

Aortic valve replacement with the composite Labcor™ porcine bioprosthesis in the elderly

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Background. This paper presents the analysis of clinical results of the composite porcine Labcor™ bioprosthesis in the replacement of aortic valves in the elderly.

Methods. This retrospective study was carried out in the Thoracic and Cardiovascular Surgical Department, La Pitié-Salpêtrière Hospital, Paris, for replacement of calcified, stenosed aortic valves between 1988 and 1995. It involved a series of 100 patients aged 70 and over (mean: 80±5 years ranging from 70 to 90). There were 63 female and 37 male patients. Preoperatively, five patients were in NYHA Class I, 23 in Class II, 65 in Class III and 7 in Class IV.

Results. Fifteen patients died in the early postoperative stage and 13 during the follow-up period. There was no evidence of valve failure. The average follow-up was 32 months and the actuarial survival rate at 5 years was 74±5%. Complications due to bleeding occurred in 3 patients taking anticoagulant treatment. There were neither valvular thrombosis nor embolism. Two patients presented with prosthetic endocarditis. Two patients received a reoperation because of leakage (1 septic). The five-year follow-up showed that 96% of patients did not require further surgery. When this study was completed, 83% of patients were in Class I or II versus 71% in Class III or IV prior to surgery.

Conclusions. In the early/middle follow-up term, the results obtained when replacing the aortic valve with the composite Labcor™ bioprosthesis in the elderly are satisfying. Nevertheless, further long-term assessment is needed.

Key words: Bioprosthesis - Aortic valve surgery - Aged - Heart valve prosthesis.

The valuable role of aortic valve replacement (AVR) in the elderly has been established as far as improvement of the survival rate^{1,2} is concerned. The second major goal of this surgical procedure is to pro-

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vide an improved quality of life for these patients. Due to technological advances in sampling, fixation and mounting techniques for bioprostheses, these devices are, at the present time, the primary choice for many surgical teams in the elderly.³⁻⁶

Actually, good hemodynamic results with these prostheses in the aortic position, low risk of degeneration of biological devices in the elderly and, last, but not least, little or no need for long-term anticoagulant treatment, offer these patients a quality of life which is undoubtedly higher than that associated with mechanical prostheses.⁷⁻¹⁰

The porcine heterograft, Labcor™ (Labcor Laboratorios, Belo Horizonte, Brasil) (Fig. 1), is original because of its "composite" nature which provides a special hemodynamic performance, particularly with small diameter prostheses as well as the usual advantages of porcine bioprostheses. Also, its "low-profile" design has proven useful during implantation. We favored the use of this bioprosthesis in the elderly presenting with calcific aortic stenosis (CAS), since the need for implanting small diameter prostheses in these patients is frequent. This work reports preliminary results of a series of 100 consecutive surgical patients.

Materials and methods

Patients

One hundred patients underwent AVR with a Labcor™ bioprosthesis between January 1988 and

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Fig. 1.—Labcor aortic bioprosthesis.

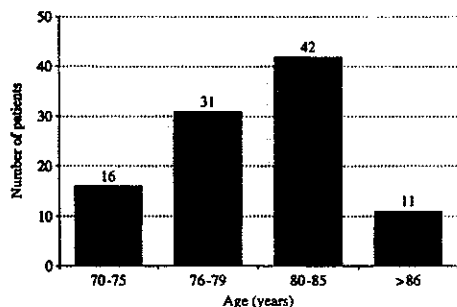


Fig. 2.—Number of patients by age.

December 1995. Indication for surgery was calcific aortic stenosis. The study population involved 63 female and 37 male patients whose mean age was 80 ± 5 years, ranging from 70 to 90 years (Fig. 2). More than half the cohort of patients (53%) was over 80.

The functional impairment during the preoperative period was determined according to NYHA classification: sixty-five patients were in Class III, twenty-three in Class II and seven in Class IV. For five patients in Class I, indications for surgery were either angina or syncope. The mean cardiothoracic ratio was $49 \pm 3\%$. Preoperative coronary angiography was performed in all cases. Twenty-six patients presented with coronary lesions which required revascularization procedures. There were 15 cases of coronary lesions on

one vessel, 6 cases involved 2 vessels and 5 cases involved 3 vessels.

During the same period, 2717 patients received an aortic valve replacement; among them 143 patients had received another type of bioprosthesis (Hancock, Liotta, Intact).

