

Mitroflow and PERIMOUNT Magna 10 years outcomes a direct propensity match analysis to assess reintervention rates and long follow-up mortality

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Journal of Cardiac Surgery. 2019; **34**: 1279–87.

Key points

- Survival and intervention-free survival rates were significantly higher for patients with the Carpentier-Edwards PERIMOUNT Magna valve than for those with the Mitroflow valve (Sorin Inc.).
- The Carpentier-Edwards PERIMOUNT Magna valve appears to offer better short- and long-term outcomes.

Background information

- Bioprostheses are the most common valve type used for AVR in the UK.
- In 2017, the UK Medicine and Healthcare products Regulatory Agency issued a Medical Device Alert about early SVD in 19- to 21-mm Mitroflow LX valves implanted between 2005 and 2014.

Aim

- To compare outcomes up to 10 years for the Carpentier-Edwards PERIMOUNT Magna valve and the Mitroflow valve.

Type of study

- A single-centre, retrospective study with propensity matching.

Endpoints

- Aortic valve reintervention and all-cause mortality rates.

Methods

- The analysis included 2,608 patients who had undergone AVR with the Mitroflow valve (n=352) or the Carpentier-Edwards PERIMOUNT Magna valve (n=2,256) between 1999 and 2014.
 - All patients underwent a full sternotomy with a low degree of hypothermia.

- The patients were propensity matched 3:1, resulting in 233 patients in the Mitroflow group and 699 patients in the Carpentier-Edwards PERIMOUNT Magna valve group.
- Patients with multiple valve replacements or combined procedures were excluded from the analysis.
- Median follow-up for the complete data set was 6.95 years (interquartile range 4.99–9.69).

Results

Patient characteristics

- After propensity matching, there were no significant differences in baseline characteristics.
- The mean patient age was 74 years.

Outcomes

- The Mitroflow group had a higher rate of aortic valve reintervention than the Carpentier-Edwards PERIMOUNT Magna valve group (4.7% vs 1.0%, $p < 0.001$).



- The incidence of reintervention was similar in the first 2 years, after which the rate increased more sharply for the Mitroflow valve.
- In addition, mortality at 3, 5 and 10 years was significantly higher in the Mitroflow group (Figure 1).
- The Carpentier-Edwards PERIMOUNT Magna valve group showed a gradual decline in cumulative probability of survival over time, to around 72–75% at 10 years.
- The Mitroflow valve group showed a steeper decline in cumulative probability of survival, to less than 50% at 10 years.

Limitations

- This was a non-randomised, retrospective, single-centre study.
- Echocardiographic follow-up was inconsistent because a number of patients were referred to the study centre from other hospitals, and their follow-up was lost.
- Data on cardiac *versus* non-cardiac deaths are yet to be analysed.

- Data were insufficient to be able to compare the outcomes of the 19- and 21-mm Mitroflow valves with larger valves.

Conclusion

The Mitroflow group had significantly lower rates of survival and intervention-free survival than the Carpentier-Edwards PERIMOUNT Magna valve group. The Carpentier-Edwards PERIMOUNT Magna valve appears to offer better short- and long-term outcomes than the Mitroflow valve. Larger studies are required to validate these results.

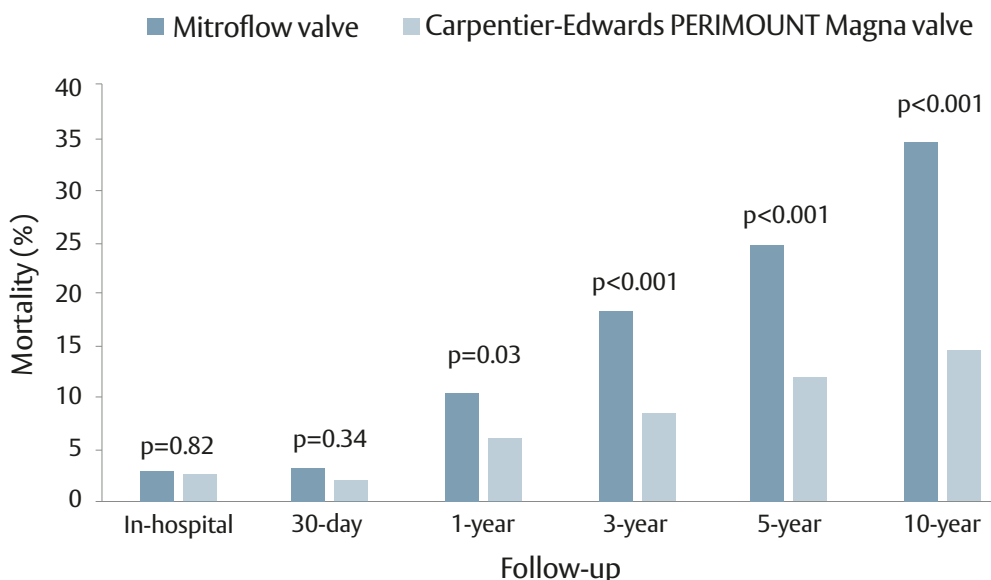
This document is a summary of the Theologou T et al. paper and covers key information including aim, type of study, methods, results, limitations and conclusions.

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

Abbreviations

AVR: aortic valve replacement
SVD: structural valve degeneration

Figure 1. Propensity-matched mortality at various timepoints, by valve model.



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