Mitral valve replacement with glutaraldehyde preserved aortic allografts

Claudio A. Salles a,b,*, Enio Buffolo c, José Carlos Andrade c, J. Honório Palma c, Roney R.P. Silva a, Ricardo Santiago a, Ivan S. Casagrande b, Maria Consolação V. Moreira a,b

a Hospital Felício Rocho, Belo Horizonte, M.G., Brazil
b Federal University of Minas Gerais, Medical School, Belo Horizonte, M.G., Brazil
c Federal University of São Paulo, School of Medicine, São Paulo, Brazil

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Abstract

Objective: To present long-term results after mitral valve replacement with stent mounted glutaraldehyde preserved aortic allografts in patients older than 15 years. The clinical support for this study was to combine the glutaraldehyde technique of biological tissue preservation with the advantages of allografts when compared to xenografts. This was demonstrated in previous studies using other methods of tissue processing. Methods: Between September 1984 and November 1994, 70 patients aged 16–77 years (mean 35.4 years) underwent mitral valve replacement with this preserved and mounted allograft. Of these, 40 patients (57.2%) were aged 16–35 years and 15 (21.4%) were 20 years old or younger; 46 (65.7%) were females and 24 (34.3%) males. Single mitral valve replacement was performed in 60 patients and 10 were also subjected to other combined cardiac procedures. Human aortic valves were obtained during routine autopsy, processed in glutaraldehyde and mounted into flexible stents, using the same technique as that used for porcine bioprostheses. Results: Hospital mortality was 1.4%. Total follow-up was 543.1 patient-years, corresponding to a mean follow-up of 7.9 years per patient. Echocardiography demonstrated a hemodynamic performance similar to porcine bioprostheses. Late mortality was 0.7 ± 0.6% per patient-year and the causes were congestive heart failure in 2, prosthetic endocarditis in 1 and acute myocardial infarction in 1. The 12-year actuarial survival was 92.4 ± 3.2%. The incidence of late complications was 5.2 ± 1.2% per patient-year, including congestive heart failure, prosthetic endocarditis, periprosthetic leak, thromboembolic episodes, recurrence of rheumatic disease, coronary artery disease and allograft failure. Complications related to heart disease represented 2.8 ± 0.6% and allobioprosthesis-related 2.4 ± 0.5% per patient-year. The 12-year actuarial freedom from primary valve failure was 81.0 ± 15.0%. The incidence of reoperations was 1.5 ± 0.8% per patient-year and the main indication was prosthetic endocarditis. Other causes were periprosthetic leak, aortic insufficiency in the native aortic valve and allobioprosthesis dysfunction. Functional results demonstrated a significant improvement in patients clinical condition. Conclusion: This 12-year follow-up shows a very low incidence of primary allograft failure for patients older than 15 years undergoing mitral valve replacement, and much superior than our results with porcine bioprosthesis in the same age group. This supports our assumption that this investigational valve represents a new advance in cardiac valve surgery. © 1998 Elsevier Science B.V. All rights reserved.

Keywords: Cardiac valves; Allografts; Homografts; Bioprosthesis; Glutaraldehyde

1. Introduction

In 1962, Ross [1] and Barratt-Boyes [2] introduced the use of viable aortic allografts for cardiac valve replacement. Since then, several methods of aortic valve
preservation and sterilization have been used, including free-hand and mounted, viable and nonviable aortic allografts, [3–6]. O’Brien introduced the method of cryopreservation in 1975, which has shown improvement in long-term results of aortic valve replacement [7,6]. In 1995, Yacoub [8] reported the use of fully viable aortic allografts, obtained from multiorgan donors or from cardiac transplant recipients under sterile conditions, which were kept in tissue-culture medium and implanted as soon as possible. He pointed out that all methods of valve processing, including antibiotic sterilization and cryopreservation, have the potential to alter the viability as well as the physical and antigenic properties of the valve.

Experimental studies on the use of allograft mitral valve for partial or total replacement of the mitral valve were performed in the 1960s with relatively good short-term results. In 1967, Senning reported the first mitral valve replacement in human with a mitral allograft followed by other reports, which were discontinued due to their poor results [9]. Recently, in 1995, Acar et al reported partial and total replacement of the mitral apparatus using mitral valve allografts with good functional results at a mean follow-up of 12 months [10].

