

Chapter 11: Step-by-step guide: transfemoral Corevalve Evolut TAVR

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Essential or Key Steps

- Confirm transcatheter heart valve (THV) size by 3D CT and ECHO
- Confirm THV deployment side, i.e. right or left femoral artery
- Vascular access
- Place and confirm transvenous RV pacing catheter
- Sheath insertion
- Diagnostic pigtail catheter in the non-coronary cusp always
- Establish coplanar view
- Cross the native valve
- Hemodynamics
- THV positioning
- Assess placement at 2/3 deployment (valve can be recaptured and repositioned at this point)
- THV full deployment
- Assess THV post-deployment by hemodynamics, ECHO and arteriography
- Device and sheath removal
- Vascular closure

Pearls and Pitfalls

- Valve sizing is key. 3D imaging is crucial and 3 D CTA is most common.
- CT annular diameter measurements are based on perimeter derived diameter.
- If diameter is borderline between two valve sizes, consider the larger valve size if the SOV width is adequate.
- Be judicious with the use of contrast to avoid renal injury.
- The goals of arterial puncture include: anterior wall stick, below the inguinal ligament at the midway of the femoral head, above areas of calcification, and above the bifurcation.
- Percutaneous access that is too high increases the risk of retroperitoneal bleed. Access that is too low risks cannulation of the superficial femoral artery. Consider performing an iliac angiogram with runoff from the contralateral access site to visualize proper access site.
- For the Perclose percutaneous femoral artery closure device, be sure to dissect through the soft tissue to the top of the femoral artery. Otherwise, the sutures may lock in the soft tissue with inadequate closure of the arteriotomy.
- Avoid excess force when advancing the transvenous pacing wire since this may perforate the right atrium or right ventricle.
- Consider using a pre curved wire for valve deployment.

- After crossing the aortic valve, always be mindful of the position of the stiff wire. Too deep risks puncture while too shallow risks losing wire access. If the wire appears to be entrapped within the mitral valve chordae, consider adjusting the wire position to avoid damage to the chordae with THV delivery.

Background

The CoreValve Pivotal Extreme Risk IDE trial Showed superiority to medical treatment for non-operable patients with symptomatic severe aortic stenosis. ¹The High risk randomized trial showed superior outcomes for TAVR with the self-expanding CoreValve versus surgery. ² The SURTAVI intermediate risk randomized trial showed non-inferior results to surgery. ³The second generation Evolut R and the third generation Evolut Pro have showed improved outcomes over the first generation valve.

Valve Sizing

Valve sizing should follow the IFU sizing chart

Valve Size Selection	Evolut™ PRO Bioprosthesis			Evolut™ R Bioprosthesis
				
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter (A)	17*/18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter†	53.4*/56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-94.2 mm
Sinus of Valsalva Diameter (Mean) (B)	≥25 mm	≥27 mm	≥29 mm	≥31 mm
Sinus of Valsalva Height (Mean) (C)	≥15 mm	≥15 mm	≥15 mm	≥16 mm

*Measurement for TAV-in-SAV only. | †Annulus Perimeter = Annulus Diameter x π
NOTE: Evolut PRO valve size selection is identical to Evolut™ R valve size selection criteria

Procedural Steps

Once the appropriate patient and valve are selected, the procedure is divided into five sequential steps – access, valve crossing, balloon aortic valvuloplasty (BAV), valve implantation, and access closure. Additional considerations are selection of anesthesia (local with sedation vs. general anesthesia), and placement of a temporary pacing wire in the right ventricle. The vast majority of our cases are done using conscious sedation, although we remain fairly liberal about the use of general anesthesia. In cases performed under general anesthesia, patients are extubated before leaving the operating room, except in extreme cases that warrant gradual weaning from mechanical ventilatory support. In fact, the level of anesthesia is lightened once the valve is implanted, in anticipation of early waking and extubation. The anesthesiologist places a temporary screw-in pacer wire via the right internal jugular vein at the beginning

of the case.

