Original articles

Clinical and hemodynamic evaluation of 21 mm and 23 mm Cryolife-O'Brien stentless bioprostheses implanted in the aortic position

Sandro Gelsomino, Romeo Frassani, Lorenzo Porreca, Giorgio Morocutti*, Ugolino Livi

*Department of Cardiothoracic Surgery, *Department of Cardiology, General Hospital "S. Maria della Misericordia", Udine, Italy*

Key words:
Aortic valve replacement; Bioprostheses; Stentless valves.

Background. **The aim of this study was to investigate early and mid-term results after aortic valve replacement with Cryolife-O'Brien stentless bioprosthesis, model 300.**

Methods. **Records of 59 patients who received a 21 or 23 mm (Group A) aortic Cryolife-O'Brien stentless valve were retrospectively reviewed and compared to 54 patients who received a valve ≥ 25 mm (Group B). Group A patients were mainly female (p < 0.001), were older (p = 0.034), had dominant aortic stenosis (p = 0.011), and a smaller (p < 0.001) body surface area. Effective orifice area index was larger (p = 0.041) and left ventricular mass index higher (p = 0.024) in Group B.**

Results. **The actuarial survival at 5.5 years was 94.9 ± 2.3% and 92.5 ± 4.3% in Group A and B respectively (p = NS). The actuarial freedom from all events was 85.1 ± 6.1% and 88.2 ± 5.2% in Group A vs Group B respectively (p = NS). At late echocardiographic studies performed between 4 and 42 months (mean 27.3 ± 6.1 months) postoperatively, peak and mean gradients decreased and effective orifice area index increased over the follow-up period (p = NS between groups). Left ventricular mass index decreased by 25% (p < 0.001) in Group A and by 20% (p < 0.001) in Group B from preoperatively and a further 13% (p = 0.034) and 8.5% (p = 0.004), respectively, from the early to the late study. No significant difference in left ventricular mass regression was noticed between groups (p = NS).**

Conclusions. **The Cryolife-O'Brien porcine stentless bioprosthesis showed satisfactory mid-term results and may represent a good choice for patients with a small aortic annulus selected for a biological valve.**

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Address:

Dr. Sandro Gelsomino

U.O. Cardiotoracica Azienda Ospedaliera "S. Maria della Misericordia" Piazzale S. Maria della Misericordia, 15 33100 Udine
E-mail: sandrogelsomino @virgilio.it

Concern has been raised about significant residual gradients when small aortic prostheses are used, particularly in patients with a large body surface area (BSA), in whom a patient-prosthesis mismatch may often occur[1]. Previous studies have shown that this discrepancy between the effective orifice area (EOA) of an aortic prosthetic valve and patient's BSA, resulting in an abnormally high gradient, had important negative effects on the patient's hemodynamic status[2,3].

In addition, left ventricular hypertrophy that develops in response to chronic disease of the aortic valve has been demonstrated to be an independent cardiac risk factor associated with a higher incidence of cardiovascular clinical events and death[4]. Moreover, incomplete regression of left ventricular hypertrophy after aortic valve replacement has been shown to significantly reduce the 10-year survival[5].

Stentless biological valves have been widely used during the past 10 years with good functional and hemodynamic results and residual transvalvular low gradients[6], even in patients with small aortic roots[7]. Furthermore, early and late regression of the left ventricular mass (LVM) after implantation of stentless valves has been obtained[8].

The aim of the present study was to evaluate the hemodynamic performance and clinical results of small-sized (21 or 23 mm) Cryolife-O'Brien stentless porcine bioprostheses (Cryolife International, Marietta, GA, USA).

