Aortic Valve Replacement with the Labcor TLPB Supra™ Porcine Bioprosthesis: Intermediate Clinical and Echocardiographic Outcomes

Markus Schlömicher, Zulfugar Taghiyev, Yazan Al-Jabery, Peter Lukas Haldenwang, Leif Markthaler, Vadim Moustafine, Axel Maria Laczkovics, Justus Thomas Strauch, Matthias Bechtel

Department of Cardiothoracic Surgery, Ruhr-University Hospital Bergmannsheil, Bürkle-de-la-Camp Platz. 1, 44789 Bochum, Germany

Background and aim of the study: **The Labcor TBLP Supra™ prosthesis is a second-generation tissue valve that has evolved from the Labcor TBLP™ prosthesis, first introduced in 1984. The Supra prosthesis is a triple-composite porcine valve, with no specific anticalcification treatment being used in its production other than standard tissue fixation with 0.4% glutaraldehyde. To date, more than 100,000 Supra valves have been implanted, mainly in South America. Despite this remarkably high number of implants, only marginal data exist concerning durability and safety issues. Hence, the study aim was to analyze short-term and intermediate outcomes relating to the clinical and hemodynamic performance of the Supra valve, as well as complication rates**

Methods: **A follow up study was initiated to evaluate outcomes and durability of the Labcor Supra prosthesis. Between September 2004 and October 2010, a total of 331 patients (mean age 75.8 ± 7.2 years; mean logistic EuroSCORE 8.5 ± 2.3%) underwent aortic valve replacement using the Supra porcine bioprosthesis.**

Results: **The 30-day mortality rate was 4.8% (n = 16). The overall actuarial five-year survival was 72.3 ± 4.9%, and eight-year survival was 60.4 ± 5.6%. Actuarial freedom from reoperation was 96.3 ± 2.4% after five years, and 92.5 ± 3.5% after eight years. Actuarial freedom from structural valve deterioration (SVD) was 99.7 ± 0.3% at five years, and 97.2 ± 0.8% at eight years; actuarial freedom from thromboembolism was 97.5 ± 1.0% and 95.7 ± 1.6% at these times. Actuarial freedom from event rates for endocarditis were 99.5 ± 0.3% and 96.8 ± 0.6%, and 96.1 ± 0.9% and 93.0 ± 1.4% for reoperation**

Conclusion: **No evidence was found of increased rates of SVD. All parameters studied were comparable to those examined for other second-generation porcine prostheses. Further long-term follow up investigations are required however, for the final judgment of this prosthesis.**

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The Labcor TBLP Supra™ prosthesis (Labcor Laboratõrios, Belo Horizonte, Brazil) is a second-generation tissue valve which has evolved from the Labcor TBLPTM prosthesis that was first introduced in 1984. Like other second-generation tissue valves, the Supra it has been designed for enhanced durability and hemodynamic performance. Structurally, the Supra is a triple-composite porcine valve mounted on a flexible acetal copolymer stent which is covered by a polyester tubular fabric. The tissue fixation process is conducted with zero pressure using 0.4% glutaraldehyde, and no additional specific anticalcification treatment is used (Fig. 1).

To date, a total of more than 100,000 Labcor TBLP and Labcor TBLP Supra valves have been implanted worldwide, mainly in Brazil and other countries of South America. Yet, despite this remarkably high number of implants, only marginal data concerning the durability and safety issues of the valves exist. It should be noted that porcine tissue derived from the Labcor family of valves is also used in the Symetis AccurateTM transcatheter heart valve.

The aim of the present study was to analyze intermediate results relating to the clinical and hemodynamic performance of the Supra valve, as well as complication rates, in a large series of patients who underwent AVR with or without concomitant bypass surgery.

Address for correspondence:

Markus Schlömicher, Department of Cardiothoracic Surgery, Ruhr-University Hospital Bergmannsheil, Bürkle de la Camp Platz 1, 44789 Bochum, Germany
e-mail: markus.schloemicher@bergmannsheil.de

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Figure 1: The Labcor TLBP Supra valve.

