Relative amplitude index: A new tool for hemodynamic evaluation of periprosthetic regurgitation after transcatheter valve implantation

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Objective: The impact of paravalvular aortic regurgitation (PAR) on hemodynamic performance after transcatheter aortic valve implantation (TAVI) remains disputable. Common parameters such as the diastolic blood pressure or the blood pressure amplitude do not provide reproducible results. The aim of our study was to evaluate the impact of PAR on hemodynamics and outcome using the relative amplitude index (RAI).

Methods: PAR was prospectively evaluated by echocardiography before discharge in 110 patients. The RAI was calculated according to the formula: RAI = [(Post-TAVI BP amplitude)/(Post-TAVI SBP) − (Pre-TAVI BP amplitude)/(Pre-TAVI SBP)] × 100%, where BP is blood pressure and SBP is systolic blood pressure. Correlations of increased RAI with perioperative outcome were investigated and factors influencing mortality were isolated.

Results: The incidence of moderate and severe PAR after TAVI was 9% and 1%, respectively. Diastolic pressure or post-TAVI amplitude did not correlate to perioperative outcome. RAI increased from 2 when PAR was <2+ to 7 when PAR was ≥2+ ($P = .006$). A cut-off value of RAI ≥14 was associated with increased perioperative mortality (29 vs 5%; $P = .013$) and acute renal injury requiring dialysis (71 vs 18%; $P = .001$). RAI ≥14 was also associated with higher follow-up mortality at 1 year (57 vs 16%; $P = .007$). RAI ≥14 (odds ratio [OR], 3.390; 95% confidence interval [CI], 1.6-7.194; $P = .00146$), PAR ≥2+ (OR, 4.717; 95% CI, 1.828-12.195; $P = .00135$), and perioperative renal replacement therapy (OR, 12.820; 95% CI, 5.181-31.250; $P = .00031$) were found to be independent predictors of mortality at 1 year.

Conclusions: The RAI is a useful tool to predict perioperative and 1-year outcome in patients with PAR after TAVI. (J Thorac Cardiovasc Surg 2014;147:1021-9)

Supplemental material is available online.

Surgical aortic valve replacement (AVR) is the procedure of choice for symptom reduction and improvement of survival in patients with severe aortic stenosis.[1] Among high-risk surgical patients, transcatheter aortic valve implantation (TAVI) is a noninferior therapy compared with standard AVR in terms of all-cause mortality at 30 days and 1 year. In this patient cohort, 30-day mortality was low both in the AVR group (6.5%) and the TAVI group (3.4%) although early-generation devices were used.[2] Both TAVI and AVR are associated with different periprocedural hazards, such as more frequent major vascular and neurologic complications with TAVI, as well as more major bleeding events and atrial fibrillation with surgical AVR. Increased risk for paravalvular regurgitation (PAR) has been the common denominator of all TAVI series so far.[3] Although there was no difference at 30 days, 1-year mortality was significantly higher in patients with PAR ≥2+, regardless of access and left ventricular function.[4] The finding that PAR ≥2+ is an independent predictor of midterm to long-term mortality has also been confirmed from the 2-year data of the PARTNER (Placement of AoRtic TraNscathetER Valves) trial.[5]

To provide increased understanding of the impact of PAR on hemodynamics after TAVI, the aortic regurgitation index, defined as the ratio of the gradient between diastolic pressure in the aorta and the left ventricular end-diastolic pressure to systolic blood pressure (SBP) has been developed. This index gives additional prognostic information

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Disclosures: S. Müller is a stockholder of Edwards Lifesciences and has lectured for Actelion Pharmaceuticals Inc. T. Bartel has received remuneration from Edwards Lifesciences and Biosense Webster. L. Müller has acted as consultant for Edwards Lifesciences, B Braun Aesculap, and St Jude Medical, and has lectured for Edwards Lifesciences. All other authors have nothing to disclose with regard to commercial support.

Read at the 93rd Annual Meeting of The American Association for Thoracic Surgery, Minneapolis, Minnesota, May 4-8, 2013.

Received for publication May 4, 2013; revisions received Sept 4, 2013; accepted for publication Nov 8, 2013; available ahead of print Dec 16, 2013.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2013.11.011

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Abbreviations and Acronyms

AVR = aortic valve replacement
CI = confidence interval
CPB = cardiopulmonary bypass
CT = computed tomography
DBP = diastolic blood pressure
LVEF = left ventricular ejection fraction
OR = odds ratio
PAR = paravalvular aortic regurgitation
RAI = relative amplitude index
ROC = receiver operating characteristics
SBP = systolic blood pressure
TAVI = transcatheter aortic valve implantation
VARC = Valve Academic Research Consortium

to the echocardiography; a value less than 25 is an independent predictor of 1-year mortality and is associated with increased rates of PAR.[6] Although this was the first attempt to establish causality based on hemodynamics between PAR and long-term outcome after TAVI, the need for a detailed echocardiographic evaluation or even better invasive hemodynamic evaluation is still a limiting factor that precludes assessment and treatment in the postoperative period.

