Chapter 10: Step-by-step guide: Transfemoral Sapien S3 TAVR

Omar F. Hadidi, MD, Tom C. Nguyen, MD
UT Houston

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
- Diagnostic pigtail catheter in the right coronary cusp (note: some centers place in the non coronary cusp)
- Establish coplanar view
- Sheath insertion
- Cross the native valve
- THV positioning
- THV deployment
- Assess THV post-deployment by ECHO and fluoroscopy
- Device and sheath removal
- Vascular closure

Pearls and Pitfalls

- Valve sizing is key. Use of a multimodality imaging to confirm valve size is paramount.
- CT annular diameter measurements tend to be larger than 2D TTE/TEE diameter measurements.
- TEE annular diameter measurements tend to be larger than TTE.
- If diameter is borderline between two valve sizes, consider the smaller valve size if there is severe annular calcification, narrow root and low coronary ostia, narrow STJ, mitral annular calcification, porcelain aorta, and/or bulky leaflets.
- If diameter is borderline between two valve sizes, an alternative approach is balloon sizing.
- 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.

- Find the “whip” of the catheter when attempting to cross the aortic valve. If having difficulty crossing the aortic valve, consider rapid pacing to open the aortic leaflets.
- 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.
- Ensure 1:1 pacing wire capture during valve deployment. If not, then ABORT and reposition the pacing wire. The lack of pacing wire capture is a common cause of valve embolization.
- During the S3 deployment, the valve foreshortens mainly on ventricular side. The THV outflow (aortic) side is relatively stable. Thus, during deployment, focus on the top frame of the THV on the aortic side.
- If low coronary height and concern for coronary obstruction, consider placement of a wire into the left main pre-mounted with a stent.

Background

The original PARTNER trial demonstrated improved outcomes for patients with severe, symptomatic aortic stenosis treated with transcatheter aortic valve replacement (TAVR) in comparison to medical management in high surgical risk or inoperable patients[1]. The third generation Edwards Sapien S3 device was developed with a new cobalt chromium frame geometry designed for low profile delivery and a polyethylene terephthalate (PET) outer skirt to minimize paravalvular regurgitation. A revised expandable sheath (Edwards eSheath) in a 14F (20, 23 and 26mm THV) and 16F (29mm THV) system facilitates delivery in lower vessel diameters and higher rates of transfemoral procedures.

Patient Evaluation

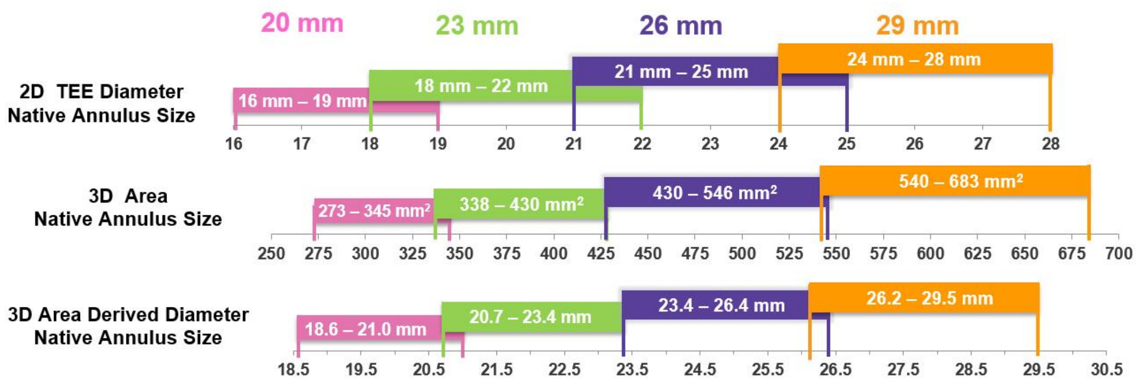
Pre-procedural planning is critical for success. Patient evaluation for S3 THV is similar to prior devices and has been described in prior chapters. At a minimum, patient workup requires a gated 3D contrast enhanced CT scan, ECHO, left heart catherization, assessment of patient frailty, and most importantly, evaluation by a multidisciplinary heart team.

