Effectiveness and Safety of the ACURATE Neo Prosthesis in 1,000 Patients With Aortic Stenosis

Won-Keun Kim, MD[a,b,*], Helge Möllmann, MD, PhD[c], Christoph Liebetrau, MD, PhD[a], Matthias Renker, MD[a], Thomas Walther, MD, PhD[d], and Christian W. Hamm, MD, PhD[a,b]

The ACURATE *neo* transcatheter heart valve has demonstrated a balanced profile with low rates of permanent pacemaker implantation, low risk of coronary obstruction, and favorable hemodynamic properties whilst having an acceptable rate of ≥moderate paravalvular leakage (PVL). Here, we report in-hospital results and assess the learning curve for implantation of the ACURATE *neo* device in a large, single-center cohort. The cohort of this retrospective, observational study comprised 1,000 consecutive patients with severe aortic stenosis who underwent transfemoral transcatheter aortic valve implantation using the ACURATE *neo* prosthesis between May 2012 and December 2019. We determined procedural outcomes with emphasis on PVL and analyzed the learning curve. The median age was 81.9 years [IQR 78.8; 85.1], and the Euroscore II was 4.2% [IQR 2.7; 7.3]. The rate of PVL ≥moderate measured by echocardiography at discharge was 3.7% (37 of 988). We observed a learning curve, with a decline in ≥moderate PVL from 6.7% in the first quartile to 0.8% in the last quartile, that was related to better patient selection, more oversizing, and consideration of the amount and distribution of aortic valve calcification. In this thus far largest single-center experience using the ACURATE *neo* prosthesis, we demonstrate that after completing a learning curve and observation of precepts that include patient selection, careful sizing, and procedural aspects, the rate of ≥moderate PVL may be reduced to <1%. **(Am J Cardiol 2020;131:12−16)**

The ongoing evolution of transcatheter aortic valve implantation (TAVI) together with an accelerated technological progress,[1] leads to the availability of a variety of transcatheter heart valve (THV) prostheses with specific principles of deployment.[2,3] Among the self-expanding THV, the ACURATE *neo* (Boston Scientific, Marlborough, Massachusetts) is commonly used across Europe, Asia, South America, Canada, and Australia. In numerous observational studies, it has demonstrated a balanced profile, with low rates of permanent pacemaker implantation, low risk of coronary obstruction, and favorable hemodynamic properties whilst having a higher but acceptable rate of ≥moderate paravalvular leakage (PVL) compared with other THV.[4−9] Recently, we have shown that careful selection, sizing, and positioning of the prosthesis is a prerequisite for good procedural results;[10] however, data in the literature are conflicting regarding acute outcomes.[11] Here, we present our experience using the ACURATE *neo* device in a large, single-center cohort, including in-hospital results according to VARC-2 criteria and assessment of the learning curve.

Methods

The study population comprised 1,000 consecutive patients with severe aortic stenosis who underwent transfemoral TAVI using the ACURATE *neo* prosthesis at our center between May 2012 and December 2019. During the study period, a total of 2,406 transfemoral TAVIs were performed using various balloon-expandable and self-expanding prostheses. Device selection was based on comorbidities and MDCT criteria including possible access route, annulus size, coronary distance, and total amount and distribution of aortic valve calcification. Details on the design of the ACURATE *neo* and the implantation technique have been described previously.[12] Sizing was based on the area-derived effective annulus diameter until 2015, and thereafter it was based on the perimeter-derived annulus diameter, which now is the official recommendation. In borderline sizes, additional variables were taken into account, including device landing zone calcification, and other aortic root dimensions.

Baseline characteristics were prospectively documented in a database that included demographics, co-morbidities, risk scores, and echocardiography data. Patients gave informed consent for the procedure. The study adhered to the Declaration of Helsinki and was approved by the local ethics committee.

[a]Kerckhoff Heart Center, Department of Cardiology, Bad Nauheim, Germany; [b]Department of Cardiology, Justus-Liebig University of Giessen, Giessen, Germany; [c]Department of Cardiology, St. Johannes Hospital, Dortmund, Germany; and [d]Department of Cardiac Surgery, Johann-Wolfgang-Goethe University, Frankfurt, Germany. Manuscript received April 19, 2020; revised manuscript received and accepted May 27, 2020.

