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Comparison of procedural, clinical and valve performance results of transcatheter aortic valve replacement in patients with bicuspid versus tricuspid aortic stenosis☆

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ABSTRACT

Background: Limited date describing the procedural, clinical and valve performance results of transcatheter aortic valve replacement (TAVR) in patients with bicuspid versus tricuspid aortic stenosis (TAV).
Methods: Procedural and clinical results were defined and reported according to VARC-2 criteria.
Results: Consecutive 87 patients with BAV and 70 patients with TAV were included. Compared to patients with TAV, patients with BAV had similar incidence of second valve implantation (14.9% vs 12.9%, $p = 0.708$), more than mild paravalvular leakage (PVL, 40.2% vs 31.9%, $p = 0.288$), permanent pacemaker implantation (PPM, 24.1% vs 28.6%, $p = 0.53$). Furthermore, the procedural and clinical results of TAVR also did not differ between patients with type 0 and type 1 (second valve implantation: 18.4% vs 11.8%, $p = 0.71$, PVL: 38.8% vs 41.2%, $p = 0.83$, PPM: 18.4% vs 31.6%, $p = 0.16$). The hemodynamic outcomes were similar in patients with BAV and TAV at 1-year (maximum velocity, 2.3 vs 2.2 m/s, $p = 0.307$) and 2-year (2.3 vs 2.1 m/s, $p = 0.184$) follow-up respectively. Adjusted binary logistic regression analysis found oversizing ratio at 14.45–20.57% is at lower risk for more than mild PVL (OR, 0.069, 95% CI, 0.011–0.428, $p = 0.004$). Moreover, the Kaplan–Meier survival analysis revealed that TAVR in type 0 BAV, type 1 BAV and TAV have comparable risk for midterm mortality (Log rank, $p = 0.772$).
Conclusion: TAVR in whatever type of BAV appeared to be safe and efficacy, and TAVR in BAV was associated with comparable bioprosthetic function during follow up compared to patients with TAV.

1. Introduction

Increasing evidence demonstrates transcatheter aortic valve replacement (TAVR) to be an alternative strategy to surgical aortic valve replacement (SAVR) in selected patients with severely stenotic aortic valve disease [1,2]. TAVR in bicuspid aortic stenosis (BAV) is still regarded as off-label indication due to its unique morphological features including severely calcified leaflets, elliptic annulus and enlarged ascending aorta [3]. Whereas, limited data have revealed encouraging procedural and clinical outcomes of TAVR in patients with BAV [4–10].

Given the expanding indications of TAVR shift to patients who are younger and at lower surgical risk, TAVR would encounter more patients with BAV which constitutes >40% septuagenarians undergoing isolated SAVR for aortic stenosis reported by previous study [11–13]. The high incidence of adverse procedural outcome including paravalvular leakage (PVL) and permanent pacemaker implantation (PPM) warrants special attention [6,14]. And, whether the results of TAVR in the BAV differed between subtypes of BAV is unknown which deserved to be illustrated. Furthermore, in vivo studies showed that the incidence of non-circular stent shape was higher in BAV which may have negative impact on the durability of post-TAVR bioprosthesis [15,16]. Thus, the present study compared procedural, clinical and mid-term hemodynamic results between patients with BAV and tricuspid aortic stenosis (TAV) to demonstrate the safety, efficacy and feasibility of TAVR in different types of BAV. And the

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potential predictors of adverse events in patients with BAV and TAV were also identified in the present study.

2. Methods

This study was approved by the institutional review board, and informed consent was obtained from all of the patients.

2.1. Patients

Consecutive patients with severe symptomatic aortic stenosis, who underwent TAVR using the first generation self-expandable valve at our institution between April 2012 and February 2017, were included in this study (Fig. 1). All the patients were prospectively enrolled and assessed. The indication for TAVR was discussed in all patients by our multidisciplinary Heart Team. The type of the aortic valve is defined according to the number of cusps as well as the number and spatial orientation of the raphe which is in accordance with a previous study reported by Sievers et al. [17]. One patient underwent emergent TAVR, thus the type of aortic valve was defined through echocardiography. Others were identified by multi-slice computed tomography (MSCT).

2.2. Pre-TAVR measurements of aortic root

Computed tomography angiography was routinely performed to guide the selection of the access route and the prosthesis size. The dimensions of aortic root were evaluated by MSCT using OsiriX DICOM Viewer software (OsiriX Foundation, Geneva, Switzerland), the volume of aortic root calcification was calculated by FluoroCT 3.0 (Circle Cardiovascular Imaging Inc., Calgary, Canada). And, the calcification of left ventricle output tract was also analyzed in a semiquantitative method which was described in a previous study [18]. In addition, the elliptical index of aortic root structure was calculated by using the formula "elliptical index = (1 − short / long axis) × 100". The percentage of oversizing or undersizing was calculated using the following formula "% oversizing = (prosthesis nominal perimeter / MDCT annular perimeter − 1) × 100".

