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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.

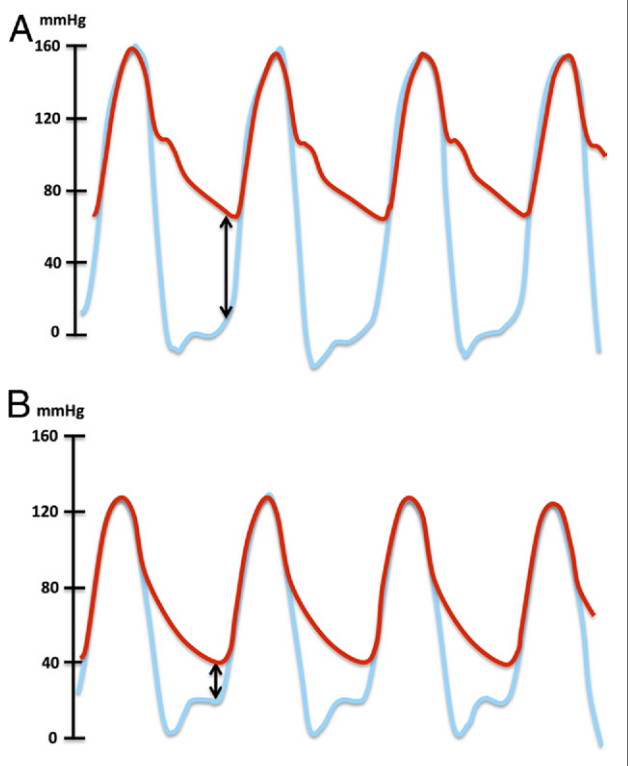

Figure 1 Calculation of the AR Index

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

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of false positive and false negative findings. Survival according to the occurrence of periAR and the AR index cutoff value was determined with use of the Kaplan-Meier method. We performed a multivariate Cox regression analysis to examine the association of the AR index and the severity of periAR with 1-year mortality. Statistical significance was assumed when the null hypothesis could be rejected at $p < 0.05$. Statistical analyses were conducted with PASW Statistics (version 18.0.3, IBM Corporation, Somer, New York) and MedCalc (version 11.6.1.0, MedCalc Software, Mariakerke, Belgium). The investigators initiated the study, had full access to the data, and wrote the manuscript. All authors vouch for the data and the analysis.

Results

Baseline characteristics. The TAVI was performed in 146 patients at high risk for open heart surgery (mean Society of Thoracic Surgeons mortality score: 9.8 ± 7.3%; mean logistic European System for Cardiac Operative Risk Evaluation score: 30.2 ± 18.0%). Echocardiographic assessment of the periAR until Day 3 after TAVI demonstrated that 53 patients (36.3%) had no signs of periAR and 71 patients (48.6%) had only mild periAR, whereas 18 patients (12.3%) and 4 patients (2.7%) suffered from moderate and severe periAR, respectively. The echocardiographic periAR grading strongly correlated with the post-procedural angiogram ($r = 0.88$; $p < 0.001$) (Online Fig. 1). To meet the recently

