Percutaneous Valve-In-Valve Therapy

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Disclosures

• Consultant-Medtronic
  • Maker of Melody valve

• Investigator-Edwards Life Sciences
  • COMPASSION trial
    • Sapien valve in pulmonic position
Always Good Be Back At A Surgical Meeting
Background

• Transcatheter valves have now been deployed into all 4 cardiac valve positions…and then some
  • RA-PA Fontan conduits
  • Bilateral branch PA’s
  • LV apical-AO conduits
• Largest experience in CHD…right heart
  • Pulmonic
  • Tricuspid
• Continues to be tremendous interest in technical aspects surrounding pulmonary valve replacement
  • Increasing appreciation of importance of chronic pulmonary regurgitation
    • Limited lifespan of RV-PA conduits
    • Advent of percutaneous therapy
• Pulmonary valve replacement (PVR) currently represents the most frequent reoperation performed for adults with CHD*
• Bioprosthetic valves are being used with increasing frequency in the pulmonic position
  • Increasing number of survivors
  • Limited availability of homografts
  • Appealing surgical features

*Gaimberti et al, Pediatric Cardiol, 2013
Bioprosthetic Pulmonary Valves (BPV): Safety

76 patients (18-64 yrs)

Porcine Valves (27/25/23 mm)

13.5 days Median LOS

2 deaths

*Gaimberti et al, Pediatric Cardiol, 2013
Bioprosthetic Pulmonary Valves (BPV): Safety

- 170 patients (4-62yrs)
- Multiple BPV
- 2 deaths
  1.2% mortality

*Lee et al, JACC, 2012
Bioprosthetic Pulmonary Valves (BPV): Effective

Right ventricular data at 1-year control magnetic resonance imaging

<table>
<thead>
<tr>
<th>Variable</th>
<th>Preoperative (mean ± SD)</th>
<th>Postoperative (mean ± SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regurgitant fraction (%)</td>
<td>45 ± 8</td>
<td>7 ± 6</td>
<td>0.001</td>
</tr>
<tr>
<td>RVEDV (ml/m²)</td>
<td>154 ± 47</td>
<td>97 ± 34</td>
<td>0.001</td>
</tr>
<tr>
<td>RVEDV/LVEDV</td>
<td>2.34 ± 0.75</td>
<td>1.26 ± 0.49</td>
<td>0.001</td>
</tr>
</tbody>
</table>

SD standard deviation, RVEDV right ventricle end-diastolic volume, LVEDV left ventricle end-diastolic volume

*Gaimberti et al, Pediatric Cardiol, 2013
Bioprosthetic Pulmonary Valves (BPV): Longevity

*Lee et al, JACC, 2012*
BPV Modes of failure

A | Wear and tear
B | Calcification
C | Pannus
D | Endocarditis
E | Thrombus

Piazza et al, JACC, 2011
BPV Modes of failure

• Regurgitation
  o Leaflet degeneration
  o Frozen leaflet

• Stenosis
  o Calcification
  o Frozen leaflet
  o Suboptimal angle at implant
Is there a role for transcatheter pulmonary valve therapy for BPV failure?

Medtronic Melody

Edwards Sapien
Is there a role for transcatheter pulmonary valve therapy for BPV failure?

**CURRENT STATUS OF MELODY TPV IN U.S.A.**

- Melody valve received FDA HDE approval Jan ‘10
  - Restore RVOT **conduit** function
  - Prolong **conduit** lifespan and defer need for surgical **conduit** replacement

Adjunct to Surgical Management

Preserve RV function in Patients with Dysfunctional RVOT Conduits
Is there a role for transcatheter therapy for BPV failure?

CURRENT STATUS OF SAPIEN TPV IN U.S.A.

- Sapien valve in clinical trial for conduit dysfunction
  - COMPASSION
- FDA approved for use in aortic valve disease

NO TPV currently approved specifically for treatment of BPV dysfunction
Melody Transcatheter Pulmonary Valve

• Modified Contegra
  o Bovine Jugular Vein Graft
  o Thinned
• Platinum Iridium Stent
  o 28 mm length
• Single size
  o Expandable form 18-22mm
Melody Transcatheter Pulmonary Valve

- Hand-crimped
- Ensemble delivery system
  - 16-22 Fr
  - Self-sheathing
  - BIB
    - 18-22 mm
Melody Transcatheter Pulmonary Valve

• Hand-crimped
• Ensemble delivery system
  ○ 16-22 Fr
  ○ Self-sheathing
  ○ BIB
    ▪ 18-22 mm
Melody Transcatheter Pulmonary Valve

• Delivered over a guide wire via
  o Femoral vein
  o Jugular vein
  o Trans-ventricular
  o Surgically
Is there a role for TPV therapy for BPV failure?

