

# Transcatheter Valve-in-Valve Therapy Using a Balloon Expanding Valve for Treatment of Aortic Paravalvular Leakage



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Aortic paravalvular leakage (PVL) is a recognised complication of surgically replaced valves which is often treated using vascular plugs. Whilst transcatheter valve-in-valve therapy has been increasingly used for failed surgical bioprostheses, it is not considered as a treatment option for aortic PVL. However, the newer design of transcatheter aortic valves has a fabric skirt to create a more effective seal around the annulus. To our best knowledge, for the first time, we report successful adoption of the valve-in-valve therapy for the treatment of PVL in surgical bioprosthetic aortic valves such that the fabric skirt is placed immediately below the regurgitant orifice resulting in significant reduction in the PVL.

## Keywords

Aortic valve • Paravalvular regurgitation • Valve-in-valve therapy • Transcatheter aortic valve implantation

## Introduction

Aortic paravalvular regurgitation (PVL) is a recognised complication of surgically replaced valves and transcatheter aortic valve implantation (TAVI). Vascular plugs are often used to treat clinically significant aortic PVL in surgically replaced valves and their use in treatment of post TAVI PVL is emerging, although it can be technically challenging owing to the crescentic shape of the defects and their serpiginous path [1]. Whilst transcatheter valve-in-valve therapy has been increasingly used for failed surgical bioprostheses, it is not considered as a treatment option for aortic PVL [2]. However, it has been occasionally used during TAVI valve deployment to seal associated significant PVL.

The Sapien 3 (Edwards Lifesciences, Irvine, CA, USA) transcatheter heart valve (THV) has an outer fabric skirt to create a more effective seal around the annulus in order to reduce PVL. Adoption of the valve-in-valve technique in treating aortic PVL in selected bioprosthetic or TAVI valves using the Sapien 3 THV such that the fabric skirt is placed immediately below the regurgitant orifice would be expected to result in a significant reduction in the severity of regurgitation. We present a series of three cases that have been successfully treated with this strategy. All cases were discussed in a multidisciplinary Heart Team meeting and deemed high risk for open heart surgery. None of the cases had patient prosthesis mismatch. The procedures were done under general anaesthesia with two dimensional (2D) and

