Percutaneous Access for TEVAR

The Preclose technique and the Proglide device offer safe and effective percutaneous access for thoracic endovascular aortic repair.

BY W. ANTHONY LEE, MD

Suture-mediated closure devices may be used to achieve early hemostasis after percutaneous arterial access without the need for manual compression and prolonged bed rest. However, these devices have been limited to closure of small-diameter (≤10 F) sheaths. Thoracic endovascular aortic repairs (TEVAR) typically involve sheaths and delivery systems with 22- to 25-F profiles (7.1- to 8.9-mm outer diameter), which are beyond the treatable range of arteriotomies of these closure devices.

A technique of closing arteriotomies after percutaneous access with up to 22-F sheaths has been previously described (Preclose technique) using the 10-F Perclose Prostar XL (Abbott Vascular, Santa Clara, CA) off-label by deploying the device before inserting the large sheath with the sutures left out and tied at the end of the procedure.[1] Technical success ranged from 62% to 100% in the reported series and was partly dependent on the sheath size used.[1-3] In this article, a variation of the Preclose technique using the 6-F Perclose Proglide (Abbott Vascular) device during TEVAR[4] is described.

MATERIALS AND TECHNIQUE

Perclose Proglide

The Perclose Proglide is a 6-F suture-mediated closure device that is inserted over a .035-inch guidewire and designed to close arteriotomies after placement of 5- to 7-F sheaths (Figure 1). A single 3–0 polypropylene suture is deployed with a full-thickness, vertically oriented bite of the artery using a pair of nitinol needles. The two strands of a preformed slipknot are color coded to indicate the tying strand and the locking strand. The arteriotomy is closed by pulling on the tying strand, pushing the preformed slipknot down using the accompanying knot pusher, and locking the knot by retracting on the locking strand. The guidewire is removed during the deployment

Figure 1. Perclose Proglide 6-F suture-mediated closure device.

of the sutures but is replaced before removing the device to maintain access to the artery. The list price for each device is $295.

Preclose Technique

The common femoral artery is accessed percutaneously using a micropuncture kit (21-gauge needle with an .018-inch guidewire and 3-F introducer [Cook Medical, Bloomington, IN]). Care should be taken to puncture the common femoral artery along its anterior aspect at least 1 cm proximal to the origin of the profunda femoris artery. This is always confirmed with a small manual injection of contrast using an ipsilateral oblique projection of the image intensifier. A .035-inch guidewire is inserted into the aorta, and the puncture site is dilated
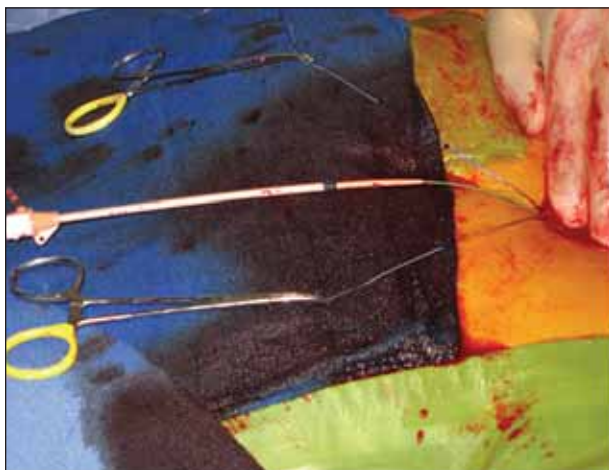
Figure 2. Two Proglide devices were deployed, the sutures tagged with hemostats, and guidewire access was maintained. A 7-F sheath was used to maintain hemostasis, and the sutures were placed under the blue towel to avoid inadvertent entanglement with other devices during the TEVAR procedure.
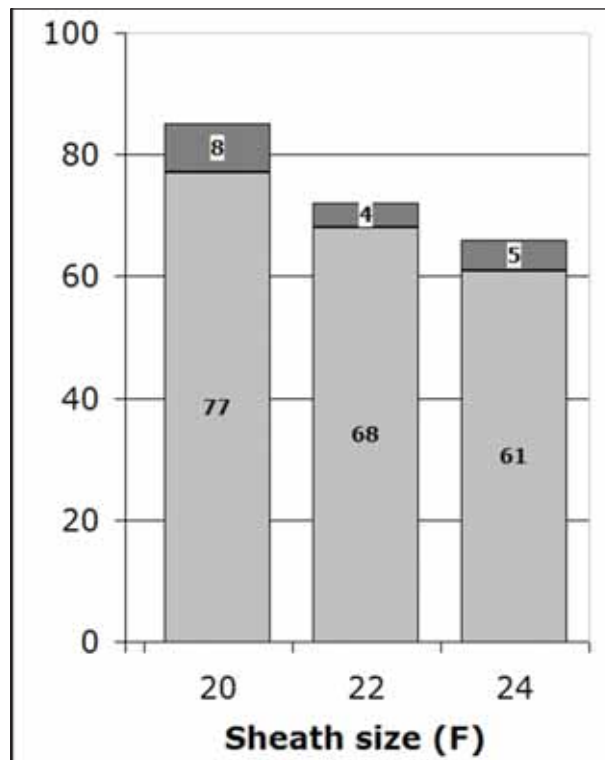

