AP valves 2023: Myths and Truths About ACURATE Neo2



Comparing with Current Clinical Outcomes



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Current trend of TAVI: Shift in the metrics of 'what matters?'





The ACURATE neo2 valve





A "improved" new device with unique characteristics

The PREVIOUS ACURATE valve



\checkmark Clinical data of the previous value



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

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Bruno A et al. JACC Cardiovascular interv 2022, Husser et al. JACC Cardiovascular interv 2017



Patients with severe dortic stenosis requiring intervention United Heart team decision United Heart team decision							
TABLE 4 Outcome at 30 Days							
	ACURATE neo (n = 311)	SAPIEN 3 (n = 622)	p Value				
Early safety 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, nondisabling, 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 kidney 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				

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

TABLE 3 Device Failure						
	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 mm Hg)	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			
Values are n (%). *Multiple events possible; counting only first event.						

†No prosthesis mismatch, mean aortic valve gradient <20 mm Hg, or peak velocity <3 m/s, without moderate or severe prosthetic valve aortic regurgitation of the first implanted prosthesis.

PVL = paravalvular leakage.

n=311

n=622

Bruno A et al. JACC Cardiovascular interv 2022, Husser et al. JACC Cardiovascular interv 2017

Compared to the previous valve

 \checkmark

Competitor's incidence STUDY Incidence Competitor Acurate neo (Boston Scientific) SAVI-TF Registry⁽¹⁾ 4.1% (procedural) _ -MORENA Registry⁽²⁾ Sapien 3 (Edwards) 1.8% (30-d) 4.8% (30-d) SCOPE | RCT⁽³⁾ 9% (30-d) Sapien 3 (Edwards) 3% (30-d) 4.5% (30-d) 3.6% (30-d) Mauri V et al. Sapien 3 (Edwards) (small annuli)⁽⁴⁾ NEOPRO Registry⁽⁵⁾ 8.7% (30-d) 10.9% (30-d) Evolut PRO (Medtronic) SCOPE II RCT⁽⁶⁾ 10% (30-d) CoreValve/Evolut 3% (30-d) (Medtronic) Not negligile more-than-mild PVL incidence



STRUCTURAL

Transcatheter Aortic Valve Replacement With Self-Expanding ACURATE neo2

Postprocedural Hemodynamic and Short-Term Clinical Outcomes

Propensity-Matched Comparison of ACURATE neo Versus ACURATE neo2 The ITAL-neo Registry



Bruno A et al. JACC Cardiovascular interv 2022

The ACURATE neo2 valve



✓ Registry data: Early neo2 Registry +

Design	 Investigator-initiated and conducted, single arm, multicenter and retrospective Registry, from 12 European centers in Germany, Sweden, Denmark, Austria, Finland, Switzerland and the Netherlands
Objective	• To document and report the first real-world, large scale set of clinical results for the ACURATE <i>neo2</i> Aortic Valve System
Primary Outcomes	• Paravalvular leak, post-operative mean gradient, PPI, 30-day Mortality and Stroke
Sample Size	• 554 patients from September 2020 to March 2021



Primary outcomes	N=554
Post-operative Paravalvular leak >mild %	1.3
Post-operative mean gradient (mmHg)	9
New pacemaker implantation (in-hospital) %	6.0
Mortality (30 days) %	1.3
Stroke (in-hospital) %	2.1



Aortic regurgitation severity grade



The ACURATE neo2 valve: Unique data





In regards of device specific characteristics

✓ PVL and conduction disorders

✓ Coronary access and Commissure alignment



Paravalvular leak (PVL)

- ✓ PVL is common after TAVI and has been linked with worse survival (Esp, > moderate PVL).
- ✓ The prevalence of PVL after TAVI varies from 7% to 40%.

✓ Pacemaker (PM) implantation

- ✓ AV conduction disturbances requiring PPM implantation are common (upto 40%) and clinically important adverse events.
- \checkmark Related to the close proximity of the AV conduction system to the AV complex.



