Transcatheter Pulmonary Valve Replacement Using The Melody Valve: Indications, Techniques, Outcomes

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Disclosures

- Consultant to Medtronic Inc.
- Research Support (supplies) from Medtronic Inc.
Goals

• Discuss Indications, Techniques and outcomes of TPV using the Melody valve
• Go through typical cases (2)
• Briefly discuss “off-label” use of Melody valve in pulmonary position
PPVI: a brief history

- Percutaneous Pulmonary valve implantation (PPVI)
- Melody® Valve (Medtronic, Inc.)
- Sapien® valve (Edwards, Inc.)
<table>
<thead>
<tr>
<th>Year</th>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>September</td>
<td>First Melody® TPV implant – Necker Hospital, Paris France, Prof. Philipp Bonhoeffer</td>
</tr>
<tr>
<td>2003</td>
<td>April</td>
<td>First implant with revised Melody® TPV – Great Ormond Street Hospital, London UK</td>
</tr>
<tr>
<td>2005</td>
<td>May</td>
<td>Data closure for CE and IDE submissions – 89 patients implanted: 21 w/ original TPV, 68 w/ revised Melody® TPV</td>
</tr>
<tr>
<td></td>
<td>September</td>
<td>100th patient receives a Melody® TPV</td>
</tr>
<tr>
<td>2006</td>
<td>September</td>
<td>CE Mark received; first transcatheter valve commercially available</td>
</tr>
<tr>
<td></td>
<td>December</td>
<td>Melody® TPV receives Health Canada approval; first commercially available TCV in North America</td>
</tr>
<tr>
<td>2007</td>
<td>January</td>
<td>First U.S. implant – Children’s Hospital Boston</td>
</tr>
<tr>
<td>2009</td>
<td>July</td>
<td>1,000th patient receives a Melody® TPV</td>
</tr>
<tr>
<td>2010</td>
<td>January</td>
<td>FDA Approval of Melody® TPV under HDE designation; first transcatheter valve approved for commercial use in the U.S.</td>
</tr>
</tbody>
</table>

**Chart courtesy of Medtronic Inc.**
## Melody® valve Global Clinical Experience through November 2014

<table>
<thead>
<tr>
<th>Geography</th>
<th>Patients</th>
<th># Implanting Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest of world</td>
<td>3500</td>
<td>110ish</td>
</tr>
<tr>
<td>US</td>
<td>3,800</td>
<td>90</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>7,300</strong></td>
<td><strong>200ish</strong></td>
</tr>
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</table>

**Chart courtesy of Medtronic Inc.**
Who is eligible for PPVI?

(patient population?)

Estimated at 20% of all CHD Patients

Anomalies of the RVOT

- Tetralogy of Fallot
  - With Pulmonary Stenosis
  - With Pulmonary Atresia

- Truncus Arteriosus

- Transposition Great Arteries

- Others
  - With Pulmonary Stenosis
  - With Pulmonary Atresia

- RV–PA Conduit
- RV–PA Conduit
- RV–PA Conduit
- RV–PA Conduit

Surgical correction of outflow tract – non-conduit

~ 85% of all RVOT Pts.

~ 15% of RVOT Patients

PPVI = RV–PA conduit “rehabilitation”

**Chart courtesy of Medtronic Inc.**
PPVI: Just for conduits?
(mostly)

Max diameter 22 mm

Medtronic Melody® Valve

Max diameter 26 mm

Edwards SAPIEN® Valve
Dilated / Distorted RVOT

RVOT = 3 cm (at least)
Melody® valve specs

- Melody Valve (22)
  - (18mm) Bovine jugular vein
  - CP stent (platinum-Iridium)
  - Functional range: 16 – 22mm

- Delivery system =
  - 22Fr Ensemble® sheath (18, 20 or 22mm)
  - Super-stiff 0.035” guidewire

- “New” Melody Valve 20
  - 16-20mm
Indications for PPVI
Inclusion Criteria
• Age ≥ 5 years
• Weight ≥ 30 kg
• Conduit ≥ 16 mm
• Conduit dysfunction

Exclusion Criteria
• Active endocarditis
• Contra-indication to MRI (initially – was removed as an exclusion)

NYHA II, III, IV
- Mean RVOT gradient ≥ 35 mmHg, or
- Moderate or Severe PR

NYHA I
- Mean RVOT gradient ≥ 40 mmHg, or
- Severe PR with RV dilation or dysfunction
Indications for Meldoy Valve

