

Improvements in Femoral Access and Closure for TAVR

A focus on early recognition and prompt percutaneous endovascular management of failure of femoral artery percutaneous preclosure.

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The common femoral artery remains the most commonly used access site for insertion of large-bore access sheaths. Driven by the clinical need for insertion of large-caliber access sheaths in transcatheter aortic valve replacement (TAVR), it is essential that an operator be cognizant of the potential complications and prompt management to ensure a good procedural outcome. Vascular complications have been the most frequently reported complication in transfemoral valve implantation due to the large-sized sheath needed to deliver the device. More importantly, this is associated with major postprocedural morbidity and mortality and increased length of hospital stay.¹⁻³

Of the 179 patients enrolled in the TAVR cohort of the pivotal PARTNER I trial, 29 patients (16.2%) experienced major vascular complications, and this negatively affected the mortality rate in that arm of the study, even though this group still had a better outcome compared to the control group who received standard therapy.⁴ Fortunately, the continued improvement in operators' skills and increasing TAVR site experience with the procedure have significantly decreased the rates of vascular complications.⁵ This is coupled with technologic advancement in the development of lower-profile aortic valves and support frames that can be delivered in a smaller-diameter sheath.

The acceptance of TAVR as a therapeutic option for patients with severe symptomatic aortic stenosis (AS) who are not surgical candidates has impelled operators to advance the interventional technique and perform the procedure as least invasively as possible. The success of the suture-mediated preclosure technique for large-bore access site hemostasis in endovascular aortic aneurysm repair⁶⁻⁹ has resulted in its adoption in TAVR with implantation of

the device using the purely percutaneous technique.¹⁰ This obviates the need for open femoral cutdown and avoids the many potential complications associated with surgical arteriotomy and also negates the need for general anesthesia or

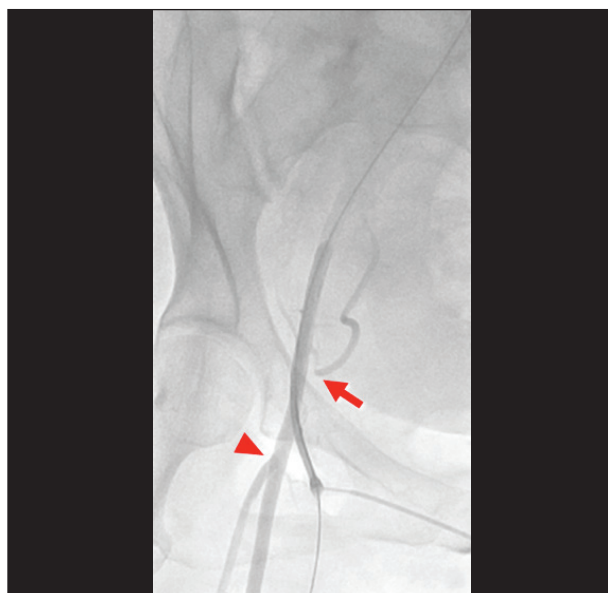


Figure 1. Angiography of the right common femoral artery arteriotomy site taken at a right anterior oblique 30° ipsilateral view. The femoral arterial sheath was inserted into the mid-segment of the right common femoral artery. Ideally, the access site should be below the inferior epigastric artery (arrow) and above the femoral bifurcation (arrowhead). A high stick above the inferior epigastric artery (ie, above the inguinal ligament) increases the risk of retroperitoneal hemorrhage. A low stick increases the risk for access site hematoma and pseudoaneurysm formation.

