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ORIGINAL STUDIES

EDITORIAL COMMENT: Expert Article Analysis for:
A novel self-expanding transcatheter heart valve: Shaping the story beyond accuracy

One-year clinical outcome with a novel self-expanding transcatheter heart valve

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Abstract

Objectives: To evaluate 1-year outcome using the ACURATE neo (Symetis S.A., a Boston Scientific Company, Ecublens, Switzerland) according to the updated Valve Academic Research Consortium (VARC-2) with emphasis on the composite endpoints "clinical efficacy after 30 days" and "time-related valve safety".

Background: Initial reports on the clinical performance of patients treated with the ACURATE neo are promising; however, information regarding one-year outcome is scarce, especially with regard to the composite endpoints proposed by the VARC-2.

Methods: One hundred and fifty one consecutive patients undergoing transfemoral transcatheter aortic valve replacement (TAVR) with the ACURATE neo for severe aortic valve stenosis were enrolled. Data were prospectively collected and event rates during follow-up were calculated as the Kaplan–Meier estimates.

Results: Mean age was 81.1 ± 5.9 years and 49.7% (75/151) were female with a median logistic EuroScore of 13.8% [8.2–20.5]. Device success was achieved in 88.1% (133/151) and procedure related mortality was 0.7% (1/151). At one-year, all-cause mortality was 3.3% (5/151), while permanent pacemaker implantation occurred in 12.7% (19/151) of patients. The "clinical efficacy after 30 days" was observed in 24.8% (37/151), where the main contributor was symptom worsening in 14.8% (22/151) of cases. "Time-related valve safety" occurred in 22.0% (33/151) with structural valve deterioration as main contributor in 10.7% (16/151) of cases.

Conclusions: Using the ACURATE neo, we found a favorable safety profile with low all-cause mortality at 1 year. The reported VARC-2 defined composite endpoints at 1 year reveal low rates of "clinical efficacy after 30 days" and "time-related valve safety".

KEYWORDS

ACURATE neo, aortic valve stenosis, outcome, transfemoral transcatheter aortic valve replacement, VARC-2

1 | INTRODUCTION

Since the first procedures performed in 2002, transcatheter aortic valve replacement (TAVR) has rapidly evolved from a treatment for inoperable patients to a standard therapeutic strategy for high-risk patients with ongoing extension toward intermediate and low-risk populations.[1,2] With advances in so called "next" generation transcatheter heart valves (THVs), increasing operator experience and development of low-profile

delivery systems, procedural outcomes have improved considerably. Indeed, one-year mortality rates have been reduced from 24% with early generation devices[3] to 12% with next generation devices.[1]

Various next generation THVs are currently available, among them the self-expanding ACURATE neo (Symetis S.A., a Boston Scientific Company, Ecublens, Switzerland). Large-scale data on this novel THV are scarce. So far, initial data from the SAVI TF[4,5] and the MORENA multicentre registry[4,5] appear promising. Both registries have shown good short-term results and a 30-day mortality rate ranging from 1.4 to 2.3%. Of special note for a self-expanding device, the rate of new permanent pacemaker implantation (PPI) was very low, ranging between 8.3 and 10.2%.[6]

As far as longer-term outcomes are concerned, one-year clinical data from the SAVI TF registry reported a very low all-cause mortality rate of 8.4%.[7] Apart from these, however, one-year outcome data for the ACURATE neo is scarce, especially with regard to composite endpoints at 1 year as proposed by the updated criteria of the Valvular Academic Research Consortium (VARC-2).[8] These well-defined endpoints are important for the comparability of data and enable a standardized assessment of outcome. Therefore, this study provides one-year outcome according to the VARC-2 criteria with the novel self-expanding ACURATE neo from a single center.

2 | METHODS

2.1 | Patient population

Between January 2014 and October 2016, all patients undergoing TAVR using the ACURATE neo for severe symptomatic stenosis of the native aortic valve at our institution were included (n = 151). All cases were discussed in the multidisciplinary heart team and consensus was achieved regarding the therapeutic strategy. All patients provided written informed consent prior to the procedure. TAVR was performed in a hybrid operating suite under general anesthesia or conscious sedation.

2.2 | Multislice computed tomography data analysis and prosthesis size selection

Multislice computed tomography (MSCT) was performed as part of the standard pre-procedural screening protocol. Aortic annulus measurements were assessed in multiple plane reconstructions according to the guidelines of the Society of Cardiovascular Computed Tomography[9] and as previously described.[10] Dedicated FDA-approved software (OsiriX MD 3.9.4, Pixmeo, Switzerland) was employed.

The technical features of the ACURATE neo have been previously described.[11] The ACURATE neo is currently available in three sizes—small, medium and large—covering a range from 21 to 27 mm annulus diameter. The final decision on prosthesis size was left at the discretion of the physicians performing the procedure and was based on both, MSCT measurements and individual anatomical features.

