Percutaneous Femoral Access for TAVR

Improving upon the applicability and success of existing suture-mediated devices used in percutaneous TAVR procedures.

BY ROBERT M. BERSIN, MD, MPH

The clinical benefit of percutaneous intervention over a surgical approach has been well demonstrated for a number of procedures and has been best demonstrated for endovascular repair of abdominal aneurysms (EVAR) and thoracic aneurysms (TEVAR). It was noted early in the EVAR and TEVAR experience that if patients could undergo endograft implantation under local anesthesia as compared to general anesthesia, the rates of systemic, cardiac, and pulmonary access site complications were reduced by at least 50% or more, and early mortality rates were also favorably affected (Table 1).[1]

The development of the Perclose Prostar XL suture-mediated closure device (Abbott Vascular, Santa Clara, CA) for larger (≥ 10 F) sheaths in 1998 led to immediate interest in the application of this device for percutaneous delivery of EVAR and TEVAR devices. Since the first reported use of the Perclose Prostar XL device by Haas[2] in 1999 for percutaneous delivery of 16- to 22-F EVAR devices, at least 12 publications on 1,148 patients have followed, using either the 10-F Perclose Prostar XL or the double ProGlide technique (Abbott Vascular) for delivery of 14- to 24-F EVAR/TEVAR devices. The technical success rate of this approach has exceeded 90% since 2002 (Table 2).

In the single largest series of percutaneous vascular access for EVAR/TEVAR reported by Eisenack in 2009,[3] 93% of a consecutive series of 535 patients were found to have anatomy suitable for a percutaneous approach, and the technical success rate was 96% in those patients who were treated percutaneously. Only 3.5% of patients required surgical conversion to complete the procedure. Thus, not only can a suture-mediated percutaneous approach be performed with a high degree of technical success (96%), but the vast majority of patients also have eligible anatomy for this approach (93%). These excellent contemporary results of percutaneous access stimulated a randomized trial of percutaneous versus surgical access for

TABLE 1. EVAR COMPLICATIONS AS A FUNCTION OF TYPE OF ANESTHESIA USED

EVAR Complications	Local Anesthesia (N = 169)	General Anesthesia (N = 1,744)	*P* Value
Systemic	9%	18%	< .01
Cardiac	1.8%	6.3%*	= .04
Pulmonary	1.2%	3.6%*	= .03
Sepsis	0.6%	1.6%	= .006
Access site	4.8%	8.3%	< .0001
Early death	3.6%	4.3%*	< .05*

**Significant at* P *< .05.*

TABLE 2. REPORTS OF LARGE-VESSEL CLOSURE WITH SUTURE-MEDIATED CLOSURE DEVICES IN THE LITERATURE					
Author and Year	**Physician Specialty**	**Sheath F Size**	**SMCD**	**No. of Patients**	**Technical Success**
Haas 1999	IC	16–22	PS	12	100%
Traul 2000	VS	16–24	PS	17	64%
Teh 2001	VS/IR	16–22	PS	44	85%
Rachel 2002	VS	16–22	PS	44	76%
Howell 2002	IC	16–22	PS	30	96%
Torsello 2003	VS	14–25	PS	15	93%
Morasch 2004	VS	12–18	PS	47	93%
Starnes 2006	VS	12–24	PS	49	94%
Jean-Baptiste 2007	VS	12–24	PS	19	92%
Lee 2008	VS	12–24	PG	292	94%
Eisenack 2009	VS	14–24	PG	500	96%
Smith 2009	VS	NR	PG/PS	22	100%
Krajcer 2010	IC	9–19	PS	57	98%

Abbreviations: IC, interventional cardiologist; IR, interventional radiologist; PG, double ProGlide; PS, Perclose Prostar XL; SMCD, suture-mediated closure device; VS, vascular surgeon.

EVAR called the PEVAR trial. In the PEVAR trial, the lead-in phase of percutaneous access required surgical conversion to complete device delivery in only 2.6% of patients.[4] The randomized portion of the trial is still underway, so the final outcomes of percutaneous versus surgical access are pending. Nonetheless, the results from the lead-in phase of the PEVAR trial support that the percutaneous approach can be done safely and effectively.