See page 16 for disclosure information.

*Corresponding author: W. Kim, MD, Kerckhoff Heart Center, Department of Cardiology, Benekestrasse 2-8, 61231 Bad Nauheim, Tel.: +49 (0)6032-996-2246; fax: +49 (0)6032-996-2313.

E-mail address: w.kim@kerckhoff-klinik.de (W.-K. Kim).

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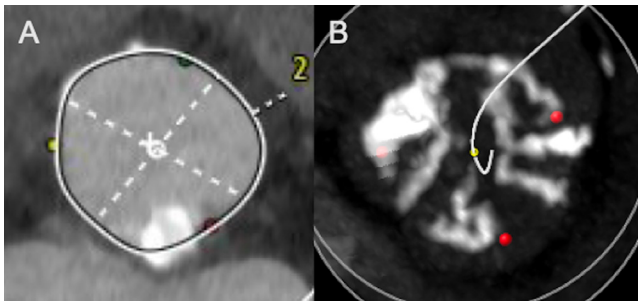

Figure 1. Compact peri-annular calcium. *Panel A:* Intra-annular protrusion of a calcium nodule. *Panel B:* Compact calcification in the peri-annular region of the non-coronary cusp.

Preprocedural multidetector computed tomography (MDCT) was performed using a 64-slice or a 192-slice dual-source scanner (Somatom Definition or Force, Siemens Healthcare, Forchheim, Germany) as previously described.[13] MDCT datasets were analyzed using a dedicated software (3mensio, Pie Medical, The Netherlands). We performed standard measurements of the aortic root and determined the cover index [CI = 100 × (prosthesis diameter−MDCT annulus size)/prosthesis diameter] for the perimeter-derived annulus diameter and calculated the ratio between annulus and sinotubular junction height (annulus/STJ height-ratio). The aortic valve calcium score (AVCS) was measured according to the Agatston method using noncontrast-enhanced MDCT scans.[14] The presence of compact peri-annular calcium was determined by visual estimation of the aortic valve in short axis views and maximum intensity projections (Figure 1).

The primary outcome measure was PVL ≥moderate at discharge, secondary outcome measures were device success according to the Valvular Academic Research Consortium (VARC)-2 criteria,[15] permanent pacemaker implantation (PPI), major stroke, major bleedings, major vascular complications, annular rupture, coronary obstruction, mean prosthesis gradient at discharge, and 30-day mortality. PVL was assessed via transthoracic echocardiography immediately postprocedurally (after the deployment of the first prosthesis and postdilatation but prior to bail-out measures including the implantation of a second valve or conversion to surgical aortic valve replacement) and at discharge according to established criteria.[16] For this purpose, transthoracic echocardiograms were independently reviewed by 2 experienced cardiologists, who were blinded to clinical data with mutual consent in the case of disagreement.

Patients who required conversion to surgical aortic valve replacement or underwent a second valve implantation were excluded from PVL analysis at discharge. The implantation depth of the prosthesis was determined upon final angiography as described previously.[7] Follow-up data on 30-day mortality were obtained during outpatient visits, from the most recent medical reports, or via telephone interview.

Continuous variables are presented as median and interquartile range [IQR]; categorical data are presented as numbers and percentages. Continuous data were compared with the Mann-Whitney U test or Kruskal-Wallis rank test. For categorical data, either the 2-sided Fisher's exact or the Chi-square test was applied, as appropriate. Intra- and