Table 1 Baseline Characteristics According to the Severity of PeriAR

	All Patients (N = 146)	None/Mild PeriAR (n = 124)	Moderate/Severe PeriAR (n = 22)	p Value
Age (yrs)	80.5 ± 6.6	80.6 ± 6.7	79.6 ± 6.0	0.52
Male	70 (47.9)	53 (42.7)	17 (77.3)	0.003
Logistic EuroSCORE (%)	30.2 ± 18.0	30.0 ± 18.0	31.4 ± 18.1	0.75
STS score: mortality (%)	9.8 ± 7.3	9.9 ± 7.2	9.0 ± 6.6	0.61
Body mass index (kg/m^2)	24.7 (22.1/27.9)	24.8 (22.3/28.0)	23.3 (21.0/27.0)	0.20
Height (cm)	167.2 ± 8.9	166.0 ± 8.1	173.8 ± 10.1	<0.001
Weight (kg)	70.0 (63.0/80.0)	70.0 (63.0/80.0)	70.0 (60.0/89.5)	0.88
Coronary artery disease	89 (61.0)	72 (58.1)	17 (77.3)	0.09
Peripheral artery disease	55 (37.7)	44 (35.5)	11 (50.0)	0.20
Previous MI	43 (29.7)	34 (27.4)	9 (42.9)	0.15
Previous PCI	58 (39.7)	47 (37.9)	11 (50.0)	0.29
Previous CABG	18 (12.3)	14 (11.3)	4 (18.2)	0.37
Previous stroke	37 (25.3)	31 (25.0)	6 (27.3)	0.82
Chronic renal failure	82 (56.2)	67 (54.0)	15 (68.2)	0.22
COPD	40 (27.4)	33 (26.6)	7 (31.8)	0.61
Pulmonary hypertension	54 (37.0)	44 (35.5)	10 (45.5)	0.37
LVEF (%)	44.5 ± 14.5	45.5 ± 14.0	39.1 ± 16.3	0.05
LVEF ≤30%	35 (24.0)	27 (21.8)	8 (36.4)	0.14
Aortic valve area (cm^2)	0.67 ± 0.15	0.68 ± 0.16	0.64 ± 0.14	0.28
Mean aortic gradient (mm Hg)	38.0 (29.0/51.0)	38.0 (29.8/47.3)	44.5 (24.8/58.3)	0.44
Pre-procedural AR				0.65
None	68 (46.6)	60 (48.4)	8 (36.4)	
Mild	64 (43.8)	53 (42.7)	11 (50.0)	
Moderate	13 (8.9)	10 (8.1)	3 (13.6)	
Severe	1 (0.7)	1 (0.8)	0 (0)	
Aortic annulus diameter (mm)	23.5 ± 2.1	23.2 ± 1.9	25.1 ± 2.4	<0.001
Aortic annulus ≥26 mm	21 (14.4)	11 (8.9)	10 (45.5)	<0.001
Balloon valvuloplasty size (mm)	22.0 (20.0/25.0)	22.0 (20.0/25.0)	25.0 (22.0/25.0)	0.001
Implantation depth NCC (mm)	9.9 ± 5.9	9.7 ± 6.3	10.7 ± 3.2	0.50
Implantation depth LCC (mm)	10.6 ± 4.0	10.2 ± 4.1	12.3 ± 3.2	0.029
CoreValve prosthesis size				0.70
26 mm	64 (43.8)	56 (45.2)	8 (36.4)	
29 mm	82 (56.2)	68 (54.8)	14 (63.6)	
Access site				0.13
Transfemoral	134 (91.8)	112 (90.3)	22 (100.0)	
Trans-subclavian	12 (8.2)	12 (9.7)	0 (0)	

Values are mean ± SD n (%).

AKI = acute kidney injury; AR = aortic regurgitation; CABG = coronary artery bypass grafting; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; EuroSCORE = European System for Cardiac Operative Risk Evaluation score; LCC = left-coronary cusp; MI = myocardial infarction; NCC = non-coronary cusp; NT-proBNP = N-terminal pro-hormone brain natriuretic peptide; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; periAR = peri-prosthetic aortic regurgitation; STS = Society of Thoracic Surgeons.

published VARC criteria for the assessment of the severity of periAR (7), the echocardiographic grading was used for further analysis.

For the comparison of baseline characteristics, patients were divided into 2 groups according to the occurrence of echocardiographically confirmed periAR (none/mild vs. moderate/severe) after TAVI. The latter was considered clinically relevant. Patients with moderate/severe periAR were more often male (77.3% vs. 42.7%; $p = 0.003$) and taller (173.8 ± 10.1 cm vs. 166.0 ± 8.1 cm; $p < 0.001$) than patients with none/mild periAR (Table 1). The mean aortic annulus diameter was significantly larger (25.1 ± 2.4 mm vs. 23.2 ± 1.9 mm; $p < 0.001$) and the cover index was significantly lower (10.1 ± 6.1% vs. 16.0 ± 4.6%; $p < 0.001$) in patients suffering from moderate/severe periAR, compared with patients with none/mild periAR (Table 2).

