ADVERTORIAL

ACURATE *neo*: A "very safe" TAVI system providing "extremely good results in almost all patients"

The ACURATE *neo* (Boston Scientific) is a transcatheter aortic valve implantation (TAVI) device made of a self-expanding nitinol frame and porcine pericardial leaflets in a supra-annular position. Data not only indicate that it is a safe and effective device, but also show that it may be especially beneficial in patients with reduced left ventricular function and/or a small aortic annulus.

Christian Hengstenberg

According to Christian Hengstenberg (Division of Cardiology, Department of Internal Medicine II, Medical University of Vienna, Vienna, Austria), ACURATE *neo* is a "very safe device". He comments that with the valve, "you have very high rates of implantation success and a low pacemaker rate". "Everything looks nice with this device," Hengstenberg adds.

Data from the SAVI-TF registry support his assertion that the device is safe and effective.[1] In *EuroIntervention*, Helge Möllmann (Department of Cardiology, Kerckhoff Heart and Lung Center, Bad Nauheim, Germany) and colleagues report the outcomes of 1,000 patients who underwent TAVI with the ACURATE *neo* in the SAVI-TF registry. They state that at 30 days, the rate of all-cause mortality (the primary endpoint) was 1.4% and that the early safety composite occurred in 8.6% of patients (disabling stroke was 1.2% and permanent pacemaker implantation was 8.3%). "New York Heart Association (NYHA) Class improved significantly from baseline with 90% of patients in NYHA Class I or II at 30 days," they add.

Möllmann *et al* observed that the rate of permanent pacemaker implantation seen in their registry was lower than that seen with other devices, noting that CoreValve Evolut R (Medtronic) is associated with a permanent pacemaker rate of 22.1%. Additionally, they comment that its "very low pacemaker rate" might make ACURATE *neo* "particularly useful for patients with reduced left ventricular ejection fraction".

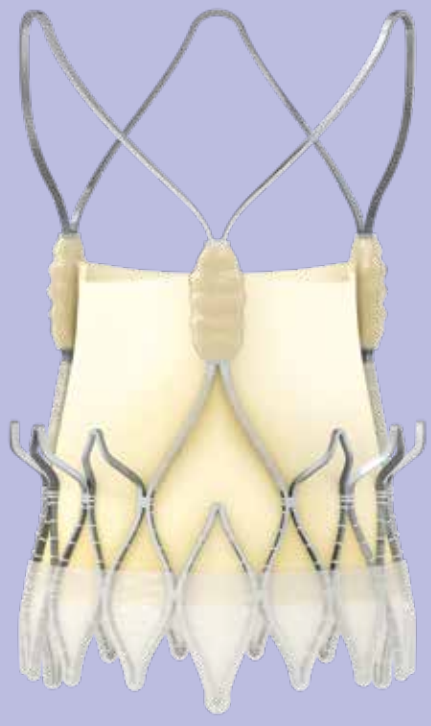
Hengstenberg, who was one of the investigators in the SAVI-TF registry, suggests that the mechanism of release of ACURATE *neo* may explain why it appears to have a lower pacemaker rate than other devices. He comments: "Other self-expanding valves have a 'bottom-up' release mechanism. Therefore, you start in the left ventricle and this may irritate the conduction system—you have to remember that you are in a beating heart, so there will always be a little bit of motion and movement. With ACURATE *neo*, you have a 'top-down' mechanism of release; so, you deploy first the upper part in the aortic valve and only then in the lower part in the subannular area. I think this is, therefore, less of an irritant to the conduction system."

Avoiding the need for a permanent pacemaker, according to Hengstenberg, is an important consideration. He explains that implanting a permanent pacemaker not only prolongs the hospital stay and increases the cost of the procedure, but also is a "negative influence" on patient outcomes.

Two ongoing randomised controlled trials—SCOPE 1 and SCOPE 2—are evaluating how ACURATE *neo* compares with existing devices (Edward Lifesciences' SAPIEN 3 and Medtronic's Corevalve family, respectively). However, in the meantime, propensity-matched studies have provided some insight into how the device fares in comparison to Edwards' SAPIEN 3.