Valve Sizing

The next critical step requires accurate determination of THV valve size. Details of valve sizing are described in a different chapter, but important tenants will be discussed here. Valve sizing should be thoughtful and systematic, since most mishaps can be thwarted with proper THV size selection. The aortic annulus is a dynamic structure that gets larger during systole and smaller during diastole. Annular measurements should be taken during systole, typically 25%-45% of the R-R interval. The use of contrast enhanced gated CT and TEE are important for accurate valve sizing. It’s important to note potential size variations depending on imaging modality. More specifically, 3D CT derived annular diameter measurements tend to be larger than 2D TTE/TEE measurements and TEE measurements tend to be larger than than TTE. For borderline measurements, it’s important to incorporate data from both the CT and ECHO to help guide annular dimensions. If diameter is borderline between two valve sizes, consider the smaller valve size if there is severe annular calcification, narrow root and low coronary ostia, narrow

STJ, mitral annular calcification, porcelain aorta, and/or bulky leaflets. If there is still controversy regarding valve size, consider balloon sizing.

Once the native annulus diameter and/or area has been confirmed, the below sizing chart can be used to determine THV size.



Access

After establishing THV valve size, the next step requires access evaluation. For 20mm, 23mm and 26mm S3 THV, the minimum vessel diameter is 5.5mm. For 29mm S3 THV, the minimum vessel diameter is 6.0mm. For the side of THV deployment, the iliac vessel should also be devoid of circumferential calcium and relatively non-tortuous.

Following evaluation of the bilateral iliac and femoral arteries by CTA, obtaining access can be initiated. Surgical cut-down and percutaneous access are the two options for TF TAVR, although most TAVRs can be performed via percutaneous access. There are some benefits of surgical access, including simplicity of arterial repair, direct visualization of the arterial access site, and tactile detection of arterial calcium. Percutaneous access provides the benefits of providing tissue/tract support for sheath insertion, decreased risk of wound infection, and faster recovery.

The next step involves bilateral access of the femoral artery and vein. In select situations, one can obtain access to bilateral femoral arteries and a contralateral femoral vein. Goals of percutaneous access are familiar to operators. Using a micropuncture needle, operators aim to access the femoral artery with an anterior stick, below the inguinal ligament and above the femoral bifurcation, avoiding small branches or areas of calcification. Given the size of the sheath and the potential for complications, confirmation with an iliac angiogram is typically performed with use of a pigtail catheter or IMA catheter and the crossover method. If necessary, the vessel may be dilated with the dilator (past the aortic bifurcation) prior to sheath insertion. Preclosure of the arteriotomy site using Perclose Proglide (typically with two sutures) or Prostar XL devices are performed to load the sutures at the margin of the arteriotomy. The sutures are then clamped with a hemostat and covered by drapes to be used for closure at the conclusion of the procedure. Both devices have been shown to be safe and efficacious in preventing vascular complications[2].

The Edwards eSheath should be inspected prior to use and discarded if damaged. Weight based heparin (100 U/kg) should be administered prior to sheath insertion with a goal activated clotting time (ACT) of >250. The sheath should be hydrated prior to insertion without wiping off the hydrophilic coating. The sheath should be inserted with the Edwards logo facing upward over a stiff wire (Meier, Supracore, Lunderquist, etc) that is held with tension to provide a firm rail for placement. Insert the sheath slowly with a continuous motion allows gradual dilation of the vessel. Ensure visualization of the sheath tip under fluoroscopy and advance past the aortic bifurcation. Once inserted, suture the sheath in place and intermittently flush per standard practice.

