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CASE REPORT
Adult congenital heart disease

Pulmonary valve replacement in a large and tortuous right ventricle outflow tract with a 32 mm Myval valve under local anaesthesia: challenges and technical considerations: a case report

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Background Pulmonary valve replacement in patients with congenital heart diseases and heart failure is challenging.

Case summary Here, we describe a case of a patient who had surgical fallot repair with chronic heart failure. Investigations found severe biventricular dysfunction and enlargement due to chronic pulmonary regurgitation. The right ventricle outflow tract was tortuous and large with a diameter of 35 mm. Percutaneous pulmonary valve implantation (PPVI) was done after a challenging pre-stenting. A 32 mm Myval valve over-sized to 35 mm was used for PPVI, which yielded a good result.

Discussion A 32 mm Myval valve is effective at extending the possibilities of PPVI in a large and tortuous right ventricle outflow tract not accessible for the other valves.

Keywords Percutaneous pulmonary valve implantation • Fallot • Heart failure • Myval • Case report

ESC curriculum 6.2 Heart failure with reduced ejection fraction • 9.7 Adult congenital heart disease • 2.4 Cardiac computed tomography

Learning points

- A 32 mm Myval valve is effective at extending the possibilities of percutaneous pulmonary valve implantation (PPVI) in right ventricle outflow tracts (RVOTs) larger than 30 mm.
- This Myval valve could be used in a complex RVOT, which is not suitable for auto-expandable valves.
- Three-dimensional reconstruction and printing are useful to plan a complex PPVI.
- Percutaneous pulmonary valve implantation is challenging in patients with congenital heart diseases, therefore necessitating new techniques. Surgery should be considered if possible.

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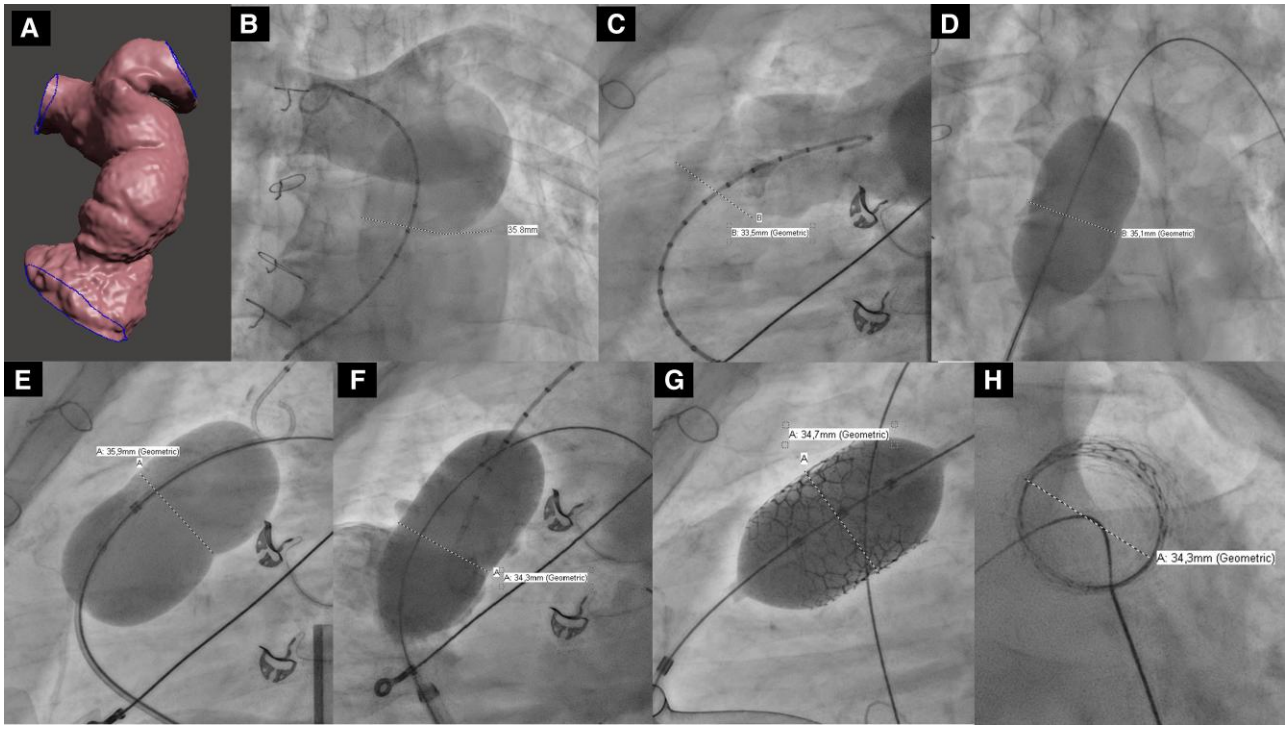
Introduction

