

# ACURATE *neo*™

## Aortic Valve System

### Outcome of Next-Generation Transcatheter Valves in Small Aortic Annuli: A Multicenter Propensity-Matched Comparison

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



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Mauri et al.: ACURATE neo vs. SAPIEN 3 in small Annuli



## Structural Heart Disease

# 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

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## Short-Term Outcome and Hemodynamic Performance of Next-Generation Self-Expanding Versus Balloon-Expandable Transcatheter Aortic Valves in Patients With Small Aortic Annulus<sup>1</sup>

### STUDY DESIGN

Retrospective, 1:1 propensity-matched multicenter comparison of ACURATE *neo*<sup>™</sup> (N = 92) and SAPIEN 3 (N = 92) from 5 high volume centers in Germany.

### RESULTS

- **Similar performance for ACURATE *neo* and SAPIEN 3** with no significant differences at 30 days and at 1 year in key safety outcomes, including the VARC-2 early safety composite, all-cause mortality, stroke, bleeding and vascular complications.
- **Similar rates of moderate PVL** (4.5% vs 3,6%; n.s.), no severe PVL in both groups.
- **Lower, but not significant new permanent pacemaker rates** in ACURATE *neo* group (12% vs.15.2%; n.s.).
- **Lower 30-day and 1-year mean transvalvular gradients** with ACURATE *neo* (9,3/6,6 mmHg vs. 14,5/17,5 mmHg; p<0.001/p=0,008).
- **Lower rate of total Prosthesis-Patient-Mismatch (PPM)** in ACURATE *neo* (41% vs. 67%; p=0.002) and severe PPM (3% vs. 22%; p=0.004).

### CONCLUSION

- This retrospective comparison of safety and performance of ACURATE *neo* and SAPIEN 3 in patients with small aortic annuli shows a **comparable safety profile and superior hemodynamics regarding transvalvular gradients, iEOA and frequency of Prosthesis-Patient-Mismatch in ACURATE *neo* patients.**
- This **may be particularly beneficial in patients with small aortic annulus**, who are at risk for Prosthesis-Patient-Mismatch, which has shown to be a strong predictor of short- and long-term mortality and premature bioprosthetic degeneration.\*

\* Head SJ, et al.: The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement. Eur Heart J, 2012;33:1518-29.

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

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## Study Design

- Retrospective, multicenter propensity score matched comparison of hemodynamic performance and clinical outcome up to 1 year of the self-expanding, supra-annular Symetis ACURATE *neo* valve and the balloon-expandable, intra-annular Edwards SAPIEN 3 valve in patients with small aortic annulus.
- 246 patients with symptomatic severe aortic stenosis and small annular dimension undergoing transfemoral TAVR between Feb. 2014 and Aug. 2016 at 5 high-volume centers in Germany (DHZ Munich, UK Regensburg, Kerckhoff Klinikum Bad Nauheim, UK Cologne, UKE Hamburg, JoHo Dortmund).
- Inclusion criteria: small annular dimension defined as an annulus area  $<400 \text{ mm}^2$  and transfemoral TAVR with either ACURATE *neo* size S or Edwards SAPIEN 3 size 23 mm.
- Effective Orifice Area (EOA) was indexed to body surface area (iEOA).
- Patient-Prosthesis-Mismatch (PPM) was defined as an iEOA  $\leq 0.85 \text{ cm}^2/\text{m}^2$  and classified moderate ( $0.65 \text{ cm}^2/\text{m}^2 < \text{iEOA} \leq 0.85 \text{ cm}^2/\text{m}^2$ ) or severe ( $\text{iEOA} \leq 0.65 \text{ cm}^2/\text{m}^2$ ) in accordance to the VARC-2 recommendations.