In the contralateral femoral artery, a diagnostic pigtail catheter is advanced into the right coronary cusp for root aortography (Note: Some centers will put the pigtail in the non coronary cusp).

Pacing Wire

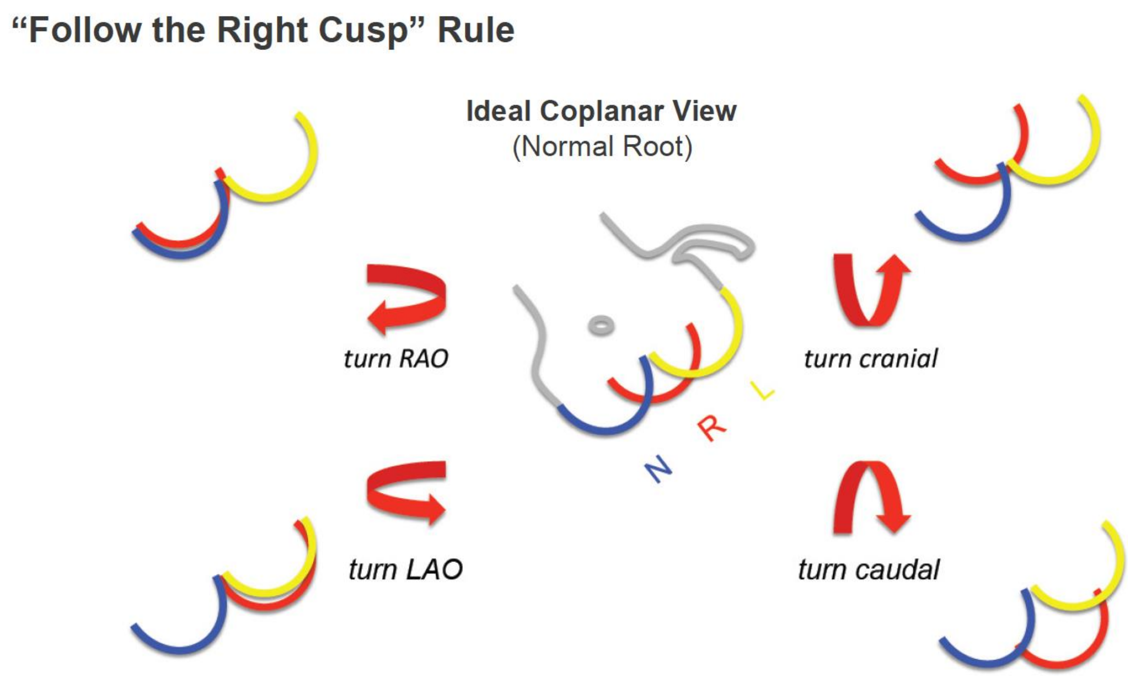
Rapid ventricular pacing during balloon valvuloplasty and valve deployment ensures proper positioning and limits motion during balloon inflation. The transvenous pacemaker is generally introduced through a sheath into the patient's right femoral vein. Balloon tipped or bipolar, rigid pacemaker catheters can then be passed through the sheath and placed in the RV apex. Most transvenous pacing catheters are 3-5 F, bipolar, and 100 cm in length. The wire can be flexible, semi floating, or rigid/non-floating. The rigid wires should only be used under fluoroscopic guidance. Although rigid wires provide more maneuverability, they are also at higher risk for causing ventricular perforation. Once connected to the generator, set the generator to a HR 10-20 bpm greater than the patient's resting HR. Set the pacing threshold at a high current output (~10 mA) and gradually decrease the output until capture is lost. Increase the threshold to 2-3x the level of capture loss. An appropriately placed catheter will capture at < 2mA. Once the pacing wire has been confirmed, secure the wire to the skin using a 3-0 silk or Prolene suture to avoid dislodgement. Incomplete capture with ventricular escape beats during THV deployment can be disastrous and is a common cause for valve embolization.

