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Transapical Transcatheter Aortic Valve for Severe Aortic Regurgitation

Expanding the Limits

Daniel Wendt, MD, PhD,* Philipp Kahlert, MD, PhD,† Susanne Pasa, MD,* Karim El-Chilali, MD,† Fadi Al-Rashid, MD,† Konstantinos Tsagakis, MD,* Daniel Sebastian Dohle, MD,* Raimund Erbel, MD, PhD,† Heinz Jakob, MD, PhD,* Matthias Thielmann, MD, PhD*

ABSTRACT

OBJECTIVES This study sought to evaluate the self-expandable ACURATE TA device (Symetis SA, Ecublens, Switzerland) in a cohort of patients with pure aortic regurgitation (AR).

BACKGROUND Transcatheter aortic valve replacement (TAVR) has been initially considered as an alternative for high-risk patients with aortic stenosis. Although the current experience is limited, TAVR might be also an alternative to treat patients with pure, severe AR.

METHODS Between April 2012 and December 2013, a total of 8 high-risk patients with pure, severe AR were enrolled (grade III+). Clinical and hemodynamic data as well as data on device and procedure parameters and outcomes were collected.

RESULTS Patient mean was 72.5 ± 8.4 years, and 37.5% of patients were female. Logistic EuroSCORE was 34.0 ± 7.9% and the Society of Thoracic Surgeons score was 7.3 ± 3.3% on average. Two patients had undergone emergency aortic operation before due to acute type A aortic dissection, and both were treated by replacement of the ascending aorta (including root reconstruction) and the aortic arch combined with or without E-vita Open stent graft (Jotec GmbH, Hechingen, Germany) (January 2011 and March 2012), whereas the other patients experienced primary AR. All patients underwent successful transapical TAVR with the transapical ACURATE TA device (size small, n = 1, size medium, n = 3, size large, n = 4) without any intraprocedural complications according to the Valve Academic Research Consortium 2 criteria. Post-procedure AR grade I+ or lower, as revealed by transoesophageal echocardiography and angiography, was present in all 8 patients. At 30 days, the stroke incidence and all-cause mortality rate were 0%.

CONCLUSIONS This small single-center series demonstrates the feasibility of transapical TAVR with the self-expandable ACURATE TA device in high-risk patients with severe AR. (J Am Coll Cardiol Intv 2014;7:1159–67)

Transcatheter aortic valve replacement (TAVR) has been well established in the treatment of high-risk patients presenting with aortic valve stenosis and has changed the paradigms in the treatment of aortic valve stenosis (1,2). The original concept of this technique is based in principle on implanting an oversized balloon- or self-expandable transcatheter heart valve (THV) into the calcified native aortic annulus (3). As a result, aortic calcification is presumably essential for stable fixation of the stent frame. This follows from the fact that pure, severe aortic regurgitation (AR) has been considered a relative contraindication to TAVR due to the absence of aortic calcification.

The purpose of the present study was therefore to evaluate the feasibility and early results of off-label

From the *Department of Thoracic and Cardiovascular Surgery, West-German Heart Center Essen, University Hospital Essen, Germany; and the †Department of Cardiology, West-German Heart Center Essen, University Hospital Essen, Essen, Germany. Drs. Kahlert and Wendt are proctors for Edwards Lifesciences. Dr. Thielmann is a proctor for Symetis SA. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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ABBREVIATIONS AND ACRONYMS

AAD = acute aortic dissection

AR = aortic regurgitation

NYHA = New York Heart Association

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

TEE = transesophageal echocardiography

TTE = transthoracic echocardiography

VARC = Valve Academic Research Consortium

transapical TAVR by the use of the self-expandable and self-positioning ACURATE TA (Symetis SA, Ecublens, Switzerland) THV in a cohort of high-risk patients with pure AR.

