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STRUCTURAL

The SAVI-TF Registry

1-Year Outcomes of the European Post-Market Registry Using the ACURATE neo Transcatheter Heart Valve Under Real-World Conditions in 1,000 Patients

Won-Keun Kim, MD,[a,b] Christian Hengstenberg, MD,[c,d,e] Michael Hilker, MD,[f] Sebastian Kerber, MD,[g] Ulrich Schäfer, MD,[h] Tanja Rudolph, MD,[i] Axel Linke, MD,[j] Norbert Franz, MD,[k] Thomas Kuntze, MD,[l] Holger Nef, MD,[m] Utz Kappert, MD,[n] Michael O. Zembala, MD,[o] Stefan Toggweiler, MD,[p] Thomas Walther, MD,[q,r] Helge Möllmann, MD[a,s]

ABSTRACT

OBJECTIVES The SAVI-TF (Symetis ACURATE neo Valve Implantation Using Transfemoral Access) registry was initiated to study the ACURATE neo transcatheter heart valve in a large patient population treated under real-world conditions.

BACKGROUND The self-expanding, supra-annular ACURATE neo prosthesis is a transcatheter heart valve that gained the Conformité Européene mark in 2014, but only limited clinical data are available so far.

METHODS This prospective, multicenter registry enrolled 1,000 patients at 25 European centers who were followed for 1 year post-procedure.

RESULTS Mean patient age was 81.1 ± 5.2 years; mean logistic European System for Cardiac Operative Risk Evaluation I score, European System for Cardiac Operative Risk Evaluation II score, and Society of Thoracic Surgeons score were 18.1 ± 12.5%, 6.6 ± 7.5%, and 6.0 ± 5.6%, respectively. At 1 year, 8.0% (95% confidence interval [CI]: 6.3% to 9.7%) of patients had died, 2.3% (95% CI: 1.3% to 3.2%) had disabling strokes, and 9.9% (95% CI: 8.1% to 11.8%) had permanent pacemaker implantations. Through 1 year, 5 reinterventions (0.5%; 95% CI: 0.1% to 1.0%) were performed: 3 valve-in-valve and 2 surgical aortic valve replacements. Mean effective orifice area was 1.84 ± 0.43 cm^2, mean gradient was 7.3 ± 3.7 mm Hg, and greater than mild paravalvular leakage was observed in 3.6% of patients.

CONCLUSIONS Transfemoral implantation of the ACURATE neo prosthesis resulted in favorable 1-year clinical and echocardiographic outcomes with very low mortality and new pacemaker rates. (J Am Coll Cardiol Intv 2018;11:1368–74)

From the [a]Department of Cardiology, Kerckhoff Heart and Lung Center, Bad Nauheim, Germany; [b]Department of Cardiac Surgery, Kerckhoff Heart and Lung Center, Bad Nauheim, Germany; [c]Klinik für Herz- und Kreislauferkrankungen, Deutsches Herzzentrum München, Technische Universität München, Munich, Germany; [d]Deutsches Zentrum für Herz- und Kreislauf-Forschung e.V. (German Center for Cardiovascular Research), Partner Site Munich Heart Alliance, Munich, Germany; [e]Universitätsklinik für Innere Medizin II, Klinische Abteilung für Kardiologie, Medizinische Universität Wien, Vienna, Germany; [f]Department of Cardiothoracic Surgery, University Medical Center Regensburg, Regensburg, Germany; [g]Department of Cardiology, Herz- und Gefässklinik Bad Neustadt, Bad Neustadt an der Saale, Germany; [h]Department of Cardiology, University Heart Center Hamburg, Hamburg, Germany; [i]Department of Cardiology, Heart Center, University Hospital Cologne, Cologne, Germany; [j]Department of Cardiology, Heart Center Leipzig University, Leipzig, Germany; [k]Department of Cardiology, Schüchtermann-Schiller'sche Kliniken, Bad Rothenfelde, Germany; [l]Department of Cardiac Surgery, Central Hospital Bad Berka, Bad Berka, Germany; [m]Department of Cardiology, University Hospital Giessen and Marburg, Giessen, Germany; [n]Department of Cardiac Surgery, University Heart Center Dresden, Dresden, Germany; [o]Department of Cardiac, Vascular and Endovascular Surgery and Transplantology, Medical University of Silesia in Katowice, Silesian Center for Heart Diseases in Zabrze, Zabrze, Poland; [p]Heart Center Lucerne, Luzerner Kantonsspital, Lucerne, Switzerland; [q]Department of Cardiac Surgery, Kerckhoff Heart and Lung Center, Bad Nauheim,