It is also essential to monitor the position of the pacemaker catheter throughout the procedure to avoid the risk of pacemaker lead perforation. Prior to the procedure, ICD arrhythmia detections should be discontinued to avoid inappropriate ICD discharges. Implanted pacemakers should be placed in VVI mode. At the time of rapid ventricular pacing, operator must ensure 1:1 pacing (typically at a rate of 160 – 220 bpm). Hemodynamic response should include an SBP < 50mmHg and pulse pressure < 10mmHg.

Determine Co-Planar Angles

The aortic valve apparatus consists of the aortic annulus, sinuses of Valsalva, coronary ostia, commissures and the sinotubular junction. The three cusps of the aortic valve are connected to the wall of the LVOT at three "hinge points". When these three anchor points are connected, an oval shaped ring is formed. This ring is the primary target for transcatheter heart valve sizing and placement[3]. Obtaining a fluoroscopic image in which all three cusp bases are in the same plane is critical for proper positioning of the transcatheter heart valve.

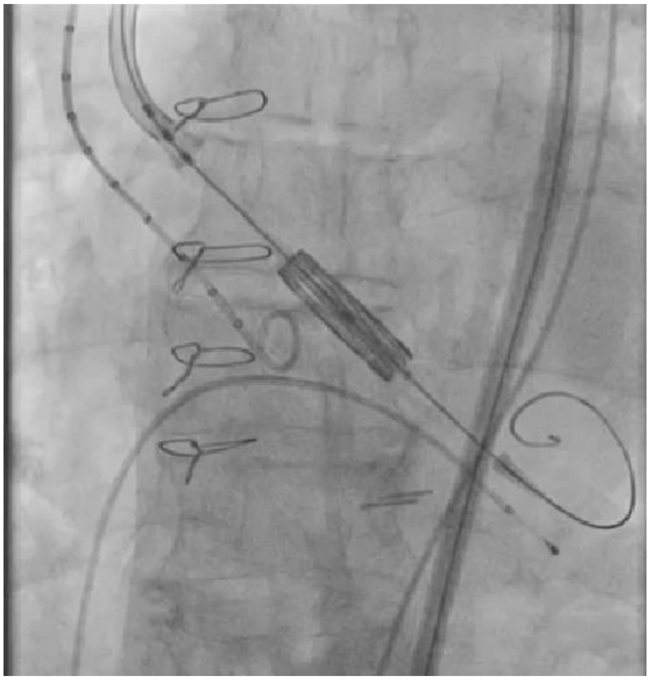
This co-planar angle can be pre-determined using CT angiography prior to the procedure. However, due to patient motion, placement, and overlapping structures (TEE probe, spine, etc), the angle often requires minor adjustment. If unsure of the optimal co-planar angle, we recommend starting with a 10° LAO and 10° cranial position. Operators have been advised to “follow the right cusp” in terms of positioning the aortic annulus. First, identify the right coronary cusp (RCC). If the RCC is on the “right” side, overlapping the non-coronary cusp (NCC), the C-arm must be lead to a more RAO projection to follow the right cusp. If the RCC appears deeper than the other cusps, the C-arm must be lead in a caudal direction for proper alignment[4]. Once the RCC is aligned between the NCC and LCC and the hinge points of the three cusps are in the same plane, the operator can proceed to the next step.



1. Kasel, Albert M., et al. "Anatomic guided crossing of a stenotic aortic valve under fluoroscopy:“right cusp rule, part III”." JACC: Cardiovascular Interventions 8.1 Part A (2015): 119-120.

