



ACURATE neo2 post-procedural hemodynamic and short-term clinical outcomes

The ITAL-neo Registry

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Potential conflicts of interest

Speaker's name : Andrea Buono

☒ I do not have any potential conflict of interest to declare

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Background

Acurate *neo* (Boston Scientific)



STUDY	Incidence	Competitor	Competitor's incidence
SAVI-TF Registry ⁽¹⁾	4.1% (procedural)	-	-
MORENA Registry ⁽²⁾	4.8% (30-d)	Sapien 3 (Edwards)	1.8% (30-d)
SCOPE I RCT ⁽³⁾	9% (30-d)	Sapien 3 (Edwards)	3% (30-d)
Mauri V et al. (small annuli) ⁽⁴⁾	4.5% (30-d)	Sapien 3 (Edwards)	3.6% (30-d)
NEOPRO Registry ⁽⁵⁾	10.9% (30-d)	Evolut PRO (Medtronic)	8.7% (30-d)
SCOPE II RCT ⁽⁶⁾	10% (30-d)	CoreValve/Evolut (Medtronic)	3% (30-d)

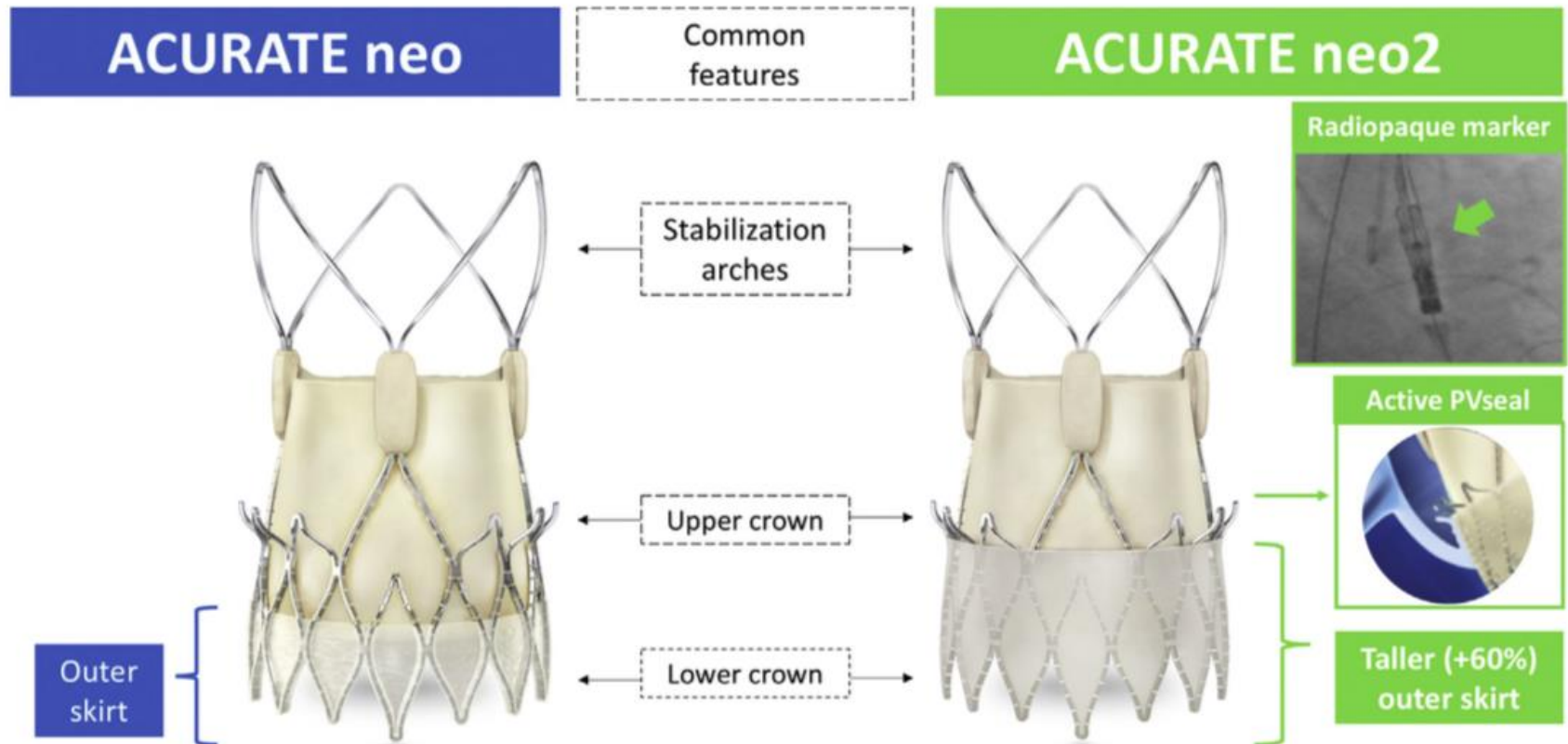
Not negligible more-than-mild PVL incidence

