Although transcatheter pulmonary valve replacement using the Melody valve (Medtronic Inc, Minneapolis, MN) has become widely adopted, it has only been formally studied in patients with right ventricle-to-pulmonary artery conduits <22 mm in diameter.1,2 Such patients compose only a small proportion of individuals with right ventricular outflow tract (RVOT) dysfunction, and there is interest and potential utility to broadening the indications for Melody valve implantation. We report nonstandard use of Melody valve in 3 noncandidate patients and discuss salient technical points.

Patient 1
A 25-year-old man with early surgical correction of pulmonary atresia intact septum during infancy, presented with severe PR and no gradient across the RVOT and branch pulmonary arteries (PAs). Calibration using a compliant balloon showed RVOT diameter of 25 mm, making the patient unsuitable for the Melody valve, using the conventional technique (Figure 1 and online-only Data Supplement video clips I and II).

Patient 2
An 18-year-old man with pulmonary atresia and ventricular septal defect underwent palliative Blalock-Taussig shunt in the immediate postnatal period and subsequently, complete repair without pulmonary valved or nonvalved conduit. A false RVOT aneurysm was closed, using an atrial septal defect occluder. The patient presented with native left PA stenosis, severe pulmonary regurgitation (PR), and worsening functional status. There was no gradient across the RVOT, which measured 25 mm (Figure 2).

Patient 3
A 31-year-old man underwent the Ross procedure with 23-mm homograft to the RVOT in early childhood. Redo surgery was required over time, with a new mechanical aortic valve along with patch enlargement of the pulmonary homograft and devalvulation. The patient presented with gradual decline in functional status, severe PR, no gradient across the RVOT, and RVOT size of 24 mm (Figure 3).

PA Jailing Technique
The smallest or stenosed branch of the PA was used as the initial anchor for multiple stents and subsequently for Melody valve insertion. Stenting was started from that PA branch, all the way down to the RVOT with overlapping uncovered stents, thus jailing the opposite PA. An uncovered bare metal stent with an open cell design (EV3 maxLD) was crimped over a BIB balloon (22×3.5, Numed Inc) and deployed in the suitable branch PA. An overlap of 50% was achieved with subsequent, proximally deployed stents, until the RVOT was reached. After deployment of the last stent, an RVOT angiogram was performed to look for patency of the contralateral vessel. In patient 2, an additional overlapping CP covered stent (Numed Inc.) was placed in the RVOT to reduce the RVOT size (Russian dolls technique) and to exclude a false aneurysm of the RVOT.

Melody Valve Implantation
Melody valve implantation was performed by standard technique, using a 22-mm Ensemble catheter (Medtronic Inc), either concomitant (patients 2 and 3) or 2 months after the bare metal stent RVOT preparation (patient 1). The stiff guide wire was preferably parked in the jailed PA to define the main pulmonary artery (MPA) bifurcation and thereby prevent accidental and possibly catastrophic covering of the jailed PA. In patient 3, this could not be achieved because of difficult angulation and trajectory; the wire was therefore parked ipsilateral in the stented PA and extreme care was exercised to prevent any degree of flow compromise to the
jailed PA by the Melody stent valve covering. The aim was to position the valve within the prestented region as low as possible and well below the MPA bifurcation. Postdilatation of the Melody valve using a 22-mm (patients 1 and 3) or 24-mm (patient 2) noncompliant balloon was done to reduce the degree of paraprosthetic leak. Hemodynamic and angiographic assessment was repeated at the end of the procedure. Patient 3 required elective recatheterization 48 hours after valve implant due to persistent elevated, isosystemic, systolic left PA (LPA) and RV pressures. The jailed RPA was

Figure 1. Cineangiogram still frames demonstrate the jailing technique in patient 1. A, Angiogram on 4-chamber view shows the anatomy of the right ventricular outflow tract (RVOT) and pulmonary artery (PA) tree. B, RV angiogram after placement of open-cell, bare metal stents shows symmetrical perfusion of the 2 PAs and incomplete apposition of the stents to the RVOT. C, Angiogram shows opening of the cells at the level of the jailed PA before Melody insertion. D, Final angiogram shows reduction of pulmonary regurgitation with a small amount of paraprosthetic leak.

