

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Company

Consulting Fees/Honoraria

NeoChord Inc.

Faculty disclosure information can be found on the app

Background

- As TAVR candidates are increasingly younger and at lower surgical risk, it becomes crucial to minimize potential procedural complications and provide surgical-like long-term outcomes
- Post-procedural moderate or severe paravalvular aortic regurgitation (AR) is a relevant complication after TAVR that has been found to be associated with adverse short- and long-term outcomes.¹
- Moderate or severe Paravalvular AR
 - SCOPE I: ACURATE neo 9% vs. 3% Sapien 3²
 - SCOPE II: ACURATE neo 10% vs. 3% CoreValve Evolut³

¹ Athappan G et al. J Am Coll Cardiol. 2013 Apr 16;61(15):1585-95.

² Lanz J et al. Lancet. 2019 Nov 2;394(10209):1619-1628.

³ Tamburino C et al. Circulation. 2020 Dec 22;142(25):2431-2442.

Background

ACURATE *neo*



ACURATE *neo2*



60% enlarged
sealing skirt

Release: September 2020



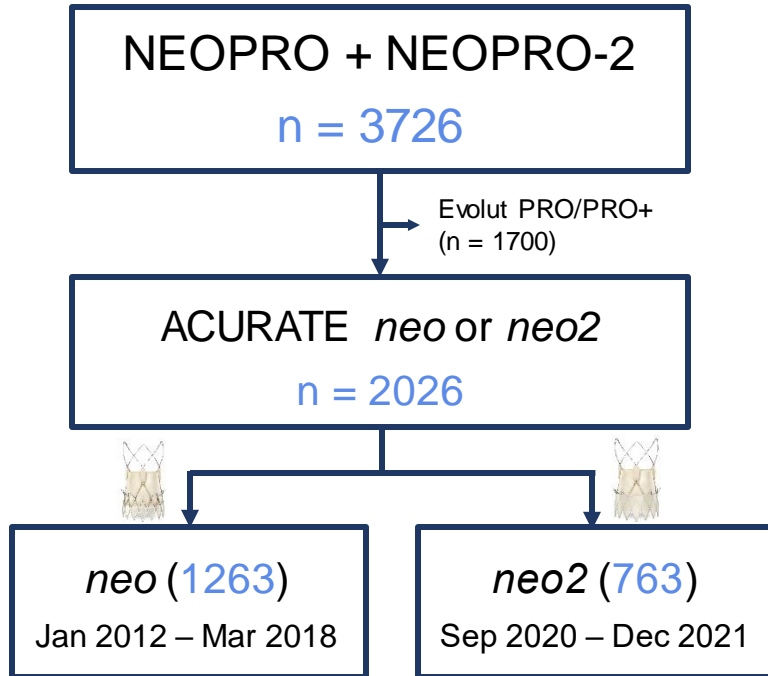
Radiopaque Positioning Marker



14F iSLEEVE™
Expandable Introducer

Study Design

Retrospective, Observational, Real-world registries (29 Centers, 13 Countries)



Primary Endpoint

Moderate or Severe paravalvular AR

Secondary Endpoints

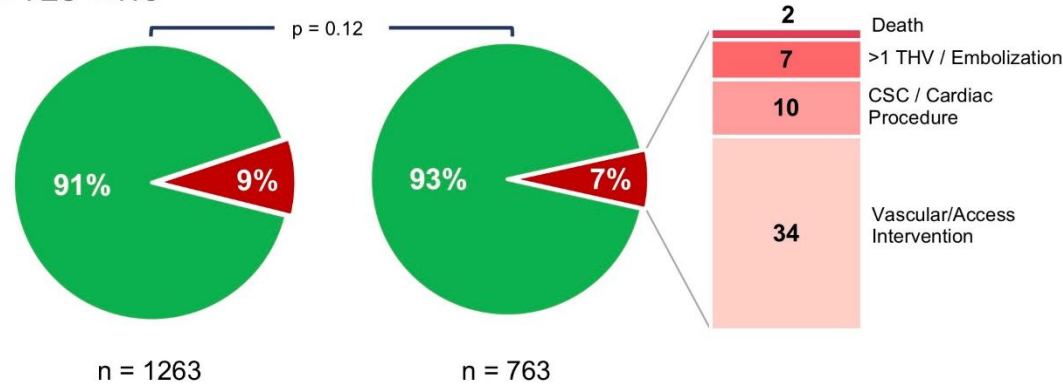
- 30-day VARC-3 clinical outcomes ¹
- 30-day new PPI
- 1-year overall survival