- (1) Möllmann H et al. EuroIntervention. 2018 Feb 2;13(15):e1764-e1770.
- (2) Husser O et al. JACC Cardiovasc Interv. 2017 Oct 23;10(20):2078-2087.
- (3) Lanz J et al. Lancet. 2019 Nov 2;394(10209):1619-1628.
- (4) Mauri V et al. Circ Cardiovasc Interv. 2017 Oct;10(10):e005013.
- (5) Pagnesi M et al. JACC Cardiovasc Interv. 2019 Mar 11;12(5):433-443.
- (6) Tamburino C et al. Circulation. 2020 Dec 22;142(25):2431-2442.

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Background

Second-generation ACURATE neo2 was lunched in September 2020

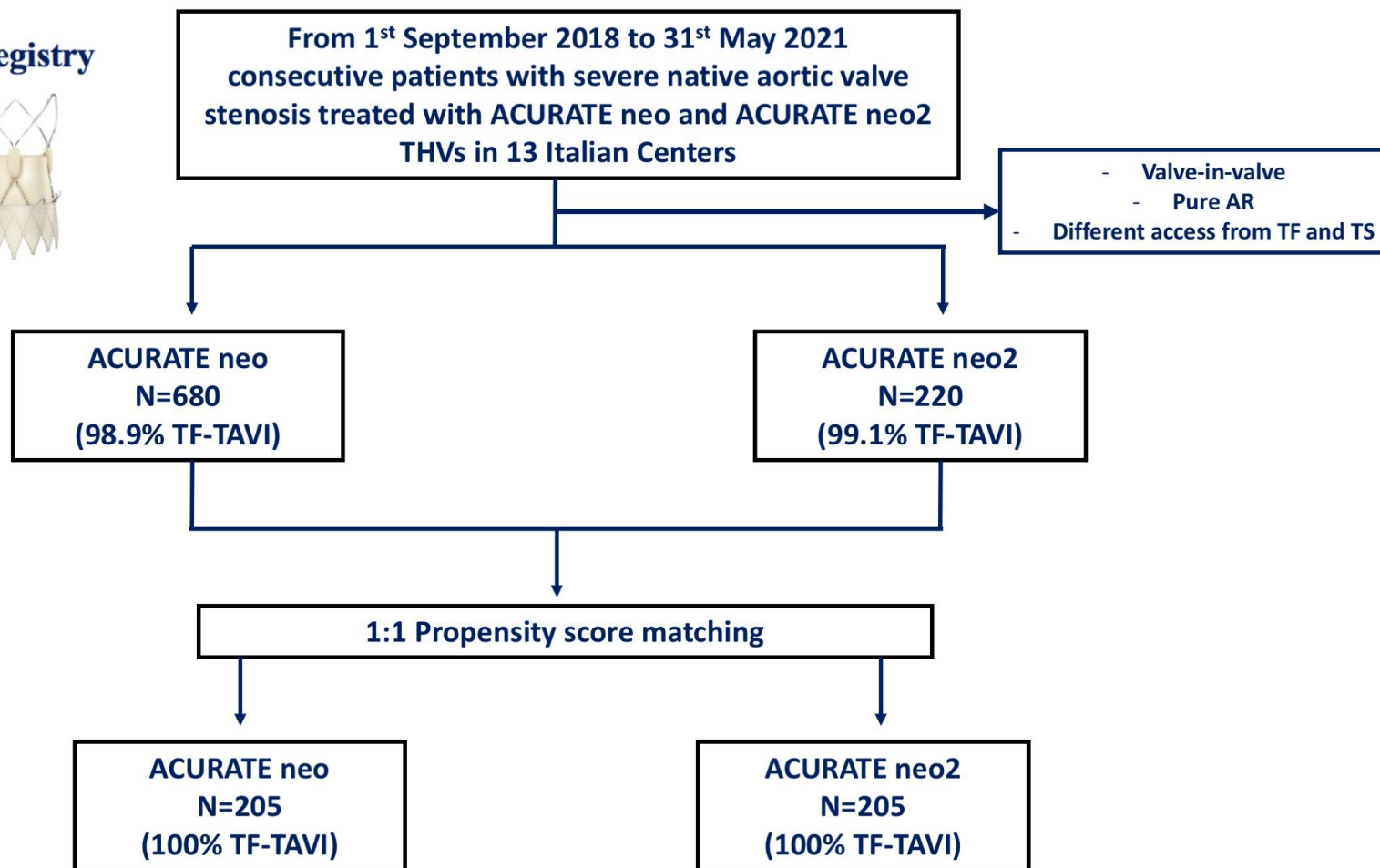