Fresh and cryopreserved unstented aortic valve allografts were used for mitral valve replacement in experimental and clinical studies in the 1950s and 1960s. Yacoub introduced the technique of suturing the aortic graft into a Dacron conduit, which was called ‘top hat’ graft. He reported, in 1972, satisfactory short-term results in a series of 191 patients undergoing mitral valve replacement [9].

Porcine aortic valves chemically processed and stent mounted were introduced into clinical use by Binet [11] in 1965 with good initial results. Different methods of tissue preservation were employed, including the formaldehyde. However, a very high incidence of early rupture and fibrocalcific degeneration of valve leaflets was observed, resulting in valve dysfunction. On the other hand, Buffolo [4] reported much better results using human aortic valves treated by similar methods of tissue processing and mounted on a nonflexible stent.

The introduction of glutaraldehyde for biological tissue preservation by Carpentier [12] in 1969 resulted in increased collagen cross-linking preserving the integrity of collagen fibers, increasing the stability of biological tissue and decreasing biodegradation. This improvement in tissue preservation provided relatively inert biological tissue by decreasing its antigenicity and the utilization of flexible valve stents allowed the rehabilitation of xenografts for cardiac valve replacement. The material resulting from biological tissue processing by the glutaraldehyde was named bioprosthesis by Carpentier. Good long-term results were reported with glutaraldehyde-preserved porcine aortic valves [13–15]. However, the incidence of biodegradation of the collagen on these valves was observed to be very high in children and young patients, resulting in early valve dysfunction due to fibrocalcific degeneration [16–18]. One of the explanations is the increased calcium turnover in children, making foreign tissue such as the porcine aortic valve more susceptible to calcification when implanted in young patients. Glutaraldehyde fixation treatment markedly decreases the antigenicity of the biological tissue, but it does not make them totally biological inert. It has been considered that immunological factors may have an effect in some young patients receiving xenobioprosthesis and eventually may lead to an accelerated rejection phenomenon, which results in relatively early degeneration of the bioprostheses [17].

In order to obtain a better valve substitute, especially to be used in the mitral position and in young patients, it was decided to combine the relatively good results obtained in the past with the chemically treated and stent mounted human aortic valves [4,5] with the advantages of the glutaraldehyde method of tissue processing [12]. Allogenic tissue processed by glutaraldehyde may result in less reactive biological tissue from the immunological point of view, when compared to glutaraldehyde treated xenografts. The immunological factors which may lead to rejection phenomenon can be considered most unlikely in young patients undergoing a valve replacement with a glutaraldehyde preserved aortic allograft. With the objective of obtaining a good quality control, an industrial laboratory with experience in the manufacturing of xenobioprostheses was selected (Laborcor Laboratories, Belo Horizonte, Brazil) to process aortic allografts using the same technique of glutaraldehyde tissue preservation and valve mounting utilized for porcine aortic bioprostheses. This cardiac valve substitute was defined as a glutaraldehyde-processed stent mounted aortic allograft or as an allobioprosthesis [19].

In previous reports this bioprostheses performance was shown in different age groups, and in mitral, tricuspid and aortic positions, as well as in high risk patients for valve replacement, i.e. children and patients with previous calcified xenobioprosthesis [20–23]. Besides the good initial and mid-term results in durability obtained with the allobioprosthesis, when compared to xenobioprosthesis, a relatively high incidence of late fibrocalcification in patients aged 15 years or younger was demonstrated. The 5-year actuarial freedom from valve failure due to fibrocalcific degeneration for this pediatric age group was reported 69.9 ± 8.8% [22], and the 10-year actuarial freedom was 34.2 ± 11.2% [23], which on the other hand, is far superior to our results with porcine aortic bioprosthesis in the same age group, as well as the results reported in the literature [16–18].

The objective of the present study is to report long-term results after mitral valve replacement with stent
mounted glutaraldehyde preserved aortic allografts in patients older than 15 years.