Baseline Characteristics

Clinical Characteristics	Total (2026)	ACURATE neo (1263)	ACURATE neo2 (763)	<i>p value</i>
Age, years	82 ± 5.8	82 ± 5.8	82 ± 5.9	0.822
Male	694 (34)	444 (35)	250 (33)	0.303
BMI	27 ± 5	27 ± 5	27 ± 5	0.281
BSA	1.82 ± 0.21	1.82 ± 0.21	1.82 ± 0.22	0.314
Hypertension	1726 (87)	1079 (88)	647 (85)	0.055
Diabetes Mellitus	598 (30)	379 (30)	219 (29)	0.571
Atrial Fibrillation	648 (32)	408 (33)	240 (32)	0.772
Previous Stroke	209 (10)	126 (10)	83 (11)	0.719
Peripheral Vascular Disease	271 (13)	156 (12)	115 (15)	0.093
Previous Myocardial Infarction	220 (11)	138 (12)	82 (11)	0.689
Previous PCI	582 (29)	370 (29)	212 (28)	0.496
Previous CABG	194 (10)	147 (12)	47 (6)	<0.001
COPD	369 (18)	244 (19)	125 (16)	0.114
eGFR, ml/min/1.73m ²	60 ± 25	58 ± 22	64 ± 29	<0.001
Prior PM/ICD	219 (11)	158 (12)	61 (8)	0.002
NYHA class III/IV	1397 (69)	981 (78)	416 (55)	<0.001
Euroscore II	3.9 [2.5, 6.6]	4.4 [2.7, 7.2]	3.1 [2.1, 5.1]	<0.001
STS score (mortality)	4 [2.8, 5.8]	4.1 [2.9, 6.1]	3.5 [2.5, 5]	<0.001

VARC 3 – Technical Success

■ YES ■ NO



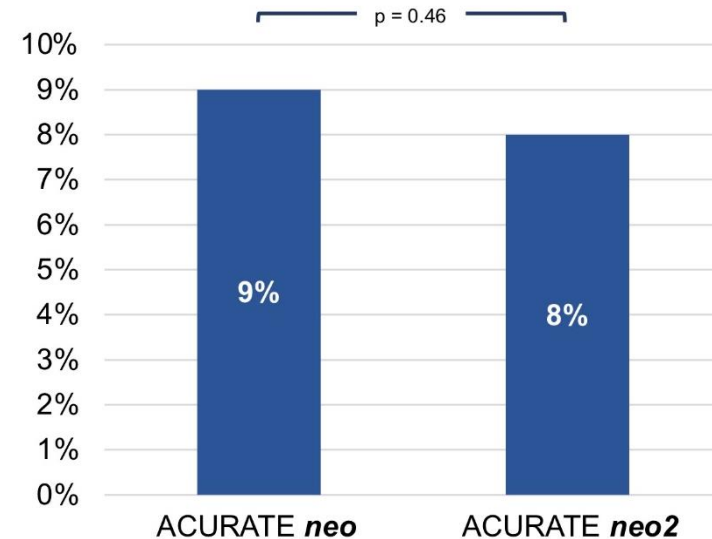
ACURATE *neo*

ACURATE *neo2*

Technical success (at exit from procedure room)¹

- Freedom from mortality
- Successful access, delivery of the device, and retrieval of the delivery system
- Correct positioning of a single prosthetic heart valve into the proper anatomical location
- Freedom from surgery or intervention related to the device or to a major vascular or access-related, or cardiac structural complication

