A practical overview of the technique, devices, and outcomes of suture-mediated access site closure after transfemoral TAVR.

BY KAFFER KARA, MD; FADI AL-RASHID, MD; POLYKARPOS C. PATSALIS, MD; RAIMITUND ERBEL, MD, FESC, FACC, FAHA; AND PHILIPP KAHLE, MD, FESC

Access site management after transcatheter aortic valve replacement (TAVR) is one of the key steps of the procedure. Despite continuous technical refinements with significant downsizing of the large-bore delivery devices required for this novel treatment option for inoperable and high-risk patients with symptomatic aortic valve stenosis, access site complications after TAVR remain among the most frequent complications of this intervention. These have been associated with significantly increased mortality.1

Since the introduction of the retrograde, transfemoral TAVR approach (TF-TAVR) by Hanzel2 and Webb,3 access and closure techniques have continuously evolved toward a completely percutaneous procedure. Initially, access site preparation and closure were performed surgically or with percutaneous puncture and surgical closure at the end of the procedure. In view of the general clinical benefits of percutaneous interventions over surgical approaches (ie, reduction of systemic, cardiac, and pulmonary complications), a completely percutaneous TF-TAVR procedure was soon contemplated. Reminiscent of what was known of percutaneous closure after large-bore arterial access in the setting of endovascular aortic repair4 and balloon aortic valvuloplasty, the concept of “preclosure” using suture-mediated vascular closure devices was adopted for the TF-TAVR procedure,5,6 and there is now a clear trend in favor of a completely percutaneous intervention using preclosure over surgical access site closure or planned surgical access. As a consequence of the percutaneous approach, general anesthesia—which may not be feasible in some of the elderly TAVR patients who often present with severe chronic obstructive lung disease—can now be avoided, and TF-TAVR be performed under anesthesiologist-controlled conscious sedation.

In this article, we provide a practical overview of the techniques and devices used for suture-mediated access site closure after TF-TAVR and report on the outcomes of this approach.

DEVICES AND TECHNIQUE

Devices

There are currently two suture-mediated vascular closure devices that are available for preclosure use: the 6-F Perclose ProGlide device and the 10-F Prostar XL device (Abbott Vascular, Santa Clara, CA). Introduced in 1997, the Perclose device was the first suture-based vascular closure device on the market and was intended for use with 5- to 8-F sheaths for femoral access site closure after coronary angiography and intervention. It places a suture through the arterial wall like a stapler in a single-stitch fashion (ie, from the outside in) and uses a pretied, self-locking surgical sliding knot for hemostasis. The mechanism of the Prostar XL device, designed for use in 8.5- to 10-F arterial access, is different and based on the delivery of two pairs of needles from the inside to the outside of the artery. These needles are captured by the barrel of the delivery system and are then extracorporated with the sutures, which are used for closure by tying a fisherman’s knot for hemostasis. The mechanism of the Prostar XL device, designed for use in 8.5- to 10-F arterial access, is different and based on the delivery of two pairs of needles from the inside to the outside of the artery. These needles are captured by the barrel of the delivery system and are then extracorporated with the sutures, which are used for closure by tying a fisherman’s knot for hemostasis. Both of these devices can be used in the so-called preclosure technique, for which the sutures are preloaded through the margins of the arteriotomy before access sheath insertion and are left extracorporally for closure at the end of the procedure.
Aside from patient selection with careful attention to known potential causes of vascular closure device failure such as severe femoral artery calcification or obesity, an appropriate common femoral artery puncture above the femoral artery bifurcation and below the epigastric artery origin is key to successful preclosure. Hence, common femoral artery puncture should be performed meticulously using real-time ultrasound guidance, fluoroscopy, or angiography.

