Cardiology in the Young

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Mini-invasive surgical approach for hybrid pulmonary valve implantation: an option for very high-risk patients

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Brief Report

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Abstract

Transcatheter pulmonary valve replacement is the first choice to treat residual or recurrent right ventricular outflow tract dysfunction. Surgery is an effective option when anatomy is not permissive for transcatheter procedures. When surgical risk is too high, hybrid procedures might be considered.

In this paper, we describe the first use of Harmony valve in Europe in a 59 years old patient with a huge right ventricular outflow tract. The procedure was performed by a hybrid approach: before valve deployment, through an anterior mini-thoracotomy, the pulmonary artery was plicated to create a landing zone. The valve was deployed by trans-femoral venous approach. It was secured by putting a suture on the distal stent raw under fluoroscopic guidance. The procedure was uneventful and patient's New York Heart Association class rapidly improved from III–IV to II.

In conclusion, hybrid strategies might represent an acceptable option for huge right ventricular outflow tract, to be less invasive and to minimise device embolisation risks. When a good match between patient's anatomy and device can be achieved, a mini-invasive or micro-invasive surgical approach might be considered to minimise bleeding risks and shorten the hospital's length of stay.

Transcatheter pulmonary valve replacement is currently the primary treatment option for residual right ventricular outflow tract dysfunction.[1] The first procedure in humans was described by Bonhoeffer et al. in 2000.[2] Over the past two decades, various devices have been developed for transcatheter pulmonary valve replacement, including balloon-expandable and self-expandable valves.[3] Balloon-expandable devices are typically used for narrower or stenotic right ventricular outflow tract, while self-expandable valves are favoured for wider and native right ventricular outflow tracts. However, transcatheter pulmonary valve replacement is often not recommended for cases with exceedingly large right ventricular outflow tracts. For this reason, it is usually recommended to opt for a surgical approach.[1] Therefore, a custom-made hybrid approach might be a viable alternative for managing pulmonary valve regurgitation in patients with a significantly dilated right ventricular outflow tract.

This article introduces a novel hybrid strategy for the management of pulmonary valve regurgitation in patients with a large right ventricular outflow tract.

A 59-year-old male patient was referred to our Center for Severe Heart Failure in Congenital Heart Disease. He had a history of surgical intervention at age six for pulmonary valve stenosis and an atrial septal defect, including surgical valvectomy, right ventricular outflow tract enlargement with a patch, and atrial septal defect closure with a patch.

The patient was initially managed outside of adult CHD centres. Over time, he developed severe pulmonary valve regurgitation, severe right ventricular dilatation, severe tricuspid valve regurgitation, and permanent atrial fibrillation. He was only referred to our centre after developing severe liver cirrhosis, portal hypertension, splenomegaly, severe thrombocytopenia, ascites, chronic right pleural effusion, and mild chronic renal failure, necessitating surgical treatment for pulmonary valve regurgitation and tricuspid valve regurgitation.

A comprehensive non-invasive imaging evaluation and a multidisciplinary discussion with the Adult Congenital Heart Team revealed that the right ventricular outflow tract was too large for available devices in the European Union (right ventricular outflow tract measurements: minimum diameter 40 mm, distal pulmonary trunk diameter 44 mm, annular diameter 52 mm) (Figure 1a). In particular, the procedure was judged not feasible with Venus p Valve (Venus Medtech, Shangai, China) because of a waist > 36 mm. On November 2023, a transcatheter pulmonary valve replacement with Alterra Adaptive Pre-stent (Edwards Lifesciences, Irvine,

