JACC: CARDIOVASCULAR INTERVENTIONS VOL. 18, NO. 1, 2025

ORIGINAL RESEARCH

STRUCTURAL

1-Year Outcomes of Transcatheter Aortic Valve Replacement Using a Self-Expanding vs Balloon-Expandable Transcatheter Aortic Valve

Won-Keun Kim, MD,[a,b,c,d,*] Costanza Pellegrini, MD,[e,f,*] Clemens Eckel, MD,[g,h] Matthias Renker, MD,[a,d] Christina Grothusen, MD,[g,i] Yeong-Hoon Choi, MD,[b,d] Efstratios I. Charitos, MD, PhD,[b] Charlotte Duesmann, MD,[e,f] Johannes Blumenstein, MD,[g,h] Tobias Rheude, MD,[e,f] Samuel Sossalla, MD,[a,c,d] Michael Joner, MD,[e,f] Helge Möllmann, MD[g]

ABSTRACT

BACKGROUND Mid-term comparative data for the self-expanding ACURATE neo2 transcatheter heart valve and the balloon-expandable SAPIEN 3 Ultra are lacking.

OBJECTIVES The aim of this study was to compare 1-year outcomes after transcatheter aortic valve replacement of these 2 valves.

METHODS A total of 2,106 patients from 3 centers (neo2, n = 1,166; Ultra, n = 940) undergoing transfemoral transcatheter aortic valve replacement were analyzed retrospectively. The primary endpoint was the composite of all-cause mortality, stroke, and rehospitalization at 1 year. Secondary endpoints were the individual components of the primary endpoint at 1 year. To adjust for baseline differences, nearest neighbor propensity score matching was used.

RESULTS After matching (702 pairs), baseline characteristics were similar between groups. Device success was more common in the neo2 group (87.5% vs 82.3%; $P = 0.007$), irrespective of matching. DP mean after the procedure was higher for Ultra (13 mm Hg [Q1-Q3: 10-15 mm Hg] vs 8 mm Hg [Q1-Q3: 6-11] mm Hg; $P < 0.001$). Rates of paravalvular leakage, device embolization, and multiple valve implantations were more common in the neo2 arm, whereas major cardiac structural complications and major vascular complications occurred more frequently in the Ultra group. All other in-hospital complication rates were similar between the 2 groups. At 1 year, the cumulative incidence of the primary endpoint (14.1% for neo2 vs 14.5% for Ultra; $P = 0.819$) was similar between the groups. Likewise, the individual components showed no difference between the groups.

CONCLUSIONS Despite differing immediate results, the outcomes at 1 year, including the composite of all-cause mortality, stroke, or hospitalization, were similar for neo2 and Ultra transcatheter heart valves.

From the [a]Department of Cardiology, Kerckhoff Heart Center, Bad Nauheim, Germany; [b]Department of Cardiac Surgery, Kerckhoff Heart Center, Bad Nauheim, Germany; [c]Department of Cardiology, Justus-Liebig University of Giessen, Giessen, Germany; [d]German Center for Cardiovascular Research, Rhein-Main Partner Site, Bad Nauheim, Germany; [e]Klinik für Herz- und Kreislauferkrankungen, Deutsches Herzzentrum München, Technical University Munich, Munich, Germany; [f]Deutsches Zentrum für Herz- und Kreislauf-Forschung e.V., Partner Site Munich Heart Alliance, Munich, Germany; [g]Department of Cardiology, St. Johannes Hospital, Dortmund, Germany; [h]Department of Internal Medicine, Carl von Ossietzky University, Oldenburg, Germany; and the [i]Department of Cardiac Surgery, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany. *Drs Kim and Pellegrini contributed equally to this work.

ISSN 1936-8798 https://doi.org/10.1016/j.jcin.2024.09.042

Major progress in the field of transcatheter aortic valve replacement (TAVR) has led to substantial improvements in outcomes.[1] A crucial determinant of procedural success is the selection of the most suitable transcatheter heart valve (THV) tailored to patient-specific anatomical and clinical considerations.[2] Given the increasing choice of different types and generations of THVs, it has become imperative to discern specific device characteristics through comparative analyses.

Among commercially available devices, the self-expanding ACURATE neo2 (neo2, Boston Scientific) and the balloon-expandable SAPIEN 3 Ultra (Ultra, Edwards Lifesciences) represent recent iterations. However, the most recent iteration of the SAPIEN family, the Resilia valve, has not been available during the study period. A previous retrospective multicenter analysis showed similar immediate procedural outcomes overall between the neo2 and the Ultra, albeit with lower transvalvular gradients for the neo2 and lower rates of mild paravalvular leakage (PVL) for the Ultra.[3] However, the postprocedural outcomes beyond 30 days for these specific THVs remain unexplored, which represents a critical knowledge gap, as results may diverge at mid-term or long-term follow-up.[4]

Therefore, our study was designed to examine the 1-year outcomes of transfemoral TAVR using the neo2 or Ultra THV.

