

Implantation of Aortic Stentless Bioprosthesis: Case Series

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Aim. To present our preliminary results with stentless aortic valve bioprostheses.

Methods. From November 2001 to February 2002, 15 patients (8 men and 7 women) underwent aortic valve replacement with aortic stentless bioprosthesis. The patients' age ranged from 50 to 79 years (mean \pm SD, 63.3 ± 5.7 years). Three patients had aortic stenosis, 3 aortic regurgitation, and 9 combined aortic pathology. Mean \pm SD left ventricle ejection fraction was $53.0 \pm 13.9\%$. Median EuroSCORE was 4 (range, 3-10). Mean \pm SD sinotubular junction diameter measured by transesophageal echo (TEE) was 22.9 ± 1.97 mm preoperatively, and the diameter of implanted prostheses was 25.9 ± 2.4 mm. All valves were implanted using subcoronary technique. In 5 patients, concomitant myocardial revascularization was performed.

Results. Mean \pm SD total bypass time was 126.7 ± 45.9 min (range, 96-180) and cross-clamp time was 88.7 ± 15.6 min (range 69-118). There were no in-hospital deaths or neurological complications. All patients were discharged with only antiaggregation agents in therapy. TEE control was performed 1 week after the surgery. The mean systolic gradient across the prosthesis was 25.6 ± 5.6 mm Hg and maximum 25.9 ± 7.3 mm Hg. No aortic insufficiency was observed in 6 and only minor in 9 patients in postoperative TEE.

Conclusion. Although the implantation of aortic stentless bioprosthesis is technically challenging and time-consuming, early postoperative hemodynamic results are satisfactory.

Key words: aortic valve insufficiency; aortic valve; aortic valve stenosis; bioprosthesis; heart valve prosthesis; heart valve prosthesis implantation; aortic valve replacement, stentless

Since 1991, when St. Jude manufactured the Toronto stentless porcine valve, more than a decade of clinical experience has accumulated (1-3). The main advantages of stentless aortic bioprostheses include excellent early and mid-term hemodynamics, with decrease in transvalvular gradient immediately postoperatively and then gradually over time (4); increase in effective orifice area (5); and reduction of left ventricle mass (6). Fewer valve-related complications and better long-term survival, especially in group of patients between 60 and 69 years of age, was also reported (7). We present our experience with the first 15 consecutive patients undergoing implantation of aortic stentless valve bioprosthesis between November 2001 and February 2002.

Patients and Methods

Patients

From November 2001 until February 2002, all patients eligible for aortic valve replacement with bioprosthesis were subjected to stentless valve implantation. There were 15 patients, 8 men and 7 women (Table 1). The mean \pm SD age of the patients was 63.3 ± 5.7 years. The patients met the following criteria for aortic valve replacement: measured peak pressure gradient ≥ 50 mm Hg, aortic valve area 0.8 cm² or less; measured peak pressure ≥ 75 mm Hg in asymptomatic patients; and pressure gradient

< 50 mm Hg in patients with symptoms and verified significant left ventricular hypertrophy. Aortic valve replacement is necessary in patients with aortic regurgitation who present with symptoms, as they are likely to have enlarged left ventricle. In asymptomatic patients, operation is feasible when left ventricle end-systolic diameter reaches 50 mm (9). Counterindications for

Table 1. Clinical characteristics of 15 patients undergoing implantation of a stentless aortic bioprosthesis

Patients' data	No. of patients
Sex:	
men	8
women	7
Age (years, mean \pm SD, range)	63.3 ± 5.7 (50-79)
Disease:	
arterial hypertension ^a	11
hyperlipidemia ^b	9
diabetes mellitus ^c	5
coronary artery ^d disease	5
atrial fibrillation	2
EuroSCORE ^e (median, range)	4 (3-10)
aortic stenosis (AS)	3
aortic regurgitation (AR)	3
combined AS and AR	9

^aSystolic blood pressure $> 140/90$ mm Hg (8).

^bCholesterol > 5.5 and low-density lipoproteins > 3 mmol/L (8).

^cSerum levels of glucose > 6.7 mmol/L after fasting, measured on several occasions (8).

^dAtherosclerotic obstruction of coronary artery lumen (8).

^eEuropean System for Cardiac Operative Risk Evaluation scoring system (10).

stentless bioprosthesis implantation include disproportion between sinotubular ridge and aortic annulus of more than 10% in diameter, and/or heavily calcified aortic annulus and subannular area, respectively (1). The implant we used in all patients was Toronto Stentless Porcine Valve (St. Jude Medical Ltd, St. Paul, MN, USA). Preoperative risk was calculated according to the European System for Cardiac Operative Risk Evaluation scoring system (EuroSCORE) (10). The follow-up after surgery lasted 30 days. All surgeries were performed by a single surgeon using cardiopulmonary bypass and moderate hypothermia. Cardiac arrest was performed with a single antegrade dose of blood cardioplegia, followed by a continuous retrograde blood cardioplegia. Mean \pm SD cross-clamp time was 88.7 ± 15.6 min (range 69-118), total bypass time 126.7 ± 45.9 min (range 96-180), and total procedure time was 230.5 ± 28.3 min (range 170-310). Subcoronary technique was used for the implantation of Toronto stentless biological aortic prosthesis (1). The mean \pm SD size of valves implanted was 25.9 ± 2.4 mm (range 21-29), with one valve size 21 mm, 2 valves size 23, 3 valves size 25, 6 valves size 27, and 3 valves size 29. Coronary artery disease was diagnosed in 5 patients, so concomitant myocardial revascularization was performed.

