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Original Article

Clinical utility of a predictive model for paravalvular aortic regurgitation after transcatheter aortic valve implantation with a self-expandable prosthesis ☆

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ABSTRACT

Background: A predictive model for Paravalvular aortic regurgitation (PAR) integrating the left ventricular outflow tract-to-ascending aorta angle (LVOT-AO) and depth to the non-coronary cusp (NCC) after TAVI with CoreValve prosthesis (MCP) was retrospectively identified (2 × ∠LVOT-AO + [depth to NCC-10]2; cutoff = 50). However, the validity and clinical utility of this model remain unknown.

Methods: A total of 100 patients (79.6 ± 7 years, mean EuroScore 24.9 ± 16.3%, 41 males) constituted a validation cohort for the predictive model. Both angle (LVOT-AO) and depth to NCC were considered during patient selection and device implantation.

Results: Significant AR occurred in 16% (group A) vs. 84% (group B). Angle ∠LVOT-AO and depth to NCC were larger in group A compared to group B (16.4 ± 7.2 vs. 11.8 ± 4.1, $p < 0.001$, and 9.1 ± 4.8 mm vs. 6.6 ± 2.7 mm, $p = 0.004$). The model showed a sensitivity of 68.7% and a specificity of 88.1% in prediction of PAR. Comparing the derivation cohort (initial experience, $n = 50$) and validation cohort (later experience, $n = 100$) it is showed that the ∠LVOT-AO, valve depth and PAR were significantly lower (12.5 ± 4.9 and 6.9 ± 3.2 mm vs. 19.7 ± 7.9 and 10.4 ± 3.7 mm, 40% vs. 16% respectively, all $p < 0.001$) in the validation cohort.

Conclusion: The predictive model for significant PAR after TAVI using MCP is valid with a reassuring specificity and an acceptable sensitivity. A strategy incorporating these anatomical and procedural variables improves PAR after TAVI.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is becoming a mature technique with a growing impact on the treatment of patients with severe aortic stenosis. Accumulating data have indicated promising results concerning procedural success, quality of life improvement, short- and more recently long-term outcomes,[1] but the clinically relevant limitations of TAVI are the occurrence of aortic regurgitation (AR) after valve implantation, which is mainly of paravalvular origin.[2,3] Data from various registries randomized TAVI trials have linked the occurrence of post-TAVI paravalvular AR (PAR) with increased in-hospital and long-term mortality,[2–6] which highlights the importance of prediction, prevention and treatment of PAR after TAVI.

We have recently identified anatomical and procedural variables strongly linked to the occurrence of PAR after implantation of the self-expandable Medtronic CoreValve prosthesis (MCP, Medtronic, Inc., Minneapolis, MN, USA), and a predictive model integrating the left ventricular outflow tract-to-ascending aorta angle (∠LVOT-AO) and device depth in relation to the non-coronary cusp (NCC) was retrospectively identified (2 × ∠LVOT-AO + [depth to NCC-10][2]; cutoff = 50). [7] The purpose of the current study was to prospectively validate the previously derived model, and to investigate the clinical impact of adopting a strategy incorporating these measurable anatomical and procedural variables on the occurrence of PAR after TAVI using MCP.

2. Methods

2.1. Patient population

The previously published predictive model was retrospectively derived from a cohort of 50 consecutive patients treated with TAVI

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using MCP.[7] The model is as follows: 2 × ∠LVOT-AO + [depth to NCC-10][2]; with a calculated cutoff of 50. The test is positive if it has a value of ≥50, and the predicted sensitivity was 85% and the specificity 86.7% for detection of significant (≥2/4) PAR after TAVI.[7]

In the period of 2 years, 108 consecutive patients were further treated with transfemoral TAVI using MCP at our institution. All patients had severe symptomatic aortic stenosis with an aortic valve area (AVA) <1.0 cm^2 or a body surface area-indexed AVA (iAVA) <0.6 cm^2/m^2. The baseline operative risk of the patients was calculated by the logistic European System for Cardiac Operative Risk Evaluation score (EuroSCORE).[8] The decision to perform TAVI was made by a multi-disciplinary team consisting of an interventional cardiologist, a conservative cardiologist, a cardiac surgeon and an anaesthesiologist, as suggested by current recommendations.[9] Eight patients were excluded from analysis (4 patients due to failure of valve implantation and 4 patients with previous bioprosthetic aortic valve replacement [valve-in-valve]), and thus the final study population consisted of 100 patients, which constituted a validation cohort where the suggested predictive model was prospectively evaluated. Data collection was approved by the institutional review board, and all patients provided a written informed consent for analysis of their anonymized data.