Figure 2. Cineangiogram still frames demonstrate the jailing technique in patient 2. A, Angiograms on 4-chamber views show the anatomy of the right ventricular outflow tract (RVOT) and PA tree. The right pulmonary artery (RPA) is smaller than the left PA (LPA). B, Still frame shows 3 EV3 36/12 stents from the RPA to the RVOT and a CP covered stent (Numed Inc.) to cover the false aneurysm of the RVOT. C and D, Final angiograms show Melody valve in place, well functioning, and the normal visualization of the jailed LPA.
angiographically patent; however, the flow was preferably directed toward the hypoplastic LPA. The stent jailing the right PA (RPA) was simultaneously dilated with 2 adjacent balloons, 1 through the stented lumen and 1 that passed through the cells of the stent and into the jailed RPA (online-only Data Supplement video clips III and IV). Systolic RV and PA pressures reduced to 40 mm Hg immediately after the procedure. No further intervention was required in other patients. There was no stent migration or valve dislodgment noted during the procedure or after a mean follow-up of 10 months (4–22 months). Follow-up echocardiography and MRI did not reveal significant pulmonary regurgitation or paraprosthetic leak, except in patient 1. The patient is scheduled for percutaneous redilatation of the Melody valve with a larger balloon catheter.

Although it has been shown that the Melody valve can be implanted in patients with an RVOT patch rather than a conduit, there is limited information about the feasibility or outcomes of its use in such patients, and it is likely that most of the patients with a patched RVOT will not be suitable candidates for standard Melody valve implant. Moreover, among the 4 patients reported by Momenah et al., all had mixed lesions with significant RV-to-PA obstruction, making these patients very similar to the ones usually treated. All patients in our case series had pulmonary regurgitation as the primary lesion with no obstruction. With a large RVOT, there is a risk of valve embolization at various steps and thus each maneuver must be clearly planned. First and foremost, patient selection with balloon calibration and sizing should be performed carefully in multiple projections before deciding if a platform for the Melody valve can be made. This will also help in selection of the balloon to be used for stent placement.

An important theoretical foundation for the approach described in this report is that, in a large RVOT that has pronounced dynamic translational motion, presenting provides a stable, circumferential platform that should facilitate stability of the implanted Melody valve. We believe this allows enough time for tissue scaffolding, thereby reducing the RVOT/MPA width and thus the risk of embolization, although we have no definitive evidence to support this belief. When implanting a Melody valve with a 22-mm balloon, one should remember that the external diameter of the Melody valve is in fact 24.06 mm. Special care should be taken to apply the stent to the pulmonary wall at the level of the trunk to avoid paraprosthetic leak and to open the mesh of the stented PA, especially if the stented PA is hypoplastic. Implanting a Melody valve in each branch PA may be an option in some patients, although potential drawbacks of such an approach in our opinion include high cost and the presence of a noncontractile RVOT proximal to the valves. In our limited experience, there were no serious adverse events associated with the PA jailing technique and no migration or displacement of the Melody valve. The advent and experience with the pulmonic Sapien valve may be very interesting because it is available in larger diameters as well. Unfortunately, we were unable to test the utility of this valve for large RVOTs because the device is currently available only for investigational use in France. However, the same technique could be used either with Melody or Sapien valves or any other upcoming valves because it provides a perfect landing zone. Some patients with tetralogy of Fallot repaired with transannular patch augmentation who have a large RVOT and with hemodynamically significant regurgitation may be considered for percutaneous pulmonary valve implantation.

Figure 3. Cineangiogram still frames demonstrate the jailing technique in patient 3. A and B, Angiograms on lateral (A) and 4-chamber views (B) show the anatomy of the right ventricular outflow tract and left pulmonary artery (LPA) stenosis. C, Angiogram after Melody insertion shows kissing technique for opening of the cells of the jailed PA. D, Final angiogram shows excellent function of the Melody valve.
implantation using the PA jailing technique, as long as a bare metal stent can be anchored in a branch PA. In our preliminary experience, short-term follow-up after Melody valve implantation using the PA jailing technique appears promising, with findings of competent valves and the absence of stent fracture or migration.

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None.

References

Key Words: pulmonary artery jailing technique ■ stent ■ Melody valve ■ transannular patch ■ adult congenital heart disease ■ bare metal stent ■ heart defects, congenital ■ percutaneous pulmonary valve implantation ■ tetralogy of Fallot
Branch Pulmonary Artery Jailing With a Bare Metal Stent to Anchor a Transcatheter Pulmonary Valve in Patients With Patched Large Right Ventricular Outflow Tract
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