Clinical material and methods

Patients

A follow up study was initiated to evaluate the outcome and durability of the Supra valve. Patients diagnosed with aortic valve disease requiring elective isolated AVR, as well as those with an additional need for concomitant bypass surgery, were included. Exclusion criteria included reoperation, endocarditis, emergency operation, preoperative hemodynamic instability and preoperative mechanical ventilation. Patients requiring concomitant procedures other than bypass surgery were also excluded from the study.

Between September 2004 and October 2010, a total of 331 patients (mean age 75.8 ± 7.2 years; mean logistic EuroSCORE 9.5 ± 1.7%) underwent AVR using the Labcor TLBP Supra porcine bioprosthesis. Only one patient was aged <65 years at the time of implantation. Concomitant bypass surgery was performed in 130 cases. In total, 261 patients (79%) were in NYHA classes III or IV, and the mean left ventricular ejection fraction (LVEF) was 61 ± 14.4%; the LVEF was below 40% in 30 patients (9%). Renal insufficiency was identified in 56 patients (16.9%), and a previous stroke had occurred in 16 patients (5%). Further patient characteristics are listed in Table I.

Approval to conduct the study was granted by the institutional review board of the Ruhr University, Bochum.

Surgical technique

All patients were operated on using standard cardiopulmonary bypass (CPB) and standard crystalloid retrograde cardioplegia (Bretschneider), through a median sternotomy. A standard hockey-stick aortotomy was usually chosen to expose the native aortic valve. A supra-anular implantation technique, using multiple interrupted pledgetted reinforced 2-0 braided sutures, was chosen. The mean size of the implanted prostheses was 22.8 ± 1.5mm. The mean aortic cross-clamp and CPB times were 73 ± 19 min and 102 ± 25 min, respectively. Postoperative anticoagulation was commenced on the second postoperative day using acetylsalicylic acid (ASA) in case of normal sinus rhythm and normal ventricular function. Patients with chronic atrial fibrillation, as well as those with a reduced left ventricular function showing ventricular dilation, were administered continuous oral anticoagulation with warfarin (International Normalized Ratio range 2.5-3.0), in accordance with recent guidelines for the management of patients with valvular heart disease (1).

Table I: Baseline characteristics of the patients (n = 330).

Parameter	Value
Age (years)*	75.8 ± 7.2
Log EuroSCORE I (%)*	9.5 ± 1.7
Concomitant bypass surgery (%)	39 (n = 130)
LVEF (%)*	61.2 ± 14.4
LVEF <40%	9 (n = 30)
Female gender (%)	48.2 (n = 159)
NYHA class ≥3 (%)	79 (n = 261)
PVD (%)	15 (n = 50)
COPD (%)	11 (n = 36)
Renal insufficiency (CC <50 ml/min) (%)	16.9 (n = 56)
Stroke (with residual paralysis) (%)	5 (n = 16)
Mean pulmonary pressure >25 mmHg (%)	12 (n = 40)
Active endocarditis	0 (n = 0)
Aortic stenosis (%)	73.3 (n = 242)
Aortic insufficiency (%)	10.6 (n = 35)
Combined lesion (%)	16 (n = 53)
Sinus rhythm (%)	87.6 (n = 289)
Atrial fibrillation (%)	9.6 (n = 32)
Preoperative pacemaker due to AV-block (%)	2.8 (n = 9)

*Values are mean ± SD.
AV: Atrioventricular; CC: Creatinine clearance; COPD: Chronic obstructive pulmonary disease; LVEF: Left ventricular ejection fraction; PVD: Peripheral vascular disease.

