Transcatheter Mitral Valve Replacement

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National Medical Director for Cardiothoracic Surgery HCA
Surgical Director for Structural Heart Disease Medical City Dallas

Tristar Cardiovascular Symposium
25 February 2016
The Mitral Valve

- Belgian anatomist and physician working in Padua, Italy
- Likened the bifoliate left AV valve to a bishop’s “mitre” leading to the adoption of the term “Mitral Valve”

Andreas Vesalius
Prevalence of MR

• Large incidence of mitral regurgitation in the population
  – 0.7% of adults below age 45 have moderate to severe MR
  – 10% of adults over age 75 have moderate to severe MR
  – In every age group MR is the most common valvular disorder
    • ≈2% of the total population equally distributed between men and women
Etiology of Mitral Regurgitation

Carpentier Classification

Type I

Type II

Type IIIa

Type IIIb
Complexity of Mitral Anatomy

- Mitral valve has 6 functional components
  - Annulus
  - Leaflets
  - Chordae Tendinae
  - Papillary muscles
  - Left Atrium and Ventricle
- Much more complex than the aortic valve
Complexity of Mitral Anatomy

- MV annulus has a 3-D saddle shaped appearance
  - Elevated Ant. and post. segments are the highest points
  - Trigones are the lowest points
- The mitral – Aortic angle changes dynamically over the cardiac cycle
- Valve closes during systole as opposed to diastole
Complex Anatomy

- Annulus dilates asymmetrically, generally in the A-P plane
- Pathologic states characterized by multiple structural abnormalities
Surgical Options For Mitral Regurgitation

- Annular Repairs
- Mitral Replacements
- Leaflet repairs
- Ventricular remodeling
- Neochords
Trends in Mitral Valve Surgery in the United States: Results From The Society of Thoracic Surgeons Adult Cardiac Database

James S. Gammie, MD, Shubin Sheng, PhD, Bartley P. Griffith, MD, Eric D. Peterson, MD, J. Scott Rankin, MD, Sean M. O’Brien, PhD, and James M. Brown, MD

Division of Cardiac Surgery, University of Maryland Medical Center, Baltimore, Maryland; Duke Clinical Research Institute, Durham, North Carolina; and Centennial Medical Center, Vanderbilt University, Nashville, Tennessee

- 210,529 Mitral Valve operations 2000-2007

EXCLUDE:

- 127,261 Concomitant CABG, aortic valve surgery and other valve (except tricuspid and atrial fibrillation correction)
- 7,967 Infective Endocarditis
- 15,670 Reoperations
- 1,198 Resuscitation, Cardiogenic Shock
- 36 Pulmonary Procedure
- 27 Patients with Missing Gender

58,370 Isolated Primary Mitral Valve Operations
Operative Data

32,699 Mitral Repairs:

– 32 % Annuloplasty only
– 66 % Reconstruction with annuloplasty
– 2.4 % Reconstruction without annuloplasty

25,671 Mitral Replacements
Rates of Mitral Repair

![Graph showing the rates of Mitral Repair from 2000 to 2007. The y-axis represents the percentage of repaired cases, ranging from 0 to 100. The x-axis represents the years 2000 to 2007. The graph indicates an increasing trend in the percentage of Mitral Repair over the years.]
Prosthesis Selection Evolving
Mitral Repair by Age

Ann Thorac Surg 2009;87:1431-1439

- <55
- >=55 & <60
- >=60 and <65
- >=65 and <70
- >=70 and <75
- >=75 and <80
- >=80

Percent

p < .0001
Unadjusted Outcomes

Elective mitral valve repair (n = 28,140)
  • Operative mortality 1.2 %

Asymptomatic elective mitral valve repair (n = 6176)
  • Operative mortality 0.6 %
Unadjusted operative mortality by preoperative NYHA class

<table>
<thead>
<tr>
<th>NYHA class</th>
<th>Repair mortality (%)</th>
<th>Replace mortality (%)</th>
<th>Overall mortality (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0.64</td>
<td>2.07</td>
<td>1.09</td>
</tr>
<tr>
<td>II</td>
<td>0.87</td>
<td>2.59</td>
<td>1.51</td>
</tr>
<tr>
<td>III</td>
<td>1.80</td>
<td>3.71</td>
<td>2.75</td>
</tr>
<tr>
<td>IV</td>
<td>3.71</td>
<td>7.14</td>
<td>5.66</td>
</tr>
</tbody>
</table>

