German Aortic Valve Registry

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M. Böhm, G. Heusch, A.-K. Funkat, T. Meinertz, T. Neumann,
K. Papoutsis, S. Schneider, A. Welz for the GARY-Executive Board

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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>
</table>

Rationale

• Nationwide complete survey of patients with aortic valve disease undergoing invasive procedures:
  • surgical (AVR), replacement/reconstruction
  • 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; 88 active centers/ 7 inactive
- The only exclusion criterion: no informed consent.
- Follow-up: in-hospital, 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, Jena Valve, Symetis, St Jude, Sorin

• Support:
  German Cardiac Society (DGK)
  German Society for Thoracic and Cardiovascular Surgery
  German Heart Foundation
Patients
(360 Ross and David excluded)

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>CAD</td>
<td>18.6</td>
<td>97.1</td>
<td>53.6</td>
<td>56.1</td>
</tr>
<tr>
<td>LV-EF &lt;30%</td>
<td>3.1</td>
<td>5.1</td>
<td>9.3</td>
<td>7.5</td>
</tr>
<tr>
<td>A. fib.</td>
<td>15.9</td>
<td>15.0</td>
<td>28.9</td>
<td>29.5</td>
</tr>
<tr>
<td>Art. HT</td>
<td>79.5</td>
<td>86.1</td>
<td>86.4</td>
<td>90.0</td>
</tr>
<tr>
<td>Pulm. HT</td>
<td>10.8</td>
<td>11.1</td>
<td>39.8</td>
<td>23.4</td>
</tr>
<tr>
<td>COPD</td>
<td>10.0</td>
<td>12.2</td>
<td>19.8</td>
<td>20.5</td>
</tr>
<tr>
<td>IDDM</td>
<td>8.2</td>
<td>12.9</td>
<td>13.3</td>
<td>17.5</td>
</tr>
</tbody>
</table>

All p < 0.001
Baseline Characteristics

Patients > 75 years

<table>
<thead>
<tr>
<th></th>
<th>n=6517</th>
<th>n=3458</th>
<th>n=2689</th>
<th>n=1177</th>
</tr>
</thead>
<tbody>
<tr>
<td>without CABG</td>
<td>33,3%</td>
<td>44,9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>with CABG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>transvascular</td>
<td></td>
<td></td>
<td>86,3%</td>
<td></td>
</tr>
<tr>
<td>transapical</td>
<td></td>
<td></td>
<td></td>
<td>84,0%</td>
</tr>
</tbody>
</table>

Surgical AVR

TAVI
Results – Outcome

Mortality (in-hospital)

<table>
<thead>
<tr>
<th></th>
<th>n=6517</th>
<th>n=3458</th>
<th>n=2689</th>
<th>n=1177</th>
</tr>
</thead>
<tbody>
<tr>
<td>without CABG</td>
<td>2.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>with CABG</td>
<td></td>
<td>4.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>transvascular</td>
<td></td>
<td></td>
<td>5.1%</td>
<td></td>
</tr>
<tr>
<td>transapical</td>
<td></td>
<td></td>
<td></td>
<td>7.7%</td>
</tr>
</tbody>
</table>

Surgical AVR | TAVI
Results – Procedure

New Pacemaker

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n=6517</th>
<th>n=3458</th>
<th>n=2689</th>
<th>n=1177</th>
</tr>
</thead>
<tbody>
<tr>
<td>without CABG</td>
<td>4.6%</td>
<td></td>
<td>3.9%</td>
<td></td>
</tr>
<tr>
<td>with CABG</td>
<td></td>
<td></td>
<td>23.7%</td>
<td></td>
</tr>
<tr>
<td>transvascular</td>
<td></td>
<td></td>
<td></td>
<td>9.9%</td>
</tr>
<tr>
<td>transapical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Surgical AVR

TAVI
1 year follow-up: 13,860 patients

2011: 13,860 patients included

Follow-up: 13,595 patients → 98,1 %

- direct follow-up: 89,5 %
- indirect follow-up: 8,6 %
  (National population register)