Follow up

All patients were followed up on annual basis. Follow up data concerning valve-related complications were obtained through telephone interviews with patients, relatives and referring physicians. All data were collected from medical charts (including data for any suspected complications), autopsy reports, or death certificates. The cumulative follow up time was 2203 patient-years (pt-yr), with a median follow up of 6.7 years. The overall follow up rate was 99%. Postoperative outcomes were assessed in accordance with the Valve Academic Research Consortium

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definitions (2). Echocardiographic assessments of the valve were performed after five years.

Echocardiographic analysis

Hemodynamic results were obtained using two-dimensional echocardiography. The follow up rate at five years was 98% (n = 220). The median echocardiographic follow up time was 5.6 years. Transvalvular gradients were determined using the Bernoulli equation. Prosthetic aortic regurgitation was classified as none or trace, mild, moderate, or severe according to recent guidelines (3). The effective orifice area (EOA) was calculated using the continuity equation (3). An ellipsoid biplane area-length method was used to calculate left ventricular volumes. The specific weight of myocardial muscle (1.05 g/ml) was multiplied by the myocardial volume to calculate the left ventricular myocardial mass. A left ventricular end-diastolic volume <70 ml/m2, and a left ventricular mass index <96 g/m2 for women and <116 g/m2 for men, were considered normal.

Statistical analysis

Statistical analyses were performed using XLSTAT 6.1 statistical software. Continuous variables were presented as mean ± SD, and categoric variables were summarized as numbers and percentages of subjects in each category. Survival analyses, as well as the calculation of actuarial freedom from complications, were performed using the Kaplan-Meier method. A standard confidence level of 95% was chosen. Cumulative survival functions were compared using the log-rank and Wilcoxon test. Early event rates were calculated as the number of events divided by the total number of subjects receiving implants, expressed as a percentage. Late events were summarized using linear rates (% per pt-year), and calculated by dividing the number of late events by the sum of patient-years.

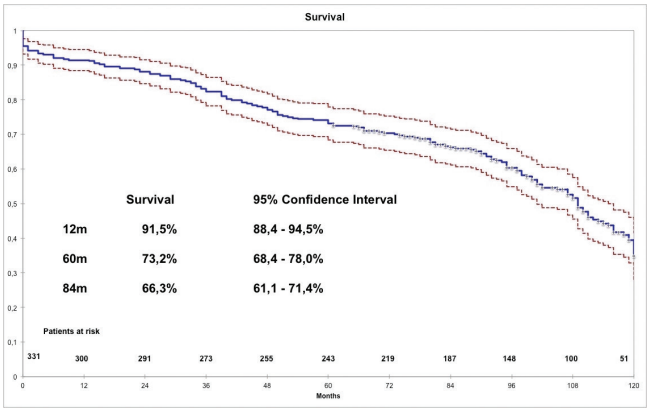

Figure 2: Actuarial survival. The red dotted lines depict confidence intervals. m: Months.

Results

The 30-day mortality rate was 4.8% (n = 16). Seven patients (3.5%) who underwent isolated AVR, and nine (6.9%) with concomitant bypass surgery, died within this 30-day period, though there was no evidence of valve failure. One fatal stroke occurred within 30 days which was regarded as valve-related. Redo AVR was performed in seven cases. Specific adverse event rates are summarized in Table II. No patients with active endocarditis were included in this analysis, and no aortic root enlargement was performed.

Survival

The overall actuarial five-year survival was 72.3 ± 4.9%, and eight-year survival was 60.4 ± 5.6% (Fig.

Table II: Adverse events.

Adverse event	No. of patients	%/pt-yr	Actuarial freedom from event*	
			5 years	8 years
Thromboembolism	12	0.6	97.5 ± 1.0	95,7 ± 1,6
Permanent neurologic deficit	4	0.2	98.7 ± 1.0	98.7 ± 1.0
TIA	6	0.3	99.2 ± 0.6	98.3 ± 1.1
Peripheral embolic event	2	0.1	99.6 ± 0.4	99.2 ± 0.5
Valve thrombosis	0	0.0	100 ± 0.0	100 ± 0.0
Structural valve deterioration	8	0.4	99.7 ± 0.3	97.2 ± 0.8
Endocarditis	9	0.2	99.5 ± 0.3	96.8 ± 0.6
Paravalvular leak	5	0.2	99.1 ± 0.5	98.3 ± 0.8
Major hemorrhage	7	0.3	97.3 ± 1.3	95.7 ± 1.4
Reoperation	18	0.8	96.1 ± 0.9	93.0 ± 1.4

*Values are % ± SE.

