Comparison of the Hemodynamic Performance and Midterm Outcome of Percutaneous versus Surgical Stentless Bioprostheses for Aortic Stenosis with Anticipated Patient Prosthesis Mismatch

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Disclosure

- None
introduction

- Patient prosthetic mismatch (PPM)
  - Effective Orifice Area (EOA) of the implanted prosthesis is too small to body size area
  - Results in:
    - High post transplant gradient
    - Less regression of LVH
    - More cardiac events
    - Higher mortality
Identification of PPM

- **Indexed EOA** = in vivo EOA/BSA (cm²/m²)
  - iO EA < 0.85 cm²/m² ⇒ moderate PPM
  - iO EA < 0.65 cm²/m² ⇒ severe PPM

- **Expected PPM** -
  - Step 1 - the minimal acceptable EOA
    - Multiply known BSA by 0.85
    - Player 1: 1.5 x 0.85 = 1.275
    - Player 2: 2.15 x 0.85 = 1.82

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSA (m²)</td>
<td>1.5</td>
<td>1.75</td>
<td>2.0</td>
<td>2.25</td>
<td>2.5</td>
</tr>
<tr>
<td>cardiac output (l/min)</td>
<td>4.5</td>
<td>5.25</td>
<td>6.0</td>
<td>6.75</td>
<td>7.5</td>
</tr>
<tr>
<td>Valve EOA (cm²)</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Mean pressure gradient</td>
<td>13</td>
<td>17</td>
<td>22</td>
<td>28</td>
<td>35</td>
</tr>
</tbody>
</table>

Player 1

- H 1.6m
- W 50 kg
- BSA 1.5 m²
- Cardiac output: 4.5 l/min
- Valve EOA: 1.3 cm²
- Mean pressure gradient: 13 mmHg

Player 2

- H 2.0m
- W 80 kg
- BSA 2.15 m²
- Cardiac output: 5.25 l/min
- Valve EOA: 1.3 cm²
- Mean pressure gradient: 17 mmHg
**Expected PPM -**

Step 2 -

Compare mEOA to normal table references based on LVOT measurement (projected EOA)

**Expected PPM** →

**Minimal EOA > Projected EOA**

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**Table 1. Normal Reference Values of EOAs for the Aortic Prostheses**