Table 1
Baseline characteristics and procedural outcomes

Variable	Total cohort (n=1000)
Age (years)	81.9 [78.6-85.1]
Women	660 (66.0%)
Logistic EuroSCORE I (%)	19.3 [13.5-28.2]
EuroSCORE II (%)	4.2 [2.6-7.2]
Body mass index (kg/m^2)	26.8 [24.0-30.6]
eGFR (ml/min/1.73 m^2)	65.0 [46.0-85.0]
Hypertension	907 (90.7%)
Diabetes mellitus	326 (32.6%)
COPD	183 (18.3%)
Coronary artery disease	568 (56.8%)
Prior stroke	124 (12.4%)
Atrial fibrillation	394 (39.4%)
Previous pacemaker	111 (11.1%)
Ejection fraction (%)	65.0 [57.0-65.0]
Pmean (mmHg)	41.0 [31.0-50.0]
Aortic valve area (cm^2)	0.7 [0.6-0.8]; n=976
Annulus perimeter (mm)	23.8 [22.7-25.0]
Annulus area (mm)	23.3 [22.3-24.5]
LVOT diameter (mm)	22.6 [21.0; 24.2]; n=989
Sinus of Valsalva diameter (mm)	30.6 [28.8; 32.8]; n=998
Sinotubular junction diameter (mm)	27.4 [25.5; 29.3]; n=996
Sinotubular junction height (mm)	21.9 [20.3; 23.7]; n=998
Annulus/STJ height-ratio	1.08 [1.01; 1.17]; n=997
Ascending aorta diameter (mm)	32.9 [30.9; 35.7]; n=995
Aortic valve calcium score (AU)	2084 [1449; 2886]; n=985
Compact peri-annular calcium	176 (17.6%)
Prosthesis size	
S	254 (25.4%)
M	427 (42.7%)
L	319 (31.9%)
Cover index perimeter (%)	5.21 [3.09; 7.33]
Pre-dilatation	661 (66.1%)
Post-dilatation	387 (38.7%)
Implantation depth (mm)	
NCC	5.0 [4.0-6.0]; n=994
LCC	6.0 [4.0-6.0]; n=994
Procedure time (minutes)	36.0 [30.0-45.0]
Fluoroscopy time (minutes)	8.9 [6.6-12.2]
Contrast agent (ml)	88.0 [66.0; 110.0]
Device success (VARC-2)	906 (90.6%)
All-cause 30-day mortality	26 (2.6%)
Ejection fraction$_{post}$ (%)	65.0 [60.0; 65.0]; n=989
Pmean$_{post}$ (mmHg)	8.0 [6.0; 11.0]; n=981
Pmean≥20 mmHg	20/981 (2.0%)
AVA$_{post}$ (cm^2)	1.6 [1.4; 1.8]; n=895
PVL ≥moderate procedural	48/993 (4.8%)
PVL ≥moderate discharge	36/976 (3.7%)
Pacemaker implantation	94 (9.4%)
Implantation of a second valve	17 (1.7%)
Conversion to sternotomy	14 (1.4%)
Device embolization	15 (1.5%)
Aortic root injury	0
Aortic dissection	1 (0.1%)*
Ventricular septum defect	1 (0.1%)**
Ventricular perforation	7 (0.7%)
Coronary obstruction	0
Major bleeding	82 (8.2%)
Major vascular complication	88 (8.8%)
Major stroke	21 (2.1%)
AKI stage 2 or 3	28 (2.8%)

Data are displayed as median [Interquartile Range] and n (%).

Abbreviations: AKI = acute kidney injury; AVA$_{post}$ = post-procedural aortic valve area; COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate; ejection fraction$_{post}$ = post-procedural EF; LCC = left-coronary cusp; NCC = non-coronary cusp; Pmean = mean transaortic gradient; Pmean$_{post}$ = post-procedural mean transaortic gradient; PVL = paravalvular leakage; VARC = Valvular Academic Research Consortium.

* Aortic dissection occurred spontaneously after a delay of 2 weeks following the index-procedure.