Unknown: 1,9 %
### Kaplan-Meier mortality-rate by procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Hospital 2.1%</th>
<th>30 Days</th>
<th>180 Days</th>
<th>365 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>4.5%</td>
<td>4.5%</td>
<td>5.1%</td>
<td>7.7%</td>
</tr>
<tr>
<td>AVR+CABG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVR+TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TA TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**log-rank test p-values** (GH: <0.001)

- **AVR+CABG**
  - AVR: < 0.001
  - TAVI: < 0.001
- **TAVI**
  - AVR: < 0.001
  - TAVI: < 0.001

**Day**

- 0
- 60
- 120
- 180
- 240
- 300
- 360

**Death Rate (%)**

- 0%
- 5%
- 10%
- 15%
- 20%
- 25%
- 30%
- 35%
- 40%
Kaplan-Meier mortality-rate by procedure
Age: < 75 years; >= 75 years

Age: < 75 years

Age >= 75 years
Kaplan-Meier mortality by procedure

EuroSCORE

EuroSCORE < 10

Death Rate (%)

Day

EuroSCORE 10 - < 20

Death Rate (%)

Day

EuroSCORE 20 - < 30

Death Rate (%)

Day

EuroSCORE >= 30

Death Rate (%)

Day
Kaplan-Meier mortality by procedure

**EuroSCORE**

### EuroSCORE < 10

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+CABG</th>
<th>TV</th>
<th>TA</th>
<th>TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.376</td>
<td></td>
</tr>
<tr>
<td>AVR+CABG</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.162</td>
<td>0.011</td>
<td></td>
</tr>
<tr>
<td>TV</td>
<td>TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### EuroSCORE 10 - < 20

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+CABG</th>
<th>TV</th>
<th>TA</th>
<th>TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>0.005</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVR+CABG</td>
<td>0.162</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TV</td>
<td>TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### EuroSCORE 20 - < 30

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+CABG</th>
<th>TV</th>
<th>TA</th>
<th>TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>0.041</td>
<td>0.200</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVR+CABG</td>
<td>0.282</td>
<td>0.135</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TV</td>
<td>TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### EuroSCORE >= 30

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+CABG</th>
<th>TV</th>
<th>TA</th>
<th>TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>0.164</td>
<td>0.103</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVR+CABG</td>
<td>0.836</td>
<td>0.012</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TV</td>
<td>TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**log-rank test p-values**

(GH: <0.001)
# German Aortic Valve Disease Score „AKL-Score“

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

http://www.bqs-outcome.de/2008/ergebnisse/leistungsbereiche/hch
AKL Score Distribution

Surgical AVR

Without CABG

- 4,3% 0 - < 3%
- 13,6% 3 - < 6%
- 18,4% 6 - < 10%
- 6,9% >= 10%
- 79,7% Total

With CABG

- 2,4% 0 - < 3%
- 22,4% 3 - < 6%
- 34,4% 6 - < 10%
- 22,0% >= 10%
- 70,8% Total

TAVI

transvascular

- 26,7% 0 - < 3%
- 22,9% 3 - < 6%
- 33,5% 6 - < 10%
- 16,9% >= 10%

transapical

- 21,1% 0 - < 3%
- 34,4% 3 - < 6%
- 22,4% 6 - < 10%
- 22,0% >= 10%

Kaplan-Meier mortality by procedure
German AV-Score (AKL-Score)
Kaplan-Meier mortality by procedure
German AV-Score (AKL-Score)

German AV-Score < 3

- Log-rank test
- p-values

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+TAVI</th>
<th>TA TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AVR+TAVI</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>TV TAVI</td>
<td></td>
<td>0.203</td>
<td></td>
</tr>
</tbody>
</table>