P Genereux et al., J Am Coll Cardiol 2013;61:1125, GCM Siontis et al. J Am Coll Cardiol 2014;64:129–40

PVL and conduction disorders

Effectiveness and Safety of the ACURATE Neo Prosthesis in 1,000 Patients With Aortic Stenosis

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Predictors of paravalvular leak

Variable	Univariate Analysis Odds ratio [95% CI]	Р	Multivariable Analysis Odds ratio [95% CI]	р
Prosthesis size	1.08 [0.89; 1.31]	0.444		
AVCS, per AU	1.0006 [1.0004; 1.0009]	< 0.001	1.0003 [1.0001; 1.0006]	< 0.001
Compact peri-annular calcification	9.20 [4.99; 16.93]	< 0.001	6.15 [3.13; 12.08]	< 0.001
Bicuspid aortic valve	1.88 [0.72; 4.93]	0.201		
Cover index annulus, per %	0.87 [0.79; 0.95]	0.001	0.89 [0.80; 0.99]	0.026
Annulus/STJ height-ratio	0.07 [0.01; 0.94]	0.045	0.03 [0.02; 0.45]	0.012
Pmean, per mmHg	1.01 [0.99; 1.03]	0.140		
Implantation depth at NCC, per mm	0.93 [0.83; 1.05]	0.254		
Implantation depth at LCC, per mm	0.85 [0.75; 0.97]	0.012		

Check for

ACURATE neo learning curve

Variable	Quartile 1 (Case 1–250)	Quartile 2 (Case 251–500)	Quartile 3 (Case 501–750)	Quartile 4 (Case 751-1000)	р
Cover index (%)	3.87 [1.86; 6.37]	5.13 [3.04; 7.30]	5.38 [3.39; 7.52]	6.17 [4.20; 7.90]	< 0.001
Aortic valve calcium score (AU)	2395 [1646; 3111]	2049 [1494; 2872]	1955 [1385; 2893]	1989 [1280; 2726]	< 0.001
Compact peri-annular Ca ⁺⁺ formation	64 (25.6%)	41 (16.4%)	42 (16.8%)	29 (11.6%)	0.001
Implantation depth at LCC (mm)	5.0 [3.0; 6.0]	6.0 [5.0; 7.0]	6.0 [4.0; 6.0]	5.0 [4.0; 6.0]	< 0.001
Device success (VARC-2)	171 (85.5%)	177 (88.5%)	181 (90.5%)	186 (93.0%)	0.002
≥moderate PVL at discharge	18/243 (7.4%)	7/241 (2.9%)	9/246 (3.7%)	2/246 (0.8%)	0.001
≥moderate PVL procedural	21/246 (8.5%)	13/249 (5.2%)	11 (4.4%)	3 (1.2%)	0.002
Permanent pacemaker	25 (10.0%)	26 (10.4%)	26 (10.4%)	17 (6.8%)	0.444
TVH embolization	5 (2.0%)	4 (1.6%)	3 (1.2%)	3 (1.2%)	0.496
Need for second THV	3 (1.2%)	7 (2.8%)	4 (1.6%)	3 (1.2%)	0.462
Major vascular complication	32 (12.8%)	26 (10.4%)	14 (5.6%)	16 (6.4%)	0.013
Major stroke	4 (1.6%)	7 (2.8%)	5 (2.0%)	5 (2.0%)	0.820
30-day all-cause mortality	12 (4.8%)	9 (3.6%)	3 (1.2%)	2 (0.8%)	0.012



Center learning curve across quartiles of 1,000 ACURATE *neo™* cases with respect to PVL and 30day mortality



■ PVL ≥2 ■ 30-Day All-cause Mortality

****** Cover Index =

(Prosthesis diameter-Annulus size)