Methods

Patient population. Between November 1993 and July 1999, 113 patients underwent aortic valve replacement with a Cryolife-O'Brien stentless bioprosthesis, model 300, at our Institution (Fig. 1). Among them 59 (52.2%) patients received a 21 or 23 mm valve and they represented the first study group (Group A). Fifty-four (47.7%) patients who received a Cryolife-O'Brien aortic valve ≥ 25 mm in the same period were used for comparison (Group B). Clinical data are given in table I. According to previous reports[9] patients with smaller valves were predominantly female ($p < 0.001$), were older ($p = 0.034$), had dominant aortic stenosis ($p = 0.011$), and a smaller BSA ($p < 0.001$). There were no further significant differences in demographic and clinical data between the two groups. Follow-up information was obtained from outpatient clinic appointments or by telephone interviews made between 1 and 68 postoperative months (mean 37.3 months). No patient was lost to follow-up. Patients routinely received warfarin sodium (coumadin) for 3 months after the operation. At a recent follow-up 7 (12.9%) patients in Group A and 11 (19.3%) in Group B continued to receive anticoagulation therapy because of atrial fibrillation. Operative and long-term mortality was collected using the Edmunds[10] guidelines for reporting morbidity and mortality after cardiac valvular operations.

Table I. Preoperative clinical data.

Variable	Group A (n = 59)	Group B (n = 54)	p
Age (years)	75.6 ± 6.1	67.2 ± 6.4	0.034
Elderly (> 70 years)	34 (57.6%)	21 (38.8%)	0.026
Sex			< 0.001
Male	16 (27.1%)	44 (81.5%)	
Female	43 (79.2 %)	10 (18.5%)	
Body surface area (m^2)	1.67 ± 0.12	1.8 ± 0.18	< 0.001
NYHA functional class			NS
II	10 (16.9%)	8 (14.9 %)	
III	40 (67.8%)	35 (64.8%)	
IV	9 (15.2%)	11 (20.3%)	
Congestive heart failure	3 (5%)	3 (5.5%)	NS
Heart rate (b/min)	78 ± 12	72 ± 18	NS
Atrial fibrillation	12 (20.3%)	9 (16.7%)	NS
Diabetes	11 (18.6%)	13 (14.1%)	NS
Aortic valve pathology			0.011
Stenosis	35 (59.3 %)	25 (46.2%)	
Insufficiency	3 (5.1%)	4 (7.5%)	
Mixed lesion	19 (32.2%)	22 (40.7%)	
Previous AVR	2 (3.4%)	3 (5.6%)	
Etiology			NS
Calcific	40 (67.8%)	37 (68.5%)	
Bicuspid	12 (20.3%)	11 (20.4%)	
Rheumatic	2 (3.4%)	2 (3.7%)	
Infective	3 (5.1%)	1 (1.9%)	
Bioprosthesis failure	2 (3.4%)	3 (5.6%)	
Coronary artery disease	18 (30.5%)	17 (31.4%)	NS
Mitral valve disease	10 (16.9%)	8 (14.8%)	NS

AVR = aortic valve replacement.

Echocardiographic studies. Echocardiographic studies were performed using a Hewlett-Packard Sonos 5500 ultrasound system with a 2.5 MHz transducer (Hewlett-Packard, Andover, MA, USA). All patients underwent preoperative, predischarge and late transthoracic echocardiography performed at a mean of 27.3 ± 6.1 months postoperatively (range 4-42 months). Examination included two-dimensional, two-dimensional derived M-mode, continuous and pulsed wave Doppler and color Doppler analyses. Left parasternal, apical and periapical, right parasternal, subcostal, and suprasternal standard views were employed. The presence of aortic regurgitation was quantified using color flow Doppler; ratios of either percent diameter or percent area of the jet to that of the left ventricular outflow tract (LVOT) in the long- or short-axis views were calculated. Aortic regurgitation was defined as trivial (grade I), mild (grade II), moderate (grade III) or severe (grade IV) if the ratio of the jet diameter to LVOT diameter in the long-axis view was < 24%, 24 to < 45%, 45 to < 65%, or ≥ 65%, respectively. Similarly, aortic regurgitation was defined as trivial, mild, moderate or severe if the ratio of the jet area to LVOT area in the short-axis view was < 4%, 4 to < 25%, 25 to < 60%, or ≥ 60%, respectively.

