Who is Not a TAVR Candidate?

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Disclosures

No Financial Relationships

Who is Not a TAVR Candidate?

Objectives
- Changing paradigm for TAVR patient selection
- Importance of selecting patients likely to benefit from AVR
- Favorable and unfavorable anatomy (bicuspид)
- Factors to consider in young & low risk patients
The Old Paradigm for Selecting TAVR Candidates was Based on Perceived Risk for Surgical AVR

<table>
<thead>
<tr>
<th>Surgical Risk</th>
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<tr>
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Why not offer TAVR in 2020?

Patient Selection is Based on a Combination of Clinical and Anatomical Factors

Clinical Factors & Anticipated Benefit
- Age
- Quality of life
- Symptom burden
- Goals of care
- Poly-valvular disease
- Concomitant CAD

Anatomical & Technical Factors
- TF access
- Coronary clearance
- Annular size
- Bicuspid morphology
- Aortic insufficiency
- Surgical valve type
- LVOT anatomy

1. Will this patient benefit (mortality, QOL) from AVR?
2. What is best technical approach (TAVR or SAVR)?
Selecting Patients with Anticipated Benefit from AVR is Critically Important

Poor Outcome 1 Year s/p TAVR in 252 US Centers (N=13,351)

**Risk Factors**
- Lower mean AV gradient
- Lower baseline QOL (KCCQ OS)
- Home oxygen
- Higher creatinine level
- Baseline atrial fibrillation
- Baseline diabetes mellitus

Arnold SV et al. *Circ Cardiovasc Qual Outcomes*. 2018

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76yo man with amyloidosis, ESRD, recent prolonged hospitalization for SARS-Cov-2 pneumonia

- Severe AS (MG=46 mmHg)
- Cardiac amyloid (Tn 0.6, NTBNP>35k)

Reconsider for TAVR pending clinical course

- Recent months long hospitalization
- Symptoms of fatigue
- Wheelchair bound
- Anatomy suitable for TF-TAVR
Factors Influencing Patient Selection Vary by Risk Strata

Inoperable

Futility?
Will the patient benefit?
What is the overall prognosis?
Are the symptoms due to AS?

Low Risk

Anatomy?
Annular/root dimensions?
Bicuspid morphology?
LVOT calcification?
TF access?

Bicuspid Aortic Valve Anatomy is Complex & Variable

Sievers Type 0
“True bicuspid”
No raphe
5%

Sievers Type 1
1 raphe
Symmetrical
90%

Sievers Type 2
“Unicuspid”
2 raphes
5%

Sievers Type 1
1 raphe
Asymmetrical
 Favorable vs. Unfavorable Bicuspid Anatomy for TAVR

**Favorable**
- Mildly calcified raphe
- 3 symmetrical sinuses (Sievers 1)
- Normal aortic root dimensions

**Unfavorable**
- Sievers type 0, 2
- Asymmetric Sievers 1
  - Deep sinus / long leaflet
- Heavily calcified Raphe
- Horizontal aorta
- Ascending aortopathy
- Very large annulus

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TAVR in Bicuspid Aortic Valves Requires Careful Attention to Anatomic Factors

*Outcomes of Commercial TAVR in 170,959 Patients in US (2011-2018)*

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Bicuspid (N=5412)</th>
<th>Tricuspid (N=165547)</th>
</tr>
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<tbody>
<tr>
<td>Death</td>
<td>2.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Stroke</td>
<td>2.2%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Major / Life-threatening Bleeding</td>
<td>5.7%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Need for 2nd THV</td>
<td>1.7%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Mod/Severe PVL</td>
<td>4.4%</td>
<td>3.2%</td>
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P-values:
- Death: P=0.48
- Stroke: P=0.15
- Major / Life-threatening Bleeding: P=0.16
- Need for 2nd THV: P=0.002
- Mod/Severe PVL: P<0.001

Halim SA et al. *Circulation*. 2020
TAVR in Bicuspid Aortic Valves Requires Careful Attention to Anatomic Factors


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<thead>
<tr>
<th></th>
<th>Death</th>
<th>Stroke</th>
<th>Conversion to OHS</th>
<th>New Pacemaker</th>
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<tr>
<td>Bicuspid</td>
<td>1.7%</td>
<td>2.1%</td>
<td>0.9%</td>
<td>7.3%</td>
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Makkar R et al. JAMA. 2019

74yo asymptomatic man with bicuspid AV

- Treadmill: 6 METs, normal BP response, limited by spinal stenosis

Severe AS

Unfavorable bicuspid anatomy for TAVR

Awaiting Bentall procedure (Surgical AVR + aortic root replacement)

Ascending aortic aneurysm meeting surgical threshold
69yo asymptomatic man with bicuspid AV

- Treadmill: 7 METs, normal BP response, +aVR/V1 ST elevation

Severe AS  \hspace{1cm} \text{Favorable TAVR anatomy} \hspace{1cm} \text{LAD IFR 0.66}

Treated with CABG + SAVR (25mm Magna)

Long-Term Considerations are now Important for TAVR Patient Selection

- Elderly & higher risk
- Multiple comorbidities
- No other treatment options

Can we offer few \textit{years} of longevity with good quality of life?

- Younger & few comorbidities
- Multiple treatment options

\textit{Can we offer decades} of longevity with good quality of life?

Will multiple valve procedures be feasible?
The Risk of Coronary Obstruction with TAV-in-TAV is a Concern for Younger Patients


"TAV-in-TAV may not be feasible in >20% of S3 TAVR procedures"

BASILICA Procedure to Protect Coronary Perfusion may not be Feasible for Some TAV-in-TAV

Leaflet can be lacerated (BASILICA) to protect left main blood flow

Leaflet laceration is not helpful, because TAV commissure is in front of the left main
Potential Reasons to Avoid TAVR

**Inoperable**
- Anticipated survival <1-2 years
- No anticipated QOL benefit

**Low Risk**
- Young age
- High CAD complexity
- Pure aortic regurgitation
- Unfavorable bicuspid anatomy
- Current/future concerns of coronary obstruction

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Thank You