Prosthesis diameter

Kim et al. Am J Cardiol 2020;131:12–16

PVL and conduction disorders



✓ Comparison of PPI between two THVs

Transcatheter Valve SELECTion in Patients With Right Bundle Branch Block and Impact on Pacemaker Implantations

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TABLE 3 Device Failure						
	SAPIEN 3 (n = 198)	ACURATE neo (n = 98)	p Value	SAPIEN 3 (n = 65)	ACURATE neo (n = 65)	p Value
Device failure	13 (6.6)	8 (8.2)	0.792	4 (6.2)	6 (9.2)	0.742
Procedural-related death	3 (1.5)	1 (1.0)	1.000	1 (1.5)	1 (1.5)	1.000
Correct position	196 (99.0)	97 (99.0)	1.000	65 (100.0)	64 (98.5)	1.000
Intended performance	187 (94.9)	91 (92.9)	0.651	62 (95.4)	60 (92.3)	0.718
PVL II+	3 (1.5)	4 (4.1)	0.225	0 (0.0)	3 (4.6)	0.244
Elevated gradient (>20 mm Hg)	6 (3.0)	1 (1.0)	0.431	3 (4.6)	0 (0.0)	0.244
Multiple valves	1 (0.5)	2 (2.0)	0.255	0 (0.0)	2 (3.1)	0.496
Post-procedural mean gradient, mm Hg	11.0 (8.0-13.0)	8.0 (6.0-10.0)	<0.001	11.0 (9.0-13.5)	7.0 (5.0-10.0)	<0.001
Conversion to sternotomy	1 (0.5)	0 (0.0)	1.000	0 (0)	0 (0)	_

- ✓ The SELECT RBBB (Transcatheter heart valve SELECTion in Patients with **Right Bundle Branch Block** multicenter registry) registry
- Patients with **Complete RBBB**, enrolled from 7 Centers in \checkmark Germany and Switzerland (January 2014-July 2017, N=296)



Clinical Outcomes at 30d and Procedural Characteristics

Husser, O et al. JACC Cardiovasc Interv. 2019;12(18):1781-1793

PVL and conduction disorders



The Radial force: One important factor that determines PVL and PPI



The ACURATE neo2 valve





In regards of device specific characteristics

✓ PVL and conduction disorders

✓ Commissure alignment and coronary access

Commissural Alignment

What is Commissural Alignment?

- Aligning the artificial THV with the native AV.
- Essential for future coronary access
- Maintain natural hemodynamics in the peri-ostial area
- More important in younger age / low risk TAVI candidates

Why is Commissural alignment needed?

- "Lifetime management" ready for TAVI in TAVI
- Improve coronary access
- Improve sinus washout
- Reduce leaflet thrombosis





✓ The **RE-ACCESS study**

FIGURE 1 Study Participant Flow



TABLE 3 Procedural Characteristics							
	Overall (N = 300)	Coronary Artery Accessible (n = 277)	Coronary Artery Not Accessible (n = 23)	p Value			
Mean TAV implantation depth, mm	-6.2 ± 2.9	-6.2 ± 3.0	-5.0 ± 1.2	<0.01			
TAV/annular oversizing by area, %	$\textbf{22.4} \pm \textbf{19.8}$	20.1 ± 18.7	$\textbf{36.9} \pm \textbf{10.9}$	<0.01			
TAV/annular oversizing by perimeter, %	12.3 ± 8.5	11.3 ± 8.1	23.5 ± 4.5	<0.01			
TAV-SoV relation, %*	-12.6 ± 9.8	-13.6 ± 9.3	-0.7 ± 7.7	<0.01			
TAV-SoV relation, %†	-19.6 ± 7.8	-19.9 ± 7.9	-16.8 ± 6.1	0.03			
Medtronic Evolut R/PRO 23 mm 26 mm 29 mm 34 mm	123 (41.0) 0 (0.0) 78 (26.0) 36 (12.0) 9 (3.0)	101 (36.5) 0 (0.0) 62 (22.4) 30 (10.8) 9 (3.2)	22 (95.7) 0 (0.0) 16 (69.6) 6 (26.1) 0 (0.0)	<0.01			
Edwards SAPIEN 3/ULTRA 20 mm 23 mm 26 mm 29 mm	96 (32.0) 0 (0.0) 24 (8.0) 45 (15.0) 27 (9.0)	95 (34.3) 0 (0.0) 23 (8.3) 45 (16.2) 27 (9.7)	1 (4.3) 0 (0.0) 1 (4.3) 0 (0.0) 0 (0.0)	<0.01			
Boston Scientific Acurate neo Size S Size M Size L	72 (24.0) 21 (7.0) 39 (13.0) 12 (4.0)	72 (26.0) 21 (7.6) 39 (14.1) 12 (4.3)	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)	<0.01			
Abbott Portico 23 mm 25 mm 27 mm 29 mm	9 (3.0) O (0.0) 6 (2.0) 3 (1.0) O (0.0)	9 (3.2) 0 (0.0) 6 (2.2) 3 (1.1) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)	0.38			

