ScienceDirect

JACC: Cardiovascular Interventions

Volume 15, Issue 11, 13 June 2022, Pages 1101-1110

New Research Paper

Structural

Transcatheter Aortic Valve Replacement With Self-Expanding ACURATE neo2: PostproceduralHemodynamic and Short-Term ClinicalOutcomes

Andrea Buono MD [a], Riccardo Gorla MD [b], Alfonso Ielasi MD [c], Giuliano Costa MD [d], Ottavia Cozzi MD [e], Marco Ancona MD [f], Francesco Soriano MD [g], Marco De Carlo MD [h], Erica Ferrara MD [i], Francesco Giannini MD [j], Mauro Massussi MD [k], Luca Nai Fovino MD [l], Gaetano Pero MD [a], Luca Bettari MD [a], Elena Acerbi BSc [b], Antonio Messina MD [m], Carmelo Sgroi MD [d], Mariano Pellicano MD [c], Jinwei Sun MD [g], Francesco Gallo MD [n]... Diego Maffeo MD [a]

Show more

Referred to by Neo to Neo2

JACC: Cardiovascular Interventions, Volume 15, Issue 11, 13 June 2022, Pages 1111-1112

Won-Keun Kim, Helge Möllmann

View PDF

Abstract

Background

The first-generation ACURATE neo transcatheter heart valve (THV) (Boston Scientific) was associated with a non-negligible occurrence of moderate or greater paravalvular aortic regurgitation (AR) following transcatheter aortic valve replacement. To overcome this issue, the ACURATE neo2 iteration, which incorporates a taller outer skirt aimed at reducing the occurrence of paravalvular AR, has recently been developed.

Objectives

The aim of this study was to assess the efficacy and safety of the ACURATE neo2 (Boston Scientific) THV in patients with severe aortic valve stenosis.

Methods

ITAL-neo was an observational, retrospective, multicenter registry enrolling consecutive patients with severe aortic valve stenosis, treated with first- and second-generation ACURATE neo THVs, via transfemoral and trans-subclavian access, in 13 Italian centers. One-to-one propensity score matching was applied to account for baseline characteristics unbalance. The primary endpoint was the occurrence of moderate or greater paravalvular AR on predischarge echocardiographic assessment. Secondary endpoints included postprocedural technical success and 90-day device success and safety.

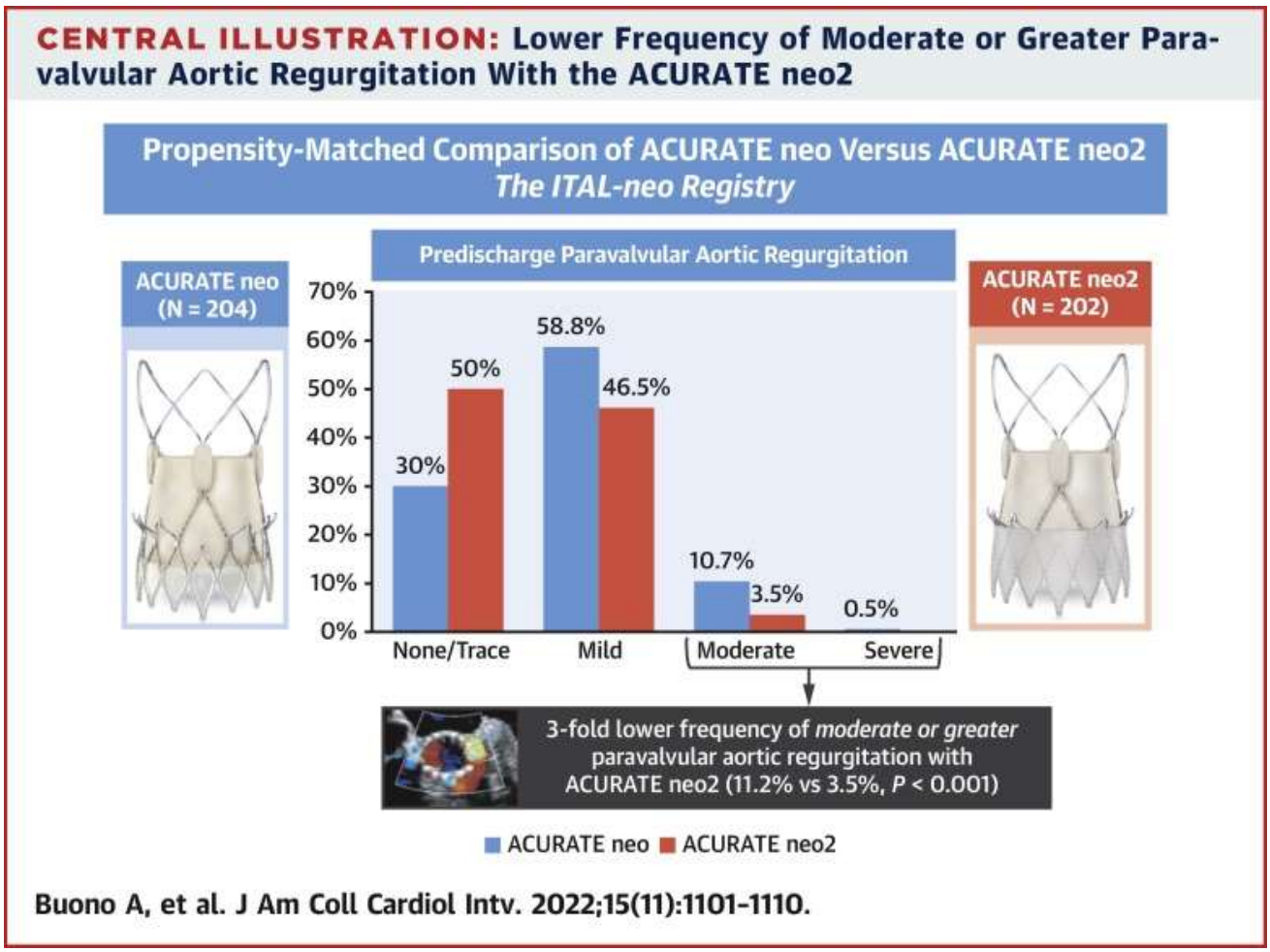
Results

Among 900 patients included in the registry, 220 received the ACURATE neo2 THV, whereas 680 were treated with the first-generation device. A total of 410 patients were compared after 1:1 propensity score matching. The ACURATE neo2 THV was associated with a 3-fold lower frequency of postprocedural moderate or greater paravalvular AR (11.2% vs 3.5%; $P < 0.001$). No other hemodynamic differences were observed. Postprocedural technical success was similar between the 2 cohorts. Fewer adverse events were observed in patients treated with the ACURATE neo2 at 90 days.

