SAVR in the Era of TAVR

Vinod H. Thourani, MD

Bernie Marcus Chief of Cardiovascular Surgery
Marcus Heart and Vascular Center and Valve Center
Piedmont Heart Institute
Atlanta, GA, USA

PAR Annual Course
Athens, GA
February, 2020
Disclosures

• Abbott Vascular
  – National Co-PI: Mitral in MAC Arm (SUMMIT trial)
  – Advisor, Research

• Boston Scientific
  – National Co-PI: REPRISE IV trial
  – Steering Committee: ACURATE trial
  – Advisor, Research

• Cryolife
  – Executive Committee, PROACT X trial

• Edwards Lifesciences
  – National Co-PI: CLASP IIF
  – National PI: Harpoon Trial

• Gore Vascular
  – Advisory board

• JenaValve
  – Advisory Board
  – National Co-PI: EFS trial
TVT Registry
TAVR and TAVR ViV Procedures

TVT Registry Datamart Data as of 6/6/19
SAVR and TAVR Volumes
TAVR Mortality

In-Hospital, 30 Day, and One Year Mortality

<table>
<thead>
<tr>
<th>Year</th>
<th>In Hospital</th>
<th>30 Day</th>
<th>1yr (CMS linked data)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>5.7%</td>
<td>7.5%</td>
<td>26.4%</td>
</tr>
<tr>
<td>2013</td>
<td>5.2%</td>
<td>7%</td>
<td>21.8%</td>
</tr>
<tr>
<td>2014</td>
<td>4.1%</td>
<td>6%</td>
<td>21.6%</td>
</tr>
<tr>
<td>2015</td>
<td>2.9%</td>
<td>4.4%</td>
<td>18.2%</td>
</tr>
<tr>
<td>2016</td>
<td>2%</td>
<td>3.2%</td>
<td>15.3%</td>
</tr>
<tr>
<td>2017</td>
<td>1.7%</td>
<td>2.9%</td>
<td>13.9%</td>
</tr>
<tr>
<td>2018 Q1</td>
<td>1.6%</td>
<td>2.8%</td>
<td></td>
</tr>
</tbody>
</table>
TAVR Stroke
In-Hospital, 30 Day, and One Year Stroke

<table>
<thead>
<tr>
<th>Year</th>
<th>In Hospital</th>
<th>30 Day</th>
<th>One Yr CMS linked</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2.2%</td>
<td>2.8%</td>
<td>3.9%</td>
</tr>
<tr>
<td>2013</td>
<td>2.0%</td>
<td>2.7%</td>
<td>3.9%</td>
</tr>
<tr>
<td>2014</td>
<td>2.2%</td>
<td>2.8%</td>
<td>4.2%</td>
</tr>
<tr>
<td>2015</td>
<td>2.0%</td>
<td>2.5%</td>
<td>4.3%</td>
</tr>
<tr>
<td>2016</td>
<td>1.8%</td>
<td>2.4%</td>
<td>4.2%</td>
</tr>
<tr>
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<td>3.9%</td>
</tr>
<tr>
<td>2018 Q1</td>
<td>1.8%</td>
<td>2.5%</td>
<td>3.9%</td>
</tr>
</tbody>
</table>
TAVR
New (No PPM pre TAVR)
In Hospital and 30 Day Pacemaker

<table>
<thead>
<tr>
<th>Year</th>
<th>In Hospital Pacemaker</th>
<th>30 Day Pacemaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>10.9%</td>
<td>14.8%</td>
</tr>
<tr>
<td>2015</td>
<td>12.9%</td>
<td>15.0%</td>
</tr>
<tr>
<td>2016</td>
<td>11.0%</td>
<td>13.0%</td>
</tr>
<tr>
<td>2017</td>
<td>9.9%</td>
<td>12.1%</td>
</tr>
<tr>
<td>2018 Q1</td>
<td>9.6%</td>
<td>12.4%</td>
</tr>
</tbody>
</table>
2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Severe AS Symptomatic (stage D)