Hemodynamic assessment of periAR. Simultaneous measurement of the left ventricular and aortic pressure showed a stepwise decrease of the gradient between LVEDP and the DBP in the aorta with increasing degree of periAR ($p < 0.001$) immediately after valve implantation (Table 2). In patients with none/mild periAR, the LVEDP decreased from 16.6 ± 5.0 mm Hg before to 13.6 ± 6.8 mm Hg ($p = 0.001$) after the procedure, whereas the LVEDP increased during the TAVI procedure in patients with post-interventional moderate/severe periAR from 14.9 ± 5.3 mm Hg to 18.3 ± 6.2 mm Hg ($p < 0.001$).

The AR index decreased in parallel with increasing severity of periAR, from 31.7 ± 10.4 in patients without periAR to 28.0 ± 8.5 in patients with mild periAR, 19.6 ± 7.6 in patients with moderate periAR, and 7.6 ± 2.6 in patients with severe periAR ($p < 0.001$) (Fig. 2).

Clinical outcomes after TAVI. Of 146 patients, 10 (6.8%) died within the first 30 days after TAVI, and 39 (26.7%) died during follow-up of up to 1 year. The echocardiographically assessed severity of periAR was significantly associated with 30-day and 1-year mortality after TAVI ($p = 0.001$ and $p < 0.001$, respectively) (Table 3). In patients with none/mild periAR, a 1-year mortality of 20.2% (25 of 124) was observed, compared with 63.6% (14 of 22) in patients with moderate/severe periAR ($p < 0.001$) (Fig. 3A).

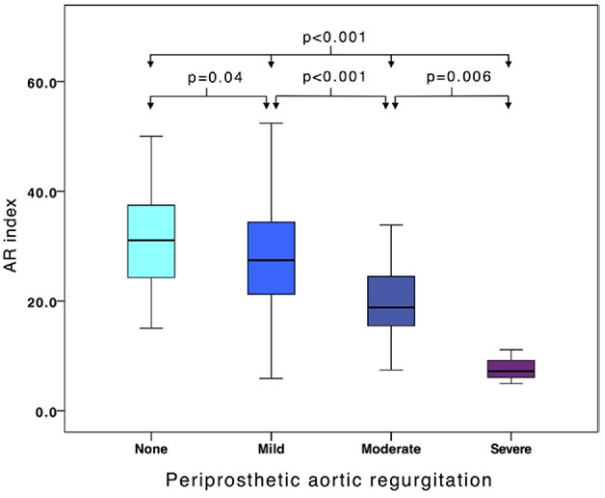

Figure 2 AR Index According to Degree of PeriAR

The AR index according to the degree of periAR as assessed by echocardiography after transcatheter aortic valve implantation. Abbreviations as in Figure 1.

In univariate regression analysis, the occurrence of moderate/severe periAR was associated with an increased risk for 1-year mortality (hazard ratio [HR]: 3.9, 95% confidence interval [CI]: 2.0 to 7.5; $p < 0.001$ after TAVI (Table 4).

The AR index and outcome. The optimal AR index cutoff value for the prediction of mortality at 1 year was calculated by receiver-operating characteristic curve analysis: 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%: $p < 0.001$) (Fig. 3B). In multivariate regression analysis, the AR index independently predicted 1-year mortality (HR: 2.9, 95% CI: 1.3 to 6.4; $p = 0.009$)—even after adjustment for the severity of periAR.