Conclusions

Transfemoral transcatheter aortic valve replacement using the ACURATE neo2 was associated with a significant lower frequency of moderate or greater paravalvular AR compared with the earlier generation ACURATE neo device, with encouraging short-term safety and efficacy.

Central Illustration



Download : Download high-res image (726KB)

Download : Download full-size image

Previous

Next

Key Words

ACURATE neo2; aortic regurgitation; paravalvular leak; self-expanding THV; SE THV; TAVR

Abbreviations and Acronyms

AR, aortic regurgitation; MSCT, multislice computed tomographic; PPM, permanent pacemaker; RCT, randomized controlled trial; SE, self-expanding; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve

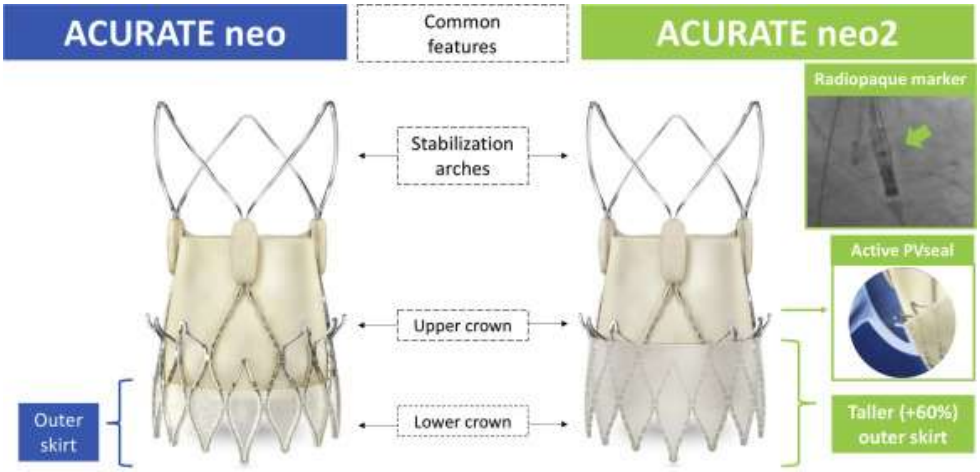
Transcatheter aortic valve replacement (TAVR) is an established treatment option for symptomatic patients with severe aortic valve stenosis. Recently, international guidelines have recommended transfemoral TAVR as the preferred mode of intervention for patients≥75 years of age, independent of their surgical risk.[1,2] Considering the predictable lowering of the age of patients who will benefit from TAVR in the coming years, minimizing procedural complications becomes imperative. Moderate or greater aortic regurgitation (AR) caused by postimplantation paravalvular leak is one of the more relevant TAVR issues so far. In fact, its occurrence has been associated with increased short- and long-term mortality.[3] The first-generation self-

expanding (SE) ACURATE neo transcatheter heart valve (THV) (Boston Scientific) was observed to be associated with a non-negligible occurrence of moderate or greater paravalvular AR, higher than that observed with balloon-expandable and other SE THVs.[4, 5, 6] For this reason, appropriate patient screening and optimized implantation have been suggested in association with ACURATE neo device.[7] To overcome this drawback, the newer generation ACURATE neo2 THV (Boston Scientific) was introduced, maintaining most of the first-generation device's characteristics (eg, SE and supra-annular design) but equipped with a taller outer pericardial skirt, extended to the upper crown of the THV stent, which has the potential to reduce postimplantation paravalvular AR. The postulated advantage of this new THV iteration will be investigated in the ongoing randomized controlled trial(RCT) ACURATE IDE (Safety and Efficacy Study ofAcurate Valve for Transcatheter Aortic ValveReplacement; NCT03735667↗). The aim of our study was to investigate the safety and efficacy of the ACURATE neo2 THV in a real-world population, comparing postprocedural hemodynamic and clinical short-term outcomes with those of patients treated with the first-generation ACURATE neo THV.

Methods

ACURATE neo and ACURATE neo2 THVs

The ACURATE neo2 THV has maintained the key features of the first-generation device, consisting of a SE Nitinol frame with porcine pericardium leaflets in the supra-annular position. Both devices are covered by an inner and an outer pericardial skirt. Compared with the ACURATE neo, the new iteration's design was implemented with a taller (+60%) outer sealing skirt (Figure 1), extended to the upper crown of the THV stent and able to guarantee a more synchronous adaptation to the native aortic annulus during the different phases of the cardiac cycle (Active PVseal technology). Moreover, the 14-F compatible transfemoral delivery system has been implemented with a new radiopaque positioning marker and an enhanced tip design, allowing a clear visual reference for easy and precise valve implantation.



