



# Transcatheter valve-in-valve implantation for degenerated surgical bioprostheses

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**Abstract:** Transcatheter valve-in-valve (VIV) procedures are less invasive than re-do open heart surgery, and have proven relatively safe and effective. In large multicentre registries morbidity and mortality risks are generally lower than with surgery, and improvement in quality of life can be profound. Outcomes continue to improve with advances in transcatheter heart valve (THV) technology, techniques, and expertise. However specific concerns remain; including residual stenosis, coronary obstruction, left ventricular outflow tract obstruction, and thrombosis. The unknown durability is a concern in patients with the potential for longevity. Transcatheter VIV procedures will likely increasingly be favoured over reoperation when bioprosthetic heart valves fail, particularly when surgical risks are high.

**Keywords:** Valve-in-valve (VIV); transcatheter aortic valve replacement (TAVR); aortic valve; aortic valve replacement

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## Introduction

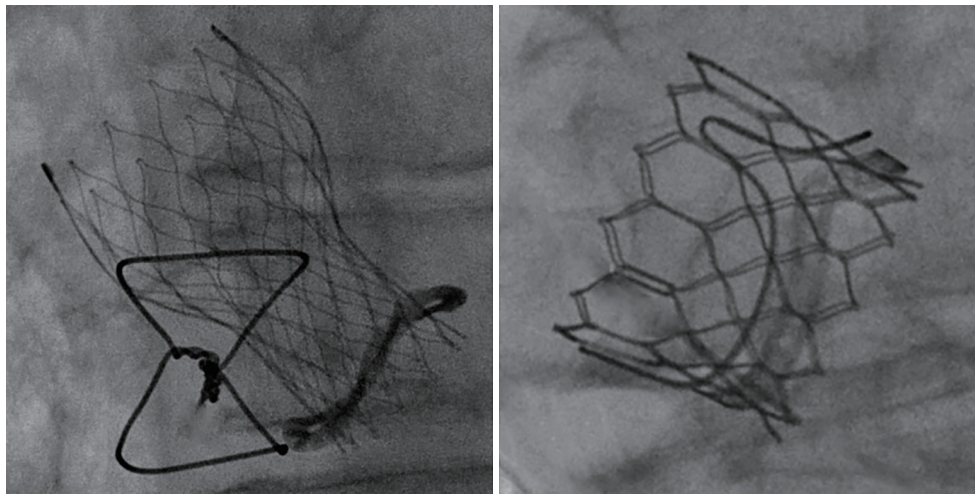
Over 275,000 surgical heart valves are implanted worldwide each year. Bioprosthetic valves are increasingly preferred over mechanical valves, due to the lower risk of thrombo-embolic complications (1,2). However, with time, animal or human tissue leaflets may weaken and calcify, leading to stenosis, regurgitation, or both. Reoperation for bioprosthetic valve failure is associated with significant risks, particularly in patients with comorbidities, including advanced age. Over the past decade less invasive transcatheter valve-in-valve (VIV) procedures have been increasingly utilised in the aortic, mitral, pulmonary and tricuspid positions.

## Aortic VIV procedure

Aortic VIV procedures were first performed in 2007 (3,4). Access is most often percutaneous from the femoral artery,

although surgical access from the left ventricular apex or other large arteries are alternatives. The most commonly used transcatheter heart valves (THVs) are the Sapien-type balloon-expandable or the CoreValve self-expandable devices (*Figure 1*). There is considerable variation in the construction of surgical valves, and detailed knowledge is required to ensure safe and effective THV implantation. Most surgical valves consist of a metal or plastic frame and sewing ring to which are sewn 3 leaflets constructed of bovine or porcine pericardial or leaflet tissue.

Surgical valves are generally labelled by the manufacturer according to their outer diameter. However it is the inner dimensions that are vital for selection of an appropriately sized THV (5). A VIV smartphone application is widely used and references a large range of commonly used surgical and transcatheter valves with descriptions, images, dimensions, photographic and fluoroscopic images, along with guidance on sizing and positioning (6).



**Figure 1** Medtronic CoreValve Evolut R (left) and Edwards SAPIEN 3 (right) THVs deployed within bioprosthetic aortic valves. THVs, transcatheter heart valves.

**Table 1** Summary of contemporary valve-in-valve baseline variables and selected outcomes

Outcome	Aortic		Mitral	
	PARTNER II VIV (Edwards SAPIEN XT) (8)	CoreValve US extended use (Medtronic CoreValve) (9)	Valve-in-valve (10)	Valve-in-ring (10)
Mean age (years)	78.9	76.7	72.9	71.4
STS score	9.1%	9.0%	9.3%	8.1%
Coronary obstruction	0.8%	0.9%	–	–
LVOT obstruction	–	–	2.3%	2.3%
Conversion to surgery	0.6%	0.5%	1.1%	4.2%
30-day mortality	2.7%	2.2%	5.7%	8.3%
30-day stroke	2.7%	0.9%	2.3%	0%
1-year mortality	12.4%	14.6%	12.6%	28.7%
Mean transvalvular gradient—pre	35.0 mmHg	37.7 mmHg	12.4 mmHg	6.9 mmHg
Mean transvalvular gradient—post	17.1 mmHg	17.0 mmHg	5.8 mmHg	6.4 mmHg
> Mild regurgitation	1.9%	3.5%	6.8%	19.4%
NYHA I–II—pre	9.9%	13.2%	11.9%	8.3%
NYHA I–II—post	89.2%	93.2%	NR	NR





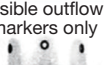

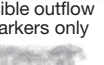





LVOT, left-ventricular outflow tract; NR, not reported.

