Surgical Outcome of Stentless Aortic Valve Replacement for Calcified Aortic Stenosis

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We have conducted aortic valve replacement (AVR) using a stentless bioprosthesis (Medtronic Freestyle valve) on 10 patients with calcified aortic stenosis since March 2004. There were 64-84 years of age and 75 ± 5.5 years old on average, and included 4 males. Implantation was conducted by a modified subcoronary method in all the patients. The preoperative New York Heart Association class was class II in 80% of the patients. The preoperative left ventricular mass and the left ventricular mass index (LVMI) were 193.1-524.1 g and 144.1-299.5 g/m^2 and, on average 328.4 ± 104.7 g and 217.3 ± 55.7 g/m^2, respectively. The annulus dimension was 18-24 mm and, on average, 20.3 ± 1.7 mm. The size of implanted valve was 19-25 mm and, on average, 21 ± 2.2 mm. The maximum pressure gradient of the aortic valve remained at 14.2-46.5 mmHg, 25.2 ± 10.2 mmHg on average, 1 or 2 months after surgery, but the LVMI significantly improved to 153.2 ± 33.9 g/m^2 (p = 0.018). The hospitalization period were 24.7 ± 16.9 days for all the patients and 19.3 ± 5.1 days for patients undergoing the AVR alone. These results show that LVMI is significantly reduced by using a stentless bioprosthesis in the early phase after surgery, and early discharge from hospital can be expected by concurrently using minimally invasive cardiac surgery.

Key words: aortic stenosis, stentless aortic bioprosthesis, MICS

INTRODUCTION

Aortic valve replacement (AVR) remains the definitive treatment for critical aortic stenosis. The results of surgery after aortic valve replacement are affected by patient-prosthetic mismatch, particularly with a small aortic annulus [1-3]. The poorer results may be due to residual postoperative gradients after surgery, which may adversely affect the regression of left ventricular mass (LVM) and lead to lower long-term survival [4]. Surgeons have intuitively attempted to insert the largest valve possible for any given annular dimension and can decide to choose a different prosthesis, perform an annular enlarging procedure [2] or alternatively insert the valve in a supra-annular position. Mechanical valves have a proportionally larger effective orifice area for a given annulus size and have been shown to produce lower gradients when compared with similarly sized bioprostheses [6, 7]. However, elderly patients are at increased risk of anticoagulant-related hemorrhage; therefore mechanical valve replacement may be inadvisable. Moreover, an annular enlarging procedure is not common due to a high operative death rate [2]. It has also been reported that there is no difference in the hemodynamic performance between the stented valve and the stentless valve [12] and that, if the internal diameter of the stented valve is consistent with that of the stentless valve, the hemodynamic profile may be almost the same [8]. However, since a large sawing cuff exists in the stented valve, there still remains uncertainty in cases where the use of such valve needs the sawing cuff to be inserted in a supra-annular position. Although placement of the stentless valve requires cumbersome procedures and the aortic cross-clamp time is prolonged, it is suitable for aortic valve replacement because of its excellent hemodynamic performance in patients with a small aortic annulus [4, 8, 9, 11]. We have aggressively conducted aortic valve replacement using stentless valves in elderly patients with calcified aortic stenosis. We report its short-term results.

PATIENTS AND METHODS

We have conducted aortic valve replacement with a stentless aortic bioprosthesis (Medtronic Freestyle; Medtronic, Inc., Minneapolis, MN) in 10 patients with calcified aortic stenosis (AS) since March 2004. The patients included 4 male patients and 6 female patients. The patients were aged 64-84 years and 75 ± 5.5 years old on average.

Minimally invasive cardiac surgery (MICS) was used concurrently in the AVR surgery alone. Ministernotomy was conducted by reverse L-shape incision of the sternum from the second right intercostal space toward the xyphoid process. A right-angled cannula was connected to the superior vena cava and inferior vena cava, and the cardiopulmonary bypass was established. Moderate hypothermia at 32-33˚C was conducted, and intermittent retrograde cold blood cardioplegia was used for myocardial protection. Implantation of a stentless valve was conducted by a modified subcoronary procedure in all the patients [13]. Arch replacement was conducted on the distal arch aortic aneurysm as a concomitant procedure.

The majority of patients (80%) had New York Heart Association (NYHA) class II symptoms preoperatively.

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Table 1 Patient profile.

	Age	Gender		NYHA	Rhythm
1	74	M	AS	II	NSR
2	73	M	AS	II	NSR
3	74	F	AS	III	NSR
4	74	M	AS, TAA	II	NSR
5	72	F	AS	IV	NSR
6	78	F	AS	II	NSR
7	64	F	AS	II	NSR
8	75	F	AS	II	NSR
9	82	F	AS	II	NSR
10	84	M	AS	II	NSR

AS: aortic stenosis; F: female; M: male; NSR: normal sinus rhythm; NYHA: New York Heart Association symptom classification; TAA: thoracic aortic aneurysm.