Postulated advantage: reduction of more-than-mild paravalvular leak

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Study design and flow-chart

Retrospective, observational, real-world, investigator-initiated registry



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Endpoints definition

PRIMARY ENDPOINT*

Rate of pre-discharge more-than-mild paravalvular aortic regurgitation at echocardiographic assessment

SECONDARY ENDPOINTS*

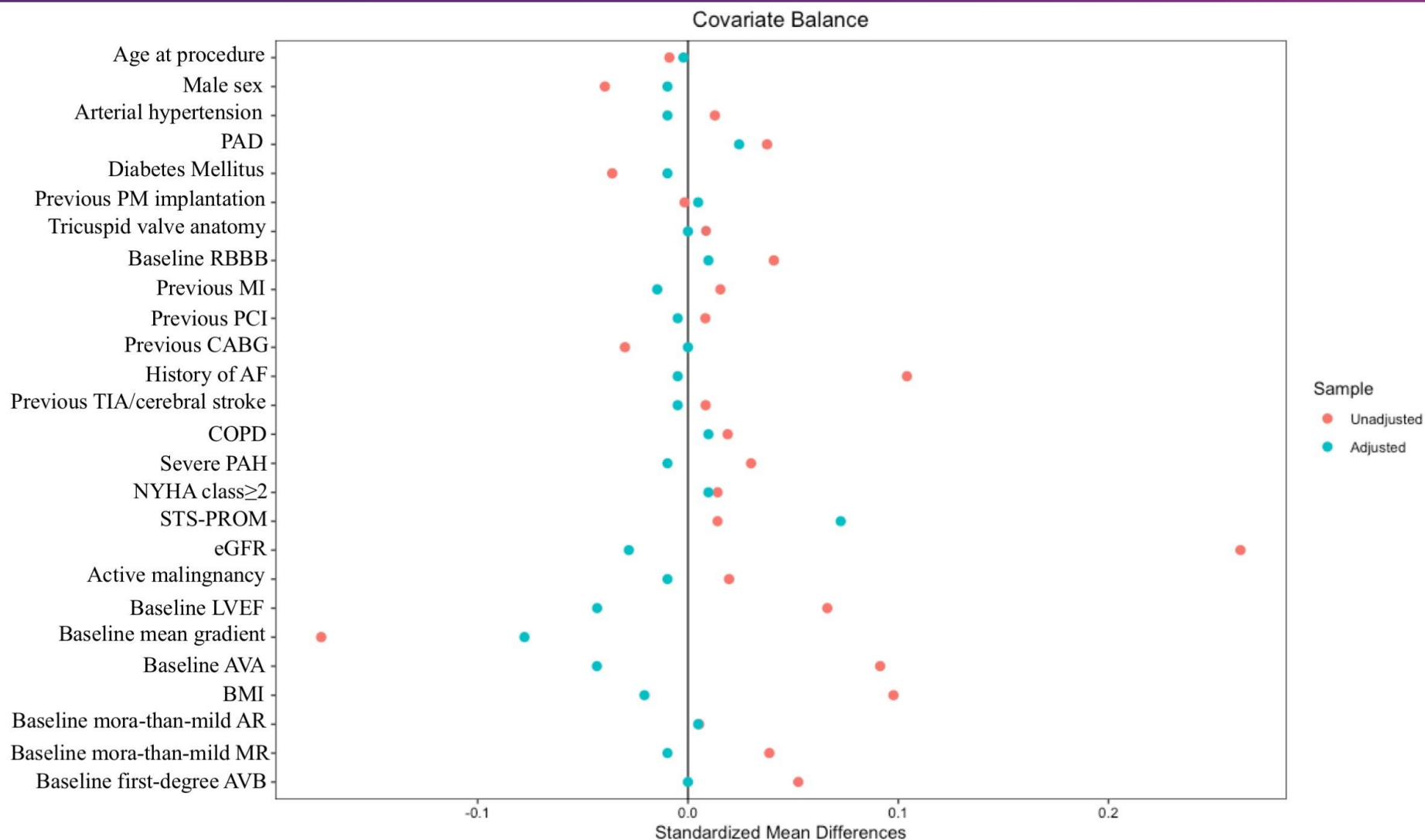
- Post-procedural technical success
 - 90-day device success
 - 90-day safety
- Single components of the pre-specified composite endpoints

