

ACURATE *neo*"

Aortic Valve System

Mauri, et al. Small Annulus Multicenter Comparison Study **ACURATE** neo vs. SAPIEN 3

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

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

Study Design

This multicenter, propensity score-matched study from 5 high-volume centers in Germany compared hemodynamics and early clinical outcomes in 246 patients with an aortic annulus area < 400 mm² undergoing transcatheter aortic valve replacement with either a selfexpanding transcatheter heart valve (ACURATE neo, n = 129) or a balloon-expandable transcatheter heart valve (SAPIEN 3, n = 117). The 1:1 propensity score matching resulted in 92 matched pairs.

Clinical Highlights

98

6.5

Early safety

composite

endpoint

P = n.s.

15

10

5

0

% of Patients

ACURATE neo comparable to SAPIEN 3 in key safety outcomes with no significant differences at 30 days and at 1 year in VARC-2 procedural, performance, and safety outcomes.

ACURATE neo (n = 92)



Safety and Performance Summary

SAPIEN 3 (n = 92)

12.0

13.3

8.3

All-cause

mortality

(1-year)

P = n.s.

2.2

1.1

All-cause

mortality

(30-dav)

P = n.s.

15.2



Permanent

pacemaker

implantation

(PPI, discharge)

P = n.s.

4.5

3.6

PVL moderate

(discharge)

P = n.s.



performance with significantly reduced risk of prosthesis-patient

ACURATE neo superior to SAPIEN 3 in hemodynamic

mismatch (PPM).



Lower mean transvalvular gradients and larger indexed effective orifice areas at discharge and sustained at 1 year



Key Results

Procedural Characteristics and Clinical Outcome

	ACURATE <i>neo</i> (n = 92)	SAPIEN 3 (n = 92)	P Value
Procedural Characteristics			
Pre-dilatation	94.6%	31.5%	< 0.001
Post-dilatation	44.6%	6.5%	< 0.001
Rapid ventricular pacing during deployment	34.8%	100%	< 0.001
Number of rapid ventricular pacing episodes	1.7 ± 0.8	1.3 ± 0.6	0.001
Sizing*			
Undersized	5.9%	0%	
Within sizing range	85.9%	77.2%	
Oversized	8.2%	22.8%	
Oversizing (area %)	15.5 ± 8.2	15.1 ± 9.9	0.705
Oversizing (perimeter %)	4.9 ± 3.5	5.3 ± 4.6	0.633
Clinical Outcome			
30-day mortality	1.1%	2.2%	1.000
1-year mortality	8.3%	13.3%	0.233
All-stroke	3.3%	2.2%	1.000
Vascular complications	12.0%	20.7%	0.152
Major	2.2%	6.5%	
Bleeding	14.1%	12.0%	0.832
Life-threatening	1.1%	1.1%	
Permanent pacemaker implantation	12.0%	15.2%	0.678
Conversion to open surgery	1.1%	0.0%	1.000
Cardiac tamponade	1.1%	1.1%	1.000
Unplanned use of cardiopulmonary bypass	1.0%	1.0%	1.000
Ventricular perforation	1.1%	0.0%	1.000
Early safety	93.5%	90.2%	0.607

*Sizing category was based on perimeter for ACURATE *neo* and area for SAPIEN 3. 1. Stuart, et al. The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement. *Eur Heart J.* 2012;33:1518-1520. 2. Flameng, et al. Prosthesis-patient mismatch predicts structural valve degeneration in bioprosthetic heart valves. Circulation. 2010;121:2123-2129.

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2

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