

Chapter 27: Transfemoral/Transseptal Mitral Valve-in-Valve using Sapien 3

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Essential or Key Steps

- Echocardiography to diagnose mode of mitral bioprosthetic valve (BPV) failure
- Gated-CT angiography (CTA) to determine BPV internal dimensions, atrial septum morphology, presence of atrial thrombus, and risk of left ventricular outflow tract obstruction (LVOTO)
- Identify manufacturer, model, and size of failed BPV
- Edwards Sapien 3 (S3) sizing according to labeled internal diameter (ID) and / or actual ID by CTA
- Establish posterior transseptal (TS) puncture
- Wire access with loop in left ventricle (LV)
- Measure mitral and aortic valve gradients
- Balloon atrial septostomy to allow passage of S3
- Mount S3 with atrial orientation of skirt (like transapical (TA) TAVR deployment)
- Deliver S3 with delivery catheter oriented “upside-down” to allow clockwise flexion
- Orient S3 co-axially within BPV and allow for atrial foreshortening

Pearls and Pitfalls

- Manufacturer’s implant card is the best way to identify BPV
- Prior operative reports can inform the status of the atrial septum which can be altered with previous surgical atrial septal defects (ASD) / patent foramen ovale (PFO) closures or TS approaches for the mitral valve
- “Valve-in-Valve Mitral” app by UBQO and Dr. Vinayak Bapat is the most commonly used reference for valve-sizing
- Pre-procedure TEE is required to distinguish valvular from paravalvular leak as the primary mode of BPV failure
- LVOTO after mitral valve-in-valve (ViV) is uncommon but should be considered in patients with LV septal hypertrophy, reduced aorto-mitral angle, narrow predicted LVOT
- Closure with a percutaneous device is recommended in cases of significant shunting across the atrial septostomy
- Re-ballooning to achieve slight ventricular flaring of the S3 is recommended to prevent late atrial migration
- TA access should be considered in patients with poor anatomy for TS approach or planned concomitant TAVR.

Background

The mode of failure of surgical mitral BPV include structural valve deterioration (SVD) and non-SVD. Patients with SVD can either have resulting stenosis or regurgitation and are often high-risk for re-operative mitral valve replacement. The Edwards S3 valve is commercially-approved for failed mitral BPV in high-risk patients using both TS and TA approaches based on outcomes from registry dataⁱ and is currently being investigated in intermediate-risk patients (NCT03193801).

Patient Evaluation

Patients with failed mitral BPV are evaluated for the mode of failure using echocardiography. Suspected paravalvular leak as the primary mode of failure is best evaluated by TEE and should be treated using percutaneous closure device prior to ViV. Risk evaluation has been described in previous chapters and is similarly pertinent to this group of patients. Anatomic suitability is determined by a CTA with volume-rendered reconstruction. Relative contraindications for mitral ViV are listed in Table 1. Review of prior operative reports may significantly impact procedure planning and procedural success. Details regarding the surgical approach to the MVR should be determined. Surgical exposure can be performed either directly through a left atriotomy or through the atrial septum via a right atriotomy. In addition, concomitant surgical closure of an ASD or PFO may have been performed. Ideal candidates for TS approach (in favor of TA approach) is listed in Table 2.

Table 1 – Relative contraindications for mitral ViV

Inability to take anticoagulation or antiplatelet medications
Active infectious endocarditis
Risk of LVOTO after implantation of S3

Table 2 – Characteristics of ideal patient for TS approach

Unobstructed femoral venous / inferior vena cava access
Favorable atrial septal anatomy (by imaging and prior operative report)
Large left atrium

Valve Sizing

The manufacturer, model, and size of the failed mitral BPV must be determined. The manufacturer's implant card is the most reliable method to identify the valve. Alternatively, the manufacturer can be directly contacted to obtain valve information. The valve model may be determined by x-ray or fluoroscopy, but valve size cannot. The prior operative report may have details, but is least reliable for identifying the valve. Valve-sizing charts (Table 3) are available to match the appropriate S3 to the corresponding BPV according to inner diameter (ID). The "Valve-in-Valve Mitral" app by UBQO and Dr. Vinayak Bapat is the most commonly used reference.ⁱⁱ Finally, CTA should be used to measure the actual ID of the BPV for in-between sizes and larger-sized valves (such as 31mm or greater) and may be of particular importance for stenotic BPV where tissue ingrowth may lead to smaller S3 sizing.

