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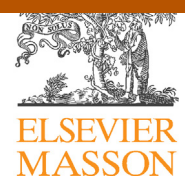

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CLINICAL RESEARCH

Results of transcatheter pulmonary valvulation in native or patched right ventricular outflow tracts

Résultats de la valvulation pulmonaire des voies d'éjection droite natives ou patchés

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KEYWORDS
Melody valve;
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Tetralogy of Fallot

Summary

Background. — Although widely accepted worldwide, indications for percutaneous valve replacement are limited to treatment of dysfunction of prosthetic conduits inserted in the right ventricular outflow tract (RVOT). There has been little evaluation of the use of the Melody® valve for patched non-circular pulmonary pathways.

Aim. — To evaluate the outcomes of Melody valve insertion in patients with a patched non-circular RVOT.

Methods. — We analysed procedural and outcomes data from 34 patients who underwent Melody valve implantation for a non-circular RVOT. RVOT preparation was done in all patients, using different techniques (conventional, Russian doll and/or PA jailing). Melody valve insertion was performed concomitantly in most patients.

Results. — All procedures were successful. Sixteen patients had complex additional procedures, including the jailing technique ($n = 5$), the Russian doll technique ($n = 6$) and multiple

Abbreviations: CI, confidence interval; PA, pulmonary artery; PPVI, percutaneous pulmonary valve implantation; RV, right ventricle; RVOT, right ventricular outflow tract.

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stent implantations (Russian jailing; $n = 5$). The remaining patients were treated using the conventional technique with systematic prestenting. Three early complications occurred: one haemoptysis; one residual RVOT obstruction needing recatheterization 48 hours after percutaneous pulmonary valve implantation; and one stent embolization during advancement of the Ensemble® delivery system. The mean follow-up period was 2.6 years postprocedure. There was no stent fracture, migration or embolization. Two patients developed a significant paraprosthetic leak and one received a second Melody valve.
Conclusions. — Careful patient selection, balloon sizing and RVOT preparation with prestenting are required to create a safe landing zone for the Melody valve. Short-term follow-up shows excellent results with no stent fracture or migration and appears promising.

MOTS CLÉS
Remplacement valvulaire pulmonaire percutané ;
Cardiopathies congénitales ;
Tétralogie de Fallot ;
Melody

Résumé
Contexte. — Bien que largement acceptées dans le monde, les indications de valvulation percutanée sont limitées au traitement des dysfonctionnements de conduits prothétiques de la voie d'éjection droite (VD-AP). L'utilisation de la valve Melody (Medtronic Inc., Minneapolis, Minnesota, États-Unis) a été peu évaluée pour les voies pulmonaires patchées non circonférentielles.
But. — Nous avons évalué le devenir de l'implantation de Melody chez des patients avec une voie VD-AP patchée non circonférentielle.
Méthodes. — Nous avons analysé les données de procédure et le devenir de 34 patients ayant reçu une valve Melody. La voie VD-AP a été préparée chez tous les patients avant la valvulation par un prestenting en utilisant quatre techniques (la technique conventionnelle, la technique des poupées russes et la technique d'emprisonnement d'une AP associée ou non à la précédente). La valvulation a été simultanée chez la grand emajorité des patients.
Résultats. — Toutes les procédures ont été réalisées avec succès. Tous ont été prestenté avant la valvulation. Dix-huit ont été traité de manière conventionnelle. Cinq ont eu une technique d'emprisonnement, 6 celle des poupées russes et 5 une technique combinée. Trois complications précoces sont survenues : une hémoptysie spontanément résolutive; un obstacle résiduel qui a nécessité un nouveau cathétérisme 48 heures après la Melody; et une embolisation précoce de stent. Le suivi moyen après la procédure était de 2,6 ans. Aucun patient n'a eu de fracture de stent, de migration ou d'embolisation de stents. Deux patients ont eu une fuite paraprothétique dont un a nécessité la pose d'une deuxième Melody.
Conclusions. — Une sélection soigneuse des patients, une calibration au ballonet et une préparation de la voie VD-AP avec prestenting utilisant une technique classique, la technique des poupées russes ou d'emprisonnement sont nécessaires pour créer une zone d'accrochage pour insérer la valve Melody aux patients ayant des voies VD-AP patchées. À court terme, les résultats sont encourageants et prometteurs sans fracture de stent ni embolisation.