PERCUTANEOUS ACCESS FOR TAVR

The experience gained with percutaneous access in the EVAR/TEVAR arena provided an excellent background for the percutaneous approach to transfemoral aortic valve replacement (TAVR) procedures. The vascular access sheaths for TAVR implants are of similar size to those used for EVAR/TEVAR and currently range from 16 to 24 F, but are generally being applied in patients who are older with more comorbidities; therefore, access issues become increasingly important in this patient population. The impact of the risk profile of the patient on the potential for access site complications cannot be overstated. In the PARTNER trial of the Sapien transfemoral aortic valve (Edwards Lifesciences, Irvine, CA) implant versus surgical aortic valve replacement (cohort A), which included patients who were surgical candidates and could be randomized, the incidence of major access site complications in the subgroup undergoing TAVR was 11%. In cohort B, which included inoperable patients, the incidence of major access site complications in patients who underwent TAVR increased to 16.2%. Major vascular access site complications were also a predictor of procedural mortality. Although vascular access was achieved by surgical cutdown in all patients in the PARTNER trial, the impact of vascular access complications on mortality has also been observed in patients undergoing percutaneous TAVR.

In a study by Hayashida et al, which examined predictors of vascular access site complications and their impact on TAVR mortality, patients with major vascular access site complications had a 30-day mortality of 22.7% compared to 7.6% in patients who did not have major vascular access site complications.[5] The authors identified the ratio of the sheath outer diameter (in millimeters) to the minimal femoral artery diameter (in millimeters) as the sheath-to-femoral artery ratio and identified a ratio of ≥ 1.05 as a predictor of access site complications and mortality. Most of the patients treated in this study underwent percutaneous access (99/127, 80%), and the access method (surgical vs percutaneous) was not found to be a predictor of vascular access complications or mortality.[5]

PERCUTANEOUS LARGE-SHEATH ACCESS

Currently, the two-stitch Perclose Prostar XL and the single-stitch ProGlide suture-mediated closure devices are the only devices available for percutaneous large-sheath (≥ 10 F) vessel closure (Figure 1). The keys to successful application of these closure devices for percutaneous

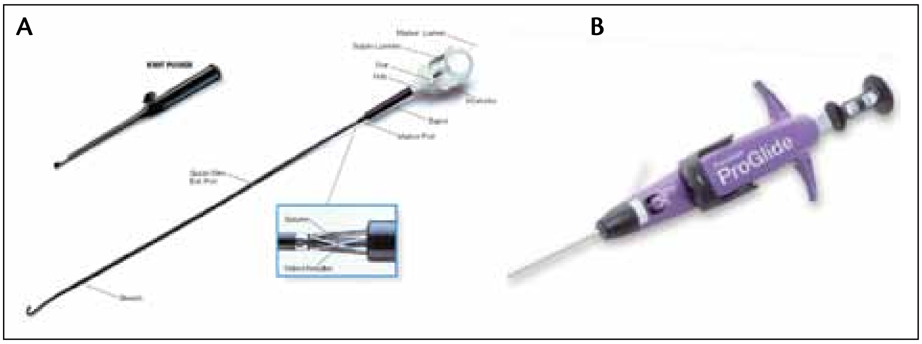

Figure 1. The Perclose Prostar XL (A) and ProGlide (B) closure devices. Images courtesy of Abbott Vascular. ©2012 Abbott. All rights reserved.

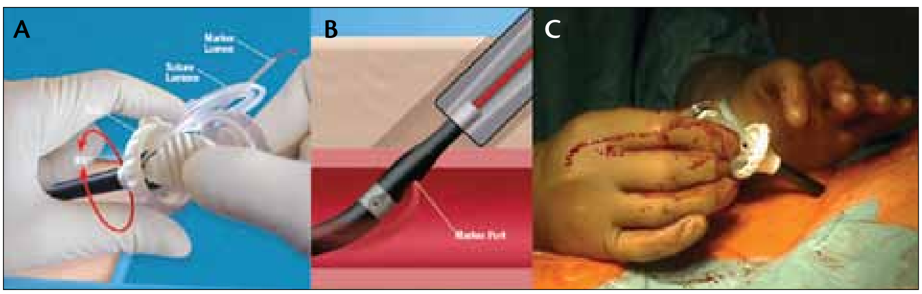

Figure 2. The 10-F Prostar XL device is advanced through the subcutaneous tissue and into the vessel by applying forward pressure on the rotating barrel at the proximal hub of the device until blood return is seen from both vessel locator ports. Images 2A and 2B courtesy of Abbott Vascular. ©2012 Abbott. All rights reserved.