* *defined according VARC-3 criteria⁽¹⁾*

(1) Généreux P, et al. Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research. J Am Coll Cardiol. 2021 Jun 1;77(21):2717-2746.

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1:1 propensity score match



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Baseline characteristics – matched cohort

	ACURATE neo N=205	ACURATE neo2 N=205	P value
Age (years), median[IQR]	84.00 [80.00, 86.00]	83.00 [81.00, 86.00]	0.746
Male sex, n (%)	68 (33.2)	66 (32.2)	0.916
NYHA class ≥ 3 , n (%)	128 (62.4)	130 (63.4)	0.919
STS-PROM, median[IQR]	3.33 [2.40, 4.80]	3.40 [2.23, 5.10]	0.679
Previous PM, n (%)	19 (9.3)	20 (9.8)	1.000
Arterial hypertension, n (%)	172 (83.9)	170 (82.9)	0.894
TIA or cerebral stroke, n (%)	17 (8.3)	16 (7.8)	1.000
History of AF, n (%)	64 (31.2)	63 (30.7)	1.000
History of CAD, n (%)	76 (37.1)	73 (35.6)	0.837
Previous PCI, n (%)	50 (24.4) 49	(23.9)	1.000

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Baseline ECG and Echo characteristics

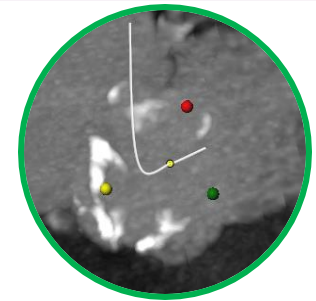
	Unmatched			Matched		
	ACURATE neo n=680	ACURATE neo2 n=220	p value	ACURATE neo n=205	ACURATE neo2 n=205	p value
First-degree AVB, n (%)	57 (8.4)	30 (13.6)	0.026	27 (13.2)	27 (13.2)	1.000
RBBB, n (%)	34 (5.0)	20 (9.1)	0.033	17 (8.3)	19 (9.3)	0.862
Tricuspid anatomy, n (%)	663 (97.5)	214 (97.3)	0.890	199 (97.1)	199 (97.1)	1.000
Mean transvalvular gradient (mmHg), median[IQR]	45.00 [39.00, 52.00]	43.00 [39.00, 50.00]	0.047	44.00 [40.00, 51.00]	43.00 [39.00, 50.00]	0.316
Max transvalvular gradient (mmHg), median[IQR]	72.00 [62.00, 85.00]	70.00 [62.00, 80.00]	0.083	71.00 [62.50, 81.50]	71.00 [63.00, 80.00]	0.649
AVA (cm ²), median[IQR]	0.70 [0.60, 0.80]	0.71 [0.60, 0.80]	0.151	0.72 [0.60, 0.80]	0.71 [0.60, 0.80]	0.719
More-than-mild AR, n (%)	120 (17.6)	40 (18.2)	0.840	37 (18.0)	38 (18.5)	1.000
LVEF, median[IQR]	57.00 [53.00, 62.00]	59.00 [54.00, 63.00]	0.178	58.00 [55.00, 64.00]	59.00 [54.00, 64.00]	0.772
More-than-mild MR, n (%)	190 (27.9)	70 (31.8)	0.268	64 (31.2)	62 (30.2)	0.915

AR: aortic regurgitation; AVA: aortic valve area; AVB: atrioventricular block; LVEF: left ventricular ejection fraction; MR: mitral regurgitation; RBBB: right bundle branch block.

