Transcatheter Pulmonary Valve Replacement
Update on progress and outcomes

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Transcatheter Pulmonary Valve Replacement - History

- In 2000, Philipp Bonhoeffer in Paris, France reported the first-in-man replacement of a pulmonary valve 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 December 2010 - first FDA approved transcatheter valve!
Melody Valve

- Bovine interval jugular vein valve mounted on platinum-iridium stent
- Trilealet valve with deep leaflet coaptation so remains competent over wide range of diameters
- Glutaraldehyde treated and outside vein layers removed before mounting on valve
Ensemble Delivery system

- Adaptation of NuMed Balloon-in-Balloon stent delivery catheter
- Addition of a “carrot” on the end of the catheter to allow single-pass delivery
- Addition of protective outer sheath that is withdrawn prior to balloon expansion
- 22Fr outer diameter
- 3 sizes 18, 20, 22mm balloons
Melody valve Indications

- Circumferential conduit or bioprosthetic valve with maximum inner diameter <24mm
- Stenosis > 35mmHg and/or regurgitation at least moderate
- Able to accommodate 22Fr sheath
- Now also indicated for dysfunctional surgically placed bioprosthetic valves
Edwards Sapien TPVR

- Sapien XT and Novaflex + delivery system approved for pulmonary replacement March 2016
- 3 sizes 23mm, 26mm, 29mm
Transcatheter pulmonary valve replacement timeline

- **April 2010** - HDE approval for Melody valve for dysfunctional conduits
- **January 2015** - Full FDA approval for Melody valve for dysfunctional conduits
- **March 2016** - FDA approval for Edwards Sapien XT for pulmonary valve replacement for dysfunctional conduits
- **March 2017** - Expanded approval for Melody valve for valve-in-valve pulmonary replacement
## TPVR vs. TAVR

<table>
<thead>
<tr>
<th></th>
<th>Aortic</th>
<th>Pulmonary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>stenosis</td>
<td>regurg and stenosis</td>
</tr>
<tr>
<td>Disease</td>
<td>degenerative</td>
<td>congenital</td>
</tr>
<tr>
<td>Age</td>
<td>older adult</td>
<td>children - adult</td>
</tr>
<tr>
<td>Annulus compliance</td>
<td>non compliant</td>
<td>very compliant</td>
</tr>
<tr>
<td>Valve position</td>
<td>annulus</td>
<td>conduit/surgical valve</td>
</tr>
<tr>
<td>Pre-stenting</td>
<td>no</td>
<td>always</td>
</tr>
<tr>
<td>Access</td>
<td>artery</td>
<td>vein</td>
</tr>
<tr>
<td>Stent mounting</td>
<td>backwards</td>
<td>forwards</td>
</tr>
<tr>
<td>Patient volume</td>
<td>high</td>
<td>low</td>
</tr>
<tr>
<td>Industry interest</td>
<td>high</td>
<td>low</td>
</tr>
</tbody>
</table>
# Melody vs. Sapien

<table>
<thead>
<tr>
<th></th>
<th>Melody</th>
<th>Sapien</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath</td>
<td>22Fr</td>
<td>“18”Fr</td>
</tr>
<tr>
<td>Delivery system</td>
<td>covers valve</td>
<td>valve “bare”</td>
</tr>
<tr>
<td>Ease of delivery</td>
<td>easy</td>
<td>can be hard</td>
</tr>
<tr>
<td>Size range</td>
<td>16mm-22mm</td>
<td>23mm-29mm</td>
</tr>
<tr>
<td>Stent rigidity</td>
<td>soft</td>
<td>rigid</td>
</tr>
<tr>
<td>Durability</td>
<td>good</td>
<td>good</td>
</tr>
<tr>
<td>Late SBE</td>
<td>higher</td>
<td>lower</td>
</tr>
</tbody>
</table>
Underlying disease needing TPVR - Mount Sinai Experience
Age at TPVR - Mount Sinai Experience

Age at Pulmonary Valve Replacement

Age (yrs)

(n)

<10 yrs
10-19 yrs
20-29 yrs
30-39 yrs
40-49 yrs
50-59 yrs
> 60 yrs
Case example - TPVR Melody

- 18 year old young woman with history of pulmonary stenosis as infant - s/p surgical pulmonary valvuloplasty at age 3 months
- Progressive pulmonary insufficiency
- Underwent surgical valve replacement with xenograft valve 1 year prior but valve developed stenosis and regurgitation quickly and patient significantly symptomatic
Case example - TPVR Melody

- RVp 75/15
- PAp 30/15 (18)
- 45mHg gradient
- Severe pulmonary insufficiency
Case example - TPVR Melody

