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# MITRAL VALVE REPLACEMENT WITH THE CARPENTIER EDWARDS BIOPROSTHESIS: The late surgical results.

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*From 1976 to 1992, 78 Carpentier -Edwards Porcine (Bioprostheses) heart valve replacement operations have been performed. Twenty-six of them were male (29%), and 52 were female (71%). In this serie all the valves were replaced in the mitral position. A close follow -up and through investigation was done on 70 patients covering 1-16 postoperative years, in order to evaluate the end results of this particular type of prosthetic valve. Functional capacity was improved in all patients. Thromboembolic event developed in 3 cases (4.3 %), prosthetic valve dysfunction was noticed in 36 cases (51.4%), and infectious valve endocarditis was diagnosed in 3 patients (4.3%). Hemolysis due to prosthetic valve was not encountered. The total mortality was 19%. We conclude that the Carpentier-Edwards porcine bioprosthesis has an acceptable performance after mitral valve replacement, and we continue to favor its use in certain conditions.*

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**T**he glutaraldehyde preserved biologic prosthesis have been utilized as cardiac valvular substitutes for over 15 years<sup>20</sup>. The porcine bioprosthesis have provided patients an excellent quality of life, with a low rate of serious thromboembolism, essential lack of thrombosis, and freedom from anticoagulant-related hemorrhage<sup>2,8,13,18</sup>. Altered durability has been the primary concern over the past 10 years with bioprostheses<sup>5,6,10</sup>. The clinical performance of the first-generation porcine bioprostheses is continually reported to determine the long-term results, especially of durability. The standart Carpentier-Edwards porcine bioprosthesis was introduced in 1971. The valve is an intraannular prosthesis with tissue fixation preserved glutaraldehyde at appoximately 60 mmHg pressure gradient<sup>4,15,19,20</sup>. The Carpentier- Edwards supraannuler valve design

(C-E SAV), is a second generation bioprosthesis which incorporates several important design improvements over earlier, first generation tissue valve<sup>16</sup>. The SAV design is a low pressure fixed. (approximately 4 mmHg) bioprosthesis, and the height of the stend in both the aortic and the mitral models is reduced as compared to standart porcine valves.

## MATERIAL and METHODS

Between 1976 - 1992, Seventy eight standart Carpentier-Edwards bioprosthesis were implanted at the University of Hacettepe, Thorasic and Cardiovascular Surgery Department. Twentysix of them were male (29%) and 52 (71%) were female. Patients were between 13 and 58 years of age and the mean age was 30,1 years  $\pm$  0,8 years (mean  $\pm$  standard error of the mean). All of the valves were implanted in mitral position. The predominantly mitral lesions were as following: stenosis in 22 patients (28.2 %), insufficiency in 21 patients (26.9%), and mixt lesions in 35 patients (44.9%). Origin of the lesions were rheumatic in 58 patients (74.4%) and degenerative in 20 patients (25.6 %). Twentysix patients (33.3 %) had congestive heart failure at the time of operation.

The operation was performed using CPB with systemic hypothermia at 28 C, and uninterrupted aortic crossclamping. During the procedure, the bioprosthetic valve was kept moist using saline solution. The size of valves inserted were  $29 \pm 0.3$  mm (median 29, range 25-33).

Procedures	no.of patients
De Vega tricuspid annuloplasty	17
Coronary artery bypass grafting	3
Closure of atrial septal defect	2
TOTAL	22

Reexploration for bleeding and cardiac tamponade was necessary in 5 patients. Positive inotropic support was used in 5 patients. Peritoneal dia-lysis was performed in 2 patients for acute renal failure .Concomitant procedures performed on 22 patients (28.2 %) are shown in Table I.

Patients who had a previous history of thromboembolism, giant left atrium or an atrial fibrillation were anticoagulated with warfarin sodium for at least two months postoperatively. 20 of the patients were in NYHA Functional Class IV and rest of them in functional Class III. 70 of the patients were followed up for 1-16 (mean 8.7 years) postoperative years. Valve dysfunction, incidence of thromboembolism, valve suture deficiency, prosthetic valve endocarditis, hemolysis and late mortality were investigated in all of these patients.

Patients and bioprosthesis statuses in relation to events were ascertained by calculation of the actuarial freedom occurrence,of the time related hazard function to pinpoint the instantaneous risk of occurrence (percent / patient year) of the event<sup>9, 12</sup>.

## RESULTS

Early mortality rate was 9 %. The causes of early mortality are shown in Table II. The three late deaths resulted from congestive heart failure, fulminant hepatitis and reoperation due to prosthetic valve endocarditis. The total mortality was 19 % .

Reoperation was performed in 39 cases,after a mean interval of  $93 \pm 32$  months (ranging from 25 to 143 months); four died because of low cardiac output. Thirtysix patients had rereplacement because of structural deterioration of the bioprosthesis, three of these patients have died. Freedom from reoperation for structural valve dysfunction was  $85.3 \pm 3.5$  % at 5 years (Fig I). The signs of valve suture deficiency were not seen. Structural deterioration was due to tissue calcification, cusp stiffening, commissural tears, cusp, frayings, perforation or a combination of such findings. Calcific deposits

Table II: Causes of early mortality.	
Cause	no. of patients
A) Valve -related mortality	
1. Prosthetic valve endocarditis	2
2. Cerebral thromboembolism	1
B) Other	
Low cardiac output	4
TOTAL	7

were present in all cases and were severe in three cases. Bioprosthetic valve endocarditis was seen, in 3 cases, and in all of these patients rereplacement of the bioprosthetic valve was performed. One of these patients died. Etiologically, coliform basillus was responsible from endocarditis.

