

Percutaneous Suture Closure for TAVR

A description of procedural steps and data regarding percutaneous access management for transcatheter aortic valve replacement.

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The most frequently reported complication of transfemoral transcatheter aortic valve replacement (TF-TAVR) has been vascular access complications due to the large sheath sizes required for device placement. Vascular complication rates have been reported to be between 8% and 30% with TF-TAVR and are associated with postoperative major morbidity and mortality.¹⁻⁵ The wide range of vascular complication rates reported is due to variability in devices (and thus access sheaths), definitions used, patient demographics, and site experience. Predictors of vascular complications in TF-TAVR include moderate to severe iliofemoral calcification and tortuosity, female sex, sheath size, and femoral artery sheath to artery ratio.⁵⁻⁹ Additionally, increasing site experience has been associated with decreased vascular complication rates.^{4,5,9}

Early recommendations for access management for the procedure included surgical cutdown; however, this rapidly progressed to suture-mediated closure as a less-invasive way to percutaneously manage access and allow earlier patient ambulation and procedure performance under conscious sedation. In this article, we review the details of this procedure, the available data, and the future directions for TF-TAVR percutaneous access management.

PROCEDURAL DESCRIPTION

Suture-mediated closure can be performed with the 6-F Perclose ProGlide device (Abbott Vascular), as well as the 10-F ProStar device (Abbott Vascular). Initial attention must be focused on the appropriate location

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of femoral arterial access in the mid-femoral head in an undiseased segment, which can be confirmed using crossover angiography with or without digital subtraction and road mapping or ultrasound guidance. The majority of our percutaneous closures are performed with the Perclose ProGlide device. Given that the device was intended for suture-mediated closure of 6- to 8-F sheaths,¹⁰ two devices are used for this procedure, both placed using a “preclose” technique (Figure 1). Once arterial access is achieved and dilated with a standard-size arterial sheath, the first ProGlide device is advanced over the guidewire, turned 30° left of center, and the first suture deployed (see the *Steps for Performing Suture-Mediated Closure of Femoral Access for TAVR* sidebar). The device is removed over a guidewire, and the sutures are secured to the side of the access site, commonly with surgical Kelly forceps.

A second ProGlide device is then advanced over the guidewire and angulated 60° orthogonal to the placement of the initial device (30° right of center), and the second set of sutures are placed. The second set of