Description of the Labcor™ bioprosthesis

The Labcor™ bioprosthesis is a composite porcine bioprosthesis. This valve is harvested immediately after animal sacrifice and immersed in a saline solution with pH 7.4 phosphate buffer. The muscular sigmoid which usually causes problems with porcine bioprostheses is removed and replaced by another free sigmoid. Therefore, the valvular orifice is larger, which, in turn, lowers the pressure gradient, and thus improves the hemodynamic performance.

The valve is then fixed in a 0.6% zero pressure glutaraldehyde solution in order to keep the integrity of collagenous fibers and tissue stability prior to its mounting on a flexible, rippled Celcon™ ring (acetal copolymer) coated with Dacron™. A "low profile" feature is provided by the ring. Enhanced coaptation between the suture ring and the anatomical morphology of the aortic orifice results from this design. Finally, the low profile design permits insertion in the supra-annular position.

Each valve is individually bench-tested and the particular hemodynamic characteristics of each individual valve are shipped with it. The aortic bioprosthesis diameters range from size 19 to 29 by increments of 2 mm.

Surgical procedure

In this series, all valve replacements were performed through a vertical median sternotomy under extracorporeal circulation (ECC). Myocardial protection was ensured using our technique of cryocardioplegia and reperfusion with warm blood.¹¹ In all cases, the valvular prosthesis was sutured using woven silicon polyester (Ticron™) single-ended sutures. The mean duration of ECC was 76.2 ± 22.7 minutes (ranging from 33 to 87 min) and aortic cross clamp time was 52 ± 15.6 minutes (ranging from 33 to 87). More than half the number of bioprostheses employed in this series were either a 19-, or a 21-mm diameter device (Fig. 3); the choice of this biological valve was made specifically in case of small annulus due to the low

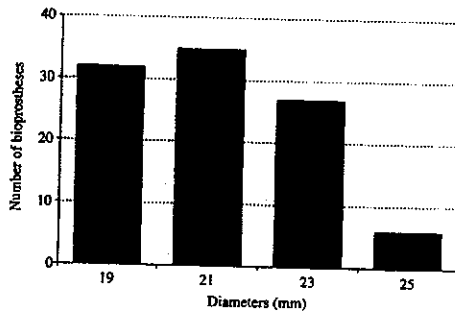


Fig. 3.—Bioprosthesis diameter.

profile design and because of the desired, improved haemodynamic performance. Twenty-six patients underwent additional single or multiple coronary bypass surgery. Fifty percent of these cases had a single bypass on the left anterior descending artery (Table I). Following surgery, all the patients received anticoagulant treatment with subcutaneous heparin and 100 mg of Aspirin. Prolonged treatment with vitamin K antagonists was only maintained in case of atrial fibrillation. The postoperative transvalvular gradient was about 20 mmHg of mercury even in small diameters (Table II).

Methodology

The data variables were recorded using a type 66 CII-HB computer and all statistical calculations were performed using the BMDP software. Calculation of percentage of complications per patient/year (linearized rates) took into account every incident of a given complication each time it occurred in a given patient. Actuarial survival curves were obtained via the Kaplan-Meier method. For the actuarial curves (freedom from complication/death), patients were ineligible to be included after occurrence of the first incidence of complication/death.

Analysis of the complications associated with the valve was performed according to the criteria defined by both the "American Association of Thoracic Surgery" and the "Society of Thoracic Surgeons".¹² Surgical mortality included all causes of deaths occurring prior to patients' release from the hospital or during the first 30 postoperative days. Structural deteriora-

TABLE I.—Types of myocardial revascularization procedures associated with AVR.

Bypassed arteries	N. cases
1 bypass	
LAD	11
CIRC	2
RCA	2
2 bypasses	
LAD, CIRC	3
LAD, RCA	1
LAD, DIAG	2
3 bypasses	
LAD, CIRC, RCA	4
LAD, DIAG, RCA	1

LAD: Left anterior descending artery; CIRC: circumflex artery; RCA: right coronary artery; DIAG: diagonal artery.

TABLE II.—Mean postoperative transvalvular gradient.

Diameter	Mean gradient
19	23.4±7.8
21	22.0±5.6
23	18.53±8.9
25	16.07±2.6

tion was defined as any intrinsic bioprosthesis dysfunction unrelated to infectious or thrombotic complications. Any cause of death linked to structural deterioration, nonstructural dysfunction, hemorrhagic or thromboembolic accident caused by anticoagulants, endocardial complication, fatal outcome of reoperation to replace the bioprosthesis or sudden death were regarded as cases of mortality linked to the valve.