Table 3. Valve Sizing

Surgical Valve True ID	SAPIEN 3 Transcatheter Heart Valve Size
16.5-19 mm	20 mm
18.5-22 mm	23 mm
22-25 mm	26 mm
25-28.5 mm	29 mm

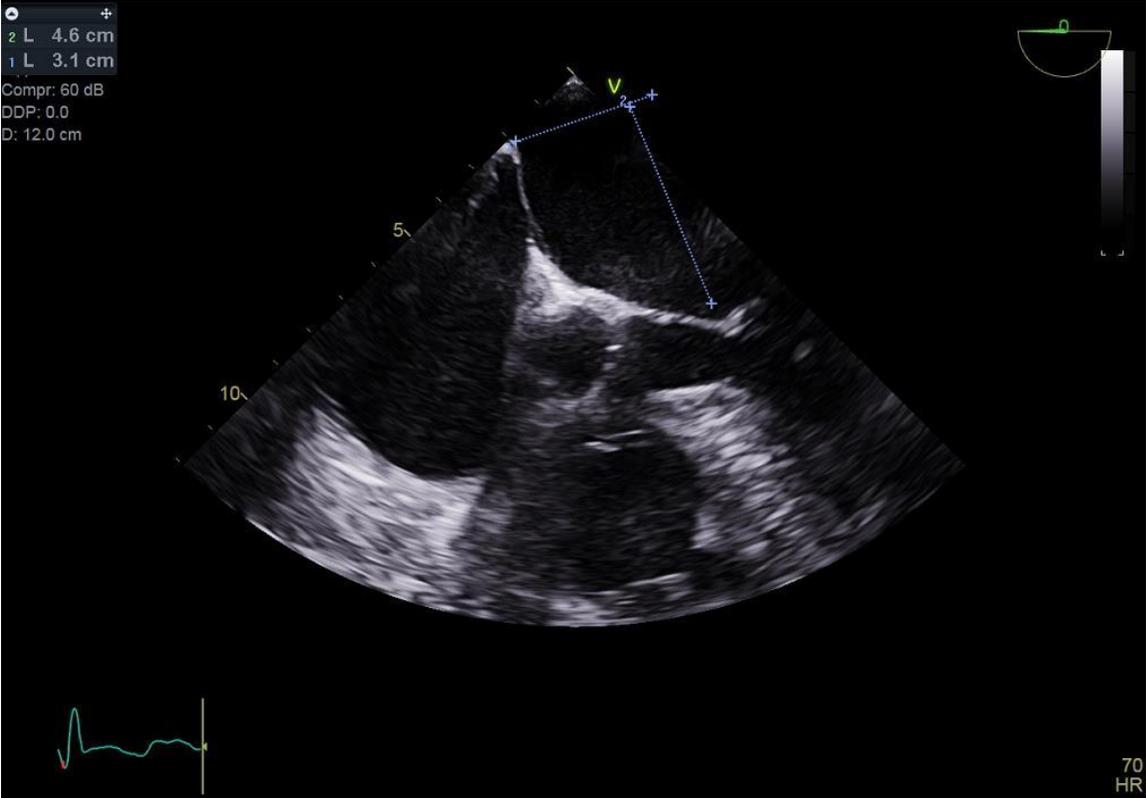
Vessel Access

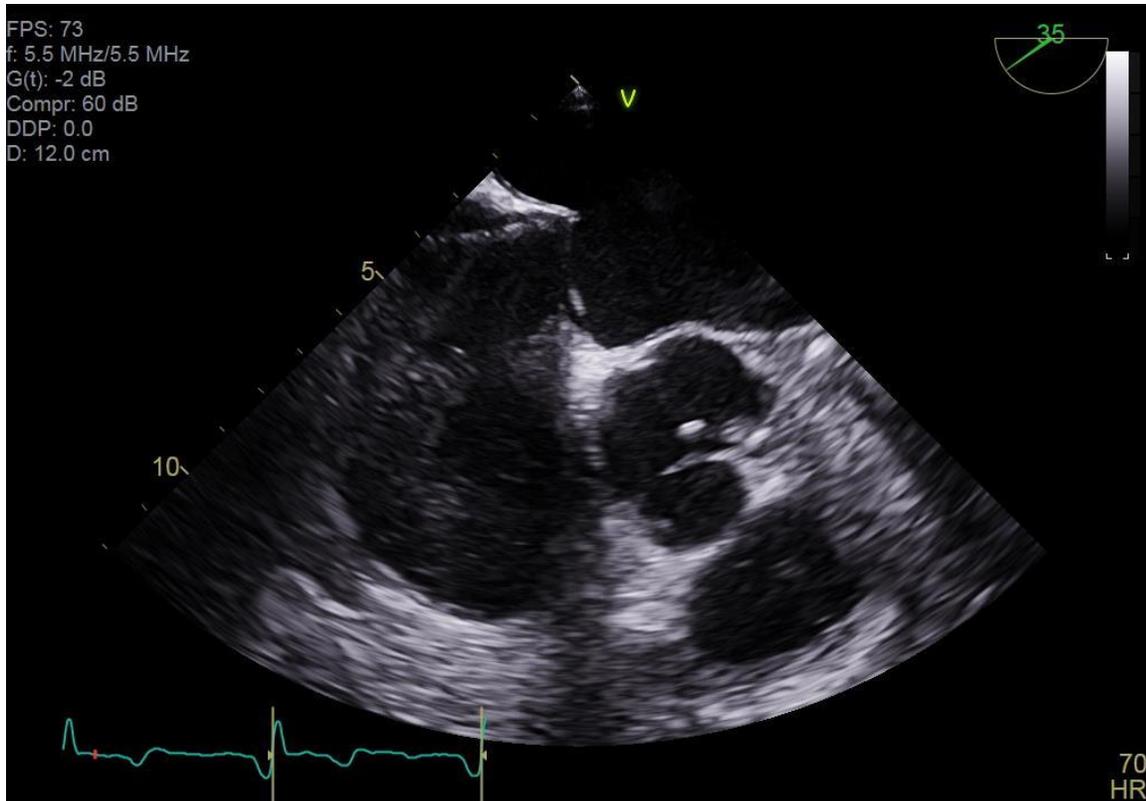
Access is obtained in the left common femoral artery with a 25 mm or longer 6Fr sheath within which a 5Fr pigtail is placed for continuous simultaneous aortic and LV pressure monitoring. Access is obtained in the left common femoral vein for placement of a transvenous pacemaker. Ipsilateral access is obtained in the right common femoral vein. After systemic heparinization, a 16 Fr Edwards eSheath is placed over a stiff wire. Alternatively, if delaying full anticoagulation is preferred, the eSheath can be placed following TS access.

Transseptal Access

A TEE-guided TS puncture is performed from within the eSheath, using a TS dilator and sheath (Mullins or SL) and TS needle (Brockenbrough). Energy-assisted TS puncture (surgical bovie or Baylis Radiofrequency NRG) can be a useful adjunct. The atrial septum is visualized in 2 TEE planes (Figure 1). A posterior (and often inferior) puncture allows for the most direct access to the mitral valve. At this point, anticoagulation for ACT 300 seconds is mandatory.