Table III: Echocardiographic data.

Valve size (mm)	No. of patients	Peak gradient (mmHg)	Mean gradient (mmHg)	EOA (cm^2)	EOAI (cm^2/m^2)	LVEF (%)	BSA (m^2)	LVMI (g/m^2)
At discharge (n = 310)								
19	29	37.3 ± 4.5	16.8 ± 2.7	1.15 ± 0.26	0.77 ± 0.11	65.1 ± 6.6	1.49 ± 0.14	149.3 ± 27.7
21	85	31.3 ± 5.5	15.6 ± 3.2	1.36 ± 0.31	0.85 ± 0.16	67.8 ± 5.1	1.60 ± 0.15	151.5 ± 31.2
23	98	29.7 ± 5.7	15.2 ± 3.1	1.47 ± 0.25	0.87 ± 0.21	61.7 ± 7.7	1.69 ± 0.11	145.7 ± 36.5
25	62	27.4 ± 6.1	13.6 ± 3.6	1.73 ± 0.33	0.95 ± 0.17	62.6 ± 6.4	1.83 ± 0.19	147.3 ± 25.9
27	36	28.2 ± 5.4	14.2 ± 2.9	2.01 ± 0.36	1.06 ± 0.18	63.1 ± 5.8	1.90 ± 0.21	142.8 ± 29.7
5-Year follow up (n = 220)								
19	20	41.2 ± 4.9	19.8 ± 2.7	1.19 ± 0.23	0.79 ± 0.14	62.1 ± 3.6	1.50 ± 0.16	132.1 ± 33.5
21	56	31.3 ± 5.5	16.3 ± 2.9	1.39 ± 0.37	0.86 ± 0.13	59.8 ± 5.1	1.62 ± 0.15	124.5 ± 35.2
23	71	29.7 ± 5.7	15.1 ± 3.4	1.47 ± 0.32	0.86 ± 0.21	61.4 ± 3.7	1.70 ± 0.14	127.1 ± 36.5
25	44	26.3 ± 6.1	13.7 ± 3.7	1.70 ± 0.28	0.92 ± 0.17	59.6 ± 2.4	1.84 ± 0.16	124.7 ± 32.9
27	29	24.5 ± 4.4	12.8 ± 2.9	1.99 ± 0.37	1.04 ± 0.18	61.8 ± 6.3	1.91 ± 0.20	125.8 ± 32.2

EOA: Effective orifice area; EOAI: Effective orifice area index; LVEF: Left ventricular ejection fraction; LVMI: Left ventricular mass index.

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2). Actuarial freedom from valve-related death was 89.0 ± 2.9% at eight years. At the five-year follow up, 80% of the patients were in NYHA class I or II, 84% showed some improvement or remained functionally stable, and 16% showed a worsening of their NYHA functional state. The majority of patients (87%) received ASA as antiplatelet therapy, while 22% were receiving warfarin.

Thromboembolism

Twelve major thromboembolic events occurred (0.6%/pt-yr). The actuarial freedom from thromboembolism and thrombosis was 97.5 ± 1.0% at five years and 95.7 ± 1.6% at eight years. A permanent neurologic deficit occurred in four patients.

Hemorrhagic events

Seven patients suffered major hemorrhagic events, which were fatal in three cases (linearized rate 0.3%/pt-yr). The actuarial freedom from hemorrhage was 97.3 ± 1.3% at five years.

