

Optimising percutaneous valve-in-valve TAVI with bioprosthetic valve fracture

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Dear Editor,

Percutaneous transcatheter aortic valve implantation (TAVI) has become an established therapy for inoperable patients, for high, intermediate and low surgical-risk patients over 65 years old with severe aortic valve stenosis (AS).^{1,2} Valve-in-valve (ViV) TAVI is an approved indication for patients with degenerated aortic surgical bioprostheses.

Several ViV TAVI registries have demonstrated good clinical outcomes.³⁻⁵ One limitation is the elevated residual mean pressure gradient (MPG ≥ 20 mmHg) after ViV TAVI, which occurred in 27% of patients, particularly in small (≤ 21 mm label size) surgical valves, as the expansion of the new transcatheter heart valve (THV) is constrained by the sewing ring.³ The high residual MPG increases the likelihood of patient-prosthesis mismatch (PPM), which results in lesser symptomatic improvement, poorer valve durability and increased mortality.^{3,6} Bioprosthetic valve fracture (BVF) was developed to break the surgical valve sewing ring, increasing the internal diameter (ID) and reducing the residual MPG.⁷ We report 2 cases of ViV TAVI that required BVF to improve valve haemodynamics.

A 65-year-old male presented with 4-month exertional dyspnoea (New York Heart Association [NYHA] class II). He underwent surgical aortic valve replacement (SAVR) with a 21 mm Perimount (Edwards Lifesciences, Irvine, CA, US) bioprosthesis (Fig. 1a) (true ID 19 mm) and a bypass with a vein graft to the right coronary artery 11 years ago. The MPG post-SAVR was 15 mmHg. Echocardiography showed normal left ventricular ejection fraction (LVEF) (60%), severe bioprosthetic AS (MPG 45 mmHg, aortic valve area [AVA] 0.8 cm²) and mild aortic regurgitation (AR), consistent with a degenerated tissue valve. Due to his elevated surgical risk (redo surgery, patent bypass graft) and refusal to consider repeat surgery, we proceeded with ViV TAVI and BVF.

Under local anaesthesia and sedation, a balloon-expandable 23 mm Sapien 3 valve (Edwards Lifesciences, Irvine, CA, US) sized according to the ViV aortic app from the App store or Google

Play store, was successfully implanted (Fig. 1b) with cerebral embolic protection using the Sentinel system (Boston Scientific, Marlborough, MA, US). The aortic MPG (simultaneous catheter measurement) was 14 mmHg. BVF was then performed using a noncompliant 22 mm True Dilatation balloon achieving better TAVI frame expansion (Fig. 1c). The final aortic MPG was 8 mmHg.

The patient was discharged 2 days post-procedure on dual antiplatelet therapy (DAPT— aspirin and clopidogrel). At 30-day follow-up, he was in NYHA functional class I. Echocardiography showed a stable Sapien 3 valve, an aortic MPG of 16 mmHg and trivial AR. Subsequent 6-month echocardiography showed aortic MPG 13 mmHg (Table 1), AVA 1.2 cm² and trivial AR.

A 76-year-old male presented with 9-month exertional dyspnoea (NYHA class III). He underwent SAVR with a 19 mm Mitroflow (Sorin Group USA Inc, Arvada, Colo, US) bioprosthesis (Fig. 1e) (true ID 15.4 mm) 9 years ago. The MPG post-SAVR was 22 mmHg. Echocardiography showed normal LVEF (60%), severe bioprosthetic AS (MPG 56 mmHg, AVA 0.7 cm²) and severe transvalvular AR (without paravalvular leak), consistent with a failed tissue valve. Due to his elevated surgical risk (redo surgery, advanced age), we proceeded with ViV TAVI and BVF.

Under local anaesthesia and sedation, a balloon-expandable 20 mm Sapien 3 valve (smallest Sapien valve based on the manufacturer's recommendation, as the ViV app does not recommend any THV due to the concerns of underexpansion and high residual gradient in such a small surgical valve) was successfully implanted (Fig. 1f) with cerebral embolic protection using the Sentinel system. The aortic MPG (simultaneous catheter measurement) was 37 mmHg. BVF was then performed using a 20-mm True Dilatation balloon achieving a significantly better TAVI frame expansion (Fig. 1g). The final aortic MPG was 14 mmHg.