Figure 3. Distribution of sheath sizes in the 223 femoral arteries accessed percutaneously with the Preclose technique. The dark gray represents the number of technical failures, and the light gray represents the successful closures within a given sheath size. The 24-F column includes 24- and 25-F delivery systems.

with a 7-F sheath. A Proglide device is advanced over the guidewire, rotated medially approximately 30°, and deployed; the strands are left out extracorporeally and tagged with a small hemostat. Guidewire access is maintained, and a second Proglide device is inserted, rotated laterally 30°, and deployed. After this device is removed, hemostasis is maintained by reinserting the 7-F sheath (Figure 2).

When the thoracic endograft is ready to be inserted, and after systemic heparinization, the access site is serially dilated (Coons dilator, Cook Medical) over a stiff guidewire to match the outer diameter of the device introducer sheath or delivery system to facilitate its entry. However, strictly speaking, this step may not be always necessary because most introducer sheaths and delivery catheters have a step-off at the interface between the dilator and the outer sheath. There is a chance that this could catch on the subcutaneous tissue or on the Perclose suture, become frayed, and cause further arterial injury. Predilating the tract may minimize this risk. The cost of the dilator set is $170.44.

After conclusion of the endovascular repair, the introducer sheath is slowly removed while applying manual compression to the groin. Stiff .035-inch guidewire access is maintained, and the preformed knots of the two sutures are cinched down over the guidewire. Manual pressure is released from the groin, and after verification of adequate hemostasis, the guidewire is removed as the very last step, and manual pressure is reapplied to the groin. Rarely, a third Proglide device may be required if there is persistent pulsatile bleeding after the second

suture is tied down. Surgical conversion is indicated if this third device fails to resolve the bleeding. In these cases, a 12-F dilator is reinserted over the guidewire to plug the arteriotomy, and the artery is repaired surgically. It is absolutely critical to the safety of this technique that guidewire access be maintained until adequacy of hemostasis is verified. Distal perfusion is confirmed with a continuous-wave Doppler, and anticoagulation is fully reversed to restore the activated clotting time to <150 seconds. Compression is maintained for 5 to 10 minutes, and the patient is kept on bed rest for 4 to 6 hours.

CLINICAL EXPERIENCE

The medical records and imaging studies of 223 femoral arteries that were percutaneously accessed with 20- to 25-F sheaths and delivery systems using the Preclose technique at a single tertiary care medical center between December 2004 and August 2007 were reviewed. All patients were followed postoperatively with CT angiography. The angiograms were evaluated

Figure 4. Initial femoral angiogram after percutaneous access with a micropuncture technique (A). Note that the puncture site is proximal to the inferior epigastric artery. Contrast extravasation at the Preclose access site (B). The bleeding site is repaired with a covered stent (C).