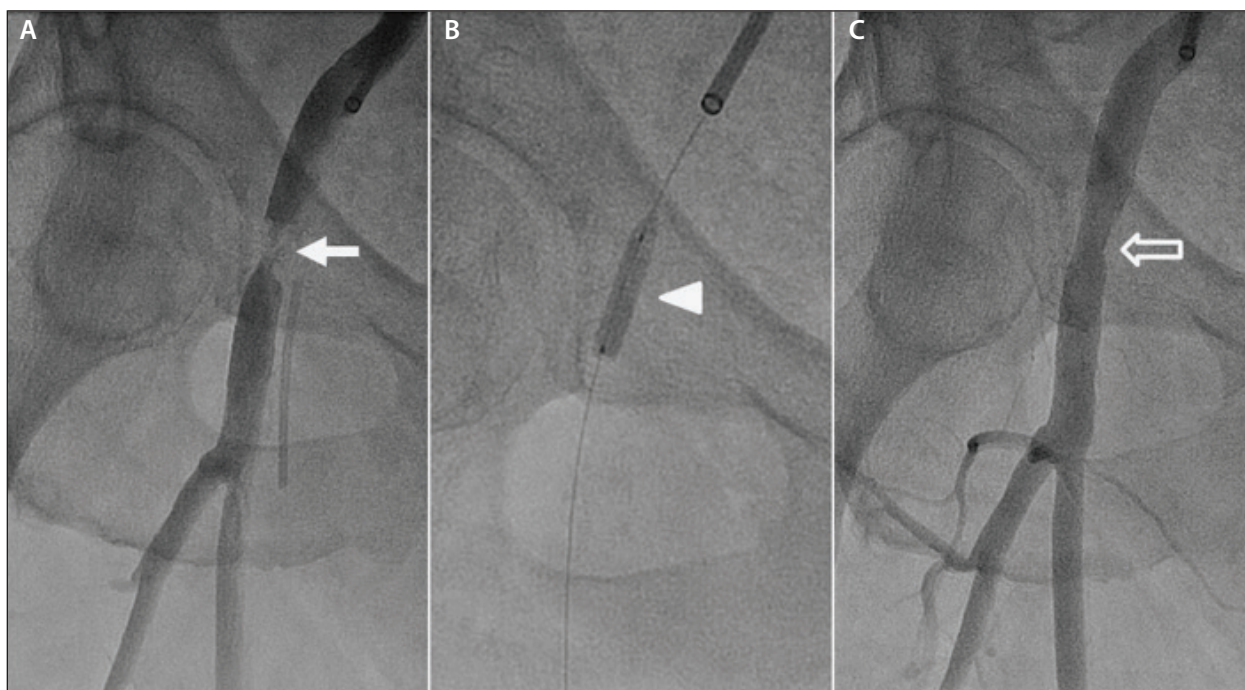


Figure 2. Iatrogenic occlusion of the right common femoral artery after tightening of the two pairs of sutures from the two Perclose ProGlide vascular closure devices deployed for preclosure (arrow) (A). Atherotomy balloon angioplasty (arrowhead) performed using a peripheral cutting balloon advanced through the contralateral femoral artery access sheath (B). Successful dilation of the occluded right common femoral artery (hollow arrow) with re-establishment of brisk flow to the distal vessels (C).

spinal anesthesia to implant the aortic valve and eludes the associated increased postprocedural morbidity.¹¹ Operator experience combined with thorough pre-TAVR morphological evaluation of the vascular access site(s) have significantly reduced major vascular complications and heralded in a true percutaneous approach to transfemoral TAVR.¹²

An emphasis on the sheath-to-femoral artery ratio (SFAR), as well as on the sheath-to-external iliac artery ratio, has almost completely eliminated most of the major vascular complications seen during the early days of TAVR. Most vascular complications encountered at present are related to failure of the suture-mediated preclosure device at the arteriotomy site. Fortunately, these are effectively managed in the angiography suite.¹² Currently, in our own institution, a purely percutaneous approach with the use of the suture-mediated preclose technique has been the de facto method when a transfemoral route for implantation has been selected. In this article, we expound on this approach with emphasis on the early recognition and prompt percutaneous endovascular intervention of TAVR-related femoral artery access site vascular complications secondary to failed preclosure.

PROCEDURAL TECHNIQUE

Preprocedural Imaging Study

Pre-TAVR imaging studies to delineate the caliber and morphology of the iliofemoral access site are routinely

performed using selective iliofemoral angiography but mostly using multislice CT angiography. In patients with renal insufficiency, the latter is performed with a pigtail catheter left in situ in the infrarenal abdominal aorta, as has been previously described.¹³ This allows the acquisition of high-quality aortoiliofemoral CT angiographic images using only 10 to 15 mL of contrast material diluted with normal saline injected intra-arterially via the pigtail catheter while the spiral CT is carried out. SFAR, defined as the ratio between the sheath outer diameter (in millimeters) and the femoral artery minimal luminal diameter (in millimeters), plays a major role in determining the suitability for a transfemoral approach to TAVR. Published data show that a SFAR of ≥ 1.05 predicted a higher rate of VARC major vascular complications.¹ Knowing the caliber size of the aortoiliofemoral arteries beforehand also comes in handy when it becomes necessary to percutaneously manage access site-related vascular complications.