Commonly, femoral artery puncture is performed under fluoroscopic and angiographic guidance (Figure 1). While fluoroscopy depicts the bony landmarks (Figure 1A), contralateral angiography provides a clear roadmap of the arterial tree (Figure 1B), thereby ensuring optimal vascular access. Practically, a hemostat is placed at the target point to facilitate orientation (Figure 1C and 1D). After the needle has been introduced into the tissue tract, fluoroscopy is performed to ensure that the needle tip is within the optimal target area, and arterial entry is performed. When the guidewire is advanced, the needle/wire interface is observed (Figure 1E) as a final check prior to sheath insertion. Sheath angiography is then performed for confirmation of a correct puncture (Figure 1F), and utilization of a micropuncture needle may offer further safety here.

A pigtail catheter placed above the femoral artery bifurcation from a contralateral access (Figure 2A and 2B) may be used as a target for needle puncture and subsequent guidewire introduction (Figure 2C and 2D) as an alternative to or in addition to fluoroscopically and angiographically guided femoral artery puncture.

After sheath insertion, heparin is administered to achieve an activated clotting time > 250 seconds, which is maintained throughout the entire procedure. A 0.035-inch guidewire is then advanced, and the sheath is removed. After preparation of a subcutaneous tissue tract using a hemostat, a single 6-F ProGlide device is deployed in the common modus operandi with readvancement of the wire via the monorail wire port on the shaft.

Figure 1. Fluoroscopically and angiographically guided femoral artery puncture. Fluoroscopy depicts the bony landmarks (A), and contralateral angiography provides a clear roadmap of the arterial tree for optimal vascular access (B). A hemostat is placed at the target point to facilitate orientation for percutaneous puncture (C and D). Once the guidewire is advanced, the needle/wire is observed (E) as a final check prior to sheath insertion. Sheath angiography is then performed for confirmation of a correct puncture (F).

Figure 2. Pigtail-guided femoral artery puncture. A pigtail catheter introduced from contralateral access and placed above the femoral artery bifurcation (A and B) is used as a target for needle puncture and subsequent guidewire introduction (C and D).
Subsequently, a 10-F sheath is inserted, and the preloaded sutures are safeguarded on the drapes with a hemostat (Figure 3A). The access vessel is then predilated and the large-bore introducer sheath inserted (B). At the end of the procedure, the preformed surgical knot is slid down to the arterial wall with a knot pusher (C) for hemostasis (D).

Contralateral angiography is performed to identify any vessel damage, specifically dissection or rupture. When the integrity of the vessels is confirmed, the introducer sheath is fully removed under manual compression, leaving the guidewire in the vessel. Some operators prefer crossover balloon occlusion of the common iliac artery over manual compression to be able to tie the sutures in a dry field. This approach, however, may increase procedural complexity and may only offer advantages for the somewhat time-consuming suture-tying of the more complex Prostar XL device. The preformed surgical knot is then slid down to the arterial wall using a knot pusher for hemostasis (Figure 3C and 3D). For final evaluation of the access vessel, another angiogram is obtained via the contralateral femoral artery. When the vasculature remains intact, the wire is removed. As an alternative to a single device, two or even three devices may be preloaded, but one device is usually sufficient.

The Prostar XL device is used in a similar fashion. The deployment mechanism, however, is a little more complex. Once the device is introduced into the vessel lumen, the sutures are deployed by a 90° rotation and traction of an O-pull ring while keeping forward pressure on the device. The sutures are then pulled out of the device hub, which is subsequently pulled back to expose the sutures below the hub to remove them. Each suture is then safeguarded separately on the drapes and manually tied at the end of the procedure using a fisherman’s knot.

**Bailout Strategies**

In contrast to procedure-related access site complications such as dissections or perforations, incomplete arteriotomy closure, or even closure device failure, vascular stenoses and occlusions are observed in association with the use of vascular closure devices. For such complications, bailout strategies should be in the armamentarium of the TAVR operator, especially experience with peripheral percutaneous interventions. In cases of closure device-induced stenosis or occlusions, percutaneous balloon angioplasty via contralateral access might be sufficient, but for closure device failure, stent implantation is usually necessary to avoid surgical repair.