Download : Download high-res image (386KB)

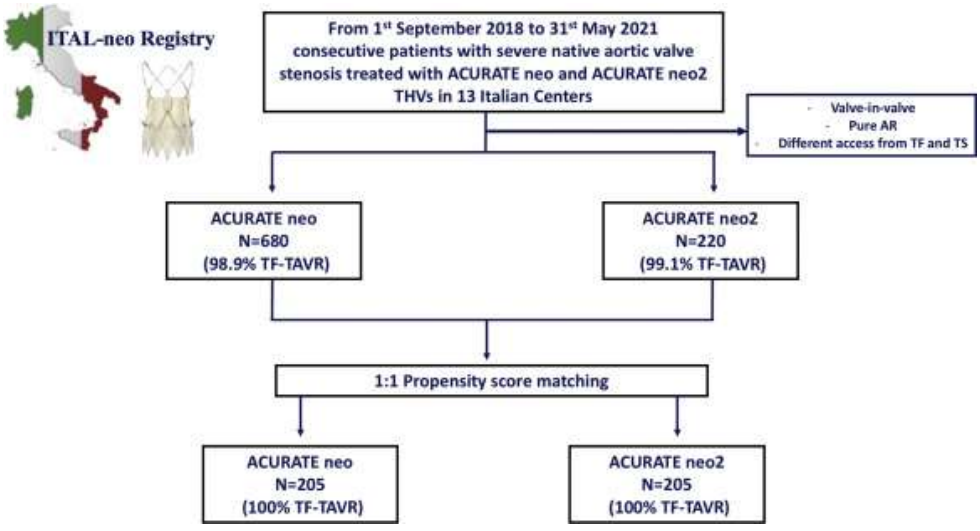
Download : Download full-size image

Figure 1. Similarities and Differences Between the ACURATE neo and ACURATE neo2 Transcatheter Heart Valves

Study design and definition

ITAL-neo was an observational, retrospective, multicenter, investigator-initiated registry with the aim of assessing the safety and efficacy of the ACURATE neo2 THV in patients with symptomatic severe aorticvalve

stenosis, deemed eligible for either transfemoral or trans-subclavian TAVR. Between September 1, 2018 and May 31, 2021, consecutive patients treated with ACURATE neo and ACURATE neo2 THVs were enrolled at 13 high-volume Italian centers. Exclusion criteria were valve-in-valve procedures, pure AR, and alternative approaches besides transfemoral or trans-subclavian. Both tricuspid and nontricuspid anatomies were included. Comparison between the 2 cohorts (ACURATE neo2 and ACURATE neo) was planned after propensity matching (Figure2). The study complied with the Declaration of Helsinki and was approved by local ethics committees. All patients provided written informed consent for the procedure and subsequent data collection on the basis of local practice and/or local Institutional Review Board approval. Local multidisciplinary heart teams evaluated all patients and confirmed the indications for TAVR. All patients underwent preprocedural screening by means of clinical assessment (demographic features, comorbidities, New York Heart Association functional class, history of angina and/or syncope, laboratory examinations, surgical risk), in addition to electrocardiographic, echocardiographic, and multislice computed tomographic (MSCT) data collection. Aortic leaflet, annular, and left ventricular outflow tract calcifications were classified and graded using a semiquantitative scoring system, as previously described.[8] Intraprocedural steps and choice of postprocedural antithrombotic regimen were left to operators' discretion. Intrahospital features (procedural data, clinical outcomes, and predischarge echocardiographic findings) were collected. Short-term clinical and echocardiographic evaluations were performed at 90days after the index procedure by medical contact (outpatient visit or phone call). Echocardiographic and MSCT images were analyzed by local expert operators at each center, following current recommendations.[9,10] Boston Scientific did not play any role as study sponsor or collaborator and did not have access to registry data during all the study phases.



Download : Download high-res image (321KB)

Download : Download full-size image

Figure2. Study Design

AR=aortic regurgitation; TAVR=transcatheter aortic valve replacement; TF=transfemoral; THV=transcatheter heart valve; TS=trans-subclavian.

Endpoints

Valve Academic Research Consortium-3 criteria were applied to define study endpoints.[10] The primary endpoint was the rate of predischarge moderate or greater paravalvular AR on transthoracic echocardiography. Secondary endpoints were postprocedural technical success, 90-day device success, 90-day safety, and the single components of the prespecified composite endpoints. In particular, device success was defined as the composite of technical success, freedom from mortality, freedom from surgery or

intervention related to the device or to a major vascular or access-related or cardiac structural complication, and intended performance of the valve (mean gradient<20 mmHg, peak velocity<3 m/s, Doppler velocity index≥0.25, and less than moderate AR) at 90 days. The safety endpoint was defined as the composite of freedom from all-cause mortality; all stroke; Valve Academic Research Consortium types 2 to 4 bleeding; major vascular, access-related, or cardiac complication; acute kidney injury stage 3 or 4; moderate or severe AR; new permanent pacemaker (PPM) because of procedure-related conduction abnormalities; and need for surgery or intervention related to the device at 90 days.

Statistical analysis

Categorical variables are reported as counts and percentages. Continuous variables are reported as median (IQR). Continuous variables were compared using Student's *t*-test or the Mann-Whitney *U* test for paired samples, and categorical variables were compared using the chi-square, Fisher exact, or McNemar test for paired samples as appropriate.

To account for the nonrandomized design of our study, propensity score matching was used to adjust for baseline confounding variables between comparison groups. The propensity score was estimated using a logistic regression model according to a nonparsimonious approach. Variables included in the propensity score are reported in Supplemental Figure 1. The nearest neighbor method and a ratio of 1:1 were used for propensity score matching. A caliperwidth of 0.1× SD of propensity score logit was used to select 2 paired samples with minimum imbalance in baseline characteristics. Balance between baseline characteristics was estimated using standardized mean difference, and values<0.1 were considered an acceptable balance between covariates (Supplemental Figure 1).

All statistical tests were 2-tailed, and a *P* value<0.05 was considered as the threshold for statistical significance. Statistical analyses were performed using R version 3.4 (R Foundation for Statistical Computing) equipped with the MatchIt package.

Considering a 10% frequency of moderate or greater paravalvular AR related to ACURATE neo THV implantation[5] and a 3-fold expected reduction with the new-generation THV (3% occurrence), to guarantee statistical power of 80% with an α error of 0.05, we estimated a sufficient sample size of 194 patients for each group.

