Melody Valve Implant Within Failed Bioprosthetic Valves in the Pulmonary Position
A Multicenter Experience

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Background—Transcatheter pulmonary valve implantation using the Melody valve has emerged as an important therapy for the treatment of postoperative right ventricular outflow tract dysfunction. Melody-in-bioprosthetic valves (BPV) is currently considered an off-label indication. We review the combined experience with transcatheter pulmonary valve implantation within BPVs from 8 centers in the United States and discuss technical aspects of the Melody-in-BPV procedure.

Methods and Results—A total of 104 patients underwent Melody-in-BPV in the pulmonary position at 8 US centers from April 2007 to January 2012. Ten different types of BPVs were intervened on, with Melody valve implantation at the intended site in all patients. Following Melody valve implant, the peak right ventricle-to-pulmonary artery gradient decreased from 38.7±16.3 to 10.9±6.7 mm Hg (P<0.001), and the right ventricular systolic pressure fell from 71.6±21.7 to 46.7±15.9 mm Hg (P<0.001). There was no serious procedural morbidity, and no deaths related to the catheterization or implant. At a median follow-up of 12 months (1–46 months), no patients had more than mild regurgitation, and 4 had a mean right ventricular outflow tract gradient ≥30 mm Hg. During follow-up, there were 2 stent fractures, 3 cases of endocarditis (2 managed with surgical explant), and 2 deaths that were unrelated to the Melody valve.

Conclusions—Transcatheter pulmonary valve implantation using the Melody valve within BPVs can be accomplished with a high rate of success, low procedure-related morbidity and mortality, and excellent short-term results. The findings of this preliminary multicenter experience suggest that the Melody valve is an effective transcatheter treatment option for failed BPVs. (Circ Cardiovasc Interv. 2012;5:862-870.)

Key Words: adult congenital heart disease ♦ bioprosthetic valve ♦ percutaneous pulmonary valve implantation ♦ percutaneous valve replacement ♦ tetralogy of Fallot ♦ valvular regurgitation

Since transcatheter pulmonary valve implantation (TPVI) using the Melody valve (Medtronic Inc, Minneapolis, MN) was first described over a decade ago,2,3 multiple studies have documented the short- and intermediate-term benefits of TPVI into dysfunctional right ventricle to pulmonary artery (RV-PA) conduits.2–5 There is little published information about Melody valve implantation within failed surgical bioprosthetic valves (BPVs) in the pulmonary position. A small number of patients with BPVs were included in reports by Bonhoeffer’s group6 and other series,6 but the published data specific to Melody TPVI within BPVs are limited to single center, small case series.7

On the basis of unpublished data from Medtronic Inc, as of January 2012, 3000 Melody valves have been implanted worldwide, with BPV patients representing <5% of the total.

Currently, implant within BPVs is not a labeled indication for the Melody valve in the United States, however, it seems that BPVs are becoming the prosthesis of choice for surgical pulmonary valve replacement in older patients at many centers. As the population of patients with congenital heart disease ages and the importance of long-term pulmonary
WHAT IS KNOWN

- Transcatheter pulmonary valve replacement within failed right ventricular to pulmonary artery conduits using the Melody valve is effective in the short and intermediate term. However, there is little published information regarding Melody valve implantation into failed bioprosthetic valves in the pulmonary position, which is currently an off-label indication.

WHAT THE STUDY ADDS

- This series reviews 104 patients who underwent Melody valve implantation into failed bioprosthetic valves in the pulmonary position at 8 centers in the United States and represents the largest experience published to date.
- We found that Melody valve implant into bioprosthetic valves can be accomplished safely and effectively with low morbidity and mortality and excellent short-term results.

Patients

This study was a retrospective analysis of patients who underwent TPVI of a Melody to BPV in the pulmonary position at 8 centers in the United States between April 2007 and January 2012, including those treated as part of the initial US investigational device exemption trial and those treated after Food and Drug Administration Humanitarian Device Exemption approval in January 2010. After Institutional Review Board approval at all participating centers, the medical, cardiac catheterization, echocardiography, and cardiac magnetic resonance imaging records were reviewed, including reports of adverse events (right ventricular outflow tract [RVOT] rupture/tear, vascular complications, bleeding, arrhythmias, and death) and RVOT reinterventions (catheterization or surgery).