Figure 5. CT angiography of a ruptured mycotic femoral pseudoaneurysm. Note the intense soft tissue inflammation around the artery.

for any late vascular sequelae at the closure sites related to the Preclose technique.

The average number of Proglide devices used was 2.01/artery; a third device was required in 2.3% cases. The overall technical success rate was 92.4% (206/223) (Figure 3). At a mean follow-up of 11 months in 156 femoral arteries with at least 6-month imaging, there were three late complications: one asymptomatic femoral artery dissection and two femoral pseudoaneurysms requiring repair. The overall rate of late complications was 1.9%.

Of the 17 early failures, most were recognized immediately in the operating room and repaired surgically or with endovascular techniques. There was no access-related mortality or limb loss. The two cases in this article are illustrative of the management of these complications.

Case 1

A 68-year-old man underwent endovascular repair of a 7.1-cm descending thoracic aortic aneurysm. The 22-F (25-F outer diameter) delivery system was percutaneously introduced using the Preclose technique and two Proglide devices through the right common femoral artery. At the conclusion of the procedure, after the Proglide sutures were tied down and the guidewire removed, the patient suddenly became hypotensive. It became evident that the likely cause was retroperitoneal bleeding. The ipsilateral superficial femoral artery (SFA) was rapidly exposed in the proximal thigh, and a 5-F sheath was inserted. A retrograde angiogram confirmed gross extravasation from the Preclose access site (Figure 4B). On review of the initial femoral angiogram obtained through the micropuncture catheter, the stick site was unusually high being several

centimeters proximal to the inferior epigastric artery, and this was unrecognized before deployment of the Proglide sutures (Figure 4A). The sheath was upsized to a 9-F sheath, and an 8- X 50-mm Viabahn (W. L. Gore & Associates, Flagstaff, AZ) covered stent was deployed at the site of bleeding (Figure 4C). The patient immediately stabilized. The SFA was repaired routinely, and the patient had an uneventful postoperative course.

Case 2

A 35-year-old man sustained a traumatic aortic transection from a severe motor vehicle accident. He underwent emergent endovascular stent graft repair of his aortic injury. The endograft was introduced through a 20-F (23-F outer diameter) delivery system after percutaneous access of the right femoral artery using the Preclose technique. The patient was discharged on postoperative day 22, but he presented 5 days later with a ruptured mycotic femoral pseudoaneurysm likely from infection of the Perclose sutures (Figure 5). On exploration, the patient was found to have severe necrotizing arteritis. He underwent extensive debridement and autogenous femoral reconstruction with a superficial femoral vein conduit (Figure 6). The patient was discharged on postoperative day 11, ambulating with a clean, granulating wound and normal pedal pulses.

DISCUSSION

Percutaneous access during endovascular aortic repairs has been difficult due to the large sizes of the delivery systems. Avoidance of surgical femoral exposure may result in shorter procedure times, fewer wound complications, and increased patient comfort. The practical size limit of achieving hemostasis with manual compression alone is

likely 12 F (sheath), although this has never been formally studied. Among the various percutaneous arterial closure devices, suture-mediated devices offer the purported advantages of a permanent suture, the least amount of intra- and extravascular foreign material, and similarity to conventional arterial repair.

Most of the reported experience[1-3] has solely involved the use of the Perclose Prostar XL device, and the technical success rates have varied widely. In contrast to the Proglide device, the Prostar XL (1) has a larger profile (10 F vs 6 F), which requires more extensive subcutaneous dissection in order for the sutures to accommodate the 20 F "collar" of the device and allow the sutures to seat properly; (2) has a more cumbersome deployment mechanism, which relies on accurate placement of four needles for its two sutures (vs two needles with one suture); (3) uses a braided suture (vs monofilament) with increased potential for infections and occasional failure of the "slip" knots to slide down; and (4) relies on the operator to tie the proper slipknot after removal of the large sheaths. Admittedly, all of these relative disadvantages can be overcome with proper technique and sufficient experience. The only advantage that the Prostar XL technique offers over the Proglide is that it typically requires only one device per femoral artery because there are already two sutures oriented in a cross-pattern and, therefore, there is a cost benefit ($425/device vs $590/two Proglide devices; Δ=$165).

