Five-year outcomes with the ACURATE neo2 valve: the Neo AS CE-mark study

Helge Möllmann
St. Johannes Hospital Dortmund
Potential conflicts of interest

Speaker's name: Helge Möllmann

☑ I have the following potential conflicts of interest to declare:

Proctor and/or speaker fees from Abbott, Boston Scientific, Edwards Lifesciences, Medtronic, SMT
What did we study?

**ACURATE neo2 Transcatheter Heart Valve**

An evolution of the prior-generation ACURATE neo valve

- Supra-annular leaflet positioning yields favorable haemodynamics
- Maintains the ease of use, good coronary access, and low pacemaker rate of ACURATE neo
- Compatible with 14F iSLEEVE introducer sheath
  - New marker band for precise alignment
  - Enhanced ACURATE neo2 sealing skirt is 60% larger, resulting in improved mitigation of PVL

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How was the study executed?

Prospective, single-arm study of TAVR patients with symptomatic AS at high risk for surgery and implanted with ACURATE neo2

PRIMARY ENDPOINT
All-cause Mortality at 30 days

SECONDARY ENDPOINTS
• Device & procedural success
• VARC-2 safety events through 5 years
• Haemodynamic function, evaluated at discharge/7d, 30d, and 1y

INDEPENDENT ENDPOINT EVALUATION
• Data Monitoring Committee (DMC) review / Clinical Events Committee (CEC) adjudication of VARC-2 endpoints
• Echocardiographic data evaluated by a core laboratory (MedStar Health Research Institute) at baseline, discharge, 30d, and 1y
How was the study executed?

120 patients were enrolled at 9 European sites between December 2016 & November 2017

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Clinical Centre</th>
<th>City, Country</th>
<th>Subjects (N=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Won-Keun Kim, MD</td>
<td>Kerckhoff Heart Center</td>
<td>Bad Nauheim, Germany</td>
<td>35</td>
</tr>
<tr>
<td>Helge Möllmann, MD</td>
<td>St. Johannes Hospital</td>
<td>Dortmund, Germany</td>
<td>33</td>
</tr>
<tr>
<td>Thilo Noack, MD</td>
<td>Heart Center Leipzig University</td>
<td>Leipzig, Germany</td>
<td>20</td>
</tr>
<tr>
<td>Michael Hilker, MD</td>
<td>University Hospital Regensburg</td>
<td>Regensburg, Germany</td>
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<tr>
<td>Lenard Conradi, MD</td>
<td>University Heart Center Hamburg</td>
<td>Hamburg, Germany</td>
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<tr>
<td>Stefan Toggweiler, MD</td>
<td>Luzerner Kantonsspital</td>
<td>Lucerne, Switzerland</td>
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<tr>
<td>Britt Hofmann, MD, PhD</td>
<td>University Hospital Halle</td>
<td>Halle, Germany</td>
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<tr>
<td>Michael Joner, MD</td>
<td>German Heart Center Munich</td>
<td>Munich, Germany</td>
<td>3</td>
</tr>
<tr>
<td>Lars Søndergaard, MD</td>
<td>Rigshospitalet, University of Copenhagen</td>
<td>Copenhagen, Denmark</td>
<td>2</td>
</tr>
</tbody>
</table>
Essential results: Patient population

Baseline Demographics & Risk

Age
82.1 ± 4.0 yrs

Gender
67.5% female 32.5% male

Mean STS Score
4.8% ± 3.8%

Mean STS Score
4.8% ± 3.8%

NYHA Class at Baseline
- 95% Class I
- 4.2% Class II
- 0.8% Class III

Medical History

COPD
10.0%

Diabetes
27.5%

Prior CAD
69.2%

Prior stroke/TIA
10.8%

Baseline conduction abnormality
47.5%

Prior pacemaker
6.7%

Echocardiographic Measurements
(Core laboratory adjudicated)

Mean AVA
0.74 ± 0.2 cm²

Mean AV gradient
40.3 ± 14.1 mmHg

Aortic regurgitation
≥ moderate
6.1%
Essential results: Study follow-up

**ACURATE neo2 Implanted n=120**

### Clinical Follow-up or Death

- **30 Days**: 98% (n=118) — 2 patients withdrew consent
  ➢ Echo at 30d: 87% (n=104)

- **1 Year**: 93% (n=111) — 7 patients withdrew consent
  ➢ Echo at 1y: 74% (n=89)

- **2 Years**: 92% (n=110) — 1 patient withdrew consent

- **3 Years**: 92% (n=110)