METHODS

Consecutive patients undergoing transfemoral TAVR for severe, native aortic stenosis between March 2019 and June 2022 at 3 German tertiary centers (Kerckhoff Heart Center, Bad Nauheim; St. Johannes Hospital, Dortmund; and German Heart Center Munich, Munich) were considered for this analysis. Exclusion criteria were procedures for bicuspid aortic valve, pure aortic regurgitation, failed surgical bioprosthesis or failed TAVR prosthesis, and missing 1-year follow-up. The indication for TAVR, the most suitable access route, and valve selection were reviewed by the heart team at each center in adherence to existing guidelines.[5,6] All procedures were performed in a hybrid room using analgosedation or local anesthesia. Details on the design of both valves and their implantation techniques have been described elsewhere.[7,8]

All data were drawn from prospective databases at each center and included baseline characteristics, echocardiographic data, preprocedural computed tomographic data, procedural metrics, and in-hospital outcomes according to Valve Academic Research Consortium-3 criteria.[9] All data were aggregated and reviewed by a single investigator and merged into a joint database. Any inconsistencies were resolved by direct communication with the principal investigator of each center. Follow-up data were obtained during outpatient visits, from the most recent medical reports, or via telephone interview. The study adhered to the Declaration of Helsinki and was approved by each local ethics committee.

OUTCOME MEASURES. The primary endpoint was the composite of all-cause mortality, any stroke, or hospitalization (valve related or decompensation) at 1 year. Secondary endpoints were the individual components of the primary endpoint at 1 year.

STATISTICAL ANALYSIS. Continuous variables are expressed as median (Q1-Q3) and were compared using the Wilcoxon rank sum test. Categorical data are presented as numbers and percentages and were compared using the Fisher exact test or chi-square test. To adjust for baseline differences, nearest neighbor 1:1 propensity matching with a caliper of 0.2 was performed and included the variables age, sex, estimated glomerular filtration rate, coronary artery disease, prior coronary artery bypass graft, left ventricular ejection fraction, mean transaortic gradient (DP mean), effective orifice area, perimeter-derived annular diameter, height of the left and right coronary arteries, and the aortic valve calcium score in the matching algorithm. The distribution and density of the propensity score are shown in Supplemental Figures 1 and 2. The C statistic of the propensity score model was determined by plotting the receiver-operating characteristic curve of the propensity scores against the actual treatment assignment (Supplemental Figure 3). The cumulative incidences of the primary endpoint (all-cause mortality, stroke,

ABBREVIATIONS AND ACRONYMS

DP mean = mean transaortic gradient

PVL = paravalvular leakage

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

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.

Manuscript received March 6, 2024; revised manuscript received August 28, 2024, accepted September 17, 2024.

and rehospitalization) were determined using time-to-event curves stratified by THV, and between-group differences were assessed using the log-rank test. Multivariable Cox regression analysis was used to identify independent predictors of the primary endpoint and all-cause mortality, including clinically relevant baseline variables with P values ≤0.1 in the univariate analysis. The proportional hazards assumption was assessed using Schoenfeld residuals. Hemodynamic outcomes were compared across different valve sizes (neo2 S vs Ultra 23 mm, neo2 M vs Ultra 26 mm, and neo2 L vs Ultra 26 mm) and categorized according to annular area using a threshold of 430 mm^2 to compare small vs large annuli.[10] A 2-sided P value of <0.05 was considered to indicate statistical significance for all analyses. All statistical analyses were performed using Stata BE version 18.0 (StataCorp) or R version 4.3.2 (R Foundation for Statistical Computing) and the package MatchIt version 4.5.5.

RESULTS

PATIENT POPULATION. A total of 2,258 patients underwent transfemoral TAVR using either the neo2 (n = 1,271) or Ultra (n = 987) THV at the 3 participating centers. After the exclusion of patients without 1-year follow-up, the final study cohort comprised 2,106 (neo2, n = 1,166; Ultra, n = 940) patients (**Figure 1**). Baseline characteristics of the crude and matched study populations are shown in **Table 1**. In the overall cohort, the median age was 82 years (Q1-Q3: 78-85 years), 52.6% were women, and the median European System for Cardiac Operative Risk Evaluation II score was 3.2% (Q1-Q3: 2.1%-5.2%). There were differences regarding baseline characteristics between the 2 THV groups, including age, sex, estimated glomerular filtration rate, coronary artery disease, left ventricular ejection fraction, DP mean, annular diameter, heights of the left and right coronary arteries, and aortic valve calcium score. After propensity matching, a total of 702 matched pairs were identified, and baseline characteristics were well balanced.