<table>
<thead>
<tr>
<th>Prosthetic Valve Size, mm</th>
<th>19</th>
<th>21</th>
<th>23</th>
<th>25</th>
<th>27</th>
<th>29</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mosaic</td>
<td>1.1±0.2</td>
<td>1.2±0.3</td>
<td>1.4±0.3</td>
<td>1.7±0.4</td>
<td>1.8±0.4</td>
<td>2.0±0.4</td>
<td>10</td>
</tr>
<tr>
<td>Hancock II</td>
<td>…</td>
<td>1.2±0.1</td>
<td>1.3±0.2</td>
<td>1.5±0.2</td>
<td>1.6±0.2</td>
<td>1.8±0.2</td>
<td>10</td>
</tr>
<tr>
<td>Carpentier-Edwards Perimount</td>
<td>1.1±0.3</td>
<td>1.3±0.4</td>
<td>1.50±0.4</td>
<td>1.80±0.4</td>
<td>2.1±0.4</td>
<td>2.2±0.4</td>
<td>10</td>
</tr>
<tr>
<td>Carpentier-Edwards Magna</td>
<td>1.3±0.3</td>
<td>1.7±0.3</td>
<td>2.1±0.4</td>
<td>2.3±0.5</td>
<td>…</td>
<td>…</td>
<td>11, 20</td>
</tr>
<tr>
<td>Biocor (Epic)*</td>
<td>…</td>
<td>1.3±0.3</td>
<td>1.6±0.3</td>
<td>1.8±0.4</td>
<td>…</td>
<td>…</td>
<td>12</td>
</tr>
<tr>
<td>Mitroflow*</td>
<td>1.1±0.1</td>
<td>1.3±0.1</td>
<td>1.5±0.2</td>
<td>1.8±0.2</td>
<td>…</td>
<td>…</td>
<td>13</td>
</tr>
<tr>
<td>Aortic stentless bioprosthesis</td>
<td>1.2±0.2</td>
<td>1.4±0.2</td>
<td>1.50±0.3</td>
<td>2.0±0.4</td>
<td>2.3±0.5</td>
<td>2.7±1.0</td>
<td>10</td>
</tr>
<tr>
<td>Medtronic Freestyle</td>
<td>1.2±0.2</td>
<td>1.4±0.2</td>
<td>1.5±0.3</td>
<td>2.0±0.4</td>
<td>2.3±0.5</td>
<td>2.7±1.0</td>
<td>10</td>
</tr>
<tr>
<td>St Jude Medical Toronto SPV</td>
<td>…</td>
<td>1.3±0.3</td>
<td>1.5±0.5</td>
<td>1.7±0.8</td>
<td>2.1±0.7</td>
<td>2.7±1.0</td>
<td>10</td>
</tr>
<tr>
<td>Aortic mechanical prostheses</td>
<td>1.2±0.2</td>
<td>1.3±0.2</td>
<td>…</td>
<td>…</td>
<td>…</td>
<td>…</td>
<td>10</td>
</tr>
<tr>
<td>Medtronic-Hall</td>
<td>1.2±0.2</td>
<td>1.3±0.2</td>
<td>…</td>
<td>…</td>
<td>…</td>
<td>…</td>
<td>10</td>
</tr>
<tr>
<td>Medtronic Advantage*</td>
<td>…</td>
<td>1.7±0.2</td>
<td>2.2±0.3</td>
<td>2.6±0.6</td>
<td>3.3±0.7</td>
<td>3.9±0.7</td>
<td>14</td>
</tr>
<tr>
<td>St Jude Medical Standard</td>
<td>1.0±0.2</td>
<td>1.4±0.2</td>
<td>1.5±0.5</td>
<td>2.1±0.4</td>
<td>2.7±0.6</td>
<td>3.2±0.3</td>
<td>10</td>
</tr>
<tr>
<td>St Jude Medical Regent</td>
<td>1.6±0.4</td>
<td>2.0±0.7</td>
<td>2.2±0.9</td>
<td>2.5±0.9</td>
<td>3.6±1.3</td>
<td>4.4±0.6</td>
<td>27</td>
</tr>
<tr>
<td>MCR On-X</td>
<td>1.5±0.2</td>
<td>1.7±0.4</td>
<td>2.0±0.6</td>
<td>2.4±0.8</td>
<td>3.2±0.6</td>
<td>3.2±0.6</td>
<td>27</td>
</tr>
<tr>
<td>Carbomedics Standard</td>
<td>1.0±0.4</td>
<td>1.5±0.3</td>
<td>1.7±0.3</td>
<td>2.0±0.4</td>
<td>2.5±0.4</td>
<td>2.6±0.4</td>
<td>10</td>
</tr>
</tbody>
</table>

EOA is expressed as mean values available in the literature.

*These results are based on a limited number of patients and thus should be interpreted with caution.
Avoidance of PPM

- Alternate complex procedures
  - Aortic root enlargement
  - Prosthetic model with superior hemodynamic performance
    - Stentless vs. stented AVR
  - TAVI
Introduction – aim of study

- Examine and compare
  - Hemodynamics
  - Early and mid term outcomes

- In patients with expected PPM that were treated by stentless AVR or TAVI
Methods