Results

Population

During the enrollment period, 900 patients were included in the registry. Of those, 220 were treated with the ACURATE neo2 THV, whereas 680 received the first-generation ACURATE neo device. Baseline characteristics are reported in Table 1. Preprocedural electrocardiographic and echocardiographic features are shown in Table 2. Patients' age at procedure was similar, and a predominance of female sex was observed in both groups. No major differences were noticed in terms of the prevalence of cardiovascular risk factors and previous PPM implantation and in terms of procedural risk for surgery. The 2 unmatched cohorts differed for lower estimated glomerular filtration rate (50 mL/min (IQR: 38.1-67.0 mL/min) vs 58.5 mL/min [IQR: 42-73 mL/min]; *P*< 0.001) and higher pre-TAVR mean transvalvular gradient (44 mmHg [IQR: 39-52 mmHg] vs 43 mmHg [IQR: 39-50 mmHg]; *P*< 0.047) in the first-generation ACURATE neo group, whereas a higher prevalence of baseline electrocardiographic conduction disturbances were observed in the ACURATE neo2 group (first-degree atrioventricular block, 8.7% vs 13.6% [*P*=0.026]; right bundle branch block, 5.0% vs 9.1% [*P*=0.033]). On the basis of 1:1 propensity score matching, 205 patients per cohort were identified (Tables 1 and 2). The 2 matched groups presented similar anatomical features at MSCT analysis

(Supplemental Table 1). Despite a more relevant degree of annular and left ventricular outflow tract calcifications in the ACURATE neo2 group, severe leaflet calcifications overlapped (28.5% in the ACURATE neo group vs 30.9% in the ACURATE neo2 group; *P*=0.085).

Table 1. Baseline Clinical Characteristics

	Unmatched			Matched		
	ACURATE neo (n=680)	ACURATE neo2 (n=220)	*P* Value	ACURATE neo (n=205)	ACURATE neo2 (n=205)	*P* Value
Age, y	83 (80-86)	83 (80.7-86.0)	0.624	84.00 (80.00-86.00)	83.00 (81.00-86.00)	0.746
BMI, kg/m^2	25.96 (23.21-29.18)	26.22 (23.00-29.71)	0.489	26.57 (24.00-29.91)	26.14 (23.00-29.38)	0.443
Male	237 (34.9)	68 (30.9)	0.288	68 (33.2)	66 (32.2)	0.916
Arterial hypertension	560 (82.4)	184 (83.6)	0.759	172 (83.9)	170 (82.9)	0.894
Diabetes mellitus	179 (26.3)	50 (22.7)	0.327	50 (24.4)	48 (23.4)	0.908
Active malignancy	33 (4.9)	15 (6.8)	0.299	16 (7.8)	14 (6.8)	0.850
Previous PM implantation	66 (9.7)	21 (9.5)	1.000	19 (9.3)	20 (9.8)	1.000
History of CAD	234 (34.4)	78 (35.5)	0.807	76 (37.1)	73 (35.6)	0.837
Previous MI	76 (11.2)	28 (12.7)	0.545	30 (14.6)	27 (13.2)	0.775
Previous PCI	152 (22.4)	51 (23.2)	0.782	50 (24.4)	49 (23.9)	1.000
Previous CABG	42 (6.2)	7 (3.2)	0.122	7 (3.4)	7 (3.4)	1.000
Previous non-CABG cardiac surgery	40 (5.8)	11 (5.0)	0.802	11 (5.4)	10 (4.9)	1.000
PAD	64 (9.4)	29 (13.2)	0.126	20 (9.8)	25 (12.2)	0.528
Carotid artery disease	81 (11.9)	27 (12.3)	0.905	20 (9.8)	24 (11.7)	0.633
History of AF	161 (23.7)	75 (34.1)	0.003	64 (31.2)	63 (30.7)	1.000
History of TIA or cerebral stroke	53 (7.8)	19 (8.6)	0.670	17 (8.3)	16 (7.8)	1.000
COPD	86 (12.6)	32 (14.5)	0.491	26 (12.7)	28 (13.7)	0.884
Severe arterial pulmonary hypertension[a]	29 (4.3)	16 (7.3)	0.107	14 (6.8)	12 (5.9)	0.840
eGFR, mL/min/1.73m^2	50.00 (38.06-67.00)	58.50 (42.00-73.00)	<0.001	56.00 (43.00-73.20)	57.00 (41.00-73.00)	0.963
NYHA functional class≥ III	420 (61.8)	139 (63.2)	0.749	128 (62.4)	130 (63.4)	0.919
Presence of angina	65 (9.6)	28 (12.7)	0.240	22 (10.7)	26 (12.7)	0.645
EuroSCORE II	3.46 (2.30-5.53)	2.98 (2.00-5.67)	0.071	3.07 (2.29-4.65)	3.01 (2.00-5.81)	0.894
STS-PROM	3.60 (2.50-5.00)	3.38 (2.23-5.10)	0.541	3.33 (2.40-4.80)	3.40 (2.23-5.10)	0.679

Values are median (IQR) or n (%).

AF=atrial fibrillation; BMI=body mass index; CABG=coronary artery bypass graft; CAD=coronary artery disease; COPD=chronic obstructive pulmonary disease; eGFR=estimated glomerular filtration rate; EuroSCORE=European System for Cardiac Operative Risk Evaluation; MI=myocardial infarction; NYHA=New York Heart Association; PAD=peripheral artery disease; PM=pacemaker; PCI=percutaneous coronary intervention; STS-PROM=Society of Thoracic Surgeons Predicted Risk of Mortality; TIA=transient ischemic attack.

[a] Defined as systolic pulmonary artery pressure≥60 mmHg on echocardiography.

Table2. Baseline Electrocardiographic and Echocardiographic 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	57 (8.4)	30 (13.6)	0.026	27 (13.2)	27 (13.2)	1.000
RBBB	34 (5.0)	20 (9.1)	0.033	17 (8.3)	19 (9.3)	0.862
Tricuspid anatomy	663 (97.5)	214 (97.3)	0.890	199 (97.1)	199 (97.1)	1.000
Mean transvalvular gradient, mmHg	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
Maximum transvalvular gradient, mmHg	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	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
Moderate or greater AR	120 (17.6)	40 (18.2)	0.840	37 (18.0)	38 (18.5)	1.000
LVEF, %	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
Moderate or greater MR	190 (27.9)	70 (31.8)	0.268	64 (31.2)	62 (30.2)	0.915

Values are n (%) or median (IQR).