Because both parameters—severity of periAR and the hemodynamic AR index—impact outcome of TAVI patients and are readily assessable immediately after valve

Table 2 Hemodynamic Variables, AR Index, and Laboratory Parameters at 48 h After TAVI According to the Degree of PeriAR

	All Patients (N= 146)	No PeriAR (n = 53)	Mild PeriAR (n = 71)	Moderate PeriAR (n = 18)	Severe PeriAR (n = 4)	p Value
LVEDP (mm Hg)	12.6 ± 8.1	11.4 ± 7.5	12.0 ± 8.3	15.6 ± 7.0	23.3 ± 7.0	0.011
Aortic diastolic pressure (mm Hg)	46.3 ± 11.9	50.4 ± 13.2	46.0 ± 10.3	40.0 ± 8.2	30.0 ± 7.1	<0.001
End-diastolic gradient (mm Hg)	33.8 ± 12.3	39.2 ± 11.1	34.0 ± 10.5	24.4 ± 9.0	6.8 ± 3.9	<0.001
AR index	27.6 ± 10.3	31.7 ± 10.4	28.0 ± 8.5	19.6 ± 7.6	7.6 ± 2.6	<0.001
Cover index (%)*	15.1 ± 5.2	16.0 ± 4.5	16.0 ± 4.7	10.1 ± 6.0	10.2 ± 7.5	<0.001
NT-proBNP (pg/ml)	1,568.5 (601.5/5,475.5)	1,649.5 (765.3/5,814.8)	1,063.0 (470.0/4,244.0)	4,333.0 (1,047.5/9,568.0)	12,197.5 (4,025.0/24,411.0)	0.009
Troponin I (ng/ml)	0.69 (0.30/1.73)	0.65 (0.28/1.48)	0.55 (0.26/1.65)	1.06 (0.67/5.22)	3.98 (0.98/5.98)	0.009

Values are mean ± SD or % (n/N). *According to the definition of Détaint et al. (4).
LVEDP = left ventricular end-diastolic pressure; NT-proBNP = N-terminal pro-hormone brain natriuretic peptide; TAVI = transcatheter aortic valve implantation; other abbreviations as in Table 1.

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Table 3 Clinical Outcomes According to the Occurrence of Moderate/Severe PeriAR After TAVI

	All Patients (N = 146)	None/Mild PeriAR (n = 124)	Moderate/Severe PeriAR (n = 22)	p Value
30-day mortality	10 (6.8)	5 (4.0)	5 (22.7)	0.001
1-yr mortality	39 (26.7)	25 (20.2)	14 (63.6)	<0.001
Stroke	8 (5.5)	6 (4.8)	2 (9.1)	0.42
MI	4 (2.7)	3 (2.4)	1 (4.5)	0.57
Minor vascular complications	28 (19.3)	24 (19.5)	4 (18.2)	0.82
Major vascular complications	11 (7.6)	10 (8.1)	1 (4.5)	0.82
AKI	34 (23.3)	25 (20.2)	9 (40.9)	0.034
Pacemaker implantation	32 (21.9)	29 (23.4)	3 (13.6)	0.31

Values are n (%).
Abbreviations as in Tables 1 and 2.

