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Aortic Regurgitation Index Defines Severity of Peri-Prosthetic Regurgitation and Predicts Outcome in Patients After Transcatheter Aortic Valve Implantation

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Objectives The aim of this study was to provide a simple, reproducible, and point-of-care assessment of peri-prosthetic aortic regurgitation (periAR) during transcatheter aortic valve implantation (TAVI) and to decipher the impact of this peri-procedural parameter on outcome.

Background Because periAR after TAVI might be associated with adverse outcome, precise quantification of periAR is of paramount importance but remains technically challenging.

Methods The severity of periAR was prospectively evaluated in 146 patients treated with the Medtronic CoreValve (Minneapolis, Minnesota) prosthesis by echocardiography, angiography, and measurement of the aortic regurgitation (AR) index, which is calculated as ratio of the gradient between diastolic blood pressure (DBP) and left ventricular end-diastolic pressure (LVEDP) to systolic blood pressure (SBP): $[(DBP - LVEDP)/SBP] \times 100$.

Results After TAVI, 53 patients (36.3%) showed no signs of periAR and 71 patients (48.6%) showed only mild periAR, whereas 18 patients (12.3%) and 4 patients (2.7%) suffered from moderate and severe periAR, respectively. The AR index decreased stepwise from 31.7 ± 10.4 in patients without periAR, to 28.0 ± 8.5 with mild periAR, 19.6 ± 7.6 with moderate periAR, and 7.6 ± 2.6 with severe periAR ($p < 0.001$), respectively. Patients with AR index <25 had a significantly increased 1-year mortality risk compared with patients with AR index ≥25 (46.0% vs. 16.7%; $p < 0.001$). The AR index provided additional prognostic information beyond the echocardiographically assessed severity of periAR and independently predicted 1-year mortality (hazard ratio: 2.9, 95% confidence interval: 1.3 to 6.4; $p = 0.009$).

Conclusions The assessment of the AR index allows a precise judgment of periAR, independently predicts 1-year mortality after TAVI, and provides additional prognostic information that is complementary to the echocardiographically assessed severity of periAR. (J Am Coll Cardiol 2012;59:1134–41) © 2012 by the American College of Cardiology Foundation

Transcatheter aortic valve implantation (TAVI) has evolved as an alternative to surgical aortic valve replacement in patients with symptomatic severe aortic stenosis who are considered to be at very high or prohibitive operative risk (1). Although the PARTNER (Placement of AoRTic TraNscathetER Valve) trial recently demonstrated that TAVI is associated with similar mortality at 30 days and 1 year in surgical high-risk patients compared with surgical aortic valve replacement, a number of TAVI-associated drawbacks have been identified, including a higher incidence of peri-prosthetic aortic regurgitation (periAR). Recently published studies report an incidence of moderate/severe periAR after TAVI of approximately 15% to 20% (1–6).

Precise echocardiographic or angiographic quantification of periAR in TAVI patients remains challenging, especially during implantation, despite the recently published Valve Academic Research Consortium (VARC) criteria (7,8).

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However, the importance of accurately defining the severity of periAR immediately after valve implantation (within the catheterization laboratory) is paramount, because increasing evidence suggests that periAR has a significant impact on short- and long-term outcome after TAVI (2,6). Thus, an objective parameter to assess directly and precisely the severity of periAR in TAVI patients during the procedure is essential to take effective countermeasures such as post-dilation, snaring, or valve-in-valve implantation to decrease periAR.

The aim of our study was to provide a simple, reproducible, and point-of-care assessment of periAR during TAVI and to decipher the impact of the aortic regurgitation (AR) index, defined as the ratio of the gradient between diastolic blood pressure (DBP) in the aorta and left ventricular end-diastolic pressure (LVEDP) to systolic blood pressure (SBP), on survival after TAVI.

Methods

Patient population. Patients (N = 146) underwent TAVI with use of the third-generation CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) and were included into this prospective study after written informed consent. Before TAVI, annulus dimension was evaluated with 3-dimensional transesophageal echocardiography (TEE), angiography of the aortic root, and multi-slice computed tomography. The TAVI was performed with biplane fluoroscopy under local anesthesia in combination with a sedative/analgesic treatment. Intraprocedural TEE was not routinely performed, and the procedure was predominantly guided by angiographic control.