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

Procedural and in-hospital outcomes

Procedural characteristics are shown in Table3. After matching, all TAVR procedures were performed via transfemoral access, with a similar prevalence of concomitant percutaneous coronary intervention (8.8% vs 8.3%; *P*=1.000). Cerebral embolic protection was used in a minority of patients in both groups (3.4% vs 2.9%; *P*=1.000). The most frequent THV size implanted was medium (25 mm). Predilatation was more frequent in the ACURATE neo2 subgroup (69% vs 92.2%; *P*< 0.001), whereas postdilatation was more common in patients treated with the first-generation ACURATE neo (48.3% vs 31.7%; *P*=0.001). Moreover, a lower contrast medium volume was delivered in the ACURATE neo2 cohort (150.00 mL [IQR: 100.00-200.00 mL] vs 127.50 mL [IQR: 80.00-188.75 mL]; *P*=0.057). Single-antiplatelet therapy was the most prescribed postprocedural antithrombotic regimen. Postprocedural technical success was similar between the 2

analyzed cohorts (95.1% for ACURATE neo vs 97.6% for ACURATE neo2; *P*=0.293), without any difference in terms of in-hospital major adverse events (Table4). Of note, few cardiovascular deaths were observed (0.5% vs 1.5%; *P*=0.623). Despite a non-negligible development of new conduction disturbances (25.9% vs 28.8%; *P*=0.580), the need for new PPM implantation was low (9.1% vs 7.6%; *P*=0.709) given the consistent percentage of postprocedural spontaneous regression.

Table3. Procedural Characteristics and Antithrombotic Regimens

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

Values are n (%) or median (IQR).

DAT=dual-antithrombotic therapy; DAPT=dual-antiplatelet therapy; LMCA=left main coronary artery; OAC=oral anticoagulation; PCI=percutaneous coronary intervention; RCA=right coronary artery; SAPT=single-antiplatelet therapy; TAT=triple-antithrombotic therapy; THV=transcatheter heart valve.

a

SAPT plus OAC.

b

DAPT plus OAC.

Table4. In-Hospital Outcomes

	ACURATE neo (n=205)	ACURATE neo2 (n=205)	*P* Value
All-cause mortality	1 (0.5)	3 (1.5)	0.623
CV death	1 (0.5)	3 (1.5)	0.623
Intraprocedural death	1 (0.5)	0 (0.0)	1.000
Periprocedural MI	1 (0.5)	0 (0.0)	1.000
Development of new AAVB and/or BBB	53 (25.9)	59 (28.8)	0.580
Spontaneous regression	21 (39.6)	27 (39.1)	1.000
Need for PPM implantation[a]	17 (9.1)	14 (7.6)	0.709
Cerebral ischemic event			1.000
TIA/nondisabling stroke	1 (0.5)	2 (1.0)	
Disabling stroke	1 (0.5)	0 (0.0)	
VARC-3 bleeding			0.947
Type 1	23 (11.2)	20 (9.8)	
Type 2	6 (2.9)	5 (2.4)	
Type 3	3 (1.5)	3 (1.5)	
Type 4	0 (0.0)	0 (0.0)	
VARC-3 vascular complication			0.862
Minor	9 (4.4)	12 (5.9)	
Major	8 (3.9)	7 (3.4)	
Coronary occlusion	1 (0.5)	1 (0.5)	0.842
Cardiac tamponade	3 (1.5)	2 (1.0)	0.842
VARC-3 AKI			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, d	1.50 (1.00-3.00)	1.00 (0.00-3.00)	0.003
Hospital length, d	7.00 (5.00-9.00)	6.00 (4.00-9.00)	0.136

Values are n (%) or median (IQR).

AAVB=advanced atrioventricular block; AKI=acute kidney injury; BBB=bundle branch block; CV=cardiovascular; PPM=permanent pacemaker; VARC-3=Valve Academic Research Consortium-3; other abbreviations as in Table 1.

[a] Patients who had permanent pacemakers at the time of the procedure were excluded from the denominator.

Acute THV performance

At predischarge echocardiographic assessment (Table 5), a significant lower frequency of moderate or greater paravalvular AR was associated with use of the ACURATE neo2 THV in comparison with the first-generation device (11.2% vs 3.5%; $P< 0.001$). No severe paravalvular AR occurred in patients treated with the new-generation device. No other echocardiographic differences were reported, neither concerning mean transvalvular gradient nor in terms of bioprosthetic area. Among prespecified secondary endpoints (Supplemental Table 2), despite numerically higher rates for the new-generation device, no significant differences between the 2 groups were observed concerning 90-day rates of device success (83.9% vs 89.8%; $P=0.108$) and safety (73.7% vs 80.0%; $P=0.160$). In particular, no patients required reintervention for valve-related dysfunction, and there were no cases of valve thrombosis or endocarditis.

Table 5. Predischarge Echocardiographic Findings

	ACURATE neo (n=204)	ACURATE neo2 (n=202)	*P* Value
LVEF, %	58 (55.00-61.00)	60 (55.00-62.75)	0.331
Mean transvalvular gradient, mmHg	6.00 (5.00-9.00)	7.00 (6.00-10.00)	0.085
Maximum transvalvular gradient, mmHg	12.50 (10.00-17.00)	14.50 (12.00-18.00)	0.065
AVA, cm^2	1.76 (1.56-2.02)	1.88 (1.60-2.19)	0.354
Prosthesis-patient mismatch, cm^2/m^2	1.00 (0.90-1.12)	1.07 (0.90-1.31)	0.150
Paravalvular AR			<0.001
None/trace	61 (30.0)	101 (50.0)	
Mild	120 (58.8)	94 (46.5)	
Moderate	22 (10.7)	7 (3.5)	
Severe	1 (0.5)	0 (0.0)	

Values are median (IQR) or n (%).