We therefore developed an index based on preoperative and post-TAVI blood pressure measurements based on the hypothesis that blood pressure amplitude increases in the presence of PAR.[7] However, preoperative blood pressure amplitude should be taken into consideration because it may be associated with preexisting regurgitation of the stenotic valve[8] or with the loss of the windkessel function and elasticity of the aortic wall in patients with severe atherosclerosis.[9]

The aim of our study was to provide a simple, easy to measure, and reproducible tool to evaluate the impact of PAR on perioperative and midterm outcome after TAVI using simple blood pressure measurements before and after the procedure and taking blood pressure amplitude into consideration.

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METHODS

Patients

One-hundred nineteen consecutive patients with a high-grade aortic stenosis underwent TAVI between March 2008 and December 2012 and were analyzed retrospectively. The study was approved by the local Ethical Committee and each patient gave informed consent.

Aortic stenosis was diagnosed by transthoracic echocardiography. Indications for surgery were based on the transthoracic echocardiography results and symptoms. A preoperative computed tomography (CT) scan with 128-slice, high-pitch, dual-source, prospective CT angiography was performed for preoperative evaluation.

A previous cardiac intervention was noted in 51 patients (43%). Almost one-third of the patients (n = 32, 27%) had previous cardiac surgery at a median of 10 years before TAVI (range, 5 to 19 years). These previous procedures included aortic valve surgery (n = 2), mitral valve surgery (n = 2), aortic and tricuspid valve surgery (n = 1), and bypass surgery (n = 27). In addition, percutaneous coronary interventions were performed in 23 patients (20%) at a median of 2 years before TAVI. In 5 patients (4%), a previous balloon valvuloplasty was performed at a median of 7 months before TAVI.

Perioperative complications, such as mortality, cardiac, lung, cerebrovascular, or renal dysfunction, implantation of a second valve caused by prosthesis migration and PAR, as well as long-term outcome regarding survival and late prosthesis dysfunction were analyzed according to the Valve Academic Research Consortium (VARC)-2 criteria.[10]

Perioperative mortality was defined as mortality within 30 days. Long-term mortality was defined as death thereafter. The follow-up period was 2 to 1721 days (median, 377 days) and was 100% complete including clinical and echocardiographic examinations. Examination visits were standardized at 30 days, 6 months, 12 months, and thereafter yearly after TAVI. Procedural outcome was analyzed according to the VARC-2 criteria regarding device success, early safety, clinical efficacy, and time-related valve safety. Renal impairment was analyzed according to the Acute Kidney Injury Network system.[10]

PAR was prospectively evaluated by echocardiography during TAVI and before discharge. Echocardiographic evaluation was based on perioperative transesophageal or intracardiac echocardiography according to the recommendations of the European Association of Echocardiography.[11] The relative amplitude index (RAI) was retrospectively calculated according to the following formula:

$$\text{RAI} = \left(\frac{\text{Post-TAVI BP amplitude}}{\text{Post-TAVI SBP}} - \frac{\text{Pre-TAVI BP amplitude}}{\text{Pre-TAVI SBP}}\right) \times 100\%$$

where BP is blood pressure and SBP is systolic blood pressure.

In our study, blood pressure was measured intraoperatively using arterial pressure. Preimplantation values were the average of at least 3 values between skin cut and balloon valvuloplasty and postimplantation values were the average of at least 3 values between valve implantation and skin suture. To evaluate the potential effect of continuous invasive blood pressure measurements on RAI, we also analyzed noninvasive blood pressure measurements in 88 patients. These included preoperative measurements at admission and the median of 5 postoperative measurements after extubation, without inotropes, and in a comparable volume status until discharge. All measurements included were performed under stable hemodynamic and rhythm conditions.

The formula was created and calculated by using intraoperative blood pressure measurements, which were collected independently from the clinical outcome. In addition to the collection of intraoperative blood pressure data, the clinical outcome and follow-up data were collected separately by 3 different investigators after Ethical Committee approval. The statistical analysis was undertaken after completion of the data set. Therefore, there is no observer bias at any time in the study and the results of the RAI calculations could not be influenced by the clinical data.

Surgical Technique

All TAVI procedures were evaluated, indicated, and performed by a heart team. During TAVI, 1 experienced cardioanesthesiologist and 1 perfusionist were always present in the operating room. Apart from the first 9 procedures, which were performed in a catheterization laboratory, all other interventions took place in the cardiac operating room with cardiopulmonary bypass (CPB) on standby using a new generation mobile C-arm (OEC 9800, Ziehm RFD, Philips Veradius, Siemens Arcadis). Each patient underwent general anesthesia and was set up with an arterial blood pressure line, intracardial echocardiography or transesophageal echocardiography, and a submerged temporal pacemaker. The surgical approach for TAVI was always performed by a cardiac surgeon as planned after a preoperative CT scan: transfemoral approach with a 3 to 4 cm incision in the groin and femoral artery preparation; transapical approach with