PROCEDURAL AND IN-HOSPITAL OUTCOMES. Procedural data and in-hospital outcomes according to Valve Academic Research Consortium 3 criteria are summarized in **Table 2** for the unmatched and matched cohort. Predilatation and postdilatation were more frequent in the neo2 group, and the amount of contrast agent used was less among neo2 recipients in both the matched and unmatched cohorts. Device success was more frequent in the neo2 group, irrespective of matching. DP mean was greater and aortic valve area was smaller in the Ultra group (Supplemental Figure 4). The comparison of DP mean and aortic valve area categorized according to annular area using a threshold of 430 mm^2 and across different valve sizes is shown in Supplemental Figures 5 and 6. Rates of PVL, device embolization, and multiple valve implantations were more common in the neo2 arm, whereas major cardiac structural complications and major vascular complications occurred more frequently in the Ultra group. All other in-hospital complication rates were similar between the 2 groups.

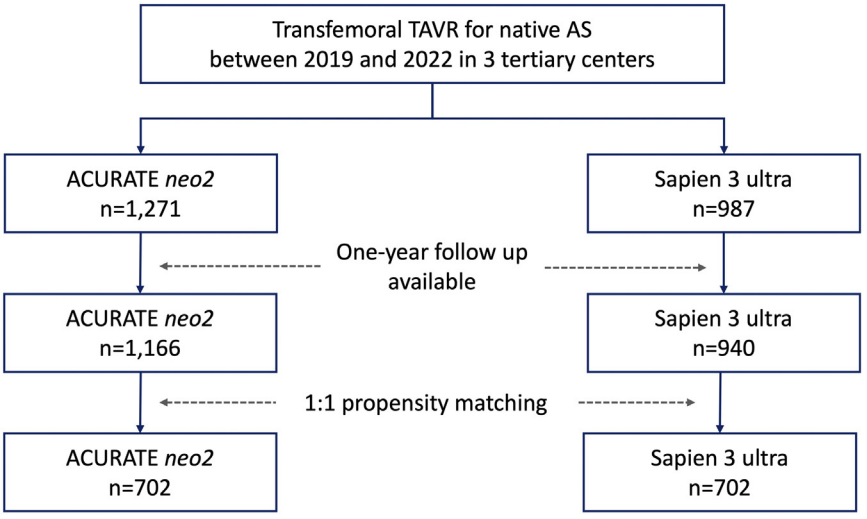
1-YEAR OUTCOMES. The median follow-up time in the overall and matched cohort was 424 days (Q1-Q3: 371-606 days) and 421 days (Q1-Q3: 371-586 days), respectively. At 1 year, the primary endpoint occurred in similar proportions between the 2 groups, irrespective of matching (unmatched: 16.0% for neo2 vs 15.5% for Ultra [$P = 0.793$]; matched: 14.1% for neo2 vs 14.5% for Ultra [$P = 0.819$]) (**Table 3**). All-cause mortality, rehospitalization, and stroke were similar between the 2 groups before and after matching. Time-to-event curves of all endpoints in the matched cohort are shown in **Figure 2**. Results of the Cox regression analysis are summarized in Supplemental Table 1 for the primary endpoint and Supplemental Table 2 for all-cause death, likewise showing no impact of valve type on outcomes.

DISCUSSION

The main finding of this study is that 1 year after transfemoral TAVR using either the neo2 or Ultra THV, the occurrence of the composite endpoint of all-cause mortality, stroke, or hospitalization was similar between the 2 platforms (**Central Illustration**, **Figure 2**).

IN-HOSPITAL AND SHORT-TERM OUTCOMES. Most in-hospital outcomes were consistent with those of our previous comparison between the neo2 and Ultra;[3] slight discrepancies may be explained by the larger sample size and the inclusion of another high-volume center. The technical success rate was similar between the 2 groups, although the causes of failure differed; whereas device embolization and multiple valve implantation were predominant during neo2 implantations, in the Ultra group, major structural cardiac complications occurred more frequently. The higher risk for device embolization when using self-expanding THVs in comparison with balloon-expandable devices has been described.[11] Device success at 30 days was significantly lower in the Ultra group, which was most likely driven by increased mean aortic valve gradients, as previously

FIGURE 1 Flowchart of the Study Cohort



AS = aortic stenosis; TAVR = transcatheter aortic valve replacement.

