Aortic Valve Replacement With the Edwards Prima Plus Stentless Bioprosthesis

Wolfgang F. Konertz, Alexandros Sidiropoulos, and Jianshi Liu

Stentless valves have shown hemodynamic superiority with speedy regression of left ventricular hypertrophy and subsequently changed surgical practice during the recent years. An increasing number of different models from different manufacturers stress the continuing interest in this form of replacement devices for aortic valve disease.

Device

The Edwards Prima Plus Stentless Bioprosthesis (Edwards Lifescience Corp, Irvine, CA) offers a full range of stentless valve technology features, including:

- Extended full porcine root to maximize implant options
- Low-pressure fixation of both the root and leaflets to produce a combination of strength and tissue flexibility while maintaining the natural valve geometry and sinus shape
- A green trimming guideline to indicate safe limits of tissue trimming for subcoronary implantation
- Three marking sutures to aid orientation of the valve during implantation
- Minimum fabric usage to enhance pliability (Figure 1).

A complete accessory system, including a specially designed holder, valve handle, and dedicated sizers, is also available.

Patients

From October 1, 1993 to December 31, 1998, 568 consecutive patients received Edwards Prima stentless aortic valves at our institution. Included in this series are 70 patients in whom the senior author performed implantation at the University of Muenster/Westfalen from 1991 to 1993. The patients ranged in age from 24 to 94 years, with a median age of 67 years (mean 65 ± 11 yrs), and 42% of the patients were female. Underlying pathology was pure aortic stenosis in 37%, aortic regurgitation in 27%, and a mixed lesion in 36%. Native or prosthetic valve endocarditis was the indication for operation in 19 patients, and 21 had undergone previous aortic valve or other cardiac surgery. A total of 352 patients received a subcoronary implantation, 183 received root inclusion cylinder implantation, and 33 received full root replacement. Concomitant cardiac repairs, most often coronary artery bypass grafting, mitral valve repair or replacement, or ascending aorta replacement, was done in 38% of the patients.
The operation is performed under cardiopulmonary bypass with antegrade warm blood cardioplegia. Exposure of the aortic valve can be obtained using a transverse or an oblique (“hockey stick”) aortotomy. We prefer the transverse approach, which makes prosthetic valve commissural alignment easier. After the diseased aortic valve is excised and all annular calcium is completely removed, sizing is performed. We use either the manufacturer’s sizer or graded ball-shaped sizers. The sizing instrument should fit snugly into the annulus. The valve allows for subcoronary or inclusion cylinder implantation as well as for full root replacement, according to the nature of the pathologic process involving the native valve, the aortic root, and the proximal ascending aorta.

SUTURE PLACEMENT AND ORIENTATION

Simple interrupted sutures of either 2-0 multifilament or 4-0 monofilament are placed in a horizontal plane in the native annulus at the level of the lowest commissure. Usually 18 to 22 stitches are needed. The valve is oriented such that the coronary ostia of the bioprosthesis align with or accommodate the coronary ostia of the patient.

Important: Because of the presence of the porcine muscle shelf under the right coronary ostium, special attention must be paid to the location of the patient’s coronary ostium. In patients where the right coronary ostium is close to the aortic annulus, modifications of the implant technique should be considered to avoid inward folding of the cloth-covered muscle shelf into the outflow area. This can be accomplished by rotating the valve so that the woven cloth beneath the right coronary ostium faces the noncoronary sinus (rotated subcoronary) or by using the bioprosthesis as a root replacement. (Courtesy of Edwards Lifesciences SAS.)
3 Trimming for subcoronary implantation. A green trimming guideline is provided externally on the bioprosthesis to indicate safe limits of tissue trimming for subcoronary or modified subcoronary implantation. The trimming guideline is placed a minimum of

- 3 mm above the top of each commissure
- 1.5 mm outside of each commissure side
- 1.5 mm above the sinus leaflet attachment area

Tissue must be trimmed above the green trimming guideline to accommodate the patient’s anatomy and to avoid contact with the leaflet attachment area. The noncoronary sinus may be left untrimmed. (Courtesy of Edwards Lifesciences SAS.)

4 Second suture line. For subcoronary implantation, the stentless bioprosthesis commissures are aligned against the patient’s aortic wall, with care taken to maintain the natural porcine valve geometry. The second suture line is performed with a running suture technique using 4/0 monofilament sutures. Starting at the base of the right sinus, the left sinus or the commissure between the left and the right sinus, the stitches are advanced under the right coronary/left coronary orifices to meet at the noncoronary sinus, where they are tied off. The aortotomy is closed in a usual manner.

Important: Needle puncture of the valve should be avoided. If this should happen inadvertently, the valve should be discarded. (Courtesy of Edwards Lifesciences SAS.)
5 Inclusion cylinder implantation. To trim the bioprosthesis for an inclusion cylinder implantation, the left and right coronary sinususes are excised. The proximal sutures are placed as for subcoronary implantation (see 2). (Courtesy of Edwards Lifesciences SAS.)

6 Completion of inclusion cylinder implantation. For inclusion cylinder implantation, the bioprosthesis commissures are aligned against the patient’s aortic wall, with care taken to maintain the natural porcine valve geometry. The bioprosthesis is secured to the patient’s aortic wall using two 5/0 monofilament sutures.