*p < 0.001, test of trend*
Unadjusted operative mortality by preoperative NYHA class

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<thead>
<tr>
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<th>Repair mortality (%)</th>
<th>Replace mortality (%)</th>
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<td>3.71</td>
<td>7.14</td>
<td>5.66</td>
</tr>
</tbody>
</table>

*Ann Thorac Surg 2009;87:1431-1439*
Trends in the Use of Less-Invasive Mitral Valve Operations

Year

2004  2005  2006  2007  2008

Percent

Conventional (Sternotomy)

Less-Invasive

P < 0.0001

Minimally Invasive MVR

Classic Sternotomy

Minimally invasive MVR
Predictors of Mitral Valve Repair: Clinical and Surgeon Factors

Steven F. Bolling, MD, Shuang Li, MS, Sean M. O’Brien, PhD, J. Matthew Brennan, MD, Richard L. Prager, MD, and James S. Gammie, MD

Section of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; Duke Clinical Research Institute, Durham, North Carolina; and Division of Cardiac Surgery, University of Maryland, Baltimore, Maryland

Mean Repair Rate = 41%
Median # Annual Operation/Surgeon = 5 (1-166)
Predictors of Mitral Valve Repair: Clinical and Surgeon Factors

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Section of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; Duke Clinical Research Institute, Durham, North Carolina; and Division of Cardiac Surgery, University of Maryland, Baltimore, Maryland

B

<table>
<thead>
<tr>
<th>Annual Mitral Volume</th>
<th>1</th>
<th>5</th>
<th>10</th>
<th>15</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predicted Probability of Repair, %</td>
<td>49.9</td>
<td>54.6</td>
<td>60.4</td>
<td>65.4</td>
<td>69.6</td>
<td>75.4</td>
<td>78.9</td>
<td>80.8</td>
<td>81.8</td>
<td>82.3</td>
<td>82.4</td>
<td>82.5</td>
<td>82.6</td>
</tr>
</tbody>
</table>
A number of patients are turned down for surgery or never referred
What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery?

Mariana Mirabel\textsuperscript{1}, Bernard Lung\textsuperscript{1*}, Gabriel Baron\textsuperscript{2}, David Messika-Zeitoun\textsuperscript{1}, Delphine Détaint\textsuperscript{1}, Jean-Louis Vanoverschelde\textsuperscript{3}, Eric G. Butchart\textsuperscript{4}, Philippe Ravaud\textsuperscript{2}, and Alec Vahanian\textsuperscript{1}

\textsuperscript{1}Cardiology Department, Bichat Hospital, AP-HP, 46 rue Henri Huchard, 75018 Paris, France; \textsuperscript{2}Epidemiology, Biostatistic, and Clinical Research Department, Bichat Hospital, AP-HP, Paris, France; \textsuperscript{3}Cliniques Universitaires Saint-Luc, Brussels, Belgium; and \textsuperscript{4}Cardiac Surgery Department, University Hospital, Cardiff, Wales, UK.
49% of patients with severe MR not offered surgery
Catheter Based Techniques
## Percutaneous Leaflet and Chordal Repair Devices

<table>
<thead>
<tr>
<th>Device name and therapy type</th>
<th>Device structure</th>
<th>Status international</th>
</tr>
</thead>
<tbody>
<tr>
<td>MitraClip (Abbot Vascular)</td>
<td>![MitraClip Image]</td>
<td>CE Mark approval gained</td>
</tr>
<tr>
<td>Edge-to-edge repair</td>
<td></td>
<td>FDA approved</td>
</tr>
<tr>
<td>NeoChord (NeoChord DS1000)</td>
<td>![NeoChord Image]</td>
<td>CE Mark approval gained</td>
</tr>
<tr>
<td>Chordal repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-Chordal-Off Pump (Valtech)</td>
<td>![V-Chordal Image]</td>
<td>First-in-man study complete</td>
</tr>
<tr>
<td>Chordal repair</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Percutaneous Chordal Repair Devices