We included patients who underwent Melody valve implant within a surgically placed BPV in the pulmonary position. Valve sizes are reported according to manufacturer specifications. Implants in the following types of RVOT conduits/valves were not included: valved stentless conduits, valved bovine jugular vein conduits, nonvalved synthetic conduits, or the conduit portion (ie, not the valve) of valved conduits containing a BPV. Also, Melody valve implants within BPVs in locations other than the RVOT (ie, in the tricuspid position) were excluded.

Melody valve implantation was performed according to standard technique. Implants performed as part of the US investigational device exemption trial followed the previously reported study protocol. Preimplantation aortography and/or selective coronary angiography was performed in all cases. Compression testing via simultaneous balloon dilation with selective coronary angiography and other interventional procedures were performed at operator discretion by interventional cardiologists trained in accordance with the Melody valve instructions for use.

Results

Patients and Diagnostic Data

A total of 104 patients met the inclusion criteria and compose the study cohort (26 patients previously reported). Demographic and anatomic data for study patients are summarized in Table 1.

| Table 1. Demographic and Anatomic Data |
|-----------------|-----------------|
| Age, y          | 26 (3–63)       |
| Weight, kg      | 68 (16–199)     |
| Underlying anatomy          |
| Tetralogy of Fallot         | 77 (74%)        |
| Truncus arteriosus          | 7 (7%)          |
| Pulmonary stenosis          | 7 (7%)          |
| Dextro-transposition of the great arteries | 4 (4%)  |
| Aortic stenosis (previous Ross procedure) | 4 (4%)  |
| Double-outlet right ventricle | 1 (1%)         |
| Other              | 4 (4%)          |
| Bioprosthetic valve type    |
| Carpenter–Edwards Perimount | 38 (37%)       |
| Medtronic Hancock Conduit   | 38 (37%)       |
| Medtronic Mosaic          | 7 (7%)          |
| Medtronic Hancock 2        | 7 (7%)          |
| Medtronic Freestyle       | 4 (4%)          |
| Sorin Mitroflow           | 3 (3%)          |
| Carpenter–Edwards aortic porcine | 3 (3%)    |
| St Jude Biocor            | 2 (2%)          |
| Ionescu-Shiley           | 1 (1%)          |
| St Jude Epic             | 1 (1%)          |
| Bioprosthetic valve size, mm | 23 (16–29)  |
| Bioprosthetic valve age, y | 9.1 (0.6–33)  |

Data are presented as median (minimum-maximum) or frequency (% of the entire 104 patient cohort)
Table 1. Four patients underwent catheterization for intended TPVI within a BPV but did not receive a Melody valve. In 3 of these patients, the BPV was either too large or the RVOT obstruction was not at the level of the BPV as suspected but at the branch pulmonary arteries. In 1 patient, during predilation of the BPV, there was compression on the left anterior descending coronary artery that arose from the right coronary and passed beneath an obstructed portion of the conduit housing a Hancock valve. The compression resulted from a change in geometry of the proximal aspect of the conduit rather than radial expansion at the site of the valve. Thus a Melody valve was not implanted. These 4 patients were excluded from further analysis.

Most patients were adults and the majority (71%) had tetralogy of Fallot as the underlying diagnosis. Melody valves were implanted in 10 different types of surgically placed BPVs, with the Carpentier–Edwards Perimount (Edwards Lifesciences LLC, Irvine, CA) and Hancock valved-conduit (Medtronic Inc, Minneapolis, MN) composing the majority (73%). Illustrative examples of implant in 6 of the different types of BPVs are demonstrated in Figures 1 through 3. The median nominal BPV size was 23 mm (16–29 mm), and the median duration from surgical BPV implant to the Melody valve procedure was 9.1 years (0.6–33.0 years).