Abbreviations as in Table 2.

90-day outcomes

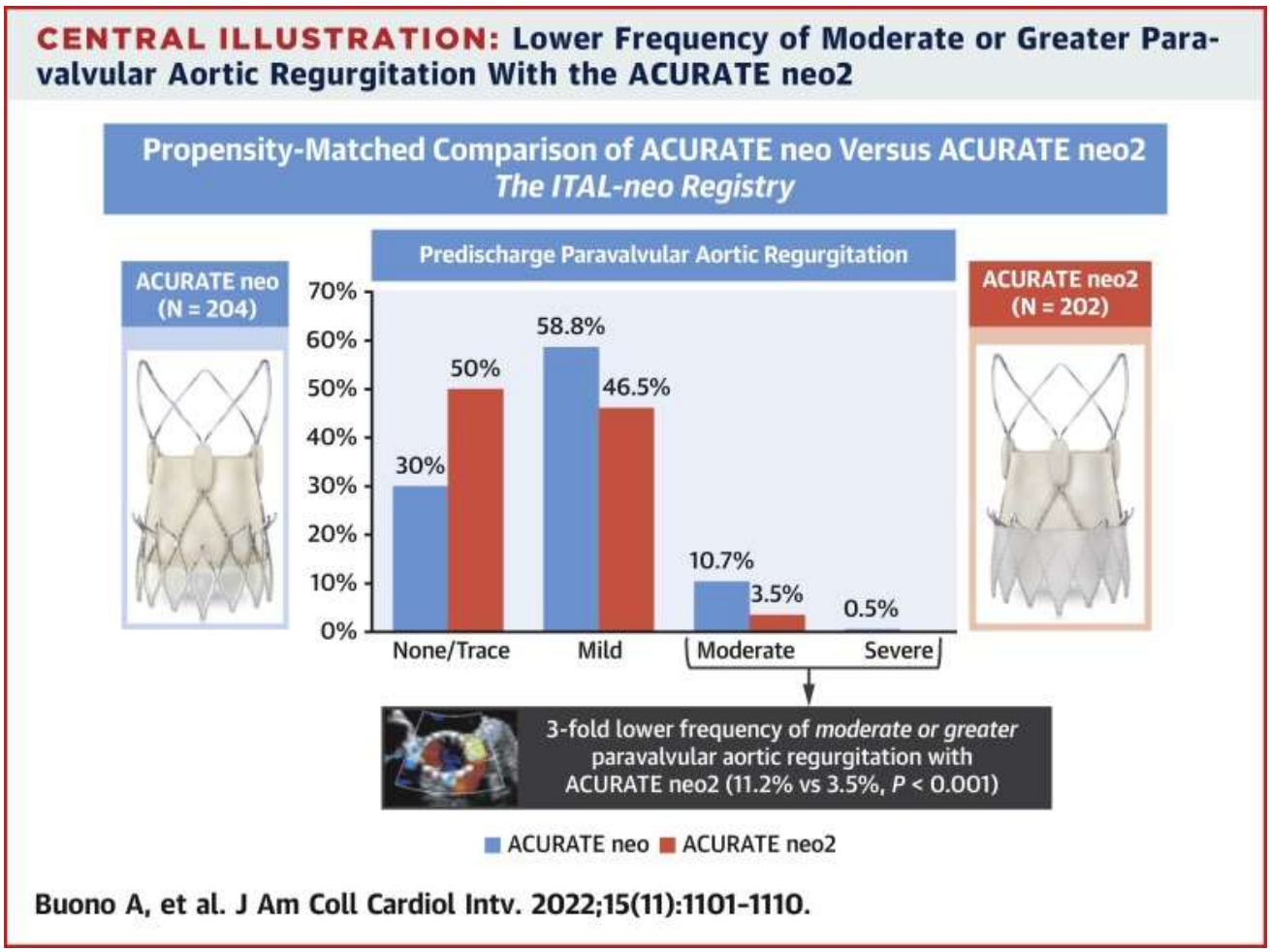
Complete 90-day clinical follow-up was available in 175 first-generation ACURATE neo and in 200 ACURATE neo2 patients. All of them had known endpoint status. A relevant benefit in symptomatic status was reported in both cohorts after THV implantation. All the components of the prespecified composite endpoints were similar, with an occurrence of 90-day cardiovascular death of 3.2% in each group. Ninety-day transthoracic echocardiograms were available in 126 ACURATE neo patients and in 113 patients treated with the new-generation device, confirming the hemodynamic findings seen at predischarge assessment, with a lower rate of moderate or greater paravalvular AR in the ACURATE neo2 cohort (12.7% vs 3.5%;

P=0.002). A subanalysis of the ACURATE neo2 groups, stratified according to THV size, did not show significant differences in the study endpoints, although lower transprosthetic gradient and larger THV areas were observed postprocedurally with ACURATE neo2 size 27 mm (Supplemental Table 3).