<table>
<thead>
<tr>
<th>Device name and therapy type</th>
<th>Device structure</th>
<th>Status international</th>
</tr>
</thead>
<tbody>
<tr>
<td>MISTRAL (Mitralix) Chordal repair</td>
<td>![Device structure image]</td>
<td>Preclinical studies underway</td>
</tr>
<tr>
<td>V-Chordal-Transfemoral (Valtech) Chordal repair</td>
<td>![Device structure image]</td>
<td>Preclinical studies underway</td>
</tr>
</tbody>
</table>
# Percutaneous Annuloplasty Devices

<table>
<thead>
<tr>
<th>Device name and therapy type</th>
<th>Device structure</th>
<th>Status international</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARILLON (Cardiac Dimensions)</td>
<td><img src="image1.png" alt="Image" /></td>
<td>CE Mark approval gained</td>
</tr>
<tr>
<td>Indirect Annuloplasty</td>
<td><img src="image2.png" alt="Image" /></td>
<td>IDE submitted for pivotal study</td>
</tr>
<tr>
<td>GDS Accucinch (GDS)</td>
<td><img src="image3.png" alt="Image" /></td>
<td>International feasibility trial underway</td>
</tr>
<tr>
<td>Direct Annuloplasty</td>
<td><img src="image4.png" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Mitralign Bident (Mitralign)</td>
<td><img src="image5.png" alt="Image" /></td>
<td>CE Mark trial completed US feasibility trial planned</td>
</tr>
<tr>
<td>Direct annuloplasty</td>
<td><img src="image6.png" alt="Image" /></td>
<td>CE Mark trial underway</td>
</tr>
<tr>
<td>Cardioband TF (Valtech)</td>
<td><img src="image7.png" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Direct annuloplasty</td>
<td><img src="image8.png" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Millipede Ring (Millipede)</td>
<td><img src="image9.png" alt="Image" /></td>
<td>Preclinicals underway</td>
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</table>
# Catheter Based Devices

<table>
<thead>
<tr>
<th>Pro’s</th>
<th>Con’s</th>
</tr>
</thead>
</table>
| • Post-repair hemodynamics similar to native valve  
• Favorable safety profile  
• No need for long-term anticoagulation  | • Requires advanced imaging  
• Steeper learning curve  
• Recurrent / residual mitral regurgitation common  
• Addresses only a single portion of the mitral apparatus per device  
  – Possible need for multiple devices depending upon the etiology of MR |
Would Transcatheter Mitral Replacement Be Better?

- Could completely eliminate MR
- Could equally treat both Functional MR (FMR) and Degenerative MR (DMR)
- Procedural success more reproducible, and operator skill less critical
- Preserves the sub-mitral apparatus
- Potentially allows V-in-V in the future
Anatomic Challenges for TMVR

- Valves are large
- Closing pressures are greater
- Anchoring of the valve by radial force and leaflet capture can cause LV outflow tract obstruction, distortion of the aortic valve, or Cx artery compression
- Chordae tendinae can impede positioning, expansion and anchoring of the prosthesis
<table>
<thead>
<tr>
<th>Device name and therapy type</th>
<th>Device structure</th>
<th>Status international</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fortis (Edwards Lifesciences)</td>
<td><img src="image" alt="Fortis Diagram" /></td>
<td>First-in-man study underway</td>
</tr>
<tr>
<td>Tiara (Neovasc)</td>
<td><img src="image" alt="Tiara Diagram" /></td>
<td>First-in-man study underway</td>
</tr>
<tr>
<td>TMVI-TA (CardiAQ)</td>
<td><img src="image" alt="TMVI-TA Diagram" /></td>
<td>First-in-man study completed</td>
</tr>
<tr>
<td>TMVI-TF (CardiAQ)</td>
<td><img src="image" alt="TMVI-TF Diagram" /></td>
<td>First-in-man study completed</td>
</tr>
<tr>
<td>Device name and therapy type</td>
<td>Device structure</td>
<td>Status international</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Medtronic TMVR (Twelve)</td>
<td></td>
<td>First-in-man study underway</td>
</tr>
<tr>
<td>MitrAssist Valve (MitrAssist)</td>
<td></td>
<td>Preclinicals underway</td>
</tr>
<tr>
<td>Navigate TMVR (NCSI)</td>
<td></td>
<td>Clinical implants have occurred</td>
</tr>
<tr>
<td>Device name and therapy type</td>
<td>Device structure</td>
<td>Status international</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Tendyne/Lutter TMVR (Tendyne)</td>
<td><img src="image" alt="Diagram" /></td>
<td>First-in-man study underway</td>
</tr>
<tr>
<td>Cardiovalve (Valtech)</td>
<td><img src="image" alt="Diagram" /></td>
<td>Preclinical studies underway</td>
</tr>
<tr>
<td>Caisson TMVR (Caisson)</td>
<td><img src="image" alt="Diagram" /></td>
<td>Preclinical studies underway</td>
</tr>
<tr>
<td>MitraCath (Emory University)</td>
<td><img src="image" alt="Diagram" /></td>
<td>In development</td>
</tr>
</tbody>
</table>
The Ideal TMVR Valve