Access

It is crucial for the operator to be facile with peripheral vascular computed tomography angiogram (CTA) image interpretation to assess the size and quality of the peripheral arteries necessary to allow access. In this chapter, we discuss transfemoral access only, as this is the access route in the vast majority of our cases. Alternative access routes are available, have been widely described, and are necessary for the advanced TAVR operator to master in cases that mandate a bailout strategy. Our default approach is percutaneous transfemoral access with preclosure using 2 suture-mediated closure devices (Perclose ProGlide[®], Abbott Laboratories, Abbott Park, IL). Ultrasound-guided alternate access of the smaller-sized or left femoral artery, if both are adequate, is performed using a micro-puncture needle and sheath, and exchanged for a 6-Fr 10-cm introducing sheath. An internal mammary artery catheter and a hydrophilic GLIDEWIRE[®] (Terumo Interventional Systems, Terumo Medical Corporation, Somerset, NJ) are used to cross the aortic bifurcation into the right common iliac and femoral arteries. The hydrophilic wire is exchanged for a 0.018-inch Platinum Plus[™] guidewire (Boston Scientific, Marlborough, MA) that remains in place as a “safety” wire during the procedure, and allows contralateral access, if required (Figure 1; #1). Fluoroscopy is utilized to identify an appropriate site for the right femoral arterial puncture, and a small 1-cm skin incision is made. The artery is accessed using a micro-puncture needle and sheath, and a 145-150-cm 0.035-inch J-tipped guidewire is placed in the arterial lumen, using the safety wire as a fluoroscopic guide. Intravenous unfractionated heparin is then administered to achieve an activated clotting time (ACT) > 250 seconds. Perclose ProGlide[®] devices are deployed at 2- and 10-o’clock positions, with maintenance of arterial access with the J-tipped guidewire. The J-tipped guidewire is then exchanged for a stiffer Amplatz Super Stiff[™] (Boston Scientific, Marlborough, Massachusetts) guidewire. The valve delivery sheath (18-Fr GORE[®] DrySeal (W. L. Gore & Associates, Inc., Flagstaff, Arizona) for 23, 26, and 29-mm and 20-Fr for 34-mm CoreValve Evolut R[®] valve) is passed over the stiff wire under fluoroscopy to ensure its seamless passage through the arterial lumen. Once the large sheath is secured in place, a checklist is reviewed to ascertain that all mission-critical steps have been completed to this point, as well as to ascertain team congruence and preparedness to deploy the valve. Next, a 5-Fr marker pigtail catheter is passed through the 6-Fr 10-cm arterial sheath in alternate access site, and placed in basal portion of the non-coronary cusp (Figure 1, #2). A series of aortograms, often with rapid right ventricular pacing to allow adequate visualization using dilute contrast, is performed at an implant angle determined from the CTA to verify linear alignment of the three cusps (coplanar image projection).

Valve Crossing and Balloon Aortic Valvuloplasty

A 6-Fr AL-1 catheter is passed through the valve delivery sheath over a 145-150 cm 0.035-inch J-tipped guidewire, and exchanged for a straight-tip wire to cross the valve. The valve is typically crossed in the left anterior oblique (LAO) projection on fluoroscopy, as it allows for early recognition of inadvertent wire entry into the left main coronary artery while attempting to cross the stenotic aortic valve. If crossing is not successful, the catheter is exchanged for an AR-1 or JR-4 catheter. Once across, the straight-tip wire is exchanged for a 300-cm J-tipped wire. The AL-1 catheter is then removed and exchanged for a 6-Fr angled pigtail catheter (Figure 1, #3). Both catheters are then connected to manometry, and peak left ventricular, and aortic systolic and diastolic pressures measured. The operator’s

attention is usually drawn to the peak-to-peak systolic separation due to valvular stenosis, but attention should also be focused on the end-diastolic separation distance between the left ventricle and the aorta. This measurement is pivotal for assessment of paravalvular leak after valve implantation. A preshaped stiff guidewire (Safari²[™], Boston Scientific, Marlborough, Massachusetts; Confida[™] Brecker, Medtronic, Inc., Minneapolis, MN; Lunderquist[®], Cook Medical, Bloomington, IN) is then placed through the angled pigtail catheter into the left ventricle, with the transition point of the guidewire held above the apex, and pointing away from the ventricular wall. It is advisable to maintain strict fluoroscopic surveillance of the guidewire in the left ventricle during valve deployment. Before performing BAV, the loaded valve delivery system is inspected under fluoroscopy (high resolution cine at 30 frames/second) to ensure that it's properly loaded. The system is held with flush ports pointing to the side to view paddle seating within pockets, and rotated a few degrees in either direction until both paddles are visualized simultaneously. A pre-implantation BAV is usually performed with rapid right ventricular pacing, the balloon size based on the minor diameter of the aortic annulus (Figure 2A).