Prosthetic valve endocarditis

Prosthetic valve endocarditis (PVE) occured in nine cases (linearized rate 0.2%/pt-r). Two cases of early valve endocarditis were seen during a six-month postoperative period. Five patients with endocarditis were reoperated on, and the postoperative outcome was fatal in two cases. Four patients were ineligible for reoperation on the basis of their moribund clinical condition. The actuarial freedom from PVE was 99.5 ± 0.3% at five years and 96.8 ± 0.6% at eight years.

Structural valve deterioration

Structural valve deterioration (SVD) occurred in eight patients (linearized rate 0.4%/pt-yr). The diagnosis was based on echocardiography in each of these eight cases, with six patients showing increased mean transvalvular gradients while two developed severe aortic insufficiency. Five patients underwent a sucessful reoperation. Three patients underwent transapical valve-in-valve (TAVI) procedures, using a 26 mm Edwards SAPIEN XT transcatheter heart valve (Edwards Lifesciences, Irvine, CA, USA) in each case. A 23 mm valve was primarily implanted in two patients, and a 25 mm prosthesis in one patient. All three procedures were performed with acceptable hemodynamic results and no PVL. The overall actuarial freedom from SVD was 99.7 ± 0.3% at five years, and 97.2 ± 0.8% at eight years (Fig. 3).

Paravalvular leak

Paravalvular leakage (PVL) occured in five patients (linearized rate 0.2%/pt-yr), all of whom underwent reoperation. The outcome was fatal in one case.

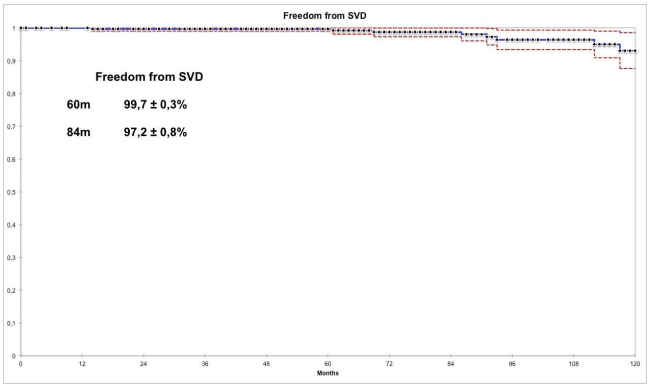

Figure 3: Freedom from structural valve deterioration (SVD). The red dotted lines depict confidence intervals. m: Months.

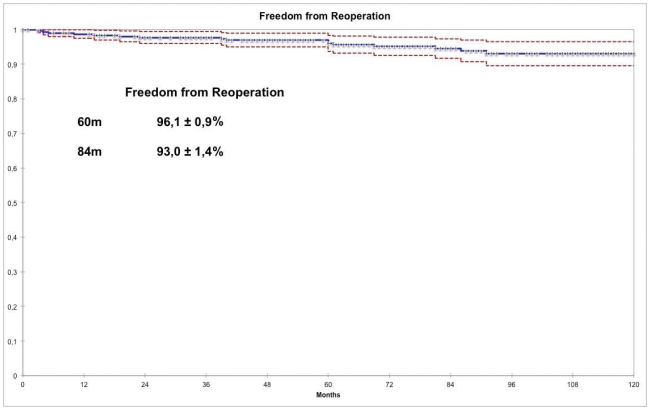

Figure 4: Freedom from reoperation. The red dotted lines depict confidence intervals. m: Months.

The actuarial freedom from PVL at five years was 98.3 ± 0.8%.

Valve-related complications

Some 59 valve-related complications occurred, including PVL, SVD, endocarditis, thromboembolism, and hemorrhage. A linearized rate of 2.8% per pt-yr was found, and the actuarial freedom from valve-related complications at eight years was 79 ± 4.5%.