Abbreviations and Acronyms

AR = aortic regurgitation
CI = confidence interval
DBP = diastolic blood pressure
HR = hazard ratio
LVEDP = left ventricular end-diastolic pressure
periAR = peri-prosthetic aortic regurgitation
SBP = systolic blood pressure
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography

The primary endpoint of this study was all-cause mortality at 1 year. Clinical outcomes and the degree of periAR were defined according to VARC criteria (7). Information about the cause of death was obtained from the treating hospital, referring cardiologist, or general practitioner. The study was approved by the local ethics committee of the University of Bonn.

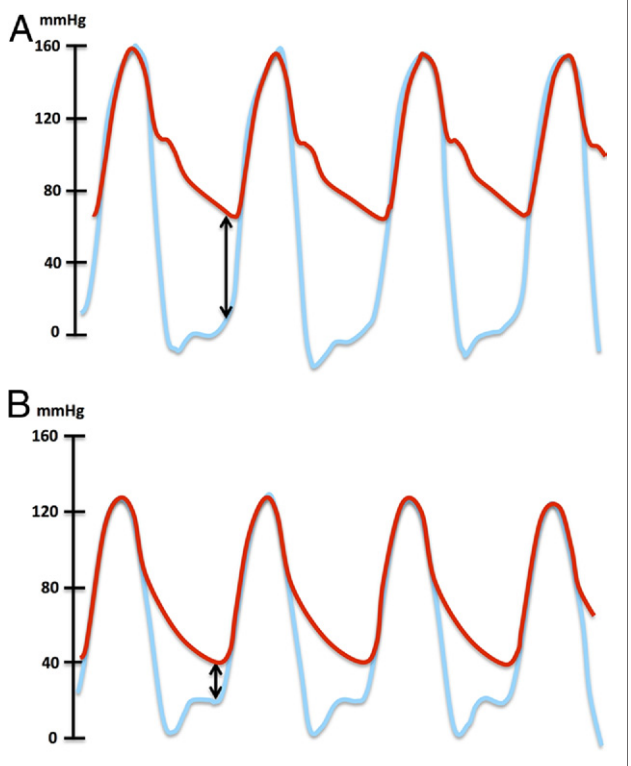

Figure 1 Calculation of the AR Index

Simultaneous determination of left ventricular end-diastolic pressure (LVEDP) **(blue line)** and diastolic blood pressure (DBP) in the aorta **(red line)** in a patient without peri-prosthetic aortic regurgitation (periAR) **(A)** and in a patient with moderate periAR **(B)** for the calculation of the aortic regurgitation (AR) index: ([DBP − LVEDP]/SBP) × 100. **(A)** AR index = ([65 − 10]/160) × 100 = 34.4. **(B)** AR index = ([40 − 20]/130) × 100 = 15.4.

Echocardiographic assessment of periAR. The occurrence and degree of periAR was assessed by angiography immediately after TAVI and by transthoracic echocardiography or TEE until Day 3 after TAVI according to the recently published VARC criteria (7). The evaluation of periAR was performed by a blinded echocardiographer who did not attend the procedure.

Hemodynamic assessment of periAR. In all patients, the pressure in the left ventricle and in the ascending aorta was determined simultaneously after the procedure. The gradient between DBP in the aorta and LVEDP was calculated over several cardiac cycles to evaluate the severity of periAR (Fig. 1). To adjust the gradient for the respective SBP of the patient, we calculated the dimensionless AR index according to the following formula: [(DBP − LVEDP)/SBP] × 100. For our analysis, we used the final calculation of the AR index just before the end of the TAVI procedure (mostly within 10 to 15 min after valve deployment).

Statistical analysis. Data are presented as mean ± SD if normally distributed or as median and interquartile range if not normally distributed. Continuous variables were tested for normal distribution with the use of the Kolmogorov–Smirnov test. Categorical variables are given as frequencies and percentages. For continuous variables, a Student *t* test was performed for comparison between 2 groups. When comparing more than 2 groups, analysis of variance or the Kruskal–Wallis test was used. For categorical variables, the chi-square or Fisher exact test were used for further analysis.

The cutoff value of the AR index for the prediction of all-cause mortality at 1 year was determined in receiver-operating characteristic curve analysis as maximum sum of sensitivity and specificity to minimize both the number