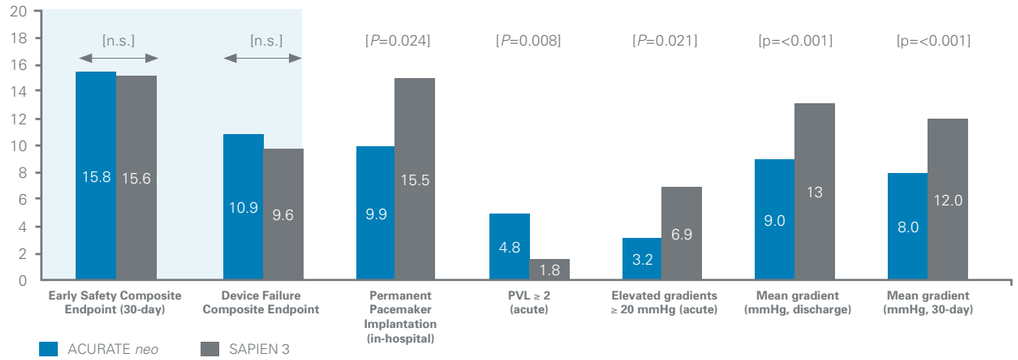
MORENA – VARC-2
Safety and Performance Endpoints
(% of patients)



MORENA – Pacemaker Rate and Hemodynamic Performance
(% of patients / mmHg)

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.*

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Multicenter Comparison of Novel Self-Expanding versus Balloon-Expandable Transcatheter Heart Valves

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PUBLICATION SUMMARY

ACURATE *neo*™ VS. SAPIEN 3

Husser, O. et al.; JACC: Cardiovascular Interventions. 10. 2078-2087. 10.1016/j.jcin.2017.06.026

PUBLICATION SUMMARY: JACC: HUSSER O. ET AL., 2017

MULTICENTRE COMPARISON OF NOVEL SELF-EXPANDING versus BALLOON-EXPANDABLE TRANSCATHETER HEART VALVES

Husser O, et al. JACC Cardiovasc Interv. 2017 Oct 23;10(20):2078-2087.
Associated Editorial: Mavromatis, K. A comparison of the ACURATE *neo*™ and SAPIEN 3 valves: Making progress. JACC Cardiovasc Interv. 2017 Oct 23;10(20):2088-2089.

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 (PPI), and vascular complications. Novel devices have shown promising initial clinical results.

The study reported is 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=810) 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 Computed Tomography.
- Calcification 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 bovine pericardial leaflets and is delivered with the Commander delivery system. At the time of the study, the SAPIEN 3 was available in 23, 26, and 29mm sizes and featured an external polyethylene terephthalate fabric seal to reduce PVL.

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 %.

	ACURATE *neo* (n=311)	SAPIEN 3 (n=622)	p Value
Device failure*	34 (10.9)	60 (9.6)	0.539
Procedural mortality	3 (1.0)	2 (0.3)	0.340
Correct position	308 (99.0)	616 (99.0)	0.999
Intended performance†	280 (90.0)	564 (90.7)	0.753
PVL II+	15 (4.8)	11 (1.8)	0.008
Elevated gradient (≥ 20 mmHg)	10 (3.2)	43 (6.9)	0.021
Multiple valves	7 (2.3)	7 (1.1)	0.251
Conversion	5 (1.6)	4 (0.6)	0.170

New Permanent Pacemaker rates and hemodynamic performance: ACURATE *neo* showed:

- 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).

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 %.

	ACURATE *neo* (n=311)	SAPIEN 3 (n=622)	p Value
Early saftey composite endpoint at 30 days*	49 (15.8)	97 (15.6)	0.941
All-cause mortality	7 (2.3)	12 (1.9)	0.742
Stroke (disabling, non-disabling, transient ischemic attack)	7 (2.3)	19 (3.1)	0.484
Coronary artery obstruction requiring intervention	2 (0.6)	0 (0)	0.046
Major vascular complication	32 (10.3)	53 (8.6)	0.710
Life-threatening bleeding	13 (4.2)	27 (4.4)	0.910
Acute kindey injury (AKIN 2/3, including renal replacement)	10 (3.2)	17 (2.8)	0.669
Valve-related dysfunction requiring repeat procedure (BAV, TAVR, or SAVR)	1 (0.3)	0 (0)	0.159
New permanent pacemaker implantation†	29 (10.2)	92 (16.4)	0.018

- Early safety composite endpoint: 15.8 % vs. 15.6 %; hazard ratio:0.97 [95 % confidence interval: 0.68 – 1.39]; p=0.88. ***(Figure 1)***.