

## Clinical Summary:

# Very long-term outcomes of the Carpentier-Edwards PERIMOUNT valve in aortic position

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## Aim

To assess long-term durability of the Carpentier-Edwards PERIMOUNT pericardial bioprosthesis implanted in the aortic position, depending on age at implantation, focusing particularly on the patient's perspective

## Type of study

A long-term (20 years), retrospective, single-centre, observational, follow-up analysis

## Endpoints

Survival, expected valve durability and freedom from major valve-related complications such as thromboembolic, bleeding, and reoperation events

## Key points

- Expected valve durability was 19.7 years for all age groups
- For patients aged 60 or below at implant, the expected valve durability remained above 17 years. For patients aged 60–70 years, expected valve durability was 22.1 years
- Freedom from reoperation due to structural valve deterioration (SVD) at 20 years was  $38.1 \pm 5.6\%$  for those aged 60 years or less,  $59.6 \pm 7.6\%$  for those 60 to 70 years, and  $98.1 \pm 0.8\%$  for the oldest group
- Evidence-based discussion between the patient and their physician about the surgery, estimated risk and number of years before reoperation due to SVD, based on patient age at surgery

## Background information

- The Carpentier-Edwards PERIMOUNT pericardial bioprosthesis is a trileaflet valve formed from bovine pericardial leaflets mounted under a flexible cobalt-chromium stent. The stent is designed to minimise structural valve deterioration
- The Carpentier-Edwards PERIMOUNT pericardial valve has demonstrated good long-term outcomes, however the impact of the age at implant on valve durability and reoperative risk remains largely unclear

## Methods

- From July 1984 to December 2008, 2,758 Carpentier-Edwards PERIMOUNT pericardial prostheses were implanted in the aortic position in 2,659 patients:
  - All patients requiring second or third valve replacements were considered new patients
  - Patients undergoing concomitant multiple valve replacements were excluded from the study
- Data were prospectively recorded following an annual patient questionnaire
  - Systematically every year patients received a clinical evaluation questionnaire and a transthoracic echocardiography was realised
  - Patients who did not respond to the questionnaire or who reported an adverse event were followed up via telephone or by personal interview

## Methods (continued)

- The bioprosthesis was considered to have deteriorated on strict echocardiographic assessment whenever severe aortic stenosis (mean transvalvular gradient >40 mmHg) and/or severe aortic regurgitation (effective regurgitant orifice area >0.30 cm<sup>2</sup>, vena contracta >0.6 cm) was observed, even if the patient was asymptomatic
- Mean follow-up time was 6.7±4.8 years for a total of 18,404 valve-years (vys)
  - Follow-up, including clinical and echocardiography measurements, were completed for 97.7% of patients
- Life expectancy and expected valve durability were estimated by the median survival time (MST) and the area under a Kaplan-Meier curve

## Results

### Survival

- At 20 years, the valve-related actuarial survival rate was 64.1±3.5%, while the overall actuarial survival
- Valve-related actuarial survival rates were higher in lower age groups:
  - 83.6±3.4% for ≤60 years
  - 68.9±6.6% for 60–70 years
  - 26.4±12.5% for >70 years
  - Age at implantation was a significant risk factor affecting survival (HR 1.065; 95% CI 1.0–1.1; p<0.001)

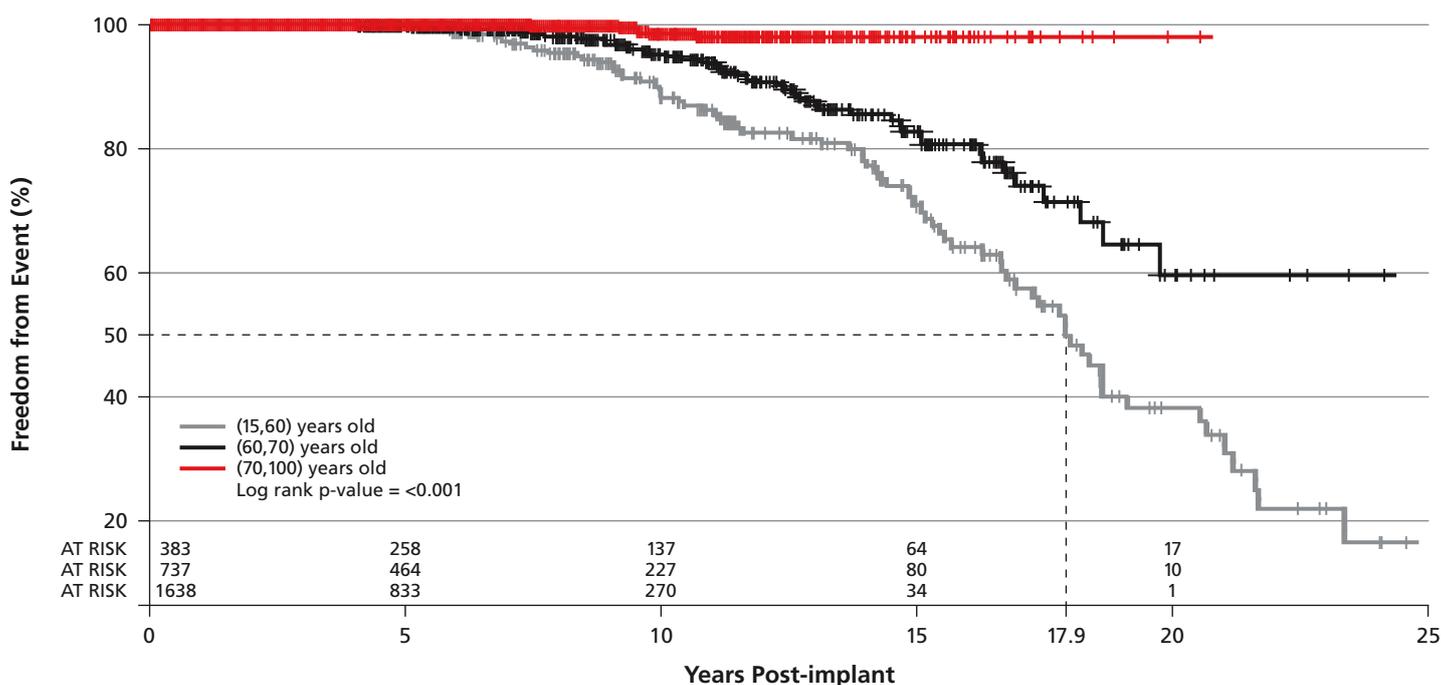
### Thromboembolic and bleeding events, endocarditis