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In 2007, the first transcatheter heart valves (THVs) gained the Conformité Européene (CE) mark. Since then, procedural techniques have been refined and newer THVs have been developed, leading to an improved safety profile, higher rates of clinical success, and more widespread adoption of the technology (1,2). Longer-term results with THVs demonstrating continued valve durability and clinical outcomes, comparable with or better than surgical valve replacement, have been reported (3–5).

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The self-expanding ACURATE neo prosthesis (Symetis, a Boston Scientific company, Ecublens, Switzerland) is a next-generation device that is implanted using a 2-step top-down deployment. The upper crowns are responsible for supra-annular anchoring of the prosthesis and capping of the native leaflets, stabilization arches contribute to axial self-alignment, and the pericardial skirt acts as a seal to prevent paravalvular leaks (PVLs) (6). The prosthesis received the CE mark in September 2014 on the basis of the TF89 CE-approval cohort (7). Thereafter, the SAVI-TF (Symetis ACURATE neo Valve Implantation Using Transfemoral Access) registry was initiated to assess outcomes with ACURATE neo in routine clinical practice in a large patient population. Thirty-day results showed promising outcomes, with very low mortality and pacemaker rates (8). We now report 1-year outcomes from SAVI-TF, which to our knowledge is the largest body of 1-year data available on ACURATE neo to date.

METHODS

The study design has been previously described (8). In brief, SAVI-TF is a prospective, single-arm, multicenter, all-comers registry of patients in whom transfemoral implantation of an ACURATE neo prosthesis was attempted.

Patients could be enrolled if they qualified for transcatheter aortic valve replacement with the ACURATE neo prosthesis via transfemoral access as per instructions for use, provided written informed consent, and were willing to attend follow-up visits. The only exclusion criterion was for patients who were not eligible for treatment with ACURATE neo. Treatment was conducted per each center's standard of care. Follow-up occurred at discharge or 7 days, at 30 days, and at 1 year post-procedure (the latter preferably as an on-site visit including echocardiography and New York Heart Association classification).

The study was registered at ClinicalTrials.gov (NCT02306226), conducted according to the Declaration of Helsinki, and approved by the local ethics committees. All patients provided written informed consent. Monitoring was not performed, but outliers were queried.

The ACURATE neo aortic bioprosthesis and the ACURATE TF transfemoral delivery system have been described previously (6–8). The supra-annular prosthesis consists of a self-expanding nitinol frame with porcine pericardial leaflets with anticalcification treatment. During the SAVI-TF registry, the ACURATE TF delivery system had to be used with an 18-F or larger introducer sheath.

Clinical endpoints were defined according to Valve Academic Research Consortium-2 criteria and included mortality, stroke (disabling and nondisabling), myocardial infarction, bleeding, acute kidney injury, vascular complications, conduction disturbances and other transcatheter aortic valve replacement-related complications (9).

Data were entered in an electronic database; database management was performed by the study sponsor. Clinical outcomes were analyzed on an