Background

Percutaneous pulmonary valve replacement using the transcatheter technique is now accepted and practiced worldwide for dysfunctional right ventricular outflow tracts (RVOTs) [1,2]. The Melody® valve (Melody transcatheter pulmonary valve; Medtronic Inc., Minneapolis, MN, USA) is available in a single diameter of 18 mm, dilatable up to 22 mm. Currently, indications are limited to dysfunctional RVOT circumferential conduits with a diameter $\leq$ 22 mm [2]. Until recently, patched or native non-circular RVOTs were considered a relative contraindication to transcatheter valvulation, but off-label uses of the valve in patched or large outflow tracts are increasingly reported in the literature [3—6]. The majority of patients requiring valvulation do not have a circular conduit. Indeed, a large number of patients have a patched native outflow tract after tetralogy of Fallot repair with the transannular patch technique. Some patients with operated tetralogy of Fallot or other operated congenital heart diseases have right ventricle (RV) to pulmonary artery (PA) conduits that have been enlarged with a patch during reintervention for stenosis. The issues with percutaneous treatment of native outflow tract or non-circular outflow tract are the size of the outflow tract, the absence of a landing zone and the non-circular shape of the outflow tract. We sought to review our experience with non-circular RVOTs, describing technical issues related to this specific type of anatomy and to study the outcome of percutaneous pulmonary valve implantation (PPVI) in a larger population.

Methods

All patients who had received a Melody valve in our centre since 2009 were reviewed and included in this study. Patients who had received a Melody valve in a non-circular outflow tract (defined as patients with no conduit, heterografts or homografts) were identified in the cohort. Data were extracted from the database and reviewed for this paper.

All patients had a preimplantation evaluation, including clinical examination, echocardiography and cardiac magnetic resonance imaging (MRI) or cardiac computed tomography in case of contraindication to magnetic resonance imaging. All procedures were performed under general anaesthesia. Informed consent approved by an ethical committee was obtained from each patient and/or their parents. Informed consent specified that patients were eligible for Melody valve implantation if a proper landing zone was present, either because of the existence of a circular conduit/homograft/heterograft or because of a calibrated patched RVOT. In the context of native tissue, the informed consent clearly specified that the patient needed a stent prior to Melody valve insertion to create a landing zone.

Cardiac catheterization was performed via percutaneous puncture of the femoral or jugular vein. The femoral artery was also accessed percutaneously for a coronary angiogram, to rule out any potential compression on the coronary arteries.

The haemodynamics and anatomy of the outflow tract and pulmonary arteries were assessed carefully. Dimensions of the RVOT were measured in at least two planes (lateral view and craniocaudal view). In cases with stenosis, assessment of the outflow tract was done using the conventional technique, using a high-pressure balloon (Atlas® balloon; Bard Medical, Covington, GA, USA). In cases with regurgitation alone, balloon calibration was done with a low-pressure compliant balloon (Tyshak® or PTS®; NuMED Inc., Hopkinton, NY, USA). The position of the coronary arteries was screened using coronary and/or aortic angiograms during RVOT balloon inflation.

Prestenting was done using available stents (ev3 Max™ LD, ev3 Endovascular Inc., Plymouth, MN, USA; CP Stent™, NuMED, Inc., Hopkinton, NY, USA). Patients were considered suitable for Melody valve placement if an appropriate landing zone could be created or existed. Patients with pure pulmonary regurgitation and RVOT/PA > 26 mm in diameter were considered for surgical valvulation. Different techniques were used to make implantation possible in case of large RVOT. These techniques have been reported in detail previously. Briefly, the Russian doll technique consisted of reducing the RVOT diameter by overlapping multiple stents (usually covered). The jailing technique consisted of using a PA branch to construct a safe landing zone in the RVOT. A first open-cell stent was positioned in the proximal left or right PA over a 22 mm balloon. A second stent was implanted using a 22 mm balloon inside the first one with an overlap of around 50% directed to the RVOT. The Melody valve (Model PB10) was then inserted as low as possible and well below the main PA bifurcation inside the stent of known diameter, using a 22 mm Ensemble® transcatheter valve delivery system (NU10; NuMED Inc., Hopkinton, NY, USA). Postdilatation of the Melody valve using a balloon of appropriate diameter (22 or 24 mm) was done to reduce the amount of paraprosthetic leak. If the RVOT was very large, thick stents (typically covered stents) were placed inside the bare-metal stent prior to Melody valve implantation. The last technique combined the Russian doll and jailing techniques ('Russian jailing'). For a large RVOT and a large PA, the method of choice was the Russian doll technique. For a large RVOT with favourable PA dimensions, the jailing technique was preferred. A combination of the two was preferred in patients with a very large RVOT and favourable PA dimensions. Patients with adequate size were treated according to the conventional technique.