Crossing Valve and Wire Positioning

To cross the native valve, a straight wire with catheter (AL1, AL2, JR4, MP, etc) support is recommended. If there’s difficulty crossing the native valve, consider rapid pacing to open up the aortic leaflets. The catheter should be slowly rotated clockwise until it “whips” with the systolic jet[5]. Once past the aortic valve, the wire can be removed and pressure gradients measured. A 0.035” Amplatz extra-stiff wire with a J-tip should then be shaped according the size of the LV. A J-tip is recommended to reduce the risk of perforation of the LV apex. The distal end of this wire is floppy, however, the stiff portion of the wire should be incorporated into the curve. The stiff portion of the wire should always extend beyond the tip of the delivery system. Slow introduction of the extra stiff wire and care should be taken to avoid the mitral valve chordae. If the stiff wire is not in the ideal location (i.e. entangled in chordae or into the left atrium), then advance a pigtail catheter over the wire, position the pigtail in the ideal location, and then slowly advance the stiff wire. Ideal wire positioning can be seen in the image below:



Balloon Aortic Valvuloplasty

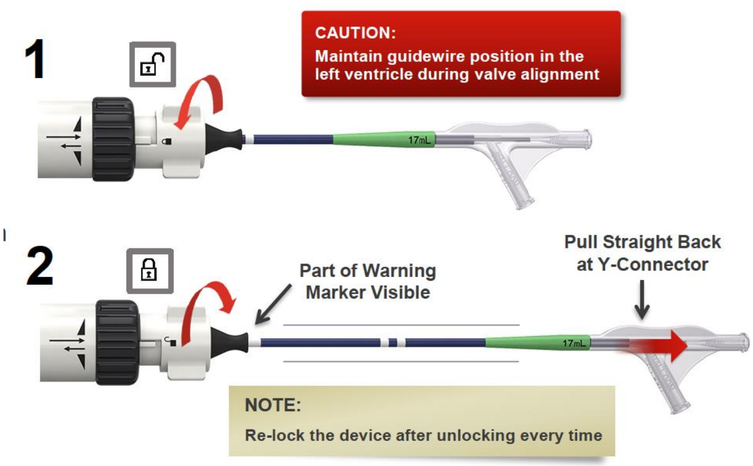
Balloon aortic valvuloplasty (BAV) is not required in all TAVR procedures but can considered in valves with high-risk anatomical features. Although previous studies have suggested that pre-dilatation with BAV may be associated with increased cerebral embolization[6], there has been concern that omitting predilation may limit expansion of the THV. BAV may be beneficial in: native valve predilation, valve sizing, coronary evaluation, severe septal hypertrophy, confirmation of annular dimensions, and displacement of native leaflets. Performing BAV in the above situations can potentially predict balloon movement during THV deployment. BAV can indicate if coronary occlusion due to heavy calcification will occur. TEE or fluoroscopy can be used to evaluate for leak around the balloon while inflated providing information about ideal valve sizing and possible THV regurgitation. Once the balloon is positioned, rapid ventricular pacing should be initiated and the balloon rapidly inflated and deflated. The inflation volume differs based on valve size, however nominal pressure (4 atm) and rated burst pressure (6 atm) is the same for every balloon. The ACT should be confirmed to be greater than 250 prior to balloon inflation. Inflation can be repeated if the balloon position is not stable. The THV should not be deployed if the balloon does not fully inflate during predilation.

A recent systematic review (n=1395) comparing outcomes with and without preimplantation BAV showed no significant differences in mortality, safety composite endpoints, moderate to severe paravalvular leak, need for postdilation, stroke/TIA, or need for permanent pacemaker implantation[7].

Valve Positioning and Deloyment

The delivery system should be inserted into the eSheath with the Edwards logo facing upwards and the flush port pointing away. If more working length is needed, the loader tube can be completely peeled away from the flex catheter. Once the delivery system is inserted into the sheath, the wire positioning should be confirmed in the left ventricle and the sheath tip distal to the aortic bifurcation.