Freedom from all valve related morbidity and mortality, including early deaths was  $76 \pm 3.1\%$  at 5 years (Fig II).

Although there was no sign of valvular or intracardiac thrombosis three patients had minor thromboembolic episodes, and anticoagulant therapy was performed. Recurrence was not seen.

Hemolysis and anticoagulant therapy-related hemorrhage was not seen.

## DISCUSSION

This study has shown that, the Standard Carpentier-Edwards bioprosthesis as a cardiac valve substitute, has provided patients with a satisfactory quality of life, with a low incidence of valve-related complications, especially thromboembolism, and anticoagulant therapy-related hemorrhage. The major late concern with porcine bioprosthesis has been long-term durability<sup>3, 17, 21, 24</sup>. Considering this disadvantages in mitral position, a bioprosthesis may be preferred in who wish to have children and, in persons involved in physically hazardous occupations or hobbies, and who have a contrindication to use anticoagulant drug, or who have a shorter life expectancy<sup>3, 14, 20, 22</sup>. The realisation that a re-replacement of the bioprosthetic valve will

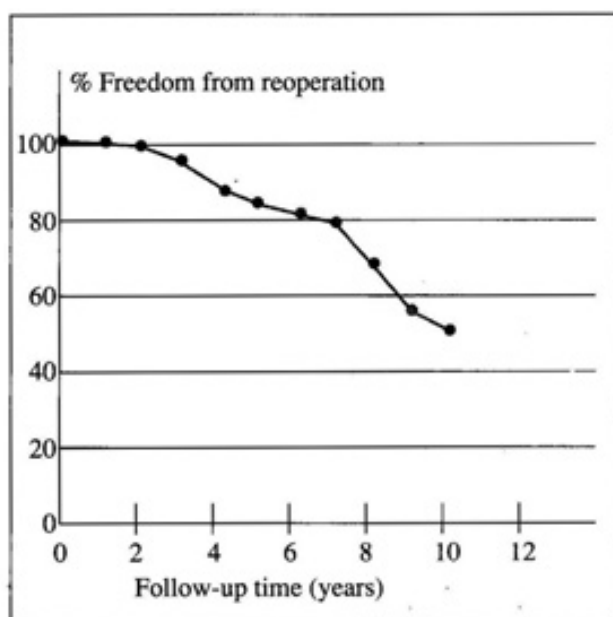


Fig I: Actuarial freedom from reoperation of mitral bioprostheses.

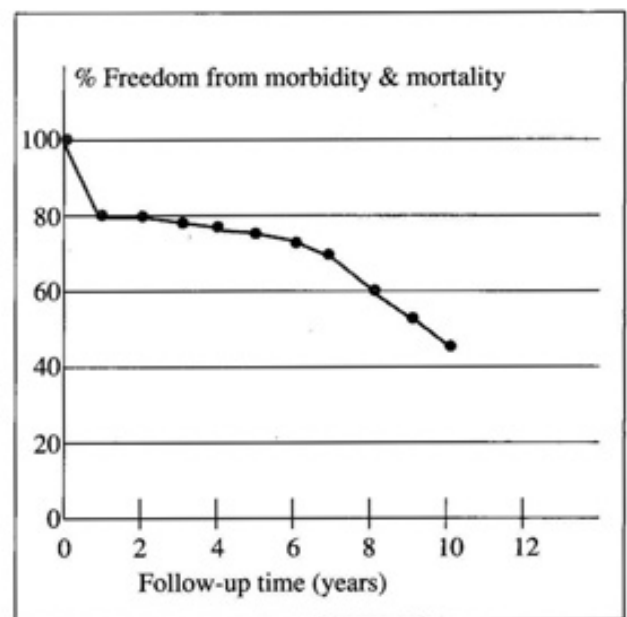


Fig II: Actuarial freedom from all valve related morbidity and mortality.

probably be needed within 10 years must always be explained to the patient. In such instances, however, selection of the most suitable prosthesis is still controversial<sup>1, 4, 7, 8, 11, 14, 20, 22</sup>. Mechanical prostheses have an intrinsic risk of thrombosis despite anticoagulant treatment, where this complication usually has an insidious onset, but with possible catastrophic consequences<sup>4, 14</sup>. Porcine bioprosthesis has been considered the valves of choice because their higher thromboresistance, usually without anticoagulation<sup>11, 23</sup>.

Second generation porcine bioprosthesis have been developed to improve hemodynamics and to reduce structural lesions<sup>16</sup>. The design of the new generation bioprostheses, have utilized different stent design and materials, better tissue selection and preservation, low pressure fixation and calcium-mitigation agents. We have not extensive experience with the new generation prostheses.

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