Table 2 Preoperative echocardiogram data.

	LVEF	FS (%)	LVM	LVMI	PG max (mmHg)	AVA (cm^2)
1	0.63	34.0	524.1	299.5	117.0	0.53
2	0.86	54.9	247.4	152.7	51.9	1.71
3	0.87	56.0	280.8	200.5	62.1	0.85
4	0.67	37.0	389.7	245.1	80.0	0.73
5	0.9	59.3	224.2	167.3	61.0	0.57
6	0.63	35.0	364.0	256.3	94.6	0.58
7	0.84	54.0	409.0	276.4	120.3	0.52
8	0.37	18.0	323.4	214.2	100.0	0.42
9	0.62	32.0	193.1	144.1	66.6	0.5
10					48.2	1.4

All the patients had a normal sinus rhythm (Table 1).

The data of preoperative transthoracic echocardiogram is shown in Table 2 (echocardiogram data are summarized in Table 2). The left ventricular ejection fraction (LVEF) was 0.37-0.9, averaging 0.71 ± 0.17. The LVM was 193.1-524.1 g and 328.4 ± 104.7 g on average. The left ventricular mass index (LVMI) was 144.1-299.5 g/m^2 and 217.3 ± 55.7 g/m^2 on average. The maximum pressure gradient (PG max) was 48.2-120.3 mmHg and 80.1 ± 26.3 mmHg on average. The aortic valve area (AVA) was 0.42-1.71 cm^2 and 0.78 ± 0.43 cm^2 on average.

Left Ventricular Mass

The LVM was calculated by the following equation:

$$LVM = 0.8 \times 1.04\ [(IVS + Dd + PW)^3 - (Dd)^3] + 0.6$$

where IVS is the thickness of the intraventricular septum at end-diastole (cm), Dd is the left ventricular end-diastolic size (cm), and PW is the left ventricular posterior wall thickness at end-diastole (cm).

The LVMI was calculated by the following equation:

$$LVMI = LVM/BSA$$

where *BSA* is the body surface area (m^2)

Maximum pressure gradient

Maximum velocities obtained from pulse wave (PW) and continuous wave (CW) Doppler were converted into pressure gradients using Bernoulli's equation:

$$PG\ max = 4 \times Vmax^2.$$

where PG max is the aortic valve maximum systolic pressure gradient in mmHg, and Vmax = max transvalvular velocity, in meters per second, as measured with CW.

Aortic valve area

AVA was measured by a trace method, or calculated by rewriting the continuity equation, as follws:

$$AVA = LVOTA \times (LVOT\ TVI/AV\ TVI)$$

where AVA is in square centimeters, LVOTA is LVOT cross-sectional area ($\Pi R^2/4$), in square centimeters, obtained from two-dimensional measurement of LVOT diameter; LVOT TVI is time velocity integral of forward blood flow, in centimeters, derived from pulse wave Doppler in the LVOT; and AV TVI is time velocity integral of forward blood flow, in centimeters, derived from transvalvular continuous wave Doppler.

Statistical analysis

Continuous variables were expressed as mean ± 1SD and were analyzed by using Student's *t* test. Categoric variables were analyzed with the χ^2 tests. A *p* value of less than 0.05 was considered significant. All statistical analyses were performed with StatMate III (ATMS, Japan).

Table 3 Valve size and implantation technique.

	Annulus diameter (mm)	Valve size (mm)	Implant technique
1	22	23	m-subcoronary
2	21	23	m-subcoronary
3	20	21	m-subcoronary
4	24	25	m-subcoronary
5	18	19	m-subcoronary
6	19	19	m-subcoronary
7	19	19	m-subcoronary
8	20	19	m-subcoronary
9	19	19	m-subcoronary
10	21	21	m-subcoronary

m-subcoronary: modified sub coronary method.

Table 4 Operative data and duration of hospital stay.

	OPE (min)	ECC (min)	AXC (min)	MICS	Skin incision (cm)	Hospital stay (d)
1	300	198	150	+	11.5	16
2	360	209	160	+	12.0	23
3	275	181	125	+	13.0	30
4	500	277	186	-		68
5	275	164	130	+	14.0	16
6	360	184	158	+	13.0	74
7	248	146	111	+	15.0	19
8	275	168	140	+	11.0	17
9	278	165	126	+	12.0	20
10	330	167	128	+	16.0	14

AXC: aortic cross-clamp time; CPB: cardiopulmonary bypass time; d: days;
MICS: minimally invasive cardiac surgery; OPE: operative time.

RESULTS

One patient died after surgery. The cause of death was respiratory failure due to pneumonia.