Haemodynamic and angiographic assessments were repeated after PPVI in all patients. All patients received heparin and antibioprophylaxis during and after the procedure according to the institutional protocol and were discharged on lifelong aspirin.

Patients were scheduled at the outpatient clinic 1, 3, 6, 12 and 24 months after PPVI, with a detailed clinical examination, transthoracic echocardiography and chest X-ray at 6, 12 and 24 months. Cine angiography was only considered in patients with suspected stent fracture, pulmonary regurgitation, increased RVOT and signs of embolism.

Results

Thirty-four patients were identified as having a non-circular conduit in our database, representing 20% of the total population.

Demographics

Mean age at implantation was 26 ± 10 years (Table 1). Overall, 58.9% of the patients had tetralogy of Fallot or pulmonary atresia with ventricular septal defect ($n = 20/34$; 95% confidence interval [CI] 40.7—75.4%); 67.6% patients had native patched RVOTs ($n = 23/34$, 95% CI 51.9—83.4%); and 32.3% had patched RVOT conduits ($n = 11/34$, 95% CI 16.6—48.1%). Typically, the posterior wall of the conduits was preserved and enlarged anteriorly with a patch. No patient had a surgical valve. Four patients were known to have only one functional PA (11.7%, 95% CI 0.9—22.6%).

Procedural data

The procedures were straightforward, with a mean duration of 91 ± 37 minutes (Table 2). Prestenting was done in all patients: 30 patients had a bare-metal stent insertion at the time of PPVI and four had a stent previously implanted (two-stage procedure). Sixteen patients (47.1%, 95% CI 29.8—64.9%) had complex additional procedures because of pure pulmonary regurgitation and because the RVOT was > 24 mm. Additional procedures included the jailing technique ($n = 5$), the Russian doll technique ($n = 6$) and multiple stent implantations (Russian jailing, $n = 5$). The Russian jailing technique became, with time, our preferred technique in patients with large RVOTs. The remaining patients ($n = 18$, 52.9%, 95% CI 36.2—69.7%) had stenotic lesions and were treated using the conventional technique with systematic prestenting.

Three early complications occurred, giving an incidence of 8.8% (95% CI 1.9—23.3%). One patient had a

Table 1 Demographic data ($n = 34$).

Congenital heart disease[a]	20 (58.9; 40.7—75.4)
TOF-pulmonary atresia + VSD	6 (17.65; 4.84—30.46)
TGA-VSD-PS	2 (5.88; 0—13.79)
Aortic stenosis	2 (5.88; 0—13.79)
Other	4 (11.76; 0.9—22.6)
Type of RVOT[a]	
Patched conduit	11 (32.3; 16.6—48.1)
Native patched RVOT	23 (67.6; 51.9—83.4)
Men/women (*n*/*n*)	16/18
Mean number (range) of surgeries	2 (1—4)
Additional lesions[a]	
One patent PA	4 (11.7; 0.9—22.6)
Mean interval ± SD between surgery and PPVI (years)	18 ± 9

PA: pulmonary artery; PPVI: percutaneous pulmonary valve implantation; PS: pulmonary stenosis; RVOT: right ventricular outflow tract; SD: standard deviation; TOF: tetralogy of Fallot; TGA: transposition of the great arteries; VSD: ventricular septal defect.
[a] Data are number (%; 95% confidence interval).

haemoptysis (presumably due to PA trauma with the wire) that resolved spontaneously. One jailing technique patient needed recatheterization 48 hours after the initial procedure because of residual RVOT obstruction. The jailed right PA was largely patent but the blood flow was directed toward the hypoplastic left PA. The stent jailing the right PA was crossed and the stent struts were dilated. As a result, systolic RV and PA pressures dropped to 40 mmHg immediately after the procedure. One Russian doll technique patient had a secondary dislodgement; the stent moved from its position during advancement of the Ensemble delivery system. The stent was secured using two additional overlapping bare-metal stents and we proceeded with the Melody valve insertion successfully.