METHODS

STUDY DESIGN. The present study was a prospective, nonrandomized, single center feasibility study including eight consecutive patients, who underwent transapical TAVR with the ACCURATE TA device at the West-German Heart Center Essen between April 2012 and December 2013. The present study obtained institutional review board approval according to the Declaration of Helsinki. Only high-risk patients with a logistic EuroSCORE >20% were enrolled in the present study. The indication for TAVR in the individual patient was discussed for each patient in an interdisciplinary consensus conference (heart team) of cardiologists and cardiac surgeons, and the patient's or physician's preference alone was not considered adequate for decision making. In addition, all patients were informed in detail about the TAVR procedure and the off-label use of the ACURATE TA device, and all patients gave written informed consent.

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The primary study endpoint was in-hospital mortality, defined as all causes of death within 30 days, including all enrolled patients. Follow-up was also performed. Patient and operative demographic characteristics were recorded in a prospective institutional database and retrospectively extracted and evaluated. Echocardiographic data were stored in an institutional parallel workflow platform (Horizon Cardiology, Medcon/McKESSON, San Francisco, California). Chronic obstructive pulmonary disease was defined according to the EuroSCORE definition. Survival was obtained by active follow-up. All outcomes were reported according to the standardized Valve Academic Research Consortium (VARC 2) criteria.

ECHOCARDIOGRAPHY. Preoperative echocardiographic assessment. *Transthoracic echocardiography.* Preoperative transthoracic 2-dimensional echocardiographic standard views were obtained with patients in the left lateral supine position using a standard ultrasound system with a 1- to 5-MHz (S5-1) probe (iE33, Philips Medical Systems, Andover, Massachusetts). Left ventricular dimensions were measured according to the recommendations of the American Society of Echocardiography. Standard gray-scale images were obtained in the standard parasternal (long and short axis) and apical views (2- and 4-chamber and apical long-axis views). Doppler flow data were acquired from the left ventricular outflow tract region in the pulsed-wave mode and from the aortic valve in the continuous-wave mode in the apical 5-chamber view. In case of atrial fibrillation, a representative heartbeat was taken.

Transesophageal echocardiography. Detailed transesophageal echocardiography (TEE) was performed before TAVR. Two-dimensional TEE was performed with the use of a standard Philips i33 ultrasound system with a multiplane (X7-2t) matrix-array probe (Philips Medical Systems). The probe consists of a transducer that provides high-resolution images and operates at broadband frequencies ranging between 2 and 7 MHz. Pre-procedural TEE was performed after administration of topical anesthesia of the pharynx and application of intravenous sedation (midazolam), after which the probe was introduced into the esophagus. Using the short-axis view, the opening of the insufficient aortic valve was captured, and the highest quality loops were viewed and evaluated after acquisition as described in the following. The aortic annulus diameter was measured by using the 3-chamber long-axis view at an ~120° angle. The diameter was measured as the largest possible diameter during systole using the inner edge to inner edge as recommended (4,5).

FOLLOW-UP ECHOCARDIOGRAPHIC EXAMINATIONS. All patients underwent a detailed pre-procedural transthoracic echocardiography (TTE) and TEE examination as described previously. Intraoperative TEE was performed with all patients under general anesthesia. Post-procedural TTE was performed during follow-up (3 to 6 months) in all patients. An experienced echocardiographer who did not attend the TAVR procedure performed all transthoracic follow-up evaluations. During follow-up TTE, color Doppler echocardiography was performed after optimizing the Nyquist limit to evaluate the presence of regurgitant valve disease. AR was evaluated according to the current recommendations. The degree of AR was classified according to the VARC-2 criteria (6). Briefly, AR severity was assessed by the grading of an experienced echocardiographer by integrating VARC-2 criteria.

TAVR PROCEDURE. All TAVRs were performed with patients under general anesthesia in a dedicated hybrid operating room offering full functionality for cardiac catheterization, anesthesiology, and cardiac surgery; a cardiopulmonary bypass circuit and clinical perfusion team was kept on stand-by. Competences of the interdisciplinary heart team, consisting of