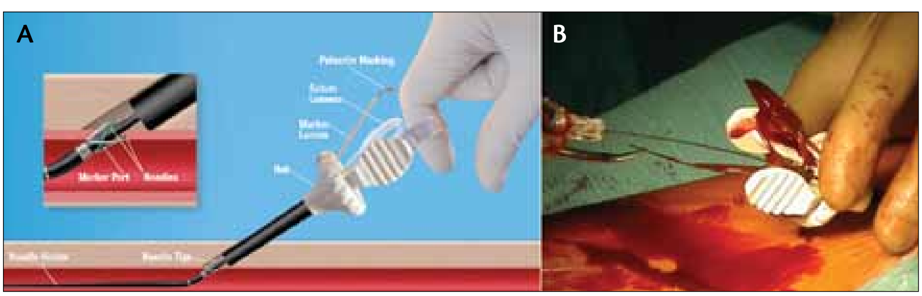

Figure 3. The sutures are deployed by rotating the O-pull ring 90° and pulling back while keeping forward pressure on the rotating barrel with the other hand. Image 3A courtesy of Abbott Vascular. ©2012 Abbott. All rights reserved.

TAVR begins with appropriate patient selection and meticulous attention to technique. Predictors of failure of the percutaneous approach for large-vessel closure include morbid obesity, femoral artery calcification, a high anatomic common femoral artery bifurcation, a percutaneous needle stick that is either too high or too low in the common femoral artery, or a stick that is made on an oblique angle to the perpendicular anteroposterior plane of the vessel. It is recommended that vascular ultrasound or digital angiographic road mapping be used for the initial percutaneous stick to ensure proper positioning of the arteriotomy in the femoral artery before proceeding with percutaneous large-vessel access. Confirmation of the proper positioning of the arteriotomy by a selective contrast injection using a small (5–6 F) sheath is recommended before proceeding with introduction of the suture-mediated closure device. Once proper positioning of the small sheath is confirmed, the sheath can be exchanged for the suture-mediated closure device(s) over a 0.035-inch guidewire. Typically, either one Prostar XL or two ProGlide devices are deployed prior to introduction of the large-diameter sheath with externalization of the sutures, which are then knotted at the end of the procedure upon removal of the sheath (so-called *vessel preclosure*). More devices can be deployed for preclosure, if necessary. A description of device deployment follows.

PRECLOSURE TECHNIQUE

After widening the arteriotomy by 1 to 2 cm and performing blunt dissection to clear the subcutaneous tissue away from the femoral artery, the 10-F Prostar XL device is advanced through the subcutaneous tissue and into the vessel by applying forward pressure on the rotating barrel at the proximal hub of the device until blood return is seen from both vessel locator ports (Figure 2). The sutures are then deployed by rotating the O-pull ring 90° and pulling back while keeping forward pressure on the rotating barrel with the other hand (Figure 3).

The sutures are then pulled out of the device hub using a needle driver. The device hub is then pulled back a sufficient distance to expose the sutures below the hub so they can be removed from the hub with a needle driver or forceps (Figure 4). Each suture is then individually secured

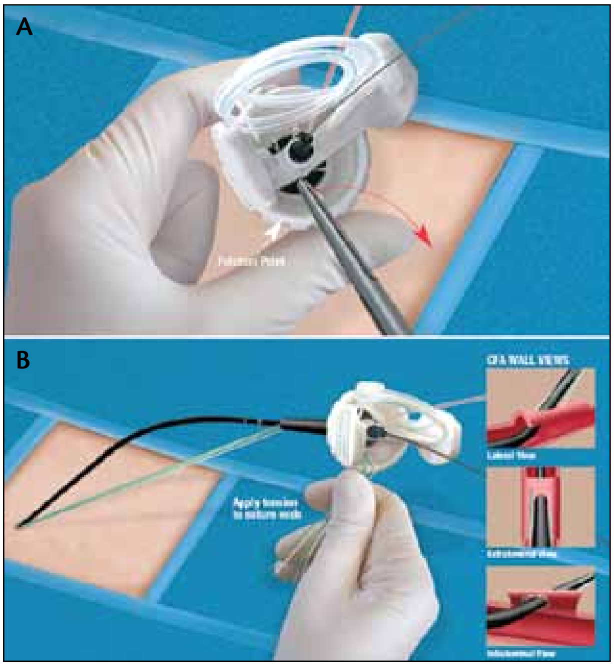

Figure 4. The device hub is pulled back a sufficient distance to expose the sutures below the hub so they can be removed from the hub with a needle driver or forceps. Images courtesy of Abbott Vascular. ©2012 Abbott. All rights reserved.

using forceps or hemostats, and the delivery device is removed by reintroduction of a 0.035-inch guidewire via the monorail wire port on the shaft of the device. A larger (≥ 10 F) sheath can then be introduced over the guidewire with the sutures in place (Figure 5).