- Inclusion:
  - At least expected moderate PPM

- Exclusion:
  - Bicuspid valve
Methods

- Retrospective
- Tel - Aviv medical center
- January 2009 – December 2011
  - 200 TAVI - 86 with at least expected moderate PPM
  - 49 stentless freestyle medtronic patient similar in characteristics to the TAVI cohort
- Echocardiography - baseline, pre-discharge and 3 months post-implantation.
- Operative risk assessment - EuroScore and Charlson Score.
<table>
<thead>
<tr>
<th>Variables</th>
<th>TAVI (total 86)</th>
<th>AVR (total 49)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSA</td>
<td>1.81±0.18</td>
<td>1.86±0.20</td>
<td>0.2</td>
</tr>
<tr>
<td>Age</td>
<td>82.4±5.05</td>
<td>73.0±7.77</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>28 (32%)</td>
<td>16 (32%)</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Echocardiographic parameters</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EF%</td>
<td>56.8±6.5</td>
<td>55.0±7.9</td>
<td>0.2</td>
</tr>
<tr>
<td>LVOT</td>
<td>1.95±0.11</td>
<td>1.94±0.13</td>
<td>0.7</td>
</tr>
<tr>
<td>Peak pressure trans-aortic gradient</td>
<td>78.8±21.3</td>
<td>75.5±31.6</td>
<td>0.5</td>
</tr>
<tr>
<td>Mean pressure trans-aortic gradient</td>
<td>47.9±13.7</td>
<td>43.1±19.2</td>
<td>0.2</td>
</tr>
<tr>
<td>AVA (cm²)</td>
<td>0.64±0.15</td>
<td>0.71±0.17</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Aortic Regurgitation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>34 (39%)</td>
<td>22 (45%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Mild</td>
<td>49 (57%)</td>
<td>22 (45%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>3 (4%)</td>
<td>3 (6%)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>0 (0%)</td>
<td>2 (4%)</td>
<td></td>
</tr>
<tr>
<td>NYHA class</td>
<td>III (75%); IV (25%)</td>
<td>II (8%); III (65%); IV (27%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>15 (17%)</td>
<td>8 (16%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>14 (16%)</td>
<td>3 (6%)</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>Logistic EuroScore II</strong></td>
<td>6.831</td>
<td>4.54</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>Charlson's score</strong></td>
<td>6.4±1.4</td>
<td>5.5±1.4</td>
<td>0.001</td>
</tr>
</tbody>
</table>
TAVI vs. SAVR

- TAVI cohort compared to SAVR
  - Older patients
  - more symptomatic
  - smaller end diastolic, end systolic diameters and LV mass
  - higher logistic Euro-score II and Charlson co-morbidity scores

- As expected TAVI patients were older and sicker.
Operative Outcomes and Operative Mortality

- TAVI
  - CoreValve
  - 47 patients (55%) had concomitant PCI
- SAVR
  - 3 patients (6%) - intervention on thoracic Aorta
  - 23 patients (47%) had concomitant CABG

- Both groups had the same length of stay in hospital – average of 7 days
Peak Pressure Gradient

- TAVI vs SAVR

- Pre Procedural: TAVI 78.8, SAVR 75.5
- Post Procedural: TAVI 16.3, SAVR 28.3
- 3 months: TAVI 14.9, SAVR 19.2

- p < 0.001
- p = 0.5
- p = 0.2
Mean Pressure Gradient

- **Pre Procedural**: TAVI (47.9) vs. SAVR (43.1), \( p < 0.0002 \)
- **Post Procedural**: TAVI (9) vs. SAVR (12.5)
- **3 months**: TAVI (8.4) vs. SAVR (9)

\( p - 0.2 \) and \( p - 0.7 \)
Aortic Regurgitation

- TAVI
- SAVR

Pre Procedural:
- 4%
- 10%

Post Procedural:
- 61%
- 7%

3 months:
- 56%

p < 0.0001

p < 0.0001
Post-procedural Patient Prosthesis Mismatch

- **TAVI**
  - Post-procedural: 6
  - 3 months: 5

- **SAVR**
  - Post-procedural: 30
  - 3 months: 19

Significance:
- Post-procedural: p = 0.002
- 3 months: p = 0.056
Mortality

- Unadjusted 3-year survival rate was superior in the SAVR vs. TAVI group - 91.6±4.0% Vs. 67.0±7.7%  p=0.01

- Adjustments for age and co-morbidity resulted in loss of the difference in mortality between the groups
A. Non Adjusted P=0.01

B. Adjusted for Age P=0.3

C. Adjusted for Charlson P=0.07

D. Adjusted for Age and Charlson P=0.4
Mortality

- Higher mortality rates associated with:
  - Older age
  - NYHA > III
  - Small stroke volume and atrial fibrillation
  - High comorbidity index
Discussion

- Immediate hemodynamic performance of TAVI is superior to the stentless valve probably due to use of an oversized valve, leading to some distension of the aortic annulus.

- Performing SAVR or TAVI are reasonable choices for patients with anticipated PPM.

- The increased un-adjusted mortality observed in TAVI is due to the differences in age and co-morbidities.

- After adjustment for the differences in age and co-morbidities between the groups the survival was similar.
Take home message

- Although TAVI should not be used as the procedure of choice in all patients with anticipated PPM, it may be considered as a possible and comparable solution in older and sicker patients with small outflow tract for body surface area.

- The higher prevalence of aortic regurgitation in TAVI may offset the beneficial effect on survival of less PPM in favor of SAVR.
Thank you 😊