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Long-term outcome of cryopreserved allograft for aortic valve replacement

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ABSTRACT

Objective: The most efficient surgical approach to severe aortic valve disease in the young adult is still debated: cryopreserved aortic allograft offers excellent hemodynamic and avoid anticoagulation, but long-term durability is influenced by structural valve deterioration (SVD). This study aimed to describe long-term results of aortic allografts and to identify factors influencing long-term durability.

Methods: From January 1993 to August 2010, 210 patients underwent aortic allograft replacement via the free-hand subcoronary implantation technique (N = 55) or root replacement with coronary reimplantation (N = 155). Clinic and echocardiographic follow-up was updated to April 2016.

Results: Overall mortality and cardiac mortality occurred in 80 (38.1%) and 64 (30.5%) patients, respectively. Reoperation was required in 69 cases (32.8%), whereas SVD required reoperation in 57 cases (27.1%). No early endocarditis occurred, whereas late endocarditis occurred in 4 patients. The free-hand technique seems to be associated with improved left ventricular remodeling compared with the root-replacement technique, and smaller allograft size represents a predictor of reoperation independently on the surgical technique used. In the overall population, there were 44 women of childbearing age, and 37 patients remained pregnant during the follow-up of the study. No differences were found in the clinical outcomes among women who had children and who did not.

Conclusions: Cryopreserved allograft is a valid option, especially in complex infective endocarditis and in women of childbearing age. A careful choice of allograft size and implantation technique can reduce the risk of SVD. (J Thorac Cardiovasc Surg 2018;■:1-9)

Allograft replacement for recurrent endocarditic pseudoaneurysm after Bentall procedure.

Central Message

Cryopreseved allograft is a valid option, especially in infective endocarditis and during childbearing age. A careful choice of allograft size and implantation technique can reduce the risk of reoperation.

Perspective

Cryopreserved allograft (CA) showed good outcomes, acceptable durability, and low reinfection rate, representing a valid option, especially in cases of complex endocarditic destruction and during childbearing age. These aspects should be considered when weighing the procedural risks of CA implantation against its long-term benefits and when these are compared with prosthetic valves.

ADULT

Diseases of the aortic valve raise difficult therapeutic problems in the young population.[1] Currently there is no unanimous consensus on the most efficient surgical approach to severe aortic valve disease in the young adult. Moreover, even the accepted surgical dogma concerning the preference in the use of autologous or allogeneic tissues in infective conditions has been recently lively debated.[2-4] Some experts have advocated the use of allograft for the lack of complications related to oral anticoagulation and

Scanning this QR code will take you to the supplemental video, appendix, and tables for the article.

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Abbreviations and Acronyms
CA = cryopreserved aortic allograft
NYHA = New York Heart Association
SVD = structural valve deterioration

the excellent quality of life permitted by the enhanced hemodynamic performance of the valves.[5-9]

Consensus on the use of cryopreserved aortic allograft (CA) remains firm in women with future plans of pregnancy and in pediatric cardiac surgery. Recently, initial steps in the use of decellularized allografts for aortic root replacement have been taken, with promising results.[10,11] However, the actual obstacle that affects long durability of the CA is structural valve degeneration (SVD). Failure of allograft conduit and valve is approximately 30%, leading frequently to reoperation.[12,13] Hence, disadvantages related to the complexity of the technique of implantation, which is not normally mastered in all the centers, the restricted the availability of CA, and the increased complexity of reoperations have limited its use.

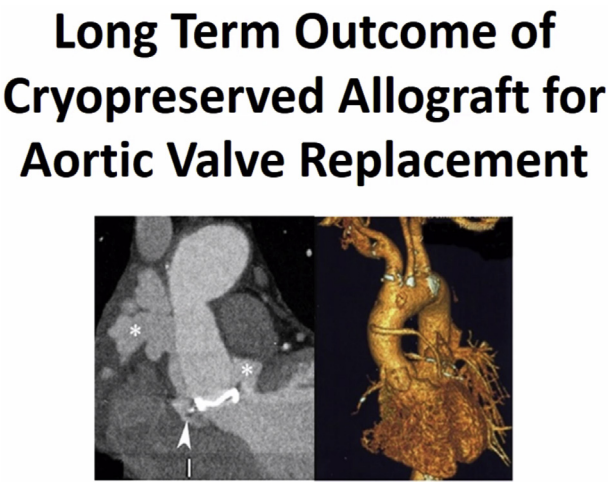
Here, we present our series of 210 patients who have undergone aortic allograft implantation and were followed up for 20 years. We aim to describe the long-term results of this procedure in our cohort and eventually to identify factors influencing long-term durability of aortic allograft (Video 1).