ABBREVIATIONS AND ACRONYMS

CE = Conformité Européene

EuroSCORE = European System for Cardiac Operative Risk Evaluation

PVL = paravalvular leak

THV = transcatheter heart valve

Germany; [r]Department of Thoracic and Cardiovascular Surgery, University Hospital, Frankfurt, Germany; and the [s]Department of Internal Medicine-I, Cardiology, St. Johannes-Hospital, Dortmund, Germany. This study was sponsored by Symetis, a Boston Scientific company. Dr. Kim is a proctor for Symetis/Boston Scientific; and has received speaking honoraria from Symetis/Boston Scientific, Edwards Lifesciences, and St. Jude Medical. Prof. Dr. Hengstenberg is a proctor for and has received speaking honoraria from Edwards Lifesciences and Symetis/Boston Scientific. Prof. Dr. Hilker and Prof. Dr. Schäfer are proctors for Symetis/Boston Scientific; and have received speaking honoraria from Symetis/Boston Scientific. Prof. Dr. Rudolph is a proctor for Edwards Lifesciences; and has received speaking honoraria from Edwards Lifesciences and Symetis/Boston Scientific. Prof. Dr. Linke has received speaking honoraria or served as a consultant for Medtronic, St. Jude Medical, Claret Medical, Edwards Lifesciences, Symetis/Boston Scientific, and Bard; and owns stock options in Claret Medical. Dr. Toggweiler serves as a proctor and consultant to Symetis/Boston Scientific; is a consultant to New Valve Technology; and has received speaking fees from Symetis/Boston Scientific, Edwards Lifesciences, and Medtronic. Dr. Zembala serves as a proctor and a consultant to Symetis/Boston Scientific, AtriCure, and Abbott. Prof. Dr. Walther is a proctor for Symetis/Boston Scientific. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Kim and Hengstenberg contributed equally to this work.

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TABLE 1 Echocardiographic Outcomes

	Baseline				1 Year			
	Overall	No Post-Dilatation	Post-Dilatation	p Value	Overall	No Post-Dilatation	Post-Dilatation	p Value
Effective orifice area (cm^2)	(n = 865)	(n = 489)	(n = 376)	0.005	(n = 257)	(n = 152)	(n = 105)	0.053
	0.72 ± 0.20	0.73 ± 0.20	0.70 ± 0.20		1.84 ± 0.43	1.78 ± 0.43	1.91 ± 0.43	
Mean gradient (mm Hg)	(n = 872)	(n = 485)	(n = 387)	<0.0001	(n = 484)	(n = 273)	(n = 211)	0.621
	42.7 ± 15.2	40.5 ± 14.8	45.6 ± 15.3		7.3 ± 3.7	7.4 ± 4.0	7.2 ± 3.3	
Aortic regurgitation	(n = 871)	(n = 486)	(n = 385)	0.352	(n = 587)*	(n = 329)*	(n = 258)*	<0.0001
Grade 0 (none/trace)	261 (30.0)	148 (30.5)	113 (29.4)		296 (50.4)	190 (57.8)	106 (41.1)	
Grade 1 (mild)	458 (52.6)	264 (54.3)	194 (50.4)		270 (46.0)	133 (40.4)	137 (53.1)	
Grade 2 (moderate)	122 (14.0)	61 (12.6)	61 (15.8)		20 (3.4)	5 (1.5)	15 (5.8)	
Grade 3 (moderate to severe)	22 (2.5)	10 (2.1)	12 (3.1)		1 (0.2)	1 (0.3)	0 (0.0)	
Grade 4 (severe)	8 (0.9)	3 (0.6)	5 (1.3)		0 (0.0)	0 (0.0)	0 (0.0)	

Values are mean ± SD or n (%). *Paravalvular leak.

intention-to-treat basis. For quantitative variables, means and SDs were calculated, and for categorical data, absolute numbers and relative frequencies are reported. Clinical events were calculated using Kaplan-Meier estimates. In a post hoc analysis, echocardiographic outcomes in patients with and without post-dilatation were compared. For a second post hoc analysis, the study centers were requested to report the number of transcatheter aortic valve replacements during the respective enrollment period. For the comparison of categorical variables, statistical differences were assessed by using chi-square or Fisher exact tests as appropriate. For continuous variables, the Student's *t*-test or analysis of variance was used. When appropriate, 95% confidence intervals were calculated. Data analysis was performed using SAS version 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

From October 2014 to April 2016, 1,000 patients were enrolled, representing 18% of the total transcatheter aortic valve replacement volume and 81% of the ACURATE neo implantations.

