Midterm, multicenter clinical and hemodynamic results for the Trifecta aortic pericardial valve

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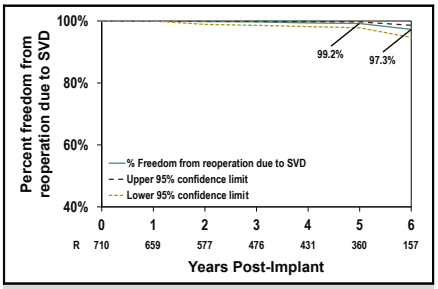
ABSTRACT

Objective: To evaluate the midterm hemodynamic performance and clinical outcomes of the Trifecta aortic pericardial valve.

Methods: In a multicenter, prospective, nonrandomized, follow-up study, 710 patients underwent surgical implantation of a pericardial stented aortic prosthesis (Trifecta valve; St Jude Medical, St. Paul, Minn). The valve is constructed from bovine pericardium mounted externally onto a titanium stent. Subjects were followed on an annual basis over 6 years.

Results: Operations were performed from 2007 to 2009, and mean age was 72.4 ± 9.3 years; 471 of 710 (66.3%) were men. Preoperatively, 361 of 710 (50.8%) of patients were in New York Heart Association class III or IV, and at 6 years postoperatively, 92 of 96 (95.8%) were New York Heart Association class I or II. Six years postoperatively, average mean gradient across all valve sizes was 11.0 mm Hg, and the average effective orifice area index was 0.80 cm^2/m^2. The proportion of patients without moderate-to-severe valvular regurgitation at 6 years was 95.2% (80/84). Six years postoperatively, freedom from valve-related mortality, nonstructural dysfunction, and paravalvular leak were 98.3%, 98.6%, and 98.9%, respectively, and freedom from reoperation due to structural valve deterioration was 97.3% (95% confidence limits, 98.6-94.7).

Conclusion: These midterm results demonstrate that the Trifecta valve is a safe and effective valve substitute with excellent hemodynamic performance and durability that is maintained through the 6-year follow-up period. (J Thorac Cardiovasc Surg 2016;■:1-9)



Freedom from reoperation due to structural valve deterioration was 97.3% at 6 years.

Central Message

Excellent hemodynamic performance and durability was maintained through 6 years of follow-up.

Perspective

Use of bioprosthetic aortic heart valves has steadily increased in recent years. The availability of a bioprosthetic aortic heart valve that has excellent hemodynamic performance and durability is particularly attractive when encountering a small aortic annulus.

ACQ

The use of bioprosthetic aortic heart valves has increased steadily in recent years as a result of increasing numbers of elderly patients undergoing aortic valve replacement, as well as anticipated improved durability of pericardial prostheses.[1] The availability of a bioprosthetic aortic heart valve with excellent hemodynamic performance and durability is attractive particularly for younger patients and those with a small aortic root. By incorporating experience from previous valve designs and leveraging improvements in tissue processing, the Trifecta aortic pericardial valve (St Jude Medical, St. Paul, Minn) was

Scanning this QR code will take you to the supplemental figures, tables, video, and appendices. To view the AATS 2016 Webcast, see the URL next to the video thumbnail.

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Abbreviations and Acronyms
NYHA = New York Heart Association
SVD = structural valve deterioration
TAVR = transcatheter aortic valve replacement

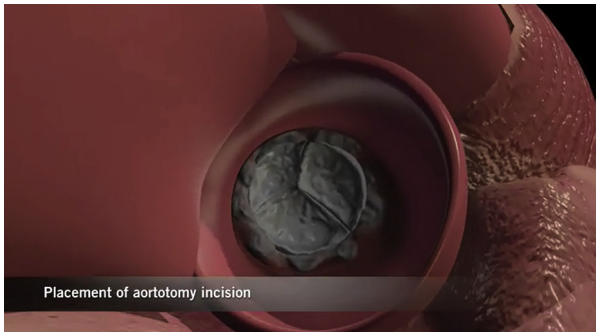
introduced into commercial use in 2010. Mid-term results on the safety and performance of the valve are reported based on a cohort of patients from the premarket approval study who consented to participate in longer-term follow-up.

MATERIALS AND METHODS

Study Design

To evaluate the mid-term clinical outcomes of the Trifecta valve, 710 eligible patients from 11 investigational sites were followed in this multicenter, prospective, nonrandomized, observational study. Valves were implanted with the use of standard methods (Video 1) between 2007 and 2009 as part of the premarket approval study (ClinicalTrials.gov number, NCT00475709) with inclusion/exclusion criteria as previously described (Appendix E1).[2] The 11 participating institutions consist of 9 investigational sites in the United States and 2 sites in Canada (Appendix E2). At each site, there were 2 or more primary surgeons who performed implants. After the premarket study was closed, 434 patients at these 11 sites moved on to participate in either a postapproval study (n = 245) mandated by the Food and Drug Administration or a voluntary postmarket long-term follow-up study (n = 189). The postapproval and long-term follow-up studies were both sponsored by St Jude Medical and registered with ClinicalTrials.gov, NCT01514162 and NCT01593917 (Figure E1). The appropriate institutional review board approval was obtained at each center, and all patients gave written informed consent to participate in each study.