Table 2 Procedural data.

Length of procedure (minutes)	91 ± 37
Postprocedure RV to PA gradient (mmHg)	9 ± 6
Prestenting	34
Additional procedure	
Jailing	5
Russian doll	6
Combined (Russian jailing)	5
Conventional procedure	18
Complications	
RVOT obstruction (jailing group)	1 (opening of the stent strut of the jailed PA)
Haemoptysis	1 (resolved spontaneously)
Embolization of stent (Russian doll group)	1 (secured with two stents followed by Melody valve)

Data are mean ± standard deviation or number. PA: pulmonary artery; RV: right ventricle; RVOT: right ventricular outflow tract.

Table 3 Follow-up data.

Median (range) duration of follow-up (months)	31 (21—41)
Valve function on last echocardiogram[a]	
No significant regurgitation	32 (94.1; 80.3—99.2)
Significant regurgitation	2 cases of paravalvular regurgitation (5.9; 0—13.8)
Additional procedures (*n*)	
Valve in valve procedure (Melody in Melody)	1
Death	0
Stent fracture	0
Stent embolization	0
Endocarditis	0

[a] Data are number (%; 95% confidence interval).

Postprocedural evolution

After a mean follow-up of 2.6 years, no stent migration occurred (Table 3). No embolization was found. No stent fracture was noticed throughout the follow-up. Valve function was excellent in most patients ($n = 32/34$, 94.1%, 95% CI 80.3—99.2%), with regurgitation being absent in 28 patients and trivial in four patients. Two patients experienced significant pulmonary regurgitation on transthoracic echocardiography; these patients were implanted using the jailing technique. The Melody valve was inserted before the gap between the RVOT and the implanted bare-metal stent filled the space. We thought wrongly that the Melody valve would fill the gap. After our experience with these patients we became more cautious about this space and our preferred method of treatment became the combined technique. Regurgitations were initially related to paravalvular leak but became valvular in one patient (Figs. 1 and 2), who required a second intervention. Intracardiac echocardiography showed complete disappearance of the valve leaflets and absence of paraprosthetic leak. The patient received a second Melody valve with an excellent mid-term (15-month) result.

Discussion

The Melody valve was initially developed with the aim of prolonging the lifespan of surgically implanted RV to PA conduits

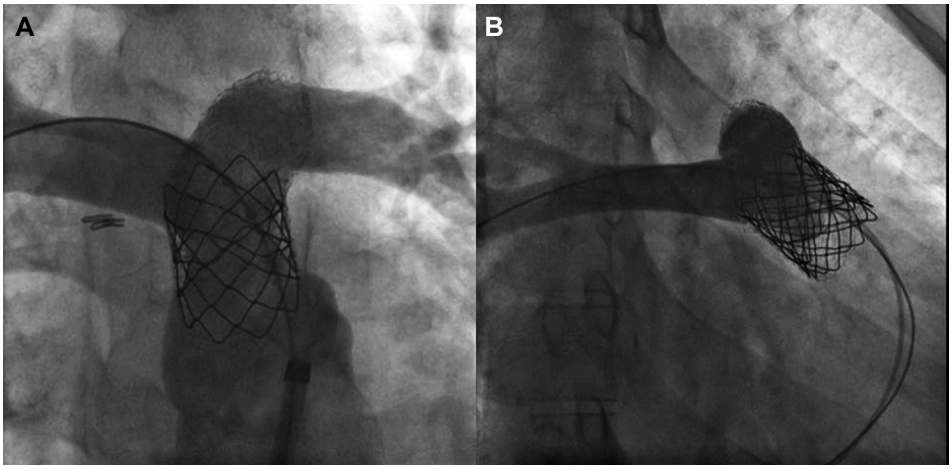

Figure 1. Still-frame angiographic images from patient with redo Melody valve following the jailing technique. A. Angiogram showing severe regurgitation despite the Melody valve being in place. B. Angiogram after insertion of a new Melody valve, showing restoration of pulmonary valve function.