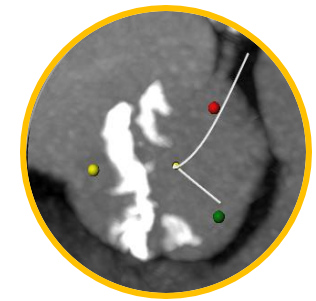
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MSCT characteristics

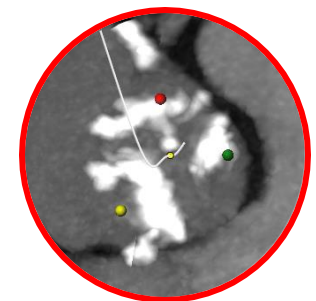
	ACURATE neo n=205	ACURATE neo2 n=205	p value
Degree of leaflets calcification, n (%):			0.085
- Mild	58 (33.7)	65 (34.0)	
- Moderate	65 (37.8)	67 (35.1)	
- Severe	49 (28.5)	59 (30.9)	
Degree of annular calcification, n (%):			0.022
- None	100 (58.8)	107 (60.1)	
- Mild	42 (24.7)	38 (21.3)	
- Moderate	25 (14.7)	18 (10.1)	
- Severe	3 (1.8)	15 (8.4)	
Degree of LVOT calcification, n (%):			0.007
- None	118 (70.2)	140 (82.8)	
- Mild	34 (20.2)	18 (10.7)	
- Moderate	15 (8.9)	7 (4.1)	
- Severe	1 (0.6)	4 (2.4)	



MILD



MODERATE



SEVERE

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Procedural data and antithrombotic regimen

	ACURATE neo n=205	ACURATE neo2 n=205	p value
Anesthesia type, n (%)			0.114
- conscious sedation	203 (99)	197 (96.1)	
- general	2 (1)	8 (3.9)	
Trans-femoral access, n (%)	205 (100)	205 (100)	1.000
Concomitant PCI, n (%)	18 (8.8)	17 (8.3)	1.000
Cerebral embolic protection, n (%)	7 (3.4)	6 (2.9)	1.000
THV size, n (%):			0.491
- 23 mm (S)	61 (29.8)	50 (24.4)	
- 25 mm (M)	84 (41.0)	91 (44.4)	
- 27 mm (L)	60 (29.3)	64 (31.2)	
Valve predilatation, n (%)	140 (69.0)	189 (92.2)	<0.001
Valve postdilatation, n (%)	99 (48.3)	65 (31.7)	0.001
Need for second THV implantation	6 (2.9)	1 (0.5)	0.122
Procedure length (min), median[IRQ]	105.00 [80.00-121.00]	100.00 [76.75, 125.00]	0.310
Contrast dye amount (ml), median[IRQ]	150.00 [100.00, 200.00]	127.50 [80.00, 188.75]	0.057
LMCA protection, n (%)	0 (0.00)	1 (0.5)	1.000
RCA protection, n (%)	0 (0.00)	0 (0.00)	NA
Post-procedural antithrombotic therapy, n (%):			NA
- SAPT	75 (37.9)	86 (42.6)	
- DAPT	62 (31.3)	47 (23.3)	
- OAC	44 (22.2)	58 (26.2)	
- DAT*	11 (5.6)	10 (5.0)	
- TAT**	3 (1.5)	1 (0.5)	