Pacemaker Implantation

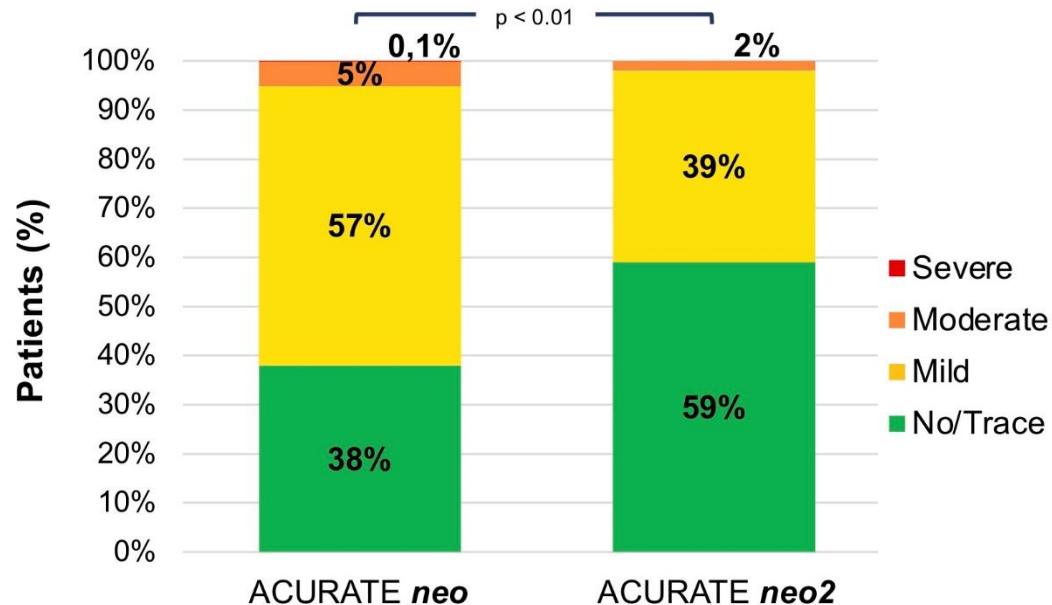


30-day Outcomes

	Total (2026)	ACURATE neo (1263)	ACURATE neo2 (763)	p value
All-cause Death	61 (3)	39 (3)	22 (3)	0.903
VARC 3 – Technical Success	1859 (92)	1149 (91)	710 (93)	0.117
VARC 3 – Device Success	1630 (82)	1024 (81)	606 (84)	0.119
VARC 3 – Intended Performance	1286 (93)	572 (90)	714 (96)	<0.001
PM Implantation	147 (8)	96 (9)	51 (8)	0.460
Acute Kidney Injury (stage 2-3)	58 (3)	37 (3)	21 (3)	0.953
Vascular Complications				<0.001
None	1700 (87)	1032 (83)	668 (94)	
Minor	156 (8)	138 (11)	18 (2)	
Major	98 (5)	75 (6)	23 (3)	
Bleeding Complications				0.020
None	1638 (86)	1011 (85)	627 (88)	
Type 1	104 (6)	65 (6)	39 (6)	
Type 2	79 (4)	56 (5)	23 (3)	
Type 3	74 (4)	56 (5)	18 (2)	
Type 4	2 (0.1)	0 (0)	2 (0.3)	
Mean aortic gradient, mmHg	8.5 ± 3.8	8 ± 3.3	8.9 ± 4.1	<0.001
AVA, cm ²	1.8 ± 0.4	1.8 ± 0.4	1.8 ± 0.4	0.826
Indexed AVA, cm ² /m ²	0.96 ± 0.2	0.96 ± 0.2	0.96 ± 0.2	0.769
Moderate or severe paravalvular AR	75 (4)	62 (5)	13 (2)	<0.001

