14] The complication profile is different from an open approach: risk of technical failure and (minor) bleeding versus the risk of lymphocele and wound complications.

Despite some reports in literature,[9,19] we think there is no extended learning curve. Before we engaged in PEVAR, we had a lot of experience with Starclose (Abbott Vascular) as the closure device for our peripheral endovascular cases, but only limited experience with ProGlide. We believe that a keen radiosurgical view on anatomical access, proper use of the device, and a correctly performed arterial puncture are the most important keys to success. ■

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