TAVR in 2015 & Beyond

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Limiting Growth
- Death
- Stroke or TIA
- AV block/pacemaker
- Vascular complications
- Paravalvular regurgitation
- Acute kidney injury

Infrequent
- Coronary obstruction
- Annular rupture
- Ventricular perforation
- Low output syndrome
- Endocarditis
- Prosthetic stenosis

Current TAVR Limitations

Expanding Indication

Operable AS pts
STS <3-4% 3-4 to 8-10% 10-15% >15% >50%
Low-risk Intermediate-risk High-risk Extreme-risk Too-sick
~40% ~15% ~15-20% ~20% ~10%

Rapid Evolution in Device Design


24F 22F 16F 14F

Sheath compatibility for a 23 mm valve

Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis
1-Year Results From the All-Comers NOTION Randomized Clinical Trial

Hannes Gustaf Birgersson Thysvag, MD; David Andreas Brinbrink, MD, DMSc; Nikolai Ehlertsen, MD, PhD; Herrick Nissen, MD, PhD; Bo Asd Kjeldsen, MD, PhD; Peter Petersen, MD; Yipeng Chang, MD; Ole Walter From, MD; Thomas Engstrom, MD, DMSc; Peter Clemmensen, MD, DMSc; Peter Ho Hansen, MD; Lennart Eldblom, MD, DMSc;
SAPIEN 3 Commander Delivery System
Distinguishing Features

- Accurate positioning
- Fine control of valve positioning
- Distal flex

SAPIEN 3 Valve Sizes

<table>
<thead>
<tr>
<th>Size</th>
<th>20 mm</th>
<th>23 mm</th>
<th>26 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expandable Sheath</td>
<td>14F</td>
<td>14F</td>
<td>14F</td>
<td>16F</td>
</tr>
<tr>
<td>Minimum Access Vessel Diameter</td>
<td>5.5 mm</td>
<td>5.5 mm</td>
<td>5.5 mm</td>
<td>6.0 mm</td>
</tr>
</tbody>
</table>

Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>S3HR Patients</th>
<th>N = 583</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average STS = 8.6%</td>
<td>(Median 8.4%)</td>
</tr>
<tr>
<td>Average Age = 82.6 yrs</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age Distribution</th>
<th>20 mm</th>
<th>25 mm</th>
<th>26 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1.9%</td>
<td>34.3%</td>
<td>38.9%</td>
<td>24.9%</td>
</tr>
<tr>
<td>Female</td>
<td>98.1%</td>
<td>65.7%</td>
<td>61.1%</td>
<td>75.1%</td>
</tr>
</tbody>
</table>

Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>S3i Patients</th>
<th>N = 1076</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average STS = 5.3%</td>
<td>(Median 5.2%)</td>
</tr>
<tr>
<td>Average Age = 81.9 yrs</td>
<td></td>
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</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>4.1%</td>
<td>32.2%</td>
<td>43.7%</td>
<td>20.9%</td>
</tr>
<tr>
<td>Female</td>
<td>95.9%</td>
<td>67.8%</td>
<td>56.3%</td>
<td>79.1%</td>
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</tbody>
</table>

Echo Findings: S3HR & S3i

Aortic Valve Area (Valve Implant Patients)

Mortality and Stroke: S3i

O:E = 0.21
(STS 5.3%)

All-Cause Mortality at 30 Days

Edwards SAPIEN Valves (As Treated Patients)

PARTNER I and II Trials

Overall and TF Patients
Embolic Protection Devices for TAVR

<table>
<thead>
<tr>
<th>Device</th>
<th>Capture Size</th>
<th>Pore Size</th>
<th>Position</th>
<th>CE Marked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claret Sentinel™ Cerebral Protection System</td>
<td>6F (radial)</td>
<td>140 micron pore size</td>
<td>Brachiocephalic and LCC</td>
<td>CE marked</td>
</tr>
<tr>
<td>Edward's Embrella™ Embolic Deflector</td>
<td>6F (radial)</td>
<td>100 micron pore size</td>
<td>Aortic arch position</td>
<td>CE marked</td>
</tr>
<tr>
<td>TriGuard™ Cerebral Protection Device</td>
<td>9F (femoral)</td>
<td>130 x 250 micron pore size</td>
<td>Aortic arch position</td>
<td>CE marked</td>
</tr>
</tbody>
</table>

CLEAN-TAVI Study: Total Lesion Number

- Protected regions:
  - 50% p=0.009
  - 57% p=0.0023
- All regions:
  - 50% p=0.0023
  - 50% p=0.0123

The boxes identify the 25%-75% CI, the black lines and number represents the median.

Valve-in-Valve Granted FDA Approval

Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

Transcatheter Aortic Valve Implantation for Failing Surgical Aortic Bioprosthetic Valve

From Concept to Clinical Application and Evaluation (Part 2)

Nicola Piazza, MD, Sabine Breitkreutz, MD, Goran Broekhuizen, MD, Hugo Houbiers, MD, Marcus-Antel Deutsch, MD, Anke Opitz, MD, Domenico Massidda, MD, Peter Tassoni-Pell, MD, PhD, Christian Schenker, MD, Rüdiger Lange, MD, PhD

Munich, Germany

Piazza, MD et al., JACC 2011;4:723

Valve-in-Valve for Bio-Prosthetic AS

Valve-in-Valve for Bio-Prosthetic AS
Transcatheter Aortic Valves Replacement (TAVR)

Surgical risk is a continuum

Operable AS pts

SAVR

???

SURTAVI/ PARTNER IIA

TAVR/ SAVR

TAVR

FUTILE

?BAV

STS: <3%

Low-risk

~40%

3-4 to 8-10%

Intermediate-risk

~15%

10-15%

High-risk

~15-20%

15-50%

Extreme-risk

~20%

>50%

Too-sick

~10%

Future TAVR Indications

- Valve-in-valve for bio-prosthetic AV failure
- Primary Treatment for All Risk Patients
- Bicuspid aortic valve stenosis
- Low flow-low gradient AS
- Asymptomatic severe AS

Emerging TAVR Devices Involving Improved Technologies, Potentially Minimizing PVL/AR after TAVR

Thank You