Follow-up

Patient follow-up was carried out by cardiologists and general practitioners as well as through telephone consultations. Ninety-six patients were followed over a total duration of 292 patient/years, *i.e.*, an average follow-up of 32 months.

Results

Hospital mortality

Fifteen patients died in the immediate postoperative period. Among them, 12 (80%) were over 80

TABLE III.—Early mortality by age.

Years	N. of patients	Early mortality N. (%)
70-80	47	3 (6)
>80	53	12 (23)

TABLE IV.—Early mortality by age/concomitant operation.

Age (years)	Early mortality	N. (%)
Isolated AVR		
70-80	35	1 (3)
>80	31	11 (28)
AVR + bypass		
70-80	12	2 (16)
>80	14	1 (7)

(Table III, IV). Three of the deceased patients (20%) had undergone an additional revascularization procedure. The causes of deaths were as follow: low cardiac output (n = 7), rhythm disturbances (n = 4), infectious complications (n = 3), tamponade (n = 1). No death was attributed to the valve itself during this period.

Morbidity

Structural deterioration.—After an average follow-up of 32 months, no structural deterioration could be observed on clinical examination. The actuarial rate of deterioration-free patients at 5 years was 100%. A midterm echocardiography study would allow better appreciation of this important factor.

Nonstructural failure.—One patient had a successful reoperation 4 years after the initial AVR because of a paraprosthesis leakage.

Hemorrhagic and thromboembolic events.—At the end of the present study, 8 patients remained on anticoagulant treatment, all of them because of atrial fibrillation. No thromboembolic events were observed; therefore, the actuarial rate of patients without thromboembolic complications at 5 years was 100%.

There were two occurrences of cerebromeningeal hemorrhages at the second postoperative month and one gastric hemorrhage in a patient with a previous history of duodenal ulcer. In total, bleeding complications represent a linearized rate of 0.01% per patient-year.

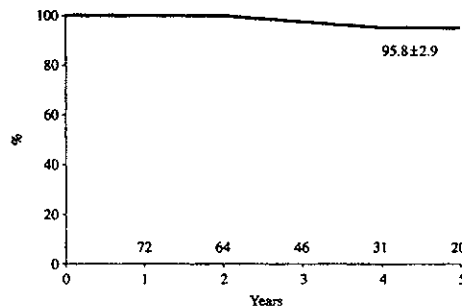


Fig. 4.—Free of all complications related to the valve.

Endocarditis.—Two patients presented with prosthetic valve endocarditis. The outcome was good for the first case under antibiotic therapy. Fourteen months after the episode, the patient had neither valve dysfunction nor recurrence of the infectious episode. In the second case, Osler endocarditis caused bioprosthesis dehiscence 3 years after the first AVR procedure. During reoperation, examination showed no deterioration of the bioprosthesis. This patient died shortly after the reoperation.

Reoperation.—Two per cent of patients (2 cases) had reoperation after 3 and 4 years, respectively. The first case was bioprosthesis dehiscence as mentioned above for endocarditis. The second one was due to non septic paraprosthesis leakage. At the five-year follow-up, the rate of complication-free patients was 96 ± 3% (Fig. 4).

Late mortality

Thirteen patients died during the late follow-up period. Seventy-six percent of these deaths were not attributable to the bioprosthesis but either to an intercurrent disease (cancer: n=2; influenza: n=1; septicemia: n=1; hepatitis: n=1, respiratory failure: n=1, renal failure: n=1), or to the progression of heart disease (n=2). In one case, the cause of death remained unproved.

Three patients (25%) died because of complications associated with the valve. One death was due to reoperation because of endocarditis. The two remaining cases involved fatal outcome of brain

hemorrhagic complications. If surgical mortality is excluded, the actuarial survival rate at 5 years was $74 \pm 5\%$ (Fig. 5).

Functional results

When follow-up was completed, 83% of patients were in NYHA class I or II, compared with 71% in class III and IV in the preoperative period (Fig. 6).

Discussion

Calcific aortic stenosis accounts for approximately 60% of cardiac valve surgery in the elderly.^{7,13} AVR provides these patients with a survival rate similar to that of the general population comparable for age. It is also better than that of the natural outcome of the disease.¹⁷ Therefore, the first goal of prolongation of life is accomplished. Improvement in the quality of life is the second major goal of this procedure. Several arguments favor the use of a bioprosthesis with regard to improvement in quality of life.