Figure 1. TEE views of the atrial septum for TS puncture





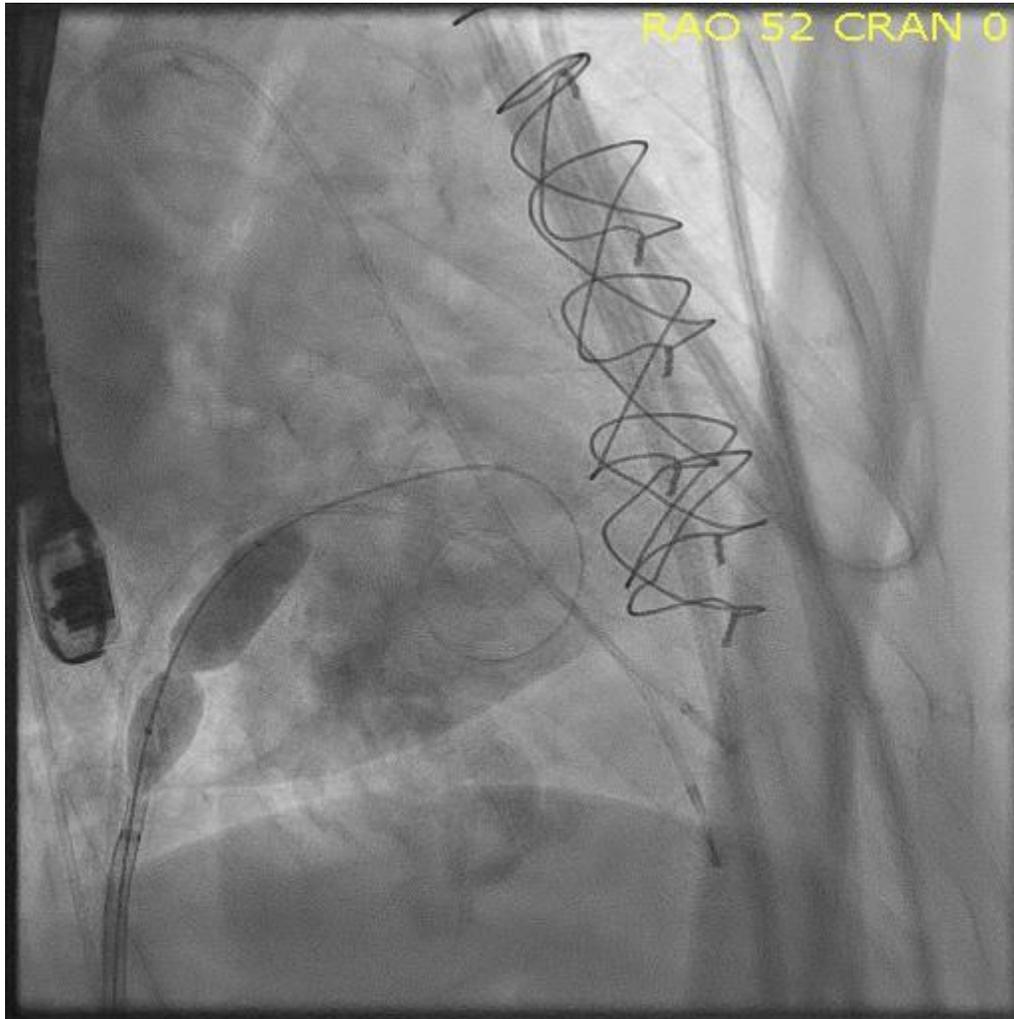
Crossing Valve

The TS sheath is exchanged for a steerable sheath (St Jude Medical Agilis NxT, Boston Scientific DiRex, Medtronic FlexCath). A gradient across the mitral valve can be measured with the steerable sheath in the LA and the pigtail (from the LFA) in the LV. A pre-shaped stiff wire (Boston Scientific Safari2 Extra Small, Medtronic Confida) is directed into the LV (**Figure 2**). A pigtail catheter can be used to position the wire into the LV apex.