Percutaneous pulmonary valve implantation (PPVI) is effective at treating right ventricle outflow tract (RVOT) dysfunction.[1] Initially, PPVI was used for small RVOTs and conduits.[1] With the development of new valves, a large native RVOT became the most frequent substrate.[1–3] New auto-expandable valves could treat a larger RVOT measuring up to 35 mm,[4] but they are not suitable for all RVOT sizes and shapes.[4] The 32 mm Myval valve (Meril, India) constitutes an alternative for large RVOTs measuring up to 35 mm.[5] Here, we describe a case of a 62-year-old non-operable patient with Tetralogy of Fallot, who had a significant enlargement of the right ventricle (RV) due to severe pulmonary regurgitation, with biventricular dysfunction. Therefore, PPVI was indicated, but it was considered challenging because of the RVOT size and shape. Finally, PPVI was done by using a 32 mm Myval valve (Meril, India), which proved to be challenging.

Summary figure



Case summary

A 62-year-old male patient was referred for shortness of breath and heart failure with New York Heart Association (NYHA) Stage III. He had a surgical repair of Tetralogy of Fallot at the age of 10, with ventricular septal defect closure and RVOT enlargement using a transannular patch. A clinical examination revealed a tachycardia (heart rate ~110 b.p.m.) with diastolic murmur in the pulmonary area and ankle swelling. Moreover, he had several comorbidities such as obesity (body mass index 37 kg/m^2), atrial fibrillation, sleep apnoea, post-capillary pulmonary hypertension, and hepatitis C. N-terminale du peptide natriurétique cérébral (NTBNP) at admission was 1952 ng/L. A cardiac computed tomography (CT) scan and magnetic resonance imaging (MRI) revealed LV dysfunction with ejection fraction (EF) at 31%, an RV end-diastolic enlargement of 244 mL/m^2, an RVEF of 35%, and severe pulmonary regurgitation (regurgitation fraction 43%). Minimal dimensions of the right ventricle outflow tract were 32 × 37 mm in the pulmonary annulus (*Figure 1A*). A 3D printed model derived from a CT scan showed a large and complex RVOT with aneurysmal dilatation of the pulmonary artery and the infundibulum (see Supplementary material online). Printed model calibration illustrated a short potential anchoring zone measuring 31 × 35 mm. Because of comorbidities, the surgery was contraindicated. Moreover, RVOT size and shape were not found suitable for auto-expandable valves. Therefore, PPVI with a 32 mm Myval valve was considered. An electrophysiological study was not performed because an implantable cardioverter defibrillator (ICD) was indicated on account of the severe LV dysfunction.[6] Medical treatment by beta-blockers, valsartan/sacubitril, and diuretics for heart failure, and apixaban for arrhythmia were initiated without relevant haemodynamic improvement.

Percutaneous pulmonary valve implantation was done in two steps under sedation and local anaesthesia. Vascular access was obtained by using the femoral vessels. Angiograms confirmed that the large and tortuous RVOT measured 33 × 35 mm (*Figure 1B* and *C*). Balloon interrogation of the right ventricle outflow tract with a 34 mm Amplatzer sizing balloon (Abbott, USA) showed a short anchoring area measuring 35 × 36 mm (*Figure 1D* and *E*). Coronary and RV occlusion tests were done by using a 35 × 60 mm Cristal balloon (Balt, Germany) (*Figure 1F*), with an almost full occlusion of the RV (see Supplementary material online). Because of the short landing zone, pre-stenting was considered necessary to decrease the risk of embolization. It was performed under rapid pacing using a 57 mm Optimus-XXL 57 stent (AntraTec, Germany) mounted on the 35 × 60 mm Cristal balloon (*Figure 1G*). This pre-stenting was challenging because of the large RVOT and the inhomogeneous inflation of the balloon (see Supplementary material online). Fortunately, the stent was