2.3 | Echocardiography and follow-up

All data up to 1 year were prospectively collected with routine ambulatory visits at the outpatients' clinic, telephone call, information from the treating physician, or other hospital documentation. Transthoracic echocardiography was performed before TAVR, at discharge, at 30 days and at 1-year in the outpatients' clinic or by the treating cardiologist. Left ventricular ejection fraction, mean transvalvular gradient and degree of paravalvular regurgitation were assessed. During follow-up, echocardiography data are reported for patients with complete echocardiography and known mortality status at 30 days (n = 142/151).

2.4 | Definition of endpoints

All clinical and procedural endpoints in-hospital and during follow-up were categorized according to the VARC-2 criteria.[12] In brief, device success was defined as absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location and intended performance.

The "early safety at 30 days" is a composite endpoint of all-cause mortality, disabling and non-disabling stroke, life-threatening bleeding, acute kidney injury (RIFLE Stage 2 or 3 or renal replacement therapy), coronary artery obstruction requiring intervention, major vascular complication and valve-related dysfunction requiring repeat procedure.

At 1 year after TAVR, the occurrence of two composite endpoints was recorded: "Time-related valve safety" is composed of structural valve deterioration (mean aortic valve gradient ≥20 mmHg, effective orifice area ≤ 0.9–1.1 cm^2 and/or moderate or severe PVL), prosthetic valve endocarditis or thrombosis, stroke and bleeding. "Clinical efficacy after 30 days" consists of all-cause mortality, disabling or non-disabling stroke, hospitalizations for valve-related symptoms or worsening of congestive heart failure (CHF), symptom worsening with NYHA class III or IV and valve-related dysfunction as described above.

Additionally, two composite endpoints at 1 year after TAVR, "death or readmission for CHF" and "death or stroke" were analyzed as these constitute composite endpoints often reported in recent trials and registries.[3,13]

2.5 | Statistical analysis

Continuous variables are expressed as mean with the standard deviation or the median with the interquartile range. The VARC-2 composite endpoint is assessed as time-to-event rates, not considering possible changes of the contributing parameters during follow-up. To this end, temporal changes in categories of New York Heart Association (NYHA) functional class, transvalvular gradients and PVL were additionally visualized by river plots using the package "riverplot". Event rates during follow-up were calculated as the Kaplan–Meier estimates. A 2-sided p-value of <0.05 was considered statistically significant for all analyses. IBM SPSS Statistics (Version 22, SPSS Inc., Chicago, IL) and R (Version 3.3.2, The R Foundation, Vienna, Austria) were used for analyses.

3 | RESULTS

3.1 | Patient characteristics, procedural and in-hospital outcome

In total, 151 patients were included in the analysis. Mean age was 81.1 ± 15.9 years and 49.7% were female. Median EuroScore I was

13.8% [8.2–20.5]. Table 1 displays the clinical and MSCT characteristics of the study population, showing moderate to severe valve calcification in 74.2% (112/151) of patients.

Procedural and in-hospital outcome is depicted in Table 2. The majority of procedures were performed under general anesthesia (94.0%) and the small, medium and large prosthesis sizes were used in 33.1, 36.4, and 30.5%, respectively. Median procedural time was 66.6 ± 22.0 min and 146.2 ± 51.9 mL of contrast was used. VARC-2 defined device success was achieved in 88.1% with paravalvular leakage II+ being the main contributor in 7.9% of cases.

One patient died in-hospital during emergency surgery for annular rupture, which occurred after implantation of a second prosthesis because of residual severe PVL. Rates of life-threatening bleeding, major vascular complications and all strokes (major or minor) were 5.3, 13.9, and 1.3%, respectively. New PPI rate in pacemaker naive patients was 10.2% (14/137) and 9.3% (14/151) considering the entire study population. Median stay on intensive care unit and in-hospital after the procedure was 1 [1–2] days and 5 [4–6] days, respectively.

3.2 | 30-day and one-year outcome after TAVR

Clinical follow-up at 1 year was complete for 97.4% of the patients. The Kaplan–Meier estimates of event rates at 30 days and 1 year are displayed in Table 3. All-cause mortality at 30 days was 0.7% and increased to 3.3% at 1 year. Cardiac mortality at 1 year was 1.3%. Rates of stroke (major or minor) and life-threatening bleeding increased by 2.1 to 3.4% and by 3.4 to 8.7% from 30 days to 1 year, respectively.

The composite of death and stroke occurred in 6.7% at 1 year (Figure 1A). Percutaneous coronary intervention at 1 year was required in 6.8% of patients; in three cases for acute myocardial infarction, and the rest for elective coronary intervention for stable symptomatic coronary artery disease. Hospitalization rates for worsening of CHF were 2.7% at 30 days and increased to 7.4% at 1 year. The cumulative incidence of death and hospitalization for CHF was 9.3% (Figure 1B). PPI rates in patients without prior pacemaker were 11.7% and 14.0%, at 30 days and 1 year, respectively. The combined early safety endpoint at 30 days occurred in 17.9%.