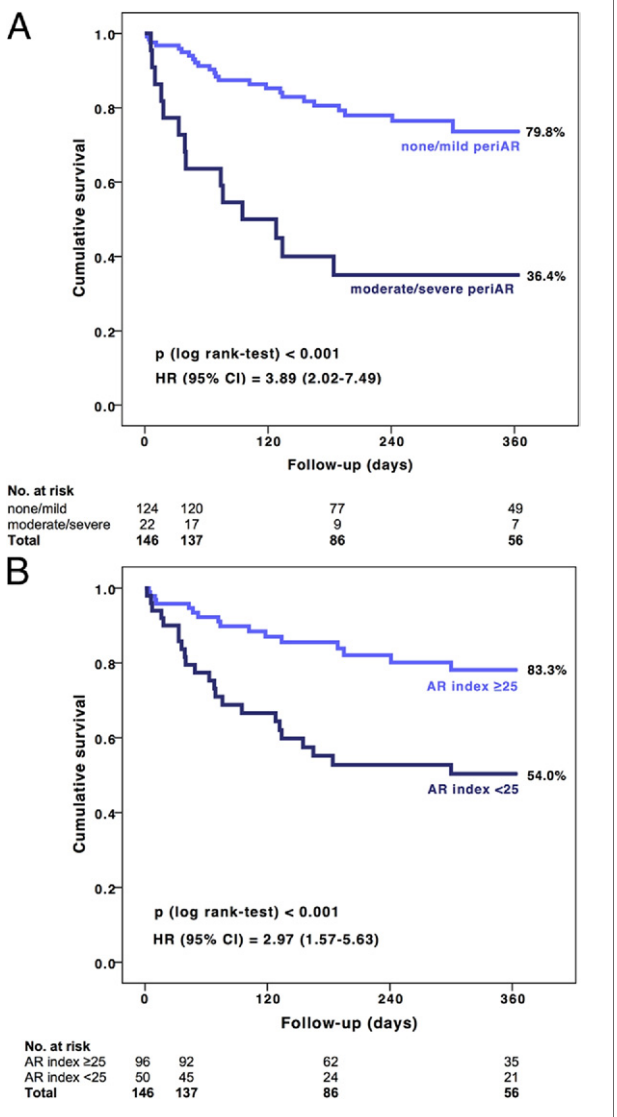

Figure 3 Freedom From All-Cause Mortality

Kaplan-Meier estimates of cumulative survival according to the degree of periAR as assessed by echocardiography **(A)** and according to the AR index **(B)**. CI = confidence interval; HR = hazard ratio; other abbreviations as in Figure 1.

implantation in the catheterization laboratory, we stratified our study population accordingly (Fig. 4). The 1-year mortality risk, attributed to the severity of periAR (none/mild vs. moderate/severe), could be further stratified by the AR index ($p < 0.001$). In patients with none/mild periAR, an AR index ≥25 (n = 91) was related to a 1-year mortality rate of 15.4%, whereas an AR index <25 (n = 33) was associated with a more-than 2-fold higher 1-year mortality rate of 33.3%. Patients with moderate/severe periAR and AR index <25 (n = 17) had the worst outcome, with a 1-year mortality rate of 70.6%.

Discussion

In this prospective study of 146 TAVI patients who underwent TAVI with the Medtronic CoreValve prosthesis, the degree of periAR after TAVI, quantified by echocardiography, was related to a significant increase in the risk of short- and long-term mortality. The AR index, which was calculated as the ratio of the end-diastolic gradient across the valve prosthesis to systolic blood pressure, decreased stepwise in parallel with increasing severity of periAR and allowed a precise judgment of the degree of periAR. This hemodynamic parameter also strongly predicted 1-year mortality after TAVI—independent of the degree of periAR—and provided additional prognostic information that was complementary to the echocardiographically assessed severity of periAR.

Predictors of periAR after TAVI. Heavily calcified cusps, misplacement of the prosthesis, and/or annulus-prosthesis-size mismatch can cause periAR (Fig. 5). We confirmed that annulus diameter and prosthesis implantation depth are associated with the occurrence of moderate/severe periAR after TAVI (3–6,9). Furthermore, the cover index, which is a surrogate for prosthesis/annulus incongruence, was significantly lower in patients with moderate/severe periAR in our study cohort (4). This significant relationship between low cover index and AR suggests that a certain degree of prosthesis oversizing is needed to ensure an adequate adaptation of the prosthesis to the aortic annulus. Conversely, recent data indicated that greater oversizing of the valve with respect to the aortic annulus was not associated

Table 4 Cox Regression Analysis of the Association Between Clinical Characteristics and 1-Year Mortality

	Univariate HR (95% CI)	p Value	Multivariate HR (95% CI)	p Value
AKI	6.1 (3.2–11.5)	<0.001	6.9 (3.4–13.9)	<0.001
Pulmonary hypertension	3.3 (1.7–6.3)	<0.001	3.5 (1.8–6.8)	<0.001
Moderate/severe periAR	3.9 (2.0–7.5)	<0.001	2.4 (1.0–5.4)	0.042
AR index <25	3.0 (1.6–5.6)	<0.001	2.9 (1.3–6.4)	0.009
Coronary artery disease	2.3 (1.1–4.9)	0.026	2.4 (1.0–5.6)	0.04
COPD	1.8 (0.9–3.6)	0.08	2.4 (1.0–5.6)	0.018
Chronic renal failure	2.0 (1.0–4.1)	0.047	0.6 (0.3–1.5)	0.29
Logistic EuroSCORE	1.0 (1.0–1.1)	<0.001	1.0 (1.0–1.0)	0.61
STS score mortality	1.1 (1.0–1.1)	<0.001	1.0 (1.0–1.1)	0.18

