CONCLUSIONS

• High success rates for transfemoral TAVI were achieved with both self-expanding ACURATE neo and balloon-expandable SAPIEN 3.

• This propensity-matched comparison found that procedural and clinical results were comparable for the two devices.

• The study also showed equivalent rates of device failure and the VARC-2 early safety composite endpoint.

• Compared with SAPIEN 3, ACURATE neo was associated with less new permanent pacemaker implantations, lower mean transvalvular gradients, and less elevated gradients, but with more paravalvular leakage.

• Further studies are required to confirm the effectiveness of these devices and also to compare ACURATE neo with other self-expanding devices, such as the Evolut R™ (Medtronic).

• The SCOPE I study, a prospective, multicenter, randomized trial, comparing ACURATE neo and SAPIEN 3 is ongoing.
PUBLICATION SUMMARY: JACC: HUSser O. et al., 2017
MULTICENTRE COMPARISON OF NOVEL SELF-EXPANDING versus BALLOON-EXPANDABLE TRANSCATHETER HEART VALVES

BACKGROUND

Transcatheter heart valve (THV) technology has advanced the management of aortic valve stenosis considerably in recent years. Transcatheter aortic valve replacement (TAVR) is undertaken using either mechanically/balloon-expanding or self-expanding technologies, both of which are associated with good patient outcome according to clinical registries. Research into both technologies has continued to progress with the aim of addressing some of the limitations of earlier-generation devices, such as paravalvular leakage (PVL), new permanent pacemaker implantations (PPM), and vascular complications. Novel devices have shown promising initial clinical results.

The study reports on the first large, multicenter, propensity-matched comparison of two of these new-generation devices: the balloon-expandable SAPIEN 3 (Edwards Lifesciences, Irvine, California) and the self-expanding ACURATE neo (Boston Scientific/ Symetis S.A., Ecublens, Switzerland).

PATIENTS & METHODS

Patients:
- 1,121 consecutive patients with symptomatic, severe stenosis of the native aortic valve were treated with transfemoral TAVR using ACURATE neo (n=311) or SAPIEN 3 (n=622) at 3 centers in Germany.
- To reduce imbalance in patient baseline characteristics and the effect of a potential selection bias, propensity matching was performed 1-to-2 matching identified 2 control cases treated with SAPIEN 3 (n=622) for each case treated with ACURATE neo (n=311).

Assessments:
- Multislice computed tomography was performed as part of the standard pre-procedural screening protocol.
- Aortic annulus measurements were assessed in multiple plane reconstructions according to the guidelines of the Society of Cardiovascular Computerized Tomography.
- Calification of the valvular apparatus was visually graded as mild/moderate or severe.

STUDY ENDPOINTS & FOLLOW-UP

- Device failure and early safety composite endpoint at 30 days according to VARC-2 criteria.
- Prospective follow-up undertaken to 30 days at each of the participating sites.
- Transthoracic echocardiography performed at baseline, before discharge, and at 30 days.

DEVICES

Self-expanding ACURATE neo:
Available in 3 sizes (small, medium, and large), consists of a self-expanding nitinol frame with a porcine pericardial leaflet valve in a supra-annular position and a pericardial sealing-skirt on the outer and inner surface of the stent body.

Balloon-expanding SAPIEN 3:
Consists of a cobalt chromium alloy frame with a porcine pericardial leaflet valve in a supra-annular position and a pericardial sealing-skirt to reduce PVL.

NEW PERMANENT PACEMAKER RATES AND HEMODYNAMIC PERFORMANCE: ACURATE NEO SHOWN:

- Significantly less new permanent pacemaker implantations (in-hospital) (9.9 % vs. 15.5 %; p=0.02).
- Significantly reduced mean gradients (<20 mmHg, 3.2 % vs. 6.9 %; p=0.02).
- More PVL II+ (4.8 % vs. 1.8 %; p=0.01).

RESULTS

In-hospital complications:
Comparable between ACURATE neo and SAPIEN 3:
- Stroke: 1.9 % vs. 2.4 %; p=0.64.
- Major vascular complications: 10.3 % vs. 8.5 %; p=0.38.
- Life-threatening bleeding: 4.2 % vs. 3.7 %; p=0.72.

Device failure (according to VARC-2):
Comparable between ACURATE neo and SAPIEN 3:
- 10.9 % vs. 9.6 %; odds ratio: 1.09 [95 % confidence interval: 0.69 – 1.73]; p=0.71 (Table 1).

Table 1: Device failure. Values are %.

<table>
<thead>
<tr>
<th></th>
<th>ACURATE neo (n=311)</th>
<th>SAPIEN 3 (n=622)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device failure*</td>
<td>36 (11.6)</td>
<td>60 (9.6)</td>
<td>0.539</td>
</tr>
<tr>
<td>Procedural mortality</td>
<td>3 (1.0)</td>
<td>2 (0.3)</td>
<td>0.340</td>
</tr>
<tr>
<td>Correct position</td>
<td>308 (99.0)</td>
<td>616 (99.0)</td>
<td>0.999</td>
</tr>
<tr>
<td>Intended performance*</td>
<td>280 (90.0)</td>
<td>564 (90.7)</td>
<td>0.763</td>
</tr>
<tr>
<td>PUL II+</td>
<td>15 (4.8)</td>
<td>11 (1.8)</td>
<td>0.008</td>
</tr>
<tr>
<td>Elevated gradient (&gt;20 mmHg)</td>
<td>10 (3.2)</td>
<td>43 (6.9)</td>
<td>0.021</td>
</tr>
<tr>
<td>Multiple valves</td>
<td>7 (2.3)</td>
<td>7 (1.1)</td>
<td>0.251</td>
</tr>
<tr>
<td>Conversion</td>
<td>5 (1.6)</td>
<td>4 (0.6)</td>
<td>0.170</td>
</tr>
</tbody>
</table>

Mortality and safety at 30 days
Comparable between ACURATE neo and SAPIEN 3:
- Mortality: 2.3 % vs. 1.9 %; p=0.74. (Table 2).

Table 2: Outcome at 30 days. Values are %.

<table>
<thead>
<tr>
<th></th>
<th>ACURATE neo (n=311)</th>
<th>SAPIEN 3 (n=622)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early safety composite endpoint at 30 days*</td>
<td>49 (15.8)</td>
<td>97 (15.6)</td>
<td>0.941</td>
</tr>
<tr>
<td>Acute kidney injury (AKIN 2/3, including renal replacement)</td>
<td>10 (3.2)</td>
<td>17 (2.8)</td>
<td>0.683</td>
</tr>
<tr>
<td>Valve-related dysfunction requiring repeat procedure (BAR, TAVR, or SAVR)</td>
<td>1 (0.3)</td>
<td>0 (0.0)</td>
<td>0.159</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>32 (10.3)</td>
<td>53 (8.6)</td>
<td>0.710</td>
</tr>
<tr>
<td>Life-threatening bleeding</td>
<td>13 (4.2)</td>
<td>27 (4.4)</td>
<td>0.910</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>10 (3.2)</td>
<td>17 (2.8)</td>
<td>0.683</td>
</tr>
</tbody>
</table>

New Permanent Pacemaker implantations:
- Early safety composite endpoint: 15.8 % vs. 16.6 %; hazard ratio 0.97 [95 % confidence interval: 0.68 – 1.38]; p=0.88. (Figure 1).