### Aortic VIV outcomes

Multiple registries have documented improving outcomes with aortic VIV procedures (7). Recent prospective aortic VIV registries demonstrated excellent 30-day and 1-year survival in nearly 600 patients with both balloon-expandable

and self-expanding THVs (*Table 1*) (8,9). Improvements in functional status and quality of life measures were dramatic, and sustained at 1-year. Residual aortic regurgitation, embolization and coronary obstruction were rare.

Higher than desirable residual transvalvular gradients

Surgical valve features	SAPIEN 3 valve positioning considerations	Surgical valve features	SAPIEN 3 valve positioning considerations
Visible stent frame 	Align the base of the central marker 3-5 mm above the base of the surgical valve stent frame 	Visible stent frame 	Align the base of the central marker 3-5 mm below the base (towards ventricle) of the surgical valve stent frame 
Visible outflow markers only 	Align the outflow of the crimped SAPIEN 3 valve 2 mm above the surgical valve outflow markers 	Visible outflow markers only 	Align the outflow of the crimped SAPIEN 3 valve 2 mm below (towards ventricle) the surgical valve outflow markers 
No visible radiopaque markers 	Align the base of the central marker with the annular plane 	No visible radiopaque markers 	Align the base of the central marker with the annular plane 
Final SAPIEN 3 valve implant depth should be targeted no more than 20% (ventricular) for optimal valve function		Final SAPIEN 3 valve implant depth should be targeted no more than 20% (atrial) for optimal valve function	

**Figure 2** Recommended positioning of the SAPIEN 3 valve in the aortic position (left) and mitral position (right).

are common after VIV procedures due to incomplete THV expansion. In VIVID registry data, around one-quarter of patients had severe patient-prosthesis mismatch (indexed effective orifice area  $<0.65 \text{ cm}^2/\text{m}^2$ ), although this did not seem to be associated with adverse clinical outcomes in the short term (11). Improved hemodynamic performance in VIV procedures may be attained by implanting the THV ‘higher’, with leaflets above the neo-annulus as seen in *Figure 2* (12). THVs with leaflets placed higher in the frame (e.g., CoreValve Evolut) may allow for “supra-annular” positioning with the potential for lower transvalvular gradients.

Recently, it has been shown that high-pressure balloon dilation has the potential to expand or fracture many surgical valves, allowing more complete THV expansion and reducing post-procedural gradients. Most bioprosthetic surgical valves yield at 8–26 ATM (notable exceptions are Hancock II and Trifecta valves) and clinical complications have been infrequent in several case series (7,13).

### Mitral VIV procedure and outcomes

Mitral VIV procedures were originally performed using a transapical approach requiring a small thoracotomy. More recently percutaneous transseptal access from the femoral vein has gained favour. Mitral bioprostheses are typically large and circular; well suited to implantation of balloon-expandable Sapien-type THVs with little or no paravalvular regurgitation and low transvalvular gradients. Clinical benefit can be profound (10,14).

Mitral annuloplasty rings and bands, however, may be

eccentrically shaped and either flexible, semi-rigid or rigid. Although valve-in-ring (VIR) procedures can be effective; risks of embolization, regurgitation, and other complications remain relatively high. Currently VIR procedures should be considered investigational (10).

Left-ventricular outflow tract (LVOT) obstruction is a rare but potentially serious complication of mitral VIV procedures. CT modelling is increasingly performed pre-procedure to assess this risk; a THV is virtually implanted and the future ‘neo-LVOT’ can be assessed (15). THV sizing guidance is available from the mitral VIV app. Given the large pressure differential between the left ventricle and left atrium, the THV should be slightly larger than the surgical valve internal dimension, aiming for a ‘conical’ deployment with the ventricular aspect of the THV flared to prevent atrial migration.

### Tricuspid and pulmonary VIV

Tricuspid and pulmonary VIV procedures have been associated with excellent outcomes (12). Femoral and jugular venous access are feasible with balloon-expandable THVs (Medtronic Melody and Edwards Sapien). Patients with prior TV repair with an incomplete annuloplasty ring have higher rates of paravalvular leak, which may require device-based closure (16).

### VIV thrombosis

There is an increasing recognition of leaflet thrombosis, particularly in the setting of VIV implantation, which

may lead to premature structural valve deterioration or stroke (17,18). Leaflet thrombosis is often subclinical, with elevated transaortic gradients detected by echocardiography. Transesophageal echocardiography may be helpful, but '4D' volume-rendered CT is the gold standard for diagnosis. Anticoagulated patients appear less likely to develop leaflet thrombosis, leading some to recommend a period of anticoagulation after VIV procedures.

### Long term outcomes

Excellent clinical outcomes have been reported at 1 year, with improvements in transaortic gradient and clinical benefit maintained (*Table 1*). However, these procedures are relatively new and the high-risk patients undergoing the procedure have had a relatively short life expectancy (19). Although THV durability appears favourable in the setting of native aortic valve stenosis, there are concerns about reduced durability in underexpanded VIV implants. Currently we know little about late durability of VIV implants.

### Summary

Transcatheter VIV procedures have proven relatively safe and effective. Morbidity and mortality risks are generally lower than with surgery, and improvement in quality of life can be profound. Outcomes continue to improve with advances in THV technology, techniques, and expertise. However specific concerns remain; including residual stenosis, coronary obstruction, left ventricular outflow tract obstruction, and thrombosis. The unknown durability is a concern in patients with the potential for longevity. Still, it seems likely that transcatheter VIV procedures will increasingly be favoured over reoperation when bioprosthetic heart valves fail, particularly when surgical risks are high.

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None.

### Footnote

*Conflicts of Interest:* JG Webb: Consultant- Edwards Lifesciences. Another author has no conflicts of interest to declare.

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