German AV-Score 3 - < 6

- Log-rank test
- p-values

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+TAVI</th>
<th>TA TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>0.001</td>
<td>0.007</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AVR+TAVI</td>
<td>0.358</td>
<td>0.056</td>
<td></td>
</tr>
<tr>
<td>TV TAVI</td>
<td></td>
<td>0.004</td>
<td></td>
</tr>
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</table>

German AV-Score 6 - < 10

- Log-rank test
- p-values

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+TAVI</th>
<th>TA TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>0.156</td>
<td>0.185</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AVR+TAVI</td>
<td>0.692</td>
<td>0.024</td>
<td></td>
</tr>
<tr>
<td>TV TAVI</td>
<td></td>
<td>0.001</td>
<td></td>
</tr>
</tbody>
</table>

German AV-Score >= 10

- Log-rank test
- p-values

<table>
<thead>
<tr>
<th>Treatment</th>
<th>AVR</th>
<th>AVR+TAVI</th>
<th>TA TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>0.964</td>
<td>0.700</td>
<td>0.026</td>
</tr>
<tr>
<td>AVR+TAVI</td>
<td>0.770</td>
<td>0.047</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TV TAVI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1-year follow-up: interviewed patients

Stroke

1-year follow-up: interviewed patients

Stroke

- Minor Stroke
- Major Stroke

without CABG
with CABG
transvascular
transapical

Surgical AVR
TAVI
1-year follow-up: interviewed patients

NYHA-classification

72 to 85% in NYHA I or II

**Surgical AVR**
- Without CABG
  - NYHA I: 14.9%
  - NYHA II: 36.6%
  - NYHA III: 47.2%
  - NYHA IV: 1.1%
  - N/A: 0.3%

- With CABG
  - NYHA I: 0.9%
  - NYHA II: 36.4%
  - NYHA III: 48.6%
  - NYHA IV: 0.4%
  - N/A: 13.7%

**TAVI**
- Transapical
  - NYHA I: 34.4%
  - NYHA II: 39.3%
  - NYHA III: 22.8%
  - NYHA IV: 2.1%

- Transvascular
  - NYHA I: 38.0%
  - NYHA II: 34.4%
  - NYHA III: 23.2%
  - NYHA IV: 1.4%
  - N/A: 1.0%
1-year follow-up: interviewed patients

Current state of health vs. state of health before procedure

\[ \approx 60\% \text{ better than before} \]

**Surgical AVR**

- Without CABG:
  - Better: 60.9%
  - Same: 26.6%
  - Worse: 12.1%
  - N/A: 0.4%

- With CABG:
  - Better: 61.9%
  - Same: 24.2%
  - Worse: 13.4%
  - N/A: 0.4%

**TAVI**

- Transvascular:
  - Better: 61.8%
  - Same: 23.0%
  - Worse: 14.8%
  - N/A: 0.4%

- Transapical:
  - Better: 57.8%
  - Same: 23.8%
  - Worse: 18.2%
  - N/A: 0.3%
1-year follow-up: interviewed patients
Patient satisfaction 1 year after intervention

93 – 96% satisfied with procedure

<table>
<thead>
<tr>
<th>Surgical AVR</th>
<th>TAVI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>without CABG</strong></td>
<td><strong>transvascular</strong></td>
</tr>
<tr>
<td>very good</td>
<td>50,5%</td>
</tr>
<tr>
<td>good</td>
<td>50,5%</td>
</tr>
<tr>
<td>satisfactory</td>
<td>9,1%</td>
</tr>
<tr>
<td>unsatisfactory</td>
<td>3,9%</td>
</tr>
<tr>
<td>N/A</td>
<td>6,3%</td>
</tr>
<tr>
<td><strong>with CABG</strong></td>
<td><strong>transapical</strong></td>
</tr>
<tr>
<td>very good</td>
<td>55,2%</td>
</tr>
<tr>
<td>good</td>
<td>32,6%</td>
</tr>
<tr>
<td>satisfactory</td>
<td>8,0%</td>
</tr>
<tr>
<td>unsatisfactory</td>
<td>3,3%</td>
</tr>
<tr>
<td>N/A</td>
<td>0,8%</td>
</tr>
</tbody>
</table>
Summary

• First large scale registry on comparing surgical & catheter based procedures with 1 year follow-up.

