Identifying Appropriate Candidates for Transcatheter Aortic Valve Replacement

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Disclosure of Financial Interest

No financial disclosures
Mrs. AC

- 90 yo woman
- EF 45%
- Severe AS; mean gradient 52; Vmax 4.4 m/s
- Mild COPD
- 3 V CABG 2003– patent grafts by recent cath
- Permanent afib
- Hx CVA with mild L sided weakness
- 3 hospitalizations in 3 months for CHF
- Turned down for surgical AVR
1 year post TAVR
Hospitalized for 3 days post procedure
No hospitalizations since TAVR
Just returned from Alaska cruise
Turned 91 yo 2 mos ago
For patients with severe AS that are not ideally suited for surgery:

**Therapeutic Options?**

- High-risk surgical aortic valve replacement
- Apical – aortic conduit or SAVR with ascending and arch replacement under circulatory arrest
- Medical management with BAV
Transfemoral Procedural Animation
TAVR is a “game changer”

1. Allows us to treat the “untreatable”
2. Minimally invasive
   • no sternotomy, beating heart (no bypass)
3. Forces us to re-evaluate how we manage valvular heart disease
A Gamechanger is Needed
Population at Risk for Aortic Stenosis is Increasing

Over 40 Million People in the US
Over the Age of 65\textsuperscript{1}

\begin{itemize}
  \item Aortic stenosis is estimated to be prevalent in up to 7% of the population over the age of 65\textsuperscript{2}
  \item Between 1990 and 2020, the population from 65 – 74 years will increase 74%
  \item 80% of adults with symptomatic aortic stenosis are male\textsuperscript{3}
\end{itemize}

\textbf{Population: 1960 to 2050 (in Millions)}
\begin{itemize}
  \item Elderly
\end{itemize}

Source: US Census Bureau, (US Census, 2010)\textsuperscript{1}

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Worse Prognosis than Many Metastatic Cancers

5-Year Survival (Distant Metastasis) (4)

- 5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

*Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuczu, MD, Cleveland Clinic
Studies show at least 40% of severe aortic stenosis (SAS) patients are not treated with an AVR.\textsuperscript{5–11}
So Who is a Candidate?

Start with the basics
Current Indications for TAVR

- Patients with severe aortic stenosis
  - Symptomatic

- Patient wants something done

- Inoperable/extreme risk
  - Due to comorbidities or for anatomic reasons

- High calculated surgical risk
  - STS calculated mortality risk in excess of 8%
Symptoms include: Dyspnea or decreased exercise tolerance, heart failure, angina, syncope and presyncope

Patients with severe aortic stenosis typically have an aortic valve area ≤ 1.0 cm²

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Valve Hemodynamics</th>
<th>Hemodynamic Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>D: Symptomatic Severe Aortic Stenosis</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>D1</td>
<td>High-gradient</td>
<td>▪ Aortic jet velocity ≥ 4m/s or mean gradient ≥ 40 mmHg&lt;br▷ Or aortic valve area index ≤ 0.6 cm²/m²</td>
<td>▪ Left ventricular diastolic dysfunction&lt;br▪ Left ventricular hypertrophy&lt;br▪ Pulmonary hypertension may be present</td>
</tr>
<tr>
<td>D2</td>
<td>Low-flow/low-gradient with reduced left ventricular ejection fraction</td>
<td>▪ Resting aortic jet velocity &lt; 4m/s or mean gradient &lt; 40 mmHg&lt;br▪ Dobutamine stress echocardiography shows aortic valve area ≤ 1.0 cm² with aortic jet velocity ≥ 4m/s at any flow rate</td>
<td>▪ Left ventricular diastolic dysfunction&lt;br▪ Left ventricular hypertrophy&lt;br▪ Left ventricular ejection fraction &lt; 50%</td>
</tr>
<tr>
<td>D3</td>
<td>Low-gradient with normal left ventricular ejection fraction or paradoxical low-flow</td>
<td>▪ Aortic jet velocity &lt; 4m/s or mean gradient &lt; 40 mmHg&lt;br▪ Indexed aortic valve area ≤ 0.6 cm²/m²&lt;br▪ Stroke volume index &lt; 35 mL/m² measured when patient is normotensive (systolic blood pressure &lt; 140 mmHg)</td>
<td>▪ Increased left ventricular relative wall thickness&lt;br▪ Small left ventricular chamber with low stroke volume&lt;br▪ Restrictive diastolic filling&lt;br▪ Left ventricular ejection fraction ≥ 50%</td>
</tr>
<tr>
<td>Echo Findings</td>
<td>TAVR (N = 348)</td>
<td>AVR (N = 351)</td>
<td>p-value</td>
</tr>
<tr>
<td>------------------------</td>
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</tr>
<tr>
<td>AVA - cm²</td>
<td>0.7 ± 0.2</td>
<td>0.6 ± 0.2</td>
<td>0.13</td>
</tr>
<tr>
<td>AVG - mm Hg</td>
<td>42.7 ± 14.6</td>
<td>43.5 ± 14.3</td>
<td>0.45</td>
</tr>
<tr>
<td>Mean LVEF - %</td>
<td>52.5 ± 13.5</td>
<td>53.3 ± 12.8</td>
<td>0.45</td>
</tr>
<tr>
<td>Moderate or severe MR - %</td>
<td>19.8</td>
<td>21.3</td>
<td>0.63</td>
</tr>
</tbody>
</table>
Characteristics of a TAVR Patient (13)