PATIENTS AND METHODS

Study Population and Operative Data

The records of 210 patients (150 males) with severe aortic disease who underwent aortic allograft replacement from January 1993 to August 2010 were reviewed and all events until April 31, 2016, were analyzed. The mean age was 40.1 ± 17.9 years (range 10-77 years) with 10 patients younger than 18 years. Four surgeons in 2 centers were involved in these cases. Details of the clinical and operative characteristics are listed in Tables 1 and 2. Surgical strategy was based on the extent of valve lesions. The technical details of aortic allograft insertion have been widely described (APPENDIX E1), and 2 techniques have been used: the free-hand subcoronary implantation technique and the allograft root replacement with coronary reimplantation.

Valve-associated events such as SVD, cardiac death, valve-related mortality, and other outcomes are defined by Valve Academic Research Consortium-2 (VARC-2) criteria. Standard 2-dimensional and Doppler echocardiographic examinations with color-flow mapping were performed on all patients 1 week before operation. Baseline echocardiography for clinical follow-up was performed immediately after the operation at the time of discharge. Follow-up echocardiography was obtained during periodical outpatient clinics or immediately before redo surgery. All echocardiographic data were analyzed in random order by 2 independent expert cardiologists blinded with regard to the clinical data and timing of the echocardiogram (APPENDIX E1).



VIDEO 1. Summary of design and main findings of the study. Video available at: http://www.jtcvsonline.org.

Statistical Analysis

Categorical variables, presented as frequencies and percentages, were compared with χ^2 analysis or the Fisher exact test. Normality criteria were checked and met for each continuous variable, which was expressed as mean and standard deviation and compared with the Student t test. Kaplan–Meier analyses were used to assess the probability of survival or other survival-related outcomes. For death and composite endpoints including death, a multivariable Cox regression model was used, including age, sex, etiology, type of implantation, size of the valve, and preoperative ejection fraction. For competing risk endpoint (such as SVD) with death, a competing risk framework was used and data reported as cumulative incidence.

Graphical presentation includes Kaplan–Meier curves to present crude survival probabilities in the overall population and cumulative incidence for competing risk endpoints. Longitudinal analysis was performed with a mixed-effect statistical package with random effects. Continuous (left ventricular end-diastolic diameter, left ventricular end-systolic diameter, left ventricular ejection fraction, etc) and ordinal (aortic valve regurgitation grade, New York Heart Association [NYHA] class) data were analyzed with the "meglm" package when evaluating echocardiographic parameters in the overall population (with specific tests for continuous and ordinal data), and "xtreg" or "xtologit" packages when evaluating the effect of the surgical treatment. As for Cox regression, proportional hazard assumption was tested with Schoenfeld residuals ("estat phtest" command) and was not violated in any described outcome. As for competing risk analysis, the proportionality assumption was checked with the option "tvc" after the command "stcrreg." Statistical analysis was performed with STATA Version 13 for Windows (StataCorp, College Station, Tex). A $P < .05$ was considered statistically significant.

RESULTS

Baseline characteristics and operative data of the patients are shown in Tables 1 and 2. Mean follow up was 13.0 ± 5.6 years, median follow-up was 13.6 (interquartile range, 9.2-17.3 years), and maximum follow up was 22.1 years. All the explants were performed at hospitals. In total, 154 patients (73.3%) were followed up more than 10 years and 82 patients (39.0%) more than 15 years. A total of 80 deaths (38.1%), 64 cardiac deaths (30.5%), and 69 reoperations (32.8%) occurred. Echocardiographic results and details about clinical outcomes are shown in Tables E1 and E2.

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