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The ACURATE Neo Transcatheter Heart Valve

A Comprehensive Analysis of Predictors of Procedural Outcome

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ABSTRACT

OBJECTIVES The aim of this study was to perform a comprehensive analysis of factors that affect procedural outcomes of transcatheter aortic valve replacement using the ACURATE neo prosthesis (Symetis/Boston, Ecublens, Switzerland).

BACKGROUND Predictors of procedural outcomes using the ACURATE neo prosthesis are poorly understood.

METHODS A total of 500 patients underwent transfemoral aortic valve replacement with the ACURATE neo prosthesis. Device landing zone calcification was stratified as severe, moderate, or mild. Anatomic and procedural predictors of second-degree or greater paravalvular leakage and permanent pacemaker implantation were assessed.

RESULTS Post-procedural second-degree or greater paravalvular leakage was more frequent with increasing device landing zone calcification (mild 0.8% vs. moderate 5.0% vs. severe 13.0%, $p < 0.001$), whereas permanent pacemaker implantation was independent of device landing zone calcification. More severe periannular calcification (odds ratio [OR]: 1.007; 95% confidence interval [CI]: 1.003 to 1.010; $p < 0.001$), less oversizing (OR: 0.867; 95% CI: 0.773 to 0.971; $p = 0.014$), the presence of annular plaque protrusions (OR: 2.756; 95% CI: 1.138 to 6.670; $p = 0.025$), and aortic movement of the delivery system after full deployment (OR: 5.593; 95% CI: 1.299 to 24.076; $p = 0.02$), and sinotubular junction height (OR: 1.156; 95% CI: 1.007 to 1.328; $p = 0.04$) independently predicted second-degree or greater paravalvular leakage. Predictors of permanent pacemaker implantation were pre-existing right bundle branch block (OR: 3.122; 95% CI: 1.261 to 7.731; $p = 0.01$) and more oversizing (OR: 1.111; 95% CI: 1.009 to 1.222; $p = 0.03$).

CONCLUSIONS Successful transcatheter aortic valve replacement using the ACURATE neo device predominantly depends on careful patient selection with appropriate oversizing and taking into account the individual anatomy and calcium distribution of the aortic root. (J Am Coll Cardiol Intv 2018;■:■–■) © 2018 by the American College of Cardiology Foundation.

Transcatheter aortic valve replacement (TAVR) has become the standard therapy for elderly patients with aortic stenosis who are at high surgical risk or inoperable (1). Moreover, recent data have demonstrated that TAVR is noninferior to conventional surgery in intermediate-risk populations (2,3), which has been recently reflected in clinical guidelines (4). The majority of improvements

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ABBREVIATIONS AND ACRONYMS

AUC = area under the curve

CI = confidence interval

CV_{Ann} = calcium volume of the annular region

CV_{DLZ} = calcium volume of the device landing zone

DLZ = device landing zone

LVOT = Left ventricular outflow tract

MDCT = multidetector computed tomographic

PPI = permanent pacemaker implantation

PVL = paravalvular leakage

RBBB = right bundle branch block

STJ = sinotubular junction

TAVR = transcatheter aortic valve replacement

in the field of TAVR are related to accumulation of knowledge and experience and the development of novel devices and delivery systems. The ACURATE neo (Symetis/Boston, Ecublens, Switzerland) is a new-generation self-expanding device that is characterized by an X-shaped stent design with a unique mechanism of deployment (5). Data from the Conformité Européene mark trial and a large post-market registry demonstrate favorable outcomes with a high rate of procedural success and low 30-day and 1-year mortality (6,7). In this study, we analyzed anatomic and procedural predictors of procedural success in a large cohort of patients implanted with the ACURATE neo valve at our institution.

METHODS

STUDY COHORT. A total of 500 consecutive patients with severe aortic stenosis undergoing transfemoral TAVR using the ACURATE neo prosthesis at our center between May 2012 and September 2017 constituted the study population. The design of the ACURATE neo prosthesis (**Figure 1**) and details of the implantation technique have been described previously (5). In brief, for stable positioning of the device, it is recommended to keep the delivery system in the outer curvature of the arch and to maintain slight forward tension. A radiopaque intersection line in the stent body, commonly referred to as the "marker band," is frequently used to indicate the correct annular position. The deployment of the device consists of step 1, in which the upper crown and the stabilization arches are released, followed by the full release of the prosthesis in step 2. The prosthesis size was selected in adherence to the recommendation of the manufacturer on the basis of the maximum area-derived effective annular diameter. The final decision was at the discretion of the operator and, particularly regarding borderline sizes, depended on additional factors, including balloon sizing, patient stature, and device landing zone (DLZ) calcification. Baseline data including demographics, comorbidities, risk scores, and echocardiographic results were drawn from a prospective database. Informed consent was obtained from each patient. The study was conducted in accordance with the Declaration of Helsinki and was approved by the local ethics committee.

FACTORS WITH POTENTIAL IMPACT ON PROCEDURAL SUCCESS. Anatomic factors. Anatomic parameters were assessed with pre-procedural multidetector computed tomographic (MDCT) imaging, which was performed using a 64-slice or a 192-slice dual-source scanner (Somatom Definition or Force, Siemens Healthcare, Forchheim, Germany) as previously described (8). Datasets were analyzed offline using dedicated U.S. Food and Drug Administration-approved software (3mensio, Pie Medical, Amsterdam, the Netherlands) by a single reader with extensive experience in cardiac imaging who was blinded to clinical data. In addition to standard measurements, we determined the cover index (100 × [prosthesis diameter − MDCT annular size]/prosthesis diameter) for area- and perimeter-derived annulus diameter in systole and diastole, annular eccentricity (maximum/minimum annular diameter), and the aortoannular angle; we also identified annular plaques with intraluminal protrusion <4 or ≥4 mm (**Figure 2**) and noted the presence of a bicuspid aortic valve. The total calcium load of the DLZ was measured according to the Agatston method using non-contrast-enhanced MDCT imaging (9). The calcium volume of the DLZ (CV_{DLZ}) was measured on contrast-enhanced MDCT images using a scan-specific threshold as described elsewhere (10). Furthermore, we stratified according to CV_{DLZ} into groups of severe (>75th percentile), moderate (25th to 75th percentiles), and mild (<25th percentile) DLZ calcification (11). The aortic valve complex was divided into 3 regions in the craniocaudal axis for separate determination of the calcium volume of the aortic valve, calcium volume of the left ventricular outflow tract, and calcium volume of the annular region (CV_{Ann}) as specified in **Figure 2**. The calcium distribution across the 3 leaflets (left coronary, right coronary, and noncoronary) was measured for the aortic valve complex (CV_{DLZ} for the left, right, and noncoronary leaflets) and for each region (calcium volume of the aortic valve for the left, right, and noncoronary leaflets; calcium volume of the left ventricular outflow tract for the left, right, and noncoronary leaflets; and CV_{Ann} for the left, right, and noncoronary leaflets) (**Figure 2**). Asymmetrical distribution was determined by calculating the maximum absolute difference between the lowest and highest value of the calcium volume of each leaflet region (ΔCV_{DLZ}, Δ calcium volume of the aortic valve, Δ calcium volume of the left ventricular outflow tract, and ΔCV_{Ann}) (12).

Procedural factors. The implantation depth, relative expansion, and coaxial position of the prosthesis were analyzed on final angiography as previously described (Online Figure 1) (13). In addition, we recorded the position of the delivery system in relation to the ascending aorta and aortic arch (outer