Comparison of long-term results between Hancock porcine bioprosthesis and Carpentier-Edwards pericardial bioprosthesis in the aortic and the mitral positions

Abstract The aim of this study was to compare the long-term results with the Carpentier-Edwards pericardial bioprosthesis, a second-generation bioprosthesis, and the Hancock porcine valve in the aortic and mitral position. Long-term results of isolated valve replacement with the Carpentier-Edwards pericardial bioprosthesis (73 valves in the aortic position and 73 valves in the mitral position) were compared with those with the Hancock porcine bioprosthesis (41 valves in the aortic and 124 valves in the mitral position). In the aortic position, the mean follow-up period was 8.2 ± 4.0 years with the Carpentier-Edwards pericardial bioprosthesis and 9.9 ± 4.4 years with the Hancock porcine bioprosthesis. In the mitral position, the mean follow-up period was 7.5 ± 4.3 years with the Carpentier-Edwards pericardial bioprosthesis and 10.0 ± 5.3 years with the Hancock porcine bioprosthesis. The results showed that the mean age at implantation was significantly higher in patients with a Carpentier-Edwards pericardial bioprosthesis (58 ± 13 years in the aortic and 51 ± 15 years in the mitral) than in those with a Hancock bioprosthesis (42 ± 13 years in the aortic and 45 ± 10 years in the mitral). In the aortic position, actuarial freedom from structural deterioration of the Carpentier-Edwards pericardial bioprosthesis was significantly better (85 ± 6% at 13 years) than that with the Hancock bioprosthesis (40 ± 10%, P < 0.02). In the mitral position, actuarial freedom from structural deterioration of the Carpentier-Edwards pericardial bioprosthesis was similar to that with the Hancock bioprosthesis (32 ± 9% and 44 ± 6% at 13 years, respectively). It is concluded that the durability of the Carpentier-Edwards pericardial bioprosthesis in the aortic position was satisfactory in the elderly patients. In the mitral position, the superior durability of the Carpentier-Edwards pericardial bioprosthesis against the Hancock bioprosthesis failed to be proved.

Key words Hancock porcine bioprosthesis · Carpentier-Edwards pericardial bioprosthesis · Structural deterioration

Introduction

The Carpentier-Edwards pericardial bioprosthesis (Baxter Healthcare, Edwards Division, Santa Ana, CA, USA) is a second-generation bioprosthetic valve that is known to have excellent hemodynamic performance and long-term durability in the aortic position. Although good durability of this valve in the mitral position was also expected, there are few data available reporting long-term durability of this biological valve in the mitral position in comparison with other biological valves.

We have previously reported our long-term experience with the Hancock porcine bioprosthesis (Medtronic, Minneapolis, MN, USA), the first-generation bioprosthetic valve. This report details our 15-year experience with the Carpentier-Edwards pericardial bioprosthesis and compares the results with that of the Hancock porcine bioprosthesis.

Patients and methods

In Kyushu University Hospital, 256 Hancock porcine bioprostheses (60 in the aortic, 169 in the mitral, 23 in the tricuspid, and 4 in the pulmonary position) were implanted in 220 patients from February 1975 through October 1981, and 183 Carpentier-Edwards pericardial bioprostheses (76 in the aortic, 87 in the mitral, 16 in the tricuspid, and 4 in the pulmonary position) were implanted in 164 patients from February 1985 through January 1995. Isolated aortic valve replacement was performed with 41 Hancock bioprostheses (AH group) and 73 Carpentier-Edwards pericardial
bioprostheses (ACEP group). Isolated mitral valve replacement was performed with 124 Hancock bioprostheses (MH group) and 73 Carpentier-Edwards pericardial bioprostheses (MCEP group).

Warfarin sodium anticoagulation was initiated in all patients after the removal of the chest tube. They received warfarin for up to 3 months after operation, and thereafter it was discontinued. If patients with mitral valve replacement had atrial fibrillation, a history of thromboembolism, or left atrial thrombus noticed at the operation, warfarin was continued indefinitely. The Thrombotest value was kept between 20% and 30%.

Follow-up was achieved either by direct contact with patients or through their referring physicians. It was completed during a 6-month closing interval ending on December 31, 1999. The follow-up rate was 98% in the AH group, 100% in the ACEP group, 96% in the MH group, and 99% in the MCEP group. The mean duration of follow-up was 9.9 ± 4.4 years (maximum, 19.5 years) in the AH group, 8.2 ± 4.0 years (maximum, 15.9 years) in the ACEP group, 10 ± 5.3 years (maximum, 20.1 years) in the MH group, and 7.5 ± 4.3 years (maximum, 14.4 years) in the MCEP group. The cumulative follow-up was 406 patient-years in the AH group, 597 patient-years in the ACEP group, 1243 patient-years in the MH group, and 550 patient-years in the MCEP group.

The definitions of postoperative events used in this study follow the “Guidelines for reporting morbidity and mortality after cardiac valvular operations”.

Analysis of differences between groups was performed by the unpaired Student's t-test for comparison of continuous variables. An actuarial analysis was calculated by the Kaplan-Meier method, and only the first event was considered in the actuarial analysis. The Mantel-Cox test was used for comparison of actuarial rates. Continuous data are represented as means ± 1 standard deviation. The actuarial probability estimates are expressed as means ± 1 standard error. Statistical analysis was performed using Stat View (Abacus Concepts, Berkeley, CA, USA) on a Macintosh computer. A p value less than 0.05 was considered significant.

**Results**

**Aortic valve replacement**

The mean age at implantation was 42 ± 13 years in the AH group and 58 ± 13 years in the ACEP group. These values are significantly different (P < 0.01). One hospital death occurred in the AH group (mortality rate, 2.4%), and two hospital deaths occurred in the ACEP group (mortality rate, 2.8%). The rates of freedom from thromboembolism, bleeding, and endocarditis at 13 years were similar in the AH and the ACEP groups: 93 ± 5% versus 93 ± 3%, 95 ± 4% versus 100%, and 89 ± 5% versus 94 ± 4%, respectively. Freedom from structural deterioration at 13 years was significantly better (P = 0.016) in the ACEP group (85 ± 6%) than in the AH group (40 ± 10%) (Fig. 1). Freedom from reoperation at 13 years tended to be better (P = 0.06) in the ACEP group (71 ± 9%) than in the AH group (38 ± 9%). There were 14 late deaths in the AH group (10 cardiac-related and 4 non-cardiac-related) and 18 late deaths in the ACEP group (9 cardiac-related and 9 non-cardiac-related). The actuarial survival rate at 13 years was similar between the groups: 60 ± 9% in the AH group and 56 ± 10% in the ACEP group (Fig. 2).

**Mitral valve replacement**

The mean age at implantation was 45 ± 10 years in the MH group and 51 ± 15 years in the MCEP group. These values