** Due to pre-dilatation, there was no post-dilatation.

Table 2
Predictors of paravalvular leak

Variable	Univariate Analysis Odds ratio [95% CI]	P	Multivariable Analysis Odds ratio [95% CI]	p
Prosthesis size	1.08 [0.89; 1.31]	0.444		
AVCS, per AU	1.0006 [1.0004; 1.0009]	<0.001	1.0003 [1.0001; 1.0006]	<0.001
Compact peri-annular calcification	9.20 [4.99; 16.93]	<0.001	6.15 [3.13; 12.08]	<0.001
Bicuspid aortic valve	1.88 [0.72; 4.93]	0.201		
Cover index annulus, per %	0.87 [0.79; 0.95]	0.001	0.89 [0.80; 0.99]	0.026
Annulus/STJ height-ratio	0.07 [0.01; 0.94]	0.045	0.03 [0.02; 0.45]	0.012
Pmean, per mmHg	1.01 [0.99; 1.03]	0.140		
Implantation depth at NCC, per mm	0.93 [0.83; 1.05]	0.254		
Implantation depth at LCC, per mm	0.85 [0.75; 0.97]	0.012		

Abbreviations: AVCS = aortic valve calcium score; CI = confidence interval; NCC = non-coronary cusp; LCC = left-coronary cusp; Pmean = mean transaortic gradient; STJ = sinotubular junction.

Table 3
ACURATE *neo* learning curve

Variable	Quartile 1 (Case 1−250)	Quartile 2 (Case 251−500)	Quartile 3 (Case 501−750)	Quartile 4 (Case 751-1000)	p
Cover index (%)	3.87 [1.86; 6.37]	5.13 [3.04; 7.30]	5.38 [3.39; 7.52]	6.17 [4.20; 7.90]	<0.001
Aortic valve calcium score (AU)	2395 [1646; 3111]	2049 [1494; 2872]	1955 [1385; 2893]	1989 [1280; 2726]	<0.001
Compact peri-annular Ca^{++} formation	64 (25.6%)	41 (16.4%)	42 (16.8%)	29 (11.6%)	0.001
Implantation depth at LCC (mm)	5.0 [3.0; 6.0]	6.0 [5.0; 7.0]	6.0 [4.0; 6.0]	5.0 [4.0; 6.0]	<0.001
Device success (VARC-2)	171 (85.5%)	177 (88.5%)	181 (90.5%)	186 (93.0%)	0.002
≥moderate PVL at discharge	18/243 (7.4%)	7/241 (2.9%)	9/246 (3.7%)	2/246 (0.8%)	0.001
≥moderate PVL procedural	21/246 (8.5%)	13/249 (5.2%)	11 (4.4%)	3 (1.2%)	0.002
Permanent pacemaker	25 (10.0%)	26 (10.4%)	26 (10.4%)	17 (6.8%)	0.444
TVH embolization	5 (2.0%)	4 (1.6%)	3 (1.2%)	3 (1.2%)	0.496
Need for second THV	3 (1.2%)	7 (2.8%)	4 (1.6%)	3 (1.2%)	0.462
Major vascular complication	32 (12.8%)	26 (10.4%)	14 (5.6%)	16 (6.4%)	0.013
Major stroke	4 (1.6%)	7 (2.8%)	5 (2.0%)	5 (2.0%)	0.820
30-day all-cause mortality	12 (4.8%)	9 (3.6%)	3 (1.2%)	2 (0.8%)	0.012

Abbreviations: LCC = left coronary cusp; PVL = paravalvular leakage; THV = transcatheter heart valve; VARC = Valvular Academic Research Consortium.

interobserver reliability for recognizing compact peri-annular calcium was analyzed on 50 randomly selected cases by means of Cohen's Kappa statistic. To assess the learning curve of the center, we compared relevant outcomes across quartiles of all TAVI procedures using the ACURATE *neo*. To determine predictors of ≥moderate PVL, we performed a multivariable logistic regression and included all variables with p values <0.1 in the univariate analysis. A 2-sided p value <0.05 was considered significant. For all statistical analyses, STATA IC version 16.0 (StataCorp LCC, Texas) was used.

