Current Access and Closure Options for TAVR Patients

Percutaneous and surgical access and the available vascular closure devices for treating this often-challenging vascular anatomy.

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Since the early 2000s, percutaneous transcatheter aortic valve replacement (TAVR) has rapidly developed. Currently, there is sufficient evidence that it can be considered as a valid alternative to conventional cardiac surgery for patients with severe aortic stenosis who are at high surgical risk.[1-3] The patients we currently treat are generally frail and elderly and are more likely to have vascular access issues.

TAVR requires an extensive preoperative workup to determine the most appropriate and suitable vascular access. In particular, thoracoabdominal CT angiography (that also includes the femoral arteries) is routinely performed to assess the integrity, tortuosity, and calcium burden of the peripheral vessels.[4,5] Based on the Swiss TAVI registry,[6] transfemoral (TF) access is the preferred route for 80% of the cases, and the transapical (TA) approach is the access of choice in 18% of patients. Transaortic (1.7%) and transsubclavian access (1.1%) are rarely used alternatives. In this article, we describe the percutaneous and surgical transfemoral access routes and the related vascular closure devices (VCDs) available for the percutaneous approach to TAVR.

TF PERCUTANEOUS ACCESS

Generally, in cases with normal anatomy, right femoral access is preferred for device delivery,[7] whereas left femoral artery access is used to perform angiography of the vascular access, to monitor the valve implantation, and whenever necessary, to achieve contralateral (right iliac) occlusion while suturing the femoral access.

Using a standard Seldinger technique, puncture of the common femoral artery is typically performed 1 to 2 cm above the femoral bifurcation, a sheath is then inserted, and a VCD is positioned. Two types of VCDs are most commonly used: the Prostar XL device (Abbott Vascular, Santa Clara, CA) (Figure 1) or, alternatively, two Perclose ProGlide devices (Abbott Vascular) (Figure 2).

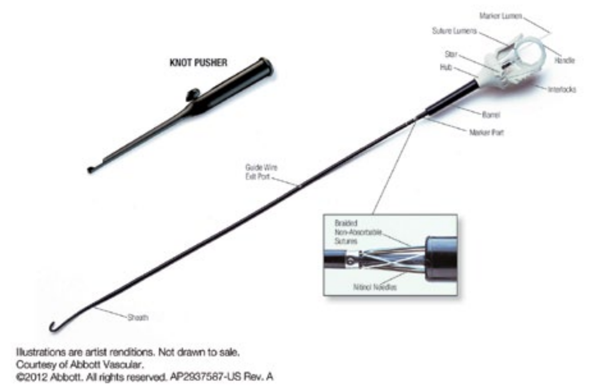

Figure 1. The Prostar XL device.

The Prostar XL device has the advantage of a single manipulation; on the other hand, its major limitation is the difficult localization of the exact level for needle extraction in obese patients and in heavily calcified arteries, which can result in bleeding after the procedure.

Based on our personal experience, we prefer to use two Perclose ProGlide devices that are inserted sequentially, facing each other with an angle of 40° to 60°. The sutures are left loose and fixed on the skin with Steri-Strips (3M, St. Paul, MN) to allow the sheath to be placed inside the artery. At present, there are no other VCDs available for the TF TAVR approach. After the sutures are well-secured on the skin, an 18-F sheath is placed, which will allow for the advancement of the delivery system.

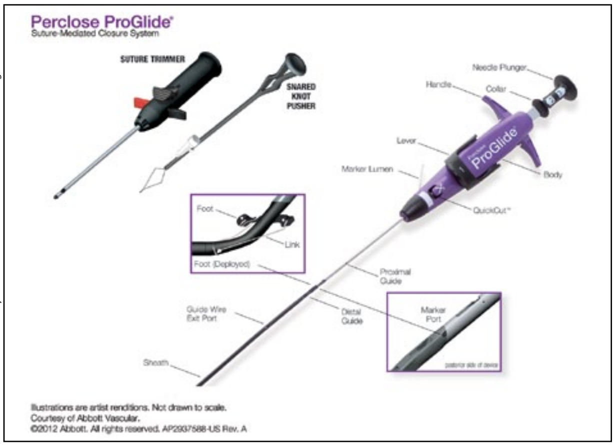

Figure 2. The Perclose ProGlide device.