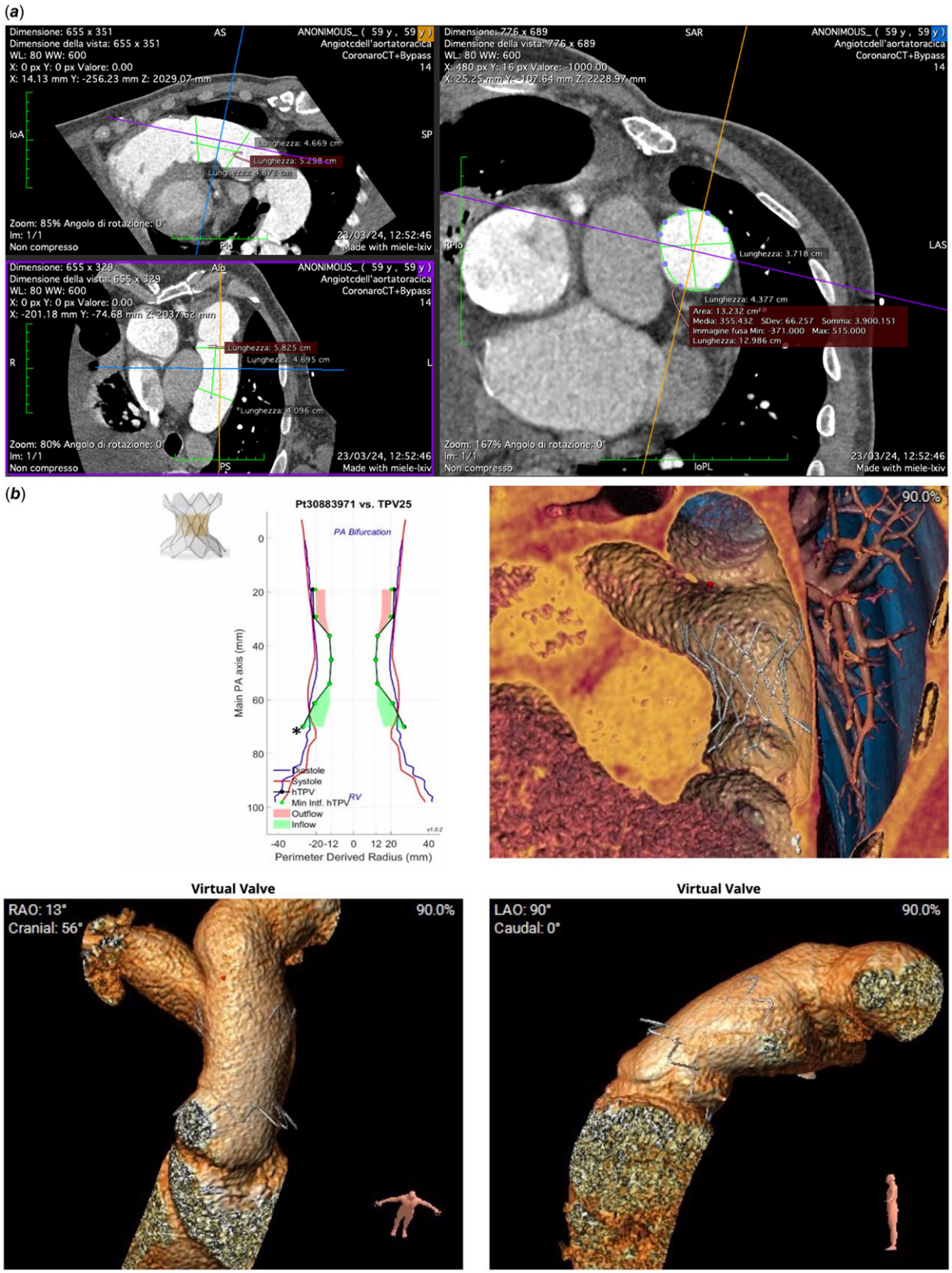

Figure 1. Pre-procedural non-invasive assessment based on Electrocardiogram gated CT scan. Images referred to 30% systolic phase. In Figure 1b, diastolic perimeters are referred to diastolic 90% phase. (***a***) Right ventricular outflow tract study by CT scan. The proximal main pulmonary artery (MPA) diameter was 48x52 mm, the distal diameter was 42x46 mm. MPA length was 55 mm. The minimum MPA area was 13.23 cm^2 (ideal diameter 41 mm). (***b***) Virtual rendering based on CT scan data for Harmony TPV 25 mm placement. The images show a potential anchoring on the proximal edge of the Harmony 25 TPV.

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California) was aborted after right ventricular outflow tract balloon interrogation for a too large right ventricular outflow tract. The surgical risk for a combined pulmonary valve regurgitation and tricuspid valve regurgitation treatment was deemed too high due to significant bleeding risks. Consequently, a custom-made hybrid approach was proposed. According to right ventricular outflow tract sizes and morphology, Harmony TPV 25 mm seemed to be the best possible fit for the patient's anatomy. Compassionate use was obtained for this case from the Ethical Committee and from the Italian Ministry of Health. However, the risk of device instability after the release was still judged to be too high by United States of America clinical experts involved in the case management (Figure 1b). Thus, a hybrid approach was proposed: to plicate the main pulmonary artery from a mini-thoracotomy approach and to secure the valve with a suture on the distal rows of the Harmony valve once deployed from a standard femoral venous access.