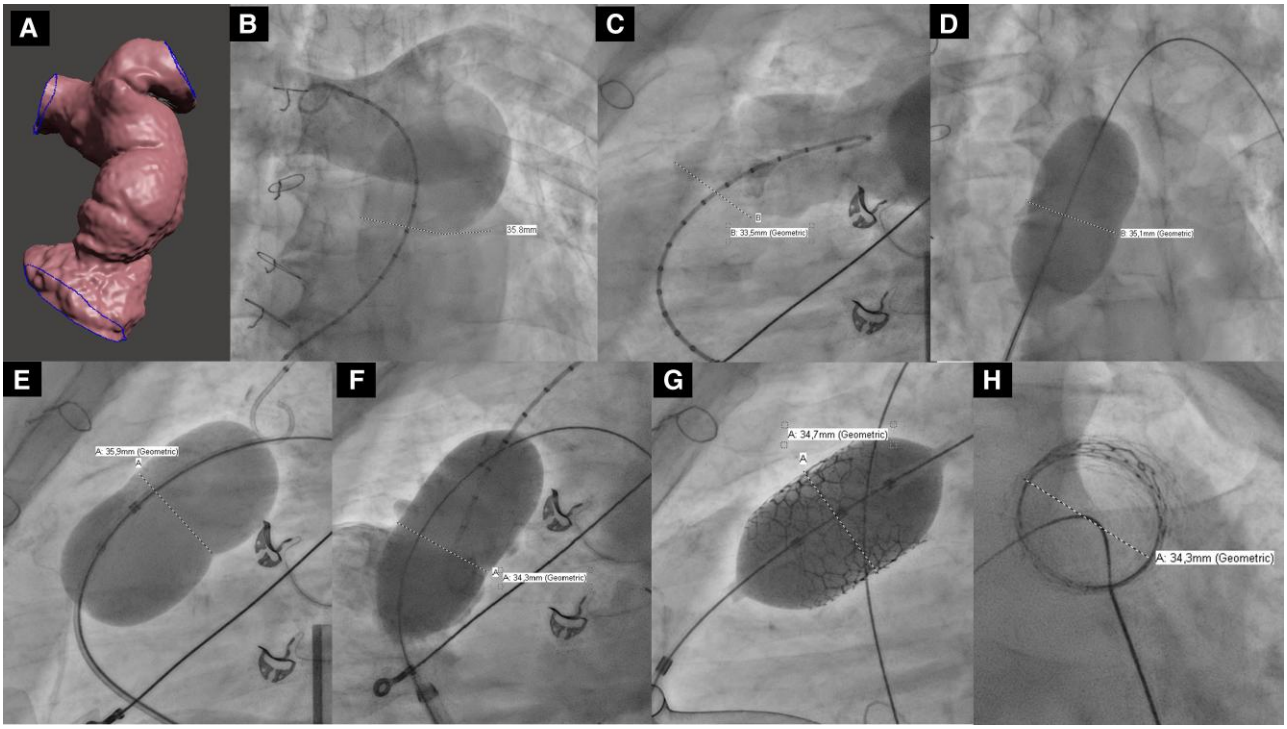


Figure 1 (*A*) Three-dimensional model created by computed tomography scan reconstruction demonstrated a large infundibulum and a tortuous right ventricle outflow tract. The sole restriction zone was located at the level of the pulmonary annulus. (*B* and *C*) The angiogram in the left anterior oblique cranial and lateral views confirmed the presence of a large and tortuous right ventricle outflow tract measured at a maximum size of 35 × 33 mm. (*D* and *E*) Right ventricle outflow tract calibration with a 34 mm Amplatzer sizing balloon showed a short restriction measured at 35 × 36 mm. (*F*) The angiogram of the right ventricle with the 35 mm Cristal balloon inflated in the right ventricle outflow tract illustrated an almost full occlusion of the right ventricle. (*G*) The valve diameter inside the pre-stenting at the end of the inflation of the balloon was 34.3 mm. (*H*) A caudal view of the valve, which had a circular shape measured at 34.3 mm. RVOT, right ventricle outflow tract.