Baseline characteristics have been previously reported (8). In brief, patients were 81.1 ± 5.2 years of age on average, and 38.8% were men. Logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) I was 18.1 ± 12.5%, logistic EuroSCORE II was 6.6 ± 7.5%, and Society of Thoracic Surgeons score was 6.0 ± 5.6%. As determined by computed tomography and site reported, calcification was mild in 19.2% (162 of 845), moderate in 47.3% (400 of 845), and severe in 30.5% (258 of 845).

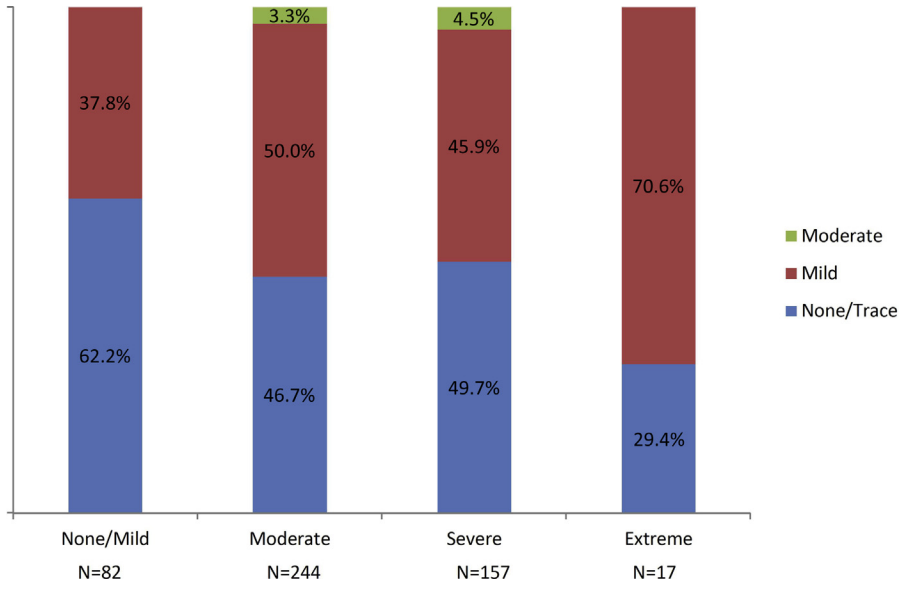
General anesthesia was used in 63.1% of patients, pre-dilatation was performed in 96.1%, implantation without rapid pacing in 48.7%, and post-dilatation in 44.8%. The procedure was aborted in 1 case, and there were 9 valve-in-valve procedures and 3 cases of conversion to surgery. Five repeat procedures (0.5%) occurred through 1 year. Three were valve-in-valve implantations (2 for aortic insufficiency on days 57 and 310 post-procedure, and 1 for the sequela of endocarditis on day 283 post-procedure) and 2 surgical aortic valve replacements (1 for valve dislocation on day 32 and 1 for aortic insufficiency on day 93).

Table 1 presents unpaired echocardiographic outcomes at 1 year post-procedure (paired data are available in Online Table 1) and compares outcomes of patients with post-dilatation with those without. More than mild PVLs were observed in 3.6% of patients (21 of 587).

Patients with post-dilatation (n = 448) had significantly higher mean gradients at baseline (45.6 ± 15.3 mm Hg vs. 40.5 ± 14.8 mm Hg; $p < 0.0001$), significantly more calcification (none, mild, moderate, severe, and extreme calcification by computed tomography in 0.3%, 13.0%, 45.1%, 36.9%, and 4.8% vs. 0%, 24.1%, 49.1%, 25.4%, and 1.3%, respectively; $p < 0.0001$) and significantly more PVLs ≥2° at 1 year (5.8% vs. 1.8%;, $p < 0.0001$). **Figure 1** displays the PVL rate stratified by baseline degree of calcification; there was a trend toward more PVLs in patients with more calcification at baseline ($p = 0.074$).