Access and Preclosure

Vascular access for insertion of a large-bore sheath is achieved in the mid-femoral artery segment using a 21-gauge micropuncture introducer set (Cook Medical). A one-stick access to a “disease-free” anterior wall of the common femoral artery is of utmost importance. Techniques to confirm that this was achieved include crossover angiogra-

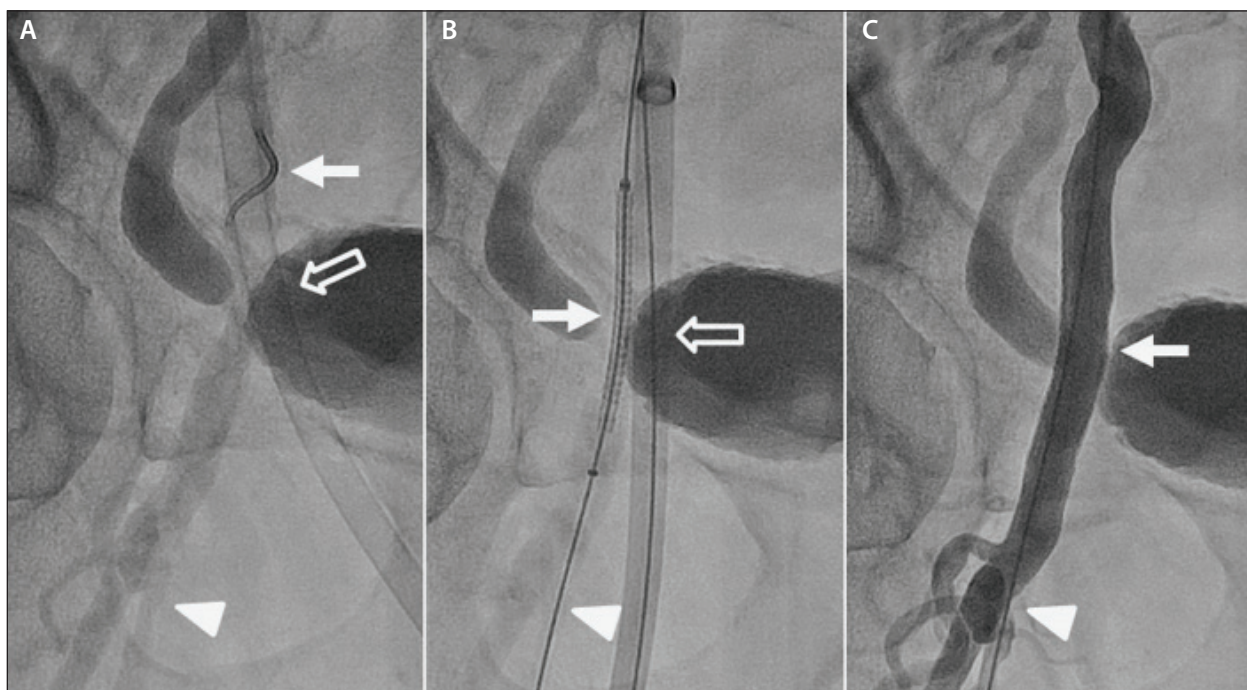


Figure 3. Failed preclosure with reinsertion of a 14-F sheath through the arteriotomy site (hollow arrow) for temporary hemostasis (A). Crossover catheter (arrow) from the contralateral iliofemoral artery used to perform selective angiography to locate the arteriotomy site and localize the SFA and deep femoral artery bifurcation (arrowhead). Positioning of a Viabahn 10- X 50-mm ePTFE-covered nitinol self-expanding stent (arrow) across the arteriotomy site (hollow arrow) over a 0.035-inch Supra Core guidewire (Abbott Vascular) (B). The device is positioned above the SFA and deep femoral artery bifurcation (arrowhead). Successful deployment of an ePTFE-covered nitinol self-expanding stent (arrow) in the right common femoral artery with complete obliteration of flow through the arteriotomy site (C). The stent graft is deployed above the SFA and deep femoral artery bifurcation (arrowhead).