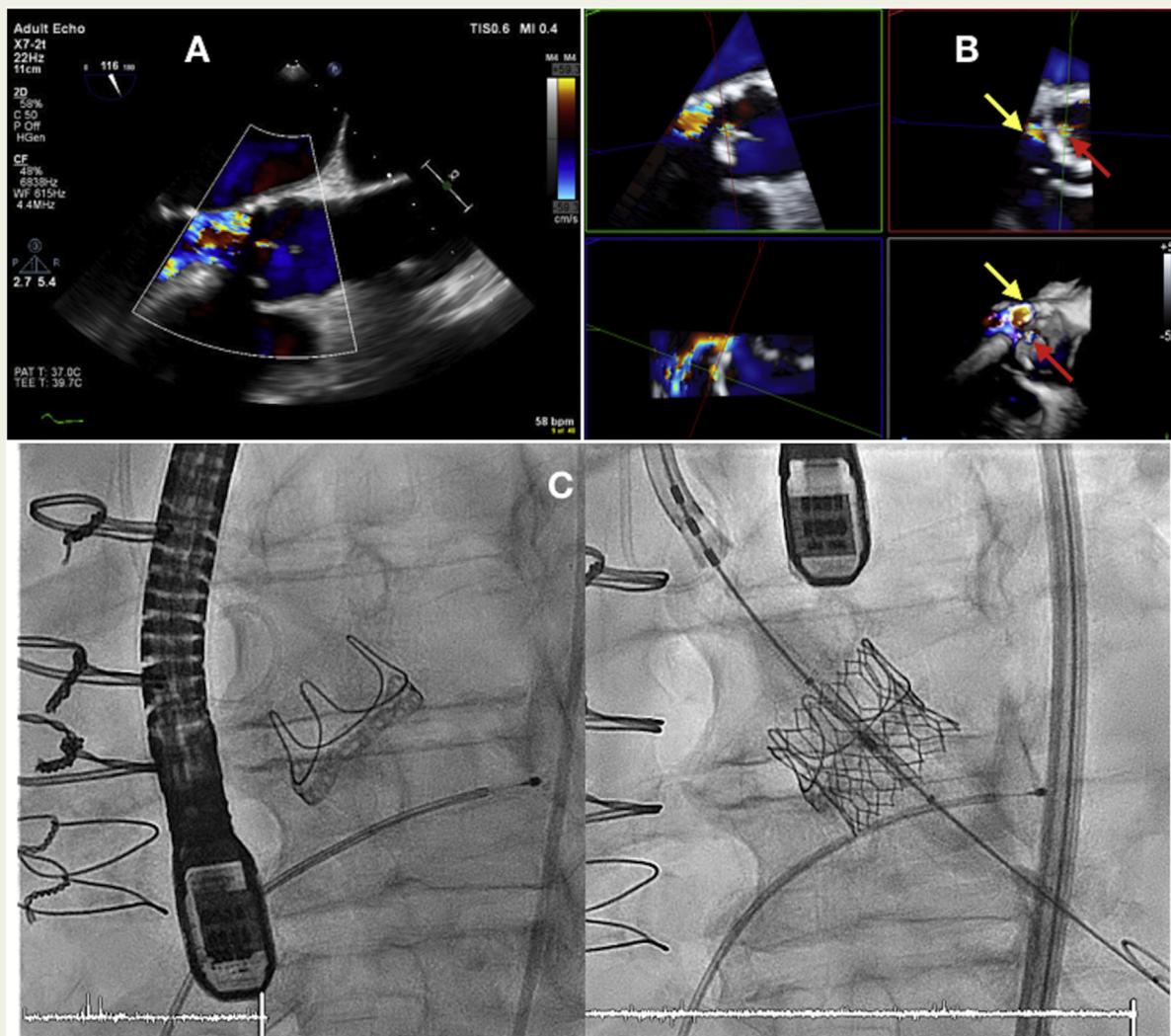
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three dimensional (3D) transoesophageal echocardiography (TOE) and fluoroscopic guidance.

## Case 1

A 64-year-old man with a significant medical history including a liver transplant, chronic kidney disease and an aortic valve replacement (25 mm Edwards Perimount Magna, Edwards LifeSciences, Irvine, CA, USA) complicated by endocarditis that had been treated medically, presented with progressive shortness of breath. Two-dimensional and 3D echocardiography showed mild transvalvular aortic regurgitation with a large paravalvular leak (see Supplementary Video S1 in the online version at DOI: [10.1016/j.hlc.2018.06.1045](https://doi.org/10.1016/j.hlc.2018.06.1045)).