• Simple and reproducible implantation
  – High success rate without MR
• Low transvalvular gradients
• No PV leak
• No LVOT, coronary sinus, or L. Cx obstruction
• Preservation of LV contractility
• No need for anticoagulation
The Ideal TMVR Valve

- Firm fixation without risk of migration or embolization
- Durable
- Low infection rates
- Able to be delivered percutaneously
Devices in Clinical Trials

- Fortis (Edwards)
- CardiaQ (Edwards)
- Twelve (Medtronic)
- Tendyne (Abbott)
- Tiara (Neovasc)
Edwards Fortis Valve

- Bovine pericardial tissue
- GLX anti-calcification mitigation
- Self-expanding
- Anchors by radial expansion and paddles capturing the mitral leaflets
- One size- 29 mm
Delivery System

- Transapical delivery system
- Repositionable
- 36 F in size
Implantation Steps

1. Open the Paddles
2. Release Atrial flange
3. Advance around AML and PML
4. Release the device
### Early Outcomes

- **13 patients treated total**
- **5 died within 30 days (38.5%)**
- **Trial currently placed on hold**

<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><strong>Site</strong></td>
<td><strong>STH</strong></td>
<td><strong>STH</strong></td>
<td><strong>STH</strong></td>
<td><strong>BUH</strong></td>
<td><strong>SMH</strong></td>
<td><strong>SPH</strong></td>
<td><strong>HL</strong></td>
<td><strong>BB</strong></td>
<td><strong>SPH</strong></td>
<td><strong>HL</strong></td>
<td><strong>HL</strong></td>
<td><strong>BN</strong></td>
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<tr>
<td><strong>Pt Info</strong></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><strong>EF</strong></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><strong>Severe MR</strong></td>
<td>FMR</td>
<td>IMR</td>
<td>IMR</td>
<td>IMR</td>
<td>IMR</td>
<td>IMR</td>
<td>IMR</td>
<td>IMR</td>
<td>FMR</td>
<td>DMR</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time (min)</strong></td>
<td>84</td>
<td>64</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
<td>84</td>
</tr>
<tr>
<td><strong>Post-Op MR Grade</strong></td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
</tr>
<tr>
<td><strong>Acute Recovery</strong></td>
<td>Slow</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Good</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>Day 76</td>
<td>Day 4</td>
<td>-</td>
<td>Day 15</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Day 7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>COD</strong></td>
<td>CHF</td>
<td>Renal failure &amp; organ failure</td>
<td>-</td>
<td>Suspect Embolic Event</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Septic shock</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Abort Prior to Chest Incision**
Edwards CardiAQ Valve

- **ONE VALVE, MULTIPLE DELIVERY SYSTEMS**
  - **TS** – Transseptal approach
  - **TA** – Transapical approach

- **UNIQUE ANCHORING MECHANISM**
  - Preserves chords and utilizes native leaflets
  - Promotes load distribution among annulus, leaflets and chords

- **DESIGNED TO PROMOTE PHYSIOLOGIC FLOW**
  - Eliminate mitral regurgitation
  - Supra-annular position and tapered outflow to minimize risk of LVOT obstruction
  - Intra-annular sealing skirt to minimize PV leak
  - Open frame cells to promote atrial flow
Edwards CardiAQ Valve