TABLE 1 Baseline characteristics

	Total patients (n = 151)
Clinical characteristics	
Age (years)	81.1 ± 5.9
Female gender	75 (49.7)
Body mass index (kg/m^2)	26.6 ± 4.8
Logistic EuroScore I	13.8 [8.2–20.5]
EuroScore II	5.1 [2.9–7.1]
New York heart association functional class III/IV	89 (58.9)
Chronic obstructive pulmonary disease	20 (13.2)
Arterial hypertension	142 (94.0)
Hypercholesterolemia	122 (80.8)
Diabetes mellitus	43 (28.5)
Glomerular filtration rate (mL/min)	52.9 ± 18.6
Peripheral vascular disease	22 (14.6)
Previous stroke	21 (13.9)
Previous pacemaker	14 (9.3)
Previous coronary artery disease	119 (78.8)
Atrial fibrillation	56 (37.1)
Echocardiographic characteristics	
Left ventricular ejection fraction <35%	4 (2.6)
Mean transaortic gradient (mmHg)	46.3 ± 13.1
Pulmonary arterial pressure ≥ 60 mmHg	9 (6.0)
Multislice computed tomography annulus measurements	
Effective diameter (mm)	23.6 ± 1.8
Perimeter (mm)	75.8 [70.3–79.6]
Area (cm^2)	4.4 ± 0.6
Moderate to severe valve calcification	112 (74.2)

All data are mean ± standard deviation, median [interquartile range] or absolute number (percentage).

TABLE 2 Procedural characteristics and complications

	Total patients (n = 151)
Procedural characteristics	
Pre-dilatation	151 (100.0)
Post-dilatation	89 (58.9)
Procedural time (min)	66.6 ± 22.0
Contrast (mL)	146.2 ± 51.9
Fluoroscopy time (min)	15.5 ± 6.5
Device success	133 (88.1)
Conversion to surgery	2 (1.3)
In-hospital characteristics	
Days on intensive care unit	1 [1–2]
Days in hospital	5 [4–6]
Ln-hospital mortality	1 (0.7)
All stroke	2 (1.3)
Major vascular complication	21 (13.9)
Life-threatening bleeding	8 (5.3)
Acute kidney injury 2/3, including dialysis	4 (2.6)
Permanent pacemaker implantation[a]	14 (9.3)

[a] PPI rate was 10.2% (14/137) when excluding patients with prior pacemaker.

3.3 | Evolution of NYHA class

Changes in NYHA functional class category before TAVR and during follow-up is visualized in Figure 2 and shows a considerable symptomatic benefit: at baseline 59% of patients were in NYHA class III/IV, while 92.7% at 30 days and 86.7% at 1 year after TAVR reported a NYHA functional class II or less. At 1 year, NYHA class was not available for 5.9% of patients, either due to death (3.3%) or was missing (2.6%). From baseline to 1 year, symptom improvement of at least one functional class was observed in 70.9% of patients.

3.4 | Echocardiographic follow-up

Echocardiographic follow-up for patients discharged alive, 30 days and 1 year was available for 100, 94.0, and 85.6%, respectively. Mean transvalvular gradients at discharge were 8.5 ± 4.0 mmHg and remained low at 30 days (7.8 ± 3.3 mmHg) and 1 year (6.9 ± 3.0 mmHg; $p < 0.001$).

TABLE 3 Cumulative Kaplan–Meier's event rates at 30-days and at 1 year

	30 days		1 year	
	Events (*n*)	KM estimate (%)	Events (*n*)	KM estimate (%)
All-cause mortality	1	0.7	5	3.3
Cardiac mortality	1	0.7	2	1.3
All stroke	2	1.3	5	3.4
Major vascular complication	21	13.9	21	13.9
Life-threatening bleeding	8	5.3	13	8.7
Acute kidney injury 2/3, including dialysis	4	2.7	4	2.7
Percutaneous coronary intervention	0	–	10	6.8
Myocardial infarction	0	–	3	2.1
Permanent pacemaker implantation[a]	16	10.6	19	12.7
Valve-related dysfunction w/ BAV, TAVR or SAVR	0	–	1	0.7
Valve-related dysfunction[b]	11	7.3	16	10.7
Endocarditis	0	–	1	0.7
Congestive heart failure w/ hospitalization	4	2.7	11	7.4
VARC-2 combined endpoints				
Early safety (at 30 days)	27	17.9	–	–
Clinical efficacy after 30 days	–	–	37	24.8
Time-related valve safety	19	12.6	33	22.0

Abbreviations: BAV, balloon aortic valvuloplasty; TAVR, transcatheter aortic valve replacement, SAVR, surgical aortic valve replacement.
[a] PPI rates at 30 days and at 1 year were 11.7% (16/137) and 14.0% (19/137), respectively, when excluding patients with prior pacemaker.
[b] Valve-related dysfunction (mean aortic valve gradient ≥20 mmHg, EOA ≤0.9–1.1 cm2 and/or, moderate or severe prosthetic valve regurgitation).

Figure 3A,B shows the development of PVL and elevated gradients (≥20 mmHg) at discharge and during follow-up of patients with known mortality status and available echocardiography at discharge and at 30 days (*n* = 142). PVL II+ was present in 4.2% at discharge and decreased to 2.8% at 1 year. While two patients had elevated gradients at discharge, transvalvular gradients decreased during follow-up, leaving no patients with elevated gradients at 30 days and 1 year. Both these patients had small aortic annuli and were treated with a "small" prosthesis. As underlying reason to this finding, valve thrombosis was ruled out by transesophageal echocardiography in one patient, while the other was already on oral anticoagulation therapy with a vitamin-K antagonist for atrial fibrillation and therefore thrombus formation an unlikely cause.