The procedure was performed under general anaesthesia and orotracheal intubation in the hybrid operating room of Padua University Hospital. An 18 Fr drainage tube was placed to drain the right pleural effusion. The right femoral vein was cannulated to deploy the valve, and the left femoral artery and vein were cannulated as backup accesses in case of an emergent need for Extra-Corporeal Membrane Oxygenator support. To access the main pulmonary artery, a 3 cm left anterior mini-thoracotomy was made in the second intercostal space based on CT scan results (Figure 2). Once the anterior wall was visualised, surgeons proceeded with pulmonary artery plication by using 3–0 Prolene sutures mounted on pledgets to create a safe landing zone for the valve. The procedure was performed in steps: a Lunderquist guidewire was placed distally in the left lung, and a 30 mm PTS-X balloon was used to simulate the valve stability. Main pulmonary artery plication was repeated three times to tighten progressively the wall in three layers to decrease the calliper. A radio-opaque marker was placed on the distal pledget to mark the plication site. Despite all this, the PTS-X balloon continued to be unstable in main pulmonary artery. Given the increasing tension on the sutures, we decided to proceed with the valve deployment, securing the distal row with a suture. The 25 mm Harmony TPV valve was advanced in a 26 Fr Dryseal, easily placed in right ventricular outflow tract. Once we obtained the desired position, the valve was deployed by accommodating the two central rows on the plicated tract. The valve was fully deployed but still secured to the delivery cable. Under fluoroscopic guidance, a 3–0 Prolene suture was placed on the distal root of the Harmony valve (Figure 3). Once stabilised, the valve was completely unscrewed from the delivery cable. Fluoroscopies and angiographies demonstrated the stability of the valve. A mild paravalvular leak was detected by trans-esophageal echo. In addition, an immediate improvement in tricuspid valve regurgitation was noted. The patient was extubated in the operating room. The drainage tubes were removed five days after the procedure. He was discharged 15 days after the procedure. The right atrial pressure decreased from 15 mmHg to 3 mmHg, and the ascites and right pleural effusion were completely resolved. A 3 cm left pleural serum-hematic effusion was still present at discharge.

At one month follow-up, the patient's symptoms deeply improved; the New York Heart Association class dropped to II; the body weight was 19 kg below the admission. No symptoms were

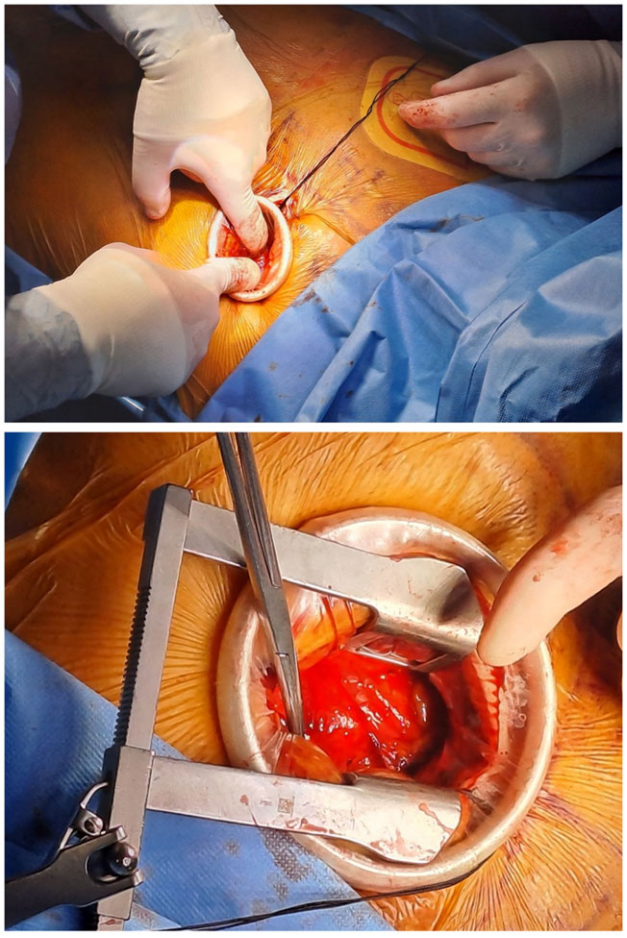

Figure 2. Anterior mini-thoracotomic access through the third intercostal space. From that access, pulmonary artery was easily approached.

