JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 12, 2015

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2015.07.013

Increased Risk of Cerebral Embolization After Implantation of a Balloon-Expandable Aortic Valve Without Prior Balloon Valvuloplasty

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ABSTRACT

OBJECTIVES The purpose of this study was to analyze the effect of transcatheter aortic valve replacement (TAVR) without versus with prior balloon aortic valvuloplasty (BAV) on the risk of cerebral embolization in patients who receive a balloon-expandable valve.

BACKGROUND Avoiding BAV prior to TAVR may simplify the procedure, but the risk of cerebral embolization is currently unknown.

METHODS A total of 87 consecutive high surgical-risk patients with no contraindications for diffusion-weighted magnetic resonance imaging (DW-MRI) were enrolled. Thirty-two patients received a balloon-expandable aortic valve with and 55 patients without BAV. The incidence, number, and volume of new ischemic lesions in DW-MRI performed 2 to 7 days after TAVI were evaluated.

RESULTS Mean age (83.8 ± 5.2 years vs. 82.9 ± 6.8 years) and sex (43.8% vs. 52.7% male) of the patients with versus without BAV, respectively, as well as other demographic and hemodynamic data were not significantly different between both groups. The procedural success rate was 93.5% with and 98.2% without BAV, and procedure duration and contrast volume were significantly lower without BAV. The incidence of new cerebral ischemic lesions in the total cohort was 66.7%. Compared with patients with BAV, those without BAV had a significantly higher total volume of cerebral ischemic lesions (235.4 ± 331.4 mm^3 vs. 89.5 ± 128.2 mm^3; $p = 0.01$).

CONCLUSIONS The implantation of a balloon-expandable aortic valve without versus with prior BAV, although performed with a shorter procedure time and lower contrast volume, is associated with a significantly higher volume of cerebral ischemic lesions. (J Am Coll Cardiol Intv 2015;8:1608–13) © 2015 by the American College of Cardiology Foundation.

Balloon aortic valvuloplasty (BAV) prior to transcatheter aortic valve replacement (TAVR) is believed to be a necessary step for the implantation of a balloon-expandable prosthesis.

BAV, however, may be associated with several adverse events. It needs rapid pacing, which, in the presence of poor left ventricular function, may increase the risk of the procedure; it may be associated with aortic rupture; and it may be in part responsible for cerebral embolization with the risk of stroke (1). Avoiding BAV may simplify the procedure, but the risk of cerebral embolization is currently unknown. For a self-expandable device, TAVR without BAV has been shown to be feasible, and the authors speculated that this approach may reduce the incidence of stroke (2).

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Manuscript received April 30, 2015; revised manuscript received July 14, 2015, accepted July 30, 2015.

The aim of the present study was to analyze the effect of implanting a balloon-expandable valve without prior BAV on cerebral embolization compared with patients who received the balloon-expandable valve after BAV.

METHODS

Consecutive patients who met the inclusion/exclusion criteria were enrolled in the present study. Inclusion criteria were the presence of symptomatic severe aortic stenosis, age >75 years, and a high surgical risk as determined by an interdisciplinary heart team.

Exclusion criteria were pacemaker, claustrophobia, refusal of diffusion-weighted magnetic resonance imaging (DW-MRI), a history of a stroke or transient ischemic attack (TIA) within the prior 6 months, renal failure (estimated glomerular filtration rate <30 ml/min, calculated from serum creatinine by the Cockcroft-Gault formula), presentation with cardiogenic shock or severe hypotension (systolic blood pressure <90 mm Hg), undergoing any other cardiac surgical or interventional procedure (e.g., concurrent coronary revascularization) during or after the TAVR procedure before DW-MRI, and experiencing a clinical apparent stroke within 3 days after TAVR.

The patients underwent a standard screening procedure including echocardiography and multislice computed tomography. Aortic annulus size was measured by multislice computed tomography and transesophageal echocardiography (TEE) and aortic effective orifice valve area by TEE.

PROCEDURE. Patients were either on dual antiplatelet therapy (aspirin 100 mg plus clopidogrel 75 mg/day) before TAVR or received a loading dose of aspirin 500 mg intravenously and clopidogrel 600 mg orally on the day of the procedure. Dual antiplatelet therapy was recommended for 6 months. Patients on oral anticoagulation therapy received a clopidogrel loading dose followed by 75 mg/day for 6 months. The TAVR procedure was performed either under general anesthesia or conscious sedation. For BAV, a dedicated Edwards SAPIEN valvuloplasty balloon catheter (Edwards Lifesciences, Irvine, California) was used. All patients received heparin to increase the activated clotting time >250 s.

DIFFUSION-WEIGHTED MAGNETIC RESONANCE IMAGING. Cerebral DW-MRI was performed 2 to 7 days after TAVR using a 1.5-T machine (Magnetom Sonata, Siemens, Erlangen, Germany). Echo planar imaging with the following parameters was used: repetition time 3,000 ms; echo time 84 ms; 19 slices with a slice thickness of 6 mm; field of view 230 mm; diffusion values b = 0, 500, and 1,000 s/mm^2; fat saturation; and time of acquisition 71 s. Additionally, apparent diffusion coefficient maps were obtained. A new lesion was defined as a focal hyperintense area detected by the fluid-attenuated inversion recovery sequence, corresponding to a restricted diffusion signal in the diffusion-weighted imaging sequence, and confirmed by apparent diffusion coefficient mapping to rule out a shine-through artefact. Two independent physicians (T.H., R.G.) analyzed the DW-MRI for new ischemic lesions. The incidence, number, and volume of new ischemic lesions in DW-MRI were evaluated by physicians unaware of the patients' treatment. Interobserver agreement revealed a kappa of 0.75 ($p < 0.001$).

ABBREVIATIONS AND ACRONYMS

BAV = balloon valvuloplasty

DW-MRI = diffusion-weighted magnetic resonance imaging

TAVR = transcatheter aortic valve replacement

DEFINITIONS. According to the Valve Academic Research Consortium-2 criteria (3), technical success was defined as successful vascular access, deployment of the device and retrieval of the delivery system, and correct position of the device in the proper anatomical location with adequate performance of the prosthetic heart valve and without use of multiple prostheses.

Major adverse cardiac and cerebrovascular events (MACCE) were defined as death, myocardial infarction, and stroke.

Stroke was defined as new prolonged (>24 h) or persistent neurological deficit.

STATISTICS. Continuous data were presented as mean ± SD and compared with the unpaired *t* test or Mann-Whitney *U* test as appropriate. Categorical data were presented as count (percentages) and compared with the chi-square test. A $p < 0.05$ was considered statistical significant. Interobserver variability was evaluated by kappa statistics. Statistical analysis was performed using GraphPad Prism version 6.0. (GraphPad Software, San Diego, California) and SPSS software (version 20.0, SPSS Inc., Chicago, Illinois).

RESULTS

A total of 87 patients were included in the study. In 32 patients, TAVR was performed with prior BAV, and in 55 patients, TAVR was performed without BAV. All patients who received an Edwards SAPIEN XT valve (n = 19) routinely had BAV before valve implantation. After the availability of the Edwards SAPIEN 3 valve, only in case of a severe asymmetric valve calcification or a planimetric aortic valve effective orifice area ≤0.5—as measured by intraprocedural TEE—was a valvuloplasty performed (n = 13). All other patients