TABLE 1 Baseline Characteristics in the Unmatched and Matched Cohorts

	ACURATE neo2 (n = 1,166)	SAPIEN 3 Ultra (n = 940)	*P* Value	ACURATE neo2 (n = 702)	SAPIEN 3 Ultra (n = 702)	*P* Value
Age, y	82 (79-85)	81 (76-85)	<0.001	82 (78-85)	81 (77-85)	0.571
Female	728 (62.4)	381 (40.5)	<0.001	339 (48.3)	339 (48.3)	1.000
Body mass index, kg/m^2	26.3 (23.7-30.0)	26.5 (24.1-29.6)	0.602	26.3 (24.0-30.1)	26.4 (24.0-29.4)	0.410
EuroSCORE II, %	3.2 (2.2-5.2)	3.2 (2.0-5.2)	0.449	3.1 (2.0-5.1)	3.3 (2.1-5.4)	0.107
Hypertension	1,042 (89.4)	833 (88.6)	0.551	624 (89.0)	630 (89.7)	0.658
Diabetes	372 (31.9)	290 (30.9)	0.605	223 (31.8)	215 (30.6)	0.645
Coronary artery disease	763 (65.4)	704 (74.9)	<0.001	507 (72.2)	516 (73.5)	0.589
Prior CABG	100 (8.6)	77 (8.2)	0.752	61 (8.7)	58 (8.3)	0.774
Peripheral artery disease	182 (15.6)	175 (18.6)	0.067	126 (17.9)	133 (18.9)	0.630
Prior stroke/TIA	148 (12.7)	118 (12.6)	0.924	81 (11.5)	90 (12.8)	0.463
Atrial fibrillation	485 (41.6)	357 (38.0)	0.092	271 (38.6)	277 (39.5)	0.743
Prior pacemaker implantation	115 (9.9)	89 (9.5)	0.761	67 (9.5)	66 (9.4)	0.927
COPD	144 (12.3)	117 (12.4)	0.947	82 (11.7)	89 (12.7)	0.568
LVEF, %	60 (55-65)	60 (51-61)	<0.001	60 (53-65)	60 (53-60)	0.131
Aortic valve area, cm^2	0.7 (0.6-0.9)	0.7 (0.6-0.8)	0.003	0.7 (0.6-0.8)	0.7 (0.6-0.9)	0.612
DP mean, mm Hg	41 (31-48)	44 (36-53)	<0.001	42 (34-51)	43 (35-51)	0.676
eGFR, mL/min	60 (44-78)	63 (48-79)	0.022	62 (46-79)	61 (47-77)	0.560
Perimeter-derived annulus, mm	23.8 (22.6-25.0)	24.9 (23.5-26.1)	<0.001	24.4 (23.2-25.5)	24.5 (23.1-25.8)	0.259
Area-derived annulus, mm	23.4 (22.2-24.6)	24.4 (23.0-25.6)	<0.001	24.0 (22.7-25.1)	24.0 (22.7-25.3)	0.531
Distance LCA, mm	13.8 (11.9-15.6)	14.0 (12.2-16.0)	<0.001	14.0 (12.0-16.0)	14.0 (12.0-16.0)	0.501
Distance RCA, mm	16.9 (15.0-18.9)	18.0 (16.0-19.5)	<0.001	17.0 (15.0-19.0)	17.0 (15.3-19.0)	0.670
AVCS, AU	2,077 (1,384-2,937)	2,951 (1,932-4,226)	<0.001	2,477 (1,755-3,450)	2,526 (1,670-3,650)	0.592
Femoral access diameter, mm	7.2 (6.1-8.3)	7.0 (6.1-8.2)	0.047	7.0 (6.0-8.2)	7.0 (6.1-8.0)	0.505

Values are median (Q1-Q3) or n (%).

AU = Agatston units; AVCS = aortic valve calcium score; COPD = chronic obstructive pulmonary disease; DP mean = mean transaortic gradient; eGFR = estimated glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LCA = left coronary artery; LVEF = left ventricular ejection fraction; RCA = right coronary artery; TIA = transient ischemic attack.

TABLE 2 Procedural Data and In-Hospital Outcomes in the Unmatched and Matched Cohorts

	ACURATE neo2 (n = 1,166)	SAPIEN 3 Ultra (n = 940)	*P* Value	ACURATE neo2 (n = 702)	SAPIEN 3 Ultra (n = 702)	*P* Value
THV size			<0.001			<0.001
20 mm	0	11 (1.2)		0	11 (1.6)	
23 mm	298 (25.6)	280 (29.8)		112 (16.0)	254 (36.2)	
25 mm	499 (42.8)	0		285 (41.5)	0	
26 mm	0	649 (69.0)		0	437 (62.3)	
27 mm	369 (31.7)	0		305 (43.4)	0	
Predilatation	1,079 (92.5)	304 (32.3)	<0.001	672 (95.7)	189 (26.9)	<0.001
Postdilatation	400 (34.3)	138 (14.7)	<0.001	271 (38.6)	91 (13.0)	<0.001
Procedural time, min	45 (37-55)	45 (36-58)	0.404	45 (37-55)	45 (35-56)	0.270
Fluoroscopy time, min	9.5 (7.0-13.3)	9.7 (6.8-13.8)	0.529	9.6 (7.2-13.4)	9.5 (6.5-13.2)	0.226
Contrast agent, mL	73 (25-120)	115 (60-160)	<0.001	80 (35-123)	110 (60-157)	<0.001
Technical success	1,073 (92.0)	884 (94.0)	0.073	651 (92.7)	657 (93.6)	0.526
Device success (30 d)	1,012 (86.8)	771 (82.0)	0.003	614 (87.5)	578 (82.3)	0.007
PVL						<0.001
None/trace				467 (67.9)	572 (82.1)	
Mild				207 (30.1)	120 (17.2)	
Moderate				14 (2.0)	5 (0.7)	
DP mean post, mm Hg	8 (6-11)	13 (10-16)	<0.001	8 (6-11)	13 (10-15)	<0.001
Aortic valve area postintervention, cm^2	1.8 (1.5-2.1)	1.6 (1.4-1.8)	<0.001	1.8 (1.5-2.1)	1.6 (1.4-1.8)	<0.001
Major cardiac structural complications	10 (0.9)	15 (1.6)	0.120	4 (0.6)	12 (1.7)	0.044
Coronary obstruction	0	2 (0.2)	0.115	0	1 (0.1)	0.317
Conversion to sternotomy	7 (0.6)	7 (0.7)	0.685	2 (0.3)	6 (0.9)	0.156
Valve embolization	12 (1.0)	2 (0.2)	0.022	9 (1.3)	2 (0.3)	0.033
Multiple valves	11 (0.9)	2 (0.2)	0.033	7 (1.0)	2 (0.3)	0.095
Major vascular complication	71 (6.1)	100 (10.6)	<0.001	47 (6.7)	76 (10.8)	0.006
Bleeding (BARC-2 types 2-4)	168 (14.4)	132 (14.0)	0.811	102 (14.5)	102 (14.5)	1.000
AKI stages 2-4	62 (5.3)	51 (5.4)	0.913	39 (5.6)	36 (5.1)	0.722
Pacemaker implantation	87 (7.5)	85 (9.0)	0.188	57 (8.1)	66 (9.4)	0.396
Stroke	24 (2.1)	22 (2.3)	0.660	12 (1.7)	17 (2.4)	0.348

