One Year Follow-up of the Melody™ Transcatheter Pulmonary Valve Multicenter Post-Approval Study

Aimee K. Armstrong, MD¹, David Balzer, MD², Allison Cabalka³, MD, Robert Gray, MD⁴, Alexander Javois, MD⁵, Jacqueline Kreutzer, MD⁶, John Moore, MD⁷, Jonathan Rome, MD⁸, Daniel Turner, MD⁹, Thomas Zellers, MD¹⁰

¹University of Michigan, ²St. Louis Children’s Hospital, ³Mayo Clinic Rochester, ⁴University of Utah, ⁵Hope Children’s Hospital, ⁶University of Pittsburgh Medical Center, ⁷Rady Children’s Hospital, ⁸Children’s Hospital of Philadelphia, ⁹Children’s Hospital of Michigan, ¹⁰Children’s Medical Center Dallas
Disclosures

Aimee K. Armstrong, MD

- **Medtronic**: Research/Research Grants
- **Edwards Lifesciences**: Research/Research Grants
- **Siemens Healthcare AX**: Consultant Fees/Honoraria
- **St. Jude Medical**: Consultant Fees/Honoraria
Melody™ Transcatheter Pulmonary Valve (TPV) is approved as a Humanitarian Use Device.

Authorized by Federal law (USA) for use in pediatric and adult patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (≥ 16 mm in diameter when originally implanted).

The effectiveness of this device for this use has not been demonstrated.
RV-PA Conduits
Congenital Heart Defects

- Tetralogy of Fallot
  - Pulmonary Stenosis
  - Pulmonary Atresia
    - Transannular patch

- Truncus Arteriosus
- D-TGA, VSD, PS
- Others

- RV–PA Conduit

\( \sim 15\% \) of RVOT Patients

\( \sim 85\% \) of RVOT Patients
RV-PA Conduit Dysfunction
Melody™ TPV

• Designed to:
  – Delay the time until surgical RV-PA conduit replacement is needed
  – Reduce the total number of open heart surgeries over a patient’s lifetime
Melody™ TPV

- Bovine Jugular Vein Valve
- Platinum Iridium Frame
  - Expandable to 18mm, 20mm or 22mm
- Delivered on the Ensemble® Delivery System
  - 22Fr Balloon-in-Balloon (BIB) catheter
- FDA Approval with HDE designation in 2010
Melody TPV Post-Approval Study

Objective

• To confirm that short-term hemodynamic effectiveness of the Melody TPV achieved by real-world providers is equivalent to the historical results established in the five-center IDE trial
Endpoints

• Primary Endpoint
  – Acceptable hemodynamic function at 6 months post-implant
    • RVOT echocardiographic mean gradient ≤ 30 mmHg
    • Regurgitation < moderate by echocardiogram
    • Freedom from conduit reintervention and reoperation

• Secondary Endpoints
  – Procedural success
  – Freedom from serious adverse events
  – Freedom from TPV dysfunction
Methods

• Prospective, non-randomized, 10-center study
• Patients with a stenotic and/or regurgitant conduit
  – ≥ 16 mm at implantation
• No weight or age limit
• Planned 5-year follow-up
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>19.9 ± 9.7</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>59.4 ± 21.7</td>
</tr>
<tr>
<td>RVOT Mean Gradient (mmHg)</td>
<td>34.6 ± 14.5</td>
</tr>
<tr>
<td>Primary Indication (%)</td>
<td></td>
</tr>
<tr>
<td>Stenotic</td>
<td>20.8</td>
</tr>
<tr>
<td>Regurgitant</td>
<td>47.5</td>
</tr>
<tr>
<td>Mixed</td>
<td>31.7</td>
</tr>
</tbody>
</table>
Subject Disposition

120 Patients

101 Attempted

100 Implanted

99 Implanted >24 Hours

1 Implant aborted due to pulmonary hemorrhage

19 Not Attempted

1 surgical removal ≤24 hours due to coronary compression

98% Procedural Success:
- Peak cath gradient <35 mmHg
- No more than mild regurgitation

Follow-up: 22 ±18.9 months
Primary Endpoint

6-month Acceptable Hemodynamic Function

- Implant Cohort with Evaluable Data (N=90): 96.7% (p<0.01)
- Implant Cohort (N=99): 87.9% (p<0.01)

Performance Goal: 75%

MELODY™ TPV
Post-Approval Study
One Year Acceptable Hemodynamic Function

- Implant Cohort with Evaluable Data (N=87): 94.3%
- Implant Cohort (N=99): 82.8%
Pulmonary Regurgitation

Percentage of Patients

Baseline (N=100)

Discharge (N=99)

6 Months (N=94)

1 Year (N=90)

Severe

Moderate

Mild

Trace

None

0%

100%

20%

40%

60%

80%

100%
Freedom from TPV Dysfunction, Reoperation, and Reintervention

IDE Trial: 93.5± 2.4% at 1 year

Number At Risk

<table>
<thead>
<tr>
<th>Months Post-Implant</th>
<th>TLV Dysfunction</th>
<th>Reoperation</th>
<th>Catheter Reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>99.0%</td>
<td>98.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>11</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>10</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>9</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>8</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>7</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>6</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>5</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>4</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>3</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>2</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>1</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
<tr>
<td>0</td>
<td>98.0%</td>
<td>98.0%</td>
<td>96.9%</td>
</tr>
</tbody>
</table>
Complications

• Serious Adverse Events
  – Procedural: 16 of 120 patients (13.3%)
    • Confined conduit tear (n=6)
      – All resolved with covered stent
    • Vascular complications (n=4)
    • Other adverse events included coronary compression, distal PA perforation, arrhythmia, fever, paravalvular leak, and pulmonary edema
  – In First Year: 8 of 99 implants >24 hours (8.1%)
    • Endocarditis (n=3), 1 with reoperation
    • Sepsis (n=1)
    • Major stent fracture requiring reoperation (n=1)
    • Pulmonary embolism (n=1)
    • Arrhythmia / palpitations (n=2)
Conclusions

- This study confirms the strong performance of the Melody TPV achieved by real-world providers with results comparable to the US IDE trial
  - Excellent hemodynamic function at 6 months (96.7%)
  - High Procedural Success (98.0%)
  - Serious Adverse Events:
    - Procedural: 13.3%
    - First year: 8.1%
  - High freedom from TPV dysfunction at 1 year (96.9%)