• Continuous increase in mortality after hospital discharge, predominately in high risk groups.

• In low and intermediate risk groups, surgical AVR (no CABG) group has better outcome than TAVI.

• TV-TAVI and conventional surgery have equal outcome in patients EURO Score > 20%, AKL Score > 6%.

• Good one year clinical outcome (QoL) and high patient satisfaction across all groups.
Conclusion

- Score > 20% or AKL Score > 6% and age > 75 yrs good cut-offs
- Mortality equal (TA-TAVI) or better (TV-TAVI) than PARTNER A.

Limitations:
- Voluntary participation of centers
- The AV risk score is derived predominately from patients with surgery, a separate risk score for TAVI is under development
Grazie!
Danke!
Kaplan-Meier mortality
TAVI: residual aortic insufficiency

<table>
<thead>
<tr>
<th>Death</th>
<th>none / trace</th>
<th>mild / severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Days</td>
<td>6.1%</td>
<td>8.8%</td>
</tr>
<tr>
<td>180 Days</td>
<td>15.5%</td>
<td>23.6%</td>
</tr>
<tr>
<td>365 Days</td>
<td>22.3%</td>
<td>26.9%</td>
</tr>
</tbody>
</table>

log-rank test p-value 0.063
Kaplan-Meier mortality
TAVI: residual aortic insufficiency

Death none trace mild severe
30 Days 6.0% 6.2% 6.7% 37.5%
180 Days 14.7% 16.3% 21.7% 50.0%
365 Days 21.2% 23.3% 25.3% 50.0%
1-year follow-up: interviewed patients

Myocardial Infarction

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n=5421</th>
<th>n=2718</th>
<th>n=1782</th>
<th>n=715</th>
</tr>
</thead>
<tbody>
<tr>
<td>without CABG</td>
<td>0.4%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>with CABG</td>
<td></td>
<td>0.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical AVR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>transvascular TAVI</td>
<td>0.6%</td>
<td></td>
<td></td>
<td>0.7%</td>
</tr>
<tr>
<td>transapical TAVI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Deutsches Aortenklappenregister
1-year follow-up: interviewed patients

Stroke

![Graph showing stroke rates for different surgical procedures and patient groups.](image-url)
1-year follow-up: interviewed patients
CABG after discharge from hospital

- Without CABG: 0.3%
- With CABG: 0.4%
- Transvascular: 0.1%
- Transapical: 0.4%

Surgical AVR
TAVI
1-year follow-up: interviewed patients
PCI after discharge from hospital

1-year follow-up: interviewed patients
PCI after discharge from hospital

<table>
<thead>
<tr>
<th>Procedure</th>
<th>without CABG</th>
<th>with CABG</th>
<th>transvascular</th>
<th>transapical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical AVR</td>
<td>0.5%</td>
<td>1.1%</td>
<td>1.9%</td>
<td>1.5%</td>
</tr>
<tr>
<td>TAVI</td>
<td></td>
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</tbody>
</table>
1-year follow-up: interviewed patients
Patients with hospital stays after the procedure
because of: complications of procedure; cardiovascular problems

1-year follow-up: interviewed patients
Patients with hospital stays after the procedure

Hospital stays

- AVR without CABG: 29.6%
- AVR with CABG: 34.4%
- TAVI transvascular: 40.2%
- TAVI transapical: 45.5%

Hospital stays for complications of the procedure

- AVR without CABG: 6.5%
- AVR with CABG: 6.5%
- TAVI transvascular: 4.4%
- TAVI transapical: 8.3%

Hospital stays for cardiovascular problems

- AVR without CABG: 11.3%
- AVR with CABG: 12.3%
- TAVI transvascular: 15.4%
- TAVI transapical: 16.9%