Paravalvular Aortic Regurgitation

Pre-discharge echocardiography

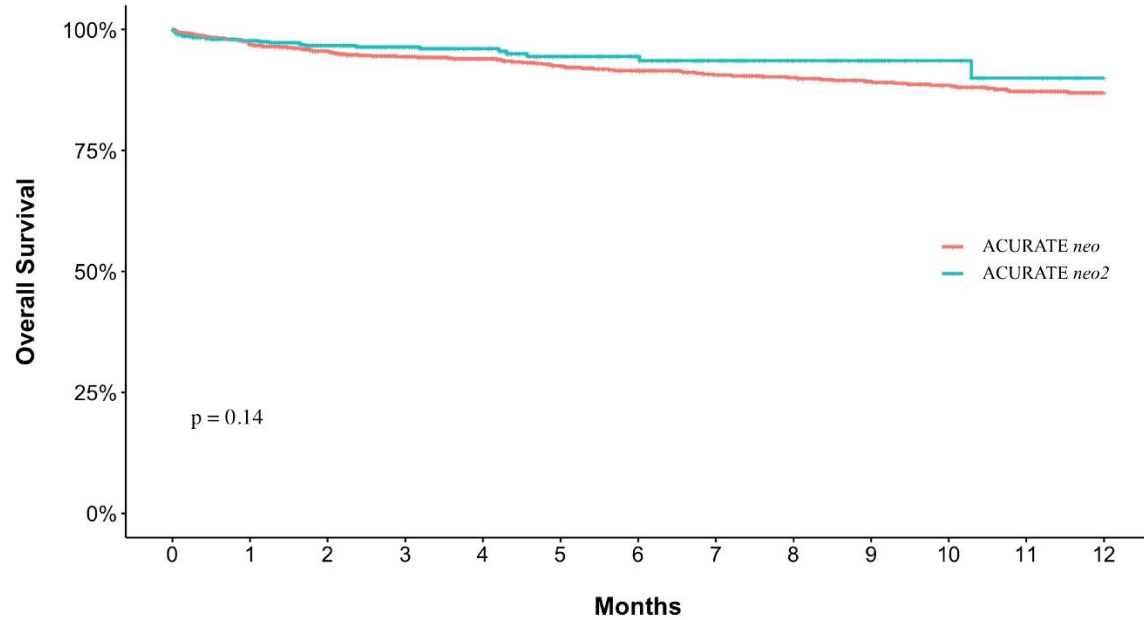


Aortic Calcification Grade ^{1,2}

	neo	neo2	<i>p</i> value
None or Mild Calcification	6/286 (2)	1/184 (0.5)	0.317
Moderate Calcification	21/428 (5)	7/311 (2)	0.077
Heavy Calcification	23/263 (9)	3/133 (2)	0.018

p value for interaction 0.671

Overall Survival



Patients at risk

ACURATE <i>neo</i>	1263	935	766	681	601	565	531	500	478	453	433	392	267
ACURATE <i>neo2</i>	763	556	398	290	200	149	110	80	55	39	27	21	13

Conclusions

- The latest-generation ACURATE *neo2* THV was associated with a significant reduction in post-procedural moderate or severe paravalvular AR as compared to the first-generation *neo* THV
- A similar need for new PPI was observed between *neo2* and *neo*
- The superior performance of the ACURATE *neo2* THV was particularly evident in severely calcific aortic valve anatomies
- TAVR with ACURATE *neo2* in combination with the expandable iSleeve is associated with reduced rates of vascular complications.

Haemodynamic performance and clinical outcomes of transcatheter aortic valve replacement with the self-expanding ACURATE neo2

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Outcomes Stratified per Aortic Valve Calcification grade

	None or Mild Calcification			Moderate Calcification			Heavy Calcification			
	neo (286)	neo2 (184)	<i>p value</i>	neo (428)	neo2 (311)	<i>p value</i>	neo (263)	neo2 (133)	<i>p value</i>	<i>p value for interaction</i>
All-cause Death	9 (3)	6 (3)	1.000	11 (3)	9 (3)	0.962	9 (4)	0 (0)	0.070	0.418
VARC 3 - Technical Success	250 (87)	167 (91)	0.332	390 (91)	287 (92)	0.669	240 (91)	128 (96)	0.105	0.404
VARC 3 - Device Success	229 (80)	150 (84)	0.311	346 (81)	244 (83)	0.524	203 (78)	100 (85)	0.172	0.691
VARC 3 - Intended Performance	262 (97)	178 (97)	0.937	377 (93)	293 (95)	0.298	214 (88)	127 (97)	0.005	0.899
PM Implantation	21 (9)	11 (7)	0.605	40 (10)	23 (9)	0.535	17 (8)	6 (6)	0.705	0.982
Mean aortic gradient, mmHg	7.6±3.4	8.5±4.2	0.023	8±3.2	9±4.1	0.001	8.2±3.6	8.9±3.9	0.023	0.141
AVA, cm ²	1.7±0.4	1.7±0.4	0.867	1.7±0.4	1.7±0.4	0.731	1.8±0.4	1.9±0.4	0.867	0.135
Indexed AVA, cm ² /m ²	0.96±0.2	0.96±0.2	0.979	0.93±0.2	0.94±0.2	0.589	0.96±0.2	1±0.2	0.979	0.208
Moderate or severe paravalvular AR	6 (2)	1 (0.5)	0.317	21 (5)	7 (2)	0.077	23 (9)	3 (2)	0.018	0.671