- First step: stent to act as rigid scaffold for Melody valve
- Expanded to 22mm with BIB balloon (inner balloon 11mm)
Case example - TPVR Melody

- Outer balloon expanded to 22mm
Case example - TPVR Melody

- Melody valve implant then done as stent within a stent
- First inner balloon inflated to 11mm then outer inflated to 22mm
Case example - TPVR Melody

- Pulmonary angiogram post-valve: no regurgitation
- No residual stenosis by pressure pullback
- Patient now asymptomatic
Case example - TPVR Melody

- Follow-up:
- This patient was in our first cohort of implants in 2010
- Asymptomatic
- Episode SBE with strep viridians in 2013 treated medically
- Valve function remains good
Case example - TPVR Edwards Sapien XT

- 45 year old man with history of aortic stenosis s/p Ross procedure 1 year ago
- Initially felt well but progressive exercise intolerance
  - able to only walk 1 block now
- Echo shows severe homograft stenosis
Case example - TPVR Edwards Sapien XT

- Severe homograft stenosis
- 60mmHg gradient from RV to PA
Case example - TPVR Edwards Sapien XT

- Progressive conduit dilations with Atlas balloons 16mm through 22mm
Case example - TPVR Edwards Sapien XT

- At maximum diameter - coronary compression testing
Case example - TPVR Edwards Sapien XT

- Post balloon dilation improved homograft caliber
- Ready for stenting?
Case example - TPVR Edwards Sapien XT

- Not so fast - homograft rupture with pseudo aneurysm
Case example - TPVR Edwards Sapien XT

- Stenting first with Palmaz 3010 stent on 22mm Ensemble delivery system
- Inner balloon
Case example - TPVR Edwards Sapien XT

- Stenting first with Palmaz 3010 stent on 22mm Ensemble delivery system
- Outer balloon
Case example - TPVR Edwards Sapien XT

- Pseudoaneurysm still present
Case example - TPVR Edwards Sapien XT

- NuMed CP covered stent
Case example - TPVR Edwards Sapien XT

- After covered stent, pseudo aneurysm covered
- No stenosis
- Free regurgitation
Case example - TPVR Edwards Sapien XT

- After covered stent, pseudo aneurysm covered
- No stenosis
- Free regurgitation
Case example - TPVR Edwards Sapien XT

- LCA still OK
Case example - TPVR Edwards Sapien XT

- Placement 23mm Sapien XT
Post Sapien, no stenosis, no regurgitation

Patient discharged next day

Feeling well and now limitless activity

Case example - TPVR Edwards Sapien XT
Results of Melody Pulmonary Regurgitation
Results of Melody
Freedom from Reoperation

[Graph showing survival rates over years post-implant for different groups: IDE, PAS, PMSS]
# Results of Melody Freedom from SAE

<table>
<thead>
<tr>
<th>Event</th>
<th>US IDE</th>
<th>US PAS</th>
<th>EU/CA PMSS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Freedom from event at 7 years (CI) (N=149)</td>
<td>Freedom from event at 5 years (CI) (N=99)</td>
<td>Freedom from event at 5 years (CI) (N=62)</td>
</tr>
<tr>
<td>Stent Fracture: Major</td>
<td>83.6% (75.7%, 89.2%)</td>
<td>91.0% (81.3%, 95.8%)</td>
<td>91.6% (81.1%, 96.4%)</td>
</tr>
<tr>
<td>Valve Dysfunction: Stenosis</td>
<td>79.3% (70.8%, 85.7%)</td>
<td>86.1% (76.1%, 92.1%)</td>
<td>82.3% (69.5%, 90.1%)</td>
</tr>
<tr>
<td>Valve Dysfunction: Regurgitation</td>
<td>99.3% (95.4%, 99.9%)</td>
<td>88.7% (75.8%, 94.9%)</td>
<td>98.3% (89.4%, 99.7%)</td>
</tr>
<tr>
<td>Prosthetic Valve Endocarditis</td>
<td>89.2% (79.7%, 94.4%)</td>
<td>84.9% (73.9%, 91.5%)</td>
<td>93.2% (82.6%, 97.4%)</td>
</tr>
<tr>
<td>Embolization of the TPV</td>
<td>100.0% (NA)</td>
<td>100.0% (NA)</td>
<td>100.0% (NA)</td>
</tr>
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Results of Sapien XT – US IDE
Freedom from PR
Future directions

- Large unmet need for pulmonary replacement in patients with Tetralogy of Fallot with right ventricular outflow tract patch
- Compliant and no place to anchor a valve
Future directions

- Medtronic Harmony valve Feasibility Trial
- 66 patients enrolled
- 20 patients implanted
- 1 migrated
- 2 surgically explanted
- Remaining 17 doing well