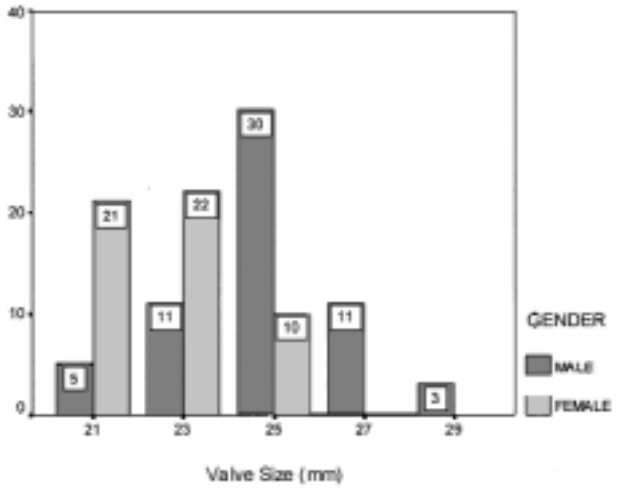

Figure 1. *Patient population. No prosthesis < 21 mm was implanted. Patients receiving a small valve were predominantly female.*

Echocardiographic measurements and calculations. All parameters were calculated by an experienced echocardiographer who was blinded to the size of the prosthesis inserted.

Peak and mean velocities in the LVOT [V_{max}^{LVOT} (m/s) and V_{mean}^{LVOT} (m/s)] were determined proximal to the valve using pulsed wave Doppler. Velocities (peak and mean) across the valve [V_{max}^{AV} (m/s) and V_{mean}^{AV} (m/s)] were calculated using continuous wave Doppler through the aortic valve.

Velocity ratio (VR) was calculated as follows:

$$VR = V_{mean}^{LVOT}/V_{mean}^{AV}$$

All Doppler measurements were averaged from 3 to 10 cardiac cycles in sinus rhythm and in atrial fibrillation, respectively.

Peak and mean pressure gradients (ΔP) were calculated by applying the modified Bernoulli equation:

$$\Delta P_{peak} = 4 (V_{max}^{AV})^2-(V_{max}^{LVOT})^2$$

$$\Delta P_{mean} = 4 (V_{mean}^{AV})^2-(V_{mean}^{LVOT})^2$$

The early-systolic diameter (D) of the LVOT was measured just below the prosthetic valve from the parasternal long-axis view. The LVOT cross-sectional area (CSA) was calculated as:

$$CSA = 3.14 * D^2/4$$

EOA was calculated according to the modified continuity equation:

$$EOA (cm^2) = (CSA) * (VR)$$

The effective orifice area index (EOAI) was calculated as:

$$EOAI (cm^2/m^2) = EOA/BSA$$

This index was used to detect mismatches between valve size and BSA. According to Pibarot et al.[11] an EOAI ≤ 0.85 cm^2/m^2 was considered evidence of a mismatch.

Cardiac output (CO) was calculated using the formula:

$$CO (l/min) = (VTI) * (EOA) * (HR)$$

where VTI is the velocity time integral in the LVOT and HR is the heart rate (b/min).

LVM was calculated with the cube method as follows:

$$LVM (g) = 0.8 *\{1.04 * [(ST + LVIDD + PW)^3 - (LVIDD)^3]\} + 0.6$$

where ST and PW are the ventricular septum (cm) and the posterior wall thickness (cm), respectively and LVIDD is the left ventricular diameter in diastole (cm).

LVM was indexed by BSA:

$$LVMI (g/m^2) = LVM/BSA$$

The study valve. The O'Brien-Angell model 300 valve is a composite design constructed from non-coronary leaflets of three porcine aortic valves (Fig. 2). Leaflets are carefully excised from valves already fixed in a 0.35% glutaraldehyde solution under very low pressure (< 2 mmHg). Leaflets are critically matched for size and symmetry to ensure competence, maximum coaptation and synchronous opening. Initial interrupted and then running sutures are placed along the free edges of the aortic wall, carrying the sutures the full length of the leaflet commissures. A blanket stitch is placed to secure the inflow surface of the valve. The absence of additional synthetic materials represents a significant difference compared to other stentless valves.

Figure 2. *The Cryolife-O'Brien porcine stentless bioprosthesis.*

Operative technique. All the operations were performed according to standard techniques described previously[12]. The selected valve was one size larger than the host annulus measured with a Hegar probe. For instance patients with a measured annulus of 19 and 21 mm, received a 21 and 23 mm prosthesis, respectively.

Operative procedures are listed in table II.