The anatomy of the iliac vessels dictates the choice of the appropriate sheath. In cases of difficult anatomy (arteries with a diameter at the lower limit of what is recommended) with a high risk of bleeding and/or vessel rupture, a special inflatable sheath (SoloPath balloon-expandable transfemoral system, Terumo Interventional Systems, Somerset, NJ) (Figure 3) can be used to reduce the amount of trauma to the vessel wall that is related to the passage of a large-bore sheath.

Only at the end of the procedure, when the sheath is finally withdrawn, are the sutures tied up to ensure final hemostasis. In our opinion, both the insertion maneuver and the final suture tend to be easier, with less risk of hemostasis failure with two ProGlide devices, as compared with the Prostar XL.

In cases with a high risk of bleeding or perforation in the iliac segment, a crossover intraluminal balloon is inserted. After having withdrawn the 18-F sheath just below the level of the aortic bifurcation, a crossover catheter (either a 4-F universal flush or a "cut" pigtail catheter) is inserted, and angiography is performed to visualize the lumen of the vessel or the sheath itself. Subsequently, the 18-F sheath is cannulated, and a Radifocus M stiff type guidewire (Terumo Interventional Systems) is advanced through the crossover catheter, straight into the 18-F sheath, and beyond the hemostatic valve of the sheath so that it can be fixed with a clamp to create a loop of the system. The contralateral short sheath is then exchanged for a 45-cm, 7-F Destination introducer (Terumo Interventional Systems), which is advanced contralaterally across the aortic bifurcation over the Terumo Stiff wire until it reaches the tip of the 18-F sheath.

The 18-F sheath is then pulled back almost until the level of the puncture site. At this point, angiography allows the operator to confirm the integrity of the vascular axis. An intraluminal balloon is crossed contralaterally over the

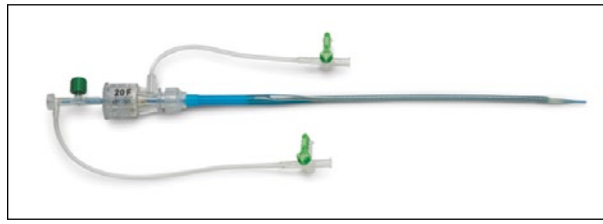

Figure 3. The SoloPath balloon-expandable transfemoral system.

Terumo wire and inflated at low pressures (2–4 atm). Once the balloon is inflated, temporary intraluminal hemostasis is achieved, allowing permanent final hemostasis by the percutaneous VCD. After tightening the final VCD suture, the intraluminal balloon is deflated. Final angiography is then performed to confirm the integrity of the vascular structure and definitive hemostasis.

In cases of suture dehiscence, the balloon can be promptly repositioned, and prolonged inflation can be applied. In the rare case of perforation, surgical exploration should be urgently performed; alternatively, a covered (self-expandable) stent can be delivered at the perforation site. In thin patients with a low risk of vascular access complications, suturing is performed without a crossover intraluminal balloon backup. In our institution, percutaneous access is preferred in 50% to 70% of patients, whereas surgical cutdown is reserved for heavily calcified vessels in obese patients.

The future of vascular access related to TAVR will depend on the development of smaller delivery catheters (14–16 F) that require smaller sheaths and thus will allow direct vascular closure without contralateral catheters and intraluminal balloon deployment.

