

# Two case reports of transcatheter valve-in-valve implantation of Sapien 3 and MyVal in degenerated biological tricuspid prosthesis valves

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## Background

Patients with severe tricuspid valve stenosis or dysfunction following degeneration of biological valve prosthesis in tricuspid position are complex, have substantial comorbidity, and very high surgical risk.

## Case summary

We report two cases with transcatheter tricuspid valve-in-valve implantation in patients with degenerated tricuspid bioprosthesis with transfemoral and transjugular access with Sapien 3 valve and MyVal, respectively.

## Discussion

In patients with high surgical risk, transcatheter tricuspid valve implantation is a good alternative. Careful consideration of optimal access site, device size, and delivery system is paramount. This case report demonstrates technically feasible and safe transcatheter valve-in-valve implantation in tricuspid position and highlights the importance of meticulous procedure planning.

## Keywords

Transcatheter valve implantation • Tricuspid bioprosthesis failure • Tricuspid valve stenosis • Valve-in-valve • Case report • Transjugular access

## ESC Curriculum

4.6 Tricuspid stenosis • 4.5 Tricuspid regurgitation • 4.10 Prosthetic valves • 7.4 Percutaneous cardiovascular post-procedure • 7.5 Cardiac surgery

## Learning points

- Transcatheter tricuspid valve-in-valve implantation is a good alternative to surgical replacement in high-risk patients.
- Meticulous procedure planning is paramount for procedural success. There are different pros and cons for transjugular vs. transfemoral access and for different valve types.

## Introduction

Patients with severe tricuspid valve disease (dysfunction) demanding tricuspid valve intervention are, although they may be young, often complex, have substantial comorbidity and often multivalve

involvement.<sup>1,2</sup> Both mechanical and bioprosthetic valves can be used in surgical replacement. While mechanical valves carry a high thromboembolic risk especially in the tricuspid position, bioprosthetic valves are often preferred despite the common demand for replacement after 10–15 years, due to degeneration.<sup>3–5</sup> In these

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patients, repeated surgery is associated with considerable increased morbidity and mortality.<sup>6</sup> Although still off label, transcatheter tricuspid valve-in-valve (ViV) replacement is a promising alternative to surgical reoperation.<sup>7</sup> The different devices available have different delivery systems and have different pros and cons.

Here, we present two cases with transcatheter tricuspid ViV implantation in patients with degenerated tricuspid bioprosthesis treated with transfemoral Sapien 3 (Edwards Lifesciences, Irvine, CA, USA) valve implantation and transjugular MyVal (Meril Life Sciences, Gujarat, India) implantation, and discuss differences in these devices.

## Timeline

### Case 1

2011 Extensive thrombus in the right atrium and ventricle. Tricuspid valve replacement, Carpentier Edwards 27 mm

November 2014 Patients presents with fatigue, dyspnoea, and peripheral oedema. Diagnostic workup reveals dysfunctional biological prosthetic tricuspid valve

April 2015 Transcatheter tricuspid valve-in-valve implantation by transfemoral access with Sapien 3 valve.

September 2019 Routine checkup. Patient asymptomatic

### Case 2

1994 Endocarditis. Tricuspid valve replacement, Mitroflow 29.

May 2017 Patient presents with mild dyspnoea, gradually worsening.

October 2020 Increasing dyspnoea, New York Heart Association (NYHA) III. Multimodality evaluation reveals dysfunctional degenerated biological prosthetic tricuspid valve

January 2021 Transcatheter tricuspid valve-in-valve implantation by transjugular access with MyVal valve.