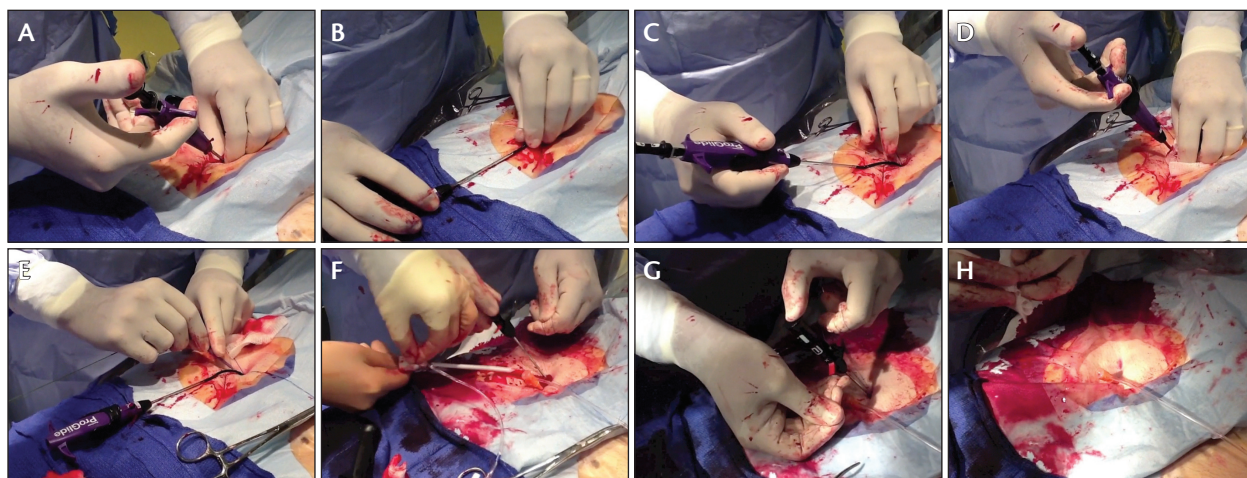


Figure 1. Suture-mediated closure of femoral access in TF-TAVR. The first ProGlide device is advanced and oriented 30° left of center, and the sutures are deployed as per the usual technique (A). The first ProGlide device is removed over a J-wire, and the sutures are secured to the side of access site (B). The second ProGlide device is advanced over the wire (C). The second device is oriented 60° orthogonal to the first device (or 30° right of center), and the sutures are deployed (D). The second ProGlide device is removed over the wire, and the sutures are secured to the side of the access site (E). The first knot is advanced with the knot pusher while the sheath is being removed (F). The J-wire is removed, and both sets of sutures are cut (G). Final picture (H).

sutures is then secured to the side of the access site, this second device is also removed over a guidewire, and a TAVR sheath dilator is placed. The guidewire is then exchanged for a stiffer wire to allow the larger TAVR sheath to be placed. After the procedure is complete, the sheath is removed, and each individual set of sutures is tightened with the knot pusher. The knot pusher can be advanced quickly while the sheath is removed, and/or an additional operator can maintain manual pressure while the knots are tightened. The access wire remains in place until successful hemostasis is confirmed, and then the sutures are cut. An additional third or fourth ProGlide device may be placed in the setting of inadequate hemostasis. Additionally, the dilator may be reintroduced prior to sheath removal to allow more gradual closure of the artery with continuous tightening of the sutures, thus avoiding a larger bolus of blood flow with sheath removal, which may pull on the sutures and result in vascular damage.

The 10-F ProStar device can also be used for percutaneous closure of TAVR access.¹¹ The ProStar device is advanced over the guidewire until blood is seen in the dedicated marker lumen, demonstrating that the device is accurately placed within the lumen of the femoral artery. The position and angle of the device are maintained while the four needles are retracted and removed from the hub. The upper and lower sets of sutures are secured to the side of the access site, and the device is removed over a wire to allow placement of the dilator prior to TAVR sheath placement. When the procedure

is completed, the sutures are tied with a sliding knot and the knot pusher. The success rates of both the ProGlide and ProStar devices increase with operator experience, as there is a learning curve associated with the use of these devices.

Percutaneous suture-mediated closure can be assisted with a reduction in hemostasis using the crossover balloon occlusion technique.^{12,13} This technique requires placement of a peripheral angioplasty balloon (typically 8–12 mm in diameter) that is advanced from the contralateral side to the access side femoral or iliac artery superior to the access site. Low-pressure inflation can temporarily occlude distal blood flow to allow percutaneous closure in a bloodless field. Although such a procedure is only rarely associated with complications, the use of distal aortic occlusion with a 22-mm X 5-cm Tyshak II balloon (B. Braun Medical, Inc.) can also be used to reduce possible iliofemoral complications.¹⁴

Crossover balloon inflation or aortic occlusion procedures are currently not performed in all percutaneous closure cases, but they may be considered in cases when the largest sheath size is utilized or in cases with challenging anatomy or suboptimal preclose results. A potential benefit of this technique is the ability to rapidly perform peripheral intervention in cases of femoral arterial dissection or perforation recognized after sheath removal to manage hemostasis in the setting of closure device failure and femoral arterial stenosis induced by device sutures. Last, careful attention to the hemodynamic status of the patient during percutane-

ous closure should be paid because hypotension or tachycardia may potentially signal unrecognized retroperitoneal bleeding.

