Is TAVR Now Indicated in Even Low Risk Aortic Valve Disease Patients

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Potential conflicts of interest

Saibal Kar, MD:

- **I do not have any potential conflict of interest**

- **I have the following potential conflicts of interest to report:**

<table>
<thead>
<tr>
<th>Honorarium:</th>
<th>Abbott Vascular, Boston Scientific</th>
</tr>
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<tr>
<td><strong>Institutional grant/research support:</strong></td>
<td>Abbott Vascular, Boston Scientific, Cardiokinetix, Mitralign</td>
</tr>
<tr>
<td><strong>Consultant:</strong></td>
<td>Abbott Vascular, Boston Scientific</td>
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</table>
Introduction

• >17,000 Cases are performed per year in US.
• TAVR is FDA approved for high and extreme surgical risk patients with symptomatic Aortic stenosis (AS)
• Studies on intermediate risk patients have been completed
• Ongoing trials on low/moderate risk surgical patients are enrolling subjects
FDA approved TAVR platforms

Balloon Expandable

Edwards SAPIEN 3 Transcatheter Heart Valve

Self – Expanding

Medtronic EvoluteR Transcatheter Heart Valve
TAVR valve in trials in US

Trials on low/moderate risk patients
- Sapien 3
- Evolute

Trials on extreme/high risk patients
- Lotus
- St. Jude Portico
- Direct Flow Medical
61 yr old male gasping for breath: history of aortic replacement in 2007. in Cardiogenic shock referred to evaluation of transplant/assist device

Ejection fraction < 10%

Mean gradient = 26 mm Hg

Severe bioprosthetic valve stenosis
Urgent TAVR using a 26 mm SAPIEN 3 valve (no support)
Discharged home in a week

Pre 4 chamber view
LVEF <10%

Day 4 4 chamber view
LVEF 25%

LV dysfunction improved
Trace AR, Peak PG = 16 mmHg, Mean PG = 10 mmHg
Clinical evidence supporting TAVR in intermediate risk patients

- Final results of the PARTNER II trial
- SAPIEN 3 TAVR Compared with Surgery in Intermediate-Risk Patients: Propensity score analysis
- 3 year data of the Corevalve Pivotal study
The PARTNER 2A Trial

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients


The PARTNER 2A Trial
Study Design

Symptomatic Severe Aortic Stenosis

Randomized Patients
n = 2032

ASSESSMENT by Heart Valve Team
Operable (STS ≥ 4%)

Yes

No

ASSESSMENT: Transfemoral Access

Transfemoral (TF)

Transapical (TA) / TransAortic (TAo)

1:1 Randomization (n = 1550)

1:1 Randomization (n = 482)

TF TAVR (n = 775)

Surgical AVR (n = 775)

TA/TAo TAVR (n = 236)

Surgical AVR (n = 246)

Primary Endpoint: All-Cause Mortality or Disabling Stroke at Two Years
PARTNER SAPIEN Platforms

Device Evolution

- **SAPIEN**
  - Valve Technology
  - Sheath Compatibility: 22-24F
  - Available Valve Sizes: 23 mm, 26 mm

- **SAPIEN XT**
  - Valve Technology
  - Sheath Compatibility: 16-20F
  - Available Valve Sizes: 23 mm, 26 mm, 29 mm

- **SAPIEN 3**
  - Valve Technology
  - Sheath Compatibility: 14-16F
  - Available Valve Sizes: 20 mm, 23 mm, 26 mm, 29 mm

*First Implant Oct 30, 2012*
Primary Endpoint

• Non-hierarchical composite of *all-cause mortality or disabling stroke*\(^*\) at two years

• Intention-to-treat population is the primary analysis;
  – As-Treated (AT) population also a pre-specified, powered analysis
  – Transfemoral (TF) subgroup pre-specified

• All patients followed for at least 2 years

• Event rates by Kaplan-Meier estimates

\(^*\) Disabling stroke = CEC adjudicated stroke by a neurologist with a modified Rankin score of 2 or greater at 30 or 90-day evaluation
Primary Endpoint (ITT)
All-Cause Mortality or Disabling Stroke

HR [95% CI] = 0.89 [0.73, 1.09]
p (log rank) = 0.253

Number at risk:
Surgery 1021
TAVR 1011

<table>
<thead>
<tr>
<th>Months from Procedure</th>
<th>Surgery</th>
<th>TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6.1%</td>
<td>8.0%</td>
</tr>
<tr>
<td>3</td>
<td>8.0%</td>
<td>10.1%</td>
</tr>
<tr>
<td>6</td>
<td>14.5%</td>
<td>15.4%</td>
</tr>
<tr>
<td>9</td>
<td>16.4%</td>
<td>18.1%</td>
</tr>
<tr>
<td>12</td>
<td>21.1%</td>
<td>19.3%</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Primary Endpoint (ITT)
All-cause Mortality or Disabling Stroke