2. Material and methods

2.1. Allograft procurement, preservation and mounting

Human aortic valves were obtained during routine autopsy. The criteria used for allograft procurement were: a donor aged 40 years or younger with no evidence of exogenous intoxication, collagenosis, systemic infection, malignant disease and death within 12 h of procurement. The ascending aorta, main pulmonary artery and the outflow tract of both ventricles were removed en bloc, rinsed in saline solution and placed in a sterile plastic jar containing a phosphate buffered saline solution at pH 7.4 and 4°C. They were immediately transported to the laboratory, where the allograft dissection was carried out under sterile conditions. The aortic valve was processed using the same technique used for porcine aortic valves utilizing purified glutaraldehyde in phosphate buffered saline solution at 0.4%, pH 7.4, and low pressure fixation. A small piece of the aortic wall was sent for microscopical examination to evaluate the integrity of collagen fibers and cells. Fig. 1 shows the aortic allograft after dissection, removal of all surrounding tissue, and after its processing in glutaraldehyde.

The glutaraldehyde preserved aortic allograft is mounted similar to the porcine bioprosthesis into a low profile flexible stent made of Celcon (acetal copolymer), and covered with a very soft Dacron fabric (Figs. 2 and 3). After the mounting process, the valves are placed in a 4% formaldehyde solution for sterilization, and serial cultures are obtained to confirm the sterility. The allografts are provided in mitral models, sizes 25–31 mm external diameter (Fig. 4).

2.2. Patients

From September 1984 to November 1994, 70 patients aged over 15 years underwent isolated mitral valve replacement using glutaraldehyde preserved stent mounted aortic allografts. Patients undergoing single mitral valve replacement were included, as well as patients undergoing concomitant cardiac surgical procedures other than valve replacement. Patients who would need a concomitant aortic and/or tricuspid valve replacement, and some patients living very far away from our Institutions were not included in this study. The latter were not included if they would not be able to return to our office every 6 months for follow-up studies.

The mean age was 35.4 years, ranging from 16 to 77 years. There were 40 patients (57.2%) aged 16–35 years, 15 (21.4%) were aged 20 years or younger, 12 (17.1%) were between 36 and 65 years, and only 3 patients (4.3%) were older than 65 years. There were 46 females (65.7%) and 24 males (34.3%). There were 17 patients...
(24.3%) who had undergone previous mitral valve operations, including mitral valvuloplasty in 5, and previous mitral valve replacement in 12, which were malfunctioning due to fibrocalcific degeneration.

The preoperative diagnoses, confirmed by echocardiography and by cardiac catheterization in many patients, are summarized in Table 1, showing isolated mitral lesions in 61.4% of them, and calcified bioprostheses, as well as other cardiac lesions combined to the mitral disease, in the remainder 27 patients (38.6%).

In all, 64 patients (91.4%) were in NYHA functional class III or IV; 50 (71.4%) were in class III, 14 (20%) in class IV, and 6 (8.6%) were in class II.

Table 2 shows that single mitral valve replacement was performed in 60 patients and the other 10 were also subjected to other combined cardiac procedures.

2.3. Surgical technique

A midline sternotomy was used as the standard incision and a right thoracotomy was employed in a few patients. Extracorporeal circulation using a bubble oxygenator was established using hemodilution and systemic hypothermia to 27°C. Myocardial protection was achieved by means of cold potassium cardioplegia (St.Thomas’ solution) injected into the aortic root. The valves were replaced with interrupted mattress sutures reinforced or not with Teflon felt pledgets.

Anticoagulant therapy was not used as a routine, except in the presence of chronic atrial fibrillation.

3. Results

The overall hospital mortality (30 days) was 1.4% (1 patient) and the cause of death was low cardiac output.

Follow-up was obtained by reexamination of patients in the office, by contact with their personal physicians, and from hospital records. All patients were expected to return to our office every 6 months for clinical examination, including echocardiography in most of them.

Doppler echocardiographic studies were performed in the early postoperative period in order to evaluate the allobioprosthesis performance, including peak velocity, peak gradient and mean gradient. The data were compared with a porcine bioprosthesis commercially available, which was demonstrated to be very similar and showed a mean gradient of 5.8 mmHg.

In the late follow-up, Doppler echocardiography was very useful in analyzing the valve leaflets performance, as well as detecting early signs of leaflets structural changes that could suggest an initial process of valve dysfunction.

Complete follow-up was obtained in 63 (91.3%) of the 69 patients who survived the operation and were discharged from hospital. Partial follow-up was obtained in 6 patients (8.7%) who could not be contacted at the closing date of this study on September 1996.

This study collected 543.1 patient-years of documented follow-up, corresponding to a mean follow-up of 7.9 years per patient. The longest follow-up was 12 years. The data were analyzed through time-related
methods, using the exponential distribution and the Kaplan-Meier product limit method of actuarial analysis [24].