At the present time, the improved durability of bioprostheses in the elderly is a well-known fact.^{3,4,10,14} In our series, none of the patients underwent reoperation for structural deterioration after an average follow-up of 32 months, and 96% of patients were free of reoperation for any reason at 5 years following the initial procedure. The current data found in the literature report a 95% rate of patients without further surgery at 5 years.^{5,8,16}

The low risk of thromboembolic complications due to anticoagulant therapy is another point in favor of the use of bioprostheses. At 10 years follow-up, the rate of patients who are free from such complications is higher than 70%.^{3,4,17,18} If mechanical valves are employed, the risk may equal or even triple that figure.^{5,7,9,16} In our series, the actuarial rate of patients without any thromboembolic complication at 5 years was 100%.

After an average follow-up of 32 months, 92% of the patients involved in this study no longer needed or used anticoagulant therapy. The linearized incidence of hemorrhagic complications was 0.01% per patient/year. These results are similar to those of Fann *et al.*¹⁹ who reported a recent series of 1594 AVRs with porcine bioprostheses. The freedom from thromboembolic events at 5, 10, and 15 years respectively was 96, 92 and 87%. The figures for hemor-

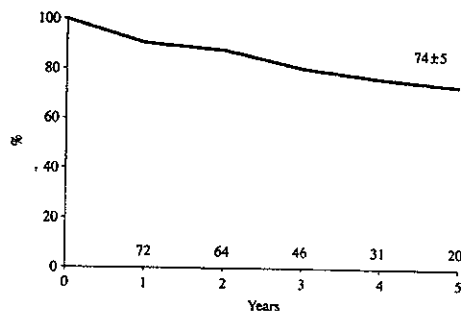


Fig. 5.—Actuarial survival.

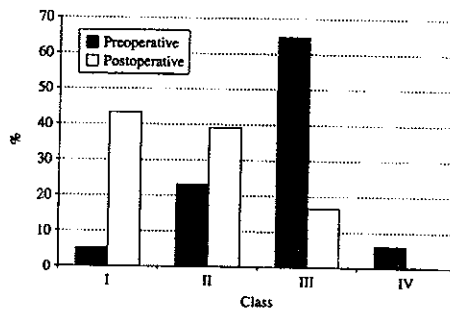


Fig. 6.—Evolution of functional status.

rhagic events at the same time periods were 97, 96 and 96%.

In this series, low complication rates account for an actuarial survival rate at 5 years of $76.7 \pm 5\%$ if surgical mortality is excluded. This result is similar to that of other studies involving bioprostheses as well as the average survival in the general population of the same age.^{4,14,16} However, we report a surgical mortality rate slightly higher than that of the literature. Several reasons may account for this. At the functional level, 93% of the deceased patients were either in Class III or IV. Also, 80% of deaths occurred in the patients aged over 80. It is acknowledged that the preoperative functional class as well as age are pejorative factors as far as the perioperative risk is

concerned.^{7 14 20} Another reason for higher surgical mortality may be that 3 among the 26 patients who underwent an additional myocardial revascularization procedure died in the immediate postoperative days (11%). The morbidity and mortality of this combined surgery is evaluated diversely and ranges from 7 to 28% in the literature.^{5 7 21}

The surgical after-effects and quality of life of the elderly who undergo AVR are mainly associated with the size of the transprosthetic gradient. Hydraulic bench tests have demonstrated that the Labcor™ bioprosthesis has shown better hemodynamic performances with lower gradients than those of other bioprostheses. This is particularly true for small size prostheses. This feature is directly linked to the "composite" nature of the bioprosthesis. Actually, replacement of the septal sigmoid by a nonmuscular sigmoid eliminates a major component of the transprosthetic gradient. The individual performances of each Labcor™ bioprosthesis are strictly tested and stated. By the end of follow-up, 83% of patients stated they were functionally improved compared to 71% in functional Class II and IV preoperatively.

Conclusions

Preliminary results with the Labcor™ bioprosthesis are satisfying and confirm the advantages that, today, can be expected following implantation of bioprostheses in the elderly. Ninety-six per cent of patients are free from reoperation at 5 years, and quality of life is improved in more than 80% of patients with low valve-related complication rates. These promising results must be further assessed in the future.

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