- **TAVR**: n = 1011, 19.3%
- **SAVR**: n = 1021, 21.1%

Relative Risk Ratio: 0.92
Upper 1-sided 97.5% CI: 1.09

Non-Inferiority p-value = 0.001

Pre-specified non-inferiority margin = 1.2

Favors TAVR
Risk ratio (test/control)
Favors Surgery

Primary Non-Inferiority Endpoint Met
Primary Endpoint (AT)
All-Cause Mortality or Disabling Stroke

HR [95% CI] = 0.87 [0.71, 1.07]
p (log rank) = 0.180
### Primary Endpoint
#### Subgroup Analysis (ITT)

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>TAVR (%)</th>
<th>AVR (%)</th>
<th>Hazard Ratio (95% CI)</th>
<th>HR (95% CI)</th>
<th>p-value for interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>19.3</td>
<td>21.1</td>
<td></td>
<td>0.89 [0.73-1.09]</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 85</td>
<td>18.0</td>
<td>19.5</td>
<td></td>
<td>0.90 [0.69-1.17]</td>
<td>0.96</td>
</tr>
<tr>
<td>≥ 85</td>
<td>21.5</td>
<td>23.6</td>
<td></td>
<td>0.89 [0.65-1.20]</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16.9</td>
<td>20.3</td>
<td></td>
<td>0.81 [0.59-1.00]</td>
<td>0.37</td>
</tr>
<tr>
<td>Male</td>
<td>21.4</td>
<td>21.7</td>
<td></td>
<td>0.96 [0.74-1.25]</td>
<td></td>
</tr>
<tr>
<td><strong>STS Score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 5</td>
<td>15.8</td>
<td>18.4</td>
<td></td>
<td>0.84 [0.61-1.16]</td>
<td>0.60</td>
</tr>
<tr>
<td>&gt; 5</td>
<td>22.4</td>
<td>23.1</td>
<td></td>
<td>0.94 [0.73-1.21]</td>
<td></td>
</tr>
<tr>
<td><strong>LV Ejection Fraction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 55</td>
<td>19.1</td>
<td>21.5</td>
<td></td>
<td>0.84 [0.56-1.25]</td>
<td>0.27</td>
</tr>
<tr>
<td>&gt; 55</td>
<td>20.1</td>
<td>18.0</td>
<td></td>
<td>1.11 [0.81-1.53]</td>
<td></td>
</tr>
<tr>
<td><strong>Mod or Severe Mitral Regurgitation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>17.8</td>
<td>20.3</td>
<td></td>
<td>0.85 [0.67-1.08]</td>
<td>0.53</td>
</tr>
<tr>
<td>Yes</td>
<td>25.9</td>
<td>24.4</td>
<td></td>
<td>1.00 [0.64-1.57]</td>
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<tr>
<td><strong>Previous CABG</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>No</td>
<td>20.6</td>
<td>22.2</td>
<td></td>
<td>0.91 [0.73-1.13]</td>
<td>0.69</td>
</tr>
<tr>
<td>Yes</td>
<td>15.3</td>
<td>18.0</td>
<td></td>
<td>0.62 [0.53-1.27]</td>
<td></td>
</tr>
<tr>
<td><strong>Peripheral Vascular Disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>18.2</td>
<td>20.7</td>
<td></td>
<td>0.85 [0.67-1.09]</td>
<td>0.47</td>
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<tr>
<td>Yes</td>
<td>22.3</td>
<td>22.0</td>
<td></td>
<td>0.99 [0.71-1.40]</td>
<td></td>
</tr>
<tr>
<td><strong>15 Foot Walk Test</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>≤ 7 secs</td>
<td>17.7</td>
<td>20.9</td>
<td></td>
<td>0.82 [0.62-1.09]</td>
<td>0.43</td>
</tr>
<tr>
<td>&gt; 7 secs</td>
<td>20.7</td>
<td>20.8</td>
<td></td>
<td>0.97 [0.71-1.31]</td>
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<tr>
<td><strong>Access Route</strong></td>
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<tr>
<td>Transfemoral</td>
<td>16.8</td>
<td>20.4</td>
<td></td>
<td>0.79 [0.62-1.00]</td>
<td>0.06</td>
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<tr>
<td>Transthoracic</td>
<td>27.7</td>
<td>23.4</td>
<td></td>
<td>1.21 [0.84-1.74]</td>
<td></td>
</tr>
</tbody>
</table>
TF Primary Endpoint (ITT)
All-cause Mortality or Disabling Stroke

