

Aortic Valve Disease With Severe Ventricular Dysfunction: Stentless Valve for Better Recovery

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Background. Stentless bioprostheses and homografts show better hemodynamic profiles compared with conventional stented bioprostheses and mechanical valves. Few data are available on stentless aortic valve implantation for patients with severe left ventricular dysfunction. The aim of this retrospective study was to assess the potential benefits of stentless aortic valve implantation for patients undergoing isolated aortic valve replacement with left ventricular ejection fraction $\leq 35\%$.

Methods. From November 1988 through March 2000, 53 patients (45 men and 8 women, aged 64.2 ± 15.2 years) with a LVEF $\leq 35\%$ (mean EF, $28.7 \pm 5.4\%$) underwent isolated, primary aortic valve replacement for chronic aortic valve disease. Twenty patients received stentless aortic valves and 33 patients received conventional stented bioprostheses and mechanical valves. Predictive factors for LVEF recovery at echocardiographic follow-up (36.2 ± 32.1 months) were analyzed by simple and multiple regression analysis.

Results. There were no significant differences between groups in early and late mortality. Stentless aortic valve

implantation required a longer aortic cross-clamp time ($p = 0.037$). The stentless aortic valve group showed a better LVEF recovery ($p = 0.016$). Stentless aortic valves had a larger indexed effective orifice area compared with conventional stented bioprostheses and mechanical valves ($p < 0.0001$). A smaller indexed effective orifice area ($p = 0.0008$), chronic obstructive pulmonary disease ($p = 0.015$), and implantation of a conventional stented bioprosthesis or mechanical valve ($p = 0.016$) were related to reduced LVEF recovery by univariate analysis. A larger indexed effective orifice area ($p = 0.024$) was an independent predictive factor for a better LVEF recovery by multivariate analysis.

Conclusions. Stentless aortic valve implantation for patients with severe left ventricular dysfunction, even if technically more demanding, is a safe procedure that warrants a larger indexed effective orifice area leading to an enhanced LVEF recovery.

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Conservative therapy for patients with severe aortic valve disease and congestive heart failure carries a high mortality rate, with a 5 year-survival of 28% for aortic regurgitation [1] and a 2-year survival $\leq 10\%$ for aortic stenosis [2]. Aortic valve replacement is the best therapeutic choice for this group of patients, even if left ventricular dysfunction (LVD) is associated with an increased operative risk [3, 4]. An incomplete relief of afterload overload by implanting an aortic prosthesis with a poor hemodynamic profile could jeopardize left ventricular ejection fraction (LVEF) recovery in these patients [5]. Stentless aortic valves (SAVs), (ie, homografts and stentless porcine bioprostheses) show a significant hemodynamic benefit [6, 7, 8] compared with conventional stented bioprostheses (CSBs) and mechanical valves (MVs). Nevertheless, few data are available on SAV implantation for patients with LVD [5, 9]. This

retrospective study compared SAVs with CSBs and MVs in consecutive patients undergoing isolated aortic valve replacement with LVEF $\leq 35\%$.

Patients and Methods

Study Population

Between November 1988 and March 2000, 1,571 patients underwent aortic valve replacement at Ospedali Riuniti in Bergamo, Ospedale G. Pasquinucci, National Research Council in Massa, Italy, and Private Hospital Poliambulanza in Brescia, Italy. Of this population, we identified all patients with LVEF $\leq 35\%$ and severe aortic valve disease. Associated coronary artery disease, combined coronary bypass graft operation, and history or clinical evidence of previous acute myocardial infarction were considered exclusion criteria. Associated procedures on other heart valves or ascending aorta, previous cardiac operation, endocarditis, and aortic dissection were also exclusion criteria.

The medical charts of 53 consecutive patients (3.4%)