CLINICAL OUTCOME DATA

The use of percutaneous suture-mediated closure devices to achieve femoral artery hemostasis for large-bore access sheaths has been well described in the cardiology and endovascular literature. Since the introduction of percutaneous vascular suture devices more than 15 years ago, the preclose technique has been successfully used for arteriotomy closure after aortic valvuloplasties¹⁵⁻¹⁷ and transcatheter aortic repairs¹⁸⁻²¹ using 12- to 25-F sheath sizes. As operators became more experienced, > 90% successful closure rate has been reported, with very few complications.^{20,21}

The initial experience with TAVR utilized both percutaneous and open surgical approaches, but open

cutdown and repair were slightly favored given the large 22- and 24-F sheaths used for the Sapien valve (Edwards Lifesciences)²² and the 21- and 24-F delivery systems for the first-generation CoreValve device (Medtronic, Inc.).²³ Furthermore, TAVR was initially studied in very high-risk patients with significant comorbidities, whose advanced age and underlying disease substrate corresponded to a high frequency of severe peripheral vascular disease and small-caliber, calcified, and tortuous vessels. Accordingly, there was a high rate of TAVR-related vascular complications in these early studies.⁷

Reinforced by the successful use of this technique for large-bore sheaths in the endovascular space, and as operator experience has increased and delivery sheath size has decreased, the use of percutaneous suture closure for transfemoral TAVR has grown rapidly.^{9,24-27} Among the published reports, the success rates using the ProGlide and Prostar XL devices are generally well above 90% for large sheaths up to 24 F (Table 1). Based on endovascular data, there is potential for a reduction in procedure time, hospital length of stay, and the need for blood transfusion, with improvements in patient comfort, satisfaction, and time to ambulation.^{18,21} In one report of endovascular repair, however, the cost savings for these improved outcomes was outweighed by the cost of the closure devices.²¹ Only one randomized trial has been performed to evaluate percutaneous access versus a surgical approach for arterial access management in TAVR; this trial demonstrated no significant difference in VARC-2 major and minor complications. However, this was a small study at a single center with significant TAVR experience.²⁸

Major vascular complications and failed hemostasis in the handful of published studies were not insignificant—up to 15% to 21% in some centers (Table 1). Although many of the stenoses, dissections, and perforations were successfully treated with angioplasty or covered stents,²⁸ several patients required an open surgical intervention or a transapical or transaortic approach to complete the TAVR procedure.²⁸ Aortic occlusion or balloon crossover may reduce blood loss,^{12,13} but 2% to 8% of patients still required surgical intervention despite stabilization using contralateral balloon occlusion.¹⁴ Bleeding remains the primary reason for conversion to open repair,¹⁹ but Perclose devices can be associated with vessel thrombosis, dissection, and limb ischemia²⁹ that may also require surgery.

Femoral calcific or aneurysmal disease and high femoral artery bifurcations can typically be avoided with careful preprocedural planning using ultrasound, CT, or angiographic imaging. However, failure of the percutaneous suture device can occur for many reasons, including

STEPS FOR PERFORMING SUTURE-MEDIATED CLOSURE OF FEMORAL ACCESS FOR TAVR

- Achieve arterial access as per usual technique and dilate with standard size arterial sheath.
- The first ProGlide device is advanced, oriented 30° left of center, and sutures are deployed as per the usual technique.
- The first ProGlide device is removed over a J-wire, and the sutures are secured to the side of the access site.
- The second ProGlide device is placed over the wire and oriented 60° orthogonal to the first device (or 30° right of center), and the sutures are deployed.
- The second ProGlide device is removed over a wire, and the sutures are secured to the side of the access site.
- The dilator is placed over the J-wire, and the wire is exchanged for a stiff wire.
- The sheath required for TAVR is placed, and the procedure is performed.
- The first knot is advanced with the knot pusher while the sheath is being removed.
- The second knot is advanced with the knot pusher. The J-wire remains in place until adequate hemostasis is confirmed.
- The J-wire is removed, and both sets of sutures are cut.