Values are n (%) or median (Q1-Q3).

AKI = acute kidney injury; BARC-2 = Bleeding Academic Research Consortium 2; DP mean = mean transaortic gradient; PVL = paravalvular leakage; THV = transcatheter heart valve.

described.[3] In line with our previous study, the rate of PVL was higher in the neo2 group[3] but was not overly high at 2.0%. The higher rate of major vascular complications among Ultra recipients is not consistent with previous findings and thus is difficult to explain.

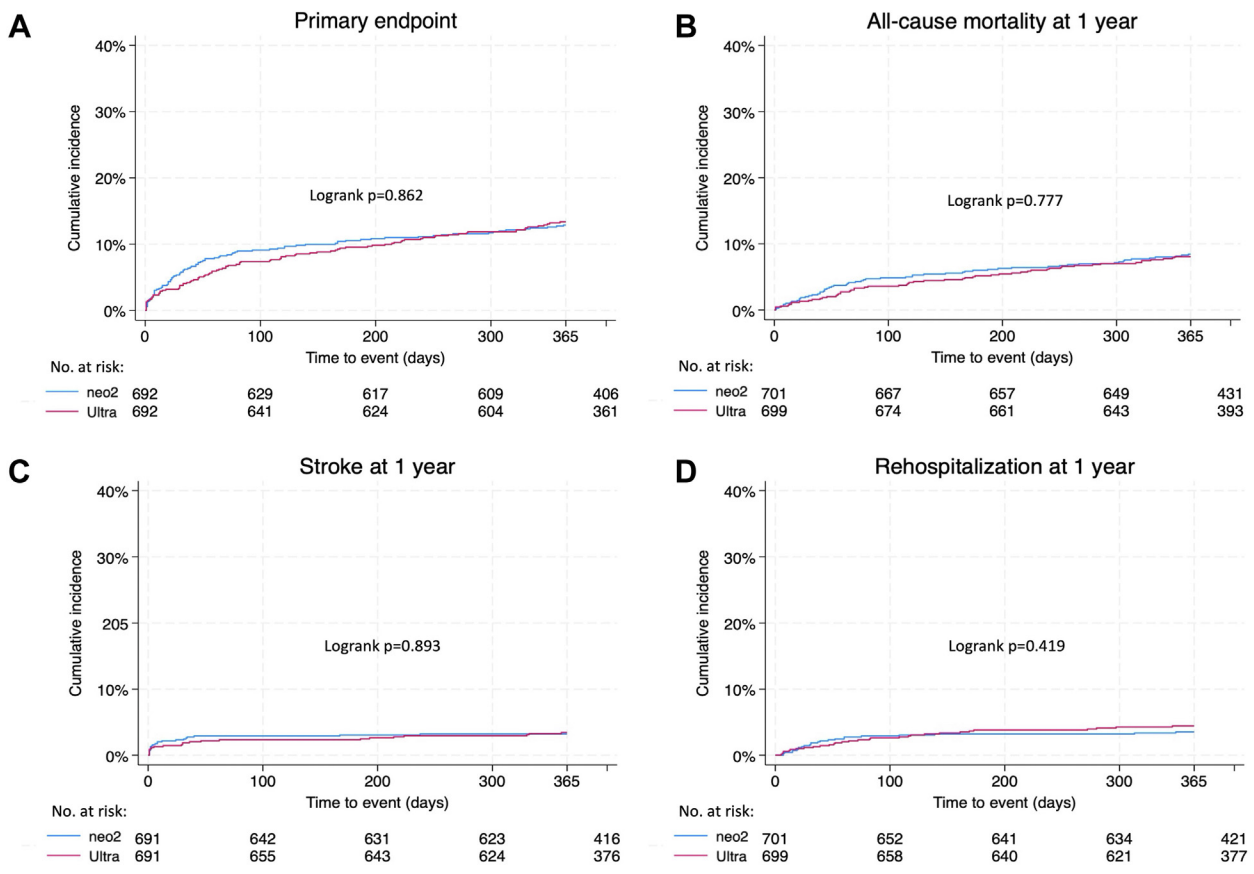
TABLE 3 1-Year Primary Outcomes in the Unmatched and Matched Cohorts