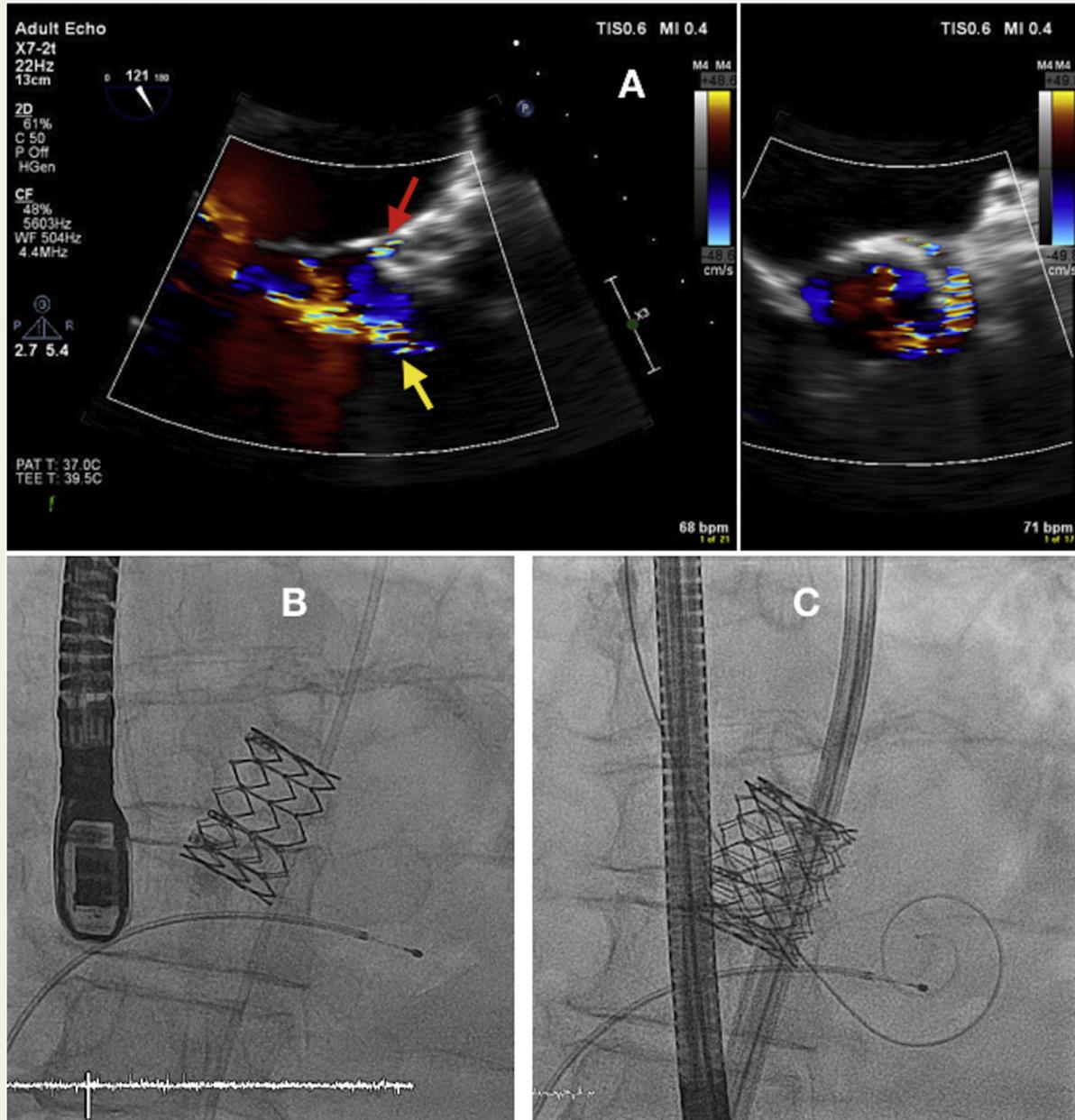
Given the size of the PVL along with the evidence of transvalvular aortic regurgitation (AR), we elected to treat him with a 26 mm Sapien 3 THV. The valve was deployed in the annular plane deliberately 2–3 mm lower than recommended for this bioprosthesis in order to maximise the sealing effect of the fabric skirt (Figure 1C). There was no residual regurgitation and the peak and mean gradients across the valve were 18 and 7 mmHg respectively. He has been followed up for more than a year and remains in New York Heart Association (NYHA) class I with no evidence of aortic regurgitation on follow-up transthoracic echocardiography (TTE) studies (see Supplementary Videos S2 and S3 in the online version at DOI: [10.1016/j.hlc.2018.06.1045](https://doi.org/10.1016/j.hlc.2018.06.1045)).



**Figure 1** Case 1

(A) 2D TOE was inconclusive in identifying the origin of the aortic regurgitation; (B) 3D colour Doppler of the aortic valve and multi planar reconstruction of the 3D dataset showing both transvalvular (red arrow) and paravalvular regurgitation (yellow arrow); (C) Fluoroscopic view of the aortic bioprosthetic valve (left) and the Sapien 3 valve in the bioprosthetic valve (right).

Abbreviations: 2D, 2-dimensional; 3D, 3-dimensional; TOE, transoesophageal echocardiograph.



**Figure 2** Case 2

(A) Illustration of the two PVL jets: a small posterior (red arrow) and a large anterior jet (yellow arrow) in mid-oesophageal long axis aortic view and the corresponding anterior jet in the short axis view. (B) Fluoroscopic view of the initial Sapien XT valve in an optimal position and (C) the Sapien 3 valve in the Sapien XT.

