Pulmonary Valve Implantation, current indications, what is new

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Congenital Cardiac Diagnoses

>20% of CHD lesions affect the RVOT

~20% repaired with conduit*

~80% repaired without conduit
Residual Lesions in TOF


The Bottom Line

Risks > Benefits

Risks ≈ Benefits

Risks < Benefits

Indications for conduit replacement (RVOT dysfunction)

- No formal guidelines regarding timing of sub-pulmonary conduit replacement

- Class IIa (LOE B):
  - It is reasonable to consider trans-catheter pulmonary valve replacement (TPVR) in the patient with ≥ moderate PR or PS provided the patient meets TPV IFU criteria

Indications for **Surgical** PVR in TOF

- Class I: Severe symptomatic PR or PS
  - Exercise intolerance otherwise not explained
  - Signs/Symptoms of heart failure
  - Syncope attributable to arrhythmia

Irreversible RV dysfunction is *generally* present by the time symptoms develop


<table>
<thead>
<tr>
<th>Criteria</th>
<th>AHA</th>
<th>ESC</th>
<th>CCS</th>
<th>Geva</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVEDvi</td>
<td>≥Moderate</td>
<td>&gt;160mL/m2</td>
<td>&gt;170mL/m2</td>
<td>&gt;150mL/m2 or Z-score &gt;4 or RV/LV end-diastolic volume ratio &gt;2</td>
</tr>
<tr>
<td>RVESVi</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>&gt;80mL/m2</td>
</tr>
<tr>
<td>RV function</td>
<td>≥Moderate RV dysfunction</td>
<td>Progressive RV dysfunction</td>
<td>≥Moderate RV dysfunction</td>
<td>RV EF &lt;47%</td>
</tr>
<tr>
<td>RVOT obstruction</td>
<td>PIG ≥50mmHg or RV/LV pressure ratio ≥0.7</td>
<td>PIG ≥80mmHg (4.3m/s)</td>
<td>RV systolic pressure ≥2/3 systemic pressure</td>
<td>RV systolic pressure ≥2/3 systemic pressure</td>
</tr>
<tr>
<td>PR</td>
<td>Severe</td>
<td>Severe</td>
<td>Free</td>
<td>≥Moderate (PRF≥25%)</td>
</tr>
<tr>
<td>TR</td>
<td>≥Moderate</td>
<td>≥Moderate</td>
<td>“Important”</td>
<td>≥Moderate</td>
</tr>
<tr>
<td>QRS duration</td>
<td>Not specified</td>
<td>&gt;180msec</td>
<td>Not specified</td>
<td>&gt;140msec</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>Symptomatic or sustained AT or VT</td>
<td>Sustained AT or VT</td>
<td>AT or VT</td>
<td>Sustained tachyarrhythmia</td>
</tr>
<tr>
<td>Surgical considerations</td>
<td>Significant residual VSD or AR</td>
<td>Not specified</td>
<td>Significant residual VSD</td>
<td>LV EF &lt;55%, large RVOT aneurysm, severe branch pulmonary artery stenosis, significant residual left-to-right shunt, severe AR or aortic dilation</td>
</tr>
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</table>
What is the real value of PPVI

**Transcatheter Pulmonary Valve Implantation: A Comprehensive Systematic Review and Meta-Analyses of Observational Studies**

**Background**—Transcatheter pulmonary valve implantation is approved for the treatment of dysfunctional right ventricle to pulmonary artery conduits. However, the literature is limited because of a small patient population, and it does not reflect changing procedural practice patterns over the last decade.

**Methods and Results**—A comprehensive search of Medline and Scopus databases from inception through August 31, 2016 was conducted using prespecified criteria. We included studies reporting transcatheter pulmonary valve implantation in at least 5 patients with a follow-up duration of 6 months or more. In 19 eligible studies, 1045 patients underwent transcatheter pulmonary valve implantation with a pooled follow-up of 2271 person-years. Procedural success rate was 94.2% (95% confidence interval [CI], 91.6–96.7%) with a conduit rupture rate of 4.1% (95% CI, 2.3–6.1%) and a target valve complication rate of 1.2% (95% CI, 0.7–2.2%). Incidence of reintervention was 4.6 per 100 person-years overall (95% CI, 3.0–6.9) with a marked reduction in studies reporting ≥75% presenting (0.9 per 100 person-years [95% CI, 1.5–3.3]) versus ≤50% presenting (5.6 per 100 person-years [95% CI, 4.6–8.5]; P=0.01). Pooled endocarditis rate was 1.4 per 100 person-years (95% CI, 0.4–5.2).

**Conclusions**—Our study provides favorable updated estimates of procedural and follow-up outcomes after transcatheter pulmonary valve implantation. Widespread adoption of prostenting has improved long-term outcomes in these patients. (J Am Heart Assoc. 2017;6:e006432. DOI: 10.1161/JAHA.117.006432.)