	ACURATE neo2 (n = 1,166)	SAPIEN 3 Ultra (n = 940)	*P* Value	ACURATE neo2 (n = 702)	SAPIEN 3 Ultra (n = 702)	*P* Value
Primary endpoint	186 (16.0)	146 (15.5)	0.793	99 (14.1)	102 (14.5)	0.819
1-y mortality	108 (9.3)	82 (8.8)	0.731	60 (8.5)	59 (8.4)	0.924
1-y stroke	64 (5.5)	41 (4.4)	0.237	32 (4.6)	31 (4.4)	0.897
1-y hospitalization	45 (3.9)	46 (4.9)	0.246	24 (3.4)	30 (4.3)	0.405

Values are n (%).

1-YEAR OUTCOMES. Primary endpoint. Up to 1 year, the cumulative incidence of the primary endpoint was similar between the neo2 and Ultra THV groups. Likewise, the individual components of the primary endpoint did not differ between the 2 groups. A direct comparison of these results with previous evidence is challenging, as this specific outcome has not been studied in an intermediate-risk cohort using latest generation THVs. In addition, our study reflects consecutive real-world outcomes without the bias of rigorous inclusion and exclusion criteria of randomized trials. In the SCOPE I (Safety and Efficacy of the Symetis ACURATE neo/TF Compared to the Edwards SAPIEN 3 Bioprosthesis) trial, which compared the ACURATE neo (the predecessor of the neo2) and SAPIEN 3 THVs in an intermediate-risk cohort, the composite endpoint of all-cause mortality, stroke, or rehospitalization occurred in approximately 20% in

FIGURE 2 **Primary Endpoint and its Individual Components at 1 Year**



Cumulative incidence rates through 1 year stratified by transcatheter heart valve. (A) Primary endpoint. (B) All-cause mortality at 1 year. (C) Stroke at 1 year. (D) Rehospitalization at 1 year.

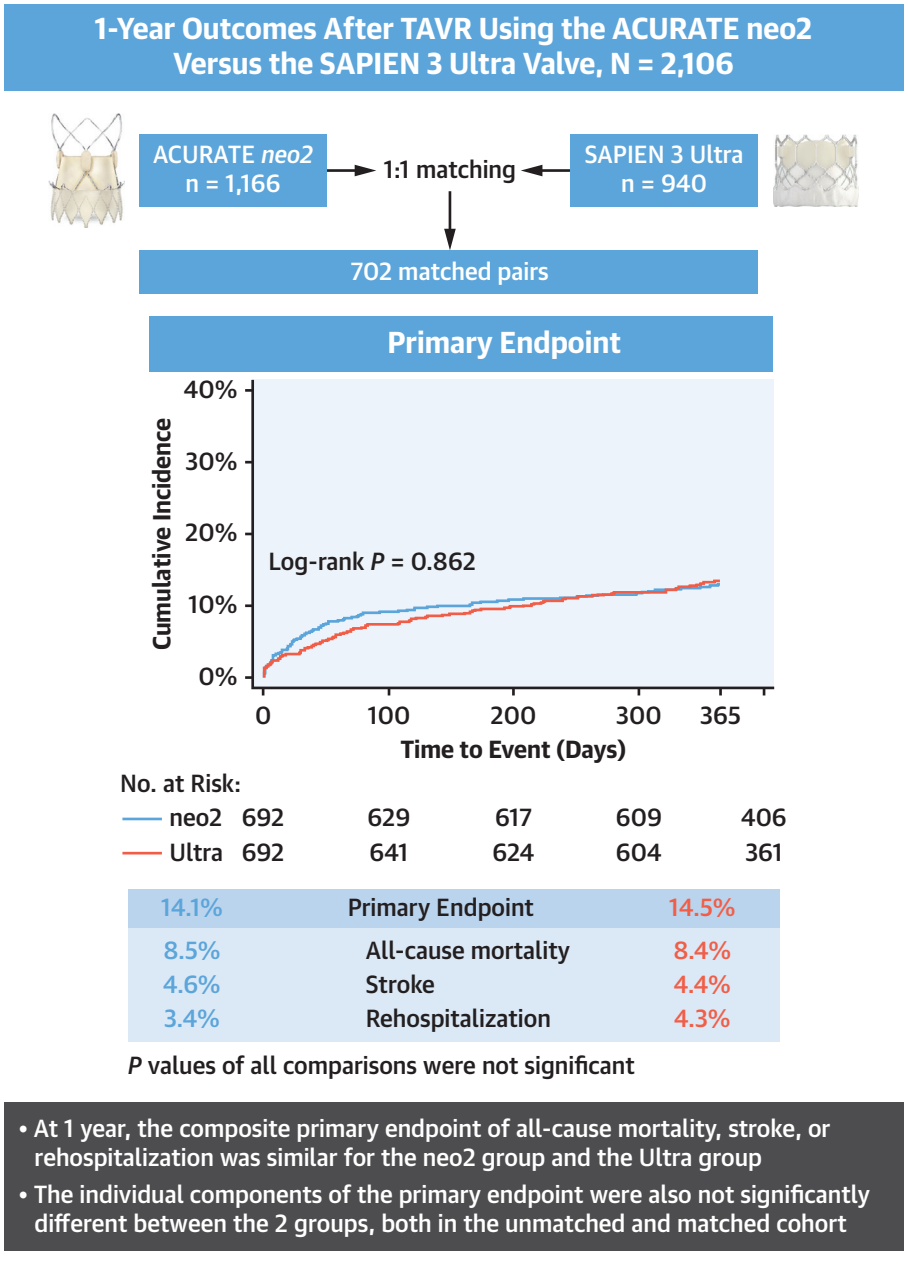
the 2 groups, without any difference between them (HR: 1.05; 95% CI: 0.76-1.45).[12] In the TAVR arms of the pivotal trials in low-risk patients, the incidence of the same combined endpoint was <10% (PARTNER [Placement of Aortic Transcatheter Valve] 3, 8.5%; EVOLUT Low Risk, 5.6%).[13,14]