Valve Implantation

Alignment

The valve delivery system is loaded onto the guidewire with the flush ports pointing up. The system is advanced over the guidewire to the aortic annulus under fluoroscopic guidance. The system usually orients itself to the anatomy as it is advanced. However, the capsule and the nose cone must always be monitored during advancement of the system to ensure safe passage through the anatomy. In highly angulated or heavily calcified anatomies, a gap may occur between the nose cone and the capsule as the system attempts to navigate a turn. In such a circumstance, the system must not be forced into passage as it may cause injury to the patient, and the guidewire is exchanged for a stiffer wire (Lunderquist[®]) to assist the system in navigating the turn. Once the valve delivery system is brought into appropriate implanting position (targeting an implant depth of 3-5 mm) (Figure 2B), a coplanar image projection is achieved to see the radiopaque marker as a straight line. The latter is preferred if both cannot be achieved together. The system is allowed to align itself within the native aortic annulus, and maintain contact with the top of the aortic arch for maximum stability.

Deployment

The first 1/3 of the bioprosthesis is deployed by very slow counterclockwise rotation of the actuator, in short increments in the direction of the marked arrows. The capsule response is 1:1 after approximately two turns of the deployment knob. The valve position is monitored under fluoroscopy throughout deployment, and the position adjusted as necessary until annular contact is achieved. The capsule has a flare feature that enables the valve to self center as it deploys (Figure 2C). In patients with aortic regurgitation, hypertension or large annuli, controlled pacing (90-130 beats/min) is considered during deployment. If the operator is satisfied with the valve position at annular contact, valve is continually deployed until just before the "point of no recapture." The operator must be cognizant of quick deployment once blood pressure drops, as cardiac output is temporarily eliminated as the aortic valve structure is temporarily occluded by the deploying valve. There is a tactile indicator ("rumble strip") that provides feedback to indicate that the capsule is nearing the "point of no recapture." The

operator must continue to turn the deployment knob until blood pressure recovers, making sure not to advance past the “point of no recapture.” Once blood pressure has recovered, approaching 80% deployment, the imaging projection should be adjusted to remove the parallax in valve inflow to determine valve position using angiography and echocardiography. If the implanting team is satisfied with valve position and performance, tension in the system is released just before full deployment (Figure 2D) to reduce potential for valve movement by retracting the guidewire, slight forward pushing on the delivery system, and turning the deployment knob very slowly to detach the paddles one at a time. The detachment of frame paddles must be confirmed under fluoroscopy, and the nose cone centered before the device is withdrawn.

Retrieval

Prior to withdrawing the valve delivery system to the descending aorta, it is ensured that the catheter tip is coaxial with the inflow portion of the bioprosthesis. The system is locked in the descending aorta by activating the deployment knob trigger, and retracting the grey hand rest to the blue deployment knob (“grey to blue”). The system is removed over the stiff wire. Wire position is maintained in the left ventricular cavity, and an angled pigtail catheter is reintroduced into the left ventricle. Simultaneous pressure tracings are then obtained, focusing on the diastolic separation between left ventricular and aortic pressure tracings. A final angiogram is performed after pullback of the angled pigtail catheter for assessment of valve placement and paravalvular leak. In addition, a transthoracic or transesophageal echocardiogram can also be obtained to confirm valve position prior to concluding the case.

Closure

The large sheath is then removed over a J-tipped guidewire, ProGlide[®] deployed, and protamine administered. If satisfactory hemostasis is achieved, the guidewire is removed. If not, an additional ProGlide[®] or Angio-Seal[™] (Terumo Interventional Systems, Terumo Medical Corporation, Somerset, NJ) vascular closure device may be deployed. A peripheral angiogram is always performed through the alternate access site to ensure vessel integrity at the large sheath access site. Alternate access site closure is performed with ProGlide[®] or Angio-Seal[™] vascular closure devices.

References:

1. Popma JJ, Adams DH, Reardon MJ, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol.* 2014;63(19):1972-1981.
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