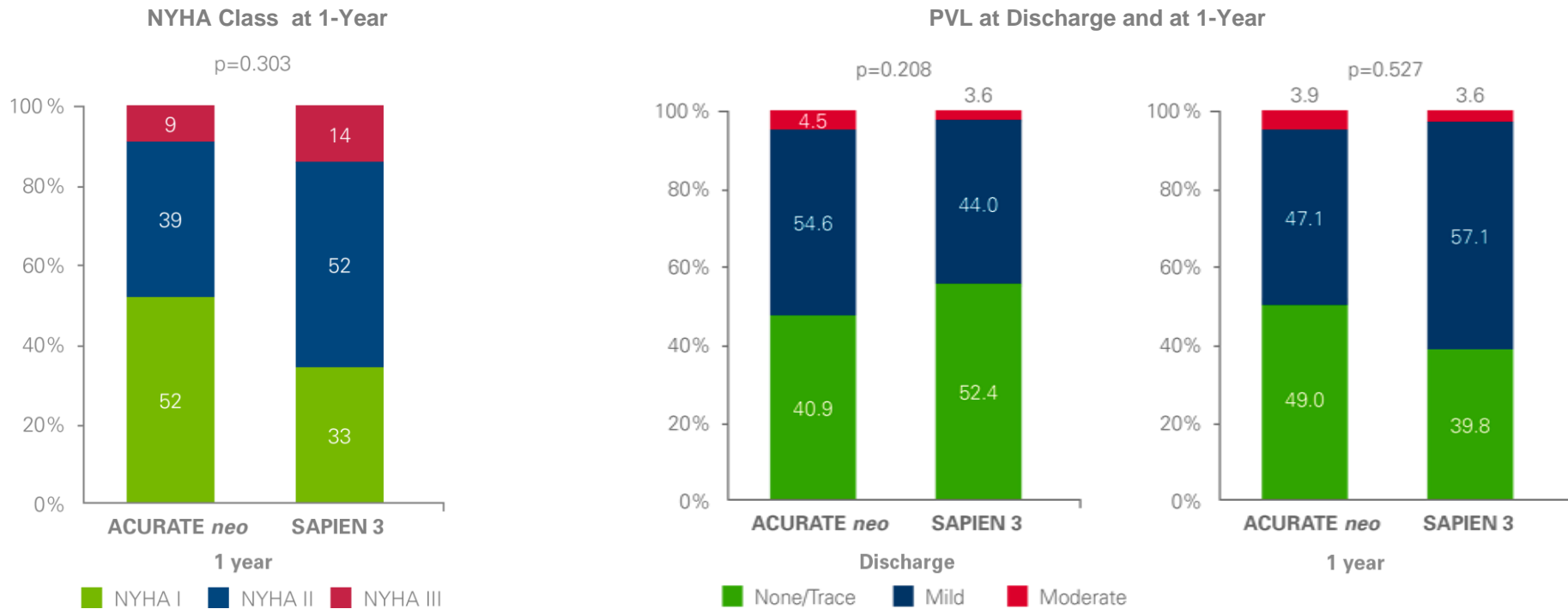
Procedural Characteristics	ACURATE <i>neo</i> N = 92	SAPIEN 3 N = 92	P Value
Pre-dilation	87 (94.6)	29 (31.5)	<0.001
Post-dilation	41 (44.6)	6 (6.5)	<0.001
Rapid ventricular pacing during deployment	32 (34.8)	92 (100.0)	<0.001
Number of rapid ventricular pacing episodes	1.7 ± 0.8	1.3 ± 0.6	0.001
<b>Sizing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

- Higher pre- and post-dilatation rate in ACURATE *neo* group due to self-expanding valve design.
- Lower rate of rapid pacing during deployment in ACURATE *neo* group.

Clinical Outcome	ACURATE <i>neo</i> N = 92	SAPIEN 3 N = 92	P Value
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 cardiopulmonary bypass	1 (1.0)	1 (1.0)	1.000
Ventricular perforation	1 (1.1)	0 (0.0)	1.000
Early safety	86 (93.5)	83 (90.2)	0.607