Hemodynamic and laboratory data were presented as mean value \pm standard deviation, or mean and range. Student's t-test was used to compare the data and $p < 0.05$ was considered statistically significant.

Results

Echocardiography early after the surgery revealed a slight increase in left ventricle ejection fraction (mean \pm SD, $54.1 \pm 13.9\%$ preoperatively and $64.1 \pm 12.0\%$ postoperatively), but this was not statistically significant (Table 2). Both maximum and mean systolic gradients significantly decreased after the surgery. Maximum gradient decreased by an average of 49.7 mm Hg, and mean systolic gradient by an average of 31.3 mm Hg (Table 2). All patients were discharged from hospital 10 days after surgery. There were no cardiac-related deaths within the first 30 postoperative days. No valve-related or neurologic complications were observed. All patients were discharged with antiaggregation therapy only. There were no specific indications, such as atrial fibrillation, for oral anticoagulation therapy. Postoperative echocardiography performed in all patients showed no aortic regurgitation in 6 and only minimal in 9 patients.

Table 2. Hemodynamic parameters (mean \pm SD, range) in 15 patients undergoing implantation of a stentless porcine valve

Parameter ^a	Preoperative	Postoperative	p ^b
LVEF (%)	54.1 ± 13.9 (25-70)	64.1 ± 12.0 (35-78)	0.157
Maximum systolic gradient (mm Hg)	80.2 ± 29.1 (23-112)	23.1 ± 2.7 (14-34)	0.004
Mean systolic gradient (mm Hg)	67.0 ± 13.1 (20-87)	15.5 ± 4.5 (12-58)	0.024
LVEDd (cm)	6.2 ± 1.0 (4.1-8.8)	4.9 ± 1.2 (2.0-6.6)	0.111

^aLVEF – left ventricle ejection fraction, LVEDd – left ventricle end-diastolic diameter.

^bStudent's t-test.

Discussion

Our initial experience with the implantation of aortic stentless bioprostheses showed good clinical and hemodynamic results, comparable with the results of other large studies (11-13). Immediately after operation, there was a significant decrease in trans-

valvular gradients and left ventricle end diastolic diameter, and increase in left ventricle ejection fraction.

Implantation of stentless aortic bioprostheses has become an attractive option in surgical treatment of aortic valve pathology. Several studies have shown clear hemodynamic advantages of stentless bioprostheses over conventional stented ones, as well as positive effect on patients' well-being and both mid- and long-term survival (11,12). Toronto Stentless Porcine Valve is sized to the sinotubular junction, which is usually larger in patients with aortic valve disease (14). Such sizing provides larger leaflets coaptation, vital for structural durability and functional results of the prosthesis, and allows some expansion of debrided annulus, which is believed to contribute in improvement of hemodynamic parameters of implanted bioprosthesis (2). Case-matched study of David et al (11) showed significantly better actuarial survival (91% vs 69%), 95% vs 81% freedom from cardiac-related death, and 81% vs 50% freedom from any valve-related complication in favor of stentless over stented prostheses at 8 years, respectively. Follow-up at 10 years showed excellent clinical outcome results, with 92% freedom from thromboembolic complications and 85% freedom from primary tissue failure (11). Degenerative changes of stentless prosthesis may develop at the same rate as in stented ones, but they may enhance patients survival rate (3,11) because their superior hemodynamic characteristics allow complete regression of left ventricular hypertrophy and restoration of normal ventricular function. For example, after stentless prosthesis implantation, as many as 83.7% patients were in New York Heart Association functional class I and 14% in class II (13).

Somewhat difficult implantation technique of stentless bioprosthesis is responsible for prolonged total bypass and aortic cross-clamp times. Both values in our group of patients were similar to those reported in larger series. Goldman et al (5) reported mean cross-clamp time of 105 min and total bypass time of 134 min in a series of 621 patients, of whom 42% of had concomitant coronary artery disease, which prolonged cross-clamp (121 vs 91 min) and bypass time (157 vs 115 min). In spite of a rather small number of cases, good clinical and echocardiographic postoperative data imply that this technique can be successfully performed in smaller hospital setting. The surgeon's learning curve can be achieved with no significant raise in valve-related morbidity and mortality by restricting the implantation criteria with respect to patient's illness and surgical complexity (15).

The increase in the left ventricular ejection fraction from 54% to 64% in our group of patients, although not statistically significant, is an encouraging clinical finding, especially in view of the report of Jin et al (16) on significant increase in left ventricular ejection fraction from 58% at two weeks after surgery to 65% at 3-year follow-up. Early postoperative values of peak and mean gradients in our group were somewhat higher than those described in similar studies (11-13). Bach et al (17) reported gradient levels similar to ours at one- and 6-year follow-up for

smaller diameters of stentless prostheses (21 and 23 mm). With further follow-up, we expect gradient values in our group to decrease steadily over time and reach levels reported for large patient series. At present, we can be satisfied with results of valve competence, its adequate sizing and implantation, and clinical outcome in early postoperative period.

Our initial experience with Toronto stentless porcine valve implantation is encouraging, with good hemodynamic parameters immediately after the surgery, no valve-related coagulation or neurologic complications, and good functional performance of our patients. Further follow-up is needed to confirm all known benefits of stentless valve implantation in this group of patients.

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