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### Disclosures

**Speaker’s name:** Christian W. Hamm  
I have the following potential conflicts of interest to report:

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Honoraria for lectures</td>
<td>Medtronic, Edwards</td>
</tr>
<tr>
<td>2. Honoraria for advisory board activities</td>
<td>Medtronic</td>
</tr>
<tr>
<td>3. Participation in clinical trials</td>
<td>Medtronic, Edwards, Symetis, Jena Valve</td>
</tr>
<tr>
<td>4. Financial shares and options:</td>
<td>no</td>
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</tbody>
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Rationale

• Nationwide complete survey of patients with aortic valve stenosis undergoing invasive procedures:
  • surgical (AVR),
  • catheter-based (TAVI) transfemoral,
  • catheter-based (TAVI) transapical,
  • valvuloplasty.

• To evaluate catheter-based procedures in comparison to surgical aortic valve replacement.

• Develop criteria for an adequate patient selection of best treatment modality.
Design

- Prospective, controlled, multicenter registry.
- All patients undergoing an invasive therapy for acquired aortic valve disease consecutively included.
- The only exclusion criterion: no informed consent.
- Follow-up: in-hospital, 30 days, 1,3, 5 years.
Data Management and Sponsorship

- **Data management:**
  BQS – Institut für Qualität & Patientensicherheit.

- **Sponsorship:**
  Investigator initiated study with unrestricted grant from:
  *Edwards, Medtronic, Symetis, Jena Valve, St Jude, Sorin*

- **Support:**
  German Cardiac Society (DGK)
  German Society for Thoracic and Cardiovascular Surgery
Patients

Inclusion from 01/01/2011 to 31/12/2011

53 cardiac surgery units

69 cardiology units

13,860 patients

6,523 surgical AVR without CABG

3,462 surgical AVR with CABG

2,694 transvascular TAVI

1,181 transapical TAVI
## Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>AVR without CABG</th>
<th>AVR with CABG</th>
<th>Transvasc. TAVI</th>
<th>Transapical TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAD</strong></td>
<td>18.6</td>
<td>97.1</td>
<td>53.6</td>
<td>56.1</td>
</tr>
<tr>
<td><strong>LV-EF &lt;30%</strong></td>
<td>3.1</td>
<td>5.1</td>
<td>9.3</td>
<td>7.5</td>
</tr>
<tr>
<td><strong>A. fib.</strong></td>
<td>15.9</td>
<td>15.0</td>
<td>28.9</td>
<td>29.5</td>
</tr>
<tr>
<td><strong>Art. HT</strong></td>
<td>79.5</td>
<td>86.1</td>
<td>86.4</td>
<td>90.0</td>
</tr>
<tr>
<td><strong>Pulm. HT</strong></td>
<td>10.8</td>
<td>11.1</td>
<td>39.8</td>
<td>23.4</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td>10.0</td>
<td>12.2</td>
<td>19.8</td>
<td>20.5</td>
</tr>
<tr>
<td><strong>IDDM</strong></td>
<td>8.2</td>
<td>12.9</td>
<td>13.3</td>
<td>17.5</td>
</tr>
</tbody>
</table>

*all p<0.001*
TAVI Valve Type

**transvascular**
- Edwards: 38.2%
- Medtronic CoreValve: 59.8%
- Others: 2.0%

**transapical**
- Edwards: 87.5%
- Symetis: 4.5%
- JenaValve: 4.5%
- Others: 3.6%

n = 2.695
n = 1.181
Baseline Characteristics

Patients > 75 years

- without CABG: 33.3%
- with CABG: 44.9%
- transvascular: 86.3%
- transapical: 84.0%

Surgical AVR

TAVI
Baseline Characteristics

Female gender

- without CABG: 39.0%
- with CABG: 28.4%
- transvascular: 58.8%
- transapical: 49.8%
Baseline Characteristics

Heart failure (NYHA III/IV)

- without CABG: 62%
- with CABG: 69%
- transvascular: 86%
- transapical: 86%

Surgical AVR  TAVI
Results – Outcome

Mortality (in-hospital)

- Without CABG: 2.1%
- With CABG: 4.5%
- Transvascular: 5.1%
- Transapical: 7.7%

Surgical AVR

TAVI
Risk-adjusted In-Hospital Mortality

Reference: AVR without CABG

< 75 years

≥ 75 years

TAVI transvascular

TAVI transapical

TAVI transvascular

TAVI transapical
Results – Outcome

Cerebrovascular Events

- without CABG: 2.2%
- with CABG: 3.6%
- transvascular: 3.7%
- transapical: 3.5%
Results – Procedure

Vascular complications

- Without CABG: 1.0%
- With CABG: 1.6%
- Transvascular: 11.9%
- Transapical: 2.5%