Reoperations

Eighteen patients underwent reoperation (linearized rate 0.9%/pt-yr). Eight patients underwent reoperation because of SVD, with three undergoing a TAVI procedure. Endocarditis was the cause of reoperation in five patients, and PVL in five. The actuarial freedom from reoperation was 96.1 ± 0.9% at five years and 93.0 ± 1.4% at eight years (Fig. 4).

Echocardiography

The echocardiographic data of patients are listed in Table III. The mean LVEF was 60.7 ± 17.4%. After five years, the mean gradient was 15.2 ± 4.2 mmHg and the mean effective orifice area (EOA) was 1.54

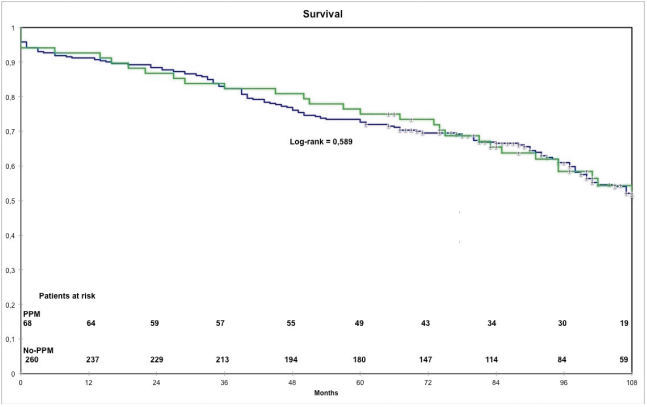

Figure 5: Actuarial survival. Green: Prosthesis-patient mismatch (PPM); Blue: Non-PPM.

cm ± 0.35 cm^2, with a mean indexed EOA (EOAI) of 0.89 ± 0.24 cm^2/m^2. The mean and peak gradients were significantly related to the smaller valve size.

Initially, 79 of 310 patients (25%) were identified as having an EOAI <0.85 cm^2/m^2, but no patient had an EOAI <0.65 cm^2/m^2. When survival functions were calculated for the group with moderate patient-prosthesis mismatch (PPM) and for the group without, no significant difference regarding cumulative survival was seen using the log-rank test (p = 0.63) or the Wilcoxon test (p = 0.82) (Fig. 5). The rate of moderate PPM was 25% (n = 78) at one year, and 32% (n = 93) at five years.

The mean LV mass index (LVMI) was 147.1 ± 33.2 g/m^2 at discharge, and 126.13 ± 35.2 g/m^2 after five years. The LV mass regression at five years was found to be significant (p< 0.001), being -23.0 ± 17.3 g (15.7 ± 11.6%) in patients without PPM, and -24.5 ± 16.7 g (16.2 ± 11.0%) in the PPM group.

Regurgitation was trivial in 43 patients (15%) and mild in 22 (8%). In total, 150 patients (68%) had no aortic regurgitation after five years.

Discussion

The results of the present study reflected the authors' experience with use of the Labcor porcine prosthesis implanted in the aortic position. Although the Labcor porcine prosthesis has been implanted in very large quantities worldwide, mainly in Brazil and other countries of South America, only marginal data regarding mid-term and long-term outcomes are available in the literature. The largest series was published by Pavie et al. (4), who reported an actuarial five-year survival rate of 74 ± 5% among 100 patients with a mean age of 80 ± 5 years at the time of implantation. These outcomes are comparable with the present data, which showed an actuarial five-year survival rate of 72.3 ± 4.9% among a patient population with a mean age of 75.8 ± 7.2 years. Unfortunately, specific preoperative risk factors were not presented in the report from Pavie and colleagues.