- Low surgical risk
  - Surgical AVR (Class I)
- Intermediate surgical risk
  - Surgical AVR (Class I)
  - TAVR (Class IIa)
- High surgical risk
  - Surgical AVR or TAVR (Class I)
- Prohibitive surgical risk
  - TAVR (Class I)
## AS and increased risk - Heart Team SAVR vs. TAVI decision: Anatomical / technical aspects

<table>
<thead>
<tr>
<th>Factor</th>
<th>Favours TAVI</th>
<th>Favours SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Favourable access for transfemoral TAVI</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Unfavourable access (any) for TAVI</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Sequelae of chest radiation</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Porcelain aorta</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Presence of intact coronary bypass grafts at risk when sternotomy is performed</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Expected patient–prosthesis mismatch</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Severe chest deformation or scoliosis</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Short distance between coronary ostia and aortic valve annulus</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Size of aortic valve annulus out of range for TAVI</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Aortic root morphology unfavourable for TAVI</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Presence of thrombi in aorta or LV</td>
<td></td>
<td>+</td>
</tr>
</tbody>
</table>
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

Primary Endpoint

Number at risk:

<table>
<thead>
<tr>
<th></th>
<th>Surgery</th>
<th>TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 months</td>
<td>454</td>
<td>496</td>
</tr>
<tr>
<td>3 months</td>
<td>408</td>
<td>475</td>
</tr>
<tr>
<td>6 months</td>
<td>390</td>
<td>467</td>
</tr>
<tr>
<td>9 months</td>
<td>381</td>
<td>462</td>
</tr>
<tr>
<td>12 months</td>
<td>377</td>
<td>456</td>
</tr>
</tbody>
</table>

Death, Stroke, or Rehosp (%)

- **Upper 95% CI of risk diff = -2.5%**
  - HR [95% CI] = 0.54 [0.37, 0.79]
  - **P_{superiority} = 0.001**
  - **P_{non-inferiority} < 0.001**

- At 12 months:
  - Surgery: 15.1%
  - TAVR: 8.5%
  - Number at risk: Surgery 374, TAVR 451
All Stroke

HR [95% CI] = 0.38 [0.15, 1.00]  
P = 0.04

Number at risk:
- Surgery: 454, 435, 427, 423, 421, 417
- TAVR: 496, 491, 491, 489, 487, 484
Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O’Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchêchê, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*
K-M All-Cause Mortality or Disabling Stroke at 1 Year

Log-rank P = 0.065

Death or Disabling Stroke (%)

No. at risk

TAVR

SAVR

30 Days

2.5

0.7

1 Year

4.6

2.7

TAVR

SAVR

725

718

648

656

435

366
K-M Disabling Stroke at 1 Year

Log-rank P = 0.024

Disabling Stroke (%)

<table>
<thead>
<tr>
<th>Months</th>
<th>TAVR</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>725</td>
<td>678</td>
</tr>
<tr>
<td>1-2</td>
<td>720</td>
<td>656</td>
</tr>
<tr>
<td>2-3</td>
<td>648</td>
<td>576</td>
</tr>
<tr>
<td>3-4</td>
<td>435</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>366</td>
<td></td>
</tr>
</tbody>
</table>

No. at risk

<table>
<thead>
<tr>
<th>Months</th>
<th>TAVR</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>725</td>
<td>678</td>
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<td>576</td>
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<tr>
<td>3-4</td>
<td>435</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>366</td>
<td></td>
</tr>
</tbody>
</table>
Low-Risk Trials: TBD

- Low risk TAVR RCTs did not include young or BAV patients
- More data is required on:
  - TAVR in BAV
  - Long-term effects of pacemaker / LBB
  - Long-term effects of mild AI
  - Consequences of leaflet thrombosis
  - TAVR durability
Excellent SAVR Outcomes in Low Risk AS Patients: STS Database

80% of patients low risk (STS score < 4%)