When vascular complications might be anticipated a priori due to vessel calcification or small artery caliber (Figure 4A), provisional placement of a guidewire...
in the superficial femoral artery (Figure 4B) offers the possibility of rapid bailout stenting in cases of arterial damage or preclose failure (Figure 4C), usually with good results (Figure 4D).

OUTCOMES
Overall, a 1.9% to 30.7% incidence of Valve Academic Research Consortium (VARC)-defined major vascular complications has been reported for TF-TAVR via percutaneous and surgical access, and such complications have been associated with increased mortality. Hayashida et al prospectively evaluated 130 TF-TAVR patients and found significantly increased rates of in-hospital (27.3% vs 9.5%) and 30-day (22.7% vs 7.6%) mortality, as well as longer hospital stays in patients with major vascular complications.1

Recent data have shown a continuous decrease in major vascular complications as a result of growing experience, profile reduction of the devices, and technical refinements. In a Canadian single-center study including 137 consecutive TF-TAVR patients treated with a percutaneous technique using two ProGlide devices, Toggweiler et al observed a reduction of major vascular complications and unplanned surgery from 8% to 1% and 28% to 2%, respectively, comparing patients treated in the fiscal year 2009/2010 versus 2010/2011.10 Another prospective single-center study including 151 consecutive TF-TAVR patients recently compared surgical access (n = 78) with percutaneous access and closure using the Prostar XL device (n = 71 of 73) and found no significant difference in major vascular complications (7.7% vs 8.2%) or 30-day mortality (7.7% vs 5.5%), implying noninferiority of the percutaneous approach. In addition, conversion to surgical cutdown occurred in only 2.7% of cases in the percutaneous treatment group.11

Success rates for percutaneous closure with regard to efficient hemostasis are high and vary from 89% to 93.5%.7,12 However, this technique entails its own closure-related complications, specifically closure-related stenosis, occlusions, or closure-device failure. In two recent studies, vascular complications associated with the percutaneous approach have been specifically evaluated.7,12 Using the Prostar XL device, overall major vascular complications were observed in 14.2% of patients undergoing CoreValve implantation (Medtronic, Inc., Minneapolis, MN), and 54% of these were related to incomplete arteriotomy closure with the device.12 Similar rates have been observed using a single ProGlide device. The overall VARC-defined major vascular complication rate was 12%, and 45% of these complications (mainly closure-device-induced stenoses) were related to preclosure.7

CONCLUSION
Overall, the results and outcomes of arterial access site preclosure using the 6-F ProGlide or the 10-F ProstarXL device in the setting of TF-TAVR appear to be encouraging, but there is room for further improve- (Continued on page 60)
ment. Several devices under development are designed to improve handling and the success of large-bore vessel closure. TAVR devices continue to get smaller, further paving the way for a completely percutaneous TF-TAVR procedure.

Kaffer Kara, MD, is with the West-German Heart Center Essen, Department of Cardiology, Essen University Hospital, University Duisburg-Essen, in Essen, Germany. Dr. Kara has disclosed that he has no financial interests related to this article. Dr. Kara may be reached at +49-201-723-84884; kaffer.kara@uk-essen.de.

Fadi Al-Rashid, MD, is with the West-German Heart Center Essen, Department of Cardiology, Essen University Hospital, University Duisburg-Essen, in Essen, Germany. Dr. Al-Rashid has disclosed that he has no financial interests related to this article.

Polykarpos C. Patsalis, MD, is with the West-German Heart Center Essen, Department of Cardiology, Essen University Hospital, University Duisburg-Essen, in Essen, Germany. Dr. Patsalis has disclosed that he has no financial interests related to this article.

Raimund Erbel, MD, FESC, FACC, FAHA, is with the West-German Heart Center Essen, Department of Cardiology, Essen University Hospital, University Duisburg-Essen, in Essen, Germany. Dr. Erbel has disclosed that he has no financial interests related to this article.

Philipp Kahlert, MD, FESC, is with the West-German Heart Center Essen, Department of Cardiology, Essen University Hospital, University Duisburg-Essen, in Essen, Germany. Dr. Kahlert has disclosed that he has no financial interests related to this article.