8-year experience with the LABCOR bioprosthesis in the Aortic position

Schlömicher M.; Haldenwang P.L.; Buchwald D.; Laczkovics A.; Bechtel M.; Moustafine V.; Strauch J.;

Klinik für Herz-Thoraxchirurgie,
Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil Bochum

Background:

Between 2004 and 2010 330 patients with a mean age of 75,8±7,2 years and mean logistic EuroSCORE of 8,5% underwent AVR with the LABCOR TLPB-A Supra porcine bioprosthesis in our institution. This paper presents clinical results against the background following a trend towards bovine devices through the last decade.

Patients and Methods:

Patients diagnosed with aortic valve stenosis requiring isolated aortic valve replacement, as well as patients with the additional need of concomitant bypass surgery were included in this follow up study. Between 09/2004 and 10/2010 a total of 330 patients received biological AVR using the LABCOR porcine bioprostheses. Concomitant bypass surgery was performed in 130 cases. Preoperatively, 69 patients (21%) were in NYHA class II, 214 (65%) in class III and 47 (14%) in class IV.

Surgical technique:

Patients were operated using standard cardiopulmonary bypass as well as standard cristalloid cardioplegia (Bretschneider). The porcine valves were implanted in a supraanular fashion using felt-armed u-stitches.

Follow-up:

Data were obtained during a 6 month interval period through telephone interviews with patients and referring physicians. Giudelines for reporting mortality and morbidity were followed in these Interviews

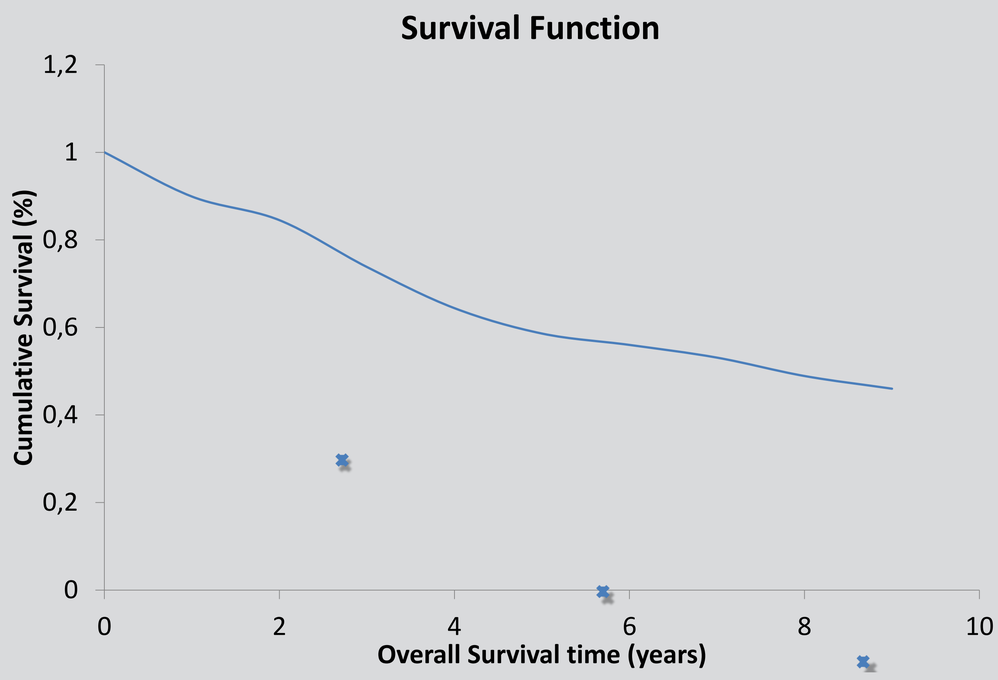
Statistical Analysis:

Statistical Analysis was performed using SPSS 20.0 statistical software. The patient population data, operative and follow up clincal data was characterized through descriptive statistics. For continuous variables, the number of patients, mean (+- SD), minimum and maximum were provided. For categorical variables, the number and percentage of patients were provided. Survival Analysis was performed using the Kaplan-Meier survival Method. Early event rates were calculated as the number of patients having the event divided by the total number of patients, 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.

Results:

The follow up rate was 98%. The 30 day mortality rate amounted 4,8% (n=16). There was no evidence of valve failure during this period. Mean follow up was 5,6 patient years. Total follow up 1441patient years.
5 year survival amounted 60% (±1,4), 8 year survival 49% (± 1,6). 50% (n=89) of the contacted patients were NYHA Class I 39% (n=69) in NYHA Class II 10% (n=18) and 0,6% (n=1) in NYHA class IV.

Out of 136 late deaths 9 were valve related (0,6%/ pt-year) with 1 case of paravalvular leakage, 6 cases of endocarditis, one stroke and one patient who suffered from cerebral hemorrhage. 26 late deaths were cardiac (1,8%/pt-year), 49 were noncardiac (3,4%/pt-year) and 56 were unexplained (3,9%/pt-year)



Adverse events:

Frequency of adverse events and actuarial freedom from valve related adverse events 5 years and 8 years after aortic valve replacement.

Adverse event	Late events		Actuarial freedom from event (% +/-SD)	
	N	%/pt-year	5 years	8 years
Thromboembolism	8	0,6	96,3 ± 1,7	92,9 ± 1,7
-Permanent neurological deficit	3	0,2	98,7 ± 1,0	98,7 ± 1,0
-TIA	3	0,2	99,2 ± 0,6	98,3 ± 1,1
-Acute myocardial infarction	2	0,1	99,4 ± 0,5	98,7 ± 0,9
-Valve Thrombosis	0	0	100 ± 0,0	100 ± 0,0
-Peripheral embolic event	1	0,1	99,3 ± 0,6	99,3 ± 0,6
Structural valve deterioration	3	0,2	99,2 ± 0,7	96,9 ± 1,4
Endocarditis	9	0,6	96,8 ± 1,4	96,8 ± 1,4
Paravalvular leak	3	0,2	99,3 ± 0,5	97,5 ± 1,5
Major hemorrhage	7	0,5	97,3 ± 1,3	95,7 ± 1,4
Reoperation	15	1,0	96,0 ± 1,8	87,3 ± 2,7
Explant	15	1,0	96,0 ± 1,8	87,3 ± 2,7

Conclusion:

In this middle follow-up term of 8 years of clinical experience in a single center, the LABCOR porcine bioprosthesis shows reliable and satisfying results comparable to other commercial porcine heart valves in a patient group with a medium risk profile. Nevertheless, further long-term assessment and echocardiographic examination is needed.