Discussion

Moderate or greater paravalvular AR is a well-known issue related to the use of THE first-generation ACURATE neo THV, with a previously reported occurrence ranging from 4.5% to 10.9%.[4, 5, 6·11, 12, 13] This limitation was driven mainly by the limited radial force of the device, which, however, represented an indisputable advantage in terms of new PPM implantation risk.[7] To overcome this aspect, the new ACURATE neo2 iteration presents a taller external skirt while holding the main design unchanged. In our registry, we compared the safety and efficacy of ACURATE neo2 THV with the first-generation device in a real-world population. The main finding of our study was a 3-fold lower occurrence of postprocedural moderate or greater paravalvular AR associated with the ACURATE neo2 THV (Central Illustration). The entity of paravalvular AR reduction did not substantially change at 90 days. These findings demonstrate better performance with the taller THV skirt and are in line with previous and recent series. In fact, we reported 11.2% and 12.7% rates of moderate or greater paravalvular AR in the first-generation ACURATE neo group, respectively, on predischarge and 90-day echocardiographic evaluations; these data are in line with the previous values observed in the SCOPE II (Safety and Efficacy Comparison of Two TAVI Systems in a Prospective Randomized Evaluation II) trial[6] and the NEOPRO (A Multicenter Comparison of Acurate NEO Versus Evolut PRO Transcatheter Heart Valves) registry.[13] Nevertheless, the observed lower frequency of paravalvular AR in our population is consistent (despite lower in magnitude) with what Rück et al[14] recently described in a 30-day preliminary retrospective analysis of the Early neo2 Registry of the Acurate neo2 TAVI Prosthesis (NCT04810195↗): using a quantitative video densitometric angiographic assessment of AR, the investigators reported 1.7% and 13.9% rates of moderate or greater paravalvular AR with the ACURATE neo2 and ACURATE neo THVs, respectively. Our finding is particularly encouraging, as nearly one-third of the enrolled patients were affected by severe leaflet calcifications, making the ACURATE neo2 a promising device also in this challenging anatomical subset. Moreover, as severe annular calcification was demonstrated to be an independent predictor of significant paravalvular leak,[15] the observed lower frequency of AR corroborates the efficacy of the taller antileak skirt on the basis of more prevalent annular calcification reported in the ACURATE neo2 group (1.8% vs 8.4%; P=0.022). Some considerations concerning procedural aspects should be made in our population. The higher percentage of valve predilatation in the ACURATE neo2 group may be read in the light of the recommendations produced after the experience with first-generation device.[7] However, this difference is similar to other available evidence.[14] On one hand, the effect of predilatation is uncertain, and its application did not have a significant impact on relevant predischarge paravalvular AR and short-term adverse events in the NEOPRO population.[16] In contrast, the higher prevalence of THV postdilatation after ACURATE neo implantation can be interpreted as a consequence of less frequent valve predilatation and/or more common transient unsatisfactory results. This aspect could also explain the larger amount of contrast dye needed in the procedures performed with the first-generation device, as more control injections could have been performed. These data may lead to the suggestion of a further increase of valve predilatation before ACURATE neo2 implantation, to optimize the result and reduce the need for postdilatation. We consider the absence of other postimplantation hemodynamic differences (mean transvalvular gradient and bioprosthetic effective orifice area) as a predictable finding because of the similar technological characteristics of the 2 devices. This similarity can also explain the overlapping rate of postprocedural technical success (a definition in which the occurrence of moderate or greater paravalvular AR is not considered). The moderate radial force of the ACURATE neo2 is also responsible for less traumatic injury of the electric conduction system. In fact, besides a non-negligible rate of new disturbances (often procedure-related and non-THV-related), we report a limited rate of new

PPM implantation. Ninety-day device success and safety are higher in patients treated with the new-generation device, although this finding is not statistically significant. However, it is important to state that our study was not designed to fully address short-term clinical endpoints, which would have required a larger cohort. Nevertheless, short-term safety data on the ACURATE neo2 are encouraging, as the rate of 90-day overall mortality (4.4%) is comparable with the results of a single-cohort analysis in which 30-day all-cause mortality was 3.3%.[17] Moreover, no relevant increase in cardiovascular adverse events was observed compared with intrahospital outcomes.



Download : Download high-res image (726KB)

Download : Download full-size image

Central Illustration. Lower Frequency of Moderate or Greater Paravalvular Aortic Regurgitation With the ACURATE neo2

Study limitations

First, selection and confounding bias cannot be excluded, because of the observational nature of the study. In this setting, data concerning the steps necessary to obtain proper THV commissural alignment were not collected.[18,19] Second, our study lacked a core laboratory for imaging analysis. Last, the short follow-up period may potentially hide conclusive results that would besignificant on a long-term basis. Indeed, evidencefrom larger cohorts (eg, Early neo2 Registry of the Acurate neo2 TAVI Prosthesis [NCT04810195↗]) and RCTs (eg, ACURATE IDE [NCT03735667↗]) are awaited.

Conclusions

The new-generation ACURATE neo2 THV, compared WITH the first-generation device, was associated with a significantly lower frequency of moderate or greater paravalvular AR in patients undergoing transfemoral TAVR for severe aortic valve stenosis. Although short-term clinical safety and efficacy outcomes are encouraging, further evidence from longer and RCTs is needed.

Perspectives

WHAT IS KNOWN? The first-generation ACURATE neo THV was associated with a non-negligible occurrence of significant paravalvular AR.

WHAT IS NEW? The new iteration ACURATE neo2 is associated with a lower frequency of moderate or greater paravalvular AR and similar technical success compared with the earlier generation device.

WHAT IS NEXT? RCTs with longer follow-up are required to confirm the clinical impact of these findings.

Funding Support and Author Disclosures

The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Appendix

Download : Download Word document (251KB)

Supplemental Figures 1 and Supplemental Tables 1–3.

Recommended articles

References

1 A. Vahanian, F. Beyersdorf, F. Praz, *et al.*
2021 ESC/EACTS guidelines for the management of valvular heart disease
Eur Heart J, 43 (7) (2022), pp. 561-632
View PDF CrossRef View in Scopus Google Scholar

2 C.M. Otto, R.A. Nishimura, R.O. Bonow, *et al.*
2020 ACC/AHA guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
J Am Coll Cardiol, 77 (4) (2021), pp. 450-500
View PDF View article View in Scopus Google Scholar

3 D.H. Adams, J.J. Popma, M.J. Reardon, *et al.*
Transcatheter aortic-valve replacement with a self-expanding prosthesis
N Engl J Med, 370 (19) (2014), pp. 1790-1798
CrossRef View in Scopus Google Scholar

4 J. Lanz, W.K. Kim, T. Walther, *et al.*

Safety and efficacy of a self-expanding versus a balloon-expandable bioprosthesis for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: a randomised non-inferiority trial