Barbanti et al., The RE-ACCESS Study; JACC CV 2020



- ✓ The **COMALIGN** study
 - ✓ A single center study including 60 consecutive patients who underwent TAVR with Self-Expanding THVs, (n=20) ACURATE neo2TM, (n=20) Evolut R/PROTM, and (n=20) PorticoTM
 - ✓ Feasibility of patient-specific implantation technique to achieve neo-commissural alignment





- ✓ The high rate of successful coronary access is due to the large opening cells at the stabilization arches and the established method of commissural alignment.
- ✓ Understanding the commissure alignment









Figure Credits: Bielauskas et al. JACC 2021





Figure Credits: Bielauskas et al. JACC 2021



Utility of the cusp-overlap technique in achieving commissural alignment with the ACURATE neo valve.



Kitamura M, et al. JACC Cardiovasc Interv. 2021;14(15):1740-1742.

Shift in the metrics of 'what matters?'





Experience in SNUH



- ✓ First case at SNUH: Aug 17th, 2022
 A total of 37 cases since, median fu duration 5.9 months
- ✓ Baseline characteristics
 - Age: 82.5±4.6 Baseline STS PROM: 4.1±1.7% Comorbidity: DM 11/37 patients HTN 29/37 patients ESRD 5/37 patients Afib 6/37 patients CAD 7/37 patients

✓ Clinical Outcomes: 1 mortality (2.7%), 1 PM implantation (2.7%), no >moderate PVL





83/M

- ✓ Diagnosed as Moderate AS in
 2019 → OPD fu at SNUH
- ✓ Aggravated dyspnea (NYHA II~III), and EchoCG showed Severe AS (2023.3)













TAVI planned with ACURATE neo2 27mm, 15.1% oversizing index



Case



TAVI planned with ACURATE neo2 27mm, 15.1% oversizing index







TAVI planned with ACURATE neo2 27mm, 15.1% oversizing index



AV mean PG 67.3 mmHg

AV mean PG 3.8 mmHg

Post dilatation with 24mm balloon \rightarrow PVL disappeared !





77/F, Severe AS







77/F, Severe AS





Evenly distributed posts

THV Cusps are overlapped

When the freecells are not visible, focus on the posts





77/F, Severe AS



Preserved coronary alignment

Conclusion

- ✓ The indications for TAVI is expanding, with new devices as treatment options.
- Unlike current generation coronary stents, each devices have distinct characteristics that lead to unique strong points.
- Meanwhile, the paradigm of treating Severe AS patients with TAVI have shifted from a *'procedural success metrics'* to *'lifetime management metrics'*.
 - ✓ Superior hemodynamics
 - ✓ Maintaining normal conduction
 - ✓ Easier coronary access etc.

 ✓ Understanding the characteristics of the ACURATE Neo2 will provide more options in the Cath Lab.