Transcatheter Mitral Valve

Vinayak (Vinnie) Bapat
Consultant Cardiac Surgeon
St. Thomas’ hospital, London
Why TMVR

• Large population with MR

• Traditional surgery
  – Large number is considered unsuitable for surgery
  – Surgical Mortality high
  – recurrence not uncommon

• Current Transcatheter options - Limited
Challenges for Transcatheter Repair options

- The mitral valve is a complex structure
- Mitral disease is heterogenous
- Transcatheter repair techniques focus on one element only:
  - annuloplasty (Internal or external)
  - Chrodae
  - Leaflets
Hence TMVR would be ideal

- Will eliminate MR
- Can treat all pathologies
- Reproducible
- Will allow VIV implant at later stage

Preserves the Mitral apparatus**
Challenges with designing a TMVR device

- Large Valve size
- Closing pressures are higher
- Anchoring has to be leaflet/annulus based
- LVOT obstruction is a possibility
Devices with FIM experience

- Fortis (Edwards)
- Tiara (NeoVasc)
- CardiaQ
- Tendyne
The Edwards Fortis TMVR

• Bovine pericardial tissue
• Anti-calcification - GLX
• Self-expanding
• Unique anchoring
• At present one size – 29
Delivery system

- Trans Apical delivery
- Multiple levels of control
- Repositionable
Fortis implantation steps

Open the Paddles

Release Atrial flange

Advance around AML and PML

Release the device
Pulsatile animal heart model

Apical View
Procedure
## Edwards FORTIS TMVR Early Clinical Experience

<table>
<thead>
<tr>
<th>Patient</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td>STH</td>
<td>STH</td>
<td>STH</td>
<td>BUH</td>
<td>SMH</td>
<td>SPH</td>
<td>HL</td>
<td>BB</td>
<td>SPH</td>
<td>HL</td>
<td>HL</td>
<td>BN</td>
</tr>
<tr>
<td>Pt Info</td>
<td>62M</td>
<td>57F</td>
<td>65M</td>
<td>72m</td>
<td>76M</td>
<td>51M</td>
<td>66M</td>
<td>77M</td>
<td>75M</td>
<td>64F</td>
<td>80M</td>
<td>77M</td>
</tr>
<tr>
<td>EF</td>
<td>10-15%</td>
<td>35-40%</td>
<td>25%</td>
<td>25%</td>
<td>30-35%</td>
<td>30-45%</td>
<td>25%</td>
<td>29%</td>
<td>25%</td>
<td>28%</td>
<td>30%</td>
<td>60%</td>
</tr>
<tr>
<td>Severe MR</td>
<td>FMR</td>
<td>IMR</td>
<td>IMR</td>
<td>IMR</td>
<td>FMR</td>
<td>FMR</td>
<td>IMR</td>
<td>FMR</td>
<td>DMR</td>
<td>FMR</td>
<td>FMR</td>
<td>DMR</td>
</tr>
<tr>
<td>Time (min)</td>
<td>84</td>
<td>69</td>
<td>36</td>
<td>31</td>
<td>37</td>
<td>67</td>
<td>25</td>
<td>70</td>
<td>73</td>
<td>43</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Post-Op MR Grade</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>Trace</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acute Recovery</td>
<td>Slow</td>
<td>N/A</td>
<td>Better</td>
<td>Better</td>
<td>Better</td>
<td>Better</td>
<td>Better</td>
<td>Slow</td>
<td>Convert to Surgery After Deployed</td>
<td>Good</td>
<td>Good</td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td>Day 76</td>
<td>Day 4</td>
<td>-</td>
<td>Day 15</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Day 7</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>COD</td>
<td>CHF Renal failure &amp; organ failure</td>
<td></td>
<td>Suspect Embolic Event</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Septic shock</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Eight more cases have been performed
Edwards FORTIS TMVR Procedure Times (to date)

Implant Duration (mins)
Insertion to Deployment

Minutes

<table>
<thead>
<tr>
<th>STH</th>
<th>STH</th>
<th>STH</th>
<th>BUH</th>
<th>SMH</th>
<th>SPH</th>
<th>CHUL</th>
<th>BB</th>
<th>SPH</th>
<th>CHUL</th>
<th>CHUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>84</td>
<td>69</td>
<td>36</td>
<td>31</td>
<td>37</td>
<td>67</td>
<td>25</td>
<td>60</td>
<td>72</td>
<td>43</td>
<td>44</td>
</tr>
</tbody>
</table>

