Summary 29

Long-term follow-up of Bentall procedure using the Perimount bioprosthesis and the Valsalva graft

Chirichilli I, Irace FG, D'Aleo S, Folino G, Weltert LP, Scaffa R, Nardella S and De Paulis R

Interactive CardioVascular and Thoracic Surgery. 2020; **30:** 679–684. doi:10.1093/icvts/ivaa007

Key points

- Valsalva sinuses prevent contact of the aortic valve leaflet with the aortic wall and facilitate smooth closure of the valve.
- The Bentall technique can be modified to include creation of a Valsalva pseudosinus.
- Outcomes for up to 16 years using a combination of the modified Bentall procedure with a Carpentier-Edwards PERIMOUNT or PERIMOUNT Magna Ease valve appear to be safe and effective with 100% freedom from SVD at 10 years.

Background information

- A sinus of Valsalva is an enlargement of the aortic root area between the aortic valve annulus and sinotubular ridge. It is thought to prevent contact of the valve leaflet with the aortic wall and to facilitate smooth closure of the aortic valve.
- Creation of Valsalva pseudosinuses, a modification to the Bentall procedure of aortic root replacement may reduce the incidence of thromboembolism and decrease stress on the coronary button anastomoses, bioprosthesis leaflets and commissures.
- The PERIMOUNT and PERIMOUNT Magna Ease valves have shown good long-term performance despite associated prosthetic valve-related complications, such as thromboembolism and endocarditis.
- The creation of Valsalva pseudosinuses during aortic valve replacement (AVR) with the PERIMOUNT or PERIMOUNT Magna Ease valves may increase valve durability and reduce valverelated complications.

Aim

• To understand the long-term outcomes of combining the Valsalva graft and PERIMOUNT or PERIMOUNT Magna Ease bioprosthesis in experienced centres.

Type of study

• Retrospective, long-term analysis.

Endpoints

• Freedom from structural valve degeneration (including dysfunction [SVD]), cardiac death, haemorrhage, thromboembolism, infective endocarditis or reoperation.

Methods

- A total of 309 patients underwent AVR using the PERIMOUNT or PERIMOUNT Magna Ease valve, combined with the Bentall procedure with Valsalva pseudosinus formation.
- Valsalva pseudosinuses were 3- or 5-mm larger than the bioprosthesis.



- Mean patient follow-up was 60 ± 45 months (range: 1–204 months).
- Follow-up data for 97% of patients were collected by outpatient visits and personal telephone interviews.

Results

Patient and procedural characteristics

 Patients were predominantly male (88%) with a mean age of 68.9 ± 6.9 years and a mean EuroSCORE II of 2.7 ± 0.9%.

Operative data

- Concomitant surgery was performed in 29% patients.
- Mean cross-clamp time was 80.2 ± 25.9 minutes. Mean cardiopulmonary bypass time was 99.6 ± 35.7 minutes.
- The 25 mm aortic valve was the most commonly used valve (48% patients).
- A 28 mm Valsalva graft was used in 52% patients.

Outcomes

• Perioperative outcome:

- Perioperative deaths occurred in 5 (1.6%) patients as a result of: multi-organ failure (n=2); mediastinitis (n=1); cerebral ischaemia (n=1) and cerebral haemorrhage (n=1).
- Long-term outcomes (Table 1):
 - There were 37 late deaths recorded (12% of patients)
 - Eight patients required reoperation: seven for infective endocarditis and one for valve degeneration.

Limitations

- Limited reporting of outcome-related events affected the power of this study.
- At-risk patients form less than 10% of the initial patient cohort.

Conclusion

The study indicates safe and effective outcomes, and long-term durability of the Bentall procedure using the PERIMOUNT or PERIMOUNT Magna Ease valves, and Valsalva grafts in experienced centres. Further long-term studies are needed to validate these outcomes in a larger patient population and over a longer period.

| Outcome % (95% CI)* | 5 years | 10 years | 15 years | 16 years |
|-------------------------------|-------------|-------------|---------------------|---------------------|
| Overall survival | 88.6 | 81.4 | 65.4 | 54.5 |
| | (83.9–92.0) | (73.5–88.4) | (43.4–80.6) | (27.5–75.2) |
| Freedom from | | | | |
| Cardiac death | 98.7 | 98.7 | 92.1 | 78.6 |
| | (95.6–99.5) | (95.6–99.5) | (65.0–97.4) | (32.5–94.0) |
| Haemorrhage | 97.5 | 95.2 | 95.2 | 95.2 |
| | (95.0–98.6) | (87.1–98.2) | (87.1–98.2) | (87.1–98.2) |
| Thromboembolism | 98.2 | 98.2 | 98.2 | 98.2 |
| | (96.0–98.9) | (96.0–98.9) | (96.0–98.9) | (96.0–98.9) |
| SVD* | 100 | 100 | 87.5 (63.2–97.1) | 87.5 (63.2–97.1) |
| Infective | 97.0 | 96.0 | 79.6 | 79.6 |
| endocarditis | (93.7–98.6) | (91.8–98.9) | (45.3–95.6) | (45.3–95.6) |
| Reoperation | 98.1 | 97.1 | 74.7 | 74.7 |
| | (94.9–99.3) | (92.8–98.8) | (41.9–90.6) | (41.9–90.6) |

Table 1: Long-term outcomes

*CI: confidence interval; SVD: structural valve degeneration

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

The full publication is available at: https://bit.ly/2XPJBnp

Abbreviations

| AVR: | aortic valve replacement | |
|---------------|--|--|
| CI: | confidence interval | |
| SVD: | structural valve degeneration | |
| EUROSCORE II: | European System for Cardiac Operative Risk | |
| | Evaluation II score | |

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, Magna, Magna Ease, PERI, PERIMOUNT and PERIMOUNT Magna are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

 ${\small @}$ 2020 Edwards Lifesciences Corporation. All rights reserved. PP--EU-0148 v1.0

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