- **TF Surgery**
- **TF TAVR**

HR: 0.79 [95% CI: 0.62, 1.00]

p (log rank) = 0.05

All-Cause Mortality or Disabling Stroke (%) vs Months from Procedure

<table>
<thead>
<tr>
<th>Months from Procedure</th>
<th>TF Surgery</th>
<th>TF TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4.9%</td>
<td>3.5%</td>
</tr>
<tr>
<td>12</td>
<td>15.9%</td>
<td>12.3%</td>
</tr>
<tr>
<td>24</td>
<td>20.4%</td>
<td>16.8%</td>
</tr>
</tbody>
</table>

Number at risk:
- TF Surgery: 775
- TF TAVR: 775
**TF Primary Endpoint (AT)**

**TF Primary Endpoint (AT) All-Cause Mortality or Disabling Stroke**

- **HR**: 0.78 [95% CI: 0.61, 0.99]
- **p (log rank)** = 0.04

### Number at risk:

<table>
<thead>
<tr>
<th>Months from Procedure</th>
<th>TF Surgery</th>
<th>TF TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>636</td>
<td>717</td>
</tr>
<tr>
<td>3</td>
<td>624</td>
<td>708</td>
</tr>
<tr>
<td>6</td>
<td>600</td>
<td>685</td>
</tr>
<tr>
<td>9</td>
<td>591</td>
<td>663</td>
</tr>
<tr>
<td>12</td>
<td>573</td>
<td>652</td>
</tr>
<tr>
<td>15</td>
<td>565</td>
<td>644</td>
</tr>
<tr>
<td>18</td>
<td>555</td>
<td>634</td>
</tr>
<tr>
<td>21</td>
<td>537</td>
<td>612</td>
</tr>
</tbody>
</table>

**TF Surgery** and **TF TAVR** show a lower incidence of adverse outcomes over time, with a significant difference observed at 24 months.
## Other Clinical Endpoints (ITT)
### At 30 Days and 2 Years

<table>
<thead>
<tr>
<th>Events (%)</th>
<th>30 Days</th>
<th></th>
<th>2 Years</th>
<th></th>
<th>p-value*</th>
<th>30 Days</th>
<th></th>
<th>2 Years</th>
<th></th>
<th>p-value*</th>
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</thead>
<tbody>
<tr>
<td>Rehospitalization</td>
<td>6.5</td>
<td>6.5</td>
<td>0.99</td>
<td>19.6</td>
<td>17.3</td>
<td>0.22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>1.2</td>
<td>1.9</td>
<td>0.22</td>
<td>3.6</td>
<td>4.1</td>
<td>0.56</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Major Vascular Complications</td>
<td>7.9</td>
<td>5.0</td>
<td>0.008</td>
<td>8.6</td>
<td>5.5</td>
<td>0.006</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Life-Threatening / Disabling Bleeding</td>
<td>10.4</td>
<td>43.4</td>
<td>&lt;0.001</td>
<td>17.3</td>
<td>47.0</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AKI (Stage III)</td>
<td>1.3</td>
<td>3.1</td>
<td>0.006</td>
<td>3.8</td>
<td>6.2</td>
<td>0.02</td>
<td></td>
<td></td>
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<tr>
<td>New Atrial Fibrillation</td>
<td>9.1</td>
<td>26.4</td>
<td>&lt;0.001</td>
<td>11.3</td>
<td>27.3</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Permanent Pacemaker</td>
<td>8.5</td>
<td>6.9</td>
<td>0.17</td>
<td>11.8</td>
<td>10.3</td>
<td>0.29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-intervention</td>
<td>0.4</td>
<td>0.0</td>
<td>0.05</td>
<td>1.4</td>
<td>0.6</td>
<td>0.09</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0.0</td>
<td>0.0</td>
<td>NA</td>
<td>1.2</td>
<td>0.7</td>
<td>0.22</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*Event rates are KM estimates, p-values are point in time*
Echocardiography Findings (VI)
Aortic Valve Area

