Severe Aortic Stenosis: TAVI

My Patient Needs Cardiac Intervention: Should I Advise him Open or Endo?

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My Patient Needs Cardiac Intervention: Should I Advise him Open or Endo?
Surgery vs. Intervention: A Robust Clinical Evidence

PTCA vs. CABG

- SOS Trial
- BARI Trial
- SYNTAX Trial
- PRECOMB Trial
- MAIN COMPARE Trial
- ERACI II Study
- ARTS Trial
- MASS II Study

Highest level of achievement
Non-inferiority level

TAVI vs. SAVR

- PARTNER Trials
- CoreValve US Pivotal Trial

Highest level of achievement
Superiority level

Adapted from Laborde JC
PARTNER A: High-Risk Patients

Hazard ratio, 0.93 (95% CI, 0.71–1.22)
P = 0.62

Death from Any Cause (%)

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Transcatheter</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months</td>
<td>0</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>348</td>
<td>298</td>
</tr>
<tr>
<td></td>
<td>351</td>
<td>252</td>
</tr>
</tbody>
</table>

PARTNER B: Inoperable Patients

Hazard ratio, 0.55 (95% CI, 0.40–0.74)
P<0.001

No. at Risk
TAVI 179 138 122 67 26
Standard therapy 179 121 83 41 12

Aortic Valve Mean Gradient

No structural valve deterioration that required re-intervention.

$p < 0.0001$

Error Bars = ± 1 Std Dev
CoreValve
U.S. Pivotal Trial

P=0.04 for superiority

Surgical replacement

Death from Any Cause (%)

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>Surgical replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Months</td>
<td>390</td>
<td>377</td>
</tr>
<tr>
<td>12 Months</td>
<td>353</td>
<td>297</td>
</tr>
<tr>
<td>STS = 7</td>
<td>329</td>
<td>274</td>
</tr>
</tbody>
</table>

CoreValve® US PIVOTAL TRIAL | Echocardiographic Findings

TAVR had significantly better valve performance over SAVR at all follow-up visits ($p<0.001$)

- **Aortic Valve Area, cm²**
  - Surgical: 48.3, 1.94, 1.94, 1.91, 1.91, 1.87
  - CoreValve TAVR: 47.7, 1.58, 1.60, 1.56, 1.57, 1.51

- **AV Mean Gradient, mm Hg**
  - Surgical: 9.9, 13.2, 11.7, 12.1, 12.4, 12.1
  - CoreValve TAVR: 8.9, 8.5, 9.1, 9.1, 9.1, 8.5
TAVI
Slowly Moving Towards Lower-Risk Patients...

Adapted from Head SJ et Kappetein P, EuroIntervention 2010;6:560-561
**TAVI Device Adoption and Experience**

- **A:** Lack of convincing evidence leads to low penetration (niche) or end
- **B:** Acceptance in daily practice with specific proven clinical indication; alternative options still indicated
- **C:** Gold Standard, replacing established therapies

Early enthusiasm, “exploding” interest

Broader application reveals downsides, issues, complications

Benefit/Concern reassessment

Adapted from Laborde JC
TAVI
Room for Improvement?

- Improved Outcome
  - Patient Selection
  - Improved Visualization/Measurement
  - Second Generation Valves
  - Embolic Protection Devices
  - Smaller Catheter Size
  - Increasing Experience
Paravalvular Leakage: Severe Aortic Regurgitation

AR index = \[
\frac{(DBP-LVEDP)}{SBP}\times100
\]

Mortality (%)

| AR index |  |  |
|----------|---------------|
| <25      | 31.3 (10/32)  |
| ≥25      | 60.0 (12/20)  |
|          | 14.3 (10/70)  |

Vasa-Nicotera M et al, J Am Coll Cardiol Intv 2012;5:858–65
Sinning JM et al, J Am Coll Cardiol. 2012;59(13):1134-1141
Moderate/Severe PVL at 30 Days
Edwards SAPIEN Valves

PARTNER I and II Trials

<table>
<thead>
<tr>
<th></th>
<th>SAPIEN</th>
<th>SAPIEN XT</th>
<th>SAPIEN 3</th>
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</thead>
<tbody>
<tr>
<td>P1B (TF)</td>
<td>12.0%</td>
<td>24.2%</td>
<td></td>
</tr>
<tr>
<td>P1A (Overall)</td>
<td>11.5%</td>
<td></td>
<td>2.9%</td>
</tr>
<tr>
<td>P2B (TF)</td>
<td>16.9%</td>
<td></td>
<td>4.2%</td>
</tr>
<tr>
<td>P2B XT (TF)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S3HR (Overall)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S3i (Overall)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sample sizes:
- P1B (TF): 179
- P1A (Overall): 344
- P2B (TF): 276
- P2B XT (TF): 284
- S3HR (Overall): 583
- S3i (Overall): 1076
TAVI
Vascular Complications