TAVR patients may present with some of the following:

- Severe, symptomatic native aortic valve stenosis
- Old age
- Frailty
- History of stroke/CVA
- History of syncope
- Reduced EF
- Heavily calcified aorta
- Prior CABG
- Prior chest radiation
- History of AFib
- History of CAD
- Prior open chest surgery
- History of COPD
- Fatigue, slow gait
- History of renal insufficiency
- Peripheral vascular disease
- Diabetes and hypertension
### PARTNER Trial Patient Characteristics (13)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVR (N = 348)</th>
<th>AVR (N = 351)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>83.6 ± 6.8</td>
<td>84.5 ± 6.4</td>
<td>0.07</td>
</tr>
<tr>
<td>Male sex – %</td>
<td>57.8</td>
<td>56.7</td>
<td>0.82</td>
</tr>
<tr>
<td>STS Score</td>
<td>11.8 ± 3.3</td>
<td>11.7 ± 3.5</td>
<td>0.61</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>29.3 ± 16.5</td>
<td>29.2 ± 15.6</td>
<td>0.93</td>
</tr>
<tr>
<td>NYHA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II – %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III or IV – %</td>
<td>94.3</td>
<td>94.0</td>
<td>0.79</td>
</tr>
<tr>
<td>CAD – %</td>
<td>74.9</td>
<td>76.9</td>
<td>0.59</td>
</tr>
<tr>
<td>Previous MI – %</td>
<td>26.8</td>
<td>30.0</td>
<td>0.40</td>
</tr>
<tr>
<td>Prior CV Intervention – %</td>
<td>72.1</td>
<td>71.6</td>
<td>0.93</td>
</tr>
<tr>
<td>Prior CABG – %</td>
<td>42.6</td>
<td>44.2</td>
<td>0.70</td>
</tr>
<tr>
<td>Prior PCI – %</td>
<td>34.0</td>
<td>32.5</td>
<td>0.68</td>
</tr>
<tr>
<td>Prior BAV – %</td>
<td>13.4</td>
<td>10.2</td>
<td>0.24</td>
</tr>
<tr>
<td>Cerebrovascular disease - %</td>
<td>29.3</td>
<td>27.4</td>
<td>0.60</td>
</tr>
<tr>
<td>Characteristic</td>
<td>TAVR (N = 348)</td>
<td>AVR (N = 351)</td>
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</tr>
<tr>
<td>--------------------------------------</td>
<td>----------------</td>
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</tr>
<tr>
<td>Peripheral vascular disease – %</td>
<td>43.0</td>
<td>41.6</td>
<td>0.76</td>
</tr>
<tr>
<td>COPD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>43.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen dependent</td>
<td>9.2</td>
<td>7.1</td>
<td>0.34</td>
</tr>
<tr>
<td>Creatinine &gt; 2mg/dL – %</td>
<td>11.1</td>
<td>7.0</td>
<td>0.06</td>
</tr>
<tr>
<td>Atrial fibrillation – %</td>
<td>40.8</td>
<td>42.7</td>
<td>0.75</td>
</tr>
<tr>
<td>Permanent pacemaker – %</td>
<td>20.0</td>
<td>21.9</td>
<td>0.58</td>
</tr>
<tr>
<td>Pulmonary hypertension – %</td>
<td>42.4</td>
<td>36.4</td>
<td>0.15</td>
</tr>
<tr>
<td>Frailty – %</td>
<td>15.6</td>
<td>17.6</td>
<td>0.58</td>
</tr>
<tr>
<td>Porcelain aorta – %</td>
<td>0.6</td>
<td>1.1</td>
<td>0.69</td>
</tr>
<tr>
<td>Chest wall radiation – %</td>
<td>0.9</td>
<td>0.9</td>
<td>1.00</td>
</tr>
<tr>
<td>Liver disease – %</td>
<td>2.0</td>
<td>2.6</td>
<td>0.80</td>
</tr>
</tbody>
</table>
Ideal Candidate for TAVR

