Bioprosthetic Aortic Valve Fracture During Valve-in-valve Transcatheter Aortic Valve Implantation

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Abstract

The limited durability of surgical bioprostheses, combined with an ageing population, has led to an increasing demand for replacing degenerated bioprosthetic surgical heart valves, which is projected to increase. Valve-in-valve transcatheter aortic valve implantation involves implanting a transcatheter heart valve within a degenerated bioprosthetic surgical heart valve. A significant minority of patients, however, are left with a suboptimal haemodynamic result with high residual gradients. This is more common with smaller surgical bioprostheses, and may be associated with a worse prognosis. The novel concept of fracturing the previously implanted bioprosthetic surgical heart valve during valve-in-valve transcatheter aortic valve implantation to create a more favourable haemodynamic profile has shown great promise, particularly in smaller valves. Herein, we describe the benefits, limitations and potential complications of this novel approach.

Keywords

Bioprosthesis aortic valve fracture, valve-in-valve, transcatheter aortic valve implantation

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The demand for replacing degenerated bioprosthetic valves (BPVs) is steadily rising owing to the increasing burden of heart disease, ageing populations, advances in surgical intervention and limited durability of current-generation surgical BPVs. The issue is exacerbated by the increasing trend of surgical BPV replacement, especially in younger patients who are likely to require future intervention.1

Transcatheter aortic valve implantation (TAVI) is a safe and effective alternative to surgical aortic valve replacement for patients across the entire risk spectrum, although the importance of the heart team in clinical decision-making remains paramount.2 Structural valve degeneration has bedevilled surgical aortic valve replacement since its inception, and studies have shown high mortality rates associated with redo surgical aortic valve replacement, estimated between 3.8% and 5.2%. Since the first valve-in-valve (VIV) TAVI procedure was performed by Wenaweser et al. in 2007, there is now a less invasive option to treat patients with degenerated BPVs.3 Patient prosthesis mismatch (PPM) following VIV TAVI, however, has emerged as a concern, particularly among patients with smaller BPVs. Bioprosthetic valve fracturing (BVF) of a BPV during VIV TAVI is a novel approach, first described in the aortic position in 2015, involving fracturing the BPV ring with high-pressure balloon inflation to improve postprocedural valvular haemodynamics.4

Valve-in-valve Transcatheter Aortic Valve Implantation

The Valve-in-Valve International Data (VIVID) registry, established in 2010, was designed to collect data on VIV TAVI procedures using both self-expanding (Medtronic) and balloon-expandable (Edwards Lifesciences) devices. It is the largest of its kind.5 The VIVID registry showed worse outcomes when VIV TAVI was performed in patients with small surgical valve sizes (label size ≤21 mm) and in those with stenosis as the primary mechanism of failure.6

Small surgical valve size (≤21 mm) was associated with a reduced 1-year survival of 74.8% compared with intermediate-sized (21–25 mm) and large (≥25 mm) BPVs, which had survival rates of 81.8% and 93.3%, respectively.3 Patients being treated for BPV stenosis had 30-day mortality rates of 10.5% compared with 4.3% for BPV regurgitation and 7.2% in the combined group (p=0.04).1 One multicentre study (n=47) describes a 30-day mortality rate of 17% after VIV TAVI (mean age 80.3 years; EuroSCORE 35%).6

PPM is assumed to be the cause of increased mortality rates after VIV TAVI and as such is a major concern.1 PPM is generally defined as an indexed effective orifice area (EOA) ≤0.85 cm²/m² and can lead to an inadequate cardiac index.7 In one series, PPM was highest among VIV TAVI within smaller BPVs and the incidence of severe PPM (EOA ≤0.65 cm²/m²) following VIV TAVI was found to be 31.8%.7 If, however, one considers that, for example, Mitroflow 19 mm and 21 mm prostheses have true internal diameters of 15.4 mm and 17.3 mm, respectively, it is perhaps not surprising that placement of a THV constrained by these diameters may not meet physiological demands. In summary, patients with small surgical BPVs undergoing VIV TAVI have higher residual gradients and higher mortality compared with patients with larger BPVs undergoing VIV TAVI.3

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Table 1: Actuarial Survival and Occurrence of Reoperation and Bleeding after 10 and 20 Years in Patients Receiving a Mechanical (Björk–Shiley) or Bioprosthetic (Porcine) Valve in a Randomised Prospective 20-Year Comparison Trial

| Valve               | 10 years (%) | 20 years (%) | p-value* |
|---------------------|--------------|--------------|----------|
| All survivors       |              |              |          |
| Björk–Shiley valve  | 58.7         | 25.0         | 0.39     |
| Porcine valve       | 53.6         | 22.6         |          |
| With original       |              |              |          |
| prosthesis intact   |              |              |          |
| Björk–Shiley valve  | 55.7         | 23.5         | <0.0001  |
| Porcine valve       | 42.6         | 6.7          |          |
| Survivors without   |              |              |          |
| a major event       |              |              |          |
| Björk–Shiley valve  | 47.0         | 13.8         | 0.0007   |
| Porcine valve       | 37.3         | 4.8          |          |