- No case of valve thrombosis was reported
- 162 thromboembolic events were reported (29 early events): linearised rate of 0.72%/valve-year (vy)
- 71 bleeding events were reported (9 early events) with one-third associated with anticoagulant usage: linearised rate of 0.34%/vy
- Endocarditis was reported in 73 patients, with 3 early events: linearised rate of 0.38%/vy

### Structural valve deterioration (SVD)

- Expected valve durability was 19.7 years for all age groups (95% CI 18.5–21.1), as calculated by the MST before valve deterioration
- Actuarial freedom from SVD was 78.6±2.2% at 15 years and 48.5±4.6% at 20 years
- SVD was reported in 157 patients (0.85%/vy).
  - Of these, 123 patients underwent reoperation to replace the valve
  - Cases of valve failure were late events; only 6 cases of SVD arose within the first 5 years (all age groups)

**Figure 1. Kaplan-Meier freedom from explant due to SVD by age groups**



### SVD stratified by age

- The population was divided into age groups at the time of implantation for subsequent analysis (Figure 1)
- For patients aged 60 or below at implant, the expected valve durability was 17.6 years
  - Freedom from SVD was 66.8±4.2% at 15 years and 37.2±5.4% at 20 years
  - Freedom from reoperation due to SVD at 15 and 20 years was 70.8±4.1% and 38.1±5.6% respectively
- For patients aged 60–70 years, expected valve durability reached 22.1 years
  - Freedom from SVD was 77.7±3.4% at 15 years and 53±8.0% at 20 years
  - Freedom from reoperation due to SVD at 15 and 20 years was 82.7±2.9% and 59.6±7.6% respectively
- For the oldest group, aged >70
  - Freedom from SVD at 15 years: 91.6±2.3%
  - Freedom from reoperation due to SVD was 98.1±0.8% at 15 and 20 years

### The patient's perspective

- Patients often ask about the need for reoperation following valve surgery. Results from this study provide an estimated risk and number of years before reoperation due to SVD, depending on age at surgery
- This allows a basis for evidence-based discussion between the patient and their physician about the surgery
- Expected valve durability was 19.7 years for combined age groups, with age at implant a significant risk factor for SVD
- There was a 4.0±1.0% probability for a patient aged ≥65 years at time of implant to experience a reoperation due to SVD, within 20 years (cumulative, or “actual”, risk analysis)
- Table 1 indicates the estimated number of years a patient could expect before requiring reoperation due to a SVD, depending on age at implant

**Table 1. Explant due to SVD by age groups – Competing Risk Estimates (with age at surgery as the unique covariate)**

Prob/Age	50 y	55 y	60 y	65 y	70 y	75 y	80 y
5%	9.2	9.9	11.1	13.1	15.1	17.8	21.6
10%	11.1	13.1	15.1	17.5	21.2	–	–
15%	13.7	15.4	17.9	23.4	–	–	–
20%	15.1	17.8	21.6	–	–	–	–
25%	16.9	19.7	–	–	–	–	–

For example, a 60-year-old patient has a 20% probability of being reoperated due to SVD after 21.6 years.

## Key insights

In terms of recommendations for the use of bioprosthetic valves, these excellent outcomes support their use in patients aged 60 years onwards, notably younger than the cut-off of 65 years currently retained in the international guidelines

Even if patients less than 60 years have a higher risk of reoperation, the associated low mortality risk of the procedure versus the increased risk of haemorrhage secondary to anticoagulation, can make the option to use bioprosthetic valves an acceptable one for this population

## Conclusion

The Carpentier-Edwards PERIMOUNT pericardial bioprosthesis demonstrated a low rate of structural decline and a low rate of valve-related events at 20 years across age groups, when implanted in the aortic position and especially in patients over 60 years of age

*This document is a summary of the Bourguignon et al. paper and covers key information, including aims, type of study, methods, results and conclusions.*

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