

Trifecta versus Perimount Magna Ease aortic valve prostheses

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The Annals of Thoracic Surgery. 2020; doi: 10.1016/j.athoracsur.2019.12.071.

Key points

- The Trifecta group had significantly higher risks of repeat AVR (all-cause), repeat AVR for structural valve failure, and repeat AVR and/or prosthetic valve endocarditis.
- The significantly higher risk of repeat AVR due to structural valve failure in the Trifecta group remained after propensity matching.

Background information

- Although SAVR bioprostheses can be affected by SVD, they are increasingly being offered to non-elderly patients.
- Long-term durability comparisons of different SAVR prostheses are limited.

Aim

- To compare the outcomes of the Trifecta and Carpentier-Edwards PERIMOUNT Magna Ease valves.

Type of study

- A retrospective, non-randomised, propensity-matched comparative analysis.

Endpoints

- Repeat AVR (all-cause)
- Repeat AVR due to structural valve failure
- Repeat AVR and/or prosthetic valve endocarditis
- Prosthetic valve endocarditis
- Late all-cause mortality.

Methods

- Data on patients with AS who had undergone SAVR (with the Trifecta or the Carpentier-Edwards PERIMOUNT Magna Ease valves) at five Finnish hospitals between January 2008 and October 2017 were obtained from the FinnValve registry (ClinicalTrials.gov: NCT03385915).
- Data on mortality were obtained via patients' death certificates from the Finnish Population Register Centre.
- Data on cardiovascular interventions were obtained from the Finnish National Institute for Health and Welfare.
- Late echocardiographic data were not included because echocardiography is neither standardised nor performed routinely in Finland.
- Prosthesis failure was defined as any structural defect resulting in significant AS and/or intraprosthetic regurgitation.
- Propensity score matching accounted for baseline and operative covariates.



Edwards

Results

Patient characteristics

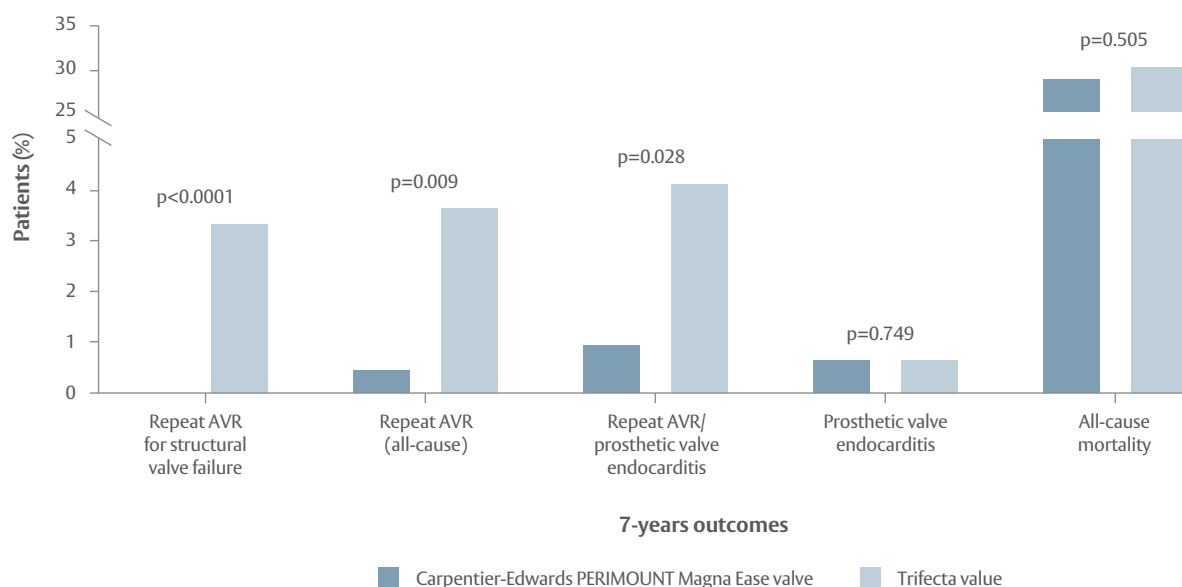
- A total of 2,216 patients (mean age 74.1 ± 6.7 years; 44.9% female) were implanted with the Trifecta valve (n=851) or the Carpentier-Edwards PERIMOUNT Magna Ease valve (n=1,365).
- Mean follow-up was 3.8 ± 2.1 years for 9,044 patient-years.
- The Trifecta group had a higher STS score than the Carpentier-Edwards PERIMOUNT Magna Ease group ($3.1 \pm 3.3\%$ vs $2.7 \pm 2.3\%$, $p=0.01$).
- Smaller valve sizes (19 mm or 21 mm) were more common in the Trifecta group (39.0% vs 26.9% , $p<0.0001$).