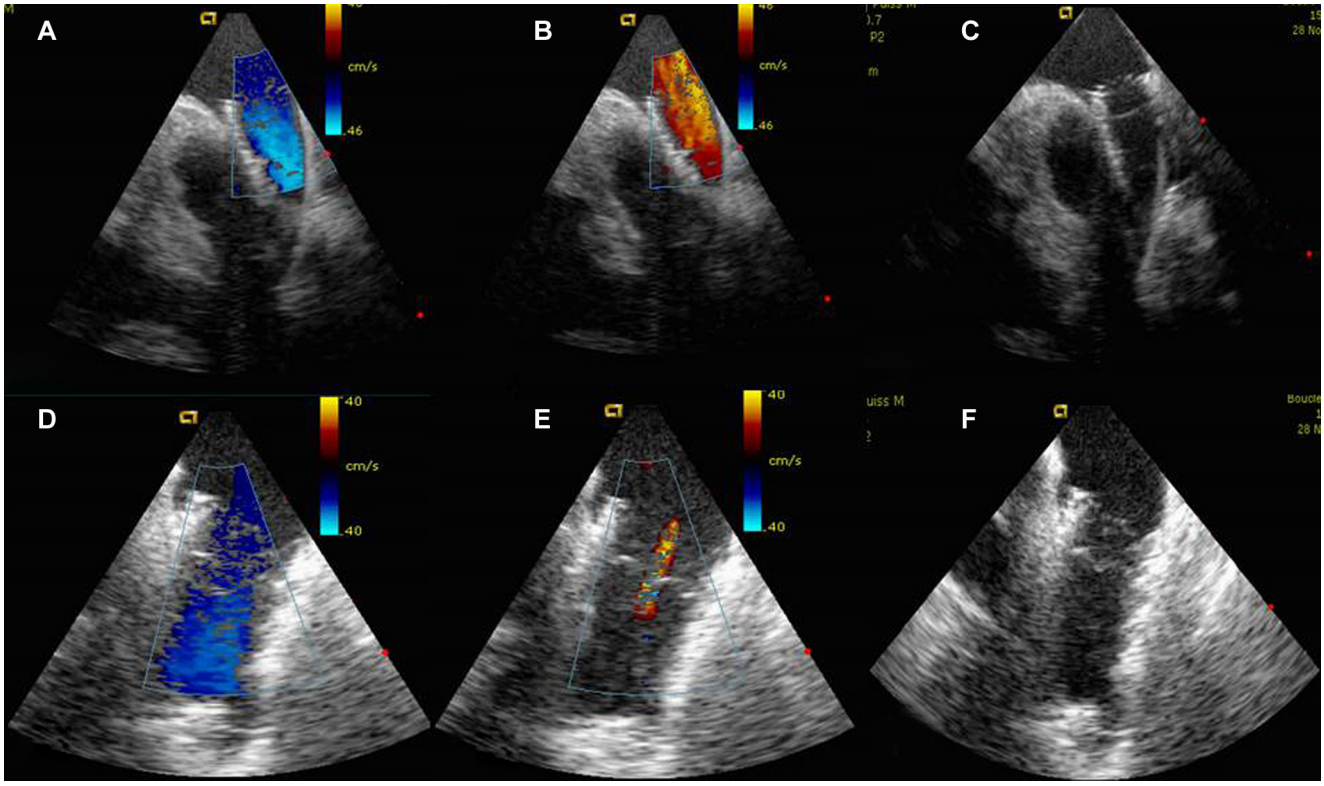

Figure 2. Still-frame echocardiographic images from patient with redo Melody valve following the jailing technique. A. Colour Doppler image showing unrestrictive forward flow through the Melody valve. B. Colour Doppler image during diastole showing free regurgitation; note the absence of paraprosthetic leak. C. Image showing Melody valve; no valve leaflet could be found (the disappearance of the leaflets explains the free regurgitation). D—F. Echocardiographic images obtained after redo Melody valve: unrestrictive forward flow (D); tiny central regurgitation (E); visualization of coapting leaflets of the new Melody valve (F).

[1,2]. The device had good and sustained haemodynamic results. With time, modification of the technique, with routine prestenting of patients, improved the overall results of the procedure [7]. Although the Melody valve is still indicated only in the treatment of dysfunctional RV to PA conduits, some have reported the use of the Melody valve for native patched RVOTs or patched conduits. Initial reports of the results of percutaneous valvulation in these settings were good [3—5,8]. One of the main limitations of the Melody valve is its size: it is available in a single diameter of 18 mm, dilatable up to 22 mm. We and others have extended the indication to non-circular RVOTs. In this paper, we sought to review the characteristics of the population of patients who had a Melody valve implanted in a non-circular outflow tract, and to review technical aspects and medium-term results of percutaneous valvulation.