• Melody Valve Instructions for use (IFU) under HDE approval (mirror the US IDE entry criteria)

• Existence of a full circumferential RVOT conduit 16mm or greater

• Dysfunctional RVOT conduit with clinical indication for intervention and either:
  • Regurgitation: $\geq$ moderate (ECHO)
  • Stenosis: Mean RVOT gradient $\geq$ 35mmHg
• no patient had more than mild pulmonary regurgitation early after implantation or during follow-up (1 year in 65 patients).
• Freedom from diagnosis of stent fracture was 77.8±4.3% at 14 months.
• **Freedom from Melody valve dysfunction or reintervention was 93.5 ±2.4% at 1 year.**
• A higher right ventricular outflow tract gradient at discharge ($P=0.003$) and younger age ($P=0.01$) were associated with shorter freedom from dysfunction.

**“Conclusions”—**In this updated report from the multicenter US Melody valve trial, we demonstrated an ongoing high rate of procedural success and encouraging short-term valve function. All reinterventions in this series were for right ventricular outflow tract obstruction, highlighting the importance of patient selection, adequate relief of obstruction, and measures to prevent and manage stent fracture.”

*(Circulation. 2010;122:507-516.)*

Key Words: catheterization ■ heart defects, congenital ■ tetralogy of Fallot ■ magnetic resonance imaging
Serious Adverse Events

**Interventional Cardiology**

**Percutaneous Pulmonary Valve Implantation**

Impact of Evolving Technology and Learning Curve on Clinical Outcomes

Philippe Lancellotti, MD, BSc, Louise Coute, MD, MRCPI; Sachin Khambhatia, MD, MRCPI; Johannes Nordmeyer, MD; Yossi Badaogafe, MD, Sibila Svezenski, MEng; Vivian Muhunyana, MRCPI; Tien Yen-Luu, BN; Giovanni Pansani, MA; Graham Dinnick, MRCPI; Semyon Galin, MRCPI; Elisa Walker, MRCPI; Victor Tsang, MD, FRCS; John Dostal, FRCP; Andrew M. England, MD, MRCPI, FRCP; Phillip+ Bahnert, MD

**Background**—Percutaneous pulmonary valve implantation was introduced in the year 2000 as a non-surgical treatment option for patients with native atrioventricular valve dysfunction.

**Methods and Results**—Between September 2000 and February 2007, 155 patients with aortic valve regurgitation underwent percutaneous pulmonary valve implantation. This led to significant reduction in left ventricular ejection fraction from 55% ± 8% to 64% ± 12% (mean pressure gradient, 16.6 ± 5.8 mm Hg; P < 0.001) and right ventricular systolic function (from 27 ± 10 to 31 ± 10 mm Hg, respectively, P < 0.02). The incidence of death was 0% at 1 year and 2.6% at 5 years.

**Serious Adverse Events**

### Percutaneous pulmonary valve implantation: two centre experience with more than 100 patients

**Objective**

The aim of the study was to provide a long-term follow-up of patients treated with percutaneous pulmonary valve implantation.

**Methods**

A total of 102 patients (mean age 43 ± 10 years, 71 males) were included in the study. All patients underwent percutaneous pulmonary valve implantation using the Melody valve (Medtronic, Minneapolis, MN, USA).

**Results**

The 30-day mortality rate was 3.9% (4 patients). At 1 year, the survival rate was 96.1% (96 patients). At 5 years, the survival rate was 92.3% (90 patients).

**Conclusion**

Percutaneous pulmonary valve implantation is a safe and effective treatment option for patients with native atrioventricular valve dysfunction.
Deaths related to PPVI?

Interventional Cardiology

Percutaneous Pulmonary Valve Implantation
Impact of Evolving Technology and Learning Curve on Clinical Outcome

Philippe Lurz, BSc; Louise Coats, MRCP; Sachin Khambhatia, MD; MBChB; Johannes Nienhüys, MD; Yvonne Baudenschip, MD; Silvia Schineto, MTI; Vivak Mathur, MRCP; Tien Yen Lai, BN; Giovanni Parascandola, MA; Graham Dentick, MRCP; Francesco Cardino, MRCP; Fiona Walker, MRCP; Victor Tsang, MD, FRCSI; John D'Onofrio, FRCP; Andrew M. English, MD, MRCP, FRCP; Philippe BJK Pottier, MD

Background—Percutaneous pulmonary valve implantation was introduced in the year 2000 as a non-surgical treatment for patients with native pulmonary outflow tract dilation.