- Bovine Pericardial Leaflets
- Left Atrial Anchors
- Open Frame Cells
- Supra-annular Position
- Intra-annular Sealing Skirt
- Tapered Outflow
- Left Ventricular Anchors

Medical City Heart and Vascular
Edwards CardiAQ Valve

- Sits supra-annular to minimize risk of LVOT obstruction even in the presence of an acute aorto-mitral angle
Edwards CardiAQ Valve

- Intra-annular sealing skirt designed to minimize paravalvular leak
Edwards CardiAQ Valve

LV Anchor Release

Valve Expansion & Leaflet Capture

Valve Release

Transseptal

Transapical
Outcomes

- 12 patients treated under compassionate use as of Nov 2015
- First-ever TMVR TS patient 2012 with 1st generation device
  - 82% male
  - Prior CABG: 73%
  - Etiology: 64% FMR, 36% DMR
  - LVEF range <20-72%
- Technical success rate (successful delivery, deployment and retrieval of DS): 82%
Outcomes

– Two procedure related deaths:
  • 1 interaction with mechanical AV
  • 1 malpositioning due to sub-leaflet calcification

– Four non-valve related deaths (all had good valve function):
  • Pneumonia (PO day 9)
  • Right heart failure/cardiac decompensation (PO day 7)
  • Multi-organ failure (PO day 18)
  • Sepsis (PO day 36)

– Total mortality 50%
Medtronic Twelve Valve

- Conforms to native anatomy
- Separates fixation & sealing from Valve function
- Isolates valve from the dynamic anatomy
- Preserves native mitral apparatus
- Ensures LVOT patency
- Treats both FMR and DMR
- One valve size treats all patients
**Conformable Outer Stent**
- Engages the annulus providing fixation & sealing while isolating the inner stent from the dynamic anatomy

**Circular Inner Stent**
- Houses a 27 mm tricuspid bovine pericardium valve (EOA = 2.4cm²)

**Flexible Brim**
- Aids imaging during delivery procedure
Medtronic Twelve Valve

Dual stent design
**Medtronic Twelve Valve**

**Fixation & Sealing**
- Cork effect produced by variable stiffness along the height of the Outer Stent
- Radial interference, small cleats, frictional elements & tissue ingrowth
- Leveraging on but not relying upon, the native leaflets
Hydraulic mechanism provides for controlled, precise deployment
No need for rotational alignment
No need to search for leaflets
Accommodates tilt & lateral misalignment
# Early Clinical Results

<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>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Deployment</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>7/8</td>
</tr>
<tr>
<td>Apical Access Time (min)</td>
<td>NA</td>
<td>29</td>
<td>25</td>
<td>25</td>
<td>20</td>
<td>25</td>
<td>53</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>Deployment Time (min)</td>
<td>NA</td>
<td>12</td>
<td>4</td>
<td>10</td>
<td>9</td>
<td>15</td>
<td>13</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Rapid Pace (sec)</td>
<td>NA</td>
<td>30</td>
<td>52</td>
<td>36</td>
<td>25</td>
<td>22</td>
<td>33</td>
<td>33</td>
<td>33</td>
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<tr>
<td>MR Grade Post</td>
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<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>Mean LVOT Gradient (mmHg)</td>
<td>NA</td>
<td>4^1</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>4^1</td>
<td>12^2</td>
<td>3.5</td>
</tr>
<tr>
<td>Mean MV Gradient (mmHg)</td>
<td>NA</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2.7</td>
</tr>
<tr>
<td>Survival (days)</td>
<td>1</td>
<td>28</td>
<td>271+</td>
<td>173+</td>
<td>89+</td>
<td>89+</td>
<td>5+</td>
<td>4+</td>
<td>660</td>
</tr>
</tbody>
</table>

* - Compassionate Use patient
1 - Peak, not mean measure
2 - TAVI present, gradient unchanged from prior to procedure, zero delta
Abbott Tendyne Mitral Valve

- D-Shaped self-expanding nitinol frame
- Porcine tri-leaflet valve
- Novel left ventricular tether to the apex
- Large valve size for varying anatomies
- Fully repositionable and retrievable
- No rapid pacing or CPB required
**Tendyne Implant Procedure**

