Clinical Highlights

St. Jude Medical Trifecta™ Aortic Valve Perioperative Performance in 200 Patients

Eduard Permanyer, Arnaldo-Javier Estigarribia, Alejandro Ysasi, Enrique Herrero, Omar Semper, Rafael Llorens
Department of Cardiac Surgery, Hospiten Rambla, Santa Cruz de Tenerife, Spain

BACKGROUND

Supra-annular placement of an aortic bioprosthesis is one approach to optimize the hemodynamic results of valve replacement. Additionally, the choice of valve material can affect hemodynamic performance. In comparative studies of bovine and porcine heart valves, bovine valves demonstrated exceptional hemodynamic results, especially in small annulus sizes.

The St. Jude Medical Trifecta aortic valve prosthesis is designed for supra-annular placement with pericardial tissue leaflets attached to an exterior valve stent to increase the opening area.

OBJECTIVES

The objectives of this prospective, single-center study were to evaluate the clinical and hemodynamic performance of the Trifecta bioprosthesis in the early postoperative period and to analyze the implant technique.

METHODS

A consecutive series of patients undergoing aortic valve replacement from July 2010 to September 2012 were analyzed prospectively.

The only inclusion criterion was the need of a biological aortic valve replacement. There were no exclusion criteria.

The Trifecta valve was the only stented biological aortic valve used at Hospiten Rambla during the time period.

Echocardiography was performed at discharge in all patients.

All echocardiographic examinations were performed transthoracically by three experienced echocardiographers.

RESULTS

- A total of 200 consecutive patients (115 males, 57.5%, and 85 females, 42.5%, with a mean age of 71.2 years ± 7.7 years, range 39 to 89 years) underwent aortic valve replacement with the Trifecta valve.
- A total of 57% of patients received size 19 mm and 21 mm valves.
- The surface area (BSA) was 1.86 ± 0.2 m², range 1.5 to 2.6 m².
- Preoperative NYHA class was as follows:
  - I 1% n=2
  - II 24% n=48
  - III 59% n=118
  - IV 16% n=32
- At discharge, 92.5% of patients (n=185) were in NYHA classes I or II.
- Peak and mean systolic pressure gradients are shown in Figure 1.

Figure 1. Trifecta Valve Mean and Peak Gradients
The mean effective orifice areas (EOAs) ranged from 1.6 to 2.5 depending on the size of the prosthesis (Figure 2).

The indexed valve effective orifice areas were very good.

The indexed valve effective orifice areas were 1.01 ± 0.2 cm²/m² (19 mm), 1.1 ± 0.3 cm²/m² (21 mm), 1.19 ± 0.3 cm²/m² (23 mm), 1.05 ± 0.1 cm²/m² (25 mm), and 1.15 ± 0.03 cm²/m² (27 mm) (Figure 3).

SUMMARY OF KEY FINDINGS

- The Trifecta aortic valve exhibited promising early hemodynamic performance in a large prospective study of 200 consecutive patients:
  - Mean gradients were in the single digits across all valve sizes.
  - There were no instances of severe prosthesis-patient mismatch (PPM). Only 6 patients (3%) had mild-to-moderate PPM.
  - Effective orifice areas were very good – 1.6 cm² for the 19 mm valve to 2.5 cm² for the 27 mm valve.
- The Trifecta valve was implanted easily with only a few technique modifications from the techniques used with other stented biological valves.

CONCLUSIONS

- The Trifecta valve provides excellent early clinical and hemodynamic performance, providing a good alternative to other biological stented aortic valves.
- Further evaluation is needed during follow-up.

No patients experienced severe prosthesis-patient mismatch (PPM) — defined as iEOA 0.65 < cm²/m². Six patients (3%) had mild-to-moderate PPM — defined as iEOA > 0.65 cm²/m² and 0.85 cm²/m², respectively.

One patient (0.5%) had significant aortic insufficiency due to prosthetic endocarditis.

Major complications during hospitalization included:
- atrial fibrillation: 18% (n=36);
- renal failure requiring hemofiltration: 3.5% (n=7); and stroke: 1.5% (n=3).
Early mortality at 30 days was 2.5% (n=5), of which one case was valve-related. (Note: the valve-related death was due to unknown reasons.)
REFERENCE


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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