phy with or without roadmapping or with direct ultrasound imaging guidance. The type of imaging guidance used is very much dependent on the operator(s) involved in the TAVR procedure. Before upsizing from the micropuncture sheath, angiography of the access site for location of the arteriotomy is routinely performed 30° to 40° ipsilateral to the access site,¹⁴ as shown in Figure 1. After confirming the proper arteriotomy site, preclosure using the suture-mediated vascular device is then carried out as previously described.¹⁵ Suture-mediated preclosure is mainly performed using two 6-F Perclose ProGlide devices (Abbott Vascular). The 10-F suture-mediated Prostar XL device (Abbott Vascular) is also used at the discretion of the operator(s).

Hemostasis

After the conclusion of the TAVR procedure, hemostasis of the large-bore femoral artery access site is carried out with deployment of the suture-mediated preclosure devices. This involves removal of the large-bore TAVR delivery sheath and tightening of the two pairs of sutures around the guidewire. If there is complete hemostasis with no residual bleeding, the guidewire is removed, and

the two pairs of knots are further tightened and locked. In the event of incomplete hemostasis with significant bleeding, an 8-F Angio-Seal vascular closure device sheath (St. Jude Medical, Inc.) is inserted into the arteriotomy site as a “test.” If the bleeding is controlled with the Angio-Seal sheath, the vascular closure device is deployed to create a final, immediate seal of the arteriotomy site. This is used as an alternative to prolonged manual compression when the suture-mediated preclosure fails to achieve immediate, complete hemostasis.¹⁶ This technique has been found to be safe and reduces the procedure time and improves efficiency. If the test fails to control the bleeding, an additional third ProGlide device can be used, and the test step with the Angio-Seal sheath is repeated if hemostasis is not achieved. Completion peripheral angiography is then performed to assess the arteriotomy site.

Managing Failure of Percutaneous Femoral Artery Closure

In the event of closure failure using either the Perclose ProGlide or Prostar XL devices, the following algorithm comes into play as we manage a potentially catastrophic large-bore access site complication (Table 1).

TABLE 1. ALGORITHM FOR SUCCESSFUL MANAGEMENT OF FEMORAL ARTERY ACCESS COMPLICATION

What is the pathological lesion?	Obstructive: there is the luxury of time to plan the intervention
	Bleeding: one needs to act fast and apply temporizing hemostasis
Anticoagulation	Obstructive: keep ACT > 250 s
	Bleeding: localized to infrainguinal common femoral artery segment vs possible retroperitoneal bleed?
Supportive therapy	Obstructive: NA
	Bleeding: hemodynamic support; immediate transfusion of blood component
Vascular access	Obstructive: 7-F sheath is more than adequate
	Bleeding: dependent on the diameter size of the ePTFE-covered nitinol self-expanding stent to be deployed
Definitive therapy	Obstructive: atherectomy, atherectomy, or plain balloon angioplasty with or without provisional stenting
	Bleeding: ePTFE-covered nitinol self-expanding stent
Follow-up	Immediate: arterial pulse Doppler evaluation with or without arterial Duplex ultrasound study
	Long-term: clinical follow-up plus arterial duplex ultrasound study
Abbreviations: ACT, activated clotting time; ePTFE, expanded polytetrafluoroethylene..	

What is the pathological lesion? The use of suture-mediated vascular preclosure devices can result in iatrogenic occlusion of the femoral artery or relevant bleeding with hemodynamic compromise. If it is the former due to misdeployment of the two pairs of preclosure sutures, one usually has the luxury of time to plan the management strategy. In contrast, one needs to act fast in a significant bleeding complication due to failure of preclosure, as the clinical outcome could be disastrous. Temporizing hemostasis should be immediately applied, and the maneuvers include manual compression of the arteriotomy site, crossover balloon occlusion, and reinsertion of the large-bore access sheath.