• >4,000 Melody implants worldwide
• Majority of implants within conduits
• Increasing experience with “off-label” uses
  o Particularly valve-in-valve
• Some think this may in fact be the “ideal” substrate for this therapy
“Ideal” Substrate for TPVR

• Identifiable landing zone
  • Visible
  • Rigid
  • Predictable response
• Limited risk coronary compression
• Limited risk of outflow tract disruption
• Limited risk of TPV stent fracture
What interventional cardiologists need to know before undertaking this

• Detailed “anatomy” of the BPV
  o ID at ring
  o ID at posts
  o Valve height
  o Leaflet material
• BPV visibility
  o What are you looking at on fluoro?
• Where is your target?
• What will be your resultant ID after Melody

<table>
<thead>
<tr>
<th>A: 31mm</th>
<th>E: 15mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>F: 20mm</td>
<td></td>
</tr>
</tbody>
</table>
Cardiologists Need to Know BPV: Valve Materials

- CE Perimount
- CE Perimount Magna
- CE Perimount Magna Ease
- Sorin Mitroflow
- Medtronic Hancock II
- Medtronic Mosaic
- CE Porcine SAV
- Biocor
- Edwards Prima Plus
- Medtronic Freestyle
- St. Jude Toronto SPV
- Sorin Freedom
Cardiologists Need to Know BPV: Structure
Cardiologists Need to Know BPV: Fluoroscopic Appearance
Know Your Melody Valve

- Detailed understanding of Melody TPV
  - ID vs OD
    - 18----20 mm
    - 20---22 mm
    - 22---24 mm
    - 24---26 mm
- Height - 28 mm out of the jar...longer with crimping
  - Shortening with implant
    - 22-26 mm
Know Your Valve!

Numbers Can Be Deceiving

Manufacturers Size Usually Refers to Outer Base Ring Diameter

**Specifications: Mosaic® Aortic Valve, Model 305**

The scalloped aortic suture ring and stent simulate the natural aortic annulus and enable implantation in either the supra-annular or intra-annular position.

<table>
<thead>
<tr>
<th>Valve Size (Stent O.D.*) (A)</th>
<th>Orifice Diameter (Stent I.D.) (B)</th>
<th>Suture Ring Diameter (C)</th>
<th>Valve Height (D)</th>
<th>Aortic Protrusion (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(±0.5 mm)</td>
<td>(±0.5 mm)</td>
<td>(±1 mm)</td>
<td>(±0.5 mm)</td>
<td>(±0.5 mm)</td>
</tr>
<tr>
<td>19</td>
<td>17.5</td>
<td>25.0</td>
<td>13.5</td>
<td>11.0</td>
</tr>
<tr>
<td>21</td>
<td>18.5</td>
<td>27.0</td>
<td>15.0</td>
<td>12.0</td>
</tr>
<tr>
<td>23</td>
<td>20.5</td>
<td>30.0</td>
<td>16.0</td>
<td>13.5</td>
</tr>
<tr>
<td>25</td>
<td>22.5</td>
<td>33.0</td>
<td>17.5</td>
<td>15.0</td>
</tr>
<tr>
<td>27</td>
<td>24.0</td>
<td>36.0</td>
<td>18.5</td>
<td>15.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>39.0</td>
<td>20.0</td>
<td>16.0</td>
</tr>
</tbody>
</table>

*nominal values, in millimeters*

*Equivalent to annulus diameter
Know Your Valve: Size
Internal Diameter vs. Manufacturers' labelled

Tissue Valves

24 B.I.B. + Melody O.D. = 26mm
Know Your Valve!

Understand the Structure
Valve in Valve
Anchor on the Ring NOT the Crown!
Valve in Valve

Anchor on the **Ring** NOT the Crown!
Stenting the Leaflets and Crown: Not Good
Procedural Details

• Usual right heart protocol to start
  ◦ RV-PA gradient
  ◦ Angiography
    ▪ Typically unhelpful
  ◦ Coronary assessment
• Balloon dilate/sizing
  ◦ High pressure
• Implant Melody
• Other interventions
• Usual right heart protocol to start
  o RV-PA gradient
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• Balloon dilate/sizing
  ◦ High pressure

• Implant Melody

• Other interventions
TP Valve-in-Valve: Pulmonic Experience to Date

Circulation: Cardiovascular Interventions

Melody® Valve Implant Within Failed Bioprosthetic Valves in the Pulmonary Position: A Multicenter Experience
CIRCCVINT/2012/972216
Melody Valve-in-Valve: Pulmonic Experience to Date

• Retrospective analysis
• 8 centers
• April 2007-Jan 2012
• Excluded
  o Any type of conduit implant
  o TPB in other BPV position
Melody Valve-in-Valve: Demographic data