Table 3. Short-Term Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>All Patients (n = 141,905)</th>
<th>PROM &lt;4% (n = 113,377)</th>
<th>PROM 4%-8% (n = 19,769)</th>
<th>PROM &gt;8% (n = 8,759)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke, n (%)</td>
<td>2,154 (1.5)</td>
<td>1,384 (1.2)</td>
<td>462 (2.3)</td>
<td>308 (3.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Deep sternal infection, n (%)</td>
<td>386 (0.3)</td>
<td>285 (0.3)</td>
<td>58 (0.3)</td>
<td>43 (0.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>New dialysis, n (%)</td>
<td>2,174 (1.5)</td>
<td>891 (0.8)</td>
<td>642 (3.3)</td>
<td>641 (7.3)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>In-hospital mortality, n (%)</td>
<td>3,609 (2.5)</td>
<td>1,564 (1.4)</td>
<td>1,014 (5.1)</td>
<td>1,031 (11.8)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Obstacles to TAVR Expansion

• Anatomical Obstacles
  – Bicuspid
  – LVOT calcium

• Durability / Thrombus

• Conducting system injury

• Paravalvular regurgitation

• Cost
Bicuspid AV Patients!

Courtesy of Joerg Kempfert
Anatomical Differences for TAVR vs SAVR
The PARTNER 2A Trial
Study Design

Symptomatic Severe Aortic Stenosis

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

Randomized Patients
n = 2,032

ASSESSMENT:
Transfemoral Access

Yes

Transfemoral (TF)
1:1 Randomization (n = 1,550)

TF TAVR (n = 775) vs. Surgical AVR (n = 775)

No

Transapical (TA) / TransAortic (TAo)
1:1 Randomization (n = 482)

TA/TAo TAVR (n = 236) vs. Surgical AVR (n = 246)

Primary Endpoint: All-Cause Mortality or Disabling Stroke at 2 Years
Aortic Valve Area
VI Population

No. of Echos:

TAVR
Surgery

Mean ± SE

P = 0.001

Thourani, TCT, 2019
Mean Aortic Valve Gradient
VI Population

Mean Gradient (mmHg)

Baseline
30 Days
1 Year
2 Years
3 Years
4 Years
5 Years

No. of Echos:
TAVR
Surgery
959
916
890
788
751
633
522
405
323

Mean ± SE

P = 0.23
# Aortic Valve Re-intervention

## Incidence and Details

<table>
<thead>
<tr>
<th>Reasons for Re-intervention*</th>
<th>TAVR (n = 21)</th>
<th>Surgery (n = 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stenosis</td>
<td>10 (48)</td>
<td>0</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>11 (52)*</td>
<td>1 (20)</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0</td>
<td>4 (80)</td>
</tr>
</tbody>
</table>

## Treatment modality

<table>
<thead>
<tr>
<th>Treatment Modality</th>
<th>TAVR (n = 21)</th>
<th>Surgery (n = 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat TAVR (TAVR-in-TAVR)</td>
<td>17 (81)</td>
<td>0</td>
</tr>
<tr>
<td>Valvuloplasty</td>
<td>1 (5)</td>
<td>0</td>
</tr>
<tr>
<td>Surgery</td>
<td>3 (14)</td>
<td>5 (100)</td>
</tr>
</tbody>
</table>

## In-Hospital Mortality

<table>
<thead>
<tr>
<th>In-Hospital Mortality</th>
<th>TAVR (n = 21)</th>
<th>Surgery (n = 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (5)</td>
<td>3 (60)</td>
</tr>
</tbody>
</table>

*TAVR cohort: 9/10 stenosis cases and 2/11 regurgitation cases were due to SVD. In the SAVR cohort, 1 case of regurgitation was due to SVD.
Freedom from Aortic Valve Re-intervention

ITT Population

HR: 3.93 [95% CI: 1.48, 10.43]
P = 0.003
Paravalvular Regurgitation
VI Population

P < 0.001 TAVR vs SAVR in all PVR categories at all FU times

No. of Echos:

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>2 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR Patients</td>
<td>73.7%</td>
<td>64.9%</td>
<td>66.8%</td>
</tr>
<tr>
<td>Surgery Patients</td>
<td>96.7%</td>
<td>95.9%</td>
<td>93.8%</td>
</tr>
</tbody>
</table>