To align the valve, the flex catheter should be retracted at the Y-connector until part of the warning marker is visible (but not past the warning marker) and the balloon lock secured. In general, this technique involves fixation of the delivery system with your left hand and pulling back the balloon catheter with your right hand. The fine adjustment knob should be slowly rotated to center the THV between the valve alignment markers with no gaps or overlap



When tracking over the aortic arch, a 30° or 40° LAO projection can be used. The flex wheel should be slowly rotated away from the operator while tracking over the arch. To avoid kinking of the system, the handle should be kept in the same orientation while flexing the catheter. When advancing the prosthetic valve through the native valve, short movements should be used and without excessive force placed on the THV. If experiencing difficulty crossing the native valve ensure the wire extends to the apex, tension should be applied on the wire, distal flex can be added to the flex catheter, or the system can be retracted and re-advanced. Factors that can make it difficult for the THV to cross the native aortic valve include heavy calcification, a wire that is biased into the commissure, horizontal heart, tortuous thoracic aortic, flex catheter kinked, and an inadequate BAV. Some trouble shooting options in difficult to cross valves include: making sure the wire is correctly extended at the apex, pull tension on the wire or reposition, add some distal flex or remove partial flex, and/or pull the system back and re-advance.

Next, the flex catheter should be retracted and off the balloon by unlocking the handle, slowly retracting the handle while maintaining the position of the balloon catheter, positioning the flex tip in the middle of the triple marker, and locking the balloon lock. (From a technical standpoint, this involves fixation of the right hand and advancing the left hand towards the right hand.)

To ensure the prosthetic valve is coaxial within the native valve, the flex wheel can be rotated or the guidewire manipulated. The prosthetic valve should be positioned with the bottom of the center marker at the base of aortic leaflet cusps (not the center of calcification). It is then acceptable to move the valve half the center marker length (1.5 mm) up or down. With the balloon lock secured, the fine adjustment wheel can be used to finely control the THV position. Ensure full release of tension in the system prior to deployment of the prosthetic valve. It is important to note that you can use the Center Marker to aid with THV positioning.

For a given S3 THV, the respective Edwards Balloon Catheter, inflation volume, and nominal pressure can be seen below:

Specifications	20 mm	23 mm	26 mm	29 mm
Balloon Catheter Dimension	16 mm x 4 cm x 130 cm	20 mm x 4 cm x 130 cm	23 mm x 4 cm x 130 cm	25 mm x 4 cm x 130 cm
Guidewire Compatibility	0.035”	0.035”	0.035”	0.035”
Minimum Introducer Sheath Size	14F	14F	14F	16F
Nominal Pressure	4 ATM	4 ATM	4 ATM	4 ATM
Nominal Volume	10 mL	16 mL	21 mL	26 mL
Rated Burst Pressure	6 ATM	6 ATM	6 ATM	6 ATM

Deployment

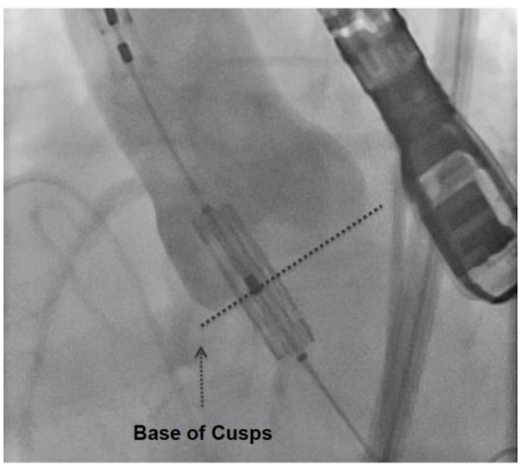
Once appropriately positioned as above, THV is ready for deployment. The operator should ensure that the flex catheter is located at the triple marker, the THV is exactly between the valve alignment markers, and the balloon lock is locked. Rapid ventricular pacing should then be initiated as described above for BAV. Slow, controlled inflation is recommended initially to ensure stability of the delivery system during deployment. If necessary, repositioning of prosthesis can only be performed in the very early stage of deployment. The completely inflated balloon should be held for 3 seconds and not to exceed 20 seconds for balloon inflation and deflation. Foreshortening of the valve occurs primarily on the THV ventricular side. Overall THV valve deployment should be roughly 80% aortic and 20% ventricular.

