CONCLUSIONS

In patients with small aortic annular dimensions undergoing TAVI, this multicentre, propensity-matched comparison reported low clinical event rates and similar safety profiles for both, the self-expanding ACURATE neo and the balloon-expandable SAPIEN 3 valves.

However, TAVI using the self-expanding ACURATE neo valve in this challenging patient population resulted in superior hemodynamics in terms of transvalvular gradients, indexed effective orifice area, and frequency of prosthesis–patient mismatch, compared with the balloon-expandable SAPIEN 3 device, and these differences were maintained at 1-year of follow-up.

Careful prosthesis selection is necessary in TAVI patients with small aortic annulus in order to optimise outcomes for each individual patient.

Figure 2: Acute, 30-day and 1-year Outcome Summary (% of patients unless otherwise stated)

Conclusions:
- In patients with small aortic annular dimensions undergoing TAVI, this multicentre, propensity-matched comparison reported low clinical event rates and similar safety profiles for both, the self-expanding ACURATE neo and the balloon-expandable SAPIEN 3 valves.
- However, TAVI using the self-expanding ACURATE neo valve in this challenging patient population resulted in superior hemodynamics in terms of transvalvular gradients, indexed effective orifice area, and frequency of prosthesis–patient mismatch, compared with the balloon-expandable SAPIEN 3 device, and these differences were maintained at 1-year of follow-up.
- Careful prosthesis selection is necessary in TAVI patients with small aortic annulus in order to optimise outcomes for each individual patient.

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246 patients with symptomatic severe aortic stenosis and small aortic annular dimension (annulus area <400 mm²) underwent transfemoral TAVR at 5 centers in Germany. (Deutsches Herzzentrum Munich; Heart Center, University of Cologne; Kardiol Clinik, Bad Nauheim; St. Johannes-Hospital, Dortmund; University Medical Center, Regensburg)

Patient Population
- A total of 129 patients were treated with the ACURATE neo valve (small size) and 117 with the SAPIEN 3 valve (23 mm).
- In the absence of established guidelines, prosthesis selection was at the discretion of the operating physicians at each center.

Due to the non-randomized nature of the study and differences in the absence of established guidelines, prosthesis selection was the discretion of the operating physicians at each center.

Study Assessments and Endpoints

Procedural outcomes: Reported according to the Valve Academic Research Consortium (VARC)-2 consensus.

Early safety: A composite endpoint of all-cause mortality, all stroke, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction requiring intervention, major vascular complication, and valve-related dysfunction requiring repeat procedure.

Transcatheter echocardiography was undertaken to assess:
- Residual paravalvular regurgitation (PPVR), classified as none/trace, mild, moderate, or severe
- Mean transvalvular gradient
- Effective orifice area (EOA): Indexed to body surface area (iEOA)

Prosthesis–patient mismatch (PPM):
Defined as an iEOA of 0.65 cm²/m² or less and area for SAPIEN 3.

Results

**Table:**

<table>
<thead>
<tr>
<th>Procedural characteristics</th>
<th>ACURATE neo n=92</th>
<th>SAPIEN 3 n=92</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-dilatation</td>
<td>87 (94.6)</td>
<td>29 (31.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-dilatation</td>
<td>41 (44.6)</td>
<td>6 (6.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Papil-ventricular pacing</td>
<td>32 (34.9)</td>
<td>92 (100.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>During deployment</td>
<td>1.7±0.8</td>
<td>1.3±0.6</td>
<td>0.001</td>
</tr>
<tr>
<td>Number of rapid ventricular pacing episodes</td>
<td>15.6±8.2</td>
<td>15.1±9.9</td>
<td>0.705</td>
</tr>
</tbody>
</table>

**Clinical outcome:**
- 30-d mortality: 1 (1.1) vs 2 (2.2) (p=0.004)
- 1-y mortality: 6 (6.3) vs 10 (13.3) (p=0.233)
- All stroke: 3 (3.3) vs 2 (2.2) (p=0.180)
- Vascular complications: 11 (12.0) vs 19 (21.7) (p=0.153)
- Major: 2 (2.2) vs 6 (6.5) (p=0.678)
- Bleeding: 13 (14.1) vs 11 (12.0) (p=0.632)
- Life threatening: 1 (1.1) vs 1 (1.1) (p=0.678)
- Permanent pacemaker implantation: 11 (12.0) vs 14 (15.2) (p=0.678)
- Conversion to open surgery: 1 (1.1) vs 0 (0.0) (p=0.678)
- Cardiac tamponade: 1 (1.1) vs 1 (1.1) (p=0.678)
- Unplanned use of cardio-pulmonary bypass: 1 (1.0) vs 1 (1.1) (p=0.678)
- Ventricular perforation: 1 (1.1) vs 0 (0.0) (p=0.678)
- Early safety: 86 (93.5) vs 83 (90.2) (p=0.637)

**Figure 1:** Echocardiographic outcomes of ACURATE neo and SAPIEN 3 at discharge and 1-year follow-up.

**THE ACURATE neo® AORTIC VALVE SYSTEM**

- Available in three sizes: small, medium and large (23, 25 and 27 mm).
- Accommodates aortic annular diameters from 21–27 mm.
- Self-expanding nitinol frame with porcine pericardial leaflets in a supra-annular position.
- Pericardial skirt acts as a seal against paravalvular regurgitation.

The ACURATE neo Aortic Valve.