Deployment

Balloon atrial septostomy is necessary to ensure smooth access of the S3 through the septum. Depending on the S3 size and septal morphology (thin vs thick), a 10-14mm balloon is advanced over the pre-shaped wire through the steerable sheath (**Figure 2**). The previously inflated balloon may be “flossed” across the septum. To avoid embolization of debris, advancing the balloon across the MV should be avoided unless the presence of severe MS requires balloon valvuloplasty to facilitate S3 delivery; in such cases, the septostomy balloon is advanced into the LV and inflated across the valve.

Figure 2. Balloon atrial septostomy with visible waist over a pre-shaped wire in LV



The S3 is mounted on the delivery system with the sealing skirt towards the left atrium (in the same orientation as for TA TAVR). The delivery system should be inserted into the eSheath “upside-down” compared to transfemoral TAVR with the Edwards logo facing downwards and the flush port pointing towards the operator. This position allows for clockwise flexion towards the mitral valve. S3 alignment on the balloon is performed in the IVC and often requires retraction of the eSheath. The S3 is advanced past the septum and into the valve with combination of catheter flexion, torque, and gentle traction on the wire to keep the S3 coaxial with the valve (Figure 3). The BPV is brought into a coplanar projection, usually a steep RAO / cauda angle. The pusher is retracted. The S3 is deployed under rapid ventricular pacing with slight ventricular flaring. (Figure 4). The conical deployment achieved with ventricular flaring eliminates the risk of late atrial migration of the S3.

Figure 3. Coaxial alignment of S3 in commonly used mitral BPV

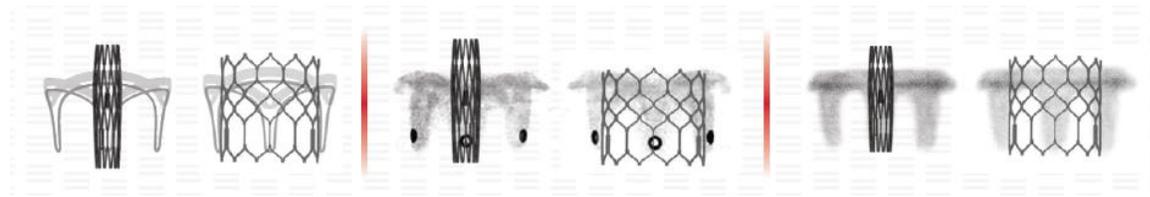
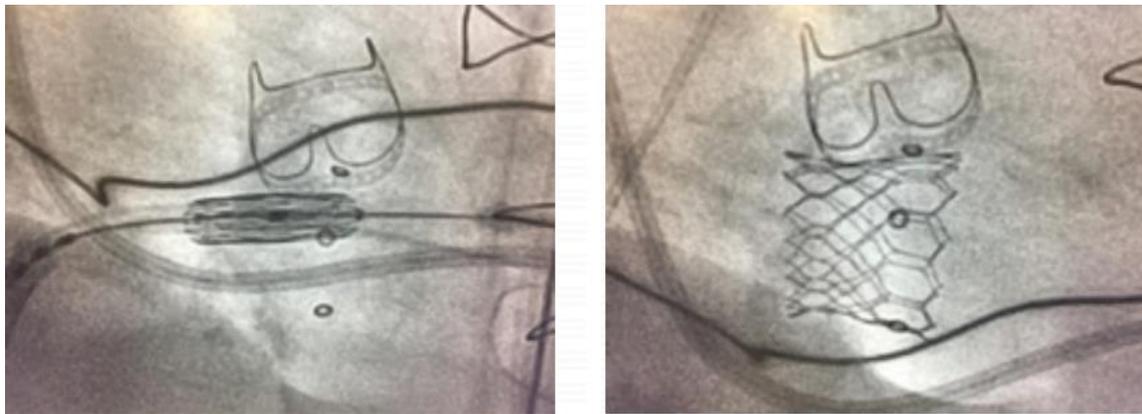


Figure 4. S3 deployment in Medtronic Mosaic with slight ventricular flaring



Evaluation

The delivery system is withdrawn into the left atrium while maintaining wire access in the LV. Valve function is evaluated by echocardiography. Repeat balloon valvuloplasty can be performed if necessary to flare the valve (paravalvular leak is rare). In addition, simultaneous LV and aortic pressures are measured to evaluate for new LVOT gradients. Mitral valve gradients are obtained after removing the delivery system. The septum is re-assessed for significant / bidirectional shunting and need for percutaneous closure.