Methods and Results—Between September 2000 and February 2007, 155 patients with native or non-native (endocarditis, congenital) pre-existing pulmonary valve implantation. This led to significant reduction in right ventricular ejection fraction (from 0.34±0.12 to 0.45±0.12 mm Hg, p<0.001) and right ventricular outflow tract gradient (from 37±38 mm Hg to 22±29 mm Hg, p<0.001). Patients were followed up for 6 months (median duration). The mean follow-up period was 37 months, and 45 patients were lost to follow-up. The overall mortality was 7 patients (1.7%).

Overall Mortality: N= 7 (1.7%)

Procedural related Deaths = 2 (0.5%) (coronary)

N= 155 + 136 + 100 = 391
Melody Valve Outcomes (longer term)

Up to Seven-Year Outcomes After Transcatheter Pulmonary Valve Replacement in the Prospective Multicenter US Melody Valve Investigational Device Exemption Trial


National Institutes of Health, Columbia, MD; Columbia University Medical Center, New York, NY; Children's Hospital Los Angeles, CA; Children's Hospital Boston, Boston, MA; University of Medicine, New Haven, CT; Seattle Children's Hospital, Seattle, WA; Nationwide Children's Hospital, Columbus, OH

Objective
- Transcatheter pulmonary valve replacement (TPVR) with the Melody valve is a safe and feasible treatment for patients with postoperative conduit (RPC) dysfunction.
- The objectives of this study are to provide mid-term and long-term outcomes in patients from the Melody Investigational Device Exemption (IDE) trial.

Methods
- The Melody valve IDE trial was a non-randomized, prospective, multicenter study which was initiated in 2007. The study protocol, and its amendments, were approved by the Food and Drug Administration, as well as each center's Institutional Review Board.
- The study enrolled 110 patients at 6 centers. Patients will be followed to 10 years post-implant.
- This follow-up evaluation was conducted annually.

Patient Flow

NYHA Functional Status

Conclusions
- Following Melody valve implantation, hemodynamics remained stable over time, and NYHA functional status improvement was sustained over time.
- At 5 years post-Melody valve implantation:
  - Estimated survival was approximately 97.1%.
  - Freedom from explant was 92.3%.
  - Freedom from any re-intervention on the Melody valve was 70 ± 3%.
  - Freedom from any major adverse event was 95 ± 3%.
  - Freedom from endocarditis was 90 ± 3%. Of the 14 patients with meltdowns (endocarditis), 9 were successfully managed with medical therapy alone.

This longer-term follow-up study of the initial Melody IDE cohort demonstrates durable improvement in hemodynamic and clinical outcomes up to seven years.

Disclosures: Dr. Cheatham, Zahn, Vincent, Jones, and McElhinney serve as consultants to Edwards Lifesciences, Inc., the manufacturer of the Melody valve, and all authors act as investigators and/or lecturers. Dr. Jones has received research funding from Edwards, Inc. Dr. Cheatham serves as a consultant to Edwards Lifesciences, Inc. Dr. Hollenbrand serves as a consultant to Abbott Vascular and Edwards Lifesciences, Inc. The study was sponsored by Edwards, Inc. Medical personnel performed statistical analysis and assisted in the preparation of the data.

Presented on behalf of the IDE investigative team at the AHA Scientific Sessions, November 2014
Melody Valve Outcomes (longer term)

Presented on behalf of the IDE investigative team at the AHA Scientific Sessions, November 2014
Melody Valve Outcomes (longer term)

Presented on behalf of the IDE investigative team at the AHA Scientific Sessions, November 2014
Melody Valve Outcomes (longer term)

Presented on behalf of the IDE investigative team at the AHA Scientific Sessions, November 2014
Incidence of Endocarditis

- **Endocarditis or Bacteremia** N=14
  - 2 → **TPV Dilation** N=2
    - 2
  - 3 → **Redo TPV** N=4
    - 2
  - 2 → **TPV Explant** N=3
    - 1
  - **Died** N=1
    - 1
    - Alive, No Reintervention after Endocarditis N=7

At 5 years, freedom from endocarditis was 89 ± 3%.
A total of 14 patients were reported to have definite/presumed endocarditis, and 9 were successfully managed with medical therapy alone.

