Medtronic Intrepid TMVR
Novel Design

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Potential conflicts of interest

Speaker's name: Vinayak Bapat

☑️ I have the following potential conflicts of interest to report:
  Consultant: EDWARDS LIFESCIENCES, MEDTRONIC
Mitral Valve Anatomy
Anatomically & Physiologically Challenging

1. Highly mobile over cardiac cycle
2. Very little to “hold on to”
3. LVOT obstruction is a possibility
4. High pressure closing pressures
5. Variable Pathology
1. **Conformable Outer Stent** engages the annulus providing fixation & sealing while isolating the inner stent from the dynamic anatomy.

2. **Circular Inner Stent** houses a 27 mm tricuspid bovine pericardium valve.

3. **Flexible Brim** aids imaging during delivery & subsequent healing.

   One implant platform regardless of delivery approach: 
   trans-apical or trans-septal.
Medtronic Intrepid TMVR
Dual Stent Design
Cork effect produced by variable stiffness along the height of the Outer Stent
Radial interference, small cleats, frictional elements & tissue ingrowth
Leveraging but not relying upon the native leaflets
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Treatable Range

Three sizes (43, 46 & 50 mm outer stent) addresses 96% of screened patients’ annular dimensions
Medtronic Intrepid TMVR
Hydraulic Deployment of Self-Expanding Stent

Step 1. Advance across valve
Step 2. Deploy brim
Step 3. Retract to desired position
Step 4. Expand fixation ring
Step 5. Release

No need for rotational alignment - No need to search for leaflets
Accommodates tilt & lateral misalignment
## Medtronic Intrepid TMVR
### Early Clinical Experience

<table>
<thead>
<tr>
<th>Sites</th>
<th>Sites Count</th>
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<tbody>
<tr>
<td>John Paul II, Krakow, Poland</td>
<td>3</td>
</tr>
<tr>
<td>Monash Heart, Melbourne, Australia</td>
<td>4</td>
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<tr>
<td>Alfred, Melbourne, Australia</td>
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<tr>
<td>St. Thomas’, London, United Kingdom</td>
<td>2</td>
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<tr>
<td>Royal Prince Alfred, Sydney, Australia</td>
<td>3</td>
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</table>
Patient Demographics

<table>
<thead>
<tr>
<th>Baseline Echocardiogram (n=15)</th>
<th>Secondary MR</th>
<th>Primary MR</th>
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<tbody>
<tr>
<td>MR Etiology</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>LVEF mean (%)</td>
<td>35</td>
<td>57</td>
</tr>
<tr>
<td>≤ 30</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>31 - 50</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 50</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>LVEDD (mm)</td>
<td>66</td>
<td>55</td>
</tr>
<tr>
<td>LVESD (mm)</td>
<td>53</td>
<td>35</td>
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<tr>
<td>MR grade ≥ 3+ (%)</td>
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<td>100</td>
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</table>
## Clinical Results

### Procedural Outcomes (n=15)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Count</th>
<th>Range</th>
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<tbody>
<tr>
<td>Successful Deployment</td>
<td>14</td>
<td></td>
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<tr>
<td>Apical Access Time (minutes)</td>
<td>31</td>
<td>19-54</td>
</tr>
<tr>
<td>Deployment Time (minutes)</td>
<td>14</td>
<td>4-29</td>
</tr>
<tr>
<td>Mean LVOT Gradient (mmHg)</td>
<td>3</td>
<td>1-9</td>
</tr>
<tr>
<td>Mean MV Gradient (mmHg)</td>
<td>4</td>
<td>2-6</td>
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</tbody>
</table>
Clinical Results

MR Grade

Pre-procedure

Latest F/U
Case Presentation

Patient 008
- 85 years male, 164 cm, 56 kg
- FMR, grade 3+, with restriction of posterior leaflet
- NYHA Class III
- LVEF: 35%

Cardiac and Medical History
- Coronary artery bypass (1990 & 1996)
- Chronic Afib
- BAV (1 month prior)
- TAVR with Sapien 3 (2 days prior)
- Diabetes, Hypertension

STS score: 10.8% mortality
Baseline Echo

Moderate to Severe MR Remained After TAVI with Sapien 3
Good Sealing & Valve Function
Trans-mitral pressure gradient is 2 mmHg (mean)
Implant Conforming to the Anatomy
6 Month Follow Up

TTE: Good Valve Function
No PVL or TVL with Patent LVOT (4 mmHg)
Conclusions

- Novel design: Fixation and function
- Adaptable to multiple approaches
- Implantation: TAVI like