The Trifecta valve is a trileaflet stented pericardial valve designed for supra-annular placement in the aortic position. The valve is fabricated via a polyester-covered titanium stent. The stent, excluding the sewing cuff, is then covered with porcine pericardial tissue. This covering is designed to provide protection from mechanical wear by allowing only tissue-to-tissue contact during valve function. A silicone insert in the polyester sewing cuff is contoured slightly to conform to the shape of the native annulus. The valve leaflets are fabricated from bovine pericardium.



VIDEO 1. Surgical implant procedure of a 71-year-old woman who underwent isolated aortic valve replacement with a 21-mm Trifecta valve as part of the premarket approval study with subsequent follow-up in the post-approval study. Echocardiogram performed at 5 years after implant shows no aortic regurgitation, a mean gradient of 9.6 mm Hg, and an effective orifice area index of 0.85 cm^2/m^2. Video available at: http://www.jtcvs.org.

The porcine and bovine pericardium are preserved and cross-linked in glutaraldehyde. Glutaraldehyde, formaldehyde and ethanol are used in the valve sterilization process. In addition, the Trifecta valve is processed with an ethanol-based anticalcification treatment (Linx AC; St Jude Medical) that in animal studies has demonstrated resistance to calcification.[3] There are no clinical data currently available that evaluate the long-term impact of the anticalcification tissue treatment in humans.

In the premarket approval study, the instructions for use recommended a postoperative antithrombotic regimen consisting of long-term, low-dose aspirin, unless contraindicated. A recommendation also is made for long-term anticoagulation therapy, unless contraindicated, in patients with risk factors for thromboembolism.

Follow-up

In the premarket approval study (NCT00475709) follow-up occurred at hospital discharge and during clinic visits at 6 months and at each year postimplant until study closure. Patients in the postapproval study (NCT01514162) continued to be followed on an annual basis with a clinic visit, whereas patients in the long-term follow-up study (NCT01593917) were followed annually with a clinic visit except for years 4 and 6, when a telephone follow-up was performed. Each clinic visit consisted of a transthoracic echocardiogram and assessments for New York Heart Association (NYHA) functional classification, serious adverse events, and general clinical status. An independent core laboratory assessed all echocardiograms, and an independent clinical events committee adjudicated adverse events. Over an interval of 6 years, 701 patients underwent 3751 clinic visits with a total of 3698 echocardiograms (98.6%) performed. The proportion of echocardiograms to clinic visits were 691 of 701 (98.6%) at discharge, 659 of 663 (99.4%) at 6 months, 648 of 650 (99.7%) at Year 1, 588 of 594 (99.0%) at Year 2, 448 of 450 (99.6%) at Year 3, 219 of 222 (98.6%) at Year 4, 358 of 369 (97.0%) at Year 5, and 87 of 102 (85.3%) at Year 6. Adverse events were classified according to the standardized definitions from The American Association for Thoracic Surgery and the Society of Thoracic Surgeons.[4] Events were classified as occurring early (within 30 days of implant) or late (≥31 days after implant).

Statistical Analysis

Statistical analyses were performed with SAS software version 9.3 (SAS institute Inc, Cary, NC). Continuous variables are presented as mean ± standard deviation and range (minimum, maximum) and categorical variables as frequencies and percentages. For late adverse events, Kaplan-Meier analyses were used to summarize the time to first adverse events. Linear mixed models (SAS PROC MIXED) were used to evaluate the change over time of the hemodynamic measurements.[5-7] As part of this evaluation, the skewed hemodynamic measurements of aortic valve gradient, effective orifice area, and effective orifice area index were transformed logarithmically to achieve a more normal distribution of dependent variables. The models also include a transformation of implant duration and valve size as fixed effects, along with a random intercept and a random slope for the implant duration (Table E1). Ordinal longitudinal mixed models (SAS PROC NLMIXED) were used to evaluate the change over time of the ordinal repeated measures of NYHA class and aortic regurgitation grade.[7] The ordinal longitudinal mixed models include the continuous variable of implant duration as a fixed effect and a random intercept (Table E2).

RESULTS

The mean age of the 710 patients was 72.4 ± 9.3 years, with 152 patients (21.4%) having an age ≥80 years. Baseline patient demographics and operative details for these patients are detailed in Table 1 and Table 2. Indications for aortic valve replacement included stenosis in 366 patients (51.6%), regurgitation in 45 patients (6.3%), and mixed