Clinical data at 1 year were available for 983 patients (98.3%), as 4 patients withdrew consent and 13 patients were lost to follow-up. Median follow-up time used for Kaplan-Meier analysis was 365 days

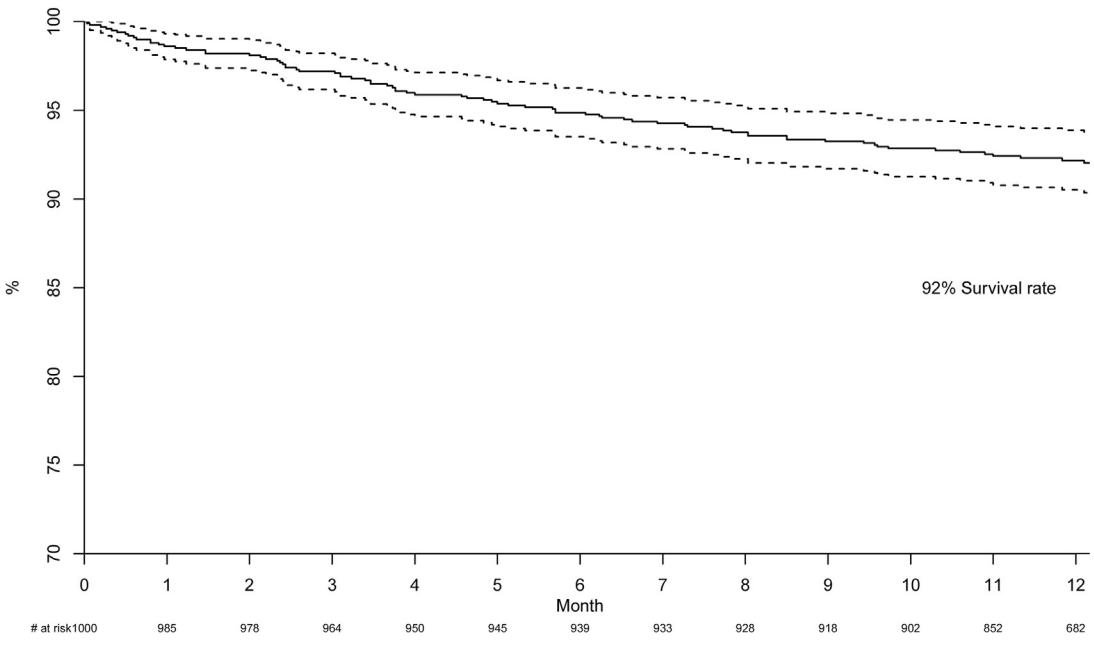
FIGURE 1 Paravalvular Leakage at 1 Year Based on Baseline Calcification Measured by Computed Tomography



Degree of calcification per site assessment. The p value was calculated using the Fisher exact test using the Monte Carlo simulation ($p = 0.074$).

(interquartile range: 350 to 365 days). The Kaplan-Meier estimated incidence of 1-year mortality was 8.0% (95% confidence interval: 6.3% to 9.7%) (Figure 2), the 1-year disabling stroke rate was 2.3% (95% confidence interval: 1.3% to 3.2%), and the permanent pacemaker rate was 9.9% (95% confidence interval: 8.1% to 11.8%). Additional clinical outcomes are shown in Table 2, and Figure 3 shows the

FIGURE 2 1-Year Kaplan-Meier Survival Estimate



Dotted lines reflect the 95% confidence interval.

TABLE 2 Kaplan-Meier Estimates of Clinical Outcomes at 1 Year

Mortality	
All-cause	78 (8.0) [6.3–9.7]
Cardiovascular	34 (3.5) [2.3–4.6]
Stroke	
All stroke	33 (3.5) [2.3–4.6]
Disabling	22 (2.3) [1.3–3.2]
Life-threatening bleeding	20 (2.0) [1.2–2.9]
Repeat procedure	5 (0.5) [0.1–1.0]
Myocardial infarction	12 (1.3) [0.6–2.0]
Endocarditis	7 (0.8) [0.2–1.4]
Valve thrombosis*	0 (0.0) [0.0–0.4]
New pacemaker implantation	98 (9.9) [8.1–11.8]

Values are n (estimated Kaplan-Meier incidence [%]) [95% confidence interval].
*Diagnosed clinically.

distribution of New York Heart Association functional class, with 87.0% of patients (655 of 753) in class I or II at 1 year.