TABLE 1. COMPARATIVE STUDIES EVALUATING PERCUTANEOUS VASCULAR CLOSURE VERSUS OPEN SURGICAL REPAIR OF THE FEMORAL ARTERY

Study	Number of Patients		Device	Sheath Sizes	Percutaneous Closure Success Rate	Procedural Complications
	Percutaneous (P)	Open (O)				
Nakamura et al (2014) ²⁷	140	134	ProGlide	22–24 F	82.1%	Major VARC complications 15% (P) vs 11.2% (O) Unplanned surgical intervention 2.9% (P) vs 4.5% (O)
Holper et al (2014) ²⁸	15	15	ProGlide	22–24 F	93%	Major VARC complications 21.4% (P) vs 7.1% (O)
Bowers et al (2014) ¹⁴	100	17	ProGlide	18–24 F	99%	Dissection 3.4%; vascular injury requiring surgical repair 3%
Kahlert et al (2013) ²⁶	94		Prostar XL ProGlide	18–24 F	89%	Major VARC complications 12%; vascular surgery 8.5%
Griese et al (2013) ²⁵	162	28	ProGlide	16–20 F	93.9%	Lack of hemostatic control 4.3%; dissection or occlusion 1.8%
Cockburn et al (2012) ¹⁷	64		Prostar XL	18 F	92.2%	Major bleeding 4.7%

tortuous, diseased vessels impeding device tracking, scar tissue or vessel calcification precluding proper deployment of the needles, or subcutaneous tissue that prevents the sutures from being tightened against the vessel wall.¹⁸

Despite these drawbacks, the > 90% success rate of percutaneous suture closure for TAVR remains encouraging. Patient discomfort, wound infections, and lymphatic fistula formation leading to seromas and lymphoceles can frequently accompany open surgical repairs.^{20,21} As operators become more proficient at using the ProGlide devices, and as newer-generation transcatheter valves use lower-profile delivery sheaths, the benefit of a completely percutaneous approach may become more apparent.

FUTURE DIRECTIONS

Almost all of the new-generation transcatheter aortic valves will be delivered through 14-F sheaths (Table 2), which will inevitably reduce vascular complications compared to older valves. The use of expandable

sheaths, such as the balloon-inflatable SoloPath (Terumo Interventional Systems) or the passively expandable eSheath (Edwards Lifesciences), also promise fewer vascular complications and will likely lead to more successful percutaneous suture closures. Furthermore, it may be possible to deliver some valves “sheathlessly,” lowering their crossing profile through the femoroiliac arteries and reducing vascular complications and suture failure.

With an all-percutaneous approach, performing TAVR under local anesthesia with conscious sedation may potentially be closer to becoming standard practice. If this practice is proven safe, the real benefit of percutaneous closure on associated procedural costs and hospital length of stay³⁰ will be more fully appreciated.

SUMMARY AND CONCLUSIONS

Prior to considering TF-TAVR, careful evaluation of preprocedural imaging can provide important information regarding the suitability of percutaneous closure. Suture-mediated closure is a safe and effective

TABLE 2. SPECIFIED DELIVERY SHEATH SIZES OF TRANSCATHETER AORTIC VALVES

Company	Valve	Sheath Size
Early Devices		
Edwards Lifesciences	Sapien	22–24 F
Medtronic, Inc.	CoreValve	18–24 F
Devices Currently Approved for Use in the United States		
Edwards Lifesciences	Sapien XT	16–20 F
Medtronic, Inc.	CoreValve	18 F
Devices Under Clinical Investigation in the United States		
Edwards Lifesciences	Sapien 3	14–16 F
Medtronic, Inc.	Evolut R	14 F
Boston Scientific Corporation	Lotus	18 F
St. Jude Medical, Inc.	Portico	18 F
Direct Flow Medical	Direct Flow	18 F

way to provide fully percutaneous closure and may be utilized with proximal arterial occlusion in the iliac artery or distal abdominal aorta. Although comparable clinical outcomes have been described for percutaneous versus surgical cutdown for TF-TAVR, there continue to be unique scenarios in which surgical access for TF-TAVR proves invaluable, such as the inability to advance the sheath or visualization of anatomy that is not amenable to sheath placement. Because experience is an established predictor of vascular complications, centers are cautioned to continue TF-TAVR as a unique interdisciplinary collaboration between interventional and surgical practitioners to successfully manage vascular access. Additionally, operators will need increased experience using such devices with smaller French sheaths prior to applying these techniques to TAVR sheaths. Newer-generation transcatheter valves will utilize smaller sheath sizes for access, providing the opportunity for more fully percutaneous transcatheter valve procedures. ■

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