A suggested THV deployment protocol can be seen below:

Operator	Sequence	Verbal
Primary Operator		"Hold Ventilation"
Anesthesiologist	Hold Ventilation	"Ventilation Held"
Primary Operator		"Pacemaker Ready"
Pacemaker Operator		"Pacemaker Ready"
Primary Operator	THV in Position	"Pacemaker On"
Pacemaker Operator	Initiate pacing	"Pacemaker On"
Primary Operator	Verify Sustained 1:1 Capture Verify SBP $\leq$ 50 mmHg Verify Pulse Pressure < 10 mmHg Verify THV Properly Positioned	"Inflate"
Secondary Operator	Slow Controlled Initial Inflation Hold for 3 Seconds Once Fully Inflated Deflate	"Inflating" "1..., 2..., 3..." "Deflating"
Primary Operator	Verify Balloon Fully Deflated	"Pacemaker Off"
Pacemaker Operator	Turn Pacemaker Off	"Pacemaker Off"
Primary Operator		"Resume Ventilation"
Anesthesiologist	Resume Ventilation	"Ventilation Resumed"

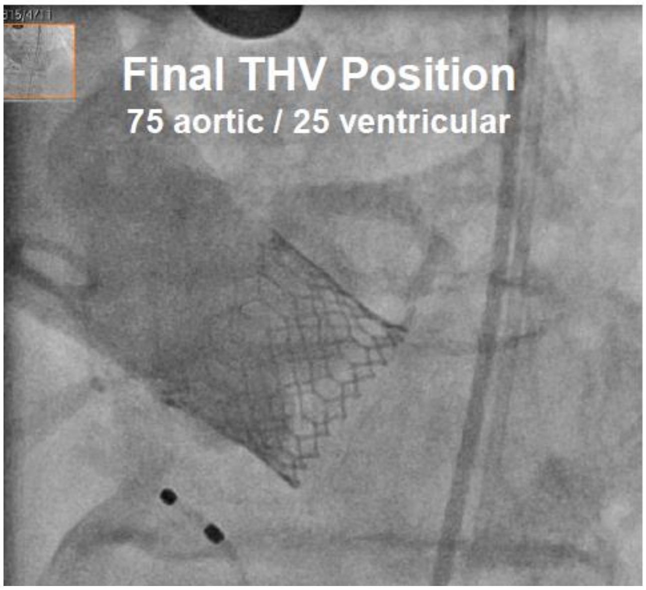
During THV deployment, however, focus on the top of the THV frame for since the valve foreshortens from the bottom up, i.e. the THV foreshortens mainly on the inflow/ventricular side. The THV outflow (aortic) side remains relatively stable throughout deployment.

A sample video of a S3 deployment can be seen here: **https://youtu.be/6DkEbTxAJ_E**



Confirmation

Following deployment of the valve, valve positioning and function should then be evaluated. The delivery system should be retracted from within the prosthetic valve. In the RAO projection, an aortogram should be performed with the wire still in the left ventricle. This will allow for assessment of valve position and expansion, the integrity of the aortic annulus, patency of the coronary arteries and THV regurgitation. The placement of the Sapien S3 following deployment is more aortic than prior Sapien valves, ideally resulting in 70-80% of the THV in the aorta. The initial severity of paravalvular leak may improve with a brief period of monitoring. Transesophageal echocardiogram (TEE) should also be utilized to assess the THV following deployment. In addition to confirmation of the above angiographic findings, short axis views can provide added information about the location of regurgitation (paravalvular vs central). TEE can identify new ventricular wall motion abnormalities, mitral regurgitation and pericardial effusion. Deep gastric views are typically the best to assess transvalvular gradients.