Crossover balloon occlusion refers to the advancement of a peripheral angioplasty balloon from the contralateral side and placement of the balloon just above the access site to temporarily occlude the inflow. However, this requires time to gain guidewire access from the contralateral femoral artery if a “crossover” guidewire is not present. Time is also needed for the advancement of the balloon catheter to the access site for occluding blood flow.

For reinsertion of the large-bore access sheath, one just needs to reinsert the device across the arteriotomy site, provided that the ipsilateral access site guidewire is still in situ. This is the preferred method, as it is quick and easy to do and provides immediate and complete temporary hemostasis. If immediately available, insertion of a smaller 14-F sheath will typically suffice in achieving hemostasis.

Anticoagulation. If the lesion is obstructive, one needs to keep the activated clotting time (ACT) > 250 seconds

to reduce any potential thromboembolic complications. In failed preclosure with significant bleeding that is not manageable as previously described, a quick review of the baseline femoral angiogram is important in localizing the arteriotomy site in relation to the inferior epigastric artery. If the bleeding is localized to the common femoral artery or temporary hemostasis has been completely achieved, reversal of anticoagulation is not given, and the ACT is kept at > 250 seconds. It is necessary to remember that as temporary hemostasis is being applied on the arteriotomy site, there is compromised or even absent antegrade flow to the distal vessels, with an increased risk for thromboembolic complications. No protamine reversal is administered, because an 18-F access site will bleed as much as an ACT of 150 or 300 seconds. In this situation, mechanical control of the bleeding arteriotomy site is needed.

Supportive therapy. An acute obstructive lesion does not alter the hemodynamic status of the patient by very much. In patients with relevant bleeding, volume resuscitation and pharmacologic hemodynamic support need to be addressed immediately. Transfusion of blood components (ie, packed red blood cells) should be given as soon as available. In our series of 25 patients with this unwanted access site complication who were successfully managed percutaneously, the mean hemoglobin decrease was 2.6 ± 1.6 g/dL and necessitated blood transfusion in 60% of the patients (unpublished data).

Vascular access. The size of the access sheath inserted in the contralateral femoral artery is determined by the device that will be used in the definitive therapy of the

TABLE 2. SHEATH SIZE NEEDED TO DELIVER AN ePTFE-COVERED NITINOL SELF-EXPANDING STENT

Device Name	Expanded Stent Graft Diameter (mm)	Expanded Stent Graft Length (mm)	Sheath Diameter Needed to Deliver Device (F)
Fluency Plus	6	40, 60, 80, 100, 120	8
	7	40, 60	8
	7	80, 100, 120	9
	8–10	40, 60, 80, 100, 120	9
	12, 13.5	40, 60, 80, 100, 120	10
Viabahn	5	25, 50, 75,* 100, 150, 250	6,* 7
	6	25, 50, 75,* 100, 150, 250	6,* 7
	7	25, 50, 75,* 100, 150, 250	7
	8	25, 50, 75,* 100, 150, 250	7
	9	50, 75,* 100, 150	9
	10	25, 50, 100, 150	11
	11	25, 50, 100	11
	13	25, 50, 100	12

Abbreviations: ePTFE, expanded polytetrafluoroethylene.
*Only in the 0.018-inch guidewire delivery system.

access site complication. In dealing with an obstructive lesion, immediate insertion of a 7-F crossover sheath (ie, a 7-F Flexor Ansel 1 sheath, Cook Medical) is immediately carried out. Other alternative crossover sheaths can also be utilized. On the other hand, in treating a bleeding access site due to failed preclosure, the sheath size is dependent on the diameter size of the expanded polytetrafluoroethylene (ePTFE)-covered nitinol self-expanding stent that will be used. This is the preferred device over balloon-expandable ePTFE-covered stents, as it is better suited for the common femoral artery, which is subject to the stresses of bending and external compression. In the United States, the currently available ePTFE-covered nitinol self-expanding stents include the Fluency Plus endovascular stent graft (Bard Peripheral Vascular, Inc.) and the Viabahn endoprosthesis (Gore & Associates). Table 2 lists the appropriate sheath sizes to use in order to successfully deliver a particular size stent graft device.