Abbreviations: PVL, paravalvular leak.

## Case 2

A 77-year-old man who had undergone a successful TAVI with a 29 mm Sapien XT THV (Figure 2B) 2 years previously presented with increasing dyspnoea and cardiac failure and evidence of gradually worsening PVL on follow-up TTE studies. A TOE revealed two broad jets of PVL (see Supplementary Video S4 in the online version at DOI: [10.1016/j.hlc.2018.06.1045](https://doi.org/10.1016/j.hlc.2018.06.1045), Figure 2A). Based on our experience with the first case

and the recognised technical difficulty of closing PVLs in the TAVI valves, the patient was treated with a 29 mm Sapien 3 valve in the previous Sapien XT (Figure 2C) with significant reduction in the severity of the PVL (see Supplementary Video S5 in the online version at DOI: [10.1016/j.hlc.2018.06.1045](https://doi.org/10.1016/j.hlc.2018.06.1045)) and acceptable peak and mean gradients across the valve (25 and 15 mmHg respectively). This patient has also been followed up for more than a year with significant clinical improvement and only trace PVL on the follow-up TTEs.

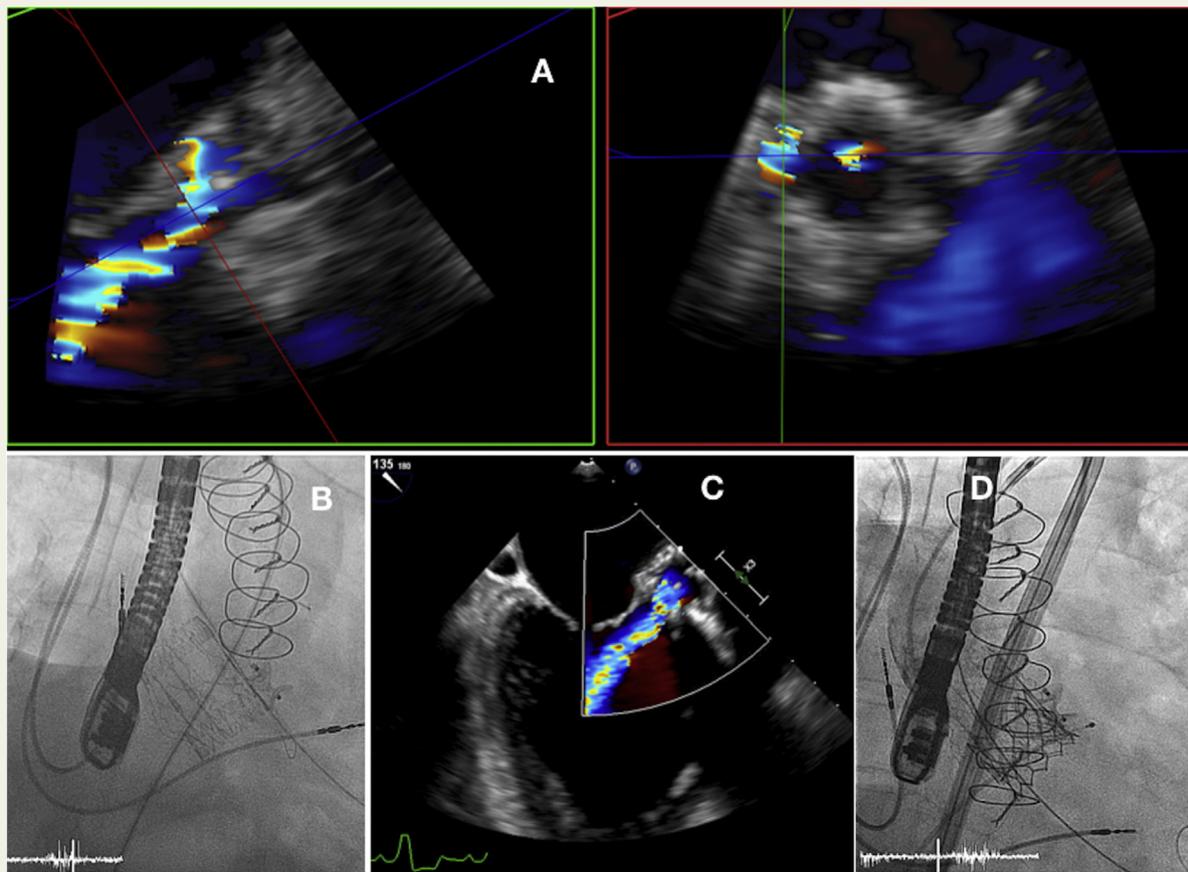
### Case 3

The third patient was a 62-year-old lady with a history of aortic valve replacement for endocarditis and a redo valve replacement using a sutureless valve (Perceval, Sorin Group, Saluggia, Italy) due to recurrence of endocarditis, who presented with exertional dyspnoea resulting from a significant PVL diagnosed on echocardiography (see Supplementary Video S6 in the online version at DOI: [10.1016/j.hlc.2018.06.1045](https://doi.org/10.1016/j.hlc.2018.06.1045), Figure 3A). In this case, we elected to close the PVL using an Amplatzer Vascular Plug II (St. Jude Medical (now Abbott), St. Paul, MN, USA). However, due to interaction between the delivery catheter and the struts of the Perceval valve it proved difficult to position the plug in an optimal position. After deploying the device, the PVL had worsened, with the development of a more crescentic defect around the valve margins (Figure 3B and C). Furthermore, manipulation of the guide catheter within the architecture of the Perceval was increasingly difficult. Given these technical

challenges we decided to deploy a 26 mm Sapien 3 'valve-in-valve' which resulted in elimination of the PVL. Again, the valve was deployed 2–3 mm lower below the annular 'suture-free' line (Figure 3D). The patient improved clinically and has been followed up for more than 3 months with no significant PVL (see Supplementary Videos S7 and S8 in the online version at DOI: [10.1016/j.hlc.2018.06.1045](https://doi.org/10.1016/j.hlc.2018.06.1045)) and a peak/mean gradient of 21/13 mmHg respectively.