February 2021 Routine checkup. Patient well. NYHA I

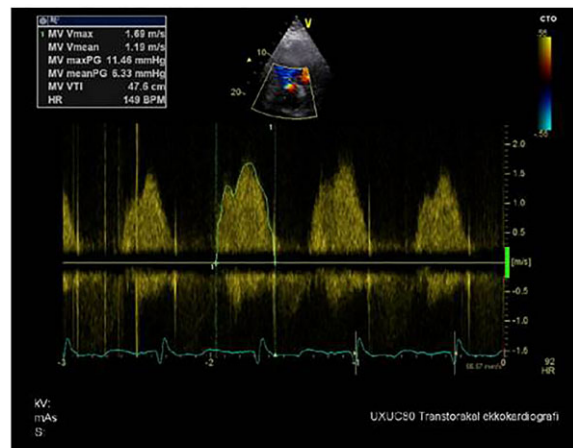
## Case 1

A 29-year-old obese woman with Type 2 diabetes presented with extensive thrombus in the right ventricle and right atrium. She was treated with surgical excision of thrombus adherent to the tricuspid valve and subsequently implantation of a Carpentier Edwards 27 mm valve. She was diagnosed with Factor V Leiden mutation and antiphospholipid syndrome and was put on warfarin with target INR 2–3 combined with aspirin 75 mg. Three years later she presented with progressing shortness of breath, fatigue, and peripheral oedema. Transthoracic and transoesophageal echocardiography revealed thickened and fixated septal cusp with peak and mean gradient over the tricuspid valve of 12 and 6 mmHg at rest, respectively. During exercise, the peak and mean gradient increased to 26 and

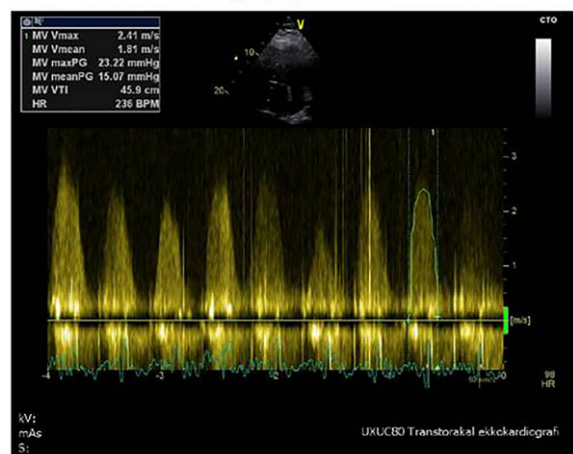
14 mmHg, respectively (Figure 1). Cardiac catheterization revealed severely increased right atrial pressure of 15 mmHg with normal end diastolic right ventricular pressure of 4 mmHg.

At multidisciplinary heart team conference, the treatment strategy considered was to offer the patient replacement of the Edwards valve through a right mini-thoracotomy. However, cardiac computed tomography (CT) performed for procedural planning revealed that the right atrium was quite small, the distance from the posterior sternum surface to the right atrium was large and an unfavourable angle of the tricuspid annulus would complicate the surgical procedure (Figure 2A). Due to the patient's unfavourable anatomy combined with high risk of infection as well as the presumed need for additional surgery within the next 10–15 years in this young patient, the risk of redo tricuspid surgery was determined to be high despite EuroSCORE II was only 3.8%. Cardiac CT showed that transcatheter tricuspid ViV replacement through the femoral vein was accessible and a more optimal treatment strategy.