Outcomes

- Overall, 7-year outcomes were more favourable for the Carpentier-Edwards PERIMOUNT Magna Ease group than the Trifecta group, but rates of valve endocarditis and late all-cause mortality were similar (Figure 1).
- Mean postoperative transvalvular gradient was lower in the Trifecta group (8.0 ± 4.0 mmHg vs 11.0 ± 4.0 mmHg, $p<0.0001$).
- Rates of repeat AVR due to structural valve failure (3.3% vs 0% , $p<0.0001$), repeat AVR (all-cause) (3.6% vs 0.4% , $p=0.009$) and repeat AVR/prosthetic valve endocarditis (4.1% vs 0.9% , $p=0.028$) were significantly higher in the Trifecta group.

- Repeat AVR was attributed to:
 - Severe paravalvular regurgitation (not regarded a mode of prosthesis failure) in 38.1% of cases, with eight patients in total: six in the Carpentier-Edwards PERIMOUNT Magna Ease group, and two in the Trifecta group.
 - Intraprosthetic regurgitation and/or severe prosthetic valve stenosis in 52.4% of cases, with 11 patients in total: one in the Carpentier-Edwards PERIMOUNT Magna Ease group and 10 in the Trifecta group.
 - Endocarditis in 19% of cases, with four patients in total: two in the Carpentier-Edwards PERIMOUNT Magna Ease group and two in the Trifecta group.
- Valve-in-valve TAVR was successfully carried out in six patients, representing 28.6% of the total number of patients undergoing repeat AVR.
- In patients who underwent repeat SAVR (n=15), intraprosthetic regurgitation was attributed to leaflet calcification (6.7%), frame deformation and leaflet restriction (6.7%), and detached and perforated leaflets (13.3%).
- After propensity matching (772 pairs), the risk of repeat AVR due to structural valve failure was significantly greater in the Trifecta group (5.7% vs 0% , $p=0.009$). Although not statistically significant, the risk of repeat AVR or prosthetic valve endocarditis ($p=0.09$) and repeat AVR (all-cause) ($p=0.053$) was higher in the Trifecta group.

Figure 1: 7-year outcomes following SAVR with the Trifecta or Carpentier-Edwards PERIMOUNT Magna Ease valves*.



*Data displayed in figure are not propensity matched.

Limitations

- The study was retrospective.
- The non-randomised study design may have introduced bias.
- Echocardiographic measurements of SVD were lacking.
- Haemodynamic data were lacking for the 27 mm and 29 mm Carpentier Edwards PERIMOUNT Magna Ease valves, so PPM was approximated based on the EOAs of the closest valve sizes.

The full publication is available at:
<http://bit.ly/biancari>

Abbreviations

AS: aortic stenosis
AVR: aortic valve replacement
EOA: effective orifice area
PPM: patient–prosthesis mismatch
SAVR: surgical aortic valve replacement
STS: Society of Thoracic Surgeons
SVD: structural valve degeneration
TAVR: transcatheter aortic valve replacement

Conclusion

In patients mostly older than 65 years, the Trifecta valve was associated with higher rates of repeat AVR due to structural valve failure compared with the Carpentier-Edwards PERIMOUNT Magna Ease valve. Longer-term comparative studies (including echocardiographic analysis of SVD) are required to confirm this finding.

This document is a summary of the Biancari F et al. paper and covers key information including aim, type of study, methods, results, limitations and conclusions.

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