All-cause mortality. Rates of all-cause mortality in the present study (unmatched cohort: 9.3% for neo2 vs 8.8% for Ultra) were within the range of the SCOPE I trial (11.1% for neo vs 8.5% for SAPIEN 3) and the SAPIEN 3 intermediate-risk study (7.4%).[12,15] In comparison with our findings for the neo2 device, 1-year all-cause mortality was slightly higher in the Conformité Européenne mark study (11.9%), which included higher risk patients. In contrast, in the PMCF (ACURATE neo2™ Post Market Clinical Follow Up) study, all-cause mortality was much lower at 5.1%,[7,16] which may be explained by the lower risk and a selection bias of patients eligible for post-TAVR computed tomography (eg, absence of atrial fibrillation and renal failure).[16]

Stroke. The stroke rates at 1 year in the unmatched cohort (5.5% for neo2, 4.4% for Ultra) are comparable with those in the SCOPE I trial (4.7% for neo, 4.2% for SAPIEN 3) and in the SAPIEN 3 intermediate-risk analysis (4.6%), whereas in the neo2 observational studies, the stroke rates of 2.5% in the Conformité Européenne mark study and 3% in the PMCF study were somewhat lower.[12,15,16]

Rehospitalization. Rates of rehospitalization (unmatched cohort: 3.9% for neo2, 4.9% for Ultra) were lower than in the SCOPE I trial (7.8% for neo, 11.5% for SAPIEN 3) and the SAPIEN 3 intermediate-risk study (11.4%).[12,15] Apart from the different risk categories between the studies, the COVID-19 pandemic may have affected hospitalization rates in the present analysis. This may particularly apply to the PMCF study, which had the lowest rate of hospitalization (1.7%).[16]

CENTRAL ILLUSTRATION **ACURATE neo2 vs SAPIEN 3 Ultra 1-Year Outcomes**



Kim W-K, et al. JACC Cardiovasc Interv. 2025;18(1):32-40.

Overview and the main outcomes. Propensity score matching identified 702 matched pairs. The primary endpoint and its components were similar between the 2 groups through 1 year. TAVR = transcatheter aortic valve replacement.

DIFFERENTIAL THV SELECTION. Our data indicate that the 2 valve platforms may yield similar 1-year efficacy and safety results. This is rather unexpected given the differing immediate outcomes showing a higher PVL burden and more frequent device embolization for neo2 vs higher mean gradients and a higher occurrence of major structural cardiac complications for the Ultra platform, but most likely the sample size was too small to detect statistically significant differences with regard to our specified

endpoints. Our results suggest that the 2 platforms may be considered equivalent options for tailored differential valve selection regarding 1-year outcomes, although outcomes beyond 1 year could differ. For instance, in patients with a high risk for relevant PVL, use of the Ultra valve may be preferred because of the higher radial force, whereas in anticipation of increased transaortic gradients, use of the neo2 valve may be the better option because of its superior hemodynamic profile.