Sheath Removal and Vascular Complications

Prior to removal of the delivery system, fully un-flex the delivery system. Ensure the balloon lock is locked and that the balloon is completely deflated. Remove the sheath without applying torque and keeping the Edwards logo facing upwards. Do not re-insert the sheath once removed past the expandable section. An appropriate sized dilator can be used to achieve hemostasis if needed. Once the sheath is removed the ProGlide® devices are deployed and protamine is administered. Hemostasis is assessed and additional ProGlide® devices may be deployed if necessary. The guidewire is then removed. Peripheral angiography is recommended through the contralateral access site to ensure vessel integrity at the large sheath access site. The contralateral vascular access site closure is performed with ProGlide® devices.

Potential Complications

A variety of complications in a large range of severity are possible during TAVR. Details of managing TAVR complications are included in another chapter, but some highlights will be discussed here.

<u>Aortic Regurgitation/Paravalvular Leak:</u> The operator must immediately assess for aortic regurgitation following THV deployment. Wide pulse pressure or lower diastolic blood pressure may indicate severe aortic regurgitation. TEE can immediately be employed to determine if the aortic regurgitation is central or paravalvular. Paravalvular regurgitation may be secondary to improper sizing, placement of the valve

too high or low in the annulus, incomplete expansion or bulky annular calcification. Central regurgitation is generally due to frozen leaflets of the prosthesis or native leaflet overhang. If paravalvular leak is clinically significant, consideration can be given to post dilation of the THV with the same balloon under rapid ventricular pacing. Special care should be taken in cases with bulky calcification of the annulus as aortic rupture is a possibility. Central aortic regurgitation may also be worsened with post dilation of the THV. Proper valve sizing is critical to avoid severe paravalvular regurgitation.

Aortic Injury: Wire/catheter or THV delivery system manipulation, in addition to THV deployment, may lead to aortic dissection. Particular care should be taken in cases with porcelain aorta, oversized THV, calcified native vasculature and obliterated (<5 mm larger than annulus) sinuses of Valsalva. Periaortic hematoma can be visualized through intraoperative transesophageal echocardiogram. Predisposing conditions include bulky calcification, steroid dependency, bulky calcification, annular/THV size mismatch, and severe intraprocedural hypertension. Management includes aggressive BP control (<130 mmHg systolic), protamine administration, and pericardial drainage in cases with accumulation of pericardial fluid. Oversized THV may lead to annular rupture as well, in which cases management included placing the patient on a cardiopulmonary bypass pump and surgery.

Coronary Occlusion: Cases in which heavily calcified aortic leaflets that are displaced in front of the coronary ostia may lead to coronary occlusion. Strict preoperative screening should include leaflet calcification, annulus to coronary distance, length of aortic leaflets, width of the sinuses of Valsalva, height of the THV, as well as evaluation of the motion of the aortic leaflets during BAV. In these cases, it is recommended to assess for coronary occlusion through an aortogram and TEE during predilation with balloon valvuloplasty. In cases with high probability of coronary occlusion, it is recommended to maintain coronary access with a guidewire and possibly a coronary balloon prior to THV deployment. In cases with compromised coronary flow following deployment, percutaneous coronary intervention should be undertaken with consideration for cardiopulmonary bypass or left ventricular assist device.

Vascular Injury: The key to management of vascular complications is proper preparation. Initial management should be controlling of the bleeding through endovascular techniques. Bleeding may be controlled through iliac occlusion balloon, Coda balloon, or placement of a dilator into the arteriotomy site. The sheath should never be reinserted once removed. Once vascular damage is suspected, use of a proximal balloon and distal cross clamp occlusion can be considered. Crossover pre-wiring techniques may be useful in complicated vascular access cases. In cases in which perforation is suspected, hemostasis can be achieved with balloon occlusion through contralateral access. A covered stent can then be deployed through an ipsilateral approach. It is critical to have surgical instruments readily available in every case and to consider vascular surgery in cases with vascular complications.

References:

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