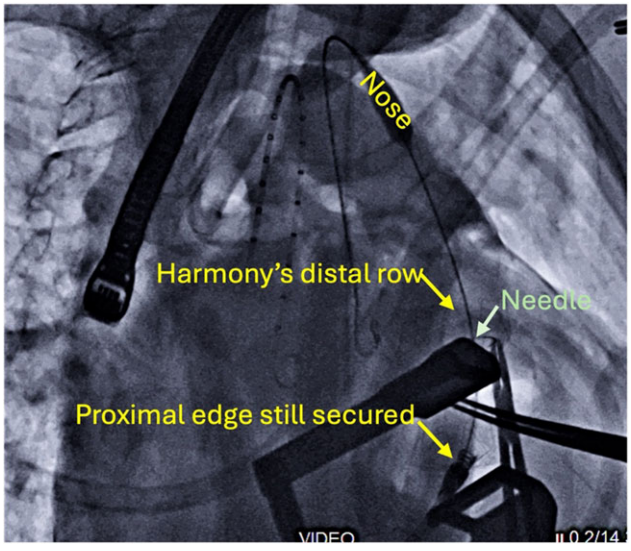

Figure 3. Device securing by placing a stich on the distal edge of Harmony valve. During the manoeuvre the valve was still attached to the delivery cable. (See also Supplemental video 1).

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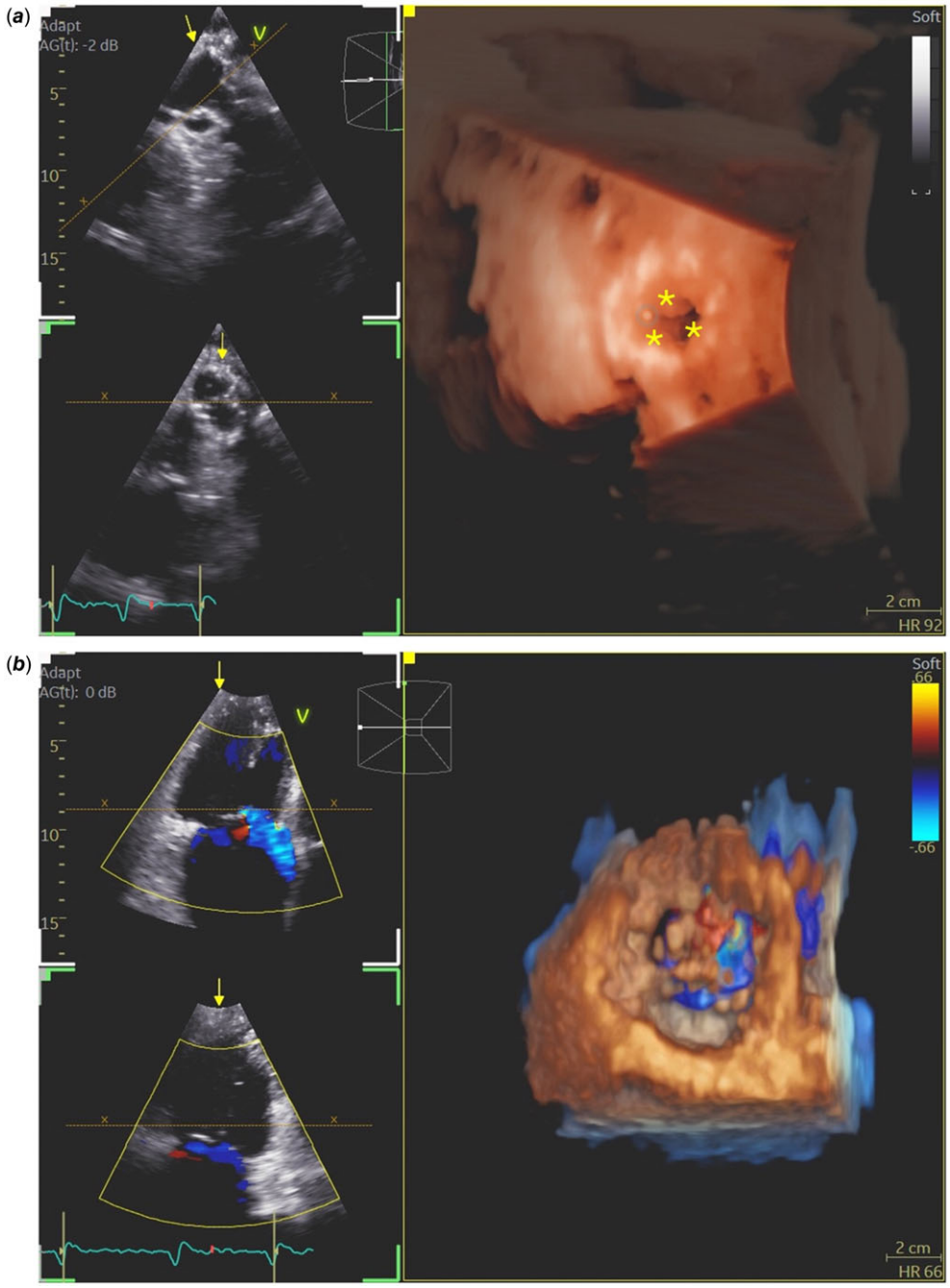