Preprocedure echocardiographic and cardiac magnetic resonance data are shown in Table 2, along with the corresponding indications for intervention, which were based on echocardiographic criteria in most cases. Almost half of the patients had combined regurgitation and stenosis as the presenting mechanism for BPV failure, and more than three-quarters had moderate-to-severe regurgitation. Only 24% of patients (n=25) had preprocedure cardiac magnetic resonance assessment, as detailed in Table 2.

Melody Valve-in-BPV Implant

Procedural data for the Melody valve implant are summarized in Table 3. Predilation of the BPV was performed to alleviate obstruction and to balloon-size the intended implant site in the majority of patients (85%) (Figure 2E). Balloon types used for predilation and inflation strategies varied. The inflation pressure, which was reported by the operator in 75 cases, was a median of 10 atm (2–20 atm). The balloon waist at the time of predilation or balloon sizing was a median of 5 mm (1.0–12.8 mm) smaller than the nominal diameter of the BPV. In general, for valve sizes <25 mm, the waist was typically smaller than the valve by <5 mm, whereas for larger valves the difference tended to be larger (Figure in the online-only Data Supplement).

Twenty-one patients (20%) underwent prestenting of the BPV before Melody valve implant (Figure 3C and 3D), and 11 (10%) had additional interventional procedures during the same catheterization.

Figure 1. Melody-in-bioprosthetic valves (BPV) implant procedure. A shows predilation of a 25 mm Carpentier–Edwards Perimount valve followed by deployment (B) and follow-up angiography. The arrow points to the waist and posterior deflection of the BPV crown.

Figure 2. Examples of Melody valve implantation in Sorin Mitroflow (A through C) and St. Jude Medical Epic bioprostheses (D through F).
The Melody valve was successfully implanted in the intended position in all cases. There were no deaths and no serious procedural adverse events. Right heart hemodynamics were significantly improved after Melody valve implantation. The peak RV-PA gradient decreased from 38.7±16.3 to 10.9±6.7 mm Hg (P<0.001), and all but 2 patients had postimplant gradients <25 mm Hg. RV systolic and diastolic pressures fell from 71.6±21.7 to 46.7±15.9 mm Hg and from 11.9±4.6 to 10.4±3.7 mm Hg, respectively (both P<0.001). The mean right atrial pressure decreased from 11.4±4.4 to 10.4±3.7 mm Hg (P=0.006). The systolic and diastolic PA pressures increased from 32.7±14.1 to 36.2±15.7 mm Hg (P<0.001) and from 12.8±5.1 to 17.2±7.1 mm Hg (P<0.001), respectively.

Follow-up information was available for 95 patients (91%) at a median of 12 months (1–46 months) after implant. There were 2 deaths during follow-up, both unrelated to the Melody valve. One was a 56-year-old patient with tetralogy of Fallot who died 9 months after TPVI from postoperative sepsis after surgical aortic root replacement (there was no indication that the root replacement was complicated by the presence of the Melody valve); the other was a 44-year-old patient with tetralogy of Fallot, severe pulmonary hypertension, and heart failure who died from hypercarbic respiratory failure exacerbated by medications used for chronic pain control. One patient developed femoral vein thrombosis requiring readmission to the hospital for thrombolytic therapy as previously reported.

Endocarditis was confirmed in 2 patients, 13 and 18 months after the TPVI procedure. The valve continued to function well in both of these patients, but because of persistent vegetations on the valve despite appropriate antibiotic therapy and sterile follow-up blood cultures, both underwent surgical explant of the Melody valve and pulmonary valve replacement without incident. There was 1 additional surgical explant, which occurred 4 months after Melody valve implant. The patient was a 46-year-old with significant residual obstruction in complex reconstructed central PAs, despite attempted angioplasty and stenting concomitant to Melody valve implantation. Because of residual obstruction distal to the Melody valve, the patient was referred for extensive surgical RVOT and branch PA reconstruction, at which time, the well functioning Melody valve was explanted. This patient had been treated for presumed endocarditis 1 month after TPVI, but there was no evidence of valve dysfunction or vegetation, either at the time of diagnosis or when it was explanted. No patients underwent transcatheter reintervention on the Melody valve. Overall, freedom from reintervention on the Melody valve, which was identical to freedom from explant, was 97±2% at 1 year and 92±5% at 2 years (Figure 4).