The patient was discharged 2 days post-procedure on DAPT. At 30-day follow-up, he was in NYHA functional class I. Echocardiography

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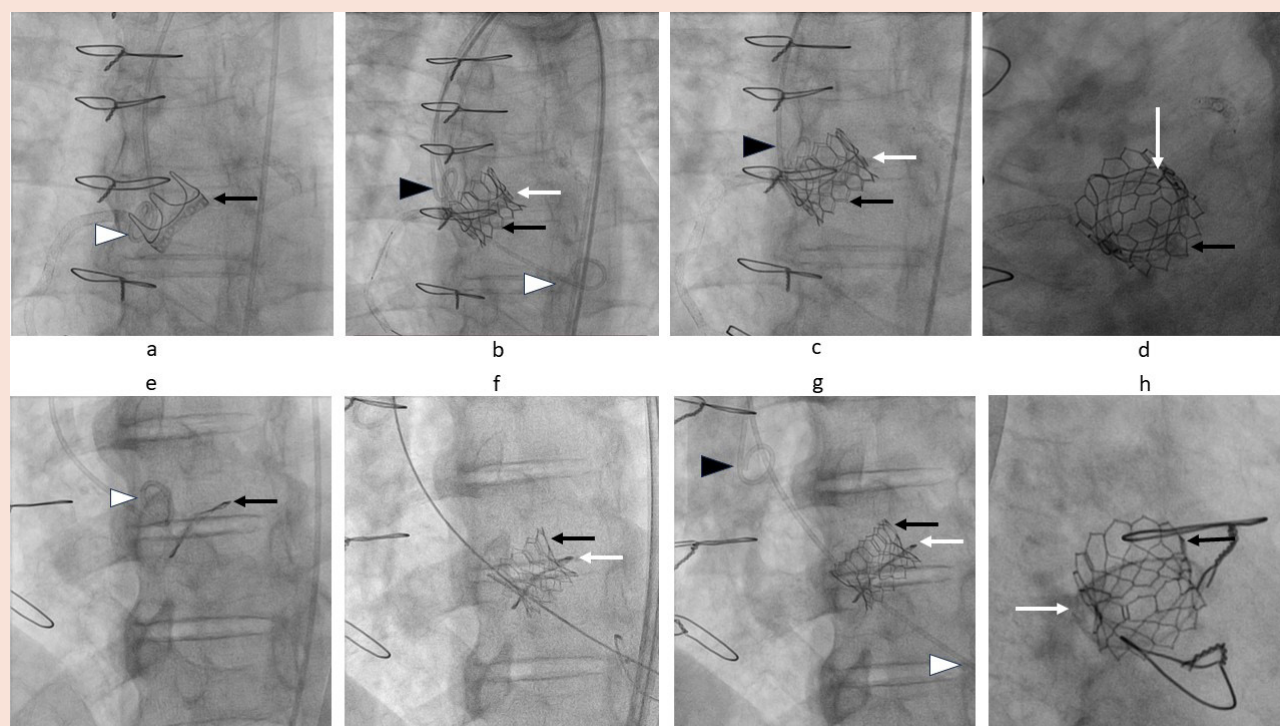
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Fig. 1. Fluoroscopic images of valve-in-valve TAVI with bioprosthetic valve fracture.



(A) Fluoroscopic image of the 21 mm Perimount surgical valve (arrow) in the aortic position. The arrowhead denotes the pigtail catheter in the aortic root. (B) Fluoroscopic image of the 23 mm Sapien 3 THV (black arrow) within the 21-mm Perimount surgical valve. The white arrow denotes the "waist" where the Sapien 3 THV is constrained by the sewing ring of the Perimount surgical valve. The black and white arrowheads denote the pigtail catheters in the aortic root and LV, respectively. (C) Fluoroscopic image of the 23-mm Sapien 3 THV (black arrow) within the 21-mm Perimount surgical valve. The white arrow shows that the Sapien 3 THV is now well expanded within the Perimount surgical valve. The black arrowhead denotes the pigtail catheters in the aortic root. Successful BVF was indicated by a sudden visual release of the "waist" of the THV and a rapid drop in the balloon inflation device pressure. (D) Fluoroscopic image of the 23-mm Sapien 3 THV (black arrow) within the 21-mm Perimount surgical valve. The white arrow denotes the fracture of the sewing ring of the Perimount surgical valve. (E) Fluoroscopic image showing the sewing ring (arrow) of the Mitroflow surgical valve (the rest of the valve is not visible). The arrowhead denotes the pigtail catheter in the aortic root. (F) Fluoroscopic image of the 20 mm Sapien 3 THV (black arrow) within the 19-mm Mitroflow sewing ring. The white arrow denotes the "waist" where the Sapien 3 THV is constrained by the sewing ring of the Mitroflow surgical valve. (G) Fluoroscopic image of the 20-mm Sapien 3 THV (black arrow) within the 19 mm Mitroflow surgical valve. The white arrow shows that the Sapien 3 THV is now well expanded within the Mitroflow surgical valve. The black and white arrowheads denote the pigtail catheters in the aortic root and LV, respectively. Successful BVF was indicated by a sudden visual release of the "waist" of the THV and a rapid drop in the balloon inflation device pressure. (H) Fluoroscopic image of the 20-mm Sapien 3 THV (black arrow) within the 21-mm Perimount surgical valve. The white arrow denotes the fracture of the sewing ring of the Mitroflow surgical valve.