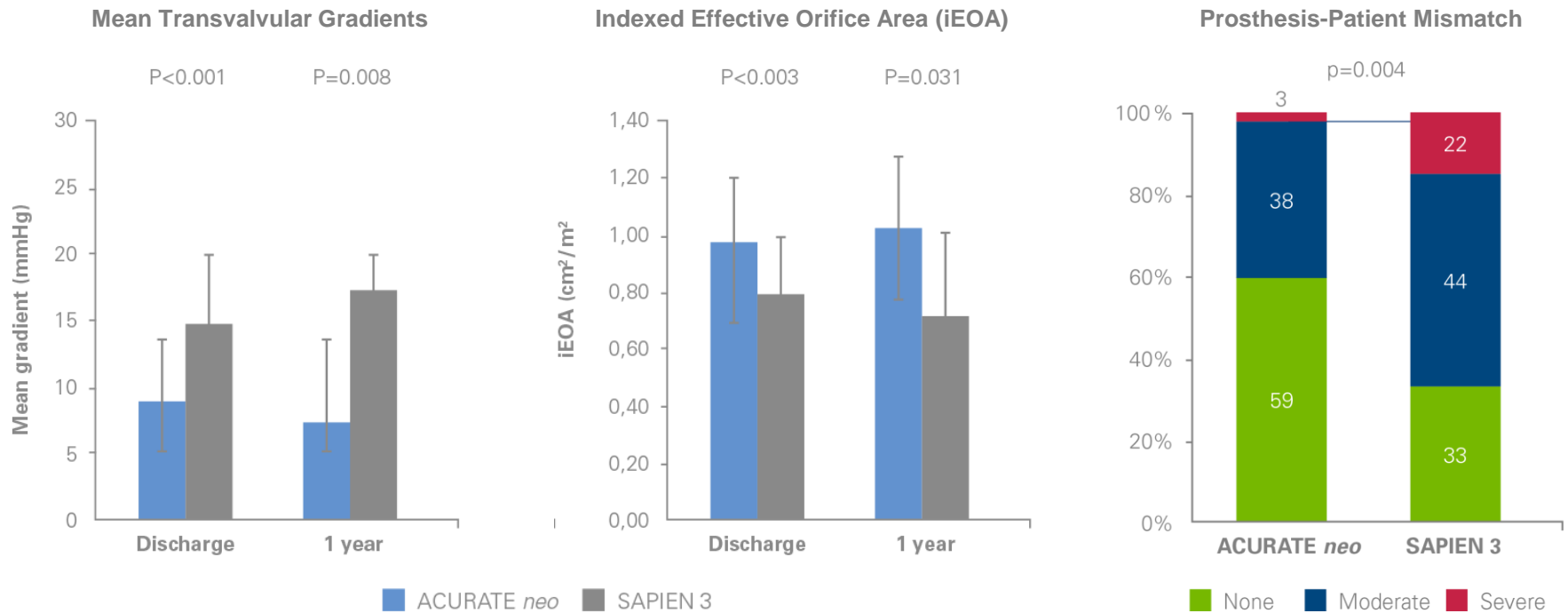
- Similar rate of periprocedural VARC-2 events including permanent pacemaker implantation.
- No significant difference in Early Safety Composite Endpoint.

## New York Heart Association (NYHA) Class & Paravalvular Leakage (PVL)



- New York Heart Association functional class at 1-year did not differ significantly between groups.
- Similar rates of PVL with no severe PVL in both groups at discharge and 1-year.