Statistical analysis. SPSS for windows release 8.0 (SPSS, Inc., Chicago, IL, USA) was used to perform data analyses. Continuous variables were expressed as mean ± SD. Discrete variables were presented as percentages. Data of each group were compared using a χ^2 or a Fisher's exact test for categoric variables and paired

Table II. Operative data.

Variable	Group A (n = 59)	Group B (n = 54)	p
Isolated AVR	34 (57.6%)	34 (64.9%)	NS
Associated procedures	27 (45.7%)	25 (46.2%)	NS
CABG	18 (30.5%)	17 (31.4%)	NS
One	9 (15.3%)	8 (14.8%)	
Two	7 (11.8%)	6 (11.1%)	
Three or more	2 (3.4%)	3 (5.5%)	
Mitral valve replacement	6 (10.2%)	5 (9.2%)	NS
Mitral valve repair	1 (1.7%)	2 (3.7%)	NS
Tricuspid annuloplasty	1 (1.7%)	1 (1.9%)	NS
Aortic cross-clamping time (min)	94.59 ± 55.76	92.46 ± 43.78	NS
Cardiopulmonary bypass time (min)	125.90 ± 73.91	122.04 ± 46.87	NS

AVR = aortic valve replacement; CABG = coronary artery bypass graft.

and unpaired Student's t tests to analyze continuous data. The one-way ANOVA analysis of variance was carried out, where appropriate, using either pooled or separate variance assumption, after testing for homogeneity of variance with the Levine test. Multiple group comparisons were performed using the Bonferroni and Tukey *post-hoc* tests. The general linear model multivariate procedure was used for regression analysis and analysis of variance for multiple dependent variables by one or more factor variables or covariates. The power of multivariate analyses was limited by the small number of postoperative events. Correlation between two variables was analyzed using Pearson and Spearman correlation tests. Death and event-free survival estimates were calculated by the product-limit method of Kaplan-Meier and reported with a 95% confidence limit and expressed ± SE; the Mantel-Cox (log-rank) test was used to test the hypothesis that there was no difference in survival between groups. Cox's proportional hazards models were used to examine the predictive value of preoperative and operative variables considered to be associated with outcome; the importance of covariates was evaluated singly and in combination and a stepwise procedure was used when the outcome variable was continuous. In all cases a p value of < 0.05 was considered statistically significant.

Results

Hospital mortality. The 30-day mortality was 3.5% (2/56 patients) in Group A and 1.95% (1/51 patients in Group B). No death was directly valve-related as demonstrated by the *postmortem* examination. Univariate analysis of risk factors identified concomitant coronary artery disease as the sole predictor of early mortality ($p < 0.001$ in both groups). Multivariate analysis identified two significant preoperative variables associated with 30-day mortality. These included a decreased preoperative gradient ($p < 0.001$ in Group A and $p = 0.012$ in Group B) and an associated coronary artery disease ($p < 0.001$ in both groups).

Late mortality. In addition to the 3 patients who died within 30 days, another 3 (1 in Group A and 2 in Group B) died during the follow-up period. The actuarial survival (Fig. 3) at 5.5 years was 94.9 ± 2.3% and 92.5 ± 4.3% ($p = 0.947$), respectively. Only the presence of coronary artery disease reduced the overall survival at univariate ($p < 0.001$ in both groups) and multivariate ($p < 0.001$ in both groups) analyses.

Functional status. At a recent follow-up in the smaller valve group, 41 (75%) patients were in New York Heart Association (NYHA) functional class I and 12 (25%) in NYHA II; in the larger valve group 39 (76.4%) patients were in NYHA I and 12 (23.6%) were in NYHA II. In both groups the functional status improved from preoperatively ($p = 0.010$ in both) and no significant difference was found between them (p = NS).

At multivariate analysis the patient's age ($p < 0.001$ in Group A and $p = 0.024$ in Group B), the preoperative NYHA functional class ($p = 0.001$ in Group A and $p = 0.004$ in Group B), the presence of a significant coronary artery disease ($p < 0.001$ in both groups), a preoperative left ventricular ejection fraction ≤ 35% ($p < 0.001$ in both groups) and a low preoperative gradient ($p < 0.001$ in both groups) were determinants of postoperative NYHA functional status.