2.2. Pre-interventional assessment

Pre-interventional patient screening included transthoracic (TTE) and transesophageal echocardiography (TEE) to confirm diagnosis, assess aortic and aortic valve dimensions and morphology, and determine the grade and distribution of calcification. Invasive cardiac evaluation with coronary angiography, left ventriculography (in 30° right anterior oblique [RAO] and 50° left anterior oblique [LAO] projections), right heart catheterization and peripheral arteriography was performed in all patients. Multislice computed tomography (CT) was not routinely performed.

2.3. Device description and procedure

The MCP consists of a trileaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent. Details of the device have been described previously.[9] Clinical and anatomic selection criteria and device size selection were in line with the published investigational study for the third-generation (18 F) CoreValve device.[9] Selection of the prosthetic valve size (26 mm inflow device for 20–23 mm annulus, 29 mm inflow device for 23–27 mm annulus and 31 mm inflow device for 26–29 mm annulus) was based on the measurements of the diameter of the aortic valve annulus obtained by TEE. Vascular access was obtained percutaneously through the common femoral artery, and the procedure was performed with local anesthesia in combination with a mild systemic sedative/analgesic treatment. Details of the implantation procedure have been described elsewhere.[9]

2.4. Angle, depth and AR assessment

The angle of the LVOT to ascending aorta was considered as the angle between the axis of the first 4 cm of the ascending aorta representing the contact surface with the upper part of the prosthesis, and the LVOT axis representing the landing zone of the prosthesis and represented by a line perpendicular to the plane of the aortic valve annulus.[7] This angle was measured using left ventriculography in RAO 30° during the pre-intervention innovise assessment as previously described by our group (Fig. 1A).

Depth of final device position in the LVOT was measured using a final aortogram of the deployed bioprosthesis in RAO projection, displaying the aortic valve in optimal alignment with all 3 leaflets visible in the same plane.[7] The depth of delivery was defined as the distance from the native aortic annular margin on the side of the NCC to the most proximal edge on the corresponding side (deepest in the left ventricle) of the deployed stent-frame (Fig. 1B). The depth of delivery from the annular margin of the left coronary cusp (LCC) to the corresponding side was also measured. Both the ∠LVOT-AO and the valve depth were measured using commercially available software (Jivex Dicom Viewer, version 4.0.2, VISUS Technology Transfer GmbH, Bochum, Germany) by 2 independent blinded observers to evaluate the reproducibility of measurements and to assess both intra- and inter-observer variability.

The endpoint of the study was the early occurrence of significant PAR, evaluated at the end of the procedure after valve implantation and corrective measures (including post-dilatation) if needed. Significant AR was defined as ≥ grade 2. Estimation of residual AR grade was done using qualitative angiography with visual estimation of the concentration of contrast medium in the left ventricle after pump injection of 35 cc of contrast in the aortic root.[10] Mild (grade 1) AR was diagnosed when a small amount of contrast entered the left ventricle during diastole and cleared with each systole. Moderate (grade 2) AR was diagnosed when more contrast entered with each diastole and faint opacification of the entire left ventricular chamber occurred, while a moderately severe (grade 3) AR was diagnosed when the left ventricular chamber was well opacified with an equal density compared with the ascending aorta. Severe (grade 4) AR was defined as complete, dense opacification of the ventricular chamber on the first beat, with the left ventricle more densely opacified than the ascending aorta.[10]

2.5. Statistical analysis

Statistical analysis was done using Minitab software (Minitab, Release 13.1, State College, Pennsylvania, USA). Data are expressed as mean ± SD, numbers and percent or as median and interquartile range. Comparisons of baseline and procedure-related characteristics of patients according to AR ≥ 2 or <2 as well as comparisons of derivation and validation cohorts were performed using the *t* test or chi-square test as appropriate. Sensitivity and specificity of the predictive model when prospectively applied were calculated. Intra- and inter-observer variability were evaluated using intra- and inter-observer variance and correlation coefficients for angles and depth and the whole predictive model. A *p*-value <0.05 was considered significant.

3. Results

3.1. Baseline characteristics

Overall, 100 consecutive patients treated with transfemoral TAVI using the MCP were included. Mean age was 79.6 ± 7.0 years and 41 patients were males. More than 70% of patients had concomitant coronary artery disease and 98% of patients were severely symptomatic at baseline with New York Heart Association functional class (NYHA) III or IV. After TAVI, 16 patients had significant post-procedural PAR (≥grade 2), while 84 patients had no, trace or grade 1 PAR after MCP implantation. Table 1 illustrates the baseline clinical characteristics of the whole cohort and a comparison of patients with (group A) and without significant PAR (group B). Patients in group A were more commonly males (75.0% vs. 34.5%, $p = 0.003$), while other clinical characteristics were comparable.

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