Lancet, 394 (10209) (2019), pp. 1619-1628

View PDF View article View in Scopus Google Scholar

5 W.K. Kim, T. Walther, C. Burgdorf, *et al.*

One-year outcomes of a randomized trial comparing a self-expanding with a balloon-expandable transcatheter aortic valve

Circulation, 143 (12) (2021), pp. 1267-1269

CrossRef View in Scopus Google Scholar

6 C. Tamburino, S. Bleiziffer, H. Thiele, *et al.*

Comparison of self-expanding bioprostheses for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: SCOPE 2 randomized clinical trial

Circulation, 142 (25) (2020), pp. 2431-2442

CrossRef View in Scopus Google Scholar

7 W.K. Kim, C. Hengstenberg, M. Hilker, *et al.*

Transcatheter aortic valve implantation with the ACURATE neo valve: indications, procedural aspects and clinical outcomes

EuroIntervention, 15 (18) (2020), pp. e1571-e1579

CrossRef Google Scholar

8 M. Barbanti, T.H. Yang, J. Rodès Cabau, *et al.*

Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement

Circulation, 128 (3) (2013), pp. 244-253

View in Scopus Google Scholar

9 W.A. Zoghbi, F.M. Asch, C. Bruce, *et al.*

Guidelines for the evaluation of valvular regurgitation after percutaneous valve repair or replacement: a report from the American Society of Echocardiography developed in collaboration with the Society for Cardiovascular Angiography and Interventions, Japanese Society of Echocardiography, and Society for Cardiovascular Magnetic Resonance

J Am Soc Echocardiogr, 32 (4) (2019), pp. 431-475

View PDF View article View in Scopus Google Scholar

10 P. Généreux, N. Piazza, M.C. Alu, *et al.*

Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research

Eur Heart J, 42 (19) (2021), pp. 1825-1857

View in Scopus Google Scholar

11 O. Husser, W.K. Kim, C. Pellegrini, *et al.*

Multicenter comparison of novel self-expanding versus balloon-expandable transcatheter heart valves

J Am Coll Cardiol Intv, 10 (20) (2017), pp. 2078-2087

View PDF View article View in Scopus Google Scholar

12 V. Mauri, W.K. Kim, M. Abumayyaleh, *et al.*
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
Circ Cardiovasc Interv, 10 (10) (2017), Article e005013
CrossRef View in Scopus Google Scholar

13 M. Pagnesi, W.K. Kim, L. Conradi, *et al.*
Transcatheter aortic valve replacement with next-generation self-expanding devices: a multicenter, retrospective, propensity-matched comparison of Evolut PRO versus ACURATE neo transcatheter heart valves
J Am Coll Cardiol Intv, 12 (5) (2019), pp. 433-443
View PDF View article View in Scopus Google Scholar

14 A. Rück, W.K. Kim, H. Kawashima, *et al.*
Paravalvular aortic regurgitation severity assessed by quantitative aortography: ACURATE neo2 versus ACURATE neo transcatheter aortic valve implantation
J Clin Med, 10 (20) (2021), p. 4627
CrossRef View in Scopus Google Scholar

15 W.K. Kim, T. Walther, C. Burgdorf, *et al.*
Predictors of prosthetic valve regurgitation after transcatheter aortic valve implantation with ACURATE neo in the SCOPE I trial
J Am Coll Cardiol Img, 15 (2) (2022), pp. 367-369
View PDF View article View in Scopus Google Scholar

16 M. Pagnesi, W.K. Kim, L. Conradi, *et al.*
Impact of predilatation prior to transcatheter aortic valve implantation with the self-expanding ACURATE neo device (from the multicenter NEOPRO registry)
Am J Cardiol, 125 (9) (2020), pp. 1369-1377
View PDF View article View in Scopus Google Scholar

17 H. Möllmann, D.M. Holzhey, M. Hilker, *et al.*
The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes
Clin Res Cardiol, 110 (12) (2021), pp. 1912-1920
CrossRef View in Scopus Google Scholar

18 M. Kitamura, J. Wilde, R. Gohmann, *et al.*
Commissural alignment of the ACURATE neo valve in transcatheter aortic valve replacement
J Am Coll Cardiol Intv, 14 (15) (2021), pp. 1740-1742
View PDF View article View in Scopus Google Scholar

19 A. Buono, A. Morello, G. Pero, *et al.*
Commissuralalignment with new-generation self-expanding transcatheter heart valves during aortic replacement

Cardiovasc Revasc Med (2021 Jul 30 published online ahead of print)

Google Scholar ↗

Cited by (12)

Transcatheter aortic valve replacement with the self-expanding ACURATE Neo2 in patients with horizontal aorta: Insights from the ITAL-neo registry

2023, International Journal of Cardiology

Show abstract

Incidence, Predictors, and Prognostic Impact of New Permanent Pacemaker Implantation After TAVR With Self-Expanding Valves

2023, JACC: Cardiovascular Interventions

Show abstract

Transcatheter aortic valve implantation with different self-expanding devices—a propensity score-matched multicenter comparison

2023, Hellenic Journal of Cardiology

> *Citation Excerpt :*
> ...The ACURATE neo device has been superseded by its successor, the ACURATE neo2, and is no longer used in clinical practice. Compared to the ACURATE neo, lower rates of moderate or severe PVR (2 – 5.5%) and PPI rates ranging from 7.6 to 15.0% have been recently described36-39. The reduction of PVR is remarkable since the difference between ACURATE neo and ACURATE neo2 is the extension of the inner and outer pericardial skirts, whereas most of the first-generation device characteristics (supra-annular design and radial forces) did not change40....

Show abstract

Neo to Neo 2 in horizontal aorta: From “impact” to “no impact” outcomes

2023, International Journal of Cardiology

First results from the ACURATE Prime XL human feasibility study

2023, Cardiovascular Revascularization Medicine

Show abstract

Neo to Neo2: A Tiny Detail With Considerable Impact

2022, JACC: Cardiovascular Interventions

View all citing articles on Scopus ↗

Lars Søndergaard MD, DMSc, served as Guest Editor for this paper.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information,

visit the Author Center.