### A Rest echocardiography

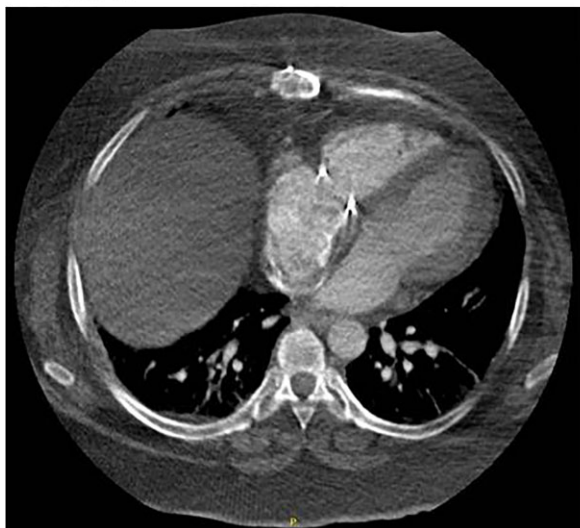


### B Exercise echocardiography 75W

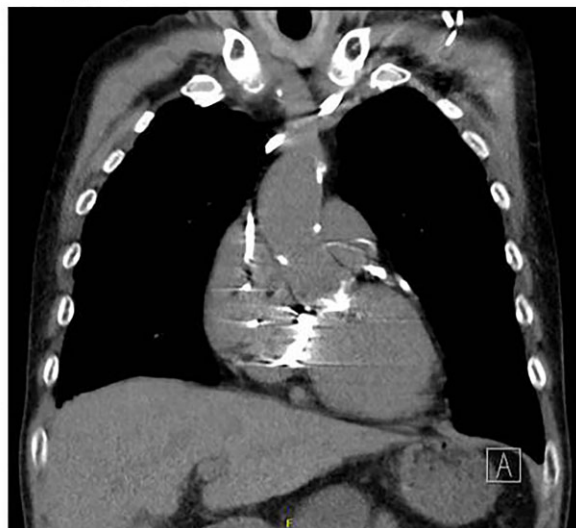


**Figure 1** Transthoracic echocardiogram at rest (A) and during exercise (B) shows severe tricuspid stenosis with mean and peak transvalvular gradients of 6 and 11 mmHg at rest (A) and 15 and 23 mmHg during exercise (B).

A Case 1



B Case 2



**Figure 2** Computed tomography scan images from (A) Case 1 and (B) Case 2.

In general anaesthesia it was attempted, but not possible, to place a temporary pacing lead in the coronary sinus and instead a lead was placed in the left ventricle through the femoral artery. The patient was heparinized with 10 000 plus 15 000 IE Heparin to reach activated clotting time (ACT) >300 s. Through a 14 french sheath in the femoral vein a 26 mm Sapien 3 valve, corresponding recommendation for ViV in a Carpentier Edwards 27 mm valve, was inserted fluoroscopic guided over the Amplatz wire in the tricuspid bioprosthesis and deployed at nominal volume under pacing 180 b.p.m. with no pre- or post-dilatation (Figure 3). The delivery system, guidewire, pacing lead, and sheaths were subsequently removed and haemostasis was obtained by Angio-seal (Terumo Medical Corporation, NJ, USA) in the femoral artery and manual compression of the femoral vein. Transoesophageal echocardiography during the procedure and transthoracic echocardiography the following day confirmed well-seated valve with optimal position, no paravalvular regurgitation, and improved transtricuspid gradient with a reduction of mean gradient to 8 mmHg. Patient was discharged from hospital after just 4 days with no procedural complications or periprocedural sequelae. The patient was treated with a combination of warfarin and clopidogrel 75 mg for 1 year and then warfarin and aspirin 75 mg. One-month postoperatively the patient reported considerable improvement of dyspnoea and no peripheral oedema, and echocardiography confirmed good valve function. After 6 years of follow-up, the valve is still functioning well with echocardiographic mean and peak tricuspid valve gradient of 5 and 10 mmHg, respectively.

