TRANSCATHETER HEART VALVE THERAPIES FOR ALL HEART VALVES: FROM AN INNOVATION STRATEGY TO MAINSTREAM THERAPY

SESSION OBJECTIVES

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THE GLOBAL BURDEN OF VALVE HEART DISEASES


Moderate or severe valvular disease in Olmsted Country (n=16,501)

Prevalence by Age

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>All valve disease</th>
<th>Mitral valve disease</th>
<th>Aortic valve disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;45</td>
<td>&lt;0.5%</td>
<td>&lt;1%</td>
<td>&lt;2%</td>
</tr>
<tr>
<td>45-54</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55-64</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥75</td>
<td>4.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.7%</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Impact on Survival

- Without valve disease
- With valve disease

p<0.0001
ADVANTAGES OF TRANSCATHETER VS. SURGICAL HEART VALVES INTERVENTIONS

PROCEDURE

INVASIVENESS
CARDIOPULMONARY BYPASS
INFECTION
STERNAL WOUND DEHISCENCE
PROLONGED VENTILATION

EARLY PERI-PROCEDURE

TAVI vs. SAVR

MORTALITY

-20%

-50
-40
-40

ATRIAL FIBRILLATION
MAJOR BLEEDING
RENAL FAILURE
# 15 Years of TAVI (2002 – 2017)

## Device Evolution

<table>
<thead>
<tr>
<th>Year</th>
<th>Device</th>
<th>Frame/Deployment</th>
<th>Valve Material/Components</th>
<th>Access</th>
<th>Anti Calcification Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>Edwards Sapien THV</td>
<td>Balloon-expansible stainless steel</td>
<td>Bovine pericardium</td>
<td>TF, TA</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Edwards Sapien XT</td>
<td>Balloon-expansible cobalt chromium</td>
<td>Bovine pericardium, Polyethylene terephtalate (PET) fabric skirt</td>
<td>TF, TA</td>
<td>Thermafix process™ (glutaraldehyde fixation)</td>
</tr>
<tr>
<td></td>
<td>Symetis Acurate TA</td>
<td>Self-expanding nitinol</td>
<td>Porcine pericardium, Polyethylene terephtalate</td>
<td>TA</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Abbott/ST Jude Portico</td>
<td>Self-expanding nitinol</td>
<td>Bovine pericardium, Polycarbonate - based urethane material</td>
<td>TF, TA, TAo</td>
<td>Linx AC technology™</td>
</tr>
<tr>
<td></td>
<td>Boston Scientific Lotus</td>
<td>Mechanically-expandable braided nitinol</td>
<td>Bovine pericardium, Polyethylene terephtalate fabric cuff</td>
<td>TAo</td>
<td>T-Guard™</td>
</tr>
<tr>
<td></td>
<td>Edwards Sapien 3</td>
<td>Balloon-expansible cobalt chromium alloy</td>
<td>Bovine pericardium, Polyethylene terephtalate</td>
<td>TAo</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>New Valve Technology Allegra</td>
<td>Self-expanding nitinol</td>
<td>Bovine pericardium</td>
<td>TAo</td>
<td>Alphateno Oleic Acid</td>
</tr>
<tr>
<td></td>
<td>Medtronic Evolut R</td>
<td>Self-expanding nitinol</td>
<td>Porcine pericardium</td>
<td>TAo</td>
<td>Thermiafix process™</td>
</tr>
<tr>
<td>2017</td>
<td>Edwards Centera</td>
<td>Self-expanding nitinol</td>
<td>Bovine pericardium</td>
<td>None</td>
<td>None</td>
</tr>
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</table>

**Medtronic CoreValve**
- Frame: Self-expanding nitinol
- Valve: Porcine pericardium
- Access: TF, TA, DA (glutaraldehyde fixation)

**Jena Valve**
- Frame: Self-expanding nitinol
- Valve: Porcine pericardium
- Access: TA (glutaraldehyde fixation)

**Symetis Acurate Neo**
- Frame: Self-expanding nitinol
- Valve: Porcine pericardium, Polyethylene terephtalate, TF, TA
- Access: TA (glutaraldehyde fixation)

**Medtronic Evolut Pro**
- Frame: Self-expanding nitinol
- Valve: Porcine pericardium
- Access: TF
- Anti Calcification Treatment: Alphateno Oleic Acid

**Boston Scientific Lotus Edge**
- Frame: Self-expanding braided nitinol
- Valve: Bovine pericardium
- Access: TF
- Anti Calcification Treatment: T-Guard™
## Indications for TAVI or SAVR

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a ‘heart team’ and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a ‘heart team’ based on the individual risk profile and anatomic suitability</td>
<td>Ila</td>
<td>B</td>
</tr>
</tbody>
</table>

### 2017

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<tr>
<td>In patients who are at increased surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥10%, or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics with TAVI being favoured in elderly patients suitable for transfemoral access</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II &lt;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>
</tr>
</tbody>
</table>

“The favourable results of TAVI have been reproduced in multiple large-scale, nationwide registries supporting the generalizability of outcomes observed in randomized controlled trials. This favours the use of TAVI over surgery in elderly patients at increased surgical risk. However, the final decision between SAVR and TAVI (including the choice of access route) should be made by the Heart Team.”
CARPENTIER CLASSIFICATION OF MITRAL REGURGITATION


**PRIMARY MR**

Type I
Normal leaflet motion

Type II
Increased leaflet motion

Type IIIa
Restricted leaflet motion (systole and diastole)

Type IIIb
Restricted leaflet motion (systole)

**SECONDARY MR**

LEAFLET PERFORATION
CORDAL ELONGATION OR RUPTURE
RHEUMATIC DISEASE
ISCHEMIC OR NONISCHEMIC LV REMODELING

ANNULAR DILATION
TECHNIQUES FOR TRANSCATHETER HEART VALVE INTERVENTIONS

TRANSCATHETER MITRAL VALVE INTERVENTIONS

TRANSCATHETER AORTIC VALVE IMPLANTATION
UNMET NEEDS AND FUTURE PERSPECTIVES

**Aortic**

- Expanding clinical indications
  - Lower risk and younger patients
  - Specific anatomic conditions (bicuspid, aortic regurgitation, failed bioprostheses)

**Mitral**

- Primary MR
  - Expanding indications
  - Refine combined repair procedures to accomplish optimal valve repair
  - Optimize valve replacement to ensure durability of intervention

**Tricuspid**

- Accumulate more data on safety and efficacy of transcatheter interventions

**Pulmonary**

- Improve freedom from reintervention
- Expand the population eligible for the procedure

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*Establish the role in secondary MR vs. medical therapy*
- 4 RCTs ongoing
TRANSCATHETER EDWARDS DEVICES

Aortic: SAPIEN, SAPIEN XT, SAPIEN 3, CENTERA

Mitral: SAPIEN, SAPIEN XT, SAPIEN 3, CENTERA

Tricuspid: PASCAL, Cardioband, FORMA, HARPOON, CARDIAQ

Pulmonary: SAPIEN
SESSION OBJECTIVES

➢ To learn about the Edwards Lifesciences innovation pipeline for the aortic, mitral, tricuspid and pulmonary valve

➢ To understand the latest and upcoming evidence in the aortic field

➢ To learn about the economic value of innovative technology