Paravalvular Regurgitation (%):
- **Mod/Severe**
- **Mild**
- **None or trace**

- **30 Days**
  - TAVR: 3.8%
  - Surgery: 2.8%

- **2 Years**
  - TAVR: 8.2%
  - Surgery: 3.5%

- **5 Years**
  - TAVR: 6.5%
  - Surgery: 5.9%

- **No. of Echos**:
  - TAVR: 872
  - Surgery: 757
  - TAVR: 609
  - Surgery: 516
  - TAVR: 310
  - Surgery: 272
Death From Any Cause by PVR Severity
VI TAVR Population

Overall Log-Rank P < 0.001

No. at risk:
None-trace 643
Mild 196
Mod-severe 33

Months
0 12 24 36 48 60

Death (%)
0 10 20 30 40 50 60 70 80

Mild vs none-trace
P = 0.07

Mild vs mod-severe
P = 0.007
Primary Endpoint: 2-Yr Landmark Analysis
VI TF Population with None-Trace PAR

Death or Disabling Stroke (%)

No. at risk:

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>494</td>
<td>555</td>
</tr>
<tr>
<td>12</td>
<td>451</td>
<td>491</td>
</tr>
<tr>
<td>24</td>
<td>437</td>
<td>469</td>
</tr>
<tr>
<td>36</td>
<td>392</td>
<td>413</td>
</tr>
<tr>
<td>48</td>
<td>335</td>
<td>359</td>
</tr>
<tr>
<td>60</td>
<td>174</td>
<td>191</td>
</tr>
</tbody>
</table>

HR: 0.87 [95% CI: 0.62, 1.22]  
HR: 1.11 [95% CI: 0.87, 1.42]
Flow Stagnation / Leaflet Thrombosis Post-TAVR

Midha et al, Circulation 2017;136:1598-1609
Association of Clinical and Economic Outcomes With Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement

Talal Aljabbary, MD, MSc; Feng Qiu, MSc; Shannon Masih, MSc, MPH; Jiming Fang, PhD; Gabby Elbaz-Greener, MD, MHA; Peter C. Austin, PhD; Josep Rodès-Cabau, MD; Dennis T. Ko, MD, MSc; Sheldon Singh, MD; Harindra C. Wijeysundera, MD, PhD

**A** Time to all-cause mortality

![Graph showing time to all-cause mortality](image)

**P** = .02 by log-rank test

<table>
<thead>
<tr>
<th>No. at risk</th>
<th>PPM group</th>
<th>Non-PPM group</th>
</tr>
</thead>
<tbody>
<tr>
<td>186</td>
<td>153</td>
<td>932</td>
</tr>
<tr>
<td>23</td>
<td>88</td>
<td>543</td>
</tr>
<tr>
<td>1071</td>
<td>143</td>
<td></td>
</tr>
</tbody>
</table>
Scenarios That May Require SAVR

- High risk for PVR (calcium in LVOT) or root rupture
- Bicuspid valve and low risk with or without enlarged aortic root
- Enlarged root (>4.5 cm or >5.5 cm) requiring replacement
- Very young pts who want mechanical valves
- Aortic annulus area > 750mm
- Predominantly AI and very little AS
- Short annulus to STJ and worried about root rupture
- Low coronaries although usually ok if root large enough
Shared decision making is not patient education or informed consent

1. Knowledge transfer
2. Patient preferences
3. Deliberation / consensus

Conclusions

- The growth in TAVR in the US has been predominantly in intermediate-risk patients
  - Growth in the next 5 years will most likely be in the low-risk population
- Heart team decision-making should continue utilize anatomic criteria for optimal patient outcomes
  - regardless for the procedure type (SAVR or TAVR)
- In younger patients, more emphasis should be placed on the most optimal procedure for long-term success
- Share-decision making should be a mainstay of the discussion with patients
Thank You!!
Vinod.Thourani@piedmont.org
404-274-3136