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

Joseph E. Bavaria, Scott McClure, Rohan S. Menon, Wilson Szeto, Sofiane Lazar, Melanie Freas, Virginia Buckley-Blaskovich, Nimesh D. Desai

University of Pennsylvania, Philadelphia, PA, USA
Abstract Presentation, The Society for Heart Valve Disease, Italy 2013

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 mid-term 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.

CONCLUSION

- With outstanding performance, the Trifecta valve may represent the last “standard” aortic valve designed.

- 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.