

## **CARDIAC VALVE REPLACEMENT WITH PERICARDIAL XENOGRAFT \*)**

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Between May 1977 and May 1980 pericardial xenograft — Ionescu-Shiley valve — was used for cardiac valve replacement in 48 patients, 33 as single mitral, 8 as single aortic and 7 as mitral and aortic valve replacement. The procedures were done in hypothermic cardio-pulmonary by-pass at 25° C with cold cardioplegia for myocardial protection. During the valve insertion several precautions were taken — to match the valve size to LV dimensions, position the valve high up in the LA after suturing, use continuous suture to avoid entrapment of the prongs by isolated sutures and to place 2 prongs parallel to the outflow tract of the LV. There were 1 operative death due to myocardial failure and one hospital death with complications not related to the valve. The overall mortality was 4.1%. All 46 surviving patients were followed up from 1 to 37 months after the operation. There was no late mortality. The first 17 patients were off anticoagulants with 1 transient ischemic attack. 29 patients were anticoagulated for 6 weeks after the operation with Prothrombin depressant. No thrombo-embolic complications were noticed in this group. There was no instance of valve failure or valve dysfunction. One case had late endocarditis. In our group of patients the pericardial xenograft

\* Presented at the 29th International Congress of European Society of Cardiovascular Surgery, Düsseldorf, 2—5 July, 1980

as cardiac valve replacement proved to meet the expected advantages—low valve related complications up to 34 months of follow-up.

### Clinical material

From May 1977 to May 1980, 48 patients underwent cardiac valve replacement with Ionescu-Shiley pericardial xenograft<sup>(1,2,3,4)</sup>. There were 20 males and 28 females with age range of 20 to 56 years; 38 patients were class III (NYHA), 6 class IV and 4 class II. Mitral valve replacement was required in 33 patients; 8 patients had isolated aortic valve replacement. Combined aortic-mitral valve replacement was required in 7 patients (Table 1). The common indications of tissue valve were applied for

Table 1

Heart valve replacement with Ionescu-Shiley pericardial Xenograft			
Valves replaced	No. of patients	Hospital deaths	Late death
Mitral	33	2	—
Aortic	8	—	—
Mitral & Aortic	7	—	—
<b>TOTAL</b>	<b>48</b>	<b>2 (4.1%)</b>	

use of pericardial xenograft; contraindications for anticoagulant treatment, women at child bearing age, difficulties in the control of chronic anticoagulant treatment (patient unreliability, occupational hazard).

### Operative Techniques

Standard cardio-pulmonary by-pass at 25°—30° C with disposable oxygenator was used with hemodilution, cold cardioplegia and local cooling for myocardial protection. The valves were rinsed thoroughly in saline with special care to remove the formaldehyde solution from the suturing skirt. During the valve insertion in mitral position few technical precautions were taken:

- match the valve size to annulus and LV dimensions,
- pull the valve up in LA following insertion,
- avoid entrapment of the prongs by using continuous suture,
- place two prongs astride to LV outlet.

For mitral valve replacement, as shown in table 2 the most common implantation diameter of the valve were 25 mm (14 patients) and 27 mm (21 patients). In 3 patients 29 mm valves were used; for aortic valve replacement — 21 mm and 23 mm (Table 2). For mitral valve replacement

Table 2

#### Ionescu-Shiley pericardial xenograft

Valve sizes Implantation diameter (mm)	21	23	25	27	29
Mitral	—	—	14	21	3
Aortic	7	7	—	—	1
<b>TOTAL</b>	<b>7</b>	<b>7</b>	<b>14</b>	<b>21</b>	<b>4</b>

continuous suture was used in 31 cases, interrupted in 4 and mixed in 3 cases. For aortic valve replacement only interrupted sutures were employed (Table 3). Additional surgical procedures performed at the time of valve replacement are shown in table 4. After the operation, measures

*Table 3*  
Ionescu-Shiley pericardial xenograft

Type of suture Valve replaced	Interrupted	Continuous	Mixed
Mitral	4	31	3
Aortic	15	—	—
<b>TOTAL</b>	<b>19</b>	<b>31</b>	<b>3</b>

*Table 4*

Additional surgical procedures performed at the time of valve replacement

Procedure	Mitral	Aortic
Tricuspid annuloplasty	4	—
Aortic valvuloplasty	1	—
Total correction Fallott's tetralogy	—	1
<b>TOTAL</b>	<b>5</b>	<b>1</b>

to obtain the optimum cardiac output were ensured as well as measures to maintain an adequate gas-exchange-ventilation, acid-base balance and fluid-electrolyte balance.

