A randomized comparison of the Cryolife O'Brien and Toronto stentless replacement aortic valves

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Objective: A composite stentless valve might be less obstructive than a preparation incorporating the porcine right coronary muscle bar. The aim of this study was to compare early hemodynamic function in a prospective series of 78 patients randomized to receive either a Toronto or Cryolife O'Brien stentless valve.

Methods: Echocardiography was performed early after surgery, between 3 and 6 months, and at 1 year after surgery.

Results: The groups were matched demographically. The Cryolife O'Brien valve was significantly less obstructive in terms of effective orifice area (1.81 vs 1.30 cm^2; $P < .0001$), mean pressure difference (7.1 vs 11.7 mm Hg; $P < .0001$), and peak velocity (1.7 vs 2.2 m/s) assessed at 1 year ($P = .001$). Bypass time was 91 (SD 22) minutes for the Cryolife O'Brien compared with 125 (SD 22) minutes ($P < .0001$) for the Toronto. There was a higher incidence of paraprosthetic regurgitation in the Cryolife O'Brien valve (16.7% vs 3.2%). Mortality and clinical events were similar.

Conclusion: The composite valve was less obstructive than the porcine valve, suggesting that stentless valves cannot be considered as a homogeneous class.

All replacement valves are obstructive compared with normal native valves,[1] but the orifice area available for flow is expected to be larger with a stentless than a stented valve. Although this was confirmed in early studies,[2,3] larger randomized studies[4-7] show conflicting results. It is possible that apparent discrepancies are partly caused by differences in the comparator stented valve, as there is some evidence that pericardial valves are hemodynamically superior to porcine valves.[8] However, it is also possible that a stentless valve manufactured from a whole porcine aortic root is more obstructive than a composite stentless valve lacking the muscle bar at the base of the right coronary cusp.

The aim of this study was therefore to compare hemodynamic function in patients prospectively randomized to either the Toronto (St Jude Medical Inc, Minneapolis MN) porcine stentless valve or the Cryolife O'Brien (Cryolife O'Brien International, NW Kennesaw, GA) tricomposite stentless valve.

Materials and Methods

Patients

A total of 80 consecutive patients scheduled to have single bioprosthetic valve replacement in the aortic position were recruited. The population sizes were calculated to detect a difference in mean effective orifice area of 0.2 cm^2 and standard deviation of 0.3 cm^2 with 80% power. A random number sequence with a block of 16 was applied at the time of listing for surgery. However, 2 patients randomized to receive a Toronto required a stented biologic valve because of dilatation of the aortic root. The study group, therefore, comprised 78 patients. The mean age was 73 (range 55-88) years and 39 (50%) were men. Demographic details are given in Table 1. The study was accepted by the Local Committee on Ethical Practice, and all patients gave written consent.

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Abbreviations and Acronyms

ANOVA = analysis of variance
CSA = left ventricular outflow cross-sectional area
ΔP = pressure difference
EOA = effective orifice area
LV = left ventricular
LVDD = left ventricular diastolic diameter
NYHA = New York Heart Association
v_1 = subaortic peak velocity
v_2 = transaortic peak velocity
VTI_1 = subaortic velocity integral
VTI_2 = aortic velocity integral

Surgery

The Toronto valve was chosen as the porcine stentless replacement. It consists of a preparation of porcine aortic root sculpted to accommodate the coronary ostia and lined externally with Dacron. The valves were implanted using a subcoronary technique with interrupted sutures for the lower suture line at the level of the annulus joining the lower midpoints of previous cuspal attachment and passing across the intercommissural triangles. The porcine commissures were suspended independently, and a running polypropylene suture was used for the upper suture line. The Cryolife O'Brien model 300 valve was chosen as the composite stentless valve. It is composed of 3 individual noncoronary porcine cusps and has no Dacron lining. The profile is lower than for the Toronto, and it is sewn using a single continuous suture to the aortic wall just above the annulus.[9]