Vascular Closure

A deep mattress or figure-of-eight stitch using a 2-0 polypropylene suture is placed at the femoral venous puncture site and the sheath is removed without twisting to avoid tearing of the blood vessel by the expandable overlap of the sheath. The deep stitch is secured and the stitch is removed on the day of discharge (Figure 5). Protamine reversal of heparin is performed only when necessary for bleeding.

Figure 5. Deep groin stitch for venous access closure.



Potential Complications

While the well-planned TS mitral ViV procedure has proven to be safe, a variety of complications are possible. Details of managing complications are included in another chapter, but some highlights are discussed here.

Cardiac perforation: Perforation can occur in the LA to the aorta or pericardial space during TS puncture. In addition, S3 deployment may lead to LV rupture. No rush to retrieve the offending device should be made and access can be maintained. A simple LA perforation into the pericardial space can be managed with protamine reversal. LA-aortic perforation may be closed with a percutaneous occluder device. Hemodynamically unstable patients should be placed on ECMO and converted to full sternotomy.

LVOT obstruction: Significant LVOTO is rare when pre-procedure planning with CT is done to exclude those at highest risk. Surgical resection of the leaflet of the surgical BPV facing the LVOT via a transaortic exposure may allow for free blood flow through the cells of the S3. More conventionally, a redo MVR can be performed. When surgery is not an option, bailout alcohol septal ablation may be performed.

Valve embolization: Not as commonly seen with ViV as with valve-in-ring or valve-in-MAC procedures, embolization may occur if the S3 is not aligned co-axially with the BPV. In the case of ventricular embolization, emergency surgery may be necessary. In the case of atrial embolization, snaring the S3 and jailing it to the atrial septum with a percutaneous occluder device may be attempted.

Paravalvular Leak: TEE can immediately determine if the mitral regurgitation is central or paravalvular. If paravalvular leak is clinically significant, consideration can be given to post-dilation of the S3 with the same or larger balloon under rapid ventricular pacing. Catheter delivered vascular plugs may also be used for paravalvular leaks.

Postoperative Care

Patients are started on life-long aspirin. Warfarin is started in postoperative day 1 and continued for at least 3 months. Bridging to therapeutic warfarin may be considered, theoretically to reduce the risk of paradoxical emboli from the venous access.

Conclusions

Transcatheter mitral ViV via the TS approach is a safe and effective therapy for failed surgical BPV. The key steps of the TS mitral ViV procedure are summarized in Table 4.

Table 4. Summary of TS mitral ViV procedure

Simultaneous LV, aortic pressure monitoring via contralateral femoral artery
RV temporary pacing wire via contralateral femoral vein
Systemic heparinization
Edwards eSheath 16F in ipsilateral femoral vein
TS access under TEE guidance
0.035” stiff wire into LA
Steerable sheath to LA to facilitate MV crossing
0.035” pre-shaped wire to LV apex
Balloon atrial septostomy
S3 introduced “upside-down” and advanced to BPV
Deployment during rapid ventricular pacing
Post-deployment evaluation
Deep groin stitch for venous closure

References:

1. Grover, F. L., et al. (2017). "2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry." *Ann Thorac Surg* **103**(3): 1021-1035.
 2. ¹ Bapat, V. (2014). "Valve-in-valve apps: why and how they were developed and how to use them." *EuroIntervention* **10 Suppl U**: U44-51.
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