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Mid-term results of bioprosthetic aortic valve replacement with the Trifecta valve: A word of caution

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Background: Structural valve deterioration (SVD) with associated bioprosthetic valve dysfunction remains an unsolved problem, exposing patients to the risk of aortic valve re-intervention after surgical aortic valve replacement (SAVR). Several strategies have been proposed to improve prosthesis design for optimal performance. The leaflets of the Trifecta valve are mounted on the outside of the prosthetic stent to achieve a larger orifice area. Although favourable early clinical outcomes have been reported, long-term durability still needs to be assessed.

Purpose: The aim of the current study was to assess the mid-term overall mortality and re-intervention rate in patients who received a Trifecta valve with a follow-up >5 years.

Methods: Patients who underwent SAVR at our centre between 2011 and 2012 were identified in the internal, prospective database. All patients with implantation of a Trifecta valve in aortic position were included. Primary endpoints were freedom from overall mortality and from re-operation at latest follow-up (FU). Additionally, assessment of echocardiographic parameters at baseline and follow-up was performed.

Results: Seventy-six patients (age 77.3±9.5 years, BMI 28.6±5.8, 68% male) were included in the study. EuroScore II was 7.2% (± 7.7) while mean STS-Mortality score was 2.4±1.1%. Of all procedures, 53% were isolated aortic valve replacements, whereas concomitant procedures were performed in 47% of cases (37% CABG, 12% mitral surgery, 8% tricuspid surgery). Baseline echocardiographic assessment showed a mean pressure gradient (MPG) of 51±21 mmHG, a peak pressure gradient (PPG) of 78±36 mmHG and a peak velocity (Vmax) of 4.2±1.1 m/s.

Thirty-day mortality was 7%. Freedom from overall mortality at 1 year and 5 years was 84% and 73%, respectively. Freedom from death and freedom from re-operation at latest FU (6.7±0.5 years) was 68% and 90%, respectively. In a composite endpoint analysis, freedom from death or re-intervention at latest follow up was 60%. A total of 7 patients underwent aortic valve re-interventions (re-replacements n=5, valve-in-valve n=2). Indications for re-interventions were SVD (n=5), NSVD (n=1, pannus ingrowth) and endocarditis (n=1). One case of re-stenosis occurred in a patient who was deemed not feasible for aortic valve re-intervention and died.

Conclusion(s): To our knowledge, this patient cohort presents with the lowest rate of freedom from re-operation (90%, 6.7±0.5 years) after SAVR with the Trifecta valve. A relatively high number of SVD and NSVD has been observed, which might be attributable to the specific leaflet mounting or the deformable valve frame of the first generation. Current results call for further investigation with prospective echocardiographic follow-up in this patient group.
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Conclusion(s):
To our knowledge, this patient cohort presents with the lowest rate of freedom from reintervention (90%, 6.7±0.5 years) after SAVR with the Trifecta valve. A relatively high number of SVD and NSVD has been observed, which might be attributable to the specific leaflet mounting or the deformable valve frame of the first generation. Current results call for further investigation with prospective echocardiographic follow-up in this patient group.

Kaplan Meier analysis