BVF: bioprosthetic valve fracture; LV: left ventricle; THV: transcatheter heart valve

showed a stable Sapien 3 valve, an aortic MPG of 18 mmHg and trivial paravalvular AR. Subsequent 3-month echocardiography showed aortic MPG 14 mmHg (Table 1), AVA 1.2 cm² and trivial AR.

ViV TAVI is increasingly performed for failed surgical bioprostheses with good results.^{3,4} In one local series, there were no procedural complications, and short-term outcomes were excellent.⁵

However, there are 2 major concerns. First, there is a risk of coronary occlusion as the valve leaflets are pushed outwards, especially in externally mounted leaflets such as the Mitroflow bioprosthesis.³ This risk can be predicted using a computerised tomography scan, which was performed in both patients. In the patient with the Mitroflow prosthesis, the left and right coronary artery heights

were 11 and 17 mm, respectively; the sinus of Valsalva diameter was 29 mm; and the sinotubular junction height was 21 mm. As the right coronary artery was higher than the Mitroflow valve height of 11 mm, there was no risk of right coronary occlusion. Because the left coronary artery was just below the Mitroflow valve height, the virtual THV to coronary (VTC) distance was then measured and was 6.8 mm, indicating low risk for coronary occlusion (VTC <4 mm is deemed high risk and VTC >6 mm low risk).⁸

Second, the residual MPG after ViV TAVI may be elevated. The global aortic ViV registry showed that elevated MPGs occurred more frequently in small surgical (≤ 21 mm label size) bioprosthesis, and with the balloon-expandable THVs.³ The self-

Table 1. Serial mean pressure gradient in mmHg.

	Baseline post-SAVR	Pre-TAVI	Post-TAVI	Post-BVF	1 month	3 months	6 months
Patient 1	15	45	14	8	16	-	13
Patient 2	22	56	37	14	18	14	-

BVF: bioprosthetic valve fracture; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation

expanding THVs, due to their supra-annular leaflet design, produced lower gradients, although PPM could still occur.³ As balloon-expandable THVs facilitate easier coronary artery access (compared to supra-annular self-expanding THVs), this was selected for the first patient as he had multiple coronary angioplasties, and may require repeat percutaneous intervention. For the second patient, a balloon-expandable THV was chosen as the upper and lower edges would flare during THV deployment, making it more secure (less embolisation risk) during BVF.

BVF to lower gradients during aortic ViV was first described in 2015.⁹ This technique utilises a noncompliant balloon (1 mm larger than the surgical valve label size) to fracture the sewing ring, increasing its true ID, optimising THV expansion and leaflet coaptation, and reducing the residual gradient.⁷

This technique has been shown to be effective and safe, if the BVF is performed after ViV TAVI. Performing BVF before ViV TAVI valve increased the risk in-hospital mortality and stroke, which were not observed if BVF followed ViV TAVI.⁷ This is an important finding as the risk of stroke and mortality during ViV TAVI was similar to native valve TAVI.¹⁰ Data on THV leaflet thrombosis after ViV TAVI are sparse, and optimal antithrombotic regimen is still uncertain, although single antiplatelet or short-term DAPT is recommended by the American College of Cardiology/American Heart Association guidelines.²

In our 2 patients, there was underexpansion of the THV that improved after BVF, with corresponding MPG reduction, good clinical outcomes and satisfactory gradients despite having small surgical bioprostheses.

In conclusion, this report demonstrates that BVF is an effective and safe method of optimising haemodynamics after ViV TAVI. This may enhance symptomatic improvement, THV durability and

survival of patients with small surgical bioprostheses, although long-term data would be required before routinely offering this therapy to low surgical-risk patients.

Keywords: aortic stenosis, bioprosthetic valve fracture, cardiology, percutaneous, transcatheter aortic valve replacement, valve-in-valve implantation

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