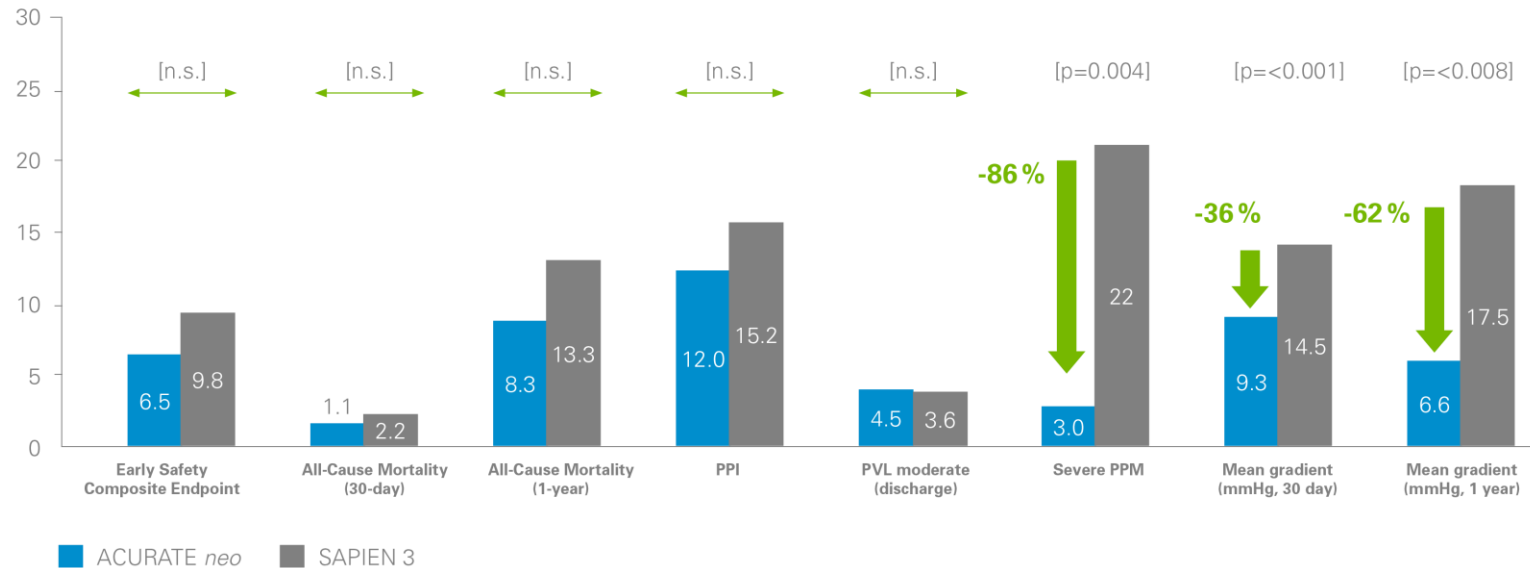
## Mean Transvalvular Gradient, Indexed Effective Orifice Area (iEOA) and Prosthesis-Patient Mismatch



- Patients in ACURATE *neo* group showed significantly lower gradients, larger iEOAs, and lower rates of Prosthesis-Patient-Mismatch (PPM), especially severe PPM (iEOA  $\leq 0.65$  cm<sup>2</sup>/m<sup>2</sup>).



## Acute and 30-day Outcome Summary<sup>1</sup> (% of patients unless otherwise stated)



- ACURATE *neo* and SAPIEN 3 show **comparable VARC-2 procedural, performance and safety outcome and low, non-statistically different mortality** at 30 days and at 1 year
- Both devices show **comparable rates of new permanent pacemaker implantation and of moderate PVL**; no severe PVL was observed with both devices

- ACURATE *neo* patients show **significantly reduced risk of severe Patient-Prosthesis mismatch and significantly lower Mean Gradients**
- **Prosthesis-patient mismatch** is present when the effective orifice area of an implanted prosthetic valve is too small in relation to body size and **has shown to be a strong predictor of short- and long-term mortality and premature bioprosthetic degeneration\***

\* Head SJ, et al.: The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement. Eur Heart J, 2012;33:1518-29.

<sup>1</sup> Mauri, V. et al.: Circ Cardiovasc Interv. 2017;10:e00501.

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## Conclusions

- Patients with small aortic annulus are at risk for Prosthesis-Patient-Mismatch, which might be a risk factor for structural valve deterioration and impaired outcome.
- This study from 5 high volume centers in Germany comprises a multicenter PS-matched comparison of hemodynamic performance and clinical outcome up to 1 year of ACURATE *neo* and SAPIEN 3 in patients with small aortic annulus.
- Results show low all-cause mortality and early safety event rates showed feasibility and safety of both valve systems with no significant differences.
- The incidence of new onset conduction disturbances requiring permanent PI was comparable in both groups.
- The ACURATE *neo* valve presented significantly lower transvalvular mean gradients and larger iEOAs at discharge and 1-year follow-up and consequently, lower rates of Patient-Prosthesis-Mismatch.