SURGICAL FEMORAL CUTDOWN

Surgical femoral cutdown is preferred for heavily calcified and tortuous peripheral vessels. It has the advantage of direct visualization of the puncture site and therefore allows more precise access and closure with a tobacco-pouch suture. On the other hand, it will increase the procedure time and will lead to a longer postprocedural recovery for the patient. Surgical femoral cutdown is usually performed via a skin incision and subcutaneous tissue dissection with subsequent arterial exposure (over a length of 5–7 cm), allowing one to avoid puncture at a point where (palpable) vessel calcification is present.

SURGICAL SUBCLAVIAN CUTDOWN

Surgical subclavian cutdown is considered when the conventional accesses (TF or TA) are not suitable, generally in frail, elderly patients with either severe peripheral arteriopathy and/or poor left ventricular function. CT angiography, with contrast injection from the right arm, generally allows evaluation of the left subclavian artery to determine the diameter (minimum required, 6 mm), tortuosity, and presence of calcifications (that would necessitate a predilatation of the vessel, in particular, at the origin of the subclavian artery).

The access consists of a left subclavicular skin incision and subsequent subcutaneous tissue dissection to isolate and expose the subclavian artery. After tangential clamping of the artery and a longitudinal arteriotomy, a Dacron prosthestic conduit (8–10 mm) is sutured to the artery to allow better hemostatic control during insertion of the sheath into the subclavian artery. Subclavian access provides better stability of the delivery system compared to TF access due to the short distance between the valve and the access site itself. The main disadvantage is the uncomfortable position the operator needs to adopt (left side of the patient), as well as the length of the delivery system, which is designed for a femoral approach at present (and thus a significant part of the delivery system remains outside of the patient). It is probable that the near future will bring new, smaller delivery systems that are specifically designed for transsubclavian access. At the end of the procedure, after the sheath is withdrawn, the subclavian artery is clamped again, the artery is sutured, and the Dacron prosthesis is cut, sutured, and left in situ after achieving final full hemostasis. The artery is finally declamped. The only valve suitable for this purpose is the self-expandable CoreValve device (Medtronic, Inc., Minneapolis, MN).

DIRECT SURGICAL TRANSAORTIC ACCESS

Direct surgical transaortic access was initially considered to be too high risk, but nowadays, it is preferred in patients with severe generalized vasculopathy, which does not allow any other peripheral vascular access option.[8] Either a right high parasternal "keyhole" thoracotomy (2° intercostal space) or a high sternotomy can be performed. Careful evaluation of the distance between the planned aortic puncture and the valvular plane is very important in order to allow the valve to expand (6 cm is the required minimum distance). After the skin incision and subcutaneous tissue dissection to isolate and expose the ascending aorta, the surgeon performs a tobacco-pouch suture around the projected puncture site. A standard Seldinger technique is then employed to cannulate the aorta and advance an 18-F sheath. Both operators stand cranially from the patient's shoulders or at the bedside, and the monitors are at the end of the bed at the patient's feet, as for the transsubclavian cutdown.

Despite initial reluctance to perform a direct Seldinger puncture of the ascending aorta, this approach is becoming popular, and the initial results regarding feasibility and safety are encouraging.[9] Direct transaortic access offers a quicker recovery with less secondary events after the procedure compared to the TA approach. As previously discussed for the subclavian cutdown, the advent of new, smaller delivery systems that are specifically developed for these purposes will simplify the "short" manipulation.

CONCLUSION

There is no doubt that TAVR has radically changed the management of elderly patients with severe aortic stenosis and a high risk for conventional surgery. This procedure has rapidly spread in the United States and Europe, and it requires much operator experience with good cardiothoracic surgical backup, as it is recommended in the United States and European guidelines.[1,2] One of the main problems of vascular access, especially the femoral approach, is reflected by the high numbers of complications,[3] which in rare cases, require emergency surgical conversion. For this particular reason, the operator's experience alone is not enough to prevent and manage potential vascular complications. Extensive anatomic evaluation of the vessels in the preoperative workup, appropriate vascular access management, and a thorough knowledge of the available VCDs are fundamental to successfully and rapidly managing the possible vascular adverse events. ■

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