Upon completion of the procedure, a fisherman's knot is made to tie each suture, and each suture is tightened and locked on the arteriotomy by advancing the suture tamper down the suture, keeping back tension on the suture with the other hand (Figure 6).

The steps taken for using two ProGlide devices rather than one Prostar XL device are similar, except that the ProGlide sutures are preknotted within the device.

PROCEDURAL OUTCOMES AND FUTURE DIRECTIONS

The percutaneous approach to TAVR using local anesthesia was first described by Cribier[6] and was evaluated in a prospective study recently reported by Durand et al.[7] A consecutive series of 151 patients underwent TAVR using surgical access for the Sapien valve (n = 78) and percutaneous closure for the Sapien XT valve (Edwards Lifesciences) using the Prostar XL device (n = 73) under local anesthesia and fluoroscopic guidance for femoral artery access was reported. The percutaneous approach was successful in 98.6% of cases. Conversion to surgical cutdown occurred in only 2.7% of cases, and conversion to general anesthesia to complete the procedure was required in only 3.3% of cases. Major access site bleeding was not different for either surgical or percutaneous access (7.7% vs 8.2%; *P* = .9). The study demonstrated that TAVR procedures can be successfully performed using percutaneous access with the Prostar XL device, with low complication rates that are identical to those that have been reported for percutaneous EVAR/TEVAR procedures.

The most common reason for conversion to surgical cutdown is a failure to achieve adequate hemostasis. Another infrequent reason is a failure of the device to deploy the suture needles through the vessel wall properly as a result of needle deflection of plaque or calcium outside the catheter hub, a problem observed with the Prostar XL device that was largely eliminated by the

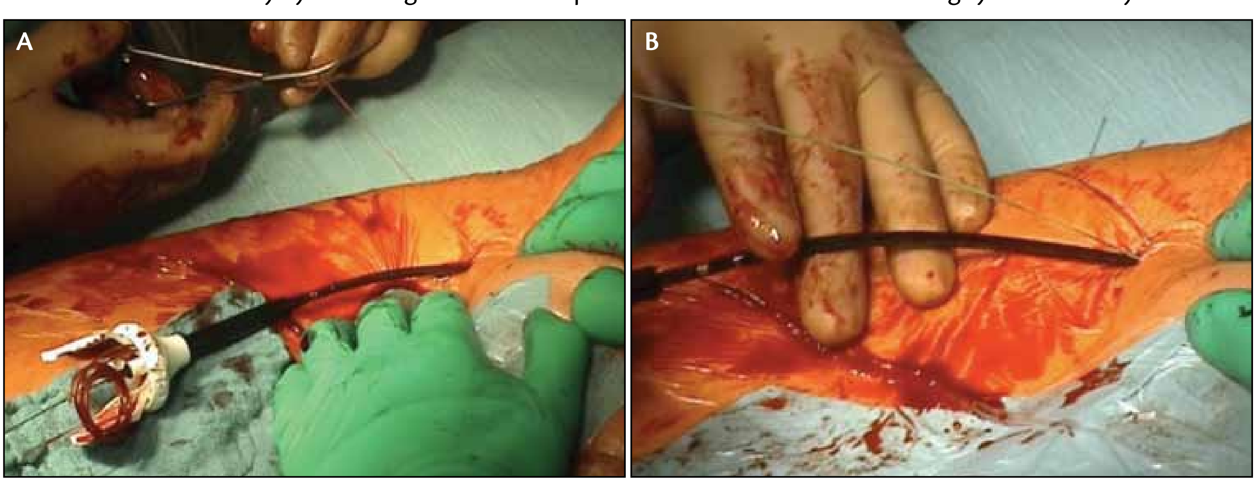

Figure 5. Each suture is individually secured using forceps or hemostats, and the delivery device is removed by reintroduction of a 0.035-inch guidewire via the monorail wire port on the shaft of the device (A). A larger (≥ 10 F) sheath can then be introduced over the guidewire with the sutures in place (B).

