Single Center Midterm Results from the FDA Pivotal Trial of the St. Jude Medical Trifecta Pericardial Aortic Valve Bioprosthesis

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BACKGROUND
Concerns about optimizing tissue valve hemodynamics has led to innovative aortic valve design. The St. Jude Medical Trifecta valve is a recent pericardial bioprosthesis that optimizes hemodynamics with a unique stent design and sewing ring specifically designed for supra-annular placement.

OBJECTIVES
The objectives of this study were to confirm the safety and efficacy of the Trifecta valve, and to present midterm data on the hemodynamic performance and adverse event rate.

METHODS
The Trifecta valve was implanted in the aortic position in 100 patients in a single center participating in a prospective, multicenter pivotal trial conducted at 18 centers in the United States.

Peri-operative variables were collected on a prospective basis.
Echocardiograms were reviewed at a core lab.
Clinical follow-up and echocardiograms were obtained at discharge, 6, 12, 24, 36, 48 and 60 months.

RESULTS
Mean age of patients at time of implant was 74.2 ± 8.3 years; 74% (N=74) were male; 30% (N=30) had a bicuspid aortic valve; 30% (N=30) had a history of diabetes; and 24% (N=24) had previous cardiac surgery. Concomitant CABG was performed in 39% (N=39) of patients.

- Hemodynamic performance was exemplary:
- Overall mean gradient (mmHg) was: 7.2 ± 3.7; 6.6 ± 3.1; 7.1 ± 3.4; 8.6 ± 4.1; 8.8 ± 4.6; 8.0 ± 4.2; 6.9 ± 4.1 at discharge, 6 months, 1, 2, 3, 4, 5 years postoperatively, respectively (Figure 1).
- Indexed effective orifice area remained stable over time.
- Aortic insufficiency: moderate (N=3): 1 intravalvular; 1 perivalvular; and 1 mixed. All other patients had none or mild.
- Durability: There were no instances of structural valve deterioration or valve-related death through the fifth year.
- Kaplan-Meier survival was 86% (N=9) at 5 years (Figure 2).
- Peri-operative mortality (N=1); Peri-operative transient ischemic attack (N=4); and permanent cerebral vascular accident (N=1)
- Explants: (N=2): 1 aberrant intramural left circumflex artery and 1 late endocarditis

SUMMARY OF KEY FINDINGS
The Trifecta aortic valve demonstrated excellent hemodynamics and durability with 5 years of follow-up.
The findings encompass 393 patient-years of data and represent the longest clinical follow-up data for this valve in the world.
With outstanding performance, the Trifecta valve may represent the last “standard” aortic valve designed.
CONCLUSION

- The St. Jude Medical Trifecta valve provides excellent hemodynamics with relatively stable values through 5-years follow-up.

**Figure 1:** Average Aortic Mean Gradient

**Figure 2:** Kaplan–Meier Survival

REFERENCE

1. Bavaria JE, McClure S, Menon RS et al. Single Center Midterm Results from the FDA Pivotal Trial of the St. Jude Medical Trifecta Pericardial Aortic Valve Bioprosthesis. 7th Biennial Scientific Meeting of the Society for Heart Valve Disease and the Heart Valve Society of America; Venice, Italy. June 22-25, 2013.

Rx Only

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Trifecta Valve is indicated as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, leak (transvalvular or perivalvular), myocardial infarction, nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other), prosthesis regurgitation, stroke, structural deterioration (calcification, leaflet tear, perforation, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to reoperation, explantation, permanent disability or death.

Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism. Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings and Instructions for Use.

Product referenced is approved for CE Mark.

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