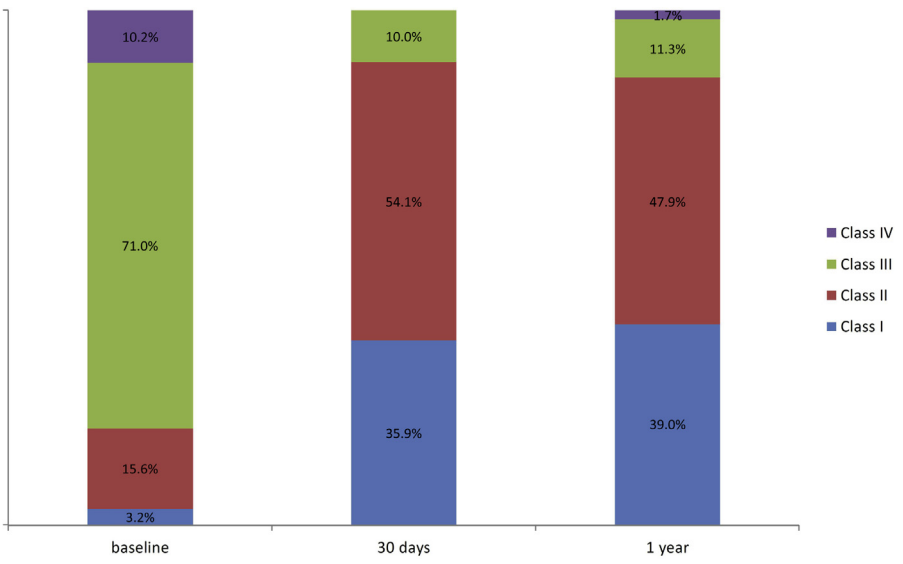
DISCUSSION

The main finding of the SAVI-TF registry is the confirmation of safety and performance of the ACURATE neo prosthesis in a large patient population treated under real-world conditions. The 1-year mortality rate of 8.0% is lower than the 22.5% rate observed in the ACURATE neo CE-mark cohort (7) but is in line with a single-center study and a multicenter evaluation in small annuli that showed mortality rates of 5.2% and 8.3%, respectively (10,11). The lower mortality compared with the CE-mark cohort may relate to the enrolled patient population (logistic EuroSCORE of 26.5% in the CE-mark cohort vs. 18.1% in our series), increasing experience with regard to patient selection and use of the device, and perhaps by the play of chance in the relatively small CE-mark cohort.

The 1-year mortality in the present study compares well with outcomes reported with other THVs in real-world registries. Specifically, 1-year mortality was 11.8% for SAPIEN 3 (Edwards Lifesciences, Irvine, California) in 1,694 transfemoral patients with a logistic EuroSCORE of 13.96% enrolled in the SOURCE 3 (Observational Study to Evaluate Safety and Performance of SAPIEN 3 THV System in Real Life Practice) registry (12), 16.0% for the CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) in 1,015 patients with a logistic EuroSCORE of 17.9% enrolled in the ADVANCE (CoreValve Advance International Post Market Study) study (13), and 11.7% for the Lotus prosthesis (Boston Scientific, Natick, Massachusetts) in nearly 1,000 patients with a Society of Thoracic Surgeons score of 6.0% enrolled in the RESPOND (Repositionable Lotus Valve System–Post-Market Evaluation of Real World Clinical Outcomes) registry (14).

Despite the fact that post-dilatation had been performed in 44.8% of patients, the disabling stroke rate at 1 year was only 2.3% (1.2% at 30 days) and was within the range of the studies described earlier, which reported rates of 1.4% to 4.0% (12–14). An analysis of 30-day data did not reveal differences in

FIGURE 3 New York Heart Association Functional Classification at Baseline, 30 Days, and 1 Year



clinical outcomes between patients with and without post-dilatation (8).