TAVI Sheath Diameter

- SAPIEN (2006)
- SAPIEN XT (2009)
- SAPIEN 3 (2013)

Diameters: 24F, 22F, 16F, 14F
TAVI Strokes


MRS = Modified Rankin Scale
All Stroke

CoreValve US Clinical Trials

ACC 2014

Surgical

Transcatheter

All Stroke (%)

Months Post-Procedure

No. at Risk

Surgical 357 322 274 249

Transcatheter 390 363 334 314

Log-rank P=0.10
Cerebral Protection System: Claret Medical Sentinel™
# Neurological Outcome

<table>
<thead>
<tr>
<th>Control</th>
<th>per protocol</th>
<th>cumulative</th>
<th>2 days (No, %)</th>
<th>7 days (No, %)</th>
<th>30 days (No, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any symptom</td>
<td>17 (34 %)</td>
<td>14 (28 %)</td>
<td>5 (10 %)</td>
<td>6 (12 %)</td>
<td></td>
</tr>
<tr>
<td>- Ataxia</td>
<td>16 (32 %)</td>
<td>12 (24 %)</td>
<td>4 (8 %)</td>
<td>5 (10 %)</td>
<td></td>
</tr>
<tr>
<td>Filter</td>
<td>Any symptom</td>
<td>11 (24 %)</td>
<td>6 (13 %)</td>
<td>6 (13 %)</td>
<td>4 (12 %)</td>
</tr>
<tr>
<td>- ataxia</td>
<td>9 (20 %)</td>
<td>4 (9 %)</td>
<td>5 (11 %)</td>
<td>4 (12 %)</td>
<td></td>
</tr>
<tr>
<td>n=45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

RR 1.458 (1.006 to 2.114), OR 2.5, p=0.08  
RR 1.559 (1.083 to 2.214), OR 3.2, p<0.05
# TAVI
Room for Improvement!

<table>
<thead>
<tr>
<th>Event</th>
<th>SAVR</th>
<th>Edwards</th>
<th>CoreValve</th>
<th>New Valves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Success (VARC)</td>
<td>&gt;99%</td>
<td>&lt;95%</td>
<td>&lt;95%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Valve Embolization</td>
<td>0</td>
<td>0.1-1%</td>
<td>&lt;0.1%</td>
<td>0</td>
</tr>
<tr>
<td>Annulus Rupture</td>
<td>&lt;0.1%</td>
<td>0.1-1%</td>
<td>&lt;0.1%</td>
<td>0</td>
</tr>
<tr>
<td>Coronary (Sub-)Occlusion</td>
<td>&lt;0.1%</td>
<td>0.1-1%</td>
<td>0.1%</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td>Valve Dislodgement</td>
<td>0</td>
<td>&lt;0.1%</td>
<td>1-3%</td>
<td>0</td>
</tr>
<tr>
<td>Need for Additional Valves</td>
<td>0</td>
<td>2-3%</td>
<td>3-5%</td>
<td>0</td>
</tr>
<tr>
<td>Paravalvular Leakage ≥2</td>
<td>&lt;3%</td>
<td>&gt;10%</td>
<td>&gt;10%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>2-9%</td>
<td>5-10%</td>
<td>10-35%</td>
<td>5-10%</td>
</tr>
<tr>
<td>Major Vascular Complications</td>
<td>&lt;5%</td>
<td>15%</td>
<td>10%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1-4%</td>
<td>2-6%</td>
<td>2-4%</td>
<td>&lt;3%</td>
</tr>
</tbody>
</table>

Adapted from Bonow RO et al, Circulation 2006;114;e84-e231
My Patient Needs Cardiac Intervention: Should I Advise him Open or Endo?

- Based on randomized trial evidence, TAVI has become an established alternative to surgical AVR in a high-risk and high-to intermediate risk population; results for intermediate-risk patients are on the way.

- Durability results look very promising.

- There has been improvement regarding paravalvular leakage, pacemaker rates, vascular access complications, and stroke rates which are addressed by new devices and valve types.
My Patient Needs Cardiac Intervention: Most Patients have Chosen Already...
Aortic Valve Therapy in Germany

Aortic Valve Therapy in Germany

Vielen Dank
für Ihre Aufmerksamkeit