**Key Words:** endocarditis - Melody valve - reintervention - transcatheter pulmonary valve

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<table>
<thead>
<tr>
<th>Parameter</th>
<th>No. of Studies</th>
<th>Events/100PY</th>
<th>Lower CI</th>
<th>Upper CI</th>
<th>n²</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>19</td>
<td>0.6</td>
<td>0.3</td>
<td>0.9</td>
<td>0.0</td>
<td>0.95</td>
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<tr>
<td>Stent fracture</td>
<td>14</td>
<td>4.4</td>
<td>2.4</td>
<td>6.3</td>
<td>797</td>
<td>0.00</td>
</tr>
<tr>
<td>Type 2/3 stent fracture</td>
<td>15</td>
<td>1.3</td>
<td>0.5</td>
<td>2.0</td>
<td>533</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Patients requiring reintervention</td>
<td>19</td>
<td>4.1</td>
<td>3.0</td>
<td>5.0</td>
<td>514</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Celluler re-interventions</td>
<td>19</td>
<td>2.7</td>
<td>1.7</td>
<td>3.7</td>
<td>447</td>
<td>0.02</td>
</tr>
<tr>
<td>Surgical reinterventions</td>
<td>19</td>
<td>1.7</td>
<td>1.2</td>
<td>2.2</td>
<td>0.0</td>
<td>0.56</td>
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<tr>
<td>Endocarditis</td>
<td>19</td>
<td>0.8</td>
<td>0.9</td>
<td>0.0</td>
<td>119</td>
<td>0.31</td>
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<tr>
<td>PPV specific endocarditis</td>
<td>19</td>
<td>0.6</td>
<td>0.3</td>
<td>0.9</td>
<td>0.0</td>
<td>0.70</td>
</tr>
<tr>
<td>Endocarditis requiring explantation/death/reintervention</td>
<td>19</td>
<td>0.6</td>
<td>0.3</td>
<td>0.9</td>
<td>0</td>
<td>0.88</td>
</tr>
</tbody>
</table>

Effect of prosthenting

- Stent fracture: >75% prosthenting 8, 2.3; <75% prosthenting 5, 7.2; Type 2/3 stent fracture: >75% prosthenting 9, 0.8; <75% prosthenting 5, 2.3.
- Patients requiring reintervention: >75% prosthenting 12, 2.9; <75% prosthenting 6, 6.5.
- Celluler reinterventions: >75% prosthenting 12, 1.5; <75% prosthenting 6, 4.4.
- Surgical reinterventions: >75% prosthenting 12, 1.3; <75% prosthenting 6, 2.2.
Systematic review and meta-analyses pooling studies reporting TPVI outcomes on conduit as well as non-conduit RVOTs with Melody and Edwards THV systems

- TPVI was found to have an **outstanding procedural success rate** with an acceptable complication profile and low need for surgical conversion.

- lower rates of infective endocarditis and TPV-related endocarditis

- More experience needs to be gained with non-conduit RVOT TPVI procedures as well as with using the newer generations of Edwards Sapien XT and Sapien 3 systems to draw concrete conclusions about the same

Journal of the American Heart Association. 2017;6:e006432
Originally published August 4, 2017

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<tr>
<th>Indications for Melody TPVR</th>
<th>Indications for Sapien XT/3 TPVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of circumferential RVOT conduit ≥ 16 mm &lt; 24 mm at implantation and RVOT dysfunction</td>
<td>RVOT conduit &gt; 18 mm/ &lt; 32 mm</td>
</tr>
<tr>
<td>Pulmonary regurgitation</td>
<td>Presence of a dysfunctional non-compliant RVOT conduit</td>
</tr>
<tr>
<td>≥ Moderate PR</td>
<td>Pulmonary regurgitation</td>
</tr>
<tr>
<td>Pulmonary stenosis</td>
<td>≥ moderate PR</td>
</tr>
<tr>
<td>RVOT mean gradient (echo) ≥ 35 mmHg</td>
<td>Pulmonary stenosis</td>
</tr>
<tr>
<td>Mixed PR/PS:</td>
<td>Mean RVOT gradient (echo) ≥ 35 mmHg</td>
</tr>
<tr>
<td>One criteria from each category</td>
<td>Kenny D et al. J Am Coll Cardiol 2011;58:2248-2256.</td>
</tr>
</tbody>
</table>

Melody™
Transcatheter Pulmonary Valve (TPV)

Designed specifically for pulmonic

- Natural Bovine Jugular Vein Valve
  - Indicated for re-expansion from 18mm to 22mm

- Platinum Iridium Frame
  - 28mm length when expanded to 18mm
  - Crimped down to 6mm on delivery system

BASELINE VENTRICULOGRAPHY
POST IMPLANTATION PULMONARY ANGIOGRAPHY

Sapien 3

Sapien XT

Sapien 3
Baseline Pulmonary Angiography

Why we do this step
Final pulmonary angiography

Indications for TPV Therapy Clinical Scenarios in Patients with PR

• Meets threshold for surgical PVR, needs a valve
  • Good candidate for TPV
  • Poor candidate for surgery ???

• Does not meet threshold for surgical PVR
  • Symptomatic
  • Asymptomatic
    • Silent symptoms
    • Asymptomatic with RV dysfunction
      • At rest
      • With exercise/pharmacologic stress
  • Prophylactic (protect RV) ??
Take home message

• RV-PA conduit and “native” RVOT repairs are distinct

• Different anatomy and pathophysiology
  • “Native” RVOT: Predominant PR
  • RV-PA Conduit: Predominant PS or Mixed

• Guidelines specific to TPVR are lacking

• Timing of PVR may be a moving target

• Very good outcome of PPVI by available valves and waiting for more

THANK YOU FOR YOUR ATTENTION