Figure 4. Trans-thoracic echo one month after the procedure. On the left, x-plane view; on the right, 3D view. (***a***) Harmony valve viewed from the right ventricle (yellow arrows), in systolic phase. The three cusps are well seen (*). (***b***) tricuspid valve regurgitation seen from ventricular view, systolic frame. There is a ++/4 tricuspid valve regurgitation, on the septal leaflet.

reported. A trans-thoracic echo demonstrated a minor paravalvular leak and significant right ventricle unloading. Ejection fraction by 3D was moderately depressed (40%), tricuspid valve regurgitation improved to mild-to-moderate, and the inferior vena cava was still dilated but collapsing during inspiration (Figure 4).

In 2021, the Food and Drug Administration approved the Harmony TPV as the first nonsurgical valve for a native right ventricular outflow tract, available in 22 mm and 25 mm sizes. That diameter is referred to as the porcine valve annulus. These valves have six rows of self-expandable Nitinol stents, with lengths of 55 mm and 51 mm, respectively, and varying diameters (32 mm distally and 41 mm proximally for the smaller size, 44 mm distally and 54 mm proximally for the larger size). Recently, Gillespie et al[5] reported the 1-year outcome in patients enrolled in the "Native Outflow Tract Early Feasibility Study," demonstrating a favourable clinical and haemodynamic outcome across studies and valve types.[5] Harmony Valve will be commercialized in Europe by January 2025. Thus, this is the first use of Harmony TPV valve in Europe.

Hybrid techniques have recently been proposed for challenging anatomies and high-risk situations,[6] aiming to avoid cardiopulmonary bypass. Median sternotomy is the most secure method for accessing the main pulmonary artery, though left thoracotomy offers a safer approach in terms of bleeding risk, albeit with challenges in surgical manoeuvrability and bleeding management. Sometimes, like in this case, reopening the chest may be hampered by bleeding or potentially fatal vascular lesions.[7–8] Performing a left thoracotomy may offer a higher level of safety in terms of reducing the risk of bleeding. However, it is important to note that this

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approach may also present challenges in terms of performing surgical manoeuvres and managing sudden bleeding.

Our experience underscores the importance of pre-procedural assessments that consider the entire device rather than just the valve. Device stability and the mitigation of paravalvular leaks rely significantly on the edges of the stent, not just the valve itself. In some devices, the distal row is bare (Sapien Valve, Venus *p* Valve, Pulsta Valve), while the stent might be fully covered in others (Melody Valve, Harmony TPV Valve).[3] In this patient, fit analysis (Figure 1b) demonstrated comprehensive coverage of the right ventricular outflow tract by the distal and proximal edges of the fully covered stent. Securing the distal device edge with a suture allowed for acceptance of larger main pulmonary artery diameters while minimising the risk of valve embolisation. The tiny surgical view significantly limited the possibility of further tightening main pulmonary artery because the amount of visible main pulmonary artery wall surface was limited. In this setting, a valve very similar to the patient's anatomy simplified the surgical step and the whole procedure.

The optimal timing for pulmonary valve regurgitation is still debated. In the literature, the largest amount of data refers to the tetralogy of Fallot patients, despite potential candidates for transcatheter pulmonary valve replacement can show large anatomical variability. The portfolio of devices for transcatheter pulmonary valve replacement, prosthetic surgical valves and conduits, surgical techniques, and hybrid approaches is continuously growing. However, in the real world, the percentage of late patients's referrals is still too high.[9] In our case, the patient was managed conservatively up to an end-stage clinical. This should be strongly discouraged because it will worsen the quality of life of these relatively young patients and exponentially increase the interventional or surgical risk when correction is undelayable.

Overall, hybrid transcatheter pulmonary valve replacement may be an attractive option for large right ventricular outflow tract in patients at high risk, as it is a less invasive procedure and reduces the chances of device embolisation. If there is a suitable match between the patient's anatomy and the device, it may be possible to choose a mini-invasive or micro-invasive surgical method. This can help reduce the chances of bleeding and shorten the patient's hospital stay.

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Ethical standard. Local Ethical Committee approved the procedure, the patient approved anonymous data dissemination.

Disclosure. Nothing to declare.

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