Valve Area (cm²)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>30 Day</th>
<th>1 Year</th>
<th>2 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>1.68</td>
<td>1.47</td>
<td>1.42</td>
<td>1.40</td>
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<tr>
<td>TAVR</td>
<td>0.70</td>
<td>0.69</td>
<td>1.57</td>
<td>1.54</td>
</tr>
</tbody>
</table>

p < 0.001

No. of Echos

<table>
<thead>
<tr>
<th></th>
<th>Surgery</th>
<th>TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>861</td>
<td>899</td>
</tr>
<tr>
<td>30 Day</td>
<td>727</td>
<td>829</td>
</tr>
<tr>
<td>1 Year</td>
<td>590</td>
<td>695</td>
</tr>
<tr>
<td>2 Year</td>
<td>488</td>
<td>567</td>
</tr>
</tbody>
</table>

Error bars represent ± Standard Deviation

p = NS
Severity of PVR at 30 Days and All-cause Mortality at 2 Years (VI)

- Overall Log-Rank p = 0.001
- Mod/Sev (reference = None/Trace) p (Log-Rank) < 0.001
- Mild (reference = None/Trace) p (Log-Rank) = 0.82

Number at risk:
- Moderate/Severe: 35
  - 0: 204
  - 3: 199
  - 6: 194
  - 9: 188
  - 12: 184
  - 15: 182
  - 18: 180
  - 21: 175
  - 24: 170
- Mild: 210
  - 0: 678
  - 3: 664
  - 6: 647
  - 9: 628
  - 12: 621
  - 15: 612
  - 18: 605
  - 21: 585
  - 24: 569

- None/Trace: 704
The PARTNER 2A Trial
Conclusions (1)

In intermediate-risk patients with symptomatic severe aortic stenosis, results from the PARTNER 2A trial demonstrated that...

• TAVR using SAPIEN XT and surgery were similar (non-inferior) for the primary endpoint (all-cause mortality or disabling stroke) at 2 years.

• In the **transfemoral subgroup** (76% of patients), TAVR using SAPIEN XT significantly reduced all-cause mortality or disabling stroke vs. surgery (ITT: \( p = 0.05 \), AT: \( p = 0.04 \)).
The PARTNER 2A Trial
Conclusions (2)

- Other clinical outcomes:
  - TAVR reduced AKI, severe bleeding, new AF, and LOS
  - Surgery reduced vascular complications and PVR
- The SAPIEN XT valve significantly increased echo AVA compared to surgery.
- In the SAPIEN XT TAVR cohort, moderate or severe PVR, but not mild PVR, was associated with increased mortality at 2 years.
SAPIEN 3 TAVR Compared with Surgery in Intermediate-Risk Patients: A Propensity Score Analysis

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis


Lancet 2016; 387:2218-2225
SAPIEN Platforms in PARTNER

Device Evolution

Valve Technology

SAPIEN

SAPIEN XT

SAPIEN 3

Sheath Compatibility

22-24F

16-20F

14-16F

Available Valve Sizes

23 mm

26 mm

23 mm

26 mm

29 mm

20 mm

23 mm

26 mm

29 mm
The PARTNER 2A and S3i Trials
Study Design
Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team

**P2 S3i**
n = 1078

- **ASSESSMENT:** Optimal Valve Delivery Access

  - Transfemoral (TF)
    - TF TAVR SAPIEN 3
  - Transapical / Transaortic (TA/TAo)
    - TA/TAo TAVR SAPIEN 3

**P2A**
n = 2032

- **ASSESSMENT:** Transfemoral Access
  - Yes
    - Transfemoral (TF)
      - 1:1 Randomization
        - TF TAVR SAPIEN XT
        - Surgical AVR
        - VS
        - TA/TAo TAVR SAPIEN 3
        - Surgical AVR
  - No
    - Transapical / TransAortic (TA/TAo)
      - 1:1 Randomization
        - Surgical AVR
        - VS
The PARTNER 2A and S3i Trials

Study Design

Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team

P2 S3i
n = 1078

ASSESSMENT: Optimal Valve Delivery Access

Transfemoral (TF)

Transapical / Transaortic (TA/TAo)

TF TAVR SAPIEN 3

TA/TAo TAVR SAPIEN 3

P2A
n = 2032

ASSESSMENT: Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization

TF TAVR SAPIEN XT

TA/TAo TAVR SAPIEN 3

No

Transapical / TransAortic (TA/TAo)

1:1 Randomization

Surgical AVR

Surgical AVR

Primary Endpoint: All-Cause Mortality, All Stroke, or Mod/Sev AR at One Year (Non-inferiority Propensity Score Analysis)
**Primary Endpoint - Non-inferiority**