Bottio et al. (5) reported a five-year actuarial survival rate of 73 ± 2.8% for another second-generation porcine bioprosthesis, the Biocor™ valve (St. Jude Medical, St. Paul, MN, USA) within a comparable patient collective with a mean age of 75 ± 6 years, while David et al. (6) reported a five-year actuarial survival of 79 ± 2.1% for the Medtronic Hancock II bioprosthesis (Medtronic, Minneapolis, MN, USA) within a patient cohort of mean age 65 years. Riess et al. (7) described a five-year actuarial survival of 81% among a patient collective with a mean age of 67 ± 8.5 years for the Medtronic Mosaic bioprosthesis (Medtronic). Dalmau et al. (8) compared the clinical and echocardiographic outcomes of the Medtronic Hancock II bioprosthesis with the Edwards Perimount Magna valve (Edwards Lifesciences, Irvine, CA, USA). A five-year actuarial survival of 79.6 ± 4.1% with the Medtronic Mosaic group reflected data from the present study (8). Survival rates of the patients are listed in Table IV.

Several studies with different tissue valves, either porcine or pericardial, have shown comparable survival rates (5-10), although it must be stressed that the mean patient age in most of these series was lower.

Table IV: Survival rates.

Reference	Valve	Mean age (years)	5-year actuarial survival (%)
Bottio et al. (5)	SJM Biocor	75 ± 6	73 ± 2.8
Pavie et al. (4)	Labcor TLBP	80 ± 5	74 ± 5.0
David et al. (6)	Medtronic Hancock II	65 ± 12	79 ± 2.
Riess et al. (7)	Medtronic Mosaic	67 ± 8.5	81 ± 2.4
Dalmau et al. (8)	Medtronic Mosaic/Carpentier-Edwards Perimount	75.6 ± 4.5	79.6 ± 4.1/94.4 ± 2.2
Dellgren et al. (10)	Carpentier-Edwards Perimount	71.3 ± 8.8	80 ± 3.0

SJM: St. Jude Medical.

The hemodynamic results achieved with the Labcor TLBP Supra prosthesis were comparable to those reported for other porcine valves (5-10). Bottio et al. (5) noted a mean transprosthetic gradient of 16.6 ± 5.3 mmHg for the Biocor valve, while Borger et al. (9) reported a value of 18.5 ± 5.5.mmHg for the Medtronic Hancock II valve. Comparable hemodynamics with a mean transvalvular gradient of 15.2 ± 4.2 mmHg were found in the present study. Porcine valves normally show significantly higher peak and mean gradients compared to pericardial bioprostheses (8-10). Dellgren et al. (8) reported transvalvular mean pressure differences of 12.3 ± 4.8 mmHg, while Dalmau et al. (10) showed mean gradients as low as 10.3 ± 3.4 mmHg for the pericardial valve group in their comparative studies.

PPM was defined by the quantification of EOAI, which is the only valid parameter by which to identify the condition (11,12). Negative effects on intermediate and long-term survival are associated with incomplete left ventricular mass regression, which can be a hemodynamic consequence of PPM.

The rate of moderate PPM, which was 25% in the present series at one year and 32% at five years, reflected published data where rates of moderate PPM between 10% and 50% have been noted, depending on the valve type and valve design (11,12). After five years, the prevalence of PPM (32%) remained stable, whereas Dalmau et al. (8) noted a significant increase in PPM among the porcine valve group (30.1% at one year versus 73.9% at five years) over a certain time period. The transprosthetic pressure gradient would be expected to decrease with increasing EOAI (11), and this correlation was strongly supported by the present data. Nevertheless, the effect of PPM and EOAI on LVM regression was less evident. At five years, most patients showed a significant regression in LVM and LVMI, irrespective of PPM occurrence. This absence of difference in LVM regression confirmed the findings from other studies (8,13). The LVM regression was 15.2 ± 8.9% at five years.

In the present series, the occurrence of moderate PPM did not affect mid-term survival, though the topic remains controversial. PPM can be associated with inferior survival and increased valve-related adverse events (11), although recently published data have disagreed and strongly support the null hypothesis (14-16).

