Short-term hemodynamic advantages of stentless CryoLife-O’Brien valve over stented bioprostheses for aortic valve replacement

Didier Chatel*, Cristina Mica, Didier Blanchard, Francis Baud, Didier Bruere, Arnaud Maudiere, Patrick Peycher

Departments of Cardiovascular Surgery and Cardiovascular Medicine, Clinique Saint Gatien, 8, place de la Cathédrale 37000 Tours, France

Received 1 April 2006; received in revised form 3 June 2006; accepted 4 June 2006

Abstract

For the CryoLife-O’Brien valve (CryoLife Inc, Kennesaw, GA, USA), implanted with a single suture line, we aimed to analyze the surgical requests and the hemodynamic results compared to stented bioprostheses. Two groups of patients requiring isolated aortic valve replacement from this population were compared retrospectively: 84 patients receiving the stentless CryoLife-O’Brien valve (Group A) and 94 patients receiving stented bioprostheses (Group B). Preoperative characteristics of patients were statistically equivalent for both groups. Statistically significant differences were observed only for operative durations and post-operative transprosthetic gradients: Aorta cross-clamp and cardio-pulmonary bypass durations were statistically longer for Group A than for Group B (45.9 ± 5.7 min vs. 41.1 ± 6.8 min; P < 0.0001; and 64.3 ± 11.6 min vs. 59.3 ± 11.9 min, respectively; P = 0.0053); maximal gradients and mean gradients were 19.9 ± 10.9 mmHg vs. 25.6 ± 10.4 mmHg (P = 0.0008) and 10.8 ± 5.3 mmHg vs. 14.8 ± 6.4 mmHg (P < 0.0001). Few surgical constraints and early post-operative hemodynamic efficiency of the stentless CryoLife-O’Brien valve means that this bioprosthesis can be intended in current practice for the aortic valve replacement in elderly patients.

© 2006 Published by European Association for Cardio-Thoracic Surgery. All rights reserved.

Keywords: Aortic valve replacement; Stentless bioprostheses

1. Introduction

Biological bioprostheses were conceived and developed to replace diseased cardiac valves in order to avoid anticoagulation. Their development evolved in cycles: initially heterologous grafts were used without prosthetic support, then such grafts were mounted on a stent with a suture ring to facilitate surgical implantation. Finally, bioprostheses were developed without stents or ring to improve hemodynamic performance, but the surgical implantation technique is more demanding for this kind of prosthesis.

The CryoLife-O’Brien stentless valve was developed to provide the implantation of a stentless bioprosthesis, according to a specific surgical technique, aiming to achieve hemodynamic improvement with possible clinical advantages.

In this study we compared the immediate outcomes of patients with isolated aortic valve stenosis treated by placement of either a CryoLife-O’Brien valve or a stented bioprosthesis.

2. Patients and methods

From September 1999 to September 2004 bioprostheses were implanted in 285 patients with aortic valve stenosis; we only studied patients without coronary artery disease and 178 were included in this study. A CryoLife-O’Brien valve was implanted in 84 patients (Group A) and the other 94 received a stented bioprosthesis (Carpentier–Edwards Perimount (Baxter Healthcare Corp, Edwards Division, Santa Ana, CA, USA); Mitroflow (Sorin Group Inc, Mitroflow Division, Vancouver, Canada); Medtronic Mosaic (Medtronic Inc, Minneapolis, MN, USA)).

Surgery was performed with normothermic cardiopulmonary bypass (CPB). Cardioplegia was maintained with repeated anterograde injections of warm blood cardioplegia solution (GIK-type) every 12 min. CryoLife-O’Brien stentless bioprostheses implantation was supra-annular, with a single line of suture using a Prolene 3/0, according to the previously reported technique [1]. Stented bioprostheses were implanted with interrupted sutures.

All patients were evaluated with early post-operative echocardiography when they were totally ambulatory, so free from any drug and pacing, and able to be discharged (generally before the 8th post-operative day).

The statistical comparison was performed according to a one-way analysis of variance with significance of 0.05.

3. Results

Pre-operative characteristics (age, morphometric data and pre-operative risk factors evaluated by EuroSCORE) (Table 1) were strictly equivalent for both groups, thus avoiding bias in the post-operative analysis of data.
Aorta cross-clamp and CPB durations were statistically longer for Group A than for Group B (45.9 ± 5.7 min (min. 32 min, max. 60 min) vs. 41.1 ± 6.8 min (min. 25, max. 70 min); P < 0.0001; and 64.3 ± 11.6 min vs. 59.3 ± 11.9 min, respectively; P = 0.0053).

The mean size of stentless bioprostheses was statistically larger than that of stented bioprostheses (25.02 mm ± 2.3 mm vs. 23.2 mm ± 1.7 mm, respectively; P < 0.0001). Distribution of bioprostheses according to size is summarized in Fig. 1.

Five patients from Group A and 6 patients from Group B died during the early post-operative period. Death during hospitalization was not statistically different between the two groups (5.9% Group A vs. 6.3% Group B; P = 0.9). Causes of death in Group A comprised cardiac failure (2 patients), multiorgan failure (1 patient), respiratory failure (1 patient) and ventricular fibrillation (1 patient). In Group B they comprised cardiac failure (4 patients), multiorgan failure (1 patient) and hemorrhage (1 patient).

Early echocardiographic evaluation of the bioprostheses showed significantly lower transprosthesis gradients in the stentless bioprostheses than in the stented bioprostheses, the maximal gradients being 19.9 ± 10.9 mmHg and 25.6 ±10.4 mmHg for Groups A and B, respectively (P = 0.0008), and mean gradients being 10.8 ± 5.3 and 14.8 ± 6.4 mmHg for Groups A and B, respectively (P < 0.0001).