Presented on behalf of the IDE investigative team at the AHA Scientific Sessions, November 2014
Melody Valve Outcomes (longer term)

Freedom From TPV Reintervention

Presented on behalf of the IDE investigative team at the AHA Scientific Sessions, November 2014
### Table 1 Summary data from published series of TPV replacement using the Melody® valve

<table>
<thead>
<tr>
<th>Author</th>
<th>No. of patients</th>
<th>Age (years)</th>
<th>Follow-up duration</th>
<th>Peak RVOT gradient (mmHg)</th>
<th>Mild or greater PR by echo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre implant</td>
<td>Post implant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre implant</td>
<td>Post implant</td>
<td>RVOT Reintervention (no. of patients)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boshoff et al. [43]</td>
<td>23</td>
<td>16.9 ± 9.7</td>
<td>1.2 ± 1.2 years</td>
<td>24.2 ± 9.6</td>
<td>7.5 ± 4.3</td>
</tr>
<tr>
<td>Butera et al. [11]</td>
<td>63</td>
<td>24 (11–65)</td>
<td>2.5 years (14)</td>
<td>45 (35–75)</td>
<td>10 (0–30)</td>
</tr>
<tr>
<td>Demkow et al. [22]</td>
<td>10</td>
<td>26.8 ± 4.0</td>
<td>6 months</td>
<td>80.6 ± 22.7</td>
<td>38.8 ± 10.4</td>
</tr>
<tr>
<td>Gillespie et al. [40]</td>
<td>104</td>
<td>26 (3–63)</td>
<td>12 months (1–46)</td>
<td>38.7 ± 16.3</td>
<td>10.9 ± 3.7</td>
</tr>
<tr>
<td>Lurz et al. [8]</td>
<td>155</td>
<td>21.2 (7–71)</td>
<td>28.4 months (0–83.7)</td>
<td>37.2 ± 20</td>
<td>17 ± 10</td>
</tr>
<tr>
<td>Martins et al. [21]</td>
<td>7</td>
<td>9-32</td>
<td>7.8 months (2.8–10.1)</td>
<td>65 ± 28</td>
<td>11 ± 4</td>
</tr>
<tr>
<td>McElhinney et al. [9]</td>
<td>136</td>
<td>19 (7–53)</td>
<td>6 months (0–30)</td>
<td>35.6 ± 15.8</td>
<td>14.4 ± 5.7</td>
</tr>
<tr>
<td>Vezmar et al. [31]</td>
<td>28</td>
<td>14.9 (10.9–19)</td>
<td>27.6 months (0–37)</td>
<td>36 ± 15</td>
<td>12 ± 7</td>
</tr>
</tbody>
</table>

Data presented as mean ± standard deviation, median (minimum – maximum), or frequency. For centers/trials reported in multiple articles, only the most recent or complete report was included in this table.

* Echocardiographic data not reported.
Melody Valve cases
Pre-procedural imaging

• ECHO is good, but......

• MRI is preferred (especially in adult patients with poor acoustic windows)
  • Detailed information on RVOT dimensions
  • Branch PA anatomy, coronary anatomy
  • RV volumes, Ejection fractions, regurgitant fractions
Supplies

• Vascular Access
  – Venous: up to 22Fr (+/- Preclosure?)
  – Arterial (BP monitoring, coronary angiography)

• Wires
  – “Stiff” guidewire
    • Lunderquist 0.035”

• Balloons and stents

• Conduit preparation
  • Predilate, prestent and check coronaries
  • Be prepared to deal with conduit fracture /rupture (covered stents)
Case #1:
Summary: indication = Severe PI

- 21-year-old male
- ToF pulmonary atresia, MAPCAS
- Infancy - ToF repair = Unifocalization + RV-PA conduit
- 6 years - RV-PA conduit revision - 20 mm pulmonary homograft
- Pulmonary hypertension
- 11 years – RV-PA conduit revision - 24 mm pulmonary homograft
- 13 years – RPA stent
- 21 years – presents to cathlab after ECHO and MRI show severe PI
- Numerous catheterizations for branch PA interventions
Case #1: PI and dilated RV

MRI data:
RVEDV = 150cc/m²
PRF% = 35%
Case #1: Baseline Angiography

AP-cranial view

Lateral view
Case #1: Balloon sizing / predilation

AP-cranial view

Lateral view
Case #1: Sighting Injection

Melody valve

AP-cranial view  Lateral view
Case #1: Melody Valve Deployment

AP-cranial view

Lateral view
Case #1: Post implant angiography

Residual leak??