Key points

- ACURATE *neo* transcatheter aortic valve system demonstrates excellent clinical outcomes and very low complication rates in 1,000 patients' international, all-comers SAVI-TF registry (Möllmann *et al*).
- Compared with SAPIEN 3, ACURATE *neo* shows comparable safety and efficacy endpoints and is associated with lower transvalvular gradients and, consequently, less prosthesis–patient mismatch in patients with small annulus (Mauri *et al*).
- There are fewer new pacemaker implantations and fewer elevated gradients with ACURATE *neo* than there are with SAPIEN 3 (Husser *et al*).



Victor Mauri (Departments of Cardiology, Heart Center, University of Cologne, Germany) and colleagues performed a multicentre, propensity-matched comparison between ACURATE *neo* and SAPIEN 3 in patients with a small aortic annulus (<400mm^2) who were undergoing TAVI.[2] After identifying 92 matched patients (from 246 patients overall), they found that the 30-day rates of death, stroke, vascular complication, and bleeding were all similar between both groups.

However, mean transvalvular gradients were significantly lower in the ACURATE *neo* group: 9.3±3.9mmHg vs. 14.5±5.5mmHg for SAPIEN 3 (p<0.001). This meant that the effective orifice area was significantly larger with ACURATE *neo* (0.96±0.3cm2/m2 vs. 0.8±0.2cm2/m2 for SAPIEN 3 patients; p=0.002). "Consequently, prosthesis-patient mismatch occurred significantly more often in the SAPIEN 3 group (41% for ACURATE *neo* vs. 67% for SAPIEN 3; p=0.002) and was classified as severe in 3% of ACURATE *neo* patients and in 22% of SAPIEN 3 patients (p=0.004)," the authors report.

ACURATE *neo* is a supra-annular valve rather than an intra-annular valve, and this may explain why it is associated with a lower rate of prosthesis-patient mismatch. Hengstenberg comments: "SAPIEN 3 is an intra-aortic valve, meaning the main valve is exactly the height of the annulus; ACURATE *neo* is a supra-annular valve, so the valve is above the annulus. If you have a small annulus to start with [as in Mauri *et al*'s study] and you put in an intra-annular valve in there, you always end up with a higher gradient." He adds that higher gradient rates—associated with prosthesis-patient mismatch—are "often linked to a less favourable outcome for the patient". Mauri *et al*, in their conclusion, comment: "Whether prosthesis-patient mismatch after TAVI translates into decreased prosthesis durability and impaired long-term outcomes remains to be elucidated. However, the results emphasise the need of careful prosthesis selection in each individual patient."

In a second multicentre study comparing ACURATE *neo* with SAPIEN 3 in a propensity-matched analysis,[3] data showed comparable safety and efficacy results for both valves with similar rates of all-cause mortality at 30 days. However, ACURATE *neo*, was associated with significantly lower rates for permanent pacemaker implantation and elevated gradients; the rate of paravalvular leak was higher with ACURATE *neo*. Study investigators Oliver Husser (Technical University Munich, Munich, Germany) and colleagues report: "In a propensity-matched comparison, we found equivalent rates of devices failure and the early safety composite endpoint with ACURATE *neo* and SAPIEN 3."

Summarising the available data for ACURATE *neo*, Hengstenberg comments that the valve is an "all comers" valve that "is capable of providing extremely good results in almost all patients". Additionally, he notes: "If there is severe calcification expanding into the left ventricular outflow tract, we know that the risk for annulus rupture is very high with balloon-expandable valves. Also, a horizontal position of the heart is sometimes very hard to treat, but not with the ACURATE *neo* valve, which is able to self-adjust its position."

References

1. Möllmann H, Hengstenberg C, Hilker M, *et al*. Real-world experience using the ACURATE neo prosthesis: 30-day outcomes of 1,000 patients enrolled in the SAVI-TF registry. *EuroIntervention* 2017. Epub.
2. Mauri V, Kim WK, Abumayyaleh M, *et al*. Short-term outcome and hemodynamic performance of next-generation self-expanding versus balloon-expandable transcatheter aortic valves in patients with small aortic annulus: A multicenter propensity-matched comparison. *Circ Cardiovasc Interv* 2017. Epub.
3. Husser O, Kim WK, Pellegrini C. Multicenter comparison of novel self-expanding versus balloon-expandable transcatheter heart valves. *JACC: Cardiovascular Interventions* 2017; 10: 2078–87

This article has been sponsored by Boston Scientific.