Conveniently, suturing is started at the lowest point. The rim of the excised coronary sinus of the prosthesis is attached around the patient’s coronary ostia to the aortic wall. The surgeon must make sure that the length of the bioprosthesis and the patient’s aorta are the same length, to avoid excess aortic wall tissue in the longitudinal direction. The aortotomy is closed with a 4-0 monofilament suture including the bioprosthesis and both margins of the patient’s aorta. (Courtesy of Edwards Lifesciences SAS.)
7 Full root replacement technique: Trimming and proximal suture line. Trimming the bioprosthesis is done similar to the root inclusion technique. For the proximal suture line, interrupted sutures of 2/0 multifilament or continuous sutures of 3/0 monofilament are placed beginning at the commissure between the left and right coronary sinuses in a horizontal plane at the level of the native annulus. If the annulus is calcified, then a strip of analogous pericardium may be incorporated into the suture line to aid hemostasis. (Courtesy of Edwards Lifesciences SAS.)

8 Coronary artery reimplantation and closure of the aorta. Beginning with the left coronary artery, the coronary buttons are sewn into the buttonholes that were made into the prosthesis earlier, using continuous 5/0 monofilament suture. Care must be taken to not rotate, kink, or place tension on the coronary arteries. Then an end-to-end anastomosis with 4/0 monofilament suture is done to attach the bioprosthesis to the patient’s ascending aorta. The distal anastomosis often requires gathering or trimming the aorta, because the native aorta is sometimes larger at the distal end, whereas the porcine aorta is the same size at both the distal and proximal ends. The suture line is started at the posterior side of the valve and then advanced forward around each side. (Courtesy of Edwards Lifesciences SAS.)
Results

Patients requiring an isolated aortic valve replacement had a mortality rate of 3.4%. Those patients requiring aortic valve replacement and concomitant cardiac surgery had an early mortality rate of 6.7%. Causes of death included cardiac failure, multiorgan failure, bleeding, sepsis, respiratory failure, and gastrointestinal ischemia. Mortality was related to whether or not concomitant surgery had to be performed. In this series, the implantation technique had no influence on mortality.

Thromboembolic events occurred in one patient as valve thrombosis requiring successful reoperation two years after the initial operation. This was related to a coagulation disorder. Reoperation because of valve degeneration was not necessary in this series.

At discharge, the mean velocity (V mean) measured at the level of the aortic valve for different valve sizes ranged between 1.8 m/s for the size 21 valve and 0.9 m/s for the size 29 valve. Normal range is <1.5 m/s. In valve sizes 21 and 23, slightly elevated velocities were recorded, indicating a mild transvalvular gradient. In valves larger than size 25, normal hemodynamics could be obtained irrespective of the operative technique used. Regurgitation >1° occurred in 18 patients (4.3%), including four patients with stentless valve endocarditis. All four underwent successful reoperation, three of them again with a stentless valve.

Discussion

This series, with more than 550 valve implants, shows that stentless valves can be implanted with low mortality and morbidity in patients requiring aortic valve replacement. We found no difference between subcoronary, root inclusion cylinder, and full root replacement in terms of morbidity, mortality, and hemodynamics at discharge or later. However, it is important to match the technique of valve replacement to the pathology of the patient's aortic valve and root. Currently, in cylindrical aortic roots of diameter 25 mm or greater, we perform a subcoronary implantation. We use the root replacement technique in a narrow and also a very wide annulus, and in patients with aneurysms of the ascending aorta. In patients with moderate anuloectasia and wide but nonaneurysmal enlargement of the aortic root, the inclusion cylinder technique may be helpful.

As with other replacement devices, concomitant surgery increases the risk of surgery. However, mortality with and without concomitant surgery is in the range reported in other series and for other replacement devices. One must take into account that our patients constitute a nonselected cohort, because our general policy is to offer stentless valves to males over age 40 to 45 and females over age 60 to 65. Data from Kirklin showed that the degeneration of bioprosthetic valves is faster in younger women than in men and after menopause is the same level in women than in men.

The versatility of the cylindrical stentless valve also allows implantation in difficult situations as true bicuspid valves with the coronary orifices in the 180-degree position. They also can be used with the same ease as other replacement devices with minimally invasive techniques (Figure 9). Aneurysms of the ascending aorta can be treated effectively with a combination of total root replacement with this tubular device and extension to the aortic arch with a Dacron prosthesis (Figure 10). In this situation, we prefer to use a gelatine-coated Dacron graft.

In our practice, the use of stentless valves has nearly totally eliminated the use of allografts for aortic valve replacement.

9 Minimally invasive aortic valve replacement after J-shaped partial sternotomy.
replacement in adults. Younger adults are treated with mechanical valves or the Ross procedure. In this setting, a cylindrical stentless valve serves well for replacement of the pulmonary valve.\textsuperscript{12}

This series underlines the good hemodynamic results that can be obtained with stentless valves. These advantageous hemodynamic results are maintained over a period of at least six years. This sort of replacement device can be used in every aortic valve or root pathology, including acute native or prosthetic valve endocarditis. The open question of the longevity of these replacement devices will be answered by ongoing studies during the next three to five years.

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REFERENCES


From the Department of Cardiovascular Surgery Charité, Humboldt-University, Berlin, Germany.
Address reprint requests to Wolfgang F. Konertz, MD, PhD, Department of Cardiovascular Surgery, Charité, Schumannstr. 20/21, 10997 Berlin, Germany. Copyright © 2001 by W.B. Saunders Company 1522-2942/01/0602-000353.00/0 doi:10.1053/otct.2001.22701