2.3. TAVR procedure

The transfemoral approach was the treatment of choice, but alternate vascular access was performed where transfemoral TAVR was not feasible due to severe calcification, tortuosity and smaller diameter. Two kinds of first generation self-expandable valves (CoreValve [Medtronic, Minneapolis, Minnesota] or Venus A-Valve [Venus MedTech Inc., Hangzhou, China]) were used which was described in our previous study [19]. Balloon pre- and post-dilation were performed according to operator discretion. The size of transcatheter heart valve was determined according to the comprehensive analysis of annular dimension and landing zone calcification. Briefly, predilation was routinely performed except for mild or none leaflet calcification. Predilation was utilized in our center for three reasons. Firstly, we could further evaluate the potential for coronary obstruction with the native leaflets actually being pushed away by the balloon. Secondly, it is helpful to determine the actual annulus size especially for borderline cases. Thirdly, how will heavy calcifications behave during the procedure can be foreseen. Briefly, the balloon size chosen equals minor diameter of annulus measured on MSCT. If the chosen balloon behaved appropriately, that was no contrast leaking to the left ventricle and coronary arteries were patent on angiography, the average diameter of the annulus would be determined as balloon size plus 3 mm. This average diameter would then be used to choose the valve size according to the sizing chart provided by manufacturer. Otherwise, if contrast leakage did exist, a one size bigger valve than selected by the average diameter will be chosen. The degree of post-TAVR paravalvular leakage (PVL) was evaluated by echocardiography and classified as none/trace (0), mild (1), moderate (2) and severe (3). In the presence of moderate or severe aortic regurgitation that was unresponsive to post-dilation, implantation of an additional valve was considered.

2.4. Follow-up and outcome definition

Patients were followed primarily by office visit and telephone interview. The medium time of follow-up period was 668 days (402 to1073 days). The definition of clinical results were in accordance with the valve academic research consortium (VARC-2) recommendation [20].

2.5. Statistical analysis

Continuous variables were presented as mean ± SD and compared using unpaired Student's *t*-test, or medians (25th–75th quartile) compared using Mann-Whitney non-parametric test. Categorical variables were expressed as percentages and compared using the Chi-squared test or Fisher's exact test. Mortality was calculated and compared with the use of Kaplan–Meier survival analysis. Binary logistic regression analysis was carried out to determine the predictors of adverse outcome and 30-day mortality, while cox proportional hazard regression was conducted to explore the risk factors of cumulative mortality. Multivariate binary logistic regression was adjusted by native valve type, oversizing ratio, left bundle branch blocker (LBBB) and implantation depth, multivariate cox proportional hazard regression was adjusted by native valve type, new-onset LBBB, baseline left ventricle ejection fraction ≤35%, new-onset PPM, major vascular complication, major bleeding and more than mild PVL. All statistical analysis was performed with SPSS version 20.0 (IBM Inc., Armonk, New York), with significance set at the two-tailed 0.05 level.

3. Results

3.1. Patient characteristics

A total of 157 patients using first generation self-expandable valve were included in our center, 70 patients (including 4 bioprosthetic valve degeneration) were defined as TAV, 87 patients were BAV (38 patients were type-1 BAV, 49 patients were type-0 BAV, Fig. 1). Patients with TAV and BAV had similar Society of Thoracic Surgeons predicted of mortality (STS PROM) score (TAV: 8.6 ± 4.4 vs BAV: 7.9 ± 4.0%, $p = 0.27$). There were no significant difference in the burden of comorbidities between patients with TAV and BAV (Table 1).

3.2. Pre-TAVR measurements on MSCT

Eleven patients were excluded in the setting of pre-TAVR measurements on MSCT, and the exclusion reason was as follows: 4 patients were degenerative bioprosthetic valve, 1 patient (BAV) have no pre-TAVR MSCT, 2 patients (1 BAV and 1 TAV) converted to open heart surgery and the other 4 patients (BAV) did not implant transcatheter heart valve (THV) due to coronary obstruction when performing balloon valvuloplasty. Patients with BAV was associated with small elliptical index in aortic annulus, compared to those patients with TAV (20.7 vs 24.4%, $p = 0.014$). Whereas, calcium volume of aortic root was larger in patients with BAV (656.5 vs 505.4 mm^3, $p = 0.048$, Table 2).

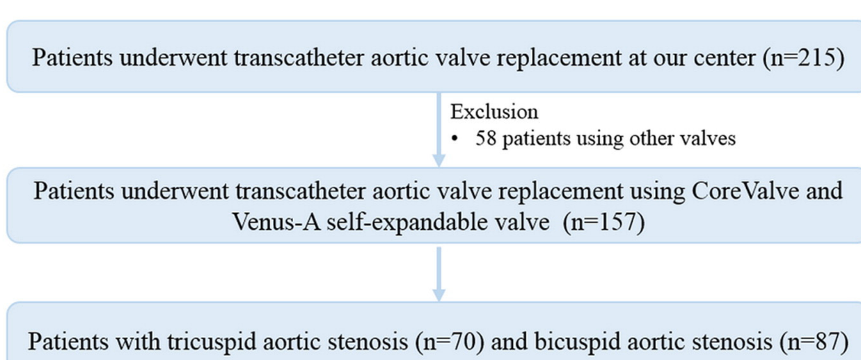

Fig. 1. Study flow chart.

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