Valve-related complications. The 5.5-year actuarial freedom from endocarditis was 95.8 ± 4.1% in Group A and 98.1 ± 1.8% in Group B ($p = 0.783$). Actuarial freedom from thromboembolism in the two study groups was 100% and 97.6 ± 2.2%, respectively (p = NS). In Group A two valves were explanted for prosthesis failure both due to technical mistakes: the first one was implanted in a non-correct intra-annular position and the second was implanted in a patient with a dilation of the ascending aorta which led to an early valve incompetence. Both patients were part of our early experience with this valve that has

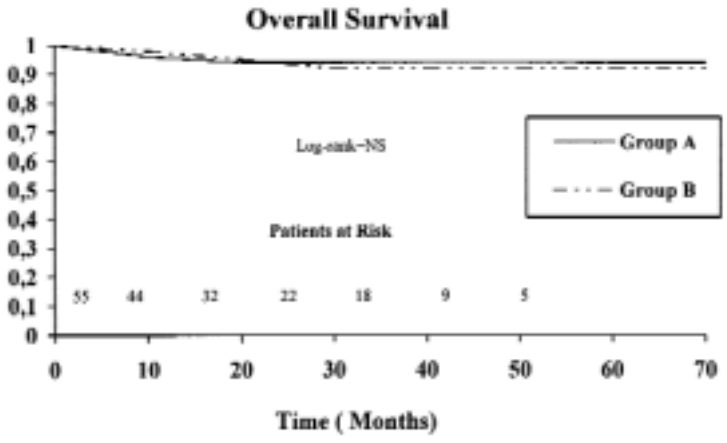

Figure 3. *Actuarial survival in patients receiving a ≤ 23 mm* (continuous line) *or a ≥ 25 mm* (dotted line) *Cryolife-O'Brien porcine stentless bioprosthesis. The Mantel-Cox (log-rank) test demonstrated no difference in 5.5-year survival.*

been recognized as being more demanding and thus necessitating a learning period. In Group B one patient had the prosthesis explanted because of deterioration after 21 months from implantation; cusp retraction and calcification were found at reoperation.

Freedom from failure at 5.5 years was 90.7 ± 2.1 vs 91.6 ± 2.5% (p = NS between groups). The actuarial freedom from all events (Fig. 4) was 85.1 ± 6.1% and 88.2 ± 5.2% in the two groups, respectively (p = NS). Multivariate analysis identified concomitant coronary artery bypass grafting as the sole predictor of late events (p < 0.001 in both groups).

Aortic regurgitation. There was a very low incidence of significant prosthesis regurgitation over the follow-up period; it was absent in 52 patients (88.1%) in Group A and 47 (87%) in Group B, graded trivial in 13 patients, 6 (10.1%) in Group A and 7 (12.9%) in Group B, and mild in 1 (1.6%) Group A patient. No significant statistical difference was noticed between groups (p = NS).

Hemodynamics. Echocardiographic data are shown in table III. In the early postoperative period left ventricular ejection fraction increased by 20 ± 9% in Group A (p < 0.001) and 14 ± 4% in Group B (p = 0.024) with a further but not statistically significant increment of 9 ± 2% and 7 ± 4% respectively. By univariate analysis the improvement of left ventricular ejection fraction was directly related to a higher preoperative gradient (Group A, p = 0.011; Group B, p = 0.029) and adversely affected by the presence of concomitant coronary artery bypass grafting (Group A, p = 0.027; Group B, p = 0.034) and low preoperative gradient (p < 0.001 in both). At multivariate analysis the extent of coronary artery disease was inversely related to the improvement of left ventricular ejection fraction in both groups (p < 0.001). Left ventricular ejection fraction was not significantly influenced by valve size at univariate and multivariate analyses. At early study mean (p < 0.001) and peak (p