### Discussion

We have shown in these three cases that significant aortic PVL can be treated successfully with valve-in-valve therapy. Waterbury *et al.* have also recently studied the utility of the valve-in-valve therapy in treatment of the PVL in TAVI valves, but, in these cases, the mechanism for AR was a valve deployed relatively high during the index procedure [3]. Our cases are different in that all three valves had been implanted in an optimal position; two were surgical valves, and the Sapien XT device had developed PVL almost a year after



**Figure 3** Case 3

(A) 3D guided 2D multiplanar reconstruction of a 3D zoomed datasets showing a large paravalvular leak. Please note that the image on the right side is the reverse image of standard short axis view. (B) Unsuccessful deployment of the vascular plug. (C) Worsening of the PVL after the unsuccessful attempt to repair the leakage. (D) Successful deployment of a 26 mm Sapien 3 valve in the sutureless valve.

Abbreviations: 2D, 2-dimensional; 3D, 3-dimensional; PVL, paravalvular leak.

initial deployment. In each case, deployment of the valve 2–3 mm lower than normal resulted in the abolition of the large PVL. Finally, the use of closure devices in the treatment of PVL in aortic sutureless valves should be approached with caution. The design of the device, and the ‘suture-free’ seal made this more challenging to deal with than the standard surgical bioprostheses. We are not aware of any previous report in the literature on the use of transcatheter valve-in-valve approach in treatment of the PVL in surgically replaced bioprosthetic aortic valves.

## Conclusion

Whilst the use of percutaneous closure devices should be the preferred initial treatment strategy for aortic PVL in both surgical and percutaneous valves, the use of ‘valve-in-valve’ therapy to treat aortic PVL should be considered in selected cases, particularly where the defect is large, multiple or crescentic and where there is any evidence of prosthetic valve degeneration. However, a larger series of patients and long-term follow-up is required to assess its feasibility and longer term outcome.

## Disclosures

Professor Monaghan is a proctor and speaker for Edwards Lifesciences.

Professor Wendler is a proctor for Edwards Lifesciences and receives consultant and speaker fees and research grant from Edwards Lifesciences.

Professor MacCarthy is a proctor for Edwards Lifesciences.

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