Results

Baseline characteristics of the study population are summarized in Table 1. The median age was 81.9 years [IQR 78.8; 85.1], and the Euroscore II was 4.2% [IQR 2.7; 7.3]. PVL ≥moderate was detected immediately after the procedure in 48 of 993 (4.8%), whereas at discharge the rate was 3.7% (36 of 976). Of note, among the cases with postprocedural ≥moderate PVL, postdilatation had either not been performed (33.3% [16 of 48]: malpositioning n = 3; inaccurate estimation by the operator n = 13) or was ineffective due to a small balloon size (>2 mm smaller than the perimeter-derived annulus size in 6.3% [3 of 48]). All-cause mortality at 30 days was 2.6%. Device success according to VARC-2 criteria was met in 90.5%. The proportion of increased gradients ≥20 mmHg was 2.0% (20 of 981) and this increase was more prevalent in small valves (size S 11 of 250 [4.4%], size M 7 of 419 [1.7%]; size L 2 of 312 [0.6%]; p = 0.006). Further procedural results are presented in Table 1. Intraobserver agreement for recognizing compact peri-annular calcium was 92% with an excellent Cohen's Kappa value of 0.83, whereas interobserver agreement was 80% with a moderate Cohen's Kappa of 0.58.

Table 2 depicts the results of univariate and multivariable regression analysis of predictors of PVL. Independent predictors of procedural ≥moderate PVL were AVCS, the presence of a peri-annular conglomerate of calcium, the cover index of the annulus, and the annulus/STJ height-ratio.

Table 3 shows an analysis of the learning curve of the center. Across the quartiles of patients enrolled, we employed more oversizing (higher cover index) and selected patients with less aortic valve calcification and less frequent peri-annular compact calcium formation. Hence, the rates of ≥moderate PVL decreased (Figure 2), whereas the frequencies of PPI, THV embolization, the use of a second THV, and stroke

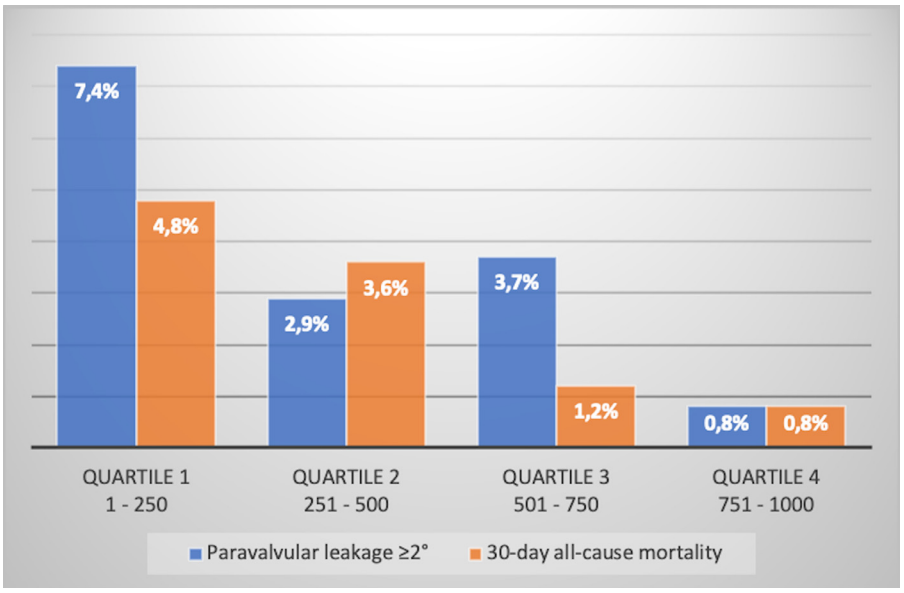

Figure 2. Center learning curve. Learning curve across quartiles of 1,000 ACURATE *neo* cases with respect to paravalvular leakage and 30-day mortality.

remained constant. Of note, the higher prosthesis position in the last quartile was associated with a numerically lower PPI rate whilst not negatively affecting the incidence of ≥moderate PVL.

Discussion

In this large, single-center experience we demonstrate favorable procedural outcomes of a newer generation of self-expanding THV in a contemporary TAVI cohort. However, in comparison to modern THV with higher radial force, rates of ≥moderate PVL are comparably high for the ACURATE *neo* prosthesis with its somewhat lower radial force, which is generally perceived as a disadvantage involving limitations in severely calcified anatomies. On the other hand, the lower radial force accounts for the advantages of the ACURATE *neo,* including low rates of PPI and low risk of coronary obstruction or aortic root injury.