CI = confidence interval; HR = hazard ratio; other abbreviations as in Table 1.

with lesser incidence and severity of periAR, suggesting that other mechanisms such as the degree of valve calcification or leaflet-commissural deformation might have additional impact (5). These observations would explain at least in part why in some of our patients the degree of periAR could not be improved, despite appropriate implantation depth and post-dilation maneuvers.

PeriAR and outcome after TAVI. Recent analyses suggested the importance of post-procedural periAR for short- and long-term outcome (2,6). In our analysis, moderate/severe periAR, which occurred in 15% of our patients, was strongly related to both 30-day and 1-year mortality. In addition, the AR index was a strong and independent predictor of 1-year mortality risk—even after adjustment for the severity of periAR—indicating the independent relevance of objectively assessed hemodynamic changes in the long run.

Our data demonstrate that all measures must be taken to avoid moderate/severe periAR. Thus, effective countermeasures to decrease periAR might increase survival. Balloon valvuloplasty is usually the first step to optimize moderate/severe periAR in patients with appropriate implantation depth of the prosthesis. Correction of a deep implantation depth of the prosthesis can be overcome by the use of snare catheters, whereas for misplaced or embolized valves, the implantation of a second prosthesis in "valve-in-valve" technique is the ultimate bailout option (3).

Quantification of periAR after TAVI. The precise quantification of the degree of periAR remains challenging, despite the recently suggested VARC criteria (3–8). Most semi-quantitative Doppler parameters of AR severity are best applied in central regurgitation jets and, hence, might not be ideal to quantify the frequently diffuse and eccentric

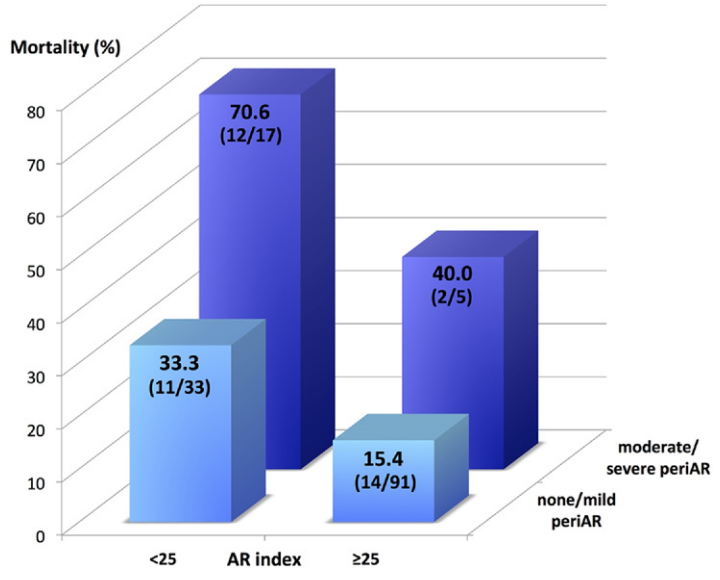

Figure 4 1-Year Mortality According to Severity of PeriAR and the AR Index

1-year all-cause mortality (%) according to the severity of periAR (none/mild vs. moderate/severe) and the AR index cutoff value. Abbreviations as in Figures 1 and 2.