3.1. Late mortality and survival

The late mortality was 0.7 ± 0.6% per patient-year, representing a total of four deaths. The causes related to heart disease were responsible for 75% of late deaths; two resulted from congestive heart failure and one was due to a myocardial infarction. The fourth death was allobioprosthesis-related and resulted from a fungus endocarditis.

The actuarial survival curve for the 70 patients undergoing mitral valve replacement calculated by the Kaplan-Meier method is shown in Fig. 5 and demonstrates a 12-year actuarial survival (± S.E.)² of 92.4 ± 3.2%, including the operative mortality.

3.2. Late complications

Late complications related to the allobioprosthesis and to heart disease are listed in Table 3, showing a total of 28 complications which were present in 21 patients, corresponding to an incidence of 5.2 ± 1.2% per patient-year. Complications related to cardiac disease represented 2.8 ± 0.6% per patient-year and allobioprosthesis-related complications represented 2.4 ± 0.5% per patient-year.

Congestive heart failure was the most frequent late complication and it occurred in patients with advanced myocardial lesions or during pregnancy. From the 8 patients, two died. One patient with coronary artery disease, who underwent myocardial revascularization at the time of mitral valve replacement returned to complain of angina, and a second patient operated on at the age of 77 died from acute myocardial infarction 5 years later. Significant aortic regurgitation (native aortic valve) developed in 2 patients and 1 had to undergo aortic valve replacement. The mitral allobioprosthesis which had a normal appearance was left in place.

Five thromboembolic episodes were reported in 4 patients. Two had major cerebrovascular embolic accidents resulting in neurological sequelae and 1 presented a mild cerebral embolism with total recovery and no sequelae. A 4th patient with a very large left atrium and

<table>
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<th>No. of patients</th>
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<td><strong>Cardiac related</strong></td>
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<td>Congestive heart failure</td>
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<tr>
<td>Aortic insufficiency</td>
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<tr>
<td>Rheumatic carditis</td>
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<td>Coronary artery disease</td>
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<tr>
<td>Tricuspid insufficiency</td>
<td>1</td>
</tr>
<tr>
<td><strong>Allobioprosthesis related</strong></td>
<td></td>
</tr>
<tr>
<td>Thromboembolism</td>
<td>4</td>
</tr>
<tr>
<td>Prosthetic endocarditis</td>
<td>4</td>
</tr>
<tr>
<td>Peri-prosthetic leak</td>
<td>2</td>
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<tr>
<td>Allobioprosthesis dysfunction</td>
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² Plus or minus two standard errors give an approximate 95% confidence interval, calculated by Greenwood’s formula.
chronic atrial fibrillation had a peripheral embolic episode to the right superficial femoral artery on the 5th postoperative day which did not result in any major consequence. The incidence of thromboembolic episodes was 0.9 ± 0.6% per patient-year.

Fungus endocarditis from *Candida albicans* occurred in a 29-year-old patient 3 months after her second valve replacement, resulting from a vaginal infection which led to reoperation (third valve replacement) and postoperative death due to a wet lung syndrome and low cardiac output. Bacterial endocarditis from *Staphylococcus aureus* occurred in 3 other patients at 2 months, 4 years and 4 months, and 10 years and 1 month after valve replacement. They underwent reoperation to replace the infected allobioprosthesis, resulting in total recovery. The last patient had undergone repair of a periprosthetic leak 5 years before, and the glutaraldehyde preserved allograft removed at this second reoperation 10 years after implantation presented a normal aspect of the valve leaflets without any sign of tissue structural degeneration or dysfunction. The incidence of prosthetic endocarditis was 0.7 ± 0.6% per patient-year.

Both patients with periprosthetic leak underwent surgical repair 9 months and 5 years after the operation, preserving the allograft.

Allobioprosthesis dysfunction due to intrinsic structural degeneration of aortic valve leaflets occurred only recently in 2 patients. One of them, a 31-year-old woman underwent reoperation to replace her mitral bioprosthesis, which was implanted 11 years and 2 months previously. A moderate fibrosis with thickening of valve leaflets and rupture of one leaflet was found, but without macroscopic evidence of calcification. The second patient, a 17-year-old girl at the time of her operation 8 years ago, showed echocardiographic evidence of mitral valve dysfunction due to a thickening of leaflets, resulting in moderate stenosis and regurgitation. She is waiting to undergo a second valve replacement. The incidence of valve dysfunction due to intrinsic structural degeneration of leaflets is 0.4 ± 0.4% per patient-year.