- **4 Years**: 92% (n=110)

- **5-Year Follow-up**: 91% (n=109) — 1 patient lost to follow-up
Essential results: Early outcomes

**Valve size implanted**

- L; 29.2%
- S; 25.8%
- M; 45.0%

**KEY PROCEDURAL OUTCOMES**

- Procedural success: 97.5%
- No periprocedural deaths
- No MI ≤72h post-procedure
- No cases of coronary obstruction or cardiac tamponade
- Major vascular complications: 2.5%
- New PPI at discharge: 13.3%
  - 56% of new PPI patients (10/18) had a baseline conduction disorder†

**PRIMARY ENDPOINT**

All-cause Mortality at 30 days

3.3%


*Procedure was considered successful in 117/120 patients (valve embolization, n=1; valve migration, n=1; conversion to open-heart surgery, n=1)

†AV block, 1st degree, n=5; RBBB, n=4; LBBB (incomplete), n=1; Other, n=1

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Essential results: Echocardiographic outcomes

Paired analysis (n=80); core-laboratory adjudicated

Core laboratory adjudicated data; mean effective orifice area is reported as time velocity integral (TVI) ratio
Essential results: Mortality & Stroke through 5 years

ITT population (N=120); time-to-event analysis

<table>
<thead>
<tr>
<th></th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause death</td>
<td>12</td>
</tr>
<tr>
<td>Cardiovascular death</td>
<td>5</td>
</tr>
<tr>
<td>All stroke</td>
<td>11</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>1</td>
</tr>
</tbody>
</table>

5y rate: 44.0%

Cardiovascular death 31.5%

All stroke 14.2%

Disabling stroke 9.9%

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EuroPCR.com
Essential results: Death through 5 years

- **Death through 5 years**
  - All death: 104, 98, 91, 81, 47
  - CV death: 104, 97, 89, 81, 44

At risk:
- All death: 104
- CV death: 104

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**Essential results: VARGC-2 Safety through 5 years**

**ITT population (N=120); time-to-event analysis**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>1y</th>
<th>2y</th>
<th>3y</th>
<th>4y</th>
<th>5y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization &gt; 30 days (for valve-related symptoms or worsening congestive heart failure)</td>
<td>4.6%</td>
<td>9.9%</td>
<td>13.2%</td>
<td>13.2%</td>
<td>14.6%*</td>
</tr>
<tr>
<td>Repeat intervention post index procedure</td>
<td>0.0%</td>
<td>1.1%†</td>
<td>1.1%</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Clinical valve thrombosis</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

*Heart failure-related, n=13; Mitral insufficiency, n=1
†n=1; patient presented with mild-to-moderate paravalvular leak and was treated with balloon valvuloplasty.

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Why is this important?

5-Year Clinical Outcomes: **Neo AS Study** vs contemporary studies

<table>
<thead>
<tr>
<th>Event</th>
<th>N</th>
<th>STS score</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARTNER 2A</td>
<td>1011</td>
<td>5.8%</td>
</tr>
<tr>
<td>SURTAVI</td>
<td>864</td>
<td>4.4%</td>
</tr>
<tr>
<td>CHOICE (balloon-exp)</td>
<td>121</td>
<td>5.6%</td>
</tr>
<tr>
<td>CHOICE (self-exp.)</td>
<td>120</td>
<td>6.2%</td>
</tr>
<tr>
<td>Neo AS</td>
<td>120</td>
<td>4.8%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Event</th>
<th>Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause death</td>
<td>46.0%</td>
</tr>
<tr>
<td>All stroke</td>
<td>47.6%</td>
</tr>
<tr>
<td>New pacemaker</td>
<td>44.0%</td>
</tr>
<tr>
<td>Rehospitalization</td>
<td>33.3%</td>
</tr>
<tr>
<td>Repeat intervention</td>
<td>14.2%</td>
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</tbody>
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Patients treated with ACURATE neo2 exhibited early improvement in valve haemodynamics and low rates of PVL through 1 year
  - No patients exhibited >moderate PVL at any time
  - PVL at 1y was evaluated as none/trace in 60.0% of patients, mild in 37.3%, moderate in 2.7%

5-year rates of all-cause mortality (44.0%) and stroke (14.2%) are comparable to other trials of TAVR patients at intermediate or high surgical risk

Patients treated with ACURATE neo2 had low rates of rehospitalization and re-intervention through 5 years

This first report of longer-term outcomes with ACURATE neo2 confirms favorable performance and sustained safety in a high-risk population of patients with severe aortic stenosis