positioned in the landing zone and it remained stable. The patient was discharged 3 days later. Percutaneous pulmonary valve implantation was done 2 months later to ensure better stent stability. A 26 Fr DrySeal sheath (Gore, USA) was used to advance the 32 mm Myval valve mounted on the navigator delivery system to the landing zone. It was inflated with 48 cc (nominal volume + 8 cc) to obtain a final diameter of 34.3 mm (*Figure 1H*). The post-operative course was uneventful. The patient was discharged 3 days later after his usual treatment with aspirin 75 mg/day, which was added for 3 months.

One month later, ICD with resynchronization function was implanted. Three months later, a significant improvement in the NYHA status from Stage III to Stage II was observed. Echocardiography demonstrated the absence of residual pulmonary valve stenosis or leak (see Supplementary material online) and LV function improvement with EF at 45%. NTBNP dropped to 652 ng/L.

Discussion

Pulmonary regurgitation after Fallot repair could induce long-term biventricular dysfunction and heart failure.[6] Right ventricle outflow tract dysfunction management is challenging in patients with such condition because of the altered clinical status. Therefore, PPVI is preferred.[6]

Right ventricle outflow tract assessment before PPVI is usually done with MRI to measure biventricular volume and function and the extent of fibrosis and pulmonary regurgitation fraction.[7] Computed tomography scan is preferred for measuring the RVOT, but with some restrictions such as the lack of distensibility assessment and irradiation. Four-dimensional flow MRI seems to be more effective at measuring the RVOT during the whole cardiac cycle with good spatial resolution.[8] Three-dimensional reconstruction and printing could be useful for obtaining more precision on RVOT morphology and to simulate the interventions.[9]

First, PPVI cases were handled by using the Melody valve with a maximum inner diameter of 22 mm, which could be implanted in an RVOT that measured up to 24 mm. Then, Sapien valves with a maximum external diameter of 29 mm (Edwards, USA) were used to repair a larger RVOT that measured 30 mm.[1,2,10]. Other techniques such as Side-by-Side and Russian dolls were used but with contrasting results.[11] Recent reports described the use of an auto-expandable valve to repair a large RVOT that measured 34 mm.[12] Nevertheless, an RVOT with a complex shape with aneurysmal dilatation or with a pyramidal shape could not be treated with these valves because of the risk of distortion of the auto-expandable stent.[12] The design of the Myval valve is quite similar to that of the Sapien 3 valve (Edwards, USA). Briefly, it is characterized by a nickel–cobalt alloy frame. The valve material is a decellularized bovine pericardium tissue fixed on the metal frame after anti-calcification treatment. The lower part of the valve frame is covered externally with a protective sealing cuff to avoid paravalvular leak.[13] The main advantage of the Myval valve is that it is a 32 mm valve that could be dilated up to 35 mm.[5] The valve implantation is further facilitated by a low profile of the delivery system, and the valve is