The results of studies conducted by Myken et al. (17), Bottio et al. (5) and Le Tourneau et al. (18) for the Biocor, Carpentier-Edwards pericardial and Carpentier-Edwards supra-annular porcine valves, respectively, were comparable with regards to valve-related complications. Myken et al. (17) reported a linearized reoperation rate of 0.9% per pt-yr, Bottio et al. (5) a linearized rate of 0.66% per pt-yr, and Le Thourneau et al. (18) a linearized rate of 1% per pt-yr for the Carpentier-Edwards supra-annular porcine valve, as well as 0% per pt-yr for the Carpentier-Edwards pericardial valve. A linearized reoperation rate of 0.8% per pt-yr was noted in the present series.

Nine cases of endocarditis occurred during follow up, resulting in a linearized endocarditis rate of 0.2% per pt-yr. Five patients underwent reoperation, whereas four were not in good condition to undergo cardiac surgery or denied their consent. Bottio et al. (5) reported a linearized rate of 0.16% per pt-yr, while Le Thourneau et al. (18) described a rate of 0.8% per pt-yr.

In the present study, a total of eight patients was observed with SVD, which implies a linearized rate of 0.4% per pt-yr. Subsequently, all eight patients underwent reoperation, with three undergoing a TAVI procedure. The actuarial freedom from SVD was 99.7 ± 0.3% after five years and 97.2 ± 0.8% after eight years. This rate of SVD was consistent with data found in the literature. Bottio et al. (5) showed an actuarial freedom from SVD of 100% after five years, and 95.8 ± 0.4% after eight years for the Biocor porcine bioprosthesis. Rizolli et al. (19) reported an actuarial freedom from SVD of 100% at five and 10 years for the Hancock II bioprosthesis, which was consistent with the data described by David et al., with rates of 100% at five years and 97 ± 1% at 10 years. Bottio et al. (5) found a linearized rate of valve-related complications of 2.8%, which was in line with an actuarial freedom from valve complications of 78 ± 4.8% at eight years, and which also matched the present data with a linearized rate of 2.5% and an actuarial freedom from valve complication of 79 ± 4.5%.

Some studies have compared rates of structural valve degeneration between younger age groups (<65 years) and older age groups (>65 years) (5,18). A comparison of different age groups could not be undertaken in the present study as only one patient was aged <65 years.

Low incidences of thromboembolism and hemorrhage are a major benefit of bioprostheses. In the present study, freedom from thromboembolic events was 97.5 ± 1.0% at five years, and 95.7 ± 1.6% at eight years, while freedom from hemorrhage was 97.3 ± 1.3% and 95.7 ± 1.4% at these times. This was comparable to findings with other bioprosthetic valves, with reported rates of between 95% and 98% at five years (5-10,17-19).

The Labcor TLBP Supra bioprosthesis is manufactured without the use of specific anticalcification treatment, and based on the results achieved at the mid-term follow up this appears not to be a disadvantage. Long-term data are still missing, however. Some attention must be drawn to the fact that the same porcine valve tissue with the same low-pressure fixation treatment is used in the well-known Symetis Accurate transcatheter heart valve. This is additionally relevant as the Symetis Accurate valve is the second most often-used transcatheter heart valve for TAVI procedures in Germany (20). These

mid-term results reassure reliable results concerning durability and safety issues relating to this tissue type.

Study limitations

The main limitations of the study were its non-randomized, single-center nature and the lack of a concurrent control group. Possible selection and performance biases due to a non-blinded study design may also represent important limitations, as well as attrition biases resulting from missing data points. The higher mean age (75.8 ± 7.2 years) was a major limitation to the study due to a general reduction in overall survival among this age cohort.

In conclusion, only marginal data concerning outcome and durability exist at present for the Labcor TLBP Supra bioprosthesis, and the present study has been the largest to be conducted to date. During a median follow up of 6.7 years, no evidence was found of increased rates of SVD. All of the parameters studied were comparable to those studied for other second- or third-generation porcine prostheses within a mid-term follow up interval. Long-term follow up data are required for a final judgment of this prosthesis, which is implanted in large numbers in some regions of the world.

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