In this particular population, the first haemodynamic assessment is crucial. Indeed, if a stenotic lesion is observed, the procedure is very similar to that for a circular conduit. This finding was the case in 53% of our population of patched RVOTs. In other cases, a specific technique was needed to make patients amenable to PPVI. The dimension of the outflow tract needs to be assessed adequately. Typically, we use a low-pressure balloon (Tyshak or PTS balloon) to localize the potential site for the bare-metal stent implantation and to size the RVOT. This sizing is done with simultaneous measurement of aortic pressure, which should drop during balloon inflation. Dye injection should be done during inflation to assure that no contrast goes into the PA. Our team has described interventional techniques to create a safe landing zone in order to be able to implant the Melody valve [4]. One of the techniques is the jailing technique, with stenting of one PA branch down to the main PA branch; the second technique is the Russian doll technique, with successive implantation of stents with decremental balloon diameters to reduce the diameter of the RVOT to a size that allows Melody valve implantation. The third technique is a combination of the first two techniques.

The first technique was used if the diameter of one of the PA branches was < 22 mm and the diameter of the RVOT was > 22 mm. The stenting is started from the smallest PA branch all the way to the RVOT with overlapping of the uncovered stents jailing the contralateral PA. Uncovered bare-metal stents with open-cell design are very effective in this situation. In the second technique, thick stents — typically covered stents — are preferable. In the jailing technique, it is difficult to predict if the Melody valve will fill the gap between the bare-metal stent and the RVOT. Two patients experienced paravalvular leak; one led to complete disappearance of the Melody leaflets. As a result, with experience, a combination of the two methods is now preferred. We tried to fill the gap with successive implantations of covered stents before implanting the Melody valve, especially in very large RVOTs. No additional paravalvular leak was noticed. Besides this complication, we had no secondary embolization or stent fracture. Valve function remains excellent. We included patients with RVOT diameters up to 26 mm. In theory, patients with larger diameters could also benefit from this technique at the price of multiple stent implantations to fill the gap between the wall and the primary stent.

Most of the patients had a one-step procedure. Some authors advocate that a two-step procedure is preferable to allow embedding of the stent to the PA wall. However, recrossing the previous stent can be challenging and increases the risk of crushing the stent during advancement of the Melody valve delivery system. As a result, we usually performed Melody valve implantation during the same procedure.

Study limitations

This review presents the results of a small population of patients with various anatomies; robust conclusions would require a larger population of patients with a longer follow-up period and comparison of the results with a population of patients with RV to PA conduits.

In addition, because we developed these techniques and pushed the limits of PPVI, the number of patients with large unrestricted patched RVOT is increasing, but PPVI with special techniques remains possible in fewer than 10%. One should remember that most of these patients are not suitable for PPVI with current devices. New dedicated devices will help to increase the indications.

A systematic review of stent fracture was not performed in these patients. Our policy regarding stent fracture is to screen patients with echocardiography and chest X-ray. If a finding could be related to stent fracture then a cine angiogram is performed. Using this protocol we might miss a portion of stent fracture. However, only clinically irrelevant and insignificant stent fractures would be missed. Finally, one should remember that the rate of stent fracture since the introduction of systematic prestenting is very low in most centres. In the particular setting of patched RVOT, the risk of stent fracture is higher. However, the number of stents placed before Melody valve insertion is also more important, providing more support and reducing the risk, at least in theory.

Conclusions

Percutaneous valvulation of patched non-circular outflow tract is feasible. Careful assessment of anatomy and haemodynamics are crucial to determine if a patient needs a complex approach or a conventional technique for PPVI. In these patients, prestenting is mandatory to create a safe landing zone and limit the risk of stent fracture. When the jailing technique is used, care should be taken to fill the gap between the RVOT and the bare-metal stent before the Melody valve is implanted, to avoid paravalvular leak. Once the Melody valve is successfully implanted, the complication rate is low and excellent haemodynamic results are sustainable.

Disclosure of interest

Y. Boudjemline is a proctor for Medtronic. The other authors declare that they have no conflicts of interest concerning this article.

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