RAO-cranial view

LAO view
Case #1: Post implant ICE

Residual leak?

Melody valve

Intracardiac ECHO (ICE) images

RV

MPA
Case #1: ICE with color doppler

Intracardiac ECHO (ICE) images

...catheter through valve

Residual leak, but.....
Case #1

Trivial central PI

Intracardiac ECHO (ICE) images
Case #1: 1-year Follow up

Stable device position.
No fractures.
Case 2
Case 2

• Diagnosis
  – Double Outlet Right Ventricle with subpulmonic VSD

• Surgical Repair
  – Pulmonary artery banding (9 days)
  – Rastelli repair with DKS anastomosis (6 mo)
  – revision of DKS with 17mm pulmonary allograft (3 yo)

• Interventional Catheterizations
  – Balloon atrial septostomy (2 days old)
  – RPA dilation; RV-PA conduit gradient ~40mmHg* (5yo)
Case #2: Summary

- 9-year-old
- PMHx significant for 3 prior conduit revisions
- Moderate PS and PI
- 17 mm homograft
Case #2: Baseline angiography

AP-cranial view  Lateral view
Case #2: Baseline angiography

AP-cranial view

Lateral view
Case #2: “Pre-stenting” of RV-PA conduit

AP-cranial view

“pre-stenting” x2

Lateral view
Case #2: Melody Deployment
Case #2: High pressure balloon dilation

AP-cranial view

Lateral view
Case #2: post implant angiography

Post intervention

AP-cranial view

Lateral view
Case #2: No PI and improved diameter of conduit

AP-cranial view

Lateral view
Case #2: Follow up

Multiple fractures in Melody stent

9-month follow-up
Case #2: follow up

9-month follow-up

front-to-back compression of Melody valve

9-month follow-up
Case #2

9-month follow-up

Competent valve despite fractures
Coronary Compression
Coronary Compression
“Off Label” Melody Valve in pulmonary position
Melody Valve Implant Within Failed Bioprosthetic Valves in the Pulmonary Position
A Multicenter Experience

Matthew J. Gillespie, MD; Jonathan J. Rome, MD; Daniel S. Levi, MD; Ryan J. Williams, BS; John F. Rhodes, MD; John P. Cheatham, MD; William E. Hellenbrand, MD; Thomas K. Jones, MD; Julic A. Vincent, MD; Evan M. Zahn, MD; Doff B. McElhinney, MD

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 in 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;00:00-00.)

Key Words: adult congenital heart disease ■ bioprosthetic valve ■ percutaneous pulmonary valve implantation ■ percutaneous valve replacement ■ tetralogy of Fallot ■ valvular regurgitation
Meldoy-in-BPV
Who is eligible for PPVI? (patient population?)

Anomalies of the RVOT

- Tetralogy of Fallot
- Anomalies of the RVOT
  - Tetralogy of Fallot
  - Truncus Arteriosus
  - Transposition Great Arteries
  - Others

With Pulmonary Stenosis
- Surgical correction of outflow tract – non-conduit

With Pulmonary Atresia
- RV–PA Conduit
- Virtually all patient will require future procedure(s) to replace the conduit and / or pulmonary valve

~ 85% of all RVOT Pts.

~ 15% of RVOT Patients

**Chart courtesy of Medtronic Inc.**
models that were used to customise and test the device, which was subsequently implanted into the patient. Following the procedure, the clinical, haemodynamic and morphological success of this approach was determined.

The new device was safely and successfully implanted as predicted by the pre-procedural modelling. There was excellent device stability, no stent fractures, no pulmonary incompetence and only trivial para-device leak at six months follow-up. The patient described marked symptomatic improvement.

Conclusions: Safe, effective percutaneous pulmonary valve implantation is possible in a patient with a dilated, native pulmonary trunk. Our methodologies, which have evolved as a direct result of recent advances in four-dimensional imaging techniques, challenge the conventional stepwise pathway of bench and animal testing prior to human application, and may be safer and more relevant, potentially reducing the number of animal experiments necessary for testing new medical devices.
Other potential strategies

- **Hypothesis**: Implantation of Melody Valves into the proximal right and left branch pulmonary arteries would reduce pulmonary regurgitation fraction (PRF) in patients s/p TAP repair for ToF.
Preclinical study: Aims

1. Develop and animal model that reproducibly mimicks postoperative ToF with dilated RVOT

2. Demonstrate that bilateral branch PA valve implantation was feasible

3. Evaluate the impact of bilateral Melody valve implantation on
   • Pulmonary Regurgitant Fraction (PRF)
   • Right (and left) ventricular size and function
Results: Angiography