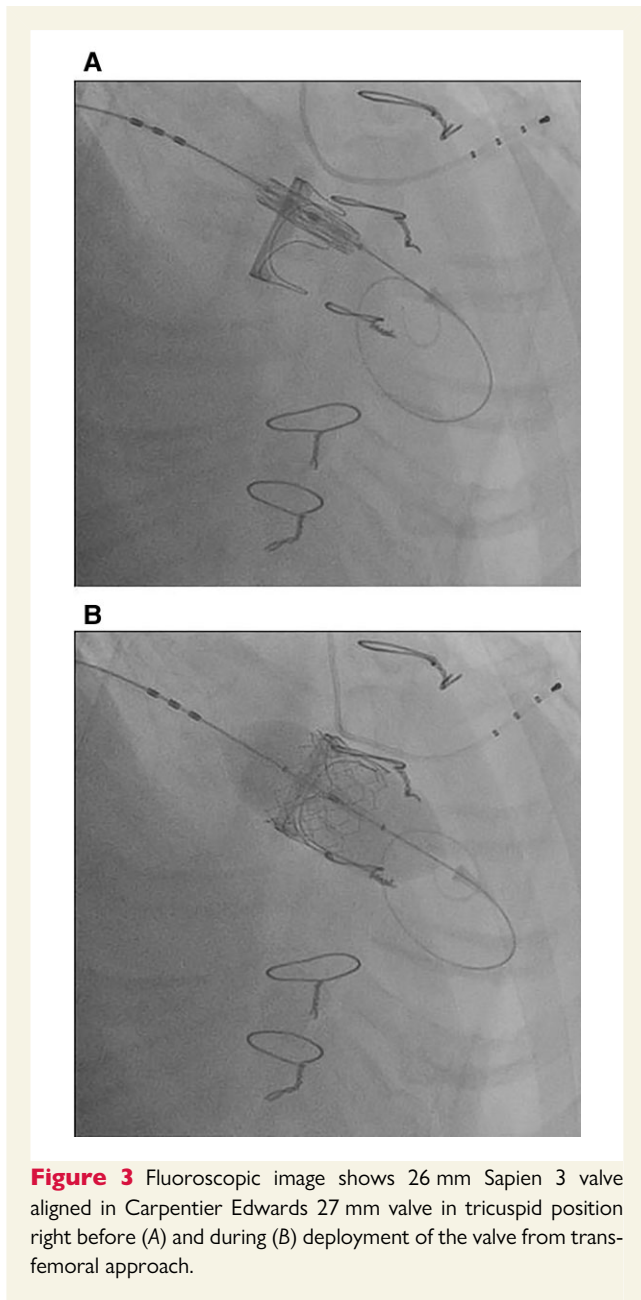
## Case 2

A 67-year-old-man with hepatitis C and a mild degree of liver cirrhosis presented with progressing dyspnoea [New York Heart Association (NYHA) III]. Twenty-six years earlier, he had undergone

surgical treatment for endocarditis with insertion of a mechanical St Jude 23 mm in aortic position, and a tricuspid valve replacement with a 29 mm Mitroflow bioprosthesis, and post-operative implantation of a DDD-pacemaker with RV-lead through the bioprosthetic tricuspid valve due to complete atrioventricular (AV) block. His symptoms had gradually progressed over a 3-year period, and annual echocardiography had revealed increasing dysfunction of the Mitroflow valve in tricuspid position. At rest, the transvalvular mean and peak gradient had gradually increased from 9 and 14 mmHg to 11 and 16–18 mmHg, respectively. At presentation, transthoracic and transoesophageal echocardiography showed normal ejection fraction and confirmed the degenerated Mitroflow valve (Figure 4). Cardiac catheterization also confirmed tricuspid valve stenosis with severely increased right atrial pressure of 15 mmHg with normal end diastolic right ventricular pressure of 2–5 mmHg.

The multidisciplinary heart team found that due to the patient's comorbidity including ischaemic heart disease and liver cirrhosis and previous tricuspid and aortic valve surgery (EuroSCORE II 5.4%), the best treatment option was transcatheter tricuspid ViV replacement and replacement of the right ventricular pacing lead to a pacing lead placed in a lateral vein via the coronary sinus to avoid crossing the tricuspid valve. Cardiac CT performed for procedural planning revealed best access for the valve replacement was through the jugular vein and also revealed the patient had a rare anatomical variant where the great cardiac vein drains directly into the superior vena cava (Figure 2B).