The 12-year actuarial freedom from primary valve leaflet failure or allobioprosthesis survival was 81 ± 15%, as demonstrated by the Kaplan-Meier actuarial curve in Fig. 6, plotted for comparison with the actuarial curve for patient survival.

### 3.3. Reoperation

There were 7 patients who underwent eight reoperations, which are listed in Table 4, corresponding to an incidence of 1.5 ± 0.8% per patient-year. The main indication for reoperation was prosthetic endocarditis, resulting in the need for allograft removal and its replacement by another prosthesis. For patients with

<table>
<thead>
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</tr>
<tr>
<td>Periprosthetic leak</td>
<td>2</td>
</tr>
<tr>
<td>Aortic insufficiency (native aortic valve)</td>
<td>1</td>
</tr>
<tr>
<td>Allobioprosthesis dysfunction</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
</tr>
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</table>

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Fig. 6. Comparison of the 12-year actuarial survival curve with the 12-year actuarial freedom from primary structural valve failure, calculated by the Kaplan-Meier method.
3.4. Functional results

The assessment of quality of life among the survivors with the allobioprosthesis in place demonstrated that the majority of patients had a significant improvement in their clinical condition after valve replacement. Preoperative and postoperative NYHA functional classes are listed in Table 5, demonstrating that before the operation 91.4% of the patients were in either functional class III or IV, and at the time of this follow-up 96.9% were in functional class I or II.

4. Discussion

The introduction of glutaraldehyde by Carpentier in 1969 [12] to process porcine aortic valves, together with the use of flexible stents for valve mounting represented an important advance in cardiac valve surgery. Xenobioprosthesis, including porcine and bovine pericardial valves processed in glutaraldehyde became commercially available and widely used during the last quarter of the century with good long-term results. The low incidence of thromboembolic complications and no need for routine anticoagulation therapy was the main advantage of these cardiac valve substitutes.

However, the incidence of fibrocalcific degeneration was demonstrated to be very high in young patients and there is no question that the low age represents the main limitation for the use of all kinds of biological valves, including xenobioprosthesis, viable and nonviable aortic allografts [7,8,16–18,23]. Several reports in the literature have shown the high incidence of early valve fibrocalcification in patients aged 15 years or younger [17], as well as in patients aged 18 or younger [18] and 20 or younger [16].

Kirklin [7] considers the low age as the only risk factor related to the use of cryopreserved aortic allografts, but in spite of that, he considers them the best substitute for the aortic valve in young patients.

Yacoub [8] reported experience using unprocessed, fully viable aortic allografts harvested under sterile conditions, which he named ‘homovital homograft’, showing a 10-year actuarial freedom from allograft failure of 89 ± 3%. The age below 30 years was considered the main risk factor for valve failure for patients undergoing aortic valve replacement, and the 10-year actuarial freedom from allograft dysfunction for patients older than 30 years was 97%.

Besides the high incidence of fibrocalcification in young patients, it was found that for all kinds of biological valves the incidence of fibrocalcific degeneration decreases with the increase in patient’s age.

Magilligan [14] reported experience with porcine bioprosthesis in 1985, pointing out that the incidence of valve failure due to fibrocalcification was higher in patients aged 35 years or younger, considering this age as the limit for obtaining good long-term durability with porcine valves. A 10-year actuarial freedom from valve failure of 80% for patients above the age of 35 years was reported.

Jamieson [13] also reported on a large series of cardiac valve replacement with porcine bioprosthesis showing a higher incidence of valve failure in patients younger than 35 years, and mentioned similar results obtained by other authors. He also reported an increase in long-term durability with the increase of patients age, particularly for patients older than 65 years and also that there was a significant difference for the bioprosthesis performance in mitral and aortic positions, demonstrating a better long-term durability in aortic position. For patients undergoing mitral valve replacement, it was shown that there was a 12-year actuarial freedom from porcine bioprosthesis dysfunction of 18% for patients 35 years or younger, 42% for patients between 36 and 50 years, 56% for patients between 51 and 65 years, and 78% for the group over 65 years [13].