Stent fractures were identified by fluoroscopic assessment in 2 patients (2%), each discovered 13 months after implantation (1 Hancock conduit and 1 Carpentier–Edwards Perimount valve) (Figure 5). One of these was in the proximal portion of the Melody valve stent frame in a patient whose Hancock conduit was immediately behind the sternum and was compressed proximal to the valve. The other was implanted into a previously fractured Carpentier–Edwards Perimount valve positioned directly behind the sternum. Prestenting was not performed in either patient. To date, neither patient has developed significant hemodynamic dysfunction of the Melody valve nor undergone RVOT reintervention. Freedom from a diagnosis of Melody valve stent fracture was 98±2% at 1 year and 95±3% at 2 years (Figure 4).

Among patients with an intact Melody valve, valve function was generally excellent on the most recent follow-up echocardiogram (Table 4). No patients had more than mild regurgitation, and only 4 had a mean RVOT gradient ≥30 mm Hg (Table 4).

Discussion

Procedural and Short-Term Outcomes of Melody Valve-in-BPV Implant

In this multicenter study of 104 patients who underwent Melody TPVI within a variety of failed surgical BPVs at 8 different centers in the United States, procedural and short-term outcomes were generally excellent. Ten different types of BPVs were intervened on, and all served as a secure landing zone for the Melody valve. There was 1 vascular complication requiring readmission for thrombolytic therapy. Otherwise, no additional significant procedural morbidity, and no deaths attributable to the Melody valve or implant procedure, were reported. This remarkable success rate, with low procedural morbidity supports the feasibility and safety of TPVI using the Melody valve in a variety of different anatomies and surgical prostheses.

One of the most significant concerns with the Melody valve implanted into RVOT conduits has been stent fracture. In this series, during a median follow-up of 12 months, only 2 stent fractures were diagnosed, both of which were discovered 13 months after implant. This is substantially lower than the other large series, where fracture rates have ranged from

Figure 3. Melody valve implantation into Medtronic Mosaic (A and B) and Freestyle (C and D) bioprostheses. The Mosaic framework has 3 radiopaque markers marking the top of each commissural post (arrows). These markers can be used to help guide Melody valve implantation.
The fact that radiographic follow-up was not standardized limits our ability to conclusively assess the overall freedom from stent fracture after Melody valve-in-BPV implant. However, the low incidence of stent fracture suggests that the structural framework present in most BPVs protects the Melody valve from compressive and rotational forces associated with cardiac contraction, similar to the benefit demonstrated with prestenting of stenotic RV-PA conduits. Size permitting, prestenting of the BPV may provide additional support to the Melody valve, perhaps, reducing the incidence of fracture even further over time.

Three of the Melody valves in this series were surgically explanted. Two (2%) of these were in patients who were diagnosed with endocarditis >1 year after Melody valve implant (13 and 18 months respectively). Cases of late endocarditis after Melody valve have been previously reported, raising some safety concerns. The retrospective nature of this report limits our ability to draw meaningful conclusions regarding the relative risks of Melody-in-BPV compared with homograft implantations. Additional information from large registries, such as the ongoing Melody valve postmarket surveillance study will hopefully yield data regarding the true incidence and annual risk of infective endocarditis. The other explant occurred 4 months after implant in a patient with distal RVOT and central PA obstruction that was unresponsive to catheter-based therapy. The Melody valve was functioning well but was removed to facilitate surgical reconstruction of the RVOT and proximal branch PAs.

### Technical Considerations for Melody Valve-in-BPV Implant

In their review of transcatheter aortic valve implantation within failed BPVs in the aortic position, Piazza et al. provided an excellent summary of the relevant physical characteristics of all of the commercially available BPVs. In addition to the tenets highlighted in their report, there are several additional considerations to be mindful of when using the Melody valve for treatment of dysfunctional BPVs in the pulmonary position.