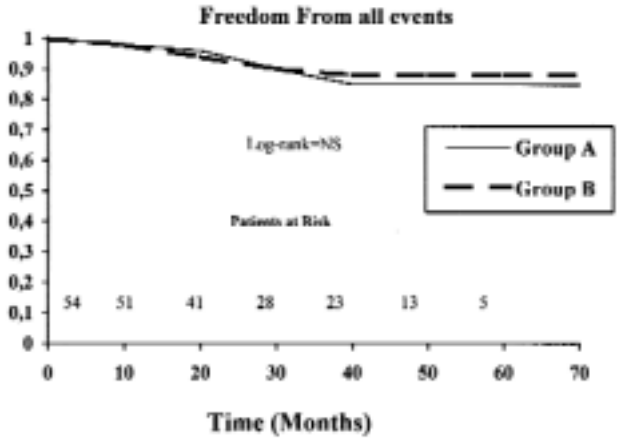

Figure 4. *Freedom from all unfavorable postoperative events in patients receiving a ≤ 23 mm* (continuous line) *or a ≥ 25 mm* (dotted line) *Cryolife-O'Brien porcine stentless bioprosthesis. There was no statistical difference between groups.*

Table III. Echocardiographic data.

	Group A (n = 59)	Group B (n = 54)	p
Peak systolic gradient (mmHg)			
Preoperative	95.2 ± 22.0	90.6 ± 31.2	NS
Early postoperative*	22.0 ± 9.4	20.0 ± 5.2	NS
Late postoperative**	12.0 ± 4.8	11.4 ± 4.1	NS
	p = 0.024§	p = 0.032§	
Mean systolic gradient (mmHg)			
Preoperative	62.2 ± 34.0	60.1 ± 19.2	NS
Early postoperative*	12.0 ± 6.3	10.0 ± 4.1	NS
Late postoperative**	7.3 ± 3.3	7.0 ± 3.1	NS
	p = 0.009§	p = 0.013§	
EOA (cm^2)			
Preoperative	0.4 ± 0.1	0.7 ± 0.2	0.028
Early postoperative*	1.4 ± 0.1	1.6 ± 0.2	NS
Late postoperative**	1.6 ± 0.5	2.1 ± 0.1	NS
	p = 0.046§	p = 0.021§	
EOAI (cm^2/m^2)			
Preoperative	0.2 ± 0.2	0.4 ± 0.2	0.041
Early postoperative*	0.8 ± 0.1	0.9 ± 0.2	NS
Late postoperative**	1.0 ± 0.2	1.1 ± 0.3	NS
	p = 0.042§	p = 0.047§	
LVM (g)			
Preoperative	302 ± 145	85 ± 136	0.045
Early postoperative*	236 ± 130	231 ± 108	NS
Late postoperative**	206 ± 110	202 ± 94	NS
	p < 0.001§	p < 0.001§	
LVMI (g/m^2)			
Preoperative	197 ± 62	175 ± 37	0.024
Early postoperative*	144 ± 18	140 ± 12	NS
Late postoperative**	125 ± 13	128 ± 17	NS
	p = 0.034§	p = 0.004§	
LVEF (%)			
Preoperative	40 ± 12	49 ± 18	NS
Early postoperative*	60 ± 7	63 ± 14	NS
Late postoperative**	69 ± 6	70 ± 11	NS
	p = NS§	p = NS§	
WT (cm)			
Preoperative	1.6 ± 0.4	1.4 ± 1.0	0.041
Early postoperative*	1.4 ± 0.2	1.2 ± 0.1	NS
Late postoperative**	1.1 ± 0.6	1.1 ± 0.1	NS
	p = 0.021§	p = 0.041§	
ST (cm)			
Preoperative	1.3 ± 0.1	1.2 ± 0.3	NS
Early postoperative*	1.1 ± 1.2	1.0 ± 0.1	NS
Late postoperative**	0.9 ± 1.0	1.1 ± 0.1	NS
	p = 0.032§	p = 0.045§	
CO (l/min)			
Preoperative	3.8 ± 1.2	4.0 ± 1.1	NS
Early postoperative*	4.2 ± 1.5	4.4 ± 1.1	NS
Late postoperative**	4.7 ± 1.2	4.9 ± 1.3	NS
	p < 0.001§	p < 0.001§	

Data were presented as mean ± SD. CO = cardiac output; EOA = effective orifice area; EOAI = effective orifice area index; LVEF = left ventricular ejection fraction; LVM = left ventricular mass; LVMI = left ventricular mass index; ST = septum thickness; WT = left ventricular end-diastolic wall thickness. * early echocardiography was performed at discharge; ** patients underwent late echocardiogram at a mean of 27.3 months postoperatively; § significance of difference between early and late echocardiographic studies.