3.5 | VARC-2 defined composite endpoints at 1 year

The "clinical efficacy after 30 days" endpoint was observed in 24.8% of the patients after 1 year. The individual contributors to this composite endpoint are depicted in Figure 4A, with worsening of NYHA functional class being the main reason in 14.8% of cases.

The composite endpoint "time-related valve safety" occurred in 22.0%. Figure 4B shows the individual contributors to this endpoint, with structural valve deterioration having a cumulative incidence of 10.7% at 12 months.

4 | DISCUSSION

In this single center observational analysis of a contemporary TAVR population treated with the novel self-expanding ACURATE neo, we found excellent clinical outcome with a notably low 1-year mortality. Furthermore, for the first time for this THV, VARC-2 defined composite endpoints at 1 year are reported, namely "clinical efficacy after 30 days" and "time-related valve safety".

4.1 | One-year outcome after TAVR with the ACURATE neo

The initial experience from the transfemoral ACURATE neo CE-approval cohort showed all-cause mortality and stroke rates at 1 year of 22.5 and 6.7%, respectively.[14] However, it must be considered that this was a high-risk, multimorbid population with a mean logistic EuroScore of 26.5%. When considering a more contemporary, in parts intermediate risk-population, such as the population treated in the SAVI-TF registry, all-cause mortality and stroke rate were much lower with 9 and 3.6%,[7] respectively. This is in line with other large-scale reports for similar risk populations treated with other contemporary THVs, such as the balloon-expandable SAPIEN 3 valve.[13,15] In a recent single-center study, an even lower one-year mortality was achieved with the ACURATE neo, namely of 5.2%.[16] This is comparable with the low mortality and stroke rate found in the present population of 3.3 and 3.4%, respectively, pointing toward excellent clinical results. These results have to be put into perspective, for example it will be interesting to see, whether a further improvement of results can be achieved by changing the anesthesiological strategy. In our analysis, conducted between 2014 and 2016 general anesthesia was applied in the vast majority of cases. Currently, however, we are observing a transition toward conscious sedation as the preferred technique with excellent, even superior results compared to general anesthesia.[17]

Low rates of PPI have been reported with the ACURATE neo, ranging from 2.3 to 9.9% at 30 days[18,19] and increasing to 11.5% at

