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Original article

Influence of stentless versus stented valves on ventricular remodeling assessed at 6 months by magnetic resonance imaging and long-term follow-up

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ABSTRACT

Background: To compare the effect of stented versus stentless bioprostheses on left ventricular remodeling and assess their impact on long-term survival.
Methods: From January 2002 to December 2009, 62 severe aortic stenosis patients without coronary artery disease were randomized for bioprosthetic aortic valve replacement. After randomization, a cross-over was possible based on intraoperative data. Ventricular remodeling was studied by cardiovascular magnetic resonance imaging six months after surgery. Long-term survival was assessed by telephone survey.
Results: Thirty-five patients received a porcine Mosaïc® Medtronic bioprosthesis (Stented Group; Medtronic, Minneapolis, MN, USA) inserted using the usual supra-annular technique and 27 received a porcine Freestyle® Medtronic bioprosthesis (Stentless Group) inserted in the subcoronary position. Mean age was 75 ± 3 and 73 ± 4 years in the stentless and stented group, respectively. Nine patients who should have been implanted with a stentless bioprosthesis received a stented bioprosthesis for anatomical reasons. At 6 months, the left ventricular mass (LVM) decreased significantly in both groups (Stentless Group: 214.6 ± 56.1 g and 156.3 ± 23 g and Stented Group: 237 ± 75.7 g and 181 ± 53.3 g, respectively after surgery and at 6 months), this decrease was significantly greater in the stentless group ($p = 0.026$). Reserve and coronary flow were increased in both groups at 6 months. Mean follow-up duration was 6.6 ± 3.0 years and 7.2 ± 4.0 years in the stentless and stented group, respectively. The 5-year actuarial survival was 87.5 ± 11.7% and 82.5 ± 17.1% for the stentless and stented group, respectively ($p = 0.81$).
Conclusion: Porcine stentless prosthesis results in a better LVM regression than a stented valve at 6 months without changing the long-term survival.

Introduction

Aortic valve replacement (AVR) is the gold-standard treatment for aortic stenosis (AS) but the ideal valve substitute does not exist. Porcine or pericardial bioprostheses do not require anticoagulants but there is a risk of reoperation due to structural deterioration. The latter is due to their immunogenic potential [1] and the stent structural components increase mechanical stress. To limit the mechanical stress, the native porcine aortic roots or nonstented xenografts (stentless) appear to be the best support [2]. Assuming that it would be possible to better reproduce the physiological status of the aortic root has led to great expectations among surgeons. The comparison between stented valve substitutes and stentless bioprostheses has shown controversial results: the mean

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pressure gradients, in particular in small aortic rings, decrease [3] and the indexed effective orifice area (EOA) increases [4–7] in patients implanted with a stentless bioprosthesis compare to a stented substitute. However, the transvalvular gradients vary with the cardiac output and it appears more interesting to assess the regression of the left ventricular hypertrophy (LVH) which is mainly observed within the first six months following surgery [5–8]. Other comparative studies have shown a normalization of the coronary blood flow, which was reduced in cases of LVH [9]. Some randomized clinical trials comparing stented and stentless bioprostheses, in particular for pericardial prostheses, have shown no difference in indexed EOA and transvalvular gradient [10,11]. In hypertensive disease, the LVH regression induced by antihypertensive treatments reduces the risk of mortality and major cardiovascular (CV) events [12,13]. The aim of this study was to compare the effect of similarly manufactured porcine stented and stentless valves on LVH regression, systolic wall stress, coronary blood flow velocity and coronary reserve assessed by magnetic resonance imaging (MRI) 6 months after AVR in AS patients and to assess the impact of the ventricular remodeling on the long-term survival.

Materials and methods

Study design

Patients were randomized 1:1 in the operating room. All patients provided written informed consent and were given a time of reflection before inclusion in the study. The study and consent form were approved by the local ethics committee. The study was conducted using an intent-to-treat approach. The primary endpoint was the comparative measurements of the left ventricular mass (LVM) regression after AVR and the secondary endpoints were the coronary reserve measurement and the long-term survival (Fig. 1).

Population

From January 2002 to December 2009, 62 consecutive patients undergoing AVR were included in this prospective randomized controlled clinical trial. Preoperative exclusion criteria were having a contraindication to MRI, being aged <18 years or ≥80 years, being pregnant or likely to be pregnant. Exclusion criteria were patients with pure aortic regurgitation or significant coronary artery disease assessed by preoperative coronarography, requiring additional valve repair or replacement and emergency surgery. In addition, when patients could not be implanted with a stentless valve for anatomical reasons, a cross-over (from stentless to stented) was performed.