The native aortic valve was completely excised with aggressive debridement of all calcium to leave a smooth tissue annulus. Both valve types were sized from the sinotubular junction as discussed by David and colleagues[10] using a cylindrical independent sizer. This had been confirmed to correspond to the sizers provided by the 2 manufacturers. The patient tissue annulus was also measured using the independent sizer to exclude oversizing. In most cases, a valve of 1 label size larger than the patient tissue annulus diameter was selected,[11] but in the presence of a large sinotubular junction, a valve of 2 label sizes larger was occasionally used. However, if the sinotubular diameter was more than 2 sizes larger than the patient tissue annulus diameter, a stented valve was implanted instead and the patient was excluded. This occurred on 2 occasions. Aortoplasty or enlargement of the sinotubular junction was not required. Standard operative procedures were used with a median sternotomy, cardiopulmonary bypass, cooling to 32°C, and cold blood cardioplegia for myocardial preservation.

Echocardiography

Studies were performed immediately before discharge, at the first postoperative visit at 6 weeks, then between 3 and 6 months, and again at 1 year. Five patients refused echocardiography at 3 to 6 months and 1 was in hospital elsewhere, and 3 patients refused restudy at 1 year. Measurements were made as recommended by the American Society of Echocardiography[12] over 3 cycles in sinus rhythm or over 6 cycles in atrial fibrillation. Left ventricular (LV) outflow diameter was measured from inner to inner edge just below the replacement aortic valve in a parasternal long-axis view frozen in systole. The largest of 3 measurements was used. Regurgitant jets were localized, then graded by a combination of the jet height and the density, and pressure half-time of the aortic regurgitant signal on continuous wave Doppler. Moderate regurgitation was defined by a jet height between 25% and 65% of the outflow diameter with a pressure half-time longer than 300 ms. Mild regurgitation was defined by a jet height less than 25% of the outflow diameter and a complete, low-intensity continuous waveform with pressure half-time longer than 500 ms. Trivial regurgitation was defined by a thin, low-momentum jet ending close to the valve with an incomplete continuous waveform. No jet in this study was found to be severe.

TABLE 1. Demographic comparison of patients receiving Toronto or Perimount valves (mean ± standard deviation)

	Cryolife O'Brien (n = 40)	Toronto (n = 38)
Age (y), mean (range)	73 (55-86)	73 (57-88)
Male:female	21:18	18:21
BSA (kg/m^2)	1.76 ± 0.20	1.77 ± 0.19
LV outflow diameter (mm)	20.5 (1.7)	19.8 ± 1.4
Etiology		
Aortic stenosis	33	33
Aortic regurgitation	3	4
Mixed AS and AR	3	2
Previous AVR	0	0
Previous CABG	1	0
Associated procedures		
Combined CABG	15	16
Aortic root replacement	0	1
Mitral valve repair	0	1
Preoperative NYHA class		
I	3	4
II	16	11
III	17	20
IV	1	1
Preoperative LVEF < 35%	4	3
Functionally bicuspid valve	5	1

AR, Aortic regurgitation; *AS*, aortic stenosis; *AVR*, aortic valve replacement; *BSA*, body surface area; *CABG*, coronary artery bypass grafting; *LV*, left ventricular; *LVEF*, left ventricular ejection fraction; *NYHA*, New York Heart Association.

Calculations

The following calculations were performed: (1) effective orifice area (EOA) by the continuity equation (EOA in cm^2) = CSA × VTI_1/VTI_2 where CSA is LV outflow cross-sectional area (cm^2) calculated from the diameter assuming circular cross section, VTI_1 is subaortic velocity integral (cm), and VTI_2 is aortic velocity integral (cm); (2) peak pressure difference across the aortic valve (peak ΔP in mm Hg) = 4 ($v_2^2 - v_1^2$) where v_2 is transaortic peak velocity (m/s) and v_1 is subaortic peak velocity (m/s); (3) mean pressure difference across the aortic valve (mean ΔP in mm Hg) = aortic mean ΔP − subaortic mean ΔP; (4) LV mass (g) = 0.83 (left ventricular diastolic diameter [LVDD] + septal thickness + pos-