Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistics, Edwards Lifesciences, Nyon, Switzerland

Background. **The Carpentier-Edwards Perimount pericardial bioprosthesis (Edwards Lifesciences, Irvine, CA) has demonstrated good long-term outcomes, but its durability remains unclear depending on age at implantation. We report our 20-year experience with the Perimount valve implanted in the aortic position, with particular attention to the probability and time to reoperation required due to bioprosthesis deterioration.**

Methods. **From 1984 to 2008 at our center, 2,659 patients (mean age, 70.7 ± 10.4 years) underwent aortic valve replacement using the Perimount pericardial bioprostheses. Patients were prospectively followed on an annual basis (mean 6.7 ± 4.8 years, range 0 to 24.6 years) with an echocardiogram at the time of follow-up. Cumulative follow-up was 18,404 valve-years. Bioprosthesis structural valve deterioration was determined by strict echocardiographic assessment.**

Results. **Overall operative mortality was 2.8%. Actuarial survival rates including early deaths averaged 52.4% ± 1.2%, 31.1% ± 1.4%, and 14.4% ± 1.7% after 10, 15, and 20 years of follow-up, respectively. Age-stratified freedom from reoperation due to structural valve deterioration at 15 and 20 years was 70.8% ± 4.1% and 38.1% ± 5.6%, respectively, for the group aged 60 years or less, 82.7% ± 2.9% and 59.6% ± 7.6% for those 60 to 70 years, and 98.1% ± 0.8% at 15 years and above for the oldest group. Expected valve durability is 19.7 years for the entire cohort.**

Conclusions. **With a low rate of valve-related events at 20 years, and particularly a low rate of structural valve deterioration, the Carpentier-Edwards Perimount pericardial bioprosthesis remains a reliable choice for a tissue valve in the aortic position, especially in patients over 60 years of age.**

(Ann Thorac Surg 2015;99:831–7)

The Carpentier-Edwards (CE) Perimount pericardial bioprosthesis (Edwards Lifesciences, Irvine, CA) is a trileaflet valve consisting of bovine pericardial leaflets mounted underneath a flexible cobalt-chromium stent. This second-generation pericardial valve was designed to minimize structural valve deterioration (SVD), which was primarily responsible for the failure of earlier generation pericardial bioprostheses [1, 2].

Several institutions have reported excellent clinical outcomes with the CE pericardial valve [3–8], but few focus on the impact of the age of the patient in terms of reoperation risk. Indeed, it largely remains unclear as to exactly how long a bioprosthesis may last in a patient operated in their 50s or 60s due to a lack of empirical long-term follow-up [9, 10].

The objective of this retrospective, observational study is to report our 20-year experience with the CE Perimount valve implanted in the aortic position, particularly focusing on the patient's perspective; in other words, the probability that a reoperation will be required due to deterioration of the bioprosthesis after a certain amount of time.

Patients and Methods

From July 1984 to December 2008, 2,758 CE Perimount pericardial bioprostheses were implanted in 2,659 patients for aortic valve replacement (AVR) in our hospital. Ninety-eight patients required a second bioprosthesis and 1 patient required a third; all were considered as new patients with a new valve. Indications of AVR with a bioprosthesis rather than a mechanical valve concerned all patients aged 60 years or older and younger patients if they met specific conditions (eg, endocarditis, short anticipated life expectancy because of comorbidities, contraindication to oral anticoagulant treatment, informed patient's choice). Patients

Accepted for publication Sept 19, 2014.

Address correspondence to Dr Bourguignon, Department of Cardiac Surgery, Trousseau Hospital, 37044 Chambray, France; e-mail: thierry-bourguignon@hotmail.fr.

Drs Aupart, Bourguignon, Marchand, and Candolfi disclose financial relationships with Edwards Lifesciences.

Published by Elsevier

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2014.09.030

Abbreviations and Acronyms

AF = atrial fibrillation
AUC = area under the curve
AVR = aortic valve replacement
CE = Carpentier-Edwards
CI = confidence interval
HR = hazard ratio
MST = median survival time
SVD = structural valve deterioration
vy = valve-year

undergoing multiple valve replacement were excluded from this study, but there was no exclusion for other concomitant operations.