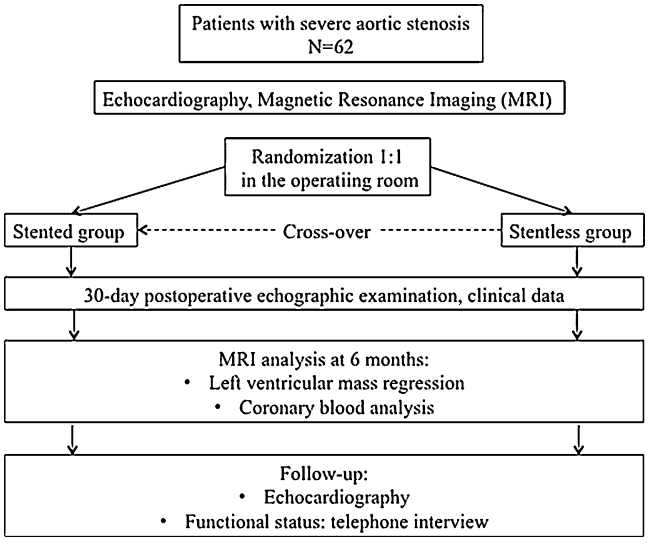

Fig. 1. Study flow-chart.

Surgical technique

AVR was performed under normothermic cardiopulmonary bypass. All patients received an antegrade cold blood cardioplegia diluted with Saint-Thomas® solution enriched with potassium. Access to the aortic valve was gained through a transverse aortotomy. After complete resection of the native aortic valve and debridement of the aortic annulus, the bioprosthesis size was assessed with the original Medtronic sizers for Freestyle stentless and Mosaic stented valves (Medtronic, Minneapolis, MN, USA), and the native annulus was calibrated with Hegar's probes. The Mosaic Cinch stented valves were implanted in supra-annular position using pledget-armed U-stitches with Cardioflon 2-0 sutures. The Freestyle® stentless prostheses were implanted in the modified subcoronary position [14] using 2 running Prolene 4-0 sutures for proximal and distal anastomoses.

Cardiovascular magnetic resonance imaging (MRI)

Patients were examined with a 1.5 T imager (Signa Horizon, GE Medical Systems, Milwaukee, WI, USA), before and 6 months after AVR using a phased-array coil. Images were acquired during repeated breath-holds with electrocardiogram-gating. A segmented k-space fast gradient-echo pulse sequence with radio frequency phase spoiling was performed in multiple short-axis views (contiguous slices of 8-mm thickness from the base to the apex) with the following parameters: repetition time 10.2 ms/echo time 2.7 ms/30° flip angle/256 × 128 matrix/320 mm × 320 mm FOV/1.25 mm × 1.25 mm pixel size, 20 phases per cardiac cycle using view sharing and uniform TR radio frequency excitation. MRI images were transferred to a multi-modality station for analysis and computation. Endocardial and epicardial borders of the left ventricle were drawn with an automatic segmentation method allowing manual corrections through an interactive interface as previously validated [15], to determine the end-diastolic and end-systolic volumes, LVM, left ventricular ejection fraction (LVEF), and regional left ventricular wall thickening. A myocardial density of 1.05 g/cm^3 was used to calculate the LVM. Regional end-systolic wall stress (SWS) was calculated from a set of five contiguous short-axis planes and averaged in the anterior, lateral, inferior, and septal sectors as previously described [16]. The SWS was calculated using the Grossman formula as follows:

$$\mathrm{SWS} = 0.133 \times \mathrm{SP} \times \frac{R}{2T \times (1 + (T/2R))}$$

where SP is the peak of systolic ventricular blood pressure in mmHg; 0.133 is a conversion factor to express the final results in 10^3 N/m^2. The radius (R) and wall thickness (T) were calculated with a 3D approach using the three-dimensional curvature [16]. SP was assessed through the noninvasive peak of systolic blood pressure recorded at the time of the MRI examination only 6 months after AVR, because this assessment is not reliable in AS before surgery. However, we assessed the T/R ratio before AVR and 6 months after surgery.

Phase contrast magnetic resonance imaging flow measurement

To acquire coronary blood flow velocities and reserve, sequences of phase contrast MRI (velocity mapping) were

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