In general anaesthesia, a temporary pacing lead was first placed in the patient's great cardiac vein through a femoral vein access. The 26-year-old right ventricular lead was removed without any complications using transvenous mechanical extraction tool (Evolution<sup>®</sup>, Cook Medical) and the patient was heparinized with 10 000 IE Heparin to reach ACT >300 s. Through a 14 french sheath from the jugular vein, a 26 mm MyVal was inserted fluoroscopic guided over the Amplatz wire in the tricuspid bioprosthesis and deployed at nominal



**Figure 3** Fluoroscopic image shows 26 mm Sapien 3 valve aligned in Carpentier Edwards 27 mm valve in tricuspid position right before (A) and during (B) deployment of the valve from transfemoral approach.

volume under pacing 180 b.p.m. (Figure 5). Transoesophageal echocardiography showed immediate reduction in the transtricuspid mean gradient to 1.5 mmHg after deployment of the MyVal valve. The delivery system, guidewire, and sheath were removed and haemostasis was obtained by 2 Perclose/Proglide (Abbott, CA, USA). Heparin was neutralized with protamine sulfate. Subsequently, a transvenous permanent pacing lead was placed in the most suitable branch of the coronary sinus. Unfortunately, it was not possible to obtain a low pacing threshold in what was judged to be a stable lead position in the coronary sinus branches, and due to complete AV block without escape rhythm we decided to place a pacing lead in the right ventricle through the newly implanted valve causing no regurgitation.

At 1-month follow-up, the patient reported considerable improvement in symptoms. The valve is functioning well with mean and peak tricuspid valve gradient of 3 and 8 mmHg, respectively.

## Discussion

We, here, describe successful transcatheter tricuspid ViV implantation with transfemoral and transjugular access with Sapien 3 valve and MyVal, respectively. Transcatheter valve replacement is a good alternative to surgical replacement in these high-risk patients.

The first challenge in patients with suspicion of tricuspid valve dysfunction is evaluating the degree of valve dysfunction and the need for intervention. A multimodality approach with both transthoracic and transoesophageal echocardiography, including 3D, as well as right heart catheterization is necessary for full evaluation of the degree of stenosis and indication for intervention.<sup>8</sup>

Cardiac CT is paramount when planning optimal transcatheter valve intervention. This provides valuable information for determining device size for native valve intervention, optimal fluoroscopic detector position and optimal access, transfemoral or transjugular, according to the angle of tricuspid annulus (Table 1).

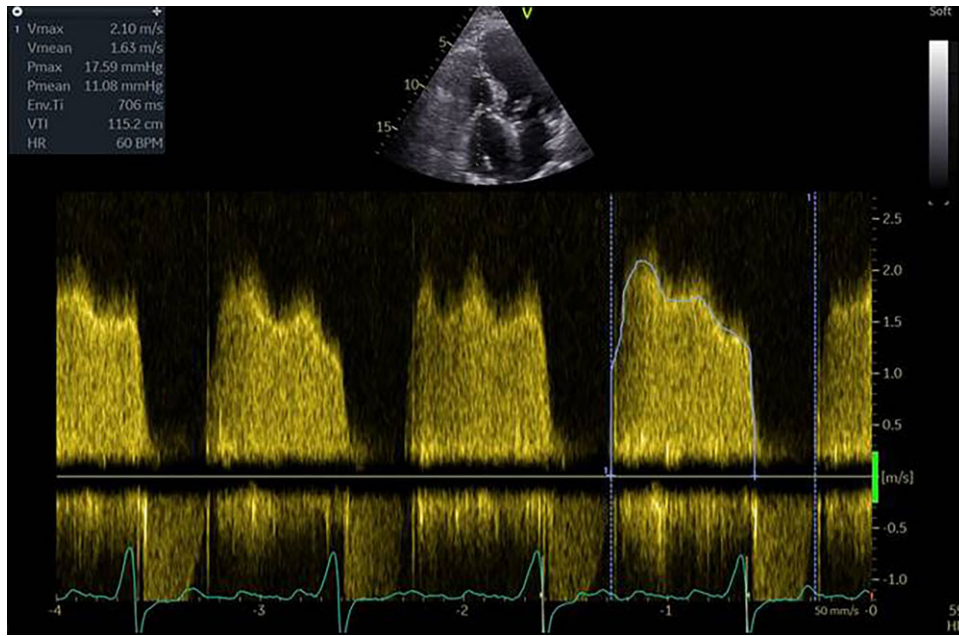
Most patients will theoretically have easier access transjugular due to the straighter route from the jugular vein to the tricuspid annulus (Figure 6). With a flex feature on the delivery system, transfemoral access is possible and once the device has been placed in the tricuspid annulus, coaxial alignment may be easier to obtain upfront from transfemoral access (Figure 6A). In the presented transjugular case, the device was not completely aligned coaxial before deployment of the valve (Figure 5), but during inflation of the delivery balloon a slight push on the wire adjusted the angle of the device so that a good alignment was achieved.

