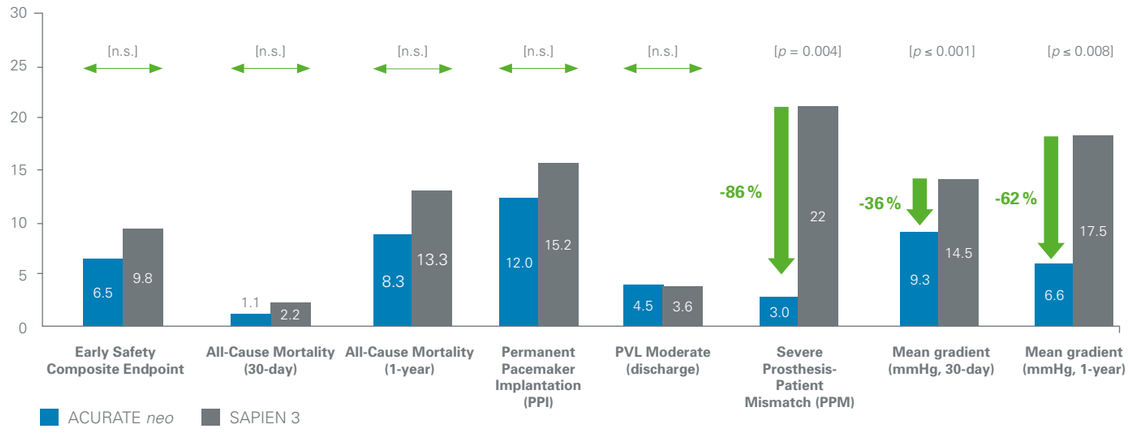
Figure 2: Acute, 30-day and 1-year Outcome Summary (% of patients unless otherwise stated)



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.*

SH-537114-AA APR2018 Printed in Germany by medicalvision.

Boston Scientific
Advancing science for life™

bostonscientific.eu/taviportfolio

DINSH0157EA

Boston Scientific
Advancing science for life™

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

TAVI IN PATIENTS WITH SMALL AORTIC ANNULUS

PUBLICATION SUMMARY

ACURATE *neo*™
VS.
SAPIEN 3

Mauri V, et al. *Circ Cardiovasc Interv.* 2017;10:e005013.

PUBLICATION SUMMARY:
SHORT-TERM OUTCOME AND HEMODYNAMIC PERFORMANCE OF NEXT-GENERATION SELF-EXPANDING versus BALLOON-EXPANDABLE TRANSCATHETER AORTIC VALVES (THV) IN PATIENTS WITH SMALL AORTIC ANNULUS: A MULTICENTER PROPENSITY-MATCHED COMPARISON

Mauri V, et al. *Circ Cardiovasc Interv.* 2017;10:e005013.

PATIENT POPULATION

- 246 patients with symptomatic severe aortic stenosis and small annular dimension (annulus area <400 mm²) underwent transfemoral TAVR at 5 centers in Germany. (Deutsches Herzzentrum Munich; Heart Center, University of Cologne; Kerckhoff Clinic, Bad Nauheim; St. Johannes-Hospital, Dortmund; University Medical Center, Regensburg)
- 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 between treatment centers, 1:1 propensity matching was used to control for confounding baseline variables (sex, age, left ventricular ejection fraction, annulus diameter, body surface area, and logistic EuroSCORE).
- ACURATE *neo* patients were matched to SAPIEN 3 patients by the means of Propensity Score (PS) matching to control for confounders. PS matching resulted in 92 matched pairs.

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.

Transthoracic echocardiography was undertaken to assess:

- Residual paravalvular regurgitation (PVR), 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 ≤0.85 cm²/m² and classified in accordance with VARC-2 recommendations as:

- Moderate iEOA (0.65 cm²/m² to ≤0.85 cm²/m²) or
- Severe iEOA (≤0.65 cm²/m²)

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.

RESULTS

	ACURATE *neo* n=92	SAPIEN 3 n=92	*p* Value
Procedural characteristics			
Pre-dilatation	87 (94.6)	29 (31.5)	<0.001
Post-dilatation	41 (44.6)	6 (6.5)	<0.001
Rapid ventricular pacing during deployment	32 (34.8)	92 (100.0)	<0.001
Number of rapid ventricular pacing episodes	1.7±0.8	1.3±0.6	0.001
Sizing*			<0.001
Undersized	5 (5.9)	0 (0)	
Within sizing range	73 (85.9)	71 (77.2)	
Oversized	7 (8.2)	21 (22.8)	
Oversizing (area %)	15.6±8.2	15.1±9.9	0.705
Oversizing (perimeter %)	4.9±3.5	5.3±4.6	0.633

* Sizing category was based on perimeter for ACURATE *neo* and area for SAPIEN 3.

	ACURATE *neo* n=92	SAPIEN 3 n=92	*p* Value
Clinical outcome			
30-d mortality	1 (1.1)	2 (2.2)	1.000
1-y mortality	6 (8.3)	10 (13.3)	0.233
All stroke	3 (3.3)	2 (2.2)	1.000
Vascular complications	11 (12.0)	19 (20.7)	0.152
Major	2 (2.2)	6 (6.5)	
Bleeding	13 (14.1)	11 (12.0)	0.832
Life threatening	1 (1.1)	1 (1.1)	
Permanent pacemaker implantation	11 (12.0)	14 (15.2)	0.678
Conversion to open surgery	1 (1.1)	0 (0.0)	1.000
Cardiac tamponade	1 (1.1)	1 (1.1)	1.000
Unplanned use of cardio-pulmonary bypass	1 (1.0)	1 (1.0)	1.000
Ventricular perforation	1 (1.1)	0 (0.0)	1.000
Early saftey	86 (93.5)	83 (90.2)	0.607

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