TAVI
Which Valve for which Patient?

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Disclosures

Presenter: Adam Witkowski

• Proctorship: Medtronic
• Speaker’s Bureau: Boston Scientific, Edwards, Medtronic
In the next 10 years, TAVR growth will increase X4!

M. Leon @ TVT 2017
Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode (continued)

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
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<tbody>
<tr>
<td>The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in the according table). In addition, the local expertise and outcomes data for the given intervention must be taken into account.</td>
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<td>SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II ≤4% or logistic EuroSCORE I &lt;10% and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).</td>
<td>I</td>
<td>B</td>
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<tr>
<td>TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.</td>
<td>I</td>
<td>B</td>
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STS database 2002-2010
n=141,905

High risk (STS > 8%)
Intermediate risk (STS 4-8%)
Low risk (STS <4%)
4 Major Procedural TAVI Problems

SAFETY
• Bleedings and vascular complications
• Stroke

EFFICACY
• Paravalvular leaks
• Patient’s frailty and futility of TAVI

Bleedings and Vascular Complications

• Femoral access is used in >90% of TAVI cases
• Despite ongoing miniaturization of TAVI delivery systems bleedings and vascular complications remain a source of problems in 2017 that are not much not different (however the incidence is lower) than in 2002
• *Major bleeding (≈13%) and *vascular complications (≈6%) strongly influence TAVI outcome

* CoreValve US Clinical Trials, ACC 2014
Impact of major vascular complications on 1-year mortality. Data from a pooled analysis of an as-treated TAVI cohort enrolled in PARTNER IA and IB.

Ultra-low profile SAPIEN 3 system expands treatment possibilities while reducing complications.

Reduction in Major Vascular Complications In Transfemoral Patients

15.9%²
N = 271
PARTNER II Trial Coh B SAPIEN Valve 23/26 mm

11.3%³
N = 262
PARTNER II Trial Coh B SAPIEN XT Valve 23/26 mm

5.3%²
N = 491
PARTNER II Trial SAPIEN 3 Valve 20/23/26/29 mm

4.2%³
N = 96
SAPIEN 3 Trial SAPIEN 3 Valve 23/26/29 mm

Sheath - Edwards RetroFlex 3 Introduction Sheath Set
Sheath Size - 22 / 24F
Minimum Vessel Access Diameter - 7.0 / 8.0 mm

1. Data on file, Edwards Lifesciences
**Stroke Rates in Randomized Trials**

Weighted average (n=8,987)

- **30-Day All Stroke**
  - Extreme Risk: 6.7%, N=179
  - Extreme Risk: 4.1%, N=276
  - High Risk: 4.6%, N=348
  - Extreme Risk: 4.3%, N=284
  - Intermediate Risk: 5.5%, N=1,011
  - Extreme Risk: 4.0%, N=489
  - High Risk: 4.9%, N=980

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**Stroke Rates with Contemporary Devices**

Weighted average (n=5,952)

- 30-Day All Stroke
  - Evolut R EV: 7.4%
  - Evolut R: 7.0%
  - AcurRx: 6.0%
  - Portico: 5.5%
  - Sapien 3: 2.7%
  - Solstice: 4.0%
  - Direct Flow: 2.7%
  - CoreValve: 6.6%
  - Lotus: 3.0%
  - Direct Flow: 7.7%

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S Kapadia @ TVT 2017
Risk of cerebrovascular events according to time after TAVI

Ghanem A et al. Current Pharmaceutical Design

Cerebral Protection Devices

S Kapadia @ TVT 2017
**Patient Level Meta-analysis: CLARET Lesion Volume in Protected Territories**

<table>
<thead>
<tr>
<th>% Change (95% CI) [Absolute Difference, mm³]</th>
<th>Favors Test</th>
<th>Favors Control</th>
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<tbody>
<tr>
<td>CLEAN-TAVI (N=94)</td>
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<tr>
<td>-52.7% (-73.8%, -15.0%) [-191]</td>
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<td>MISTRAL-C (N=36)</td>
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<tr>
<td>-66.9% (-89.4%, 3.4%) [-45]</td>
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<tr>
<td>SENTINEL (N=189)</td>
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<td>-18.9% (-53.0%, 40.2%) [-25]</td>
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<td>OVERALL (N=319)</td>
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<tr>
<td>-37.5% (-57.6%, -8.0%) [(p = 0.017) [-50]</td>
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*Patient-level data used in analyses

Data presented at Sentinel FDA Advisory Panel, February 23, 2017

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**Ulm Sentinel study**

- 802 all-comer consecutive TAVR patients at University of Ulm were prospectively enrolled
- A propensity-score analysis was done matching the 280 patients protected with Sentinel to 280 control patients

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**Cleveland Clinic** Wöhle J, Seeger J, et al. DGK Mannheim 2017: CSI-Ulm-TAVR Study clinicatlines.gov NCT02162069
Watch-TAVR

Severe AS and Atrial Fibrillation
N=400

Randomization 1:1

TAVR + Watchman
TAVR + Medical management

Randomization 3:1

Simultaneous (n=50)
Staged (n=150)

Investigator initiated
Principle Investigator
- Samir Kapadia
- Martin Leon
Sponsored by BSc

Paravalvular Leak in PARTNER 1 (TAVI cohort)
TAVI, Evolute Pro 29
Frailty is associated with increased morbidity and mortality after surgery and TAVI and futility of intervention.

The assessment of frailty should not rely on a subjective approach, such as the ‘eyeball test’, but rather on a combination of different objective estimates.

Poor mobility, as assessed by the 6-minute walk test, and oxygen dependency are the main factors associated with increased mortality after TAVI and other VHD treatments.
Should Clinical and Anatomic Factors Determine TAVI Device Selection to Achieve Best Result and Avoid Complications?

• YES – case planning is needed

• The landscape is rapidly evolving
4 Major Procedural TAVI Problems or How to Match Valve to patient?

- Bleedings and vascular complications: use smallest possible diameter of the delivery system
- Stroke: use neurprotective devices (as a routine?). Optimal antithrombotic treatment
- Paravalvular leaks: use valve with anti-leak external collar
- Frailty and futility of TAV: better patient selection!