Valve-related Events

| Reoperation         |              |              |          |
|---------------------|--------------|--------------|----------|
| Björk–Shiley valve  | 7.1          | 12.2         | <0.0001  |
| Porcine valve       | 27.0         | 67.8         |          |
| Bleeding: all       |              |              |          |
| episodes            |              |              |          |
| Björk–Shiley valve  | 15.3         | 55.6         | 0.007    |
| Porcine valve       | 7.5          | 43.6         |          |

*p-value from log rank tests, Björk-Shiley versus porcine valves at 20 years. Source: Oxenham et al. 2003. Adapted with permission from BMJ Publishing Group.

Bioprosthetic Valve Fracturing Procedure and Case Series

BVF fracture directly addresses the issue of inadequate valve diameter by forcefully dismantling the rigid scaffold of the degenerated surgical BPV (Figures 1 and 2). This allows the implantation of a valve size better suited to the patient’s native cardiac index. While the composition of BPVs vary, all are based on similar concepts. For example, the design of the Mitroflow BPV (Sorin Group; Figure 2) incorporates a bovine pericardial sheet sutured to the outside of an acetyl stent to form the leaflets. The sewing ring is made from soft radiopaque silicone covered by a Dacron mesh. The acetyl stent ring diameter can be widened via fracturing.

Bench tests describe the technique of placing a non-compliant balloon within the surgical bioprosthesis. A high-pressure stopcock is used to separately attach a syringe and an indeflator to the balloon. The balloon is inflated by hand injection at first, and is then completed with high-pressure inflation using the indeflator. This results in a single fracture point within the stiff valve ring. An audible snap can be heard with a sudden decrease in inflation pressure. The fracture can usually be confirmed visually by fluoroscopy, but not in Mosaic (Medtronic) and Mitroflow BPVs, because they have no metal ring. Haemodynamic measurements and calculation of the valve effective orifice area are performed at baseline, immediately after VIV TAVI and after BVF.

Two single-centre case series demonstrate the strategies and haemodynamic results in patients treated with VIV TAVI and BVF. The majority of these cases were to treat stenotic BPVs, with a mean age of 79 years. Of a combined cohort of 30 patients from the two cases series, 15 patients underwent BVF before TAVI and the other 15 received BVF after TAVI. This has been clearly summarised in a prior review.

Interestingly, the 15 cases of TAVI prior to BVF were all in one case series, and allow measurement of haemodynamic improvements following TAVI to be compared with further improvements post BVF. In this study, there were initial haemodynamic improvements observed following VIV TAVI, but importantly, further benefits were observed in the same patients following BVF. Mean transvalvular gradients were reduced from 20.5 ± 7.4 mmHg after initial VIV TAVI to 6.7 ± 3.7 mmHg after BVF (p<0.001). Accordingly, the mean effective orifice area increased from 1.0 ± 0.4 cm² after initial VIV TAVI to 1.8 ± 0.6 cm² after BVF (p<0.001).

A multicentre case series in which BVF was performed in 75 patients in 21 centres has recently been published. BVF success was defined as when the waist of the balloon released and/or there was a sudden drop in inflation pressure on the indeflator. The outcomes corroborate previous observational studies, and suggest that BVF can be safely performed with balloons ≥3 mm larger than the BPV true internal diameter, thereby achieving significant reductions in transvalvular gradients. The series also recommended BVF be performed after VIV TAVI, as this sequence resulted in significantly lower mean gradients as compared with BVF performed before VIV TAVI (8.1 ± 4.8 mmHg versus 16.9 ± 10.1 mmHg; p<0.001). The most
Finally, BVF after TAVI deployment is

In the case series by Nielsen-Kudsk (n=10), balloon-expandable

These studies have demonstrated

There are data to suggest that lower postprocedural mean

bench study evaluated VIV TAVI and BVF with the

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Testing Prior to an Early

Second, some have opted for BVF prior to

As mentioned

This warrants further study.

Therefore, further postdilatation using a non-compliant balloon

operators. First, fracture of the BPV ring before VIV TAVI will allow

nonetheless, there remain theoretical advantages with undertaking

BVF prior to TAVI implantation, which should be considered by

There are, however, concerns that performing BVF first may dislodge

embolic material from the degenerated BPV, leaving the patient susceptible
to stroke. This may have been the cause of stroke in two patients in the

disembodied large case series. Finally, BVF after TAVI deployment is

likely to be beneficial in balloon expandable valves as discussed below.

