Update On Transcatheter Pulmonary Valve Replacement

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Disclosures

None
Pulmonary Regurgitation

- 23% of Congenital Heart Disease has abnormality of the RVOT (usually stenosis) relieved by surgical patch or conduit between the right ventricle and pulmonary artery. Eg: Tetralogy of Fallot, Truncus Arteriosus, Transposition of Great Arteries with VSD.
Long Term Sequale of Patch vs. Conduit Repairs

**Patch**
- RV dilation
- Systolic and Diastolic Dysfunction
- Arrhythmias

**Conduit**
- RV hypertrophy
- Diastolic Dysfunction
- Arrhythmias

REGURGITATION

STENOSIS (and regurgitation)
Surgical Pulmonary Valve Replacement

- Patients can be treated surgically for conduit / pulmonary valve replacement but risks and difficulties of repeated surgeries

- Boston Children’s 2003 paper
  - 254 surgical pulmonary valve replacements
  - Patient age 10-21 years
  - Early Mortality 0.7%
  - Periop Strokes 2%
  - Early reoperation (bleeding) 3%
  - Overall SAE 7.9%
Transcatheter Pulmonary Valve Replacement - History

- In 2000, Philipp Bonhoeffer in Paris, France reported the first-in-man replacement of a pulmonary valve in a regurgitant conduit using a catheter-based system
- The original design has undergone a few revisions, and the work purchased by Medtronic
- The valve is now called Melody and the delivery system Ensemble
- HDE approval was granted for the Melody valve in conduits December 2010 - first FDA approved transcatheter valve!
- Valve-in-valve FDA approval March 2017
Melody Valve and Ensemble Delivery System

- Bovine interval jugular vein valve mounted on platinum-iridium stent
- Balloon-in-Balloon stent delivery catheter with “carrot” and protective outer sheath to allow single-pass delivery
- 3 sizes 18, 20, 22mm balloons
Transcatheter Pulmonary Valve Replacement - History

- March 2016 Edwards Sapien XT valve FDA approved for pulmonary conduits
- 20 23 26 29 mm sizes
- NB: Sapien S3 valve being used “off-label”
<table>
<thead>
<tr>
<th></th>
<th>Aortic</th>
<th>Pulmonary</th>
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<tbody>
<tr>
<td>Indication</td>
<td>Stenosis</td>
<td>Regurg and Stenosis</td>
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<tr>
<td>Disease</td>
<td>Degenerative</td>
<td>Congenital</td>
</tr>
<tr>
<td>Etiology</td>
<td>Degenerative</td>
<td>Iatrogenic!</td>
</tr>
<tr>
<td>Age</td>
<td>Older adult</td>
<td>Children - Adult</td>
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<tr>
<td>Annulus compliance</td>
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<td>Very compliant</td>
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<tr>
<td>Pre-stenting</td>
<td>No</td>
<td>Always</td>
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<tr>
<td>Access</td>
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# Melody vs. Sapien

<table>
<thead>
<tr>
<th>Feature</th>
<th>Melody</th>
<th>Sapien</th>
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<tbody>
<tr>
<td>Sheath</td>
<td>22Fr</td>
<td>“18”Fr</td>
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<tr>
<td>Delivery system</td>
<td>covers valve</td>
<td>valve “bare”</td>
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<tr>
<td>Ease of delivery</td>
<td>easy</td>
<td>can be hard</td>
</tr>
<tr>
<td>Bailout</td>
<td>easy</td>
<td>can be hard</td>
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<tr>
<td>Size range</td>
<td>16mm-22mm</td>
<td>20mm-29mm</td>
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<tr>
<td>Stent rigidity</td>
<td>soft</td>
<td>rigid</td>
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<tr>
<td>Durability</td>
<td>good</td>
<td>good</td>
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<tr>
<td>Late SBE</td>
<td>higher</td>
<td>lower</td>
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Underlying Disease Needing TPVR - Mount Sinai Experience

- Ross: 30%
- Tetralogy: 25%
- TGA: 23%
- valvar PS: 8%
- Truncus: 8%
- Other: 6%
Age at TPVR - Mount Sinai Experience

Age at Pulmonary Valve Replacement

- Age categories: <10 yrs, 10-19 yrs, 20-29 yrs, 30-39 yrs, 40-49 yrs, 50-59 yrs, >60 yrs
- Y-axis: (n)
- X-axis: Age (yrs)
Acute Outcomes

- Multicenter (17 site) registry of 530 TPVR implants over 3 years 2014-16
- Melody 88%  Sapien 12%
- SAE 9%

Medium-Term Outcomes


13% Reinterventions
But only 6%
Unplanned for PV

5% SBE
The Future

Anomalies of the RVOT

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

- Truncus Arteriosus
  - RV-PA Conduit
- Transposition Great Arteries (TGA)
  - RV-PA Conduit
- Others
  - RV-PA Conduit

Virtually all patients will require future procedure(s) to replace the conduit and/or pulmonary valve

- ~77% of RVOT patients
- ~23% of RVOT patients
Challenges of Native RVOT

- Highly variable
- Large
- Compliant anatomy
Clinical Studies

- Medtronic Harmony
- Edwards Alterra