The major concern with bioprosthesis has been long-term durability and fibrocalcification of these valve substitutes became a nightmare for cardiac surgeons.

Several investigators involved in the biochemistry of collagen cross-linking have suggested that glutaraldehye is not an ideal agent for processing of collagen tissue and it could be responsible for the calcification mechanism of bioprosthesis [25]. However, a better agent has not been found to date.

Angel reported a 20-year follow-up of patients undergoing cardiac valve replacement using fresh and cryopreserved aortic allografts used as a free-hand graft or premounted on metal support. This series include patients from the early allograft experience, including the pioneering experience with stented aortic allograft for mitral valve replacement. He found a 8.6 years median time of valve failure for patients undergoing mitral valve replacement which, in his experience, was not
different in durability when compared to xenobioprostheses [3].

It seems that premounted viable aortic allograft do not last long due to calcification and leaflet tearing, particularly when nonflexible metal stents are used. Angel believes that calcification might be related in some way to the turbulence induced by stent mounting [3]. The stress of the cusps during the closing and opening of valve leaflets mainly at the post represents a critical issue in the mechanism of cusp rupture.

Unstented aortic allografts for mitral valve replacement were used by a few surgeons but there are no reports of their use since the beginning of the 1970s [9].

The durability of fresh aortic allografts depends on continued tissue viability and it was shown by Angel that the viable fibroblasts are the only cells that survive after an aortic allograft implantation. On the other hand, these fibroblasts become nonfunctional and several years after the implantation the allografts are essentially nonviable and acellular [3].

Glutaraldehyde preserved aortic allografts are nonviable, do not depend on tissue viability and their durability is related to the tanning process resulted from the technique of tissue fixation, which provides the increase in collagen cross-linking, preserving the integrity of collagen fibers and increasing the biological tissue stability.

Acar’s initial experience with mitral valve replacement using mitral allograft seems to be promising [10]. The main question, however, would concern its durability, which depends on continued tissue viability, particularly the chordae tendinae, because of the risk of rupture causing allograft failure. It was demonstrated that the chordae viability decrease much faster than the leaflets and papillary muscles, and that they lost most of their vital functions after 24 h storage [9].

The 12-year follow-up in our group of patients aged over 15 years undergoing isolated mitral valve replacement using glutaraldehyde-preserved stent-mounted aortic allografts demonstrated that the majority of patients showed a significant improvement in their clinical condition, as shown in Table 5. The hemodynamic performance was similar to commercially available porcine bioprostheses, as demonstrated by Doppler echocardiographic studies.

The 12-year actuarial survival was 92.4 ± 3.2% and the late mortality was 0.7 ± 0.6% per patient-year. Only one death resulted from allobioprosthetic-related complication (fungus endocarditis).

Late complications related to the allograft were reported in 11 patients with a total of 12 events, corresponding to 2.4 ± 0.5% per patient-year.

The most frequent among these complications was the thromboembolism with 5 thromboembolic episodes in 4 patients, corresponding to 0.9 ± 0.6% per patient-year and resulting in neurological sequela in 2 patients, followed by prosthetic endocarditis, periprosthetic leak and allobioprosthetic dysfunction, with an incidence of 0.7, 0.4 and 0.4% per patient-year, respectively.

The 12-year actuarial freedom from allobioprosthetic dysfunction due to intrinsic structural degeneration of valve leaflets was 81 ± 15%, which is superior to the results reported in large series for the porcine bioprosthesis [13,14]. It should also be considered that 57.2% of our patients were 35 years or younger and 21.4% were 20 years or younger; these represent a group of patients with increased risk of fibrocalcific degeneration of biological valves, particularly the 21.4% of this series. Only 4.3% of patients were older than 65 years.

Since the total follow-up was not obtained in 100% of patients, but in 91.3% of them, it could be considered the worst case scenario, in which all 6 missing patients died because of valve failure. In this presumed situation, the 12-year actuarial survival also calculated by the Kaplan-Meier method, would be 78.0 ± 6.2%, and the 12-year actuarial survival free from primary valve failure 68.3 ± 15.5%. These results would still be better than those reported for porcine bioprostheses in similar age group of patients.

This 12-year follow-up supports our assumption that this glutaraldehyde-preserved and stent-mounted aortic allograft represents a new advance in cardiac valve surgery.

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