↑ **Rate of pre-dilatation**

↓ **Rate of post-dilatation**

Reasons for 2nd THV implantation

ACURATE neo

- 3 Embolizations
- 3 Malpositions

ACURATE neo2

- 1 Embolization

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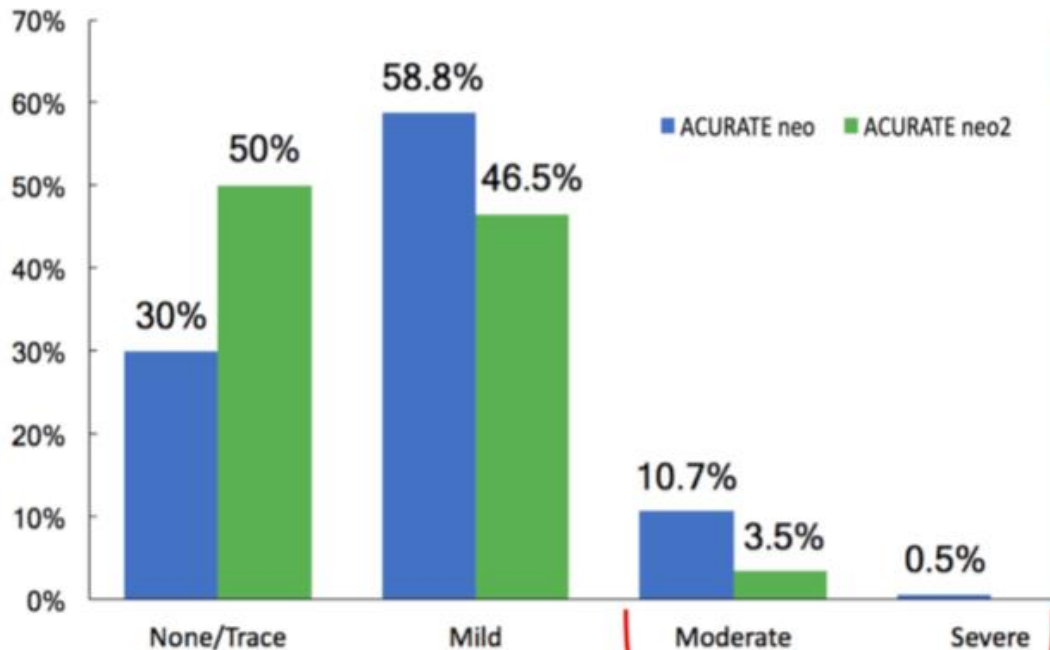
Comparable in hospital outcomes

	ACURATE neo n=205	ACURATE neo2 n=205	p value		ACURATE neo n=205	ACURATE neo2 n=205	p value
All-cause mortality, n (%)	1 (0.5)	3 (1.5)	0.623	VARC-3 bleeding, n (%)			0.947
CV death, n (%)	1 (0.5)	3 (1.5)	0.623	- Type 1	23 (11.2)	20 (9.8)	
Intra-procedural death, n (%)	1 (0.5)	0 (0.0)	1.000	- Type 2	6 (2.9)	5 (2.4)	
Peri-procedural MI, n (%):	1 (0.5)	0 (0.0)	1.000	- Type 3	3 (1.5)	3 (1.5)	
Development of new AAVB and/or BBB, n (%); of those, spontaneous regression, n (%)	53 (25.9)	59 (28.8)	0.580	- Type 4	0 (0.0)	0 (0.0)	
Need of PPM implantation, n (%)*	17 (9.1)	14 (7.6)	0.709	VARC-3 vascular complication, n (%):			0.862
Cerebral ischemic event, n (%):			1.000	- Minor	9 (4.4)	12 (5.9)	
- TIA / non-disabling stroke	1 (0.5)	2 (1.0)		- Major	8 (3.9)	7 (3.4)	
- Disabling stroke	1 (0.5)	0 (0.0)		Coronary occlusion, n (%)	1 (0.5)	1 (0.5)	0.842
				Cardiac tamponade, n (%)	3 (1.5)	2 (1.0)	0.842
				VARC-3 AKI, n (%)			0.546
				- Type 1	1 (0.5)	4 (2.0)	
				- Type 2	5 (2.5)	5 (2.5)	
				- Type 3	1 (0.5)	0 (0.0)	
				- Type 4	0 (0.0)	1 (0.5)	
				VARC-3 technical success, n (%)	195 (95.1)	200 (97.6)	0.293
				Intensive care unit stay (days), median[IRQ]	1.50 [1.00, 3.00]	1.00 [0.00, 3.00]	0.003
				Hospital length (days), median[IRQ]	7.00 [5.00, 9.00]	6.00 [4.00, 9.00]	0.136