It is clear from our results that there was a considerable center learning curve (Central Illustration) with a significant improvement in outcomes parallel to a significant reduction of relevant ≥moderate PVL over time that might be related to proper sizing and better patient selection. At the same time, the incidence of PPI, THV embolization, the implantation of a second valve, and stroke remained constant. The decrease in the rate of vascular complications may be ascribed primarily to a transition to smaller introducer sheaths in the second half of our experience.[17] With respect to the declining 30-day mortality across the quintiles, we assume a multifactorial process that includes the overall lower rate of procedural complications, growing center experience, and selection of lower risk patients.

Across the literature, rates of PVL ≥moderate using the ACURATE *neo* device range from 1.4% [7] to 9.0% [11] and are most commonly reported to be approximately 4%. This depends mainly on the study population and whether there was adjudication by a core laboratory. Indeed, most existing data on PVL were site-reported, which poses a major limitation and precludes comparability. The rate of PVL ≥moderate at discharge of 3.7% overall in the present analysis lies within the range of previously reported values; however, the most compelling aspect of our data is the continuous improvement of results with increasing site experience, leading to a rate of PVL ≥moderate below 1% in the last quartile. We assume that careful patient selection that takes into account the amount and distribution of aortic valve calcification and the employment of sufficient oversizing contributes to better outcomes. Consistent with our previous investigation of PVL predictors that included peri-annular calcium volume,[10] in the current analysis, the presence of calcium conglomerates in the peri-annular region, as assessed visually, was independently associated with PVL ≥2°. A limitation of this method may be its subjective character along with a rather poor reproducibility. Hence, the measurement of peri-annular calcium volume as shown previously may be more objective.

Another procedural aspect that should be highlighted is the consequent implementation of effective postdilatation, which was not observed in 16 cases. Thus, an important prerequisite for employment of postdilatation will be a proper intra-procedural estimation of the PVL grade.

A deeper position as measured at the left coronary cusp was associated with less PVL in the univariate analysis, but not in the multivariable analysis. In contrast, a higher prosthesis position that was noted in the last quartile did not negatively affect the incidence of ≥moderate PVL, but may have contributed to a numerically lower PPI rate (Table 3). Hence, in cases with a less calcified device landing zone and appropriate sizing, the implantation depth may play less of a role regarding the incidence of PVL. However, a deliberately higher positioning of the prothesis should not be pursued, as this may increase the risk of device embolization.

Apart from the inherent limitations of a retrospective single-center study, a major shortcoming is the absence of

echocardiographic core laboratory adjudication, in particular regarding the quantification of PVL. Measurement of the implantation depth on angiography may be imprecise and not display the true position, in particular when using the implantation plane. Nonetheless, these measurements allow for a comparative assessment of the impact of implantation depth in a large number of patients.

In conclusion, this thus far largest single-center experience using the ACURATE *neo* prosthesis demonstrates that after completing a learning curve and observation of precepts that include patient selection, careful sizing, and procedural aspects, the rate of PVL ≥moderate may be reduced to <1%.

Authors' Contribution

Helge Möllmann: drafting of the manuscript and revising it, final approval of the manuscript; *Christoph Liebetrau:* drafting of the manuscript and revising it; *Matthias Renker:* acquisition, analysis and interpretation of data, drafting of the manuscript and revising it; *Thomas Walther:* drafting of the manuscript and revising it, final approval of the manuscript; *Christian W. Hamm:* drafting of the manuscript and revising it, final approval of the manuscript.

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Disclosures

WK: Proctor fees/speaker honoraria from Boston Scientific, Abbott, Edwards Lifesciences, Medtronic; HM: Proctor fees/speaker honoraria from Abbott, Boston Scientific, Biotronic, Edwards Lifesciences; CL: lecture honoraria from Abbott, Astra Zeneca, Bayer, Berlin Chemie, Boehringer Ingelheim, Daiichi-Sankyo, and Pfizer – Bristol-Myers-Squibb; meeting expenses from Bayer and Daiichi-Sankyo; MR: lecture honoraria from Abbott; CH: Advisory board Medtronic. All other authors declare that they have no conflict of interest.

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