The operative time was 248-500 minutes and 320.1 ± 73.8 minutes on average. The cardiopulmonary bypass time was 146-277 minutes and 185.9 ± 36.8 minutes on average. The aortic cross-clamp time was 111-186 minutes and 141.4 ± 22.1 minutes on average. The operative time of AVR surgery alone except for the concurrent surgery of arch replacement was 300.1 ± 40.5 minutes, 175.7 ± 19.2 minutes and 136.4 ± 16.6 minutes, respectively. The length of skin incision in MICS was 11-16 cm and 13.1 ± 1.6 cm on average.

The annulus dimension was 19-24 mm and 20.3 ± 1.7 mm on average. The size of implanted valve was 19-25 mm and 21 ± 2.2 mm on average (Table 3 and 4).

The echocardiogram data obtained immediately before surgery and 1-2 months after surgery were compared. PG max remained at 14.2-6.5 mmHg and 25.2 ± 10.2 mmHg on average, but LVMI was greatly improved, and with a significant decrease from 217.3 ± 64.6 before surgery to 153.2 ± 33.9 ($p = 0.018$) after surgery. This value corresponded to 75.8 ± 15.4% of the preoperative value.

The hospitalization period for the patients other than the patient who died was 14-68 days and 24.7 ± 16.9 days on average. The hospitalization period for patients undergoing AVR alone was 19.3 ± 5.1 days on average. The NYHA class at 1 or 2 months after surgery was class I in all the patients.

DISCUSSION

Homograft [10] and stentless heterografts [5] have been used for human aortic valve replacement since the 1960s when there was no ideal substitute for the human aortic valve. Because of technical difficulties in implantation and the development of commercially available stented porcine valves that are easier to implant, the interest in stentless valves declined and clinical experience with homografts remained limited to a few centers.

In the 1990s, a renewed interest in stentless valves has emerged. The stenotic nature of stented prostheses, significant failure rates particularly in younger patients, and the limited availability of homografts were all key factors that mitigated the development of the current generation of stentless xenografts. The Medtronic Freestyle and Toronto SPV valves have been the most frequently implanted stentless xenografts. Both offer excellent hemodynamic performance, with significant reduction in LVM over time [11].

In Japan, the Medtronic Freestyle valve became available as a stentless bioprosthesis in 1997. Stentless aortic bioprostheses have been widely accepted due

Table 5 Changes in the LVM and LVMI before and after surgery.

	Preoperation		Postoperation		
	LVM	LVMI	LVM	LVMI	PG max
1	524.1	299.5	344.9	197.1	14.2
2	247.4	152.7	147.3	90.9	22.1
3	280.8	200.5	217.2	155.1	24.4
4	389.7	245.1			
5	224.2	167.3	202.9	151.4	26.0
6	364.0	256.3			
7	409.0	276.4	232.7	157.2	46.5
8	323.4	214.2	275.9	182.7	24.4
9	193.1	144.1	185.1	138.1	19.0
10					
		217.3 ± 55.7		153.2 ± 33.9	25.2 ± 10.2

LVM: left ventricular mass; LVMI: left ventricular mass index; PG max: maximum trans-aortic valvular pressure gradient.
Case 4: 10 patients were excluded from the study because of inability to obtain accurate M-mode echocardiographic images.

to their excellent hemodynamics such as large effective orifice area and low transvalvular gradient [4, 8, 9, 11]. However, some heterogeneity is observed in transvalvular Doppler gradients, and some patients have been found to have transvalvular gradients that are higher than anticipated, even in the early postoperative setting. Bach et al. reported that transvalvular gradients of the peak velocity $>$ 3.0 m/s remained in 6.7% (44/658) of the patients undergoing aortic valve replacement with the Freestyle bioprosthesis, which was observed particularly frequently in female patients of the valve size $\leqq$ 23 mm, who underwent a modified subcoronary implantation technique [14]. In recent times, moreover, it has been occasionally reported that there are no excellent hemodynamics with stentless bioprosthesis [12, 15], and thus the superiority of stentless bioprostheses started to wane. Since the manufacturers' labeled size of prosthetic valves is not uniform, it may be possible that incorrect comparisons or conclusions are made among various valves. If it were possible to compare the internal diameter among all valves, different results from the past ones might have been obtained [16]. However, it is a fact that, since the stentless valve is flexible and is easily applied to hard annuli of elderly patients, the ability of a stentless valve to allow dynamic expansion of the aortic root may be the mechanism resulting in increased effective orifice area [9]. The stentless bioprosthesis is still the valve of first choice for valve replacement in elderly patients with small aortic annuli for us.

CONCLUSIONS

Valve replacement using a stentless bioprosthesis was conducted on 10 elderly patients with calcified aortic stenosis. LVMI early after surgery showed significant improvement. It is anticipated that the hospitalization period may be shortened by using MICS.

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