< 0.001) drops significantly decreased from preoperatively in the smaller size group, with a further reduction at late study (mean, p = 0.009 and peak, p = 0.024). Similarly Group B showed a significant reduction in mean (p < 0.001) and peak (p < 0.001) gradients postoperatively as well as at late (mean, p = 0.013 and peak, p = 0.032) control. No difference was demonstrated between groups in reduction of mean drops at early (p = 0.614) and late (p = 0.330) echocardiograms. No significant correlation was found between patient's BSA and mean transvalvular gradients (r = 0.27, r^2 = 14, p = NS for Group A, and r = 0.31, r^2 = 0.22, p = NS for Group B).

Effective orifice area index. EOAI was larger in Group B preoperatively (p = 0.041) and showed a significant increment at early (+0.6 ± 0.1 cm^2/m^2 in Group A, p = 0.004 and +0.5 ± 0.1 cm^2/m^2 in Group B, p = 0.009; p = NS between groups) as well as at late study (+0.2 ± 0.1 cm^2/m^2 in Group A, p = 0.042 and +0.2 ± 0.1 cm^2/m^2 in Group B, p = 0.047; p = NS between groups). Twenty-four patients in Group A and 14 in Group B had an EOAI ≤ 0.85 (p = 0.170) in the early postoperative period. Absolute values of EOA were lower (1.4 ± 1.5 vs 1.8 ± 1.2 cm^2, p = 0.026), and BSA was larger (1.3 ± 0.7 vs 1.8 ± 1.2 m^2, p = 0.013) in patients with evidence of mismatch. At a recent follow-up only 2 asymptomatic patients in Group A still had evidence of mismatch (p = NS between groups).

Left ventricular mass regression. LVM index (p = 0.024) was higher in Group B, decreased by 25% (-53 ± 8 g/m^2, p < 0.001) in Group A and by 20% (-35 ± 6 g/m^2, p < 0.001) in Group B from preoperatively (p = NS between groups) and a further 13% (-19 ± 4 g/m^2, p = 0.034) and 8.5% (-12 ± 6 g/m^2, p = 0.004), respectively (Fig. 5). There was no significant difference in late LVM index regression between groups.

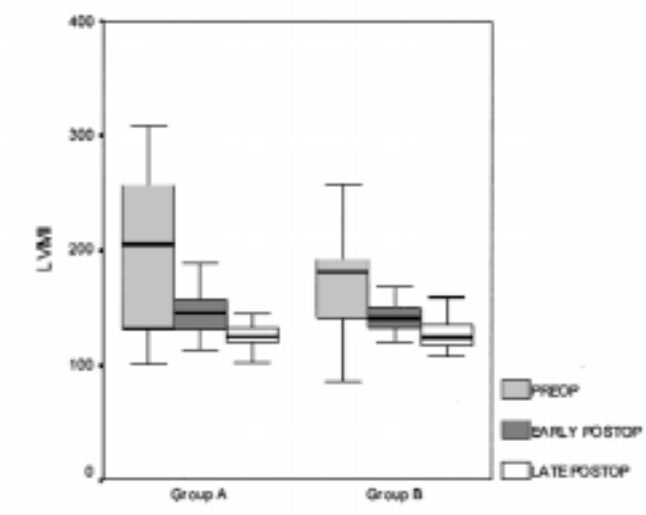

Figure 5. *The regression of left ventricular mass index (LVMI) after aortic valve replacement with a Cryolife-O'Brien stentless valve. LVMI was higher (p = 0.024) in the small-size group preoperatively. It decreased significantly in both groups at early and late studies.*

One-way ANOVA analysis of variance identified male sex (p = 0.03), left ventricular ejection fraction < 35% (p = 0.02), and NYHA functional class ≥ III (p = 0.02) as significant determinants of great LVM index. Prior myocardial infarction, concomitant carotid disease, hypertension, valve size, mean preoperative gradient, valve pathology, EOAI, and valve size were not significant independent determinants of LVM index.