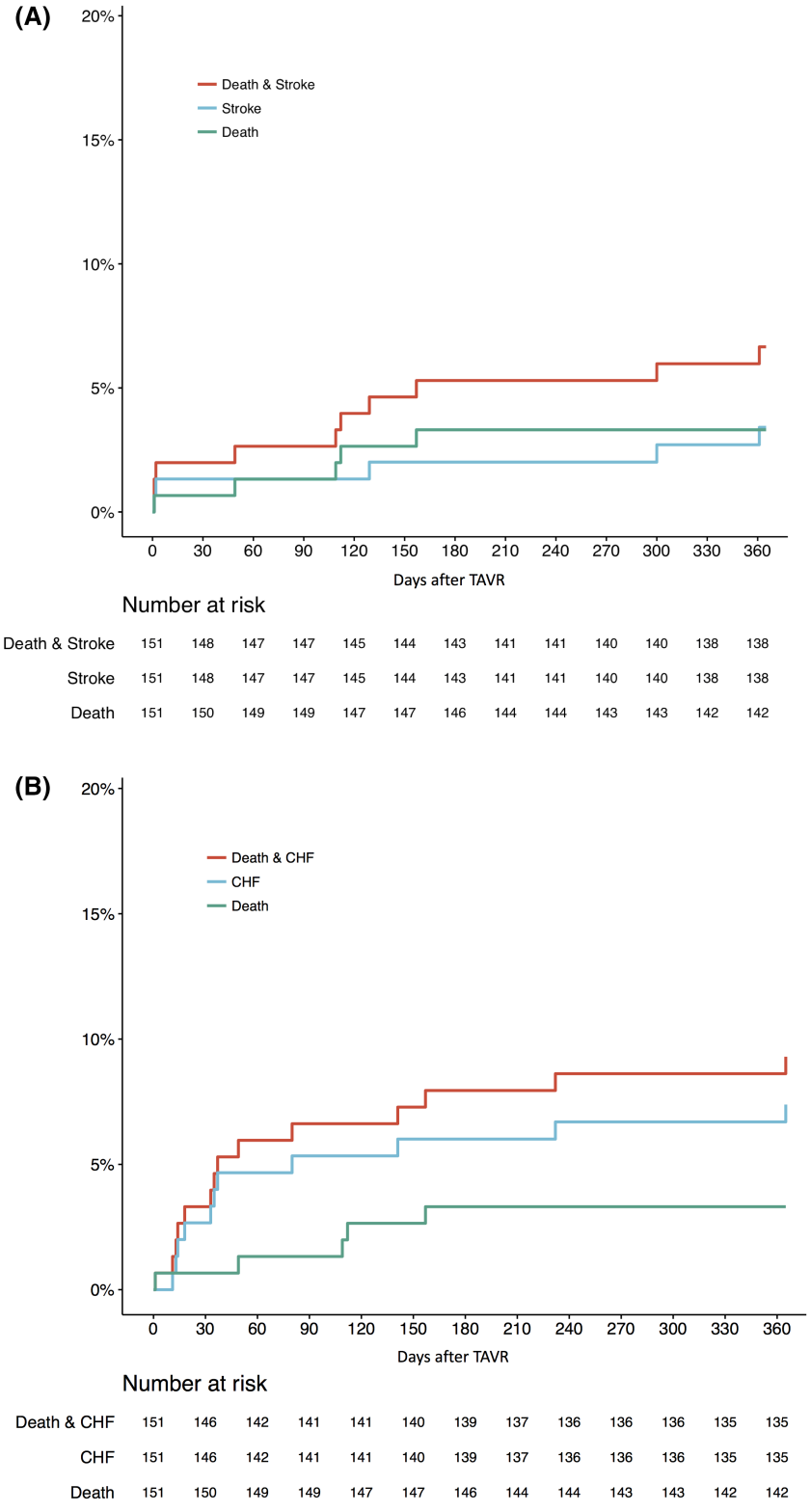


FIGURE 1 Cumulative incidence of death and stroke (A) and death and CHF (B). The Kaplan–Meier failure curves for the cumulative event rate of death and stroke (A) and death and CHF (B) during the first year after TAVR. Abbreviations: CHF, congestive heart failure [Color figure can be viewed at wileyonlinelibrary.com]

1 year.[7] PPI is still a frequent and important complication after TAVR and although earlier investigations have found no negative effect of new PPI on outcome,[20] recent data from the PARTNER trial have identified chronic pacing as an independent predictor of 1-year mortality after TAVR.[21] Therefore, low rates of new PPI are of great interest, especially when extending indications toward a lower risk and younger population. In the present study, in pacemaker naïve patients, pacemaker rates were 11.7 and 14.0%, at 30 days and 1 year, respectively. However, when considering PPI rates in TAVR population, it is very important to acknowledge differences in the prevalence

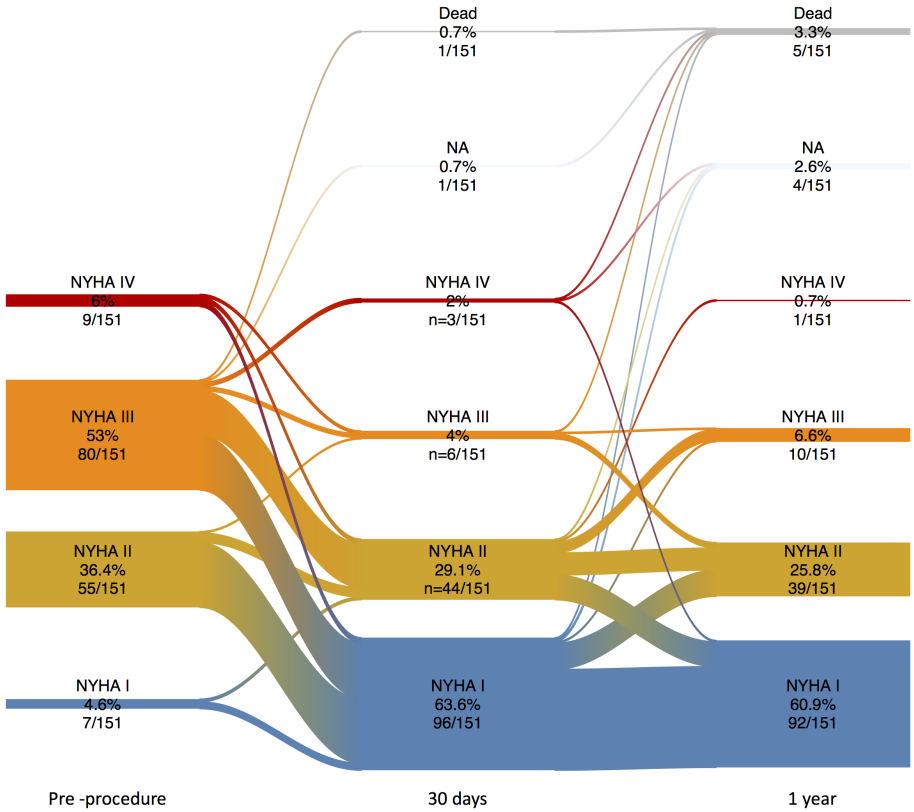


FIGURE 2 New York heart association functional class at baseline and during follow-up. Change in New York heart association functional class during the first year after TAVR [Color figure can be viewed at wileyonlinelibrary.com]

of complete right bundle branch block at admission, which is one of the main known risk factors for PPI.[22] In this population, it was 8.6%.