### Table 1

| Pre-operative characteristics of patients and models of implanted bioprostheses |
|---------------------------------|----|----------------|
| Age (years)                     | 76.9 ± 4.8 | 77.8 ± 3.5 |
| Gender (male/female)            | 48/36 | 56/38 |
| BSA (m²)                        | 1.82 ± 0.21 | 1.85 ± 0.19 |
| EuroSCORE                       | 6.73 ± 1.25 | 7.11 ± 1.42 |
| Patients with LVEF < 60% (%)    | 23 (27.3%) | 27 (28.7%) |
| Maximal aortic gradient (mmHg)  | 85 ± 21.2 | 79.6 ± 24.8 |
| Mean aortic gradient (mmHg)     | 56.8 ± 13.6 | 55.6 ± 15.8 |
| Effective orifice area (cm²)    | 0.57 ± 0.11 | 0.59 ± 0.10 |
| Prostheses model O’Brien (%)    | 84 (100%) | 0 (0%) |
| Prostheses model Edwards Perimount (%) | 0 (0%) | 33 (35.2%) |
| Prostheses model Medtronic Mosaic (%) | 0 (0%) | 24 (25.5%) |
| Prostheses model Carbomedics Mitroflow (%) | 0 (0%) | 37 (39.3%) |

BSA, Body Surface Area; LVEF, Left Ventricular Ejection Fraction.

### 4. Discussion

The value of stentless bioprostheses reported by surgeons is variable and contradictory. Although the hemodynamic profile of such prostheses has encouraged their use, most surgeons consider that the surgical techniques are more demanding (usually 2 lines of sutures), thus engendering reluctance to use them in general practice.

However, a stentless bioprosthesis with a surgically easier implantation technique such as the CryoLife-O’Brien valve, with only a single suture line, might lead to greater interest in this type of substitute valve, because it provides an improved hemodynamic profile.

The hemodynamic performance of the CryoLife-O’Brien stentless valve has already been demonstrated [1], particularly for small aortic annulus [2,3]. However, this valve has not previously been compared specifically to stented bioprostheses, apart from being included in a group of stentless valves with other stentless valve models (Freestyle, Toronto) [4], although the implantation technique is different from those of the above-mentioned stentless valves. So, for the first time the CryoLife-O’Brien valve was compared exclusively to stented in regard to both technical requirements and quantified hemodynamic advantages. In our study, aorta cross-clamp durations and CPB durations were statistically longer than reported in the literature for the implantation of other stentless valves [5,6]. The extra time required for the implantation of a stentless valve compared to that of a prostheses with a suture ring was 10% for the CryoLife-O’Brien valve and 20–30% for other stentless valves.

No additional deaths or morbidity occurred in our series, despite the longer operating time. This has also been reported in the literature for other stentless bioprostheses [7], whereas the operating time for replacing aortic valves is reported to be a factor predictive of operative mortality [8].

The implantation technique for CryoLife-O’Brien valves is clearly less demanding than for other stentless valves and is not very much more demanding than for prostheses with suture ring. It thus appears possible to implant a stentless valve to improve the hemodynamics of a replacement valve in patients suffering from stenosis of the aortic valve.
without increasing surgical constraints. Although some studies have reported a lack of clinical advantages of stentless valves [6], others have demonstrated hemodynamic and/or clinical advantages in terms of early post-operative death, long-term survival [4,9], reduction in left ventricular hypertrophy [5,10].

In routine practice the prostheses were selected according to their labeled size after measuring the aortic annulus. The CryoLife-O’Brien valves were always up-sized because of their supra-annular position; consequently the sizes of implanted prostheses were larger overall for Group A than for Group B: caliber 21 prostheses were implanted in 6% and 29% of patients in Groups A and B, respectively. This supra-annular position and the low bulkiness of the CryoLife-O’Brien stentless valves can explain their low post-operative gradients [2]. In effect the maximal and mean post-operative gradients observed in Group A in our study were 28% and 37% lower, respectively, than those in Group B. Now, a strong inverse correlation was demonstrated between low post-operative gradients and predictive indices of patient-prosthesis mismatch (PPM) [11]. This functional characteristic means that the CryoLife-O’Brien valve can reduce the risk of PPM. The concept of PPM is disputed: it has been reported that current cardiac valve prostheses (without or without stents) do not generate mismatch [12] and certain authors consider that the mismatch that has been reported has no cardiac anatomical or clinical effects [13,14], in contrast to other studies in which an adverse effect of PPM has been demonstrated in peri-operative and post-operative deaths [15]. Thus, some practitioners consider that stentless bioprostheses are more effective than stented prostheses for patients with disorders of systolic and/or diastolic function. The greater the cardiac damage, the more essential it becomes to implant a prosthesis with the most effective hemodynamics [10].

Although not randomized, our study comparing two similar groups of patients requiring isolated replacement of the aortic valve demonstrated a better hemodynamic profile for CryoLife-O’Brien valves. The small number of patients in the groups was a limitation of the study. The selective comparisons between the CryoLife-O’Brien valve and each type of stented bioprosthesis were not possible. All the patients of this study will be followed-up and will be included in a larger multicenter clinical study in order to evaluate the clinical impact of the hemodynamic advantages of the CryoLife-O’Brien valve.

5. Conclusion

The CryoLife-O’Brien valve is technically easier to implant than other stentless bioprostheses and provides a more efficient hemodynamic result than stented bioprostheses. The relationship between the surgical constraints of implanting this stentless prosthesis and the post-operative hemodynamic efficiency means that this bioprosthesis can be intended in current practice for replacement of the aortic valve in elderly patients. Moreover there is no greater risk associated with the length of the surgery. The indications for the routine use of this bioprosthesis are even more significant because the operative risk is not greater with this prosthesis compared to stented prostheses.

References