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Table 1. Preoperative Data

Age (y)	64.2 ± 15.2
Male/Female (n)	45–8
Body surface area (m ²)	1.8 ± 0.15
Hypertension (n %)	14 (26.4)
Chronic obstructive pulmonary disease (n %)	13 (24.5)
Diabetes (n %)	4 (7.5)
Peripheral vascular disease (n %)	2 (3.8)
Creatinine > 2 mg/dL (n %)	3 (5.7)
Symptom duration (years)	3.6 ± 5.8
Anginal symptoms (n %)	5 (9.4)
NYHA class	3.1 ± 0.8
Class II (n %)	12 (22.6)
Class III (n %)	22 (41.5)
Class IV (n %)	19 (35.8)
Left ventricular ejection fraction (range)	28.7 ± 5.4 (19–35)
Left ventricular end-diastolic diameter (mm) (n = 43)	63.9 ± 7.9
Peak pressure gradient for predominant stenosis (mm Hg) (n = 39)	73.4 ± 22.6
Mean pressure gradient for predominant stenosis (mm Hg) (n = 39)	44.4 ± 15.8
Aortic valve area for predominant stenosis (cm ²) (n = 39)	0.7 ± 0.2
Predominant aortic valve lesion	
Stenosis (n %)	40 (75.5)
Regurgitation (n %)	13 (24.5)
Atrial fibrillation (n %)	6 (11.3)
Left bundle block (n %)	10 (18.9)
Pacemaker (n %)	4 (7.5)
Emergency (n %)	1 (1.9)
Urgency (n %)	5 (9.4)

who fulfilled the inclusion criteria were retrospectively reviewed and processed in a structured database, with consideration of preoperative clinical data, echocardiographic measurements, and operative and postoperative data.

Preoperative Data

Demographics, comorbidities, and clinical preoperative data are described in Table 1. All patients received both transthoracic echocardiography and cardiac catheterization with selective coronary angiography before the operation.

Preoperative LVEF was assessed in all patients at 13 ± 5 days before the operation. Echocardiographic LVEF assessment was performed by the volumetric method [10] in 20 patients (37.7%) and by visual estimate in 33 (62.3%). In 44 patients (83%), a left ventricular cineangiography was also available for LVEF calculation [10]. Echocardiography has shown a good correlation with contrast ventriculography for LVEF measurements [10]. We used the angiographic data or the volumetric data by echocardiography for the analysis. Mean and peak aortic gradients were measured by Doppler echocardiography. The aortic valve area was calculated with the continuity

equation. The grade of aortic regurgitation was evaluated with color Doppler, using a four-grade, semi-quantitative scale according to the ratio of the width of the regurgitant jet at its origin to the left ventricular outflow tract diameter. Aortic valve lesions were classified as predominant stenosis and predominant regurgitation according to the conclusive judgment of the operating surgeon after summarizing preoperative hemodynamic data and intraoperative findings.

Surgical Procedure

Standard moderate hypothermic (28° to 32°C) cardiopulmonary bypass was used in all patients, with a conventional approach through a median sternotomy. Myocardial protection strategy varied according to surgeon preference. Continuous or intermittent hyperkalemic retrograde blood cardioplegia was administered in most cases (96.2%), whereas in others, cold antegrade St. Thomas II cardioplegia was used. All aortic homografts were harvested from brain dead multiorgan donors or heart transplant recipients, antibiotic sterilized, and cryopreserved at –80°C in liquid nitrogen. Aortic homografts and stentless porcine valves (Freestyle aortic root bioprosthesis; Medtronic Inc, Minneapolis, MN) were implanted with a free-hand technique in the subcoronary position, using single stitches for the proximal (annular) suture and three continuous suture for the distal (subcoronary) rim. Stented biologic valves (Carpentier-Edwards porcine, 2625; Edwards Lifesciences, Irvine, CA) were implanted in a supra-annular position using pledgetted mattress sutures. Mechanical heart valves (Carbomedics, R series, Sulzer-Carbomedics, Inc, Austin, TX; St Jude, standard, A101, St Jude Medical, Inc, St Paul, MN; Sorin, Bicarbon, Sorin-Biomedica Cardio SpA, Saluggia, VC, Italy) were implanted using interrupted simple sutures or pledgetted mattress sutures. In 47 patients (88.7%) the aortic annulus was measured at operation by means of a Hegar dilator. The aortic annulus diameter (Richard Martin Medizin-Technik GmbH, D-78532, Tuttlingen, Deutschland), divided for the patient's body surface area, was defined as an indexed annulus diameter.

Postoperative and Follow-Up Data

Operative death was defined as any death occurring within 30 days after the operation. Follow-up was conducted during a 2-month interval (ending in May 2000) by a visit or telephone interview, including a physical examination and an echocardiogram. Deaths attributed to acute myocardial infarction, congestive heart failure, and arrhythmia were considered as cardiovascular deaths, as were sudden deaths without any other specific cause, and deaths related to the prosthetic valve. Cause of death was established from hospital charts, autopsy reports (when available), or family physician interviews.

At follow-up, LVEF was evaluated by echocardiography with the volumetric method. Late recovery of left ventricular function was assessed comparing preoperative and follow-up values of LVEF. Implanted valve effective orifice area was evaluated by continuity equa-

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