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Although the numbers are too small for any formal statistical analysis, review of individual complications serves to illustrate a few key points about their management and the apparent risk factors for technical failure. Proper initial femoral puncture (ie, anterior aspect of the midcommon femoral artery) is critical. In the case of a suprainguinal puncture of the external iliac artery (as in case 1), the inguinal ligament can impede complete laying down of the slipknot and the access site too high for manual compression leading to uncontrolled hemorrhage, which may not be always recognized from the

Figure 6. Autogenous femoral reconstruction with the contralateral superficial femoral vein. The adjacent soft tissue has been extensively debrided.

small amount of bleeding at the puncture site. Maintenance of guidewire access from the beginning to the end of the closure allows management of most hemorrhagic complications by reinsertion of a sheath or large dilator, restoration of hemostasis, and unhurried surgical repair of the arteriotomy. In contrast to a suprainguinal puncture, a low femoral puncture (ie, SFA) can result in a flow-limiting dissection with limb ischemia due to the small size of the entry vessel.

Any anatomic configuration that necessitates a significant amount of pushing and/or torquing of the delivery system (eg, patients with small or diseased iliac arteries and/or severe iliac tortuosity) or procedures requiring multiple sheath exchanges can increase the risk of failure of the Preclose technique. The increased pressure and torque applied to the sheath may extend the size of the arteriotomy made by the sheath profile alone. Furthermore, it may also cause the Proglide sutures to actually pull out of the vessel altogether or reduce their purchase such that they are insufficient to reappose the arteriotomy.

The ability to completely reverse the anticoagulation is an important adjunct to the technique. Similar to open surgery, formation of clot is essential for hemostasis. Anterior or circumferential femoral calcification or groin scarring, such as from previous catheterizations (and ironically with previously placed percutaneous closure devices) or surgery, can cause misdeployment of the Proglide sutures due to the inability of the needles to penetrate through either the arterial wall or the overlying scar tissue. This increased resistance can lead to the separation of the suture from the needle. And finally, although obesity as a single measure is not necessarily a risk factor, the depth of the subcutaneous tissue can

affect the ability to properly insert the Proglide device into the artery.

The economics of percutaneous access for TEVAR deserve mention. Currently, percutaneous closures, regardless of what setting or device, are not reimbursed, and the only justification from the hospital's standpoint involves some aggregate qualitative and quantitative measures of time-saving, fixed-resource utilization, and patient satisfaction. From a physician's standpoint, surgical femoral exposure (CPT code 34812) during endovascular procedures is reimbursed at $373.82 (2006 Medicare Fee Schedule for Florida, Locality 1) per groin, which would be lost with percutaneous access. Unfortunately, this financial disincentive cannot be remedied until the Centers for Medicare & Medicaid Services recognizes this technique as a safe and effective (potentially better) alternative to open femoral exposure and assigns a CPT code with a comparable relative value units. However, this cannot occur until either the current devices receive an on-label indication for use in this manner, which in turn requires a manufacturer-sponsored investigational device exemption clinical trial or new devices specifically designed for closure of large arteriotomies become available.

CONCLUSION

Percutaneous access for TEVAR using the Preclose technique and the Proglide device is safe and effective, with a higher technical success rate than historically reported with the Prostar XL device. The technique is well tolerated by patients with almost no postoperative discomfort typical of a groin incision and rapid return to normal activities. Although to date we have not had any late ischemic events[5] due to secondary development of occlusive disease at the access sites, long-term outcomes of femoral arteries closed with the Preclose technique remain unknown, and clinical vigilance is warranted. ■

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