- RUL
- MPA
- RPA Melody Valve
- LPA Melody Valve
- sheep
Results: Angiography

RPA Melody Valve

LPA Melody Valve

sheep
Results: MRI

RUL

RPA Melody Valve

sheep

LPA Melody Valve

Melody Valve Group

RPA

LPA

RUL

MPA

Patch
Melody Valve Implantation Into the Branch Pulmonary Arteries for Treatment of Pulmonary Insufficiency in an Ovine Model of Right Ventricular Outflow Tract Dysfunction Following Tetralogy of Fallot Repair

J. Daniel Robb, MBBS, MRCP, MRCS*; Matthew A. Harris, MD*; Masahito Minakawa, MD, PhD; Evelio Rodriguez, MD; Kevin J. Koomalsingh, MD; Takashi Shuto, MD; David C. Shin, BA; Yoav Dori, MD; Andrew C. Glatz, MD; Jonathan J. Rome, MD; Robert C. Gorman, MD; Joseph H. Gorman III, MD; Matthew J. Gillespie, MD

Background—Transannular patch (TAP) repair of tetralogy of Fallot often results in significant right ventricular outflow tract (RVOT) dilation and distortion. We hypothesized that insertion of Melody valves into the proximal right and left branch pulmonary arteries (PAs) would reduce pulmonary regurgitation fraction (PRF) in an ovine model of pulmonary insufficiency and diluted RVOT.

Methods and Results—Ten sheep underwent baseline cardiac catheterization, surgical pulmonary valvectomy, and TAP placement. A subset (n=5) had Melody valves (2 devices per animal) inserted into the proximal right and left PAs during the surgical procedure. Melody valves were placed distal to the right-upper-lobe (RUL) artery branch, leaving the RUL “unprotected.” Preoperative MRIs (n=5) were used to determine baseline RV ejection fraction (RVEF) and left ventricular (LV) EF. All surviving animals (n=9) underwent MRI and catheterization 6 weeks postsurgery. Mean PRF was lower in the Melody valve group (15±6% versus 37±3%; P=0.014). The unprotected RUL was responsible for 64% of the PRF measured in the Melody valve group. In the non-Melody group, the RVEF was lower than baseline (P=0.003) and than in the Melody group (P=0.05). The LVEF was also lower in the non-Melody group versus baseline (P=0.004) and versus Melody (P=0.01).

Conclusions—Bilateral branch PA Melody valve implantation significantly reduced PRF and altered RV and LV function favorably in a model of TAP for tetralogy of Fallot. This novel intervention may offer potential benefit in treating patients with anatomically heterogeneous disease of the RVOT. (Circ Cardiovasc Interv. 2011;4:00-00.)

Key Words: MRI ■ heart valve prosthesis implantation ■ pulmonary heart disease ■ tetralogy of Fallot ■ pulmonary valve regurgitation ■ pulmonary valve stenosis
Conclusions from preclinical study

1. Postoperative RVOT dysfunction and distortion can be modeled
   - Platform for novel device development and testing?

2. Branch PA Melody Valve implantation is feasible and potentially beneficial

3. This may be an alternative approach to PPVI in anatomically complex patients
Bilateral Branch PA Melody Valve Implantation: 1st case

27-year-old With multiple co-morbidities and right heart failure - High risk surgical candidate
Bilateral Branch PA Melody Valve Implantation: 1st case
Bilateral Branch PA Melody Valve Implantation: 1st case
Bilateral Branch PA Melody Valve Implantation: 1st case
Bilateral Branch PA Melody Valve Implantation: 1st case
Bilateral Branch PA Melody Valve Implantation: 1st case
Conclusions

• PPVI with the Melody Valve is one of the most exciting developments in cardiology in the last decade
• PPVI has the potential to profoundly change the management of patients with RVOT dysfunction
  – Will this technology lead to earlier and earlier interventions?
  – If so, will this translate into improved heart health/function in the longterm?
• 7-year outcome data is encouraging
• Currently limited to “conduit rehabilitation” (mostly)
• Novel devices and approaches are needed for dilated/distorted RVOTs
  – Native outflow tract device coming soon....
  – Bilateral branch PA melody valve implantation (select cases)
Thank you
Case #2: PI + PS

Pre intervention

Post intervention

Lateral view