Fifteen years of experience with ATS mechanical heart valve prostheses

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Background: ATS Medical, Inc, developed a mechanical heart valve that has been in use since 1992. In this article, we present the results of 15 years of follow-up of patients who have undergone ATS heart valve replacement at our hospital.

Methods and Results: We performed ATS heart valve replacements on 231 patients between September 1993 and March 2008. Our operative mortality rate for the study period was 2.2%. The survival for postoperative thromboembolic events was 0.29%/pt-y for aortic valve replacement, 0.48%/pt-y for mitral, 0.80%/pt-y for double valve replacement, and overall 0.44%/pt-y. The survival after bleeding events was 0.29%/pt-y for aortic valve replacement, 0.16%/pt-y for mitral, 0%/pt-y for double valve replacement, and overall 0.19%/pt-y. Patient–prosthesis mismatch, as determined by echocardiography, was found in 83.3% of patients at 19 mm, but other sizes showed good valve function. Prosthetic valve noise was undetectable in 92.8% of patients, and quality of life was excellent.

Conclusions: Few prosthetic valve–related complications were seen with ATS heart valve replacements in this study, and the follow-up results were favorable. The international normalized ratio was maintained in the range 1.6 to 2.0 in patients with aortic valve replacement in sinus rhythm. Not only bleeding events, seen at a rate of 0.19%/pt-y, but also thromboembolic events, at 0.44%/pt-y, were low when compared with conventional mechanical valves. Prosthetic valve noise is low, and this appears to be an excellent mechanical valve from the quality of life standpoint. The ATS valve has an excellent safety profile when compared with other mechanical valves. (J Thorac Cardiovasc Surg 2010;139:1494-500)

The ATS valve (ATS Medical, Inc, Minneapolis, Minn) has an expanded valve orifice area, inasmuch as the entire orifice is made of pyrolytic carbon material, with increased durability. It has a superior safety profile, in terms of antithrombotic and hemolytic effects, in comparison with conventional prosthetic valves. It was developed as a bileaflet valve and is used around the world.[1,2] The first bileaflet valve to be developed was the St Jude Medical (SJM) valve, which was released in 1977 (St Jude Medical Inc, St Paul, Minn). It has excellent hemodynamics with central flow, and good follow-up results made it the highest-rated mechanical valve in the world.[3-5] At our hospital, we have used the SJM valve since 1978, when it was implanted in the first Japanese patient, and we have achieved reliable results.[6,7] Over an observation period of more than 10 years, thromboembolic events have been reported to occur at a rate of 0.20% to 3.5%/pt-y, valve thrombosis at 0.06% to 0.18%/pt-y, and bleeding events at 0.45% to 3.5%/pt-y, but the results vary among institutions.[4-9]

The ATS mechanical heart valve was first used in valve replacement surgery in May 1992, and its first use in Japan was at our hospital in September 1993. It was licensed by the Ministry of Health, Labour and Welfare in July 1996 and came into general use thereafter. There have been several case reports concerning this valve, confirming its usefulness, but few reports on follow-up results. In this article, we present the results of 15 years' follow-up with the ATS valve at our hospital.

PATIENTS AND METHODS

Patient Population

Between September 1993 and March 2008, 238 patients underwent valve replacement with the ATS valve at the Nihon University Itabashi Hospital, and we were able to follow up 231 of these patients, excluding those who underwent tricuspid valve replacements. At our hospital, the valve of choice was the SJM valve from 1978 and the ATS valve from 1993. Since 2006, both valves have been used in tandem. Mechanical valves are generally used only for patients less than 70 years of age at our hospital. However, when a patient is more than 70 years old and a 19-mm bioprosthetic valve cannot be implanted, a mechanical valve is selected when it is judged that the patient should have an 18-mm or smaller valve for better quality of life (QOL) in consideration of his/her general preoperative condition, rather than undergoing aortic root enlargement to allow implantation of a bioprosthetic valve. This study was approved by the Ethics Committee of Nihon University Itbashi Hospital and was registered with the University Hospital Medical Information Network (Study No. ID: 000001636). Final examinations were conducted in February 2009. The age of the patients ranged from 14 to 83 years (mean 57.3 ± 11.6 years), including 19 (8.3%) patients who

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Abbreviations and Acronyms

AP = advanced performance
AVR = aortic valve replacement
DVR = double valve replacement (AVR+MVR)
LDH = lactic acid dehydrogenase
MVR = mitral valve replacement
PPM = prosthesis–patient mismatch
PVL = paravalvular leakage
QOL = quality of life
SJM = St Jude Medical

were aged 70 years or greater. There were 143 men and 88 women. The procedure was an isolated aortic valve replacement (AVR) in 103 patients, isolated mitral valve replacement (MVR) in 92, and AVR+MVR (DVR) in 36. Other procedures performed simultaneously included the maze operation in 20 patients, coronary artery bypass in 25, tricuspid valvuloplasty in 14, replacement of the ascending aorta in 4, and left ventricular aneurysmectomy, atrial septal defect patch closure, and ventricular septal defect closure in 1 each. Twenty procedures were reoperations (Table 1). The sizes of the valve used and body surface areas are shown in Table 2.

