Although stentless aortic bioprostheses have been demonstrated to provide a hemodynamic profile more closely resembling the native valve, implantation is technically demanding. Recently introduced stented valves have shown exceptional performance compared with stentless valves. The Trifecta stented aortic bioprosthesis is designed for supra-annular placement with features conceived to improve hemodynamic performance.

OBJECTIVE

The objective of this study was to evaluate the early clinical and hemodynamic performance of the Trifecta aortic bioprosthesis in a single-center study.

METHODS

A total of 70 consecutive patients who underwent aortic valve replacement between August 2010 and December 2011 were included in the study.

Transthoracic echocardiography performed preoperatively and at discharge was used to assess hemodynamic performance.

RESULTS

Mean age of the patients was 74.7 ± 7.7 years (range 47 to 90 years) and 53% (n = 37) were female. All patients were in New York Heart Association Class III or IV. The mean body surface area was 1.95 ± 0.20 m²; mean body mass index was 28.9 ± 4.77 kg/m²; and the mean EuroSCORE was 8.36 ± 2.64.

The mean pressure gradient decreased from a preoperative value of 50 ± 17 mmHg to 9 ± 4 mmHg intraoperatively and 10 ± 4 mmHg at discharge.

Echocardiographic hemodynamic data for each valve size is shown in Table 1.

Table 1. Postoperative Hemodynamic Results for the Trifecta Valve

<table>
<thead>
<tr>
<th>Valve Size (mm)</th>
<th>n (19 mm)</th>
<th>n (21 mm)</th>
<th>n (23 mm)</th>
<th>n (25 mm)</th>
<th>n (27 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean aortic gradient (mmHg)</td>
<td>14 ± 4</td>
<td>11 ± 5</td>
<td>11 ± 3</td>
<td>8 ± 2</td>
<td>6 ± 2</td>
</tr>
</tbody>
</table>

- No severe aortic regurgitation caused by severe leakage was observed at discharge. One patient had a moderate paravalvular leak without necessity of surgical treatment.
- There were no intraoperative deaths. The 30-day in-hospital mortality was 2.85% (n = 2).
- There were two perioperative strokes (2.85%) and one late death at 60 days.
- Compared with the results reported in the literature for other stented aortic valves (Mosaic™ porcine bioprosthesis and Carpentier-Edwards PERIMOUNT™ bovine bioprosthesis), the Trifecta valve had lower mean gradients at discharge than all size-matched porcine valves.2,3 The Trifecta valve may have slightly better mean gradients than size-matched PERIMOUNT valves.
  - In this study, the mean gradients for the Trifecta valve were 14, 11, 11, 8 and 6 mmHg for the 19, 21, 23, 25 and 27 mm valve sizes, respectively.
  - For the Mosaic porcine bioprosthesis, Wong et al. have reported mean gradients of 16.1, 15.9 and 12.1 mmHg for the valve sizes 21, 23 and 25 mm, respectively.3 Similar gradients for Mosaic porcine bioprosthesis were reported by Nozohoor et al.4
  - For the Carpentier-Edwards PERIMOUNT (CEP) bovine bioprosthesis, Chambers et al. reported mean gradients of 16, 13, 8 and 10 mmHg for the valve sizes 19, 21, 23 and 25 mm, respectively.
SUMMARY OF KEY FINDINGS
- The early experience with the Trifecta valve demonstrated satisfactory hemodynamic results with low early-term morbidity and mortality.
- The Trifecta valve has better hemodynamic function than other bovine aortic prostheses, particularly in small sizes.
- The advantages of Trifecta also extend to comparisons with stentless prostheses, which are intended to provide improved hemodynamics but at the expense of a more technically demanding implant procedure.

CONCLUSIONS
- The initial experience with the Trifecta bioprosthesis demonstrates excellent outcomes with favorable hemodynamics.
- Further studies with longer follow-up are needed to confirm the preliminary results.
REFERENCES


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), mycocardial infection, nonstructural dysfunction (entrapped 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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