In general, BPVs are composed of 2 components: a tissue valve (porcine, bovine, or equine) and a supporting structure. The supporting structure is composed of metal or plastic. It can be a simple ring (eg, Hancock conduit) or, more commonly, a ring that is preformed into a complex 3-dimensional shape (eg, Carpentier–Edwards Perimount, St Jude Epic, Medtronic...
Mosaic). The stated nominal width of each device refers to the diameter of the outermost dimension at the base of the device, with the inner diameter (ID) generally 2 mm smaller. In this report, the nominal diameter of the BPVs intervened on ranged from 16 to 29 mm. Implant into valves with nominal diameters much larger than the Melody valve (on the 22 mm delivery system, the OD of the Melody valve is ±24 mm) highlights the fact that the effective ID of BPVs that have been in situ can vary significantly depending on the mechanism of failure at the time of presentation for TPVI. The ID can be close to the baseline value if the presenting problem is primarily valve insufficient, or it can be substantially smaller in patients presenting with stenosis because of heavily calcified and thickened leaflets. Balloon valvuloplasty (ie, predilation) should be performed before TPVI to alleviate stenosis when present (otherwise, balloon sizing should be performed) and to define the diameter and contour of the intended implant site. Predilation or balloon sizing are also helpful in identifying additional areas of obstruction along the RVOT, which can be a concern in some implant configurations.

The height of different BPVs also varies considerably. This factor may have important implications when implanting a Melody valve within a BPV, especially when there is significant angulation of the BPV relative to the RVOT (Figures 6 and 7). The height of the Melody valve, which is covered along its entire length, ranges from 22 to 26 mm, decreasing as the expansion diameter increases (18–24 mm). Most BPVs (Carpentier–Edwards porcine aortic or Medtronic Mosaic valves, for example) are shorter than the Melody valve, which is significant angulation of the BPV relative to the RVOT, particularly, when different camera angles can be helpful in understanding the relationship of the BPV to the RVOT, particularly, when the BPV is implanted with an angled or complex geometric relationship to the RVOT. When present, radiopaque frames (as in the Carpentier–Edwards valve) or markers (as in the commissural posts of the Medtronic Mosaic valve) offer a reliable guide for aligning the camera perpendicular to the long-axis of the valve, which can be useful for understanding its relationship to the adjacent outflow regions, defining the level(s) obstruction, and positioning the valve during deployment (Figures 1, 7C, and 7D). In the absence of a radiopaque frame or marker (as in the Freestyle valve), angiography and balloon sizing maneuvers become even more important in attaining accurate device position (Figures 2 and 3).

The optimal positional relationship between the BPV and the Melody valve implanted within it may vary according to the particular circumstances. In addition to Melody valve-BPV height mismatch and BPV-RVOT angulation, other anatomic factors, such as multiple areas of obstruction along the RVOT or retrosternal conduit position, may exist that favor implant of the Melody valve in a high or low position relative to the BPV. For example, placement of the Melody valve in a stenotic retrosternal position is a known risk factor for Melody stent fracture and was the apparent cause of 1 of the 2 stent fractures in the current series. If the conduit or RVOT housing the BPV is adjacent to the anterior chest wall or sternum, with consequent compression and RVOT obstruction, bare metal stents can be used to treat this proximal obstruction, and the Melody valve can be implanted more distally, away from the chest wall, to reduce the risk of Melody valve stent fracture (Figure 5C). Alternatively, if there is proximal RVOT obstruction for other reasons, it may be appropriate to position the Melody valve more proximally, particularly, if there is distal angulation of the BPV-PA pathway (Figure 7). In patients with BPVs that are not housed in a conduit, it is important to remember that the commissural posts of the prosthesis can splay (Figure 1A), and seating the Melody valve within the commissural posts but not across the annular ring may result in an unstable implant, as reported in at least 1 case of transcatheter valve implant within a BPV in the mitral position. Also, it is important to consider the possibility that positioning the Melody valve too proximally can result in inadequate covering of BPV leaflets, which could potentially protrude and cause obstruction. This can be anticipated and avoided with careful preimplantation assessment of the BPV and adjacent areas as described above.
In patients undergoing Melody valve implant within RVOT conduits, assessment of coronary arterial anatomy and testing for coronary compression is considered an essential safeguard. In the investigational device exemption study cohort, ≈4% of patients who were enrolled did not receive a Melody valve because of risk of coronary artery compression. In the setting of a BPV, implantation of a Melody valve is unlikely to alter the relationship of the BPV and the underlying heart, and the diameter of the BPV itself will not be increased, although the adjacent RVOT, PA, or conduit may potentially be altered. Accordingly, it does not seem likely that Melody valve implant within a BPV poses a high risk for coronary compression, in general. However, there was 1 aborted implant because of coronary compression risk (related to geometric changes in the proximal aspect of a Hancock conduit) in this series, illustrating that even though it may be unlikely, this potentially lethal complication is possible in patients being considered for TPVI within a BPV. Thus, we continue to recommend thorough evaluation of coronary anatomy, including compression testing if baseline angiography is concerning or unclear, in all patients undergoing catheterization for intended TPVI with an eye toward this potential complication.