STUDY LIMITATIONS. This was a retrospective nonrandomized study with its inherent selection bias. However, data collection was from multiple centers with a relatively large sample size, and propensity matching was used to adjust for the baseline differences between the compared groups. Hence, our data may provide a glimpse in anticipation of the randomized investigational device exemption trial results that will be published soon. The present comparison did not include the most recent iteration of the SAPIEN platform with the Resilia leaflet technology, which has been shown to have better hemodynamic properties than the Ultra.[17] Other potential limitations include the lack of independent event adjudication, health status information, core laboratory adjudication of echocardiographic and computed tomographic measurements, and echocardiographic data through 1-year follow-up.

CONCLUSIONS

Transfemoral TAVR using the neo2 or Ultra THV leads to similar outcomes at 1 year regarding the composite of all-cause mortality, stroke, or hospitalization and its individual components.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

Dr Kim has received proctor and/or speaker and/or advisory honoraria from Abbott, Boston Scientific, Edwards Lifesciences, Meril Life Sciences, Shockwave, and HID Imaging. Dr Choi has received speaker and proctor fees from Edwards Lifesciences, CytoSorbents, and Getinge. Dr Charitos is a proctor for Boston Scientific. Dr Rheude has received lecture fees from Abbott, AstraZeneca, SIS Medical, and Translumina; and has received travel support from Boston Scientific and Eli Lilly (not related to the present work). Dr Joner has received lecture fees and research grants from Edwards Lifesciences and Boston Scientific; and is a consultant for Biotronik and OrbusNeich. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Dr Won-Keun Kim, Justus-Liebig University of Giessen, Department of Cardiology, Klinikstrasse 33, 35392 Giessen, Germany. E-mail: dr.won.kim@gmail.com.

PERSPECTIVES

WHAT IS KNOWN? Observational data suggest similar immediate outcomes of transfemoral TAVR between the neo2 and Ultra THVs.

WHAT IS NEW? At 1 year, the composite of all-cause death, stroke, or rehospitalization and its individual components occurred at similar rates after transfemoral TAVR for the neo2 and Ultra THVs.

WHAT IS NEXT? These results need to be confirmed in ongoing randomized trials comparing the neo2 valve vs balloon-expandable platforms.

REFERENCES

1. Gaede L, Blumenstein J, Liebetrau C, et al. Outcome after transvascular transcatheter aortic valve implantation in 2016. *Eur Heart J*. 2018;39:667–675.

2. Werner N, Renker M, Dorr O, et al. Anatomical suitability and off-label use of contemporary transcatheter heart valves. *Int J Cardiol*. 2022;350:96–103.

3. Pellegrini C, Rheude T, Renker M, et al. ACURATE neo2 versus SAPIEN 3 Ultra for transcatheter aortic valve implantation. *EuroIntervention*. 2023;18:987–995.

4. Lanz J, Mollmann H, Kim WK, et al. Final 3-year outcomes of a randomized trial comparing a self-expanding to a balloon-expandable transcatheter aortic valve. *Circ Cardiovasc Interv*. 2023;16:e012873.

5. Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology, European Association for Cardio-Thoracic Surgery, Vahanian A, et al. Guidelines on the management of valvular heart disease (version 2012). *Eur Heart J*. 2012;33:2451–2496.

6. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J*. 2022;43:561–632.

7. Mollmann H, Holzhey DM, Hilker M, et al. The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol*. 2021;110:1912–1920.

8. Chatfield A, Sathananthan J, Wood DA, Webb JG. Next-generation balloon-expandable transcatheter heart valve: the SAPIEN 3 Ultra valve. *Future Cardiol*. 2021;17:811–816.

9. VARC-3 Writing Committee, Genereux P, Piazza N, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *J Am Coll Cardiol*. 2021;77:2717–2746.

10. Herrmann HC, Mehran R, Blackman DJ, et al. Self-expanding or balloon-expandable TAVR in patients with a small aortic annulus. *N Engl J Med*. 2024;390:1959–1971.

11. Kim WK, Schafer U, Tchetche D, et al. Incidence and outcome of peri-procedural transcatheter heart valve embolization and migration: the TRAVEL registry (Transcatheter Heart Valve Embolization and Migration). *Eur Heart J*. 2019;40:3156–3165.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 18, NO. 1, 2025
JANUARY 13, 2025:32–40

12. Lanz J, Kim WK, Walther T, 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*. 2019;394:1619–1628.

13. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380:1695–1705.

14. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706–1715.

15. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet*. 2016;387:2218–2225.

16. Kim WK, Mollmann H, Montorfano M, et al. Outcomes and performance of the ACURATE neo2 transcatheter heart valve in clinical practice: one-year results of the ACURATE neo2 PMCF study. *EuroIntervention*. 2024;20:85–94.

17. Ueyama HA, Xie J, Hanzel GS, et al. Hemodynamic comparison of Resilia and SAPIEN 3/Ultra transcatheter heart valves in transcatheter aortic valve replacement. *Circ Cardiovasc Interv*. 2024;17:e013325.

KEY WORDS ACURATE neo2, balloon-expandable, SAPIEN 3 Ultra, self-expanding, TAVR

APPENDIX For supplemental figures and tables, please see the online version of this paper.