TAVI Valve Type

Both self-expanding or balloon-expandable THVs can be used together

with BVF. Bench testing studies have shown significant differences

between self-expanding and balloon-expandable THV when they

were implanted post BVF. It was shown that the radial force of the

self-expanding THV was sufficient for complete expansion within the

fractured BPV, thus requiring no additional postdilatation.

Conversely, suboptimal results were seen when using balloon-

expandable THVs (SAPIEN XT and SAPIEN 3; Edwards Lifesciences),

where it was found that the delivery semicompliant balloon was not

robust enough to fully expand the THV within the previously fractured

BPV. Therefore, further postdilatation using a non-compliant balloon

was required. To minimise this risk, fracturing the BPV post VIV TAVI

was suggested.

A recent ex vivo bench study evaluated VIV TAVI and BVF with the

SAPIEN 3 and ACURATE neo (Boston Scientific) THVs in 19 mm and
Complications of Bioprosthetic Valve Fracture

In the aforementioned large case series, two out of 75 patients experienced postprocedural stroke (confirmed by MRI). Both patients fully recovered without any permanent neurological sequelae. There were no other direct postoperative complications observed with BVF in the three case series published to date. Despite these promising results, concerns remain regarding potential risks. Normally, the BPV ring offers protection against aortic annular rupture or aortic dissection during TAVI, but this protection may not apply after forceful BVF. Routine CT imaging was not performed after BVF in these case series, and as such the presence of subclinical injury to the aorta could not be ruled out.

Insufficient numbers of BVF case reports have been performed to confidently determine the incidence of complications, but Saxon et al. have published a review specifically highlighting complications associated with BVF. Documented complications include acute aortic and mitral valve regurgitation, prosthetic valve destabilisation and migration, coronary artery obstruction, balloon failure, and embolization.

Acute valvular regurgitation is due to damage of the leaflets during balloon dilation. The Medtronic self-expanding valve is designed with a narrowed area called the constrained area. It is within this area that the commissures attach to the nitinol frame. Therefore, inflating the balloon within the constrained region could potentially tear the leaflets. In an attempt to minimise this risk, one study proposed keeping the superior shoulder of the balloon below the constrained area during inflation (Figure 3).6

Bioprosthetic Valve Fracture in Larger Surgical Bioprostheses

Although PPM is more likely in smaller prosthetic valves, there is some evidence to suggest that underexpansion of BVFs may lead to early structural valve degeneration (perhaps because of folds in the BPV leaflets), suggesting that an upfront strategy of BVF in all degenerated surgical valves could, in theory, improve outcomes for all patients undergoing VIV TAVI. In the large case series reported by Allen et al., 36 of the 75 cases of successful BVF were in patients with intermediate- to large-sized BPVs (23–26 mm). This argues the potential feasibility for BVF as an adjunct to VIV TAVI in larger valves. Further clinical experience is required to provide insight into this novel technique.

Conclusion

BVF during TAVI results in lower residual mean gradients, and has the potential to improve clinical outcomes among patients undergoing VIV TAVI, particularly those with small diameter surgical BPVs. Recent data suggest that it is preferable to perform BVF after, rather than before, VIV TAVI, and with a larger non-compliant balloon sized ≥3 mm, greater than the true internal diameter for better haemodynamic results. BVF appears to be safe in the limited cases series published to date but more data on larger populations of patients undergoing BVF are required.11

Structural

Figure 3: The Constrained Area of a Self-expanding Transcatheter Heart Valve where the Commissures Attach to the Nitinol Frame

Constrained diameter is 20 mm for 23 mm Evolut R and 22 mm for 26 mm Evolut R

When using a high-pressure balloon larger than the constrained area of a self-expanding transcatheter valve (A), keeping the shoulder of the balloon below the constrained area appears to mitigate the risk of tearing the leaflets and creating aortic regurgitation (B). Source: Allen et al. 2017. Reproduced with permission from Elsevier.

21 mm Mitroflow BPVs. It was found that a high implantation was required to enable full expansion of the upper crown of the ACURATE neo and allow optimal leaflet function. Marked underexpansion of the lower crown of this THV within the BPV was also observed. Ultimately, however, valve gradients after BVF were similar for both THVs (8.4 mmHg ACURATE neo versus 7.8 mmHg SAPIEN 3). The final iEOAs were 2.1 cm² with the SAPIEN 3 and 2.2 cm² with the ACURATE neo.9

Complications of Bioprosthetic Valve Fracture

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