4.2 | VARC-2 composite endpoints with the ACURATE neo

The standardized definitions proposed by the updated VARC-2 set a uniform framework for evaluation and comparison of clinical outcomes after TAVR. Although the adoption of VARC-criteria has increased over time,[23,24] the application is often limited to assessment of in-hospital outcomes, while the report of important composite endpoints remains scarce,[5,25–27] and potentially impedes direct comparisons.

The endpoint "device success" is an important measure of short-term procedural success and THV function.[12] For the ACURATE neo device, success rates range from 89 to 98.7%.[4,5,14] In the present analysis, we found rates of 88.1%, mainly driven by PVL II+ in 7.9%, which seems slightly higher compared to previously reported rates of 5% for this THV.[4,18] PVL is difficult to quantify as there are different modalities for the evaluation, ranging from angiography, echocardiography, or hemodynamic assessment for example, the aortic regurgitation index.[28,29] Furthermore, timing of assessment plays an important role. Accordingly, in this analysis, we observed a different rate of PVL when considering angiography and echocardiography at discharge, namely 7.9 and 5%. Furthermore, as shown in the present study, the change of PVL II+ during follow-up, underlines the difficulty to assess this parameter. The inter-modality comparison of PVL goes beyond the scope of the present study; however, it may offer a possible explanation for this finding. Furthermore, being a self-expanding THV a continuous expansion of the device in the immediate post-implant period cannot be ruled out and may account for lower PVL rates, when assessed through echocardiography after the procedure. This hypothesis is currently under investigation in the PROGRESS PVL registry (ClinicalTrials.gov Identifier: NCT02987894).

Need for post-dilatation correlates with valve calcification, especially for self-expanding devices.[30] In the present analysis, more than two-thirds of patients had moderate to severely calcified valves and, in these patients, post-dilatation was performed significantly more often compared to patients without moderate to severe calcification (66.1% (74/112) vs. 38.5% (15/39); $p = 0.003$). This may at least partly account for the increased need of post-dilatation, as well as the slightly higher rates of PVL II+ observed in this study. Nevertheless, due to the negative prognostic impact of residual PVL, efforts must be made to further reduce PVL rates. In this regard, a next iteration of the ACURATE neo, the ACURATE neo 2.0, featuring an additional sealing skirt to reduce PVL is currently in CE mark studies.

The "early safety composite endpoint at 30 days" has been proposed by the Valve Academic Research Consortium for the assessment of patient safety in TAVR, summarizing important measures of complications, prosthesis function and mortality. Previously reported rates of the early safety composite endpoint for the ACURATE neo range from 8.6% to 15.8%,[4,5,14] while in this analysis we found rates of 17.9%, the main contributor being major vascular complications in 13.9% of patients. This finding may be attributed to the larger sheath size of 18–20 Fr necessary for the deployment of this valve representing a possible downside of this THV, especially when treating patients with small anatomies, as a higher sheath to iliofemoral artery ratio has