Preparation of the devices differs between manufactures (Figure 6). With the Edwards valve, the crimped valve is loaded onto the delivery balloon inside the patient by engaging the loader which pulls the crimped valve over the balloon while the valve is secured in place by the pusher. The crimped valve is placed in the delivery system with the inflow towards the pusher, opposite the alignment used when preparing the valve for aortic valve replacement. When the valve is pushed over and mounted on the balloon there could be a theoretical risk of damaging the valve leaflets because the balloon is pulled inside the crimped valve against the direction of the leaflet opening (Figure 6A). Second, the distance for loading of the valve on the balloon with transjugular access is very short compared with transfemoral access with the Sapien valve. In comparison, MyVal is crimped directly on the delivery balloon outside the patient (Figure 6B), which with transjugular access may be an advantage.

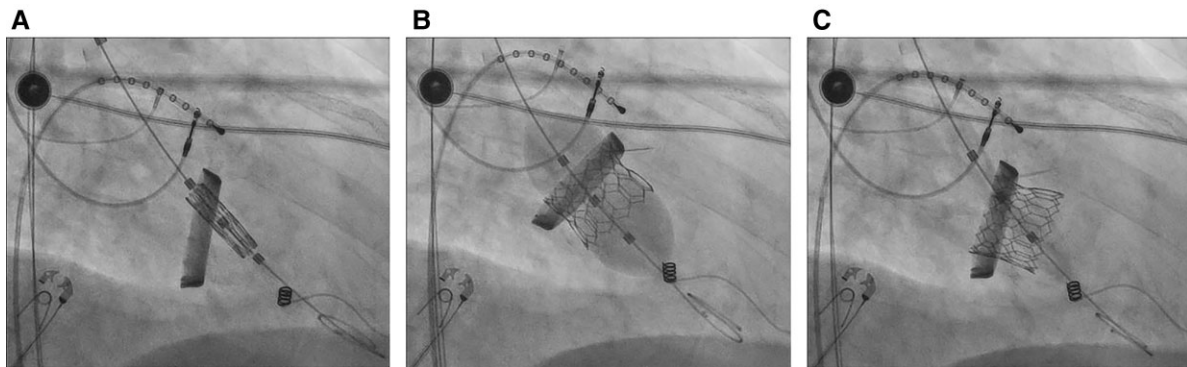
When deciding which bioprosthetic valve to use optimal valve size can influence the choice. Edwards valves have fewer valve size to choose from, while MyVal has half sizes and also offers very large devices. The most commonly demanded device sizes are available from most manufactures, and size availability is rarely the final determinant of device pick.

In conclusion, we here demonstrate technically feasible and safe ViV implantation of the Sapien 3 valve with transfemoral access and MyVal valve with transjugular access in the tricuspid position.

Meticulous procedure planning involving a multidisciplinary team is paramount for procedural success but transcatheter ViV intervention seems a good alternative treatment to surgical intervention even in patients with severe comorbidities.



**Figure 4** Transthoracic shows severe tricuspid stenosis with mean and peak transvalvular gradients of 11 and 16 mmHg.



**Figure 5** Fluoroscopic images show 26 mm MyVal valve aligned in degenerated Mitroflow valve in tricuspid position right before (A), during (B), and after (C) deployment of the valve from transjugular approach.