Furthermore, the 9.9% 1-year pacemaker rate observed in SAVI-TF is similar to or better than the pacemaker rate reported in the SOURCE 3 registry (13.6%) using the balloon-expandable SAPIEN 3 prosthesis (12) and is substantially lower than pacemaker rates reported with the CoreValve and Lotus prostheses (13,14).

Ultimately, randomized controlled trials are required to compare outcomes of the different THVs and to guide appropriate prosthesis selection. The SCOPE-I (Safety and Efficacy Comparison Of Two TAVI Systems in a Prospective Randomized Evaluation) and -II trials, randomizing the ACURATE neo versus the SAPIEN 3 and CoreValve Evolut R/Evolut PRO prostheses, respectively, are currently enrolling patients and will provide more rigorous data on outcomes with ACURATE neo in comparison with other THVs. In the meantime, a propensity-matched study provides first insights. It compared 311 patients treated with ACURATE neo with 622 SAPIEN 3 patients and showed similar in-hospital complication rates with both devices but significantly fewer pacemaker implantations in ACURATE neo patients. Furthermore, fewer patients with elevated gradients were present in the ACURATE neo group but more patients had PVLs ≥2° (15).

The PVL rate of our series is in line with recent reports for ACURATE neo (7,11,15). Comparing patients with and without post-dilatation, those with post-dilatation had significantly higher PVL rates (5.8% vs. 1.8%; $p < 0.0001$). Post-dilatation is probably more likely in patients with residual PVLs, which might be attributed to differences in baseline characteristics, emphasizing the need for careful patient selection and sizing. Interestingly, PVL ≥2° was observed only in patients with moderate and severe calcification. This is in line with a recent study that included 425 ACURATE neo patients in which PVLs were significantly more frequent in patients with moderate and severe calcification compared with those with mild calcification when PVL ≥2° occurred in only 1.6% of patients (16).

The low mean gradients and large effective orifice areas observed in this registry likely reflect the supra-annular design of the prosthesis. The particularly low gradients also contributed to the similar rate of device failure for ACURATE neo and SAPIEN 3 in a propensity matched comparison despite the higher PVL rate in the ACURATE neo group (15). The supra-annular design is potentially of particular advantage in patients with small annuli. A propensity-matched comparison in patients with small annuli showed no statistically significant difference in clinical outcomes and PVL rates compared with the SAPIEN 3 prosthesis, but lower mean gradients and larger effective orifice area indexes for ACURATE neo as well as a lower rate of severe patient-prosthesis mismatch (11).

STUDY LIMITATIONS. The SAVI-TF registry has a number of limitations. It is a single-arm study, and it is difficult to compare outcomes with those observed in other studies with different THVs. It is a real-world observational registry, and as such, echocardiography and other assessments were performed according to standard practice. There was limited monitoring. Echocardiographic outcomes and adverse events were based on site-reported data and were not independently adjudicated. Despite these limitations, the study does represent the largest clinical experience with the ACURATE neo valve and thereby provides useful information to clinicians about outcomes with ACURATE neo in routine clinical practice.

CONCLUSIONS

The international, multicenter SAVI-TF registry confirmed the safety and performance of the ACURATE neo THV. Outcomes through 1 year were favorable, with low mortality and pacemaker rates and good hemodynamic status.

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ADDRESS FOR CORRESPONDENCE: Dr. Won-Keun Kim, Kerckhoff Heart Center, Department of Cardiology, Benekestrasse 2-8, 61231 Bad Nauheim, Germany. E-mail: w.kim@kerckhoff-klinik.de.

PERSPECTIVES

WHAT IS KNOWN? The ACURATE neo THV has shown encouraging outcomes in several studies.

WHAT IS NEW? We report the largest series of patients at 1 year treated with the ACURATE neo available to date. The very low mortality and pacemaker rates and the good hemodynamic status in patients treated under real-world conditions offer encouragement for this relatively new technology.

WHAT IS NEXT? As a next step, results from randomized controlled trials are needed to gain further insights on safety and performance in relation to other THVs.

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KEY WORDS ACURATE neo, aortic stenosis, TAVR, transcatheter aortic valve replacement, transfemoral

APPENDIX For a supplemental table, please see the online version of this paper.