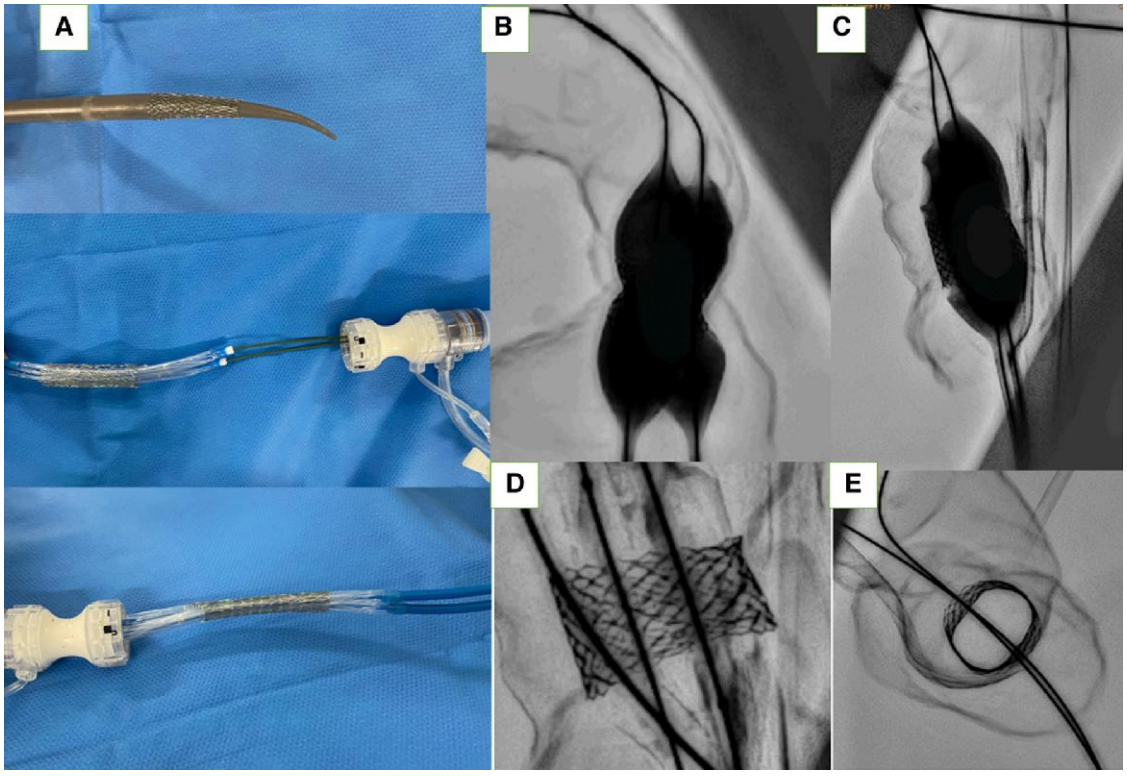


Figure 2 Demonstration of the double-balloon technique applied on a 3D printed model in the catheterization lab. (*A*) Dilatation of the stent with an introducer of 26 Fr. DrySeal sheath before crimping on the two 26 mm balloons. Then, the two balloons were easily inserted in the DrySeal sheath. (*B*) Inflation of the stent in the frontal incidence. The stent inflation was homogenous, and the two balloons are placed side by side. (*C*) Lateral view incidence at the end of the balloon inflation. There was a superposition of the two balloons. Balloon disposition was influenced by the pulmonary annular shape, giving an oval shape to the stent. (*D*) Stent shape as seen in frontal view. (*E*) Stent oval shape as seen in caudal view.

crimped directly on the balloon equipped with two stoppers.[5] Therefore, when surgery is not possible, the 32 mm Myval valve seems to be the only therapeutic option in a complex RVOT larger than 30 mm.

However, this technique remains challenging because of the lack of adapted materials. The absence of a BIB balloon (Numed, USA) larger than 30 mm makes pre-stenting difficult. As a result, a 35 mm simple balloon was used in this case with a non-homogenous inflation. Distal part inflation induced a forward shift of the balloon, which was devoid of any consequences, thanks to the use of a long stent and probably the rapid pacing technique (see Supplementary material online). The double-balloon technique could be another option with the formula [$2\pi r$ (r = required diameter) = $2\pi r' + 4r'$ (r' = balloon diameter)]. Another advantage of this later technique is the elliptical shape of the stent at the end of the inflation, which is more adaptable with the oval shape of the pulmonary annulus (*Figure 2* and see Supplementary material online).

Good short-term results with Myval valves for PPVI have been described.[13] Despite the similarity with the Sapien valves, long-term results could not be predicted, mainly in the case of valve over-expansion. The first reports of PPVI with this valve were published in 2021 and the first series were published in 2022. Therefore, more studies are necessary for determining the long-term evolution of the Sapien valve. Finally, long stent implantation with a possible partial infundibular position could induce supplementary arrhythmia risk. An electrophysiologic study is usually indicated in patients deemed to be at high risk for ventricular arrhythmia.[6] Otherwise, ICD implantation is recommended in very high-risk patients mainly in the case of severe LV dysfunction.[6] Therefore, an electrophysiologic study should be considered in all patients before Myval implantation, except in those with a systematic indication of ICD.