### Table 1 Points for consideration in planning procedure

Optimal route to tricuspid annulus depending on access site

- A straighter route from transjugular access may provide easier access to the tricuspid annulus.

The need for a flex feature on delivery system depending on access site

- Femoral access may require a delivery system with a flex feature in order to manoeuvre the valve in tricuspid position

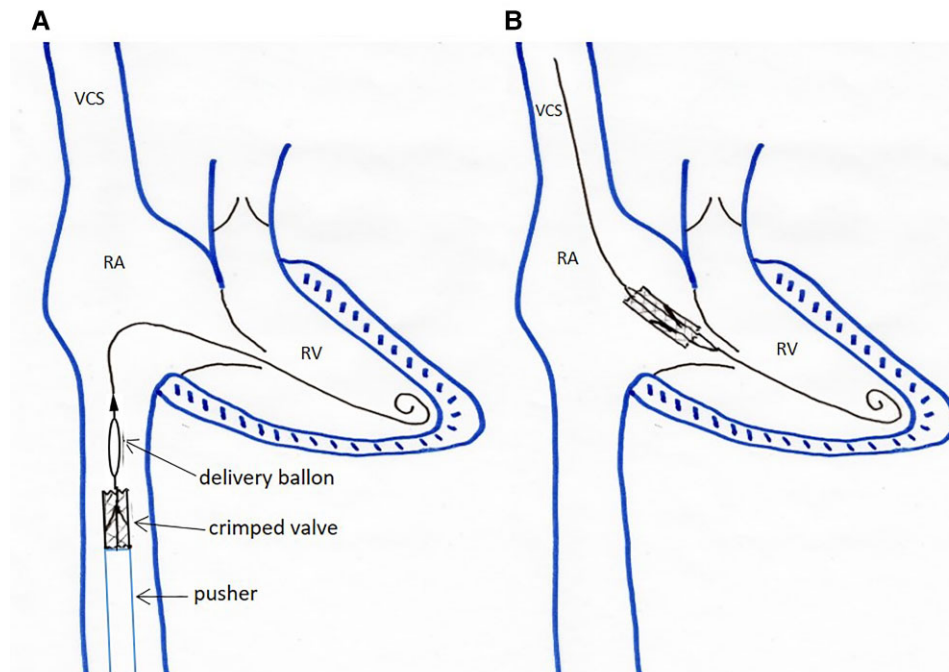
Access site for optimal alignment in valve annulus

- Coaxial alignment may be easier from transfemoral access

Preparation of valve; crimp valve on delivery balloon outside patient vs. mount valve on delivery balloon inside patient; and optimal access site for this:

- If the valve device is prepared inside the patient the distance for loading the valve on the balloon is very short from transjugular access.
- If the valve is not crimped directly on the delivery balloon there is a risk of damaging the valve leaflet as the balloon is pulled inside the crimped valve.

Available valve sizes differs between manufactures



**Figure 6** Differences in alignment and delivery systems in transfemoral and transjugular access. (A) Delivery system with flex for advancement of valve from transfemoral access. Edwards valve is loaded inside the patient. The crimped valve is pulled over the delivery balloon against the direction of the leaflets. (B) Delivery system for transjugular access with MyVal valve crimped directly on the delivery balloon outside the patient.

## Lead author biography



Dr Rebekka Vibjerg Jensen is a cardiology specialist registrar at Department of Cardiology, Aarhus University Hospital, Skejby, Denmark, where she is an interventional cardiologist. Her areas of interest include ischaemic heart disease and structural heart disease.

## Supplementary material

[Supplementary material](#) is available at *European Heart Journal—Case Reports* online.

**Slide sets:** A fully edited slide set detailing these cases and suitable for local presentation is available online as [Supplementary data](#).

**Consent:** The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidance.

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