Early hemodynamic performance of the third generation St Jude Trifecta aortic prosthesis: A systematic review and meta-analysis

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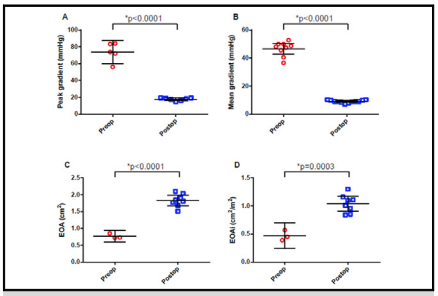
ABSTRACT

Objective: The Trifecta aortic prosthesis is a latest-generation trileaflet stented pericardial valve designed for supra-annular placement in the aortic position. Robust clinical evidence and long-term follow-up data for this new prosthesis are lacking; a systematic review was conducted to assess current evidence.

Methods: A comprehensive search from 6 electronic databases was performed, with time period parameters dating from database inception to January 2014. Results utilizing Trifecta prosthesis for aortic valve replacement (AVR) were identified.

Results: A total of 13 studies with 2549 patients undergoing AVR with this prosthesis were included in this review. The mean proportion of patients with aortic stenosis was 82.4%, with a mean gradient of 47.4 mm Hg, and a pooled effective orifice area (EOA) of 0.74 cm^2. Valve sizes of 21 mm and 23 mm were implanted in 71.3% of patients. The pooled rates of 30-day mortality, cerebrovascular accidents, and acute kidney injuries were 2.7%, 1.9%, and 2.6%, respectively. After implantation, the pooled mean gradient decreased to 9.2 mm Hg, whereas discharge EOA increased to 1.8 cm^2, compared with preoperative parameters. Among included studies with significant heterogeneity detected, most patients had satisfactory patient-prosthesis mismatch, with 2.7% having severe mismatch.

Conclusions: The present systematic review demonstrated that short-term AVR with this prosthesis provided excellent early safety and hemodynamic outcomes with acceptable mean gradients and EOA. Long-term follow-up and randomized controlled trials are warranted to confirm the early results. (J Thorac Cardiovasc Surg 2015;149:1567-75)



Significant improvement in all echocardiographic outcomes postoperatively.

Central Message

The present systematic review demonstrated that short-term Trifecta aortic valve replacement provided excellent results of early safety and haemodynamic outcomes with acceptable mean gradients and effective orifice area. Future long-term follow-up and randomized controlled trials are warranted to conform the early promising results of the Trifecta prosthesis.

Perspective

The Trifecta aortic prosthesis is a latest-generation trileaflet stented pericardial valve designed for supra-annular placement in the aortic position. There is still a lack of robust clinical evidence and long-term follow-up data for this new prosthesis, thus a systematic review was conducted to assess the current evidence available. Pooled results from 13 studies and 2549 Trifecta prosthesis patients demonstrated excellent safety and haemodynamic outcomes in the short-term, with acceptable mean gradients and effective orifice area. Future long-term follow-up and randomized control trials are warranted to conform the early promising results.

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Abbreviations and Acronyms

AVR = aortic valve replacement
CI = confidence interval
EOA = effective orifice area
EOAi = effective orifice area index
EuroSCORE = European System for Cardiac Operative Risk Evaluation
PPM = patient-prosthesis mismatch

Supplemental material is available online.

Although surgical aortic valve replacement (AVR) remains the gold standard as a treatment approach for patients with severe aortic stenosis, the design and efficacy of aortic valves have progressed and evolved with time. The latest generation of aortic valves has been manufactured with the aim of improving hemodynamic parameters and minimizing leaflet stress, while maintaining or improving the durability of previous valves.

The Trifecta (St Jude Medical Inc, St Paul, Minn) prosthesis is a third-generation, trileaflet, stented, pericardial valve designed for supra-annular placement in the aortic position.[1,2] This prosthesis consists of bovine pericardial tissue mounted on a titanium stent, the purpose of which is to optimize direct tissue-to-tissue contact and reduce mechanical wear. The valve was approved by the US Food and Drug Administration in 2010, and some studies since have advocated its potential benefits, including claims of increased effective orifice area (EOA), reduced risk of abrasion and structural valve deterioration, as well as improved resistance to cardiac stress on leaflets.[1,3-5] However, these potential benefits have yet to be verified by robust clinical evidence; randomized controlled studies and long-term follow-up data for this new prosthesis are still lacking.

Few single-center and multi-institutional studies have been conducted to investigate the efficacy and hemodynamic profile of this valve. To evaluate the current evidence

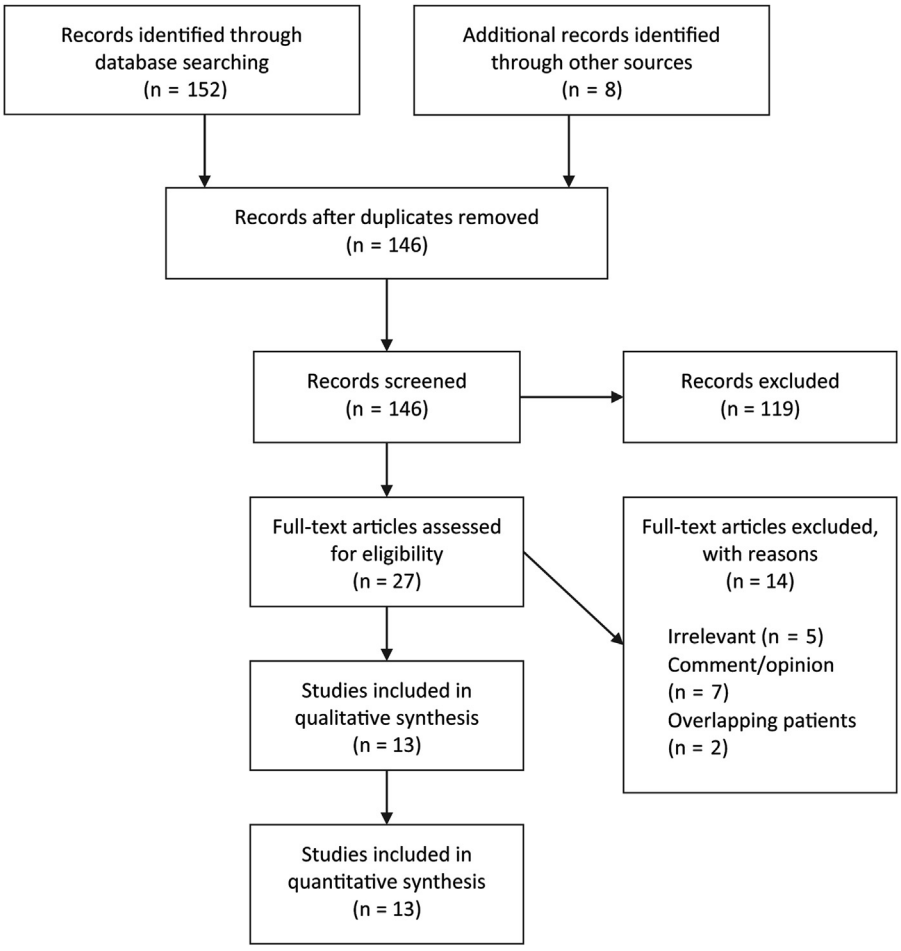

FIGURE 1. PRISMA flowchart of search strategy for studies investigating the aortic valve prosthesis.