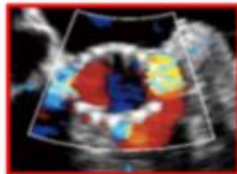
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Primary endpoint results

Pre-discharge paravalvular aortic regurgitation



	ACURATE neo n=204	ACURATE neo2 n=202	p value
LVEF, median[IQR]	58 [55.00, 61.00]	60 [55.00, 62.75]	0.331
Mean transvalvular gradient (mmHg), median[IQR]	6.00 [5.00, 9.00]	7.00 [6.00, 10.00]	0.085
Max transvalvular gradient (mmHg), median[IQR]	12.50 [10.00, 17.00]	14.50 [12.00, 18.00]	0.065
AVA (cm ²), median[IQR]	1.76 [1.56, 2.02]	1.88 [1.60, 2.19]	0.354
Prosthesis-patient mismatch (cm ² /m ²), median[IQR]	1.00 [0.90, 1.12]	1.07 [0.90, 1.31]	0.150



3-fold lower frequency of *moderate or greater* paravalvular aortic regurgitation with ACURATE neo2 (11.2% vs 3.5%, $p < 0.001$)

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90-day secondary endpoint

	ACURATE neo	ACURATE neo2	p value
VARC-3 device success, n (%)	172 (83.9)	184 (89.8)	0.108
VARC-3 early safety, n (%)	151 (73.7)	164 (80.0)	0.160

	ACURATE neo n=175	ACURATE neo2 n=200	p value <0.001
All-cause mortality, n (%)	7 (4.0)	9 (4.5)	1.000
CV death, n (%)	5 (3.2)	5 (3.2)	1.000
MI, n (%)	1 (0.6)	0 (0.0)	0.469
Cerebral ischemic event, n (%):			0.689
- TIA / non-disabling stroke	1 (0.6)	1 (0.5)	
- Disabling stroke	1 (0.6)	4 (2.0)	
Re-hospitalization, n (%)	9 (5.2)	11 (5.6)	1.000
VARC-3 bleeding, n (%):			0.909
- Type 1	23 (12.9)	23 (11.7)	
- Type 2	6 (3.4)	5 (2.5)	
- Type 3	3 (1.7)	4 (2.0)	
- Type 4	1 (0.6)	0 (0.0)	
New PPM implantation, n (%)	19 (10.9)	15 (7.7)	0.368

	ACURATE neo n=126	ACURATE neo2 n=113	p value 0.192
LVEF, median[IQR]	58.00 [55.00, 62.00]	60.00 [55.00, 63.00]	0.236
Mean transvalvular gradient (mmHg), median[IQR]	7.00 [5.00, 10.00]	7.00 [5.00, 10.00]	0.826
Max transvalvular gradient (mmHg), median[IQR]	12.00 [9.75, 17.00]	13.00 [10.00, 19.00]	0.453
Max transvalvular velocity (m/s), median[IQR]	1.73 [1.56, 2.06]	1.80 [1.58, 2.18]	0.453
AVA (cm ²), median[IQR]	1.83 [1.40, 2.10]	1.74 [1.42, 2.09]	0.621
Prosthesis-patient mismatch (cm ² /m ²), median[IQR]	1.03 [0.75]	1.03 [0.89, 1.20]	0.355
Paravalvular AR, n (%)			0.002
- None/Trace	39 (31)	58 (50.9)	
- Mild	71 (56.3)	52 (45.6)	
- Moderate	15 (11.9)	4 (3.5)	
- Severe	1 (0.8)	0 (0.0)	

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Why is this important?

- ITAL-neo is an **independent and large registry** comparing the performance of ACURATE neo2 and neo THVs
- ITAL-neo registry demonstrated a better performance of the second-generation device **showing a 3-fold reduction of more-than-mild paravalvular leak** and a **comparable technical success**
- **Data** concerning short-term clinical outcomes is **encouraging: 90-day device success and safety rates are numerically higher** (despite not being statistically significant) in the group treated with the new-generation device

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Transcatheter Aortic Valve Replacement With Self-Expanding ACURATE neo2

Postprocedural Hemodynamic and Short-Term Clinical Outcomes

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