Baseline and operative characteristics are presented in Table 1. Operative techniques were previously reported [4]. Postoperative anticoagulation therapy consisted of low molecular weight heparin enoxaparin 4,000 IU once daily until hospital discharge. Warfarin sodium was prescribed only for atrial fibrillation. Antiplatelet agents were prescribed based on cardiac (ischemic heart disease) or vascular (ischemic vascular accident, occlusive arterial disease of the lower limbs) indications only.

Data were prospectively recorded. Systematically every year, questionnaires were mailed to all patients for a clinical evaluation and a transthoracic echocardiography was realized. If the questionnaires were not returned or the patient reported an adverse event, telephone or personal interviews were conducted. At the time of follow-up, only recent echocardiographic data (<6 months) were considered. For deaths, the Social Security Death Index was used to confirm the date.

The mean duration of follow-up was 6.7 ± 4.8 years for a total of 18,404 valve-years (vy). Follow-up including clinical and echocardiographic evaluations was 97.7% complete. The closing interval for this study was 15 months. Morbidity and mortality were defined according to the guidelines [11, 12].

Table 1. Baseline and Operative Characteristics

Characteristics	Values
Patients, n	2,559
Implanted valves, n	2,758
Male, n (%)	1,886 (68.4%)
Age	
Mean ± SD, years	70.7 ± 10.4
Median (IQR), years	73 [66–78]
Range, years	16–91
Age ≤ 60 years, n (%)	383 (13.9%)
NYHA, n (%)	
I	688 (24.9%)
II	1,111 (40.3%)
III	651 (23.6%)
IV	308 (11.2%)
Atrial fibrillation, n (%)	252 (9.1%)
Etiology, n (%)	
Degenerative	2,403 (87.1%)
Reoperative	123 (4.5%)
Endocarditis	111 (4.0%)
Rheumatic	57 (2.1%)
Dissection	5 (0.2%)
Other	59 (2.1%)
Procedure, n (%)	
AVR only	1,780 (64.5%)
AVR + CABG	570 (20.7%)
AVR + CABG + other	67 (2.4%)
AVR + other	341 (12.4%)
Valve size, n (%)	
19 mm	384 (13.9%)
21 mm	888 (32.2%)
23 mm	924 (33.5%)
25 mm	511 (18.5%)
27 mm	46 (1.7%)
29 mm	5 (0.2%)

AVR = aortic valve replacement; CABG = coronary artery bypass grafting; IQR = interquartile range; NYHA = New York Heart Association functional class; SD = standard deviation.

Statistical Analysis

Kaplan-Meier actuarial analyses are presented with the Greenwood formula for the variance. Survival curves were compared using the log-rank test. Each patient's life expectancy was calculated using demographic life tables published by the French National Demographic Study Institute [13]. Life expectancy and expected valve durability are estimated by the median survival time (MST) and the area under the Kaplan-Meier curve (AUC). Univariate and multivariate Cox proportional hazards regression were used to identify risk factors. For nonfatal events, competing risk analyses [14, 15] were performed using the R *cmprsk* package (R software, version 2.13.1).

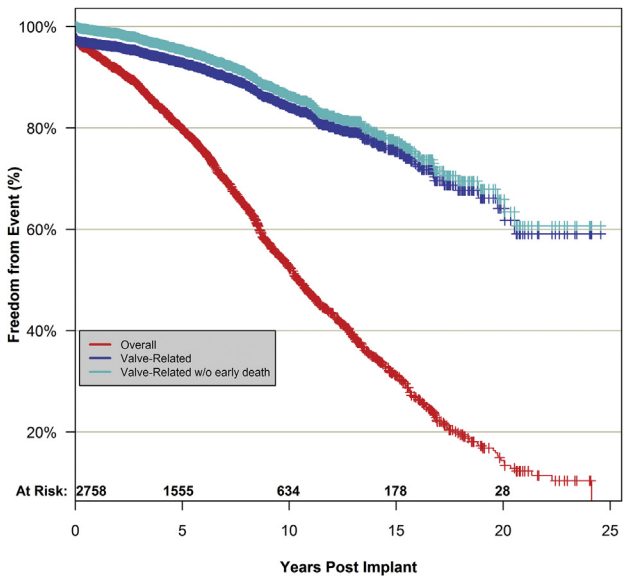

Fig 1. Overall and valve-related survival.