**Considerations for Surgical BPV Implant**

One of the questions that comes up in discussions about the role of TPVI in the lifetime management of patients with a surgically reconstructed RVOT is what size valve the surgeon should implant to optimize the eventual likelihood and outcome of TPVI. Although Melody valves were implanted into a wide range of BPV sizes in this series, our data do not provide insight into the likelihood that TPVI will be feasible and provide a good hemodynamic outcome in different size BPVs. In this series, the diameter of the predilation or sizing balloon waist was generally <2 to 3 mm smaller than the nominal valve size, which is consistent with the typical ID-OD difference of BPVs. Thus, in general, a Melody valve can be expanded to nearly full diameter in most 25-mm BPVs (ID, ≈23 mm), particularly, if aggressive predilation is performed to relieve any stenosis. That is not to say that 25 mm is the appropriate size BPV in all patients, and further studies should include among their aims a deeper understanding of that issue. The largest BPV treated in this series was 29 mm in diameter, which is likely pushing the upper limit for the Melody valve (22-mm diameter). This series focused entirely on the experience with Melody valve, but it should be recognized that other devices, such as the Edwards Sapien valve (26- and 29-mm
diameter) are available in many parts of the world, permitting valve-in-valve implantation in even larger BPVs.

Limitations

This study was limited by its retrospective design, and its largely descriptive nature. Pre and postimplantation evaluation of patients treated outside the investigational device exemption protocol varied among institutions. The relationship between valve size and balloon waist may reflect selection and procedural bias, as larger balloon waists in 27-and 29-mm valves, for example, would not permit Melody valve implant. These data are intended simply to be descriptive, not prescriptive. Follow-up for stent fracture varied by institution. Although all institutions performed fluoroscopy to screen for fractures in valves that became stenotic or regurgitant, not all institutions performed routine fluoroscopy at time points <12 months, relying instead on echocardiography and chest radiography. Therefore, it is possible that some hemodynamically insignificant fractures were missed. Also, because the duration of follow-up was relatively short in most patients, we cannot comment on the long-term function of the Melody valve after implant within a failed BPV.

Conclusions

TPVI using the Melody valve within failed bioprostheses can be accomplished with a high rate of success, low procedure-related morbidity and mortality, and excellent short-term results. Ultimately, more data will be necessary to assess the risks and benefits of TPVI in the management of patients with postoperative RVOT dysfunction, but the findings of this preliminary multicenter experience with Melody valve-in-BPV therapy are encouraging.

Disclosures

Drs Gillespie, McElhinney, Cheatham, Vincent, Jones, and Zahn are consultants for Medtronic Inc, the manufacturer of the Melody valve, and, all act as investigators or proctors.

References


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Supplemental Material

Supplemental Figure. These scatterplots depict the relationships between A) the nominal diameter of the BPV and the corresponding diameter of the balloon waist (r=0.15, p=0.26), and B) the nominal diameter of the BPV and the difference between BPV and balloon waist diameters (r=0.73, p<0.001). For coordinates with multiple identical data points, the valve size was shifted slightly to display all patients.