Discussion

Patients with small aortic roots undergoing aortic valve replacement are not an uncommon finding, especially in the elderly, and present a special challenge to the surgeon regarding the operative technique and selection of prosthesis. Although there are appropriate annulus enlarging techniques, they often result in increasing morbidity and mortality thus limiting their applicability[13]. Small-size stented porcine xenografts are preferred to mechanical valves in elderly patients because of the lack of a lifetime anticoagulation therapy and their durability, have been demonstrated to be obstructive and the stent to be a stress-factor on the tissue components[14]. Furthermore stented valves constructed with bovine pericardium showed no significant improvement in small sizes with respect to residual gradients and EOA[15]. Left ventricular hypertrophy due to left ventricular pressure and volume overload in response to aortic valve stenosis and aortic valve insufficiency has been observed to decrease after aortic valve replacement[16]. Its incomplete regression and postoperative interstitial fibrosis[17] are the consequence of high residual transvalvular gradients that also result in impaired left ventricular diastolic function[18]. Stentless porcine xenografts, first used by Binet et al.[19] in the early 1960s, provide more favorable hemodynamics because of the absence of a sewing ring and prosthetic struts; it results in a larger EOA for a specified external diameter[20] and a lower transvalvular pressure gradient[21] than stented valves as confirmed by reports of case-matched studies[22]. In addition patients who received a stentless valve presented a significantly greater early improvement in left ventricular systolic function compared with those who received a stented valve[23]. O'Brien and Clarebrough[24] first reported the use of a composite porcine stentless valve formaldehyde fixed in 1966. This bioprosthesis, fixed in glutaraldehyde, was reintroduced in 1991 and showed excellent results. The advantages of this valve can be resumed as follows: a) its complete supra-annular positioning always allows the choice of a valve one size larger than the measured host annulus independently of factors affecting other stentless valves such as the discrepancy between the labeled size and the true measured internal diameter; b) the lack of any synthetic material that should significantly lessen the risk of

postoperative infections; c) the absence of all ventricular muscle that is completely removed to offer a lower resistance to the flow. Recently Hvass et al.[25] in a multicenter study demonstrated that the Cryolife-O'Brien xenograft provides excellent hemodynamic results in patients with small aortic roots. In our report 59 (52.2%) out of 113 patients who received a 21 or 23 mm (Group A) Cryolife-O'Brien bioprosthesis in the aortic position, were retrospectively reviewed and compared to patients who received a size ≥ 25 mm of the same bioprosthesis (Group B). To avoid the operator-dependent variability of the echocardiographic measurements, all studies were performed by one experienced echocardiographer who was blinded to the size of the prosthesis inserted.

Furthermore in all cases the intraoperative measurement of the patient's annulus, the choice of the correct valve size as well as the prosthesis implantation were performed by the same experienced surgeon and thus excluded any variability due to those factors. Similar to previous reports[9], patients receiving small aortic prostheses were mainly female, older, and had dominant aortic stenosis and a smaller BSA. The number of patients with EOAI ≤ 0.85 cm^2/m^2, evidence of a patient-prosthesis mismatch, was very low and not significantly different between groups in the late postoperative period. The actuarial survival in the smaller size group was comparable to that in the larger size group and no significant difference was noticed in the proportion free from all postoperative events. All hemodynamic parameters (mean and peak gradients, ejection fraction, EOA and EOAI) improved over time without any differences between sizes. Finally both groups had comparable LVM regression early and late postoperatively.

Limitations of the study. Our report presents some limitations: a) the retrospective nature of the study; b) the small number of patients even though the relative percentage of the small size was higher than in other studies; c) the follow-up was too short to provide any definitive information about the long-term durability of the valve that has to be further explored; d) the echocardiographic examinations performed at rest gave no information about the variations in the hemodynamic parameters under stress.

All investigators are still looking for the most accurate method to compare valve size which is difficult among surgeons and among centers. The peculiarity of our study is that all the operations were performed by the same surgeon who in all cases used similar criteria to measure the patient's annulus and to select the valve size. Thus a basis for future comparisons between the stented and stentless valve in our Institution has been established.

In conclusion, the present report confirms that the Cryolife-O'Brien stentless bioprosthesis can be considered a valve of choice in patients with a small aortic annulus providing excellent hemodynamics and regression of left ventricular hypertrophy.

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