Conclusion

New imaging techniques are beneficial to plan PPVI and to choose a suitable valve. The 32 mm Myval offers great scope for exploring the possibilities of PPVI. More studies are necessary before routine deployment.

Lead author biography

Dr Houeijeh is an MD, PhD consultant and pediatric interventional cardiologist in Lille University Hospital. The main field of interest is cardiac catheterization and neonatal pulmonary hypertension.

Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports*.

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Data availability

The data underlying this article are available in the article and in its online supplementary material.

References

1. Houeijeh A, Batteux C, Karsenty C, Ramdane N, Lecerf F, Valdeolmillos E, *et al.* Long-term outcomes of transcatheter pulmonary valve implantation with melody and SAPIEN valves. *Int J Cardiol* 2023;**370**:156–166.
2. McElhinney DB, Zhang Y, Levi DS, Georgiev S, Biernacka EK, Goldstein BH, *et al.* Reintervention and survival after transcatheter pulmonary valve replacement. *J Am Coll Cardiol* 2022;**79**:18–32.
3. Le Ruz R, Plessis J, Houeijeh A, Baruteau AE, Le Gloan L, Warin Fresse K, *et al.* Edwards SAPIEN XT transcatheter pulmonary valve implantation: 5-year follow-up in a French Registry. *Catheter Cardiovasc Interv* 2021;**98**:990–999.
4. Morgan GJ, Sivakumar K, Promphan W, Goreczny S, Prachasilchai P, Qureshi S. Early clinical experience with the straight design of Venus P-valve™ in dysfunctional right ventricular outflow tracts. *Catheter Cardiovasc Interv* 2020;**96**:E653–E659.
5. Rodríguez Ogando A, Ballesteros F, Martínez JLZ. Pulmonary percutaneous valve implantation in large native right ventricular outflow tract with 32 mm Myval transcatheter heart valve. *Catheter Cardiovasc Interv* 2022;**99**:E38–E42.
6. Baumgartner H, De Backer J, Babu-Narayan SV, Budts W, Chessa M, Diller GP, *et al.* 2020 ESC guidelines for the management of adult congenital heart disease. *Eur Heart J* 2021;**42**:563–645.
7. Sakrana AA, Al-Zubaidi SA, Nasr MM, Al Ghamdi SS, Tahlawi ME. Cardiac magnetic resonance indices reflecting pulmonary regurgitation burden after tetralogy of Fallot repair. *Clin Radiol* 2017;**72**:900.e9–900.e15.
8. Elsayed A, Gilbert K, Scadeng M, Cowan B, Pushparajah K, Young A. Four-dimensional flow cardiovascular magnetic resonance in tetralogy of Fallot: a systematic review. *J Cardiovasc Magn Reson* 2021;**23**:59.
9. Houeijeh A, Petit J, Isorni MA, Sigal-Cinqualbre A, Batteux C, Karsenty C, *et al.* 3D modeling and printing in large native right ventricle outflow tract to plan complex percutaneous pulmonary valve implantation. *Int J Cardiol Congenit Heart Dis* 2021;**4**:100161.
10. Shahanavaz S, Zahn EM, Levi DS, Aboulhousn JA, Hascoet S, Qureshi AM, *et al.* Transcatheter pulmonary valve replacement with the sapien prosthesis. *J Am Coll Cardiol* 2020;**76**:2847–2858.
11. Jalal Z, Malekzadeh-Milani S, Hofbeck M, Al Najashi K, Thambo JB, Boudjemline Y. A new percutaneous pulmonary valve implantation technique for complex right ventricular outflow tracts: the "folded melody valve". *Catheter Cardiovasc Interv* 2015;**85**:604–610.
12. Morgan G, Prachasilchai P, Promphan W, Rosenthal E, Sivakumar K, Kappanayil M, *et al.* Medium-term results of percutaneous pulmonary valve implantation using the Venus P-valve: international experience. *EuroIntervention* 2019;**14**:1363–1370.
13. Odemis E, Yenidogan I. First experiences with Myval Transcatheter Heart Valve System in the treatment of severe pulmonary regurgitation in native right ventricular outflow tract and conduit dysfunction. *Cardiol Young* 2022;**32**:1609–1615.