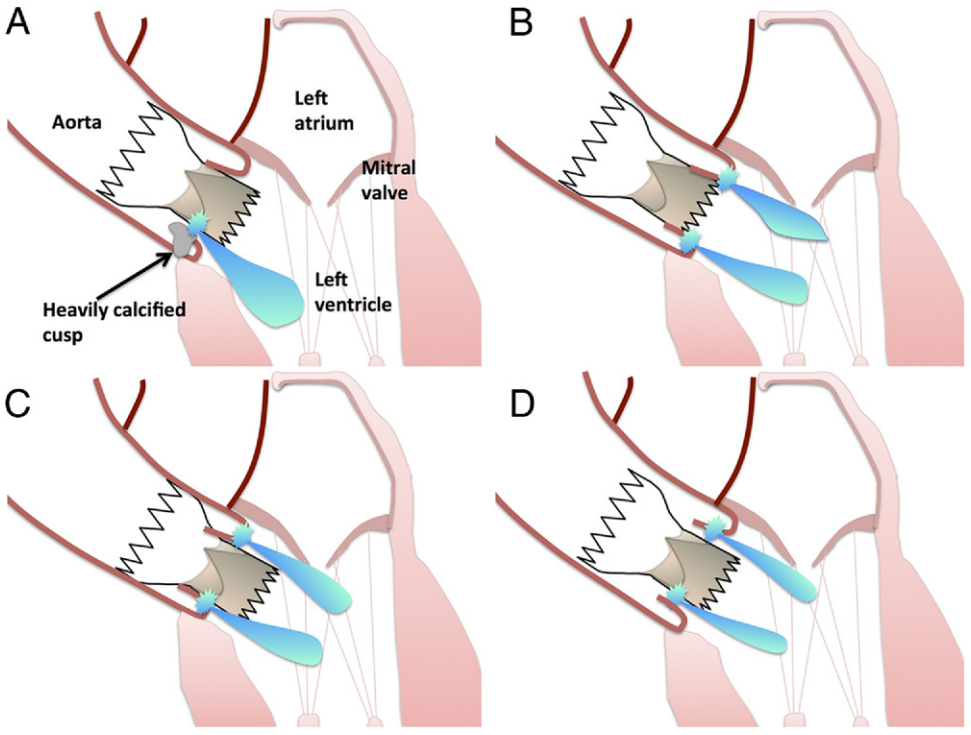

Figure 5 **Mechanisms of Peri-Prosthetic Aortic Regurgitation After Transcatheter Aortic Valve Implantation**

Paravalvular leaks with consecutive peri-prosthetic aortic regurgitation result from under-expansion of the prosthesis stent frame, which might be caused by calcifications of the annulus or the cusps of the native valve **(A)**, valve malposition with too shallow **(B)** or too deep **(C)** implantation depth of the prosthesis, and/or annulus-prosthesis-size mismatch **(D)**.

periAR with circumferential extent in TAVI patients. Despite the use of an integrative approach including several indirect parameters for determination of AR, the methodology remains imprecise (7,8). This is especially applicable for the acute implantation situation when ideal conditions for echocardiographic examination are difficult to achieve. Hemodynamic parameters are easy to quantify and might be useful for an objective, fast, and reproducible evaluation of the severity of periAR directly during the procedure—especially in patients with periAR of borderline significance–with the possibility to take effective measures to decrease periAR and thus increase survival.

Study limitations. The AR index varies with the level of the LVEDP that might be elevated due to high systemic blood pressure, concomitant diastolic dysfunction, significant myocardial ischemia during balloon valvuloplasty and valve deployment, or complications related to the TAVI procedure itself (e.g., tearing of the mitral valve with resultant regurgitation). A nonspecific elevation of the LVEDP might lead to a low transvalvular end-diastolic gradient and thus to a false positive AR index in these cases. This underscores the complementary value of the AR index, which should be used in addition to other imaging methods and has its best discriminative ability in patients with borderline periAR.

Sample size and the monocentric character are limitations of our prospective study. Thus, subgroup analyses are only hypothesis-generating. A larger controlled multicenter trial might be needed to validate our results.

Conclusions

The assessment of the AR index allows a precise judgment of periAR, independently predicts 1-year mortality after TAVI, and provides prognostic information that is complementary to the degree of periAR. This finding provides a simple-to-assess, investigator-independent, and immediately performed parameter, which can be used to guide peri-procedural clinical decisions in TAVI patients.

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Key Words: AR index ■ CoreValve ■ paravalvular leak ■ periprosthetic regurgitation ■ TAVI.

APPENDIX

For supplementary figures, please see the online version of this article.