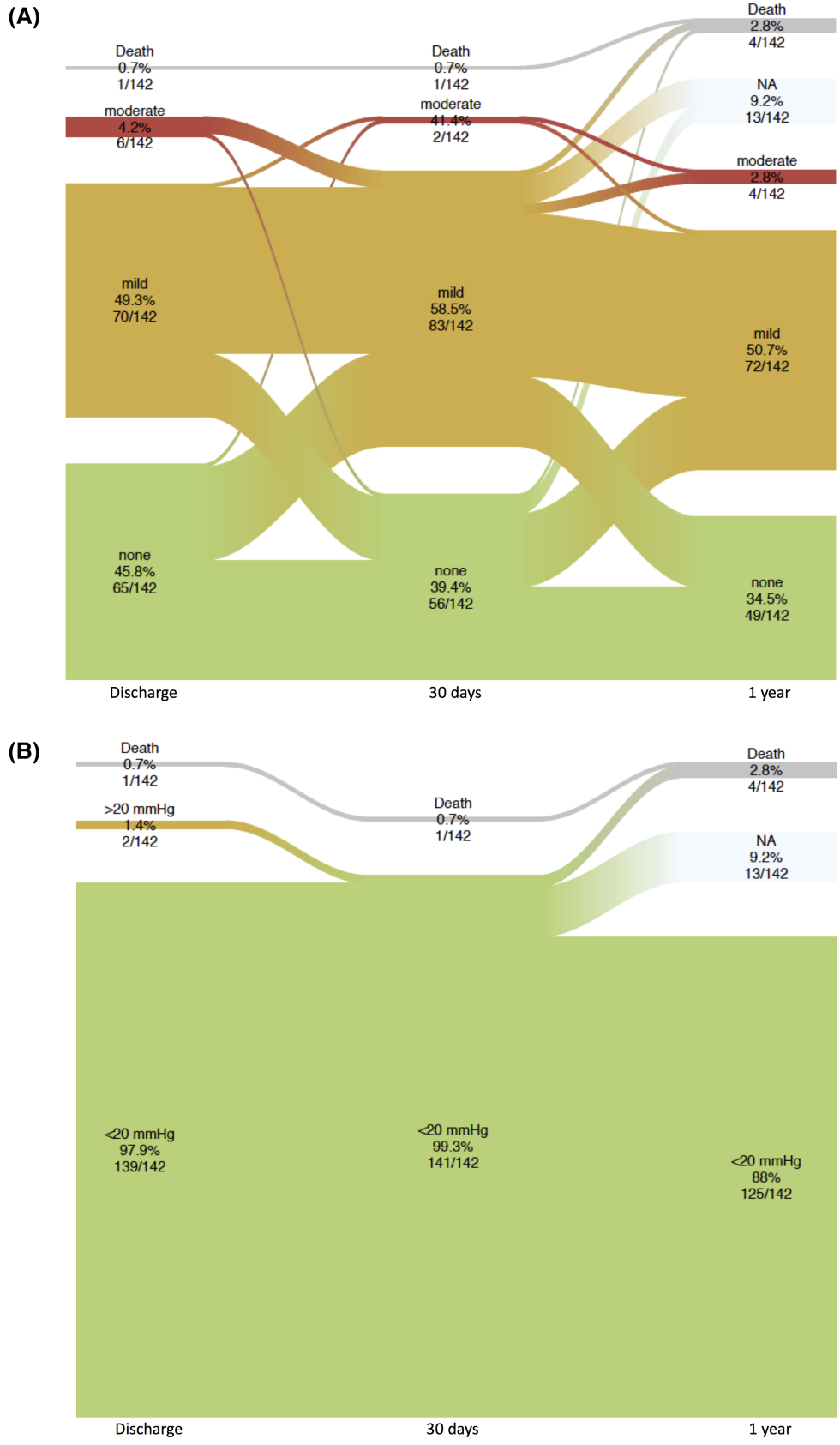
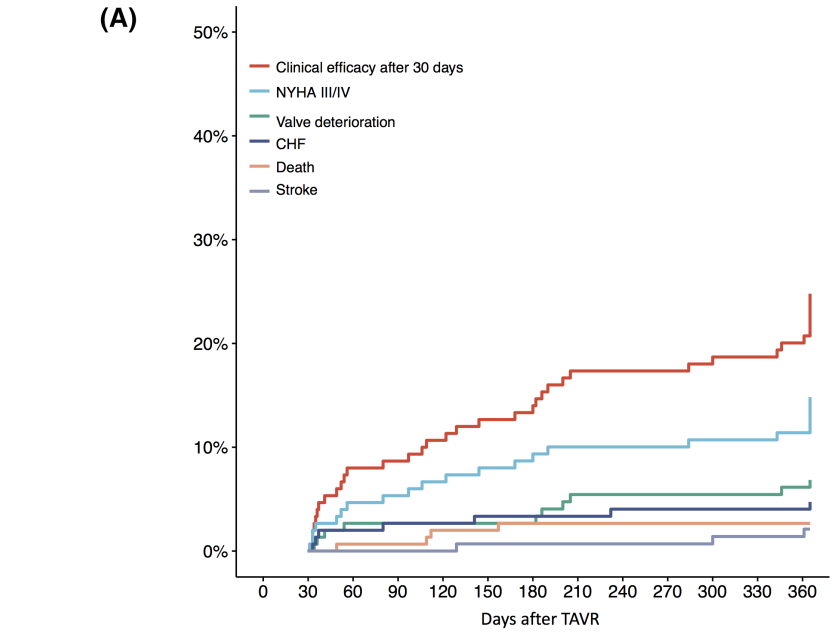
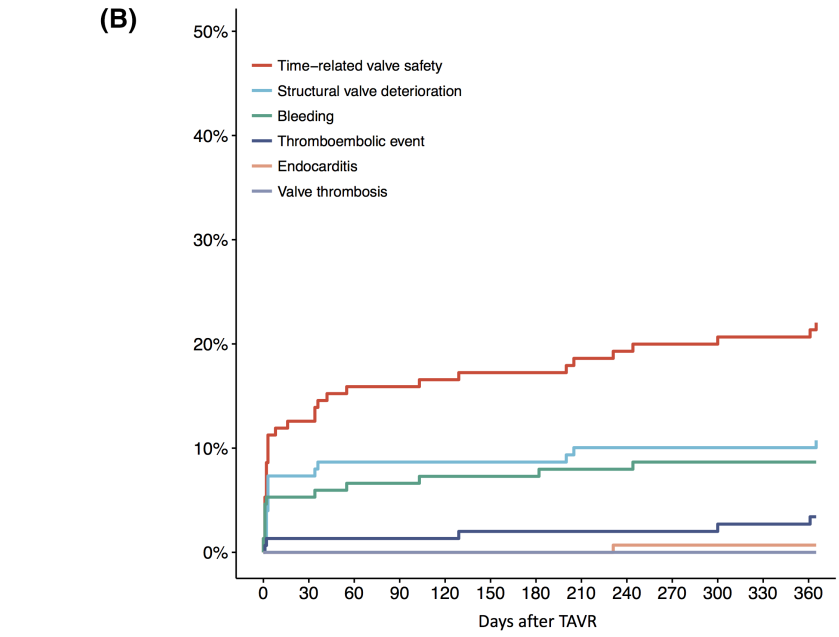