Aortic Valve Calcification

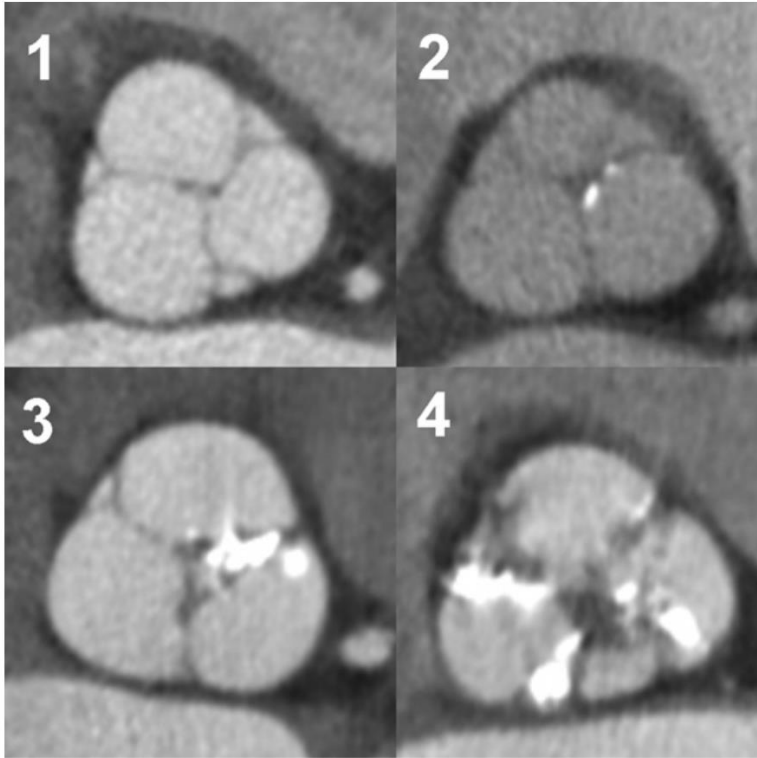


Figure 1. Assessment of Aortic Valve Calcifications

The presence and severity of aortic valve calcifications were assessed on double oblique transverse reconstructions. The degree of aortic valve calcification was graded as follows: grade 1—no calcification; grade 2—mildly calcified (small isolated spots); grade 3—moderately calcified (multiple larger spots); grade 4—heavily calcified (extensive calcification of all cusps). Extensive calcifications may hamper the ability to cross the native valve during percutaneous aortic valve replacement. Therefore, multislice computed tomography may provide important information in the selection of potential candidates.

TABLE 16 Criteria for prosthetic aortic valve regurgitation*

Three-class grading scheme	None/Trace	Mild	Mild-moderate	Moderate	Moderate-severe	Severe
Five-class grading scheme	None/Trace	Mild	Mild-moderate	Moderate	Moderate-severe	Severe
Doppler parameters (qualitative or semi-quantitative)						
Jet features†						
Extensive/wide jet origin	Absent	Absent	Absent	Present	Present	Present
Multiple jets	Possible	Possible	Often present	Often present	Usually present	Usually present
Jet path visible along the stent	Absent	Absent	Possible	Often present	Usually present	Present
Proximal flow convergence visible	Absent	Absent	Absent	Possible	Often present	Often present
E/A ratio‡	<1.0	<1.0	<1.0	≥1.5	≥1.5	≥1.5
Vena contracta width (mm)†	Not quantifiable	<2	2 to <4	4 to <5	5 to <6	≥6
Vena contracta area (mm²)§	Not quantifiable	<5	5 to <10	10 to <20	20 to <30	≥30
Jet width at its origin (%LVOT diameter)†	Narrow (<5)	Narrow (5 to <15)	Intermediate (15 to <30)	Intermediate (30 to <45)	Large (45 to <60)	Large (≥60)
Jet density (CW Doppler)	Incomplete or faint	Incomplete or faint	Variable	Dense	Dense	Dense
Jet deceleration rate (PHT, ms) ¶ ¶	Slow (>500)	Slow (>500)	Variable (200 to <500)	Variable (200 to <500)	Variable (200 to <500)	Steep (<200)
Diastolic flow reversal in proximal descending aorta ¶	Absent	Absent or brief early diastolic	Intermediate	Intermediate	Holodiastolic (end-diastolic velocity 20 to <30 cm/s)	Holodiastolic (end-diastolic velocity ≥30 cm/s)
Circumferential extent of PVR (%) (colour Doppler)**	Not quantifiable	<5	5 to <10	10 to <20	20 to <30	≥30
Doppler parameters (quantitative)						
Regurgitant volume (mL/beat)††	<15	<15	15 to <30	30 to <45	45 to <60	≥60
Regurgitant orifice area (mm²)††	<5	<5	5 to <10	10 to <20	20 to <30	≥30
Regurgitant fraction (%)††	<15	<15	15 to <30	30 to <40	40 to <50	≥50
CMR parameters						
Regurgitant fraction (%)††	<15	<15	15 to <30	30 to <40	40 to <50	≥50