Evaluating the caliber size of the common femoral artery in advance during the preprocedural imaging study facilitates the selection of the properly sized sheath for delivery of the ePTFE-covered nitinol self-expanding stent needed to manage a vascular complication.

Definitive therapy. For hemodynamically significant obstructive lesions, balloon angioplasty of the stenotic segment can be safely performed. Figure 2A illustrates iatrogenic occlusion of the right common femoral artery. Atherotomy balloon angioplasty (Figure 2B) was successfully performed to recanalize the occluded segment and restore flow distally, as shown in Figure 2C. Provisional stent-

ing with deployment of a nitinol self-expanding stent can be used to treat hemodynamically significant residual stenosis.

In significant bleeding complications secondary to preclosure failure, exclusion of the arteriotomy site with the deployment of an ePTFE-covered stent across it has been our de facto management strategy. This is the quickest and most efficacious approach when utilizing percutaneous endovascular therapy as the first-line treatment. After achieving temporary hemostasis, crossover access from the contralateral iliofemoral artery is immediately gained. This allows selective angiography of the right iliofemoral artery to localize the arteriotomy site and, more importantly, to pinpoint the superficial femoral artery (SFA) and deep femoral artery (profunda femoris) bifurcation (Figure 3A).

Angiography should be performed 30° to 40° ipsilateral to the access site in order to best visualize the bifurcation. In the deployment of the ePTFE-covered stent, one would place the device above the bifurcation, so as not to compromise blood flow to one of the bifurcating vessels. A 0.035-inch stiff guidewire is advanced across the arteriotomy site and positioned as distally in the distal SFA or popliteal artery segment as possible to provide the most support during delivery of the bulky ePTFE-covered stent graft. Figure 3B illustrates the positioning of the ePTFE-covered nitinol self-expanding stent across the arteriotomy site. Removal of the large-bore sheath is followed by immediate deployment of the ePTFE-covered nitinol self-expanding stent. Prior to withdrawal of the large-bore sheath, the guidewire of the former sheath is exchanged for a 0.035-inch stiff Glidewire (Terumo Interventional Systems). The Glidewire is left in

situ during the removal of the large-bore sheath, and the stent graft is deployed over the guidewire. The latter is only pulled out when hemostasis is achieved with the deployment of the ePTFE-covered nitinol self-expanding stent, as shown in Figure 3C. With regard to the diameter size of the implanted stent graft, the device should be oversized by 20% relative to the diameter of the vessel.

Follow-up. Arterial pulse Doppler evaluation of the affected extremity is performed postprocedurally. Lower extremity arterial duplex ultrasound study is usually performed to evaluate the affected common femoral artery, as well as the peripheral runoff of the access side. Patients are advised to be followed up at 1, 6, and 12 months after the index procedure, and yearly thereafter.

DISCUSSION

Major vascular complications during transfemoral TAVR increase 30-day mortality and have significantly declined since the reported rate of 16.2% in the PARTNER I trial.⁴ In a prospective study of 130 transfemoral “high-risk” TAVR patients, a 22.7% 30-day mortality rate was noted in the cohort who had major vascular complications using the VARC definitions.¹⁷ The updated major vascular complications as defined by Vascular Academic Research Consortium-2 (VARC-2)¹⁸ are: (1) any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudoaneurysm; (2) access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life threatening or major bleeding, visceral ischemia, or neurological impairment; (3) distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage; (4) the use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischemia or neurological impairment; (5) any new ipsilateral lower extremity ischemia documented by patient symptoms, physical examination, and/or decreased or absent blood flow on lower extremity angiography; (6) surgery for access site-related nerve injury; or (7) permanent access site-related nerve injury.

Fortunately, continued improvement in operators’ skills, increased TAVR site experience, smaller sheath profile to deliver the TAVR device, thorough evaluation of the vascular access site, stringent attention to the SFAR as well as to the sheath-to-external iliac artery ratio, and meticulous technique in gaining vascular access have significantly reduced major vascular complications. In two consecutive fiscal year periods from 2009 to 2010, major vascular complications decreased from 8% to 1% ($P = .06$), and minor

vascular complications, as defined by VARC,¹⁹ decreased from 24% to 8%.⁵

In the current era, the majority of transfemoral TAVR is performed using a purely percutaneous transfemoral approach without surgical cutdown to achieve vascular access. Most of the vascular complications currently encountered are related to failure of the suture-mediated preclosure at the arteriotomy site, leading to incomplete hemostasis. Failure of percutaneous closure leading to vascular complications requiring intervention is approximately 4% to 9.5% of TAVR cases.^{5,12,20,21} Fortunately, these are effectively managed using a percutaneous endovascular approach. Failure of preclosure results from either an obstructive process (ie, stenosis, dissection, or thrombosis) or significant bleeding that necessitates open surgical repair.