- Elderly patient with severe, symptomatic aortic stenosis (lifestyle limiting) who is otherwise reasonably “healthy”
- Individual at any age with severe, symptomatic aortic stenosis who have anatomic limitations to redo sternotomy/SAVR
Not a candidate for TAVR

- Severe mental impairment…if they can’t provide informed consent, it probably shouldn’t be done
- Debilitated by other conditions—end-stage COPD, advanced malignancy
- Coexisting severe cardiopulmonary conditions such as coexisting severe MR or severe pulmonary hypertension
- Multi-system failure
- Inability to function independently
Multidisciplinary approach ensures:

- Patient centric care
- Thorough assessment by a team of specialists
- Collaborative treatment decision
TAVR Evaluation Pathway

1. Pre-screening Review of Records
2. Clinical Evaluation
3. Gated CTA (Chest/Abdomen/Pelvis)
4. RHC/LHC Coronary Angiography
5. Functional Status Assessment (Cognitive Function, Frailty, etc.)
6. STS Score Calculation
7. Treatment Plan
While some patients may have low STS scores, certain conditions may preclude them from being suitable candidates for surgery, for example:

- Extensively calcified (porcelain) aorta
- Chest wall deformity
- Oxygen–dependent respiratory insufficiency
- Frailty
Operative Risk Increases With Age But Chronological Age is Not a Contraindication to TAVR
Prevalence of frailty increases with aging; old does not necessarily equal frail

Elderly patients achieve measurable benefit from cardiac surgery, particularly in terms of:
  ◦ Quality of life
  ◦ Increased survival
  ◦ Prevention of adverse cardiovascular events
Frailty as a Predictor of Outcome

- It is measurable and quantifiable.
- Predicts poor outcome with SAVR but also with TAVR.
- Does AS confound assessment of frailty?
The End of the Bed Test (AKA: Eyeball Test)

Same age (90) and predicted risk (12%)

One passes the “eyeball test,” one does not

Image provided courtesy of Todd Dewey, MD, Medical City Dallas
Multiple Modalities for Assessing Frailty

- PARTNER II Trial Frailty Index Assessment
  - 15–Foot Walk
  - Grip strength
  - Serum albumin
  - Katz ADLs – (Independence in dressing, bathing, toileting, transferring, feeding, continence)
Gait speed is a simple and effective test that may identify a subset of vulnerable elderly patients at incrementally higher risk or mortality and major morbidity after cardiac surgery. (14)
# Frailty Testing- Katz ADL's

<table>
<thead>
<tr>
<th>KATZ BASIC ACTIVITIES OF DAILY LIVING (ADL) SCALE</th>
<th>Independent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Bathing (sponge bath, tub bath, or shower)</td>
<td>YES</td>
</tr>
<tr>
<td>Receives either no assistance or assistance in bathing only one part of body</td>
<td></td>
</tr>
<tr>
<td>2. Dressing - Gets clothes and dresses without any assistance except for tying shoes.</td>
<td></td>
</tr>
<tr>
<td>3. Toileting - Goes to toilet room, uses toilet, arranges clothes, and returns without any assistance (may use cane or walker for support and may use bedpan/urinal at night).</td>
<td></td>
</tr>
<tr>
<td>4. Transferring - Moves in and out of bed and chair without assistance (may use can or walker).</td>
<td></td>
</tr>
<tr>
<td>5. Continence - Controls bowel and bladder completely by self (without occasional &quot;accidents&quot;).</td>
<td></td>
</tr>
<tr>
<td>6. Feeding - Feeds self without assistance (except for help with cutting meat or buttering bread).</td>
<td></td>
</tr>
</tbody>
</table>

**A score of:**
- 6- indicates full function
- 4- indicates moderate impairment
- 2- or less indicates severe functional impairment.
Not Frail

Frail
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Not Frail

Frail
Who is Too Sick for TAVR?

- If a patient’s comorbid conditions, particularly frailty and pulmonary hypertension, overwhelm the likelihood of functional recovery despite successful TAVR.
Pulmonary hypertension and TAVR outcome
Moderate/Severe MR and mortality (13)

P = 0.027 (log rank)
A Collaborative Treatment Decision

1. Patient with Severe Aortic Stenosis Identified by Referring Physician
2. Patient Referred to TAVR Valve Clinic
3. Additional Testing Completed
4. Multidisciplinary Review and Treatment Decision by TAVR Heart Team
5. Treatment Decision Discussed with Referring Physician

Devising a Treatment Plan is a Collaborative Process. Ultimate treatment choice is a collaborative decision between the physicians, patient and patient’s family.
Key to Success and Ethical Selection of Appropriate TAVR Candidates

- Distinguish those patients who are dying from aortic stenosis from those who are dying with aortic stenosis.
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References


Ben–Dor et al. AJC 2011; 107:1046–51

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