### Results

In the group of 48 operated patients (Table 1) there was 1 operative death due to myocardial failure, — patient with a thrombosed Björk-Shiley valve operated upon as an emergency after cardiac arrest and resuscitation. This death could not be related to any valve abnormality. One hospital death occurred 2 months after operation with complications not related to the valve itself (the integrity of the valve was confirmed at post-mortem examination). The hospital mortality was 4.1 % (Table 1). All hospital survivors (46) were followed up from 1 to 37 months after the operation (mean follow-up 12.2 months): 404 patients/months for mitral valve replacement; 95 patients/months for aortic valve replacement and 75 patients/months for mitral and aortic valve replacement (Table 5). The majority of mitral patients were in class III before the operation (Table 6), and in class I after the operation. In the aortic group

*Table 5*  
Follow-up of 46 hospital survivors

1 to 37 months (Mean 12.2 months)	
Valves replaced	Total months
Mitral	404
Aortic	95
Mitral & Aortic	75
<b>TOTAL</b>	<b>574</b>

Table 6  
N.Y.H.A. classification

Class	Mitral		Aortic		Mitral & Aortic	
	Preop.	Postop.	Preop.	Postop.	Preop.	Postop.
I	—	25	—	8	—	3
II	1	5	3	—	—	4
III	28	1	4	—	6	—
IV	4	—	1	—	1	—
TOTAL	33	31	8	8	7	7

before the operation 3 patients were in class II, 4 patients in class III and 1 in class IV. After the operation all aortic patients were in class I. In double valve group, there were 6 patients in class III before operation and 1 in class IV; after the operation they were in class I and II. First 17 patients (15 mitrals, 13 in AF-atrial fibrillation; 1 aortic, 1 mitral and aortic) were not anticoagulated but under chronic Persantine and Aspirin treatment. There was 1 transient ischemic episode of lower limb in this first group. The following 27 patients (16 mitrals, 11 in AF; 7 aortics, 6 mitral and aortics-2 in AF) were on anticoagulants (Prothrombin depressant) for 6 weeks and chronic Aspirin and Persantine treatment. Two patients with double valve replacement were on chronic anticoagulant treatment for mechanical valves (BS) in mitral position. No thromboembolic complications occurred in the second group of 29 patients. No valve thrombosis occurred in the entire group of patients (Table 7). There was no instance of valve failure or dysfunction (Table 8). No paravalvular

Table 7  
Embolism in 46 patients followed up for 574 months

Treatment	No. of patients	Emboli
Persantine & Aspirin	17	1 (M) Transient ischemic episode (lower limb)
Prothrombin depressant + Persantine + Aspirin for 6 weeks post op. long term	29	—
	27	—
	2	—
Absence of valve thrombosis		

Table 8  
Complications in 48 patients with pericardial xenograft

Complication	Early	Late
Valve failure	—	—
Infective Endocarditis	1	—
Paravalvular Leak	—	—
Haemolysis	—	—

leaks were noticed. Two patients with apical systolic murmur were fully reinvestigated, but LV angiography showed competent mitral valves.

### Conclusions

In our group of patients the pericardial xenograft proved to meet the expected advantages:

- low mortality and morbidity;
- very low embolic rate with limited anti-coagulation;
- absence of valve thrombosis;
- maintenance of structural and functional integrity over a period of more than 3 years.

We consider the pericardial xenograft as the valve of choice for patients in whom anti-coagulants are contraindicated and for patients with small aortic roots.

### Addendum

Since May 1980 other 10 patients have been operated upon using pericardial xenograft valve (8 mitrals, 1 aortic, 2 mitral and aortics). From the first group of 48 patients, 1 mitral patient mentioned in table 8 with endocarditis required reoperation. One late death occurred in the double valve group also due to endocarditis.

For the entire group of 58 patients the hospital mortality is 3.4 % and late mortality 1.7 %.

### References

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Received on the 10<sup>th</sup> of March, 1981.

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