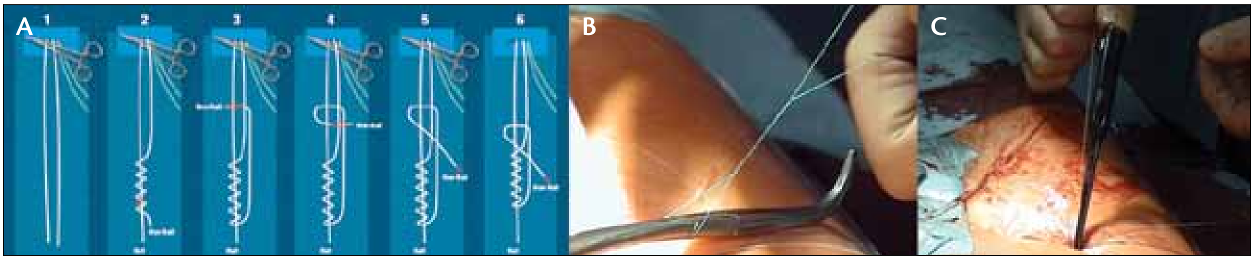

Figure 6. A fisherman's knot is made to tie each suture, and each suture is tightened and locked on the arteriotomy by advancing the suture tamper down the suture, keeping back tension on the suture with the other hand. Image 6A courtesy of Abbott Vascular.

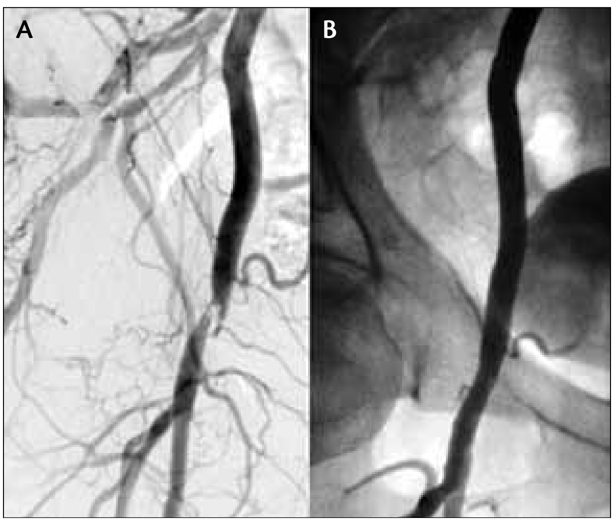

Figure 7. Perclose stenosis (A) treated with PTA (B).

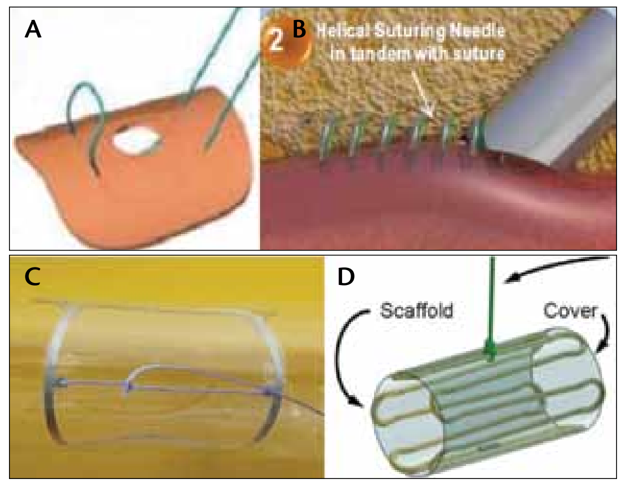

Figure 8. The Spirx mattress suture device (A), the VasoStitch running suture device (B), the Atum device (C), and the Promed vascular closure device (D).

Proglide device with the sutures being deployed from outside the vessel rather than from inside as with the Prostar. Other complications of suture-mediated closure of large sheaths include the development of a stenosis or occlusion as a result of the suture pursing the artery too tightly (Figure 7).

As a result of these encouraging results, several devices are now in development to facilitate percutaneous large-vessel closure, including two other suture-mediated devices, the Spirx mattress suture device (SpiRx, Whitmore, CA) and the VasoStitch running suture device (VasoStitch, Menlo Park, CA). Two other novel nonsuture-mediated scaffold devices, the Atum device (InSeal Medical, Caesarea, Israel) and the Promed VCD (Promed, Inc., Santa Clara, CA) are also in development (Figure 8).

These devices aim to improve upon the applicability and success of existing suture-mediated devices and enhance patient outcomes in percutaneous TAVR procedures. As TAVR device profiles continue to get smaller, the number of percutaneous TAVR procedures will increase. Because vascular access site complications remain a major predictor of morbidity and mortality in TAVR procedures, the morbidity and mortality of the implantation procedure should only improve as the techniques and devices for percutaneous access advance. ■

Robert M. Bersin, MD, MPH, is Medical Director, Endovascular Services, Swedish Medical Center in Seattle, Washington. He has disclosed that he is a consultant to Abbott Vascular. Dr. Bersin may be reached at robert.bersin@swedish.org.

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