In our series treating bleeding complications, all stent graft deployments were successful in achieving complete hemostasis and re-establishing normal flow to the periphery (unpublished data). The use of ePTFE-covered, nitinol self-expanding stents in the common femoral artery is safe and devoid of any untoward complications, despite being implanted in an area subject to bending and external compression.^{22,23} In our own series of 25 patients in whom ePTFE-covered, nitinol self-expanding stents (Viabahn endoprosthesis, Gore & Associates) were implanted, all stented common femoral arteries remained patent at the 30-day follow-up visit (unpublished data).

The deployment of either suture-mediated Prostar XL or Perclose ProGlide vascular devices in preclosing large-bore access sites exceeds the on-label arteriotomy size to be used with the devices. Notwithstanding, success of percutaneous preclosure achieving complete hemostasis is reported in > 90% of TAVR cases.²⁴⁻²⁶ This is in consonance with the high technical success rate (94%) from pooled data that included 2,257 patients who underwent percutaneous endovascular aortic repair.²⁷

This preclosure technique has allowed the realization of a pure percutaneous technique in TAVR. Use of either device is usually dictated by the operator(s) comfort in deploying the chosen device, and clinical outcome has historically been similar. A recent publication, however, showed that the use of Prostar XL preclosure in TAVR is associated with higher major vascular complications (7.4% vs 1.9%; $P < .001$) as compared to the use of two Perclose ProGlide devices, but with a similar in-hospital mortality rate.²⁸ Interestingly, use of only a single Perclose ProGlide device for preclosure to provide complete hemostasis has also been successfully performed in a cohort of 94 patients.²⁹ Percutaneous preclosure is plagued by incomplete arteriotomy closure leading to incomplete hemostasis and is the most common vascular complication presently encountered in transfemoral TAVR.

Unfortunately, this bleeding complication is not predictable and is reported to be approximately 6% to 7%.^{3,12} Failure is usually caused by vessel wall calcification that precludes proper deployment of the device needles and/or presence of subcutaneous tissue in the suture track that prevents the sutures from being apposed to the arterial wall. Needles can also be incorrectly deployed during sequential placement of the two Perclose ProGlide devices to achieve orthogonal placement of the two pairs of sutures. The routine use of ultrasound-guided femoral artery access³⁰ and the meticulous preparation of the preclose access suture track should further improve the technical success rate of preclosure. Vigilance is needed to recognize and undertake prompt percutaneous endovascular intervention of femoral artery access site vascular complications secondary to failed preclosure. Open surgical repair remains an alternative or back-up strategy to achieve hemostasis in the event of an unsuccessful closure of the arteriotomy site.

SUMMARY

A purely percutaneous transfemoral approach to TAVR has dawned and is applicable for a majority of patients in whom this treatment strategy for severe aortic stenosis is considered. In a small group of patients, surgical cutdown access for transfemoral TAVR or vascular access achieved through another route will still be needed. Careful vascular access planning and taking a preventative approach to complications should be of foremost consideration as one embarks on gaining large-bore vascular access. Despite this meticulousness, vascular complications will continue to occur and, as pointed out, is mostly related to failure of suture-mediated preclosure leading to incomplete hemostasis and significant bleeding. It is imperative that TAVR operators recognize this early and provide prompt intervention in this life-threatening access-related complication.

Percutaneous endovascular intervention affords a quick and a very effective therapeutic option in the management of access-related complications. With increased experience, this will be an essential skill requirement in the TAVR hybrid suite. Very favorable results coupled with lower periprocedural morbidity and mortality compared to open surgery should render percutaneous endovascular therapy as first-line treatment. ■

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