FIGURE 3 Echocardiographic valve performance after discharge: Paravalvular leakage (A) and transvalvular gradients (B). Change in paravalvular leakage (A) and elevated gradients during the first year after TAVR. Note that only patients with complete echocardiography and known mortality status at 30 days (n = 142) are displayed [Color figure can be viewed at wileyonlinelibrary.com]



Number at risk

Clinical efficacy after 30 days	151	151	138	137	134	131	130	123	123	123	122	120	118
NYHA III/IV	151	151	143	142	139	137	136	132	132	132	131	130	129
Valve deterioration	151	151	145	145	143	143	141	136	136	135	135	134	133
CHF	151	151	146	145	144	143	142	140	139	139	139	138	138
Death	151	151	149	149	147	147	146	144	144	143	143	142	142
Stroke	151	151	147	147	145	144	143	141	141	140	140	138	138



Number at risk

Time–related valve safety	151	132	126	126	123	122	121	119	118	117	117	115	115
Structural valve deterioration	151	139	136	136	134	134	132	130	130	129	129	128	128
Bleeding	151	143	140	140	137	137	136	134	134	133	133	132	132
Thromboembolic event	151	148	147	147	145	144	143	141	141	140	140	138	138
Endocarditis	151	150	149	149	147	147	146	144	143	142	142	141	141
Valve thrombosis	151	150	149	149	147	147	146	144	144	143	143	142	142

FIGURE 4 VARC-2 composite endpoints: "Clinical efficacy after 30 days" (A) and "Time-related valve safety" (B). The Kaplan–Meier failure curves for the cumulative event rates of "clinical efficacy after 30 days" (A) and "time-related valve safety" (B) with rates of their respective contributors [Color figure can be viewed at wileyonlinelibrary.com]

been described as predictor of vascular complications.[31] To address this issue, a novel, expandable 14 Fr sheath iSleeve (Boston Scientific, Marlborough, MA), specifically designed for the ACURATE neo is now available and may possibly further decrease rates of vascular complications.

Data on "clinical efficacy after 30 days" and "time-related valve safety" are scarce in general. Specifically, for the ACURATE neo, to the best of our knowledge, there are no reports in the present literature. We found a relatively high incidence of these composite

endpoints mostly driven by symptomatic heart failure and valve-related dysfunction. However, it must be noted, that these composite endpoints are assessed as time-to-event rates and patients are censored at time of event. Therefore, possible changes in categorical parameters during follow-up are not considered, leading to elevated rates in this analysis. In order to better visualize temporal changes of categorical data river, plots were employed. The NYHA class, a measure of symptom severity and functional limitation, may be influenced by factors beyond the procedure itself in this elderly, multi-morbid TAVR population. However, the present analysis shows that more than two-thirds of patients at 1 year after TAVR experienced symptomatic benefit with improvement of at least one functional class. This is in line with previously reported data of symptomatic relief after TAVR.[1,32] Especially in the currently treated elderly population, improving symptoms is an important goal. Valve-related-dysfunction is of great importance, especially in the light of extending the use of TAVR to a lower-risk and younger population. Therefore, understanding and analyzing parameters influencing valve durability should be of utmost importance. In this analysis, moderate or severe PVL was the main driver for valve-dysfunction in 56% of cases, while less cases were attributed to small effective orifice area (31%) and elevated transvalvular gradients (13%). The low rate of elevated transvalvular gradients is an important finding that could possibly be explained by the supra-annular position of the prosthesis, leading to lower gradients across the THV. Increases in transvalvular gradients could be a signal of early valve deterioration, as well as result of subclinical valve thickening or thrombosis.[33] Recently, a new definition of valve dysfunction was proposed by Capodanno et al,[34] which is based on assessment of transvalvular gradients and PVL alone. In contrast to the VARC-2 criteria, this definition bears the advantage of simplifying assessment of valve dysfunction on one hand, but on the other it may result in lower rates of valve degeneration. According to this definition rates of moderate and severe hemodynamic valve dysfunction at 1 year in the present study were 9.3 and 0%, respectively.

4.3 | Limitations

This single center experience is limited by the relatively small sample size, observational nature and lack of core lab analysis of echocardiographic data.

5 | CONCLUSIONS

In this single-center analysis using the novel ACURATE neo, we found a favorable safety profile with low all-cause mortality at 1 year. For the first time, VARC-2 defined composite endpoints at 1 year are reported and reveal a low proportion of patients experiencing the composite endpoint of "time-related valve safety" (20.0%) and "clinical efficacy after 30 days" (24.8%).

CONFLICT OF INTEREST

Dr. Pellegrini received minor travel grants from Edwards Lifesciences and Boston Scientific. Dr. Trenkwalder received minor travel grants from Boston Scientific. Drs. Hengstenberg and Husser received Proctor fees and minor speaker honoraria from Boston Scientific. Drs. Hengstenberg and Kasel received proctor fees and speaker honoraria from Edwards Lifesciences. Dr. Rheude has nothing to disclose. Dr. N.P. Mayr has nothing to disclose. Dr. J. Michel has nothing to disclose. Dr. A. Kastrati has nothing to disclose. Dr. H. Schunkert has nothing to disclose. Dr. M. Joner has nothing to disclose.

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