Avg: 52min
Six month follow-up Echo – Patient 3

Alive after one year

Slow improvement

Anticoagulation and Aspirin for 6 months

Followed by Aspirin alone
2014: Focused on FIH and Limited Clinical Feasibility

- Regulatory strategy spans several regions
  - Compassionate use Switzerland and the UK
  - Special access in Canada
  - Early Feasibility Study (EFS) in Germany
2015: Focus on Expanding Clinical Feasibility Experience

• Clinical feasibility studies
  – Canada
  – EU
  – US
NeoVasc - Tiara Valve

“D” shape Design
1. Help minimize PVL,
2. Avoid LVOT obstruction and
3. Avoid impingement on the aortic valve

Do not rely on native leaflets for anchoring

Single size (35mm)
Tiara delivery system

• 32F catheter
• Single knob controls deployment
• Short burst of rapid pacing (<10 seconds) at final deployment
Tiara Implant

Video courtesy Dr. A. Cheung
FIM experience

• First human implants undertaken in January / February 2014 by team at St. Paul’s Hospital (Vancouver, Canada)- 5 cases

• No intra-operative complications, no transfusions

• US feasibility will begin soon
CardiAQ Technology

MULTIPLE ACCESS ROUTE
   TA or TF

POSITIONING & CONTROL
   Sits higher in the atrium
   Minimal LVOTO

ANCHORING
   • Unique frame designed for annular attachment without radial force
   • Preserves chords and uses native leaflets
Positioning & Control

- Multi-stage controlled deployment
- Self-positioning
TA Procedure Sequence
## Clinical Update: first 4 Compassionate Patients

<table>
<thead>
<tr>
<th>Patient</th>
<th>Date</th>
<th>Implant</th>
<th>MR Type</th>
<th>TMVI Time</th>
<th>MR Pre→Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>TF-001</td>
<td>6/12/12</td>
<td>Gen 1</td>
<td>FMR</td>
<td>60 min.</td>
<td>4+ → 1+</td>
</tr>
<tr>
<td>(86y M)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TA-001</td>
<td>5/13/14</td>
<td>Gen 2</td>
<td>Deg. MR, A2 Flail</td>
<td>20 min.</td>
<td>4+ → Trace</td>
</tr>
<tr>
<td>(88y F)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TA-002</td>
<td>7/8/14</td>
<td>Gen 2</td>
<td>FMR</td>
<td>13 min.</td>
<td>4+ → Trace</td>
</tr>
<tr>
<td>(77y M)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TA-003</td>
<td>7/9/14</td>
<td>Gen 2</td>
<td>FMR</td>
<td>13 min.</td>
<td>4+ → Trace</td>
</tr>
<tr>
<td>(80y F)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Tendyne Transcatheter Mitral Valve

**Tendyne Device**
- D-Shaped Self-Expanding Nitinol Frame
- Porcine Pericardial Tri-Leaflet Valve with Large EOA
- Left Ventricular Tether to Apex
- Large Valve Size Matrix for Varying Anatomies
- Fully Repositionable and Retrievable Mitral Valve
- No Rapid Pacing or CPB Required
Tendyne Procedure

1. Insert Catheter into LA

2. Intra-Annular Deployment

3. Align D-Shape Cuff

4. Remove Catheter and Secure Tether with Apical Pad
Case example

Patient
- 75 yrs. Male
- Mod/Severe FMR
- Prior CABG, Poor lung function
- Outcome: No MR / PVL

Courtesy: Mr. Neil Moat
Tendyne Transcatheter Mitral Valve

Tendyne Status

- 8 Patient Implants-to-Date
- Primary and Secondary MR Patients all with 4+ MR
- All Patients Alive and Discharged with No/Trace MR
- Currently Enrolling in Global Feasibility Trial

FIRST TMVR IMPLANT IN US – APRIL 2015
Lessons learned

• **Patient selection:**
  Critical
  Inoperable vs high risk patients

• **Mitral valve and LV anatomy:**
  Anatomical fit for device
    Annulus
    LVOT
  Anatomical fit for ease of Implant
    LV geometry
    Papillary muscle characterisation
    P2 morphology
Lessons learned

- **Procedure** predominantly echo guided
  Imaging guided selection of apical puncture site

  Choose best spot to allow best angle to capture both leaflets

- No chordal entanglement of crossing wire

- **Post procedure** optimal anti-coagulation
Conclusions

• Proof of principal is established

• Experience will simplify patient selection, procedure and postoperative management

• Journey may mimic TAVR experience