Death, Stroke, or AR ≥ Mod at 1 Year (VI)

- Weighted Difference: -9.2%
- Upper 1-sided 95% CI: -6.0%
- Non-Inferiority p-value < 0.001

Pre-specified non-inferiority margin = 7.5%

Primary Non-Inferiority Endpoint Met

Favors TAVR

Favors Surgery
Primary Endpoint - Superiority

Death, Stroke, or AR ≥ Mod at 1 Year (VI)

Weighted Difference -9.2%
Upper 2-sided 95.0% CI -5.4%

Superiority Testing
p-value < 0.001

Superiority Achieved

Favors TAVR
Favors Surgery
Superiority Analysis
Components of Primary Endpoint (VI)

- **Mortality**
  - Weighted Difference: -5.2%
  - Upper 2-sided 95% CI: -2.4%
  - Superiority Testing p-value < 0.001

- **Stroke**
  - Weighted Difference: -3.5%
  - Upper 2-sided 95% CI: -1.1%
  - Superiority Testing p-value = 0.004

- **AR > Moderate**
  - Weighted Difference: +1.2%
  - Lower 2-sided 95% CI: +0.2%
  - Superiority Testing p-value = 0.0149
The PARTNER 2A and S3i Trials
Conclusions

• A propensity score analysis comparing SAPIEN 3 TAVR with surgery from PARTNER 2A in intermediate-risk patients at 1 year demonstrated:
  – Superiority of SAPIEN 3 TAVR for the primary endpoint, all-cause mortality, and all stroke
  – Superiority of surgery for AR ≥ moderate
Clinical evidence supporting TAVR in intermediate risk patients

- Final results of the PARTNER II trial
- SAPIEN 3 TAVR Compared with Surgery in Intermediate-Risk Patients: Propensity score analysis
- 3 year data of the Corevalve Pivotal study
High risk patients: 3 year follow up of Core valve study (TAVR versus SAVR)

All-Cause Mortality or Stroke

Log-rank P=0.006  Δ9.4

No. at Risk
TAVR  SAVR
0  391  359
12  319  257
24  273  208
36  165  128

Cedars-Sinai Medical Center
Core Valve Hemodynamics*

TAVR had significantly better valve performance vs SAVR at all follow-ups (P<0.001)

*Site-reported
Outcomes in the Randomized CoreValve US Pivotal High-risk Trial in Patients With a Society of Thoracic Surgeons Risk Score of 7% or Less

Reardon M et al. JAMA Cardiol. Published online August 17, 2016. doi:10.1001/jamacardio.2016.2257
Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

by Lars Søndergaard, Daniel Andreas Steinbrüchel, Nikolaj Ihlemann, Henrik Nissen, Bo Juel Kjeldsen, Petur Petursson, Anh Thuc Ngo, Niels Thue Olsen, Yanping Chang, Olaf Walter Franzen, Thomas Engstrøm, Peter Clemmensen, Peter Skov Olsen, and Hans Gustav Hørsted Thyregod

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Kaplan–Meier curves depicting (A) a composite rate of all-cause mortality, all stroke, and myocardial infarction (MI); (B) all-cause mortality; (C) composite rate of all-cause mortality, all stroke, and MI in transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) patients with Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) <4%; and (D) composite rate of all-cause mortality, stroke, and MI in TAVR and SAVR patients with STS-PROM ≥4%.


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Summary: Transcatheter aortic valve replacement

- TAVR is preferred treatment option of high and intermediate surgical risk patients
- Evidence of durability of the valve
- Continued improvements in technology will minimize the paravalvular AI, heart block, and stroke rates
- Further research of cerebral protection and valve thrombosis are ongoing
Conclusions: Status in US

- TAVR is FDA approved for extreme/high surgical risk patients

- FDA has expanded the indication for intermediate risk patients using the SAPIEN 3 valve

- In the real world intermediate risk patients are being treated with TAVR
  - Ongoing registries
  - Indication creep: physician preference

- Ongoing trials are evaluating the role of TAVR in low/moderate risk patients
Ongoing low risk TAVR trials

- PARTNER 3: Low risk patients with AS
- Low risk study using the EvoluteR valve
Do We really need these low risk studies

- Other than for reimbursement it is probably not necessary to do these large scale studies
- There is significant indication creep already in US and Europe for intermediate and low risk patients
- The boundary between low risk and intermediate risk is very blurry
Future

• Cardiac surgeons will have to consult interventional cardiologist prior to offering surgery to any patient with aortic stenosis