Surgical AVR
TAVI
Results – Procedure

New Pacemaker

- Without CABG: 4.6%
- With CABG: 3.9%
- Transvascular: 23.7%
- Transapical: 9.9%

Surgical AVR

TAVI
Results – Risk Score

EuroSCORE

- without CABG
- with CABG
- transvascular
- transapical

Surgical AVR
TAVI
Results – Euro Score

Euro-Score in-hospital mortality

<table>
<thead>
<tr>
<th>Surgical AVR</th>
<th>TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>without CABG</strong></td>
<td><strong>with CABG</strong></td>
</tr>
<tr>
<td>&lt; 10% observed</td>
<td>&lt; 10% observed</td>
</tr>
<tr>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>&lt; 20% observed</td>
<td>&lt; 20% observed</td>
</tr>
<tr>
<td>3.3%</td>
<td>3.3%</td>
</tr>
<tr>
<td>&lt; 30% observed</td>
<td>&lt; 30% observed</td>
</tr>
<tr>
<td>3.8%</td>
<td>4.8%</td>
</tr>
<tr>
<td>≥ 30% observed</td>
<td>≥ 30% observed</td>
</tr>
<tr>
<td>7.8%</td>
<td>8.5%</td>
</tr>
<tr>
<td><strong>expected</strong></td>
<td><strong>expected</strong></td>
</tr>
<tr>
<td>4.7%</td>
<td>5.3%</td>
</tr>
<tr>
<td>13.7%</td>
<td>14.0%</td>
</tr>
<tr>
<td>24.3%</td>
<td>24.1%</td>
</tr>
<tr>
<td>45.3%</td>
<td>45.0%</td>
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</table>
# German Aortic Valve Disease Score „AKL-Score“

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> (5 risk classes)</td>
<td><strong>LV-EF</strong> (2 risk classes)</td>
</tr>
<tr>
<td><strong>Gender</strong> (female)</td>
<td><strong>Redo-procedure</strong></td>
</tr>
<tr>
<td><strong>Body mass index</strong> (2 risk classes)</td>
<td><strong>Infection</strong> (endocarditis)</td>
</tr>
<tr>
<td><strong>Heart failure</strong> (NYHA)</td>
<td><strong>Peripheral arterial disease</strong></td>
</tr>
<tr>
<td><strong>Myocardial infarction</strong> within last three weeks</td>
<td><strong>Chronic obstructive lung disease</strong> (2 risk classes)</td>
</tr>
<tr>
<td><strong>Critical preoperative status</strong></td>
<td><strong>Renal failure</strong></td>
</tr>
<tr>
<td><strong>Pulmonary hypertension</strong></td>
<td><strong>Emergency</strong></td>
</tr>
<tr>
<td><strong>Rhythm</strong> (no sinus rhythm)</td>
<td></td>
</tr>
</tbody>
</table>

For more information, visit: [http://www.bqs-outcome.de/2008/ergebnisse/leistungsbereiche/hch](http://www.bqs-outcome.de/2008/ergebnisse/leistungsbereiche/hch)
AKL Score Distribution

**Surgical AVR**
- Without CABG: 79.7%
- With CABG: 70.8%

**TAVI**
- Transvascular: 33.5%
  - 0 - < 3%: 16.9%
  - 3 - < 6%: 22.9%
  - 6 - < 10%: 26.7%
  - >= 10%: 33.5%
- Transapical: 22.4%
  - 22%: 22.0%
  - 34.4%: 21.1%
Results – AKL Risk Score

AKL-Score in-hospital mortality

- **Surgical AVR**
- **TAVI**

Observed vs. expected mortality:
- **without CABG**
  - < 3%: 1.3%, 1.3%
  - < 6%: 3.5%, 4.1%
  - < 10%: 6.6%, 7.5%
  - ≥ 10%: 9.0%, 17.0%

- **with CABG**
  - < 3%: 2.7%, 1.5%
  - < 6%: 7.1%, 4.2%
  - < 10%: 8.2%, 7.6%
  - ≥ 10%: 16.9%, 19.7%

- **transvascular**
  - < 3%: 2.8%, 2.1%
  - < 6%: 3.9%, 4.4%
  - < 10%: 5.0%, 7.7%
  - ≥ 10%: 8.1%, 19.0%

- **transapical**
  - < 3%: 5.0%, 2.1%
  - < 6%: 4.9%, 4.4%
  - < 10%: 5.1%, 7.7%
  - ≥ 10%: 16.9%, 18.9%
Conclusions

• First large scale registry on surgical & catheter based procedures.
• TAVI performed predominantly in high risk patients.
• AKL score better reflects outcome than EuroScore.
• In-hospital mortality and complications comparable to randomized controlled studies.
• In high risk patients in-hospital mortality with TAVI at least as good as with surgical AVR.
Thank you!