104 pts
Intent to treat

100
Implanted

4
Excluded

26 y (3-63)
Median age

9.1 y (0.6-33)
Median time from surgery

3-unsuitable anatomy
1- coronary compression
Melody Valve-in-Valve: Demographic data

<table>
<thead>
<tr>
<th>Table 1 Demographic and anatomic data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
</tr>
</tbody>
</table>

**Underlying anatomy**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetralogy of Fallot</td>
<td>77 (74%)</td>
</tr>
<tr>
<td>Truncus arteriosus</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>Pulmonary Stenosis</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>d-transposition of the great arteries</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>Aortic Stenosis (prior Ross procedure)</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>Double-outlet right ventricle</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (4%)</td>
</tr>
</tbody>
</table>

**Bioprosthetic valve type**

<table>
<thead>
<tr>
<th>Type</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpentier-Edwards Perimount</td>
<td>38 (37%)</td>
</tr>
<tr>
<td>Medtronic Hancock Conduit</td>
<td>38 (37%)</td>
</tr>
<tr>
<td>Medtronic Mosaic</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>Medtronic Hancock 2</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>Medtronic Freestyle</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>Sorin Mitroflow</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Carpentier-Edwards Aortic porcine</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>St Jude Biocor</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Ionescu-Shiley</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>St Jude Epic</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

**Bioprosthetic valve Size (mm)**

| Size (mm) | 23 (16.29) |

**Bioprosthetic valve age (years)**

| Age (years) | 9.1 (0.6 – 33) |

*Data are presented as median (minimum-maximum) or frequency (% of the entire 104 patient cohort)*
Melody Valve-in-Valve: Demographic data

<table>
<thead>
<tr>
<th>Indication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stenosis</td>
<td>19 (18%)</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>37 (35%)</td>
</tr>
<tr>
<td>Both</td>
<td>49 (47%)</td>
</tr>
</tbody>
</table>
Melody Valve-in-Valve: Procedural data

• Balloon dilation/sizing
  • 85% of cases
• Balloon waist
  • 5 mm (1-12.8 mm) < manufacturer #
• Pre-stenting
  • 20%
• Additional interventions
  • 10%
Melody Valve-in-Valve: Results

- Deployment success: 100%
- Mortality: 0
- Gradient reduction
  - 38.7 mmHg → 10.9 mmHg
- RVPsys reduction
  - 71.6 mmHg → 46.7 mmHg
Melody Valve-in-Valve: Follow-up 95 (91%) pts; 12 months

- 2 late deaths unrelated to Melody
  - Sepsis post-op aortic root replacement
  - Respiratory failure
Melody Valve-in-Valve: Follow-up 95 (91%) pts; 12 months

- Endocarditis 2
  - 12 and 18 months post TPV
  - Uneventful surgical explant
- Elective surgical removal 1
  - Supra-valve and PA stenosis
  - Surgical RVOT reconstruction
- Stent fracture 2
  - Hancock conduit sternal compression
  - Fractured CE Perimount

Neither pre-stented, both good TPV function
Melody Valve-in-Valve:
Follow-up 95 (91%) pts; 12 months

TPV Fracture in BPV
Melody Valve-in-Valve:
Follow-up 95 (91%) pts; 12 months

Figure 5

Freedom from stent fracture 98±2% 1 yr, 95±3% 2 yr

Freedom from explant 97±2% 1 yr, 92±5% 2 yr
Melody Valve-in-Valve: Follow-up 95 (91%) pts; 12 months

<table>
<thead>
<tr>
<th>Pulmonary regurgitation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>75 (79%)</td>
</tr>
<tr>
<td>Trivial or mild</td>
<td>20 (21%)</td>
</tr>
<tr>
<td>Moderate or severe</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RVOT gradient (mmHg)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum instantaneous gradient</td>
<td>23 (0 – 66)</td>
</tr>
<tr>
<td>Mean gradient</td>
<td>13 (0 – 46)</td>
</tr>
</tbody>
</table>

Table 4. Follow up echocardiographic data (n=95)

Data are presented as median (minimum-maximum) or frequency (% of the entire 104 patient cohort).

Median follow up duration 12 months
Conclusions

- Melody valve-in valve can be accomplished with
  - High success rate
  - Low procedural mortality/morbidity
  - Excellent short-term results
- More data and longer follow-up needed
- Early results are encouraging
Final Opinions

- BPV may prove to be the ultimate platform for future TPV implant
- Working together, using a thoughtful planned approach, cardiac surgeons and interventional cardiologists may be able to greatly increase the interval between operations thereby reducing the cumulative lifetime morbidity these patients must endure
The Congenital Heart Program at Cedars-Sinai