- Insert Catheter into LA
- Align D-Shape Cuff
- Intra-Annular Deployment
- Remove Catheter and Secure Tether with Apical Pad
Tendyne Early Clinical Results

- 10 patients implanted in early feasibility trial
- All with either FMR or DMR, ≥4+ MR
- All patients alive and discharged with 0- trace MR
- No deaths to date
- 3 patients > 200 days
- Global feasibility trial enrolling
- 28 patients results being reported at ACC
Neovasc Tiara Mitral Valve

- “D” shape design
  - Helps to reduce PV leak
  - Reduce risk of LVOT obstruction
  - Decrease risk of impingement on the aortic valve
- Doesn’t rely on native leaflets for anchoring
- Single size (35 mm)
- 32 F delivery system
Neovasc Tiara Procedure

Positioned across the mitral valve into
The left atrium
Neovasc Tiara Procedure

Deployment of the atrial portion
Neovasc Tiara Procedure

Full deployment

Angiogram showing no compression of the Cx artery
Tiara Early Clinical Results

• 11 implants attempted to date
  – 2 patients died after being converted to urgent surgery
  – A third patient died on post-op day #4 secondary to erosion of the septum

• Early mortality 3/11 (27%)

• Currently enrolling in TIARA-1 early feasibility trial
## Table 1: Key Differences Between TAVR and Potential TMVR Subsets That May Influence TMVR Applicability and Adoption

<table>
<thead>
<tr>
<th>Aortic</th>
<th>Mitral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure and shape</td>
<td>Less complex, circular</td>
</tr>
<tr>
<td>Etiology, lesion</td>
<td>Degenerative, calcific</td>
</tr>
<tr>
<td>Anatomic risks</td>
<td>Left and right main coronary arteries, conduction</td>
</tr>
<tr>
<td>Access for catheter therapy</td>
<td>Predominantly femoral</td>
</tr>
<tr>
<td>Theoretical risk of late valve migration</td>
<td>Minimal</td>
</tr>
<tr>
<td>Typical patient age</td>
<td>70-100 yrs</td>
</tr>
<tr>
<td>Major patient comorbidity</td>
<td>Frequent</td>
</tr>
<tr>
<td>1-yr mortality risk on medical treatment</td>
<td>High</td>
</tr>
<tr>
<td>Conventional surgical option</td>
<td>Valve replacement</td>
</tr>
<tr>
<td>Long-term event-free survival with valve replacement</td>
<td>Good</td>
</tr>
<tr>
<td>Natural history of paravalvular leaks</td>
<td>Usually tolerated unless moderate or severe</td>
</tr>
<tr>
<td>Coexisting tricuspid valve dysfunction</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Extreme or high surgical risk patients</td>
<td>Common</td>
</tr>
<tr>
<td>Enrollment in clinical trials</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

LVOT = left ventricular outflow tract; TAVR = transcatheter aortic valve replacement; TMVR = transcatheter mitral valve replacement.
TMVR Lessons Learned

• Patient selection critical
  – EF ≥25-30%
  – Avoid those dying with MR instead of from MR

• MV and LV anatomy important
  – Anatomical fit for device
  – MV/LVOT angle to avoid LVOT obstruction
  – Papillary muscle anatomy
  – Chordal anatomy
  – Posterior leaflet morphology
TMVR Lessons Learned

• Procedure predominantly echo guided

• Crucial to have a coaxial approach to avoid chordal entanglement

• Appropriate anticoagulation critical to avoid thrombosis
Summary

• Proof of concept with TMVR has been achieved but challenges remain
  – Defining optimal patient groups will be difficult
  – Technical modifications will be required of the devices
    • Reduced delivery system sizes
    • Development of a percutaneous technique
    • Applicability to all types of MR
      – Functional
      – Degenerative
      – Rheumatic
      – Congenital
      – Post-infective endocarditis
Summary

• Optimal post-operative medical management remains under investigations
Conclusion

• Currently, it remains unclear whether this technology will revolutionize therapy for mitral valve disease, mirroring the course of TAVR… or remain a niche procedure reserved only for the end-stage patient