Operative Technique

Procedures were performed with patients on cardiopulmonary bypass with moderate hypothermia using cold crystalloid cardioplegic solution (St Thomas' Hospital solution). All valve replacements were performed with simple interrupted stitches with 2-0 Ethibond sutures (Ethicon, Inc, Somerville, NJ). The valve was positioned perpendicular in axis to the septum in AVR procedures and placed in an antianatomic position in MVR procedures.

Transthoracic Echocardiography

Postoperative valve function was evaluated on the basis of stability at 6 to 12 months postoperatively, using transthoracic echocardiography. Specialists in echocardiography performed all examinations. For MVR procedures, the continuous Doppler wave method was used to measure peak velocity and mean velocity in the left ventricular inflow region. The peak and mean pressure gradients were calculated by the simplified Bernoulli formula. For AVR procedures, the continuous Doppler wave method was used to measure peak velocity and mean velocity in the aortic valve distal region, from which the peak and mean pressure gradients were calculated. The effective orifice area of the artificial valve was calculated from the pressure half-time for the mitral valve and from the modified continuity equation for the aortic valve. The effective orifice area was divided by the body surface area, and the effective orifice area index was calculated. For the aortic valve, the effective orifice area index showed moderate prosthesis–patient mismatch (PPM) at 0.66 to 0.85 and severe PPM at less than 0.65. Measured values were all the average over 10 consecutive heartbeats.

Hemolysis

Serum lactic acid dehydrogenase (LDH) and haptoglobin levels were measured at 6 months postoperatively as indices of postoperative hemolysis. Deaths, including operative deaths within 6 months postoperatively, and patients with paravalvular leakage (PVL) confirmed by echocardiography, and patients with previous surgery were excluded. None of the patients had undergone blood transfusion within 1 month and none of them had diseases that could increase LDH (such as gallstones) at 6 months after surgery.

Evaluation of Prosthetic Valve Noise

Patients were interviewed regarding prosthetic valve noise at 6 months postoperatively. Early deaths and deaf patients were excluded. The following questions were asked: (1) Do you hear a prosthetic valve sound (audible)? For patients who do hear something, (2) do you sometimes hear it (sometimes disturbance)? (3) Does it disturb your daily life (daytime disturbance)? (4) Does it disturb your sleep (sleep disturbance)? (5) If there was a prosthetic valve with no noise, would you want to exchange it for your present valve (prefers less noisy valve)? For part 4, the noise index is an indicator of patient stress caused by prosthetic valve noise that we proposed in an earlier paper.[10] The level of stress is expressed numerically, with maximum stress assigned 10 points and 0 points when no stress at all is felt.

TABLE 1. Preoperative data

	AVR	MVR	DVR
No.	103	92	36
Age (y)	57.7 ± 13.7	56.7 ± 10.6	57.9 ± 7.0
Gender (male/female)	78:25	43:49	22:14
Diagnosis			
Aortic			
Stenosis	21	—	7
Regurgitation	60	—	13
Combined	20	—	16
Prosthetic valve dysfunction	2	—	0
Mitral			
Stenosis	—	20	10
Regurgitation	—	51	13
Combined	—	16	13
Prosthetic valve dysfunction	—	5	0
Reoperation	5	13	2
NHYA class			
I	1	0	0
II	23	36	3
III	51	52	20
IV	18	14	13

AVR, Isolated aortic valve replacement; *MVR,* isolated mitral valve replacement; *DVR,* double valve replacement; *NHYA,* New York Heart Association.

TABLE 2. Prosthetic valve size and body surface area

	Patient numbers	BSA (m^2)
AVR		
16 mm AP	1	1.35
18 mm AP	15	1.43 ± 0.08
19 mm	6	1.48 ± 0.19
20 mm AP	10	1.46 ± 0.15
21 mm	25	1.54 ± 0.17
22 mm AP	0	—
23 mm	45	1.67 ± 0.17
24 mm AP	4	1.77 ± 0.30
25 mm	17	1.74 ± 0.12
27 mm	16	1.75 ± 0.13
MVR		
23 mm	1	1.50
25 mm	11	1.45 ± 0.20
27 mm	58	1.53 ± 0.15
29 mm	46	1.62 ± 0.20
31 mm	12	1.65 ± 0.27

AVR, Aortic valve replacement; *AP,* advanced performance; *BSA,* body surface area; *MVR,* mitral valve replacement.

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