Original Article

The ATS bileaflet prosthetic heart valve: mid-term results from a single center

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Abstract

Background

Clinical results of ATS prosthetic heart valve use in Japan have not been fully investigated. We analyzed the mid-term results of its use in a single center.

Methods

Among 88 patients, mean age 61.1 ± 9.9 years, 32 had aortic valve replacement（AVR）, 42 mitral valve replacement（MVR）, and 14 both aortic and mitral valve replacement（DVR）. Mean follow-up was 2.5 ± 1.5 years with a cumulative follow-up of 224.2 patient-years.

Results

There were 3 early deaths（3.4%: all in the MVR group）and 7 late deaths（1.8 ± 1.7 %/patient-year: 3 valve related and 4 valve unrelated）. Survival at 5 years was 96.8 ± 17.8 % in the AVR group, 82.2 ± 37.7 % in the MVR group, and 85.7 ± 33.9 % in the DVR group. The linearized incidences of embolism（3）, bleeding events（2）, prosthetic valve endocarditis（3）, hemolysis（1）and re-operation（1）in all patients were 1.3 ± 1.5 %, 1.9 ± 1.9 %, 0.2 ± 0.6 %, 2.1 ± 1.8 % and 0.1 ± 0.6 %/patient-year, respectively. No other complications were observed.

Conclusion

The ATS prosthetic heart valve showed excellent mid-term clinical results, with a low incidence of valve-related complications.

（Key words; ATS prosthetic valve, valve replacement, mid-term results）

Introduction

In recent years, both mechanical and bioprosthetic heart valves have become more durable and less thrombogenic, showing excellent clinical outcomes and possessing hemodynamic features. However, lifelong anticoagulant therapy is inevitable for patients with mechanical prosthetic valves, while those with bioprosthetic valves have a higher risk of structural valve dysfunction than those with mechanical ones. In mechanical valves, bileaflet prosthetic heart valves rather than tilting disc valves are usually preferred,

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with surgeons choosing a replacement valve according to their preference, but with patients' informed consent. Many studies of long-term clinical results have shown excellent clinical performances for mechanical prostheses.

The ATS valve (ATS Medical, Inc., Minneapolis, USA) was introduced for clinical application at our institute in 2000. This study aimed to evaluate the clinical performance of the ATS valve implanted at a single center in Japan.

Methods

Between December 2000 and March 2006, 88 patients, 50 men and 38 women, mean age 61.1 ± 9.9 years, had 102 ATS valves implanted at the Jichi Medical University Hospital. Thirty-two patients had aortic valve replacement (AVR), 42 mitral valve replacement (MVR), and 14 both aortic and mitral valve replacement (DVR). Age distribution of each replacement group is shown in Table 1. Atrial fibrillation was preoperatively observed in 4, 34, and 10 patients in AVR, MVR, and DVR, respectively. Clinical data was evaluated on the basis of mortality and morbidity up to the end of March 2007.

Age	AVR	MVR	DVR	Totals
30~39	2	1	0	3
40~49	5	1	1	7
50~59	10	8	4	22
60~69	9	23	6	38
70~79	6	9	3	18
Totals	32	42	14	88

Table 1. Age distribution of all patients
AVR; aortic valve replacement, MVR; mitral valve replacement,
DVR; aortic and mitral valve replacement

During surgery, the myocardium was protected by moderate hypothemia, with blood cardioplegia without topical cooling being used. For MVR, the posterior mitral valve apparatus was preserved, and an anti-anatomical position chosen for implantation. In the aortic position, 21 and 23 mm valves were mainly implanted. In the mitral position, 25, 27, and 29 mm valves were mainly implanted (Table 2). Concomitant cardiac surgery procedures included tricuspid annulus repair in 23 patients, maze procedure in 15, aortic root replacement in 12, coronary artery bypass grafting in 9, and thoracic aortic aneurysm graft replacement in 5 (Table 3). Four patients with MVR had previously undergone valve surgery. Postoperative pathological examination revealed rheumatic valve disease with myxomatous degeneration as the most common valve malady followed by myxomatous degeneration, insufficiency of an aortic valve with an aortic aneurysm or dissection, and congenital malformation of the aortic valve (Table 4). For anticoagulant management, heparin sodium injection was added at 200 U/kg per day during the early postoperative period, and was then followed by administration of oral warfarin potassium and dipyridamole. The INR (international normalization ratio) was controlled to maintain values between 1.8 and 3.3 for all patients

Valve size (mm)	Aortic	Mitral
21	18	
23	28	
25		2
27		31
29		23
Totals	46	56

Table 2. Valve size for implant position

Operative Procedure	No. of Patients
Tricuspid annulus repair	23
Tricuspid valve replacement	2
Coronary artery bypass grafting	9
Maze procedure	15
Aortic root replacement	12
Thoracic aortic aneurysm graft replacement	5
Dor operation	1
VSD closure	1
ASD closure	1
F-F bypass grafting	1

Table 3. Concomitant procedures

[1].

Morbidity analysis included all cardiovascular complications as defined in Edmunds et al., Guidelines for Reporting Morbidity and Mortality after Cardiac Valve Operations [2]. Mortality data and the incidence of adverse clinical events were analyzed by the Kaplan-Meier actuarial method. The probability of freedom from the first occurrence of each complication was presented graphically according to the follow-up time. Each adverse event（death, embolism, thrombosis, bleeding events, endocarditis, non structural valve dysfunction, and re-operation）was summarized by linearized rates, calculated as the number of occurred events divided by the total number of patient-years（cumulative follow-up）. Upper confidence limits（95%）were provided for each linearized rate according to the method reported by Grunkemeier and Anderson [3]. All analyses were performed for the whole data sample and were stratified by implant site（aortic, mitral, and both aortic and mitral）. For continuous variables, descriptive statistics（mean, standard deviation, range）were provided.

At the end of March 2007, 88 patients had participated in the follow-up study through an office inter-

	Aortic	Mitral
Mixomatous degeneration	10	11
Calcified stenosis	5	0
Congenital malformation/ Marfan	11	0
Rheumatic disease	5	35
Aortic Aneurysm/ Dissection	14	0
Ischemic/ functional	0	5
Infective endocarditis	1	4
Prosthetic tissue failure	0	1
Totals	46	56

Table 4. Etiology for implant site

Definition	Overall	AVR	MVR	DVR
Embolism	1.3 [-0.2, 2.9]	1.29 [-0.2, 2.8]	0.05 [-0.2, 0.3]	0
Thrombosis	0	0	0	0
Bleeding	1.9 [0.1, 3.7]	1.5 [-0.1, 3.0]	0.4 [-0.4, 1.3]	0
Endocarditis	0.2 [-0.4, 0.8]	0.05 [-0.2, 0.3]	0	0.16 [-0.4, 0.7]
Valve related death	0.4 [-0.4, 1.3]	0	0.07 [-0.4, 0.3]	0.36 [-0.4, 1.1]

Table 5. Linearized rates and the 95% confidence interval of valve related complications
*Percentage per patient-year [range]

view, personal phone call, or mail interview. All patients were followed-up（100% follow-up）with a mean follow-up of 2.5 ± 1.5 years overall.

Results

1. Freedom from mortality and morbidity

a）Survival and clinical functional class

There were 3 early deaths（3.4%: all in the MVR group）and7late deaths（1.8 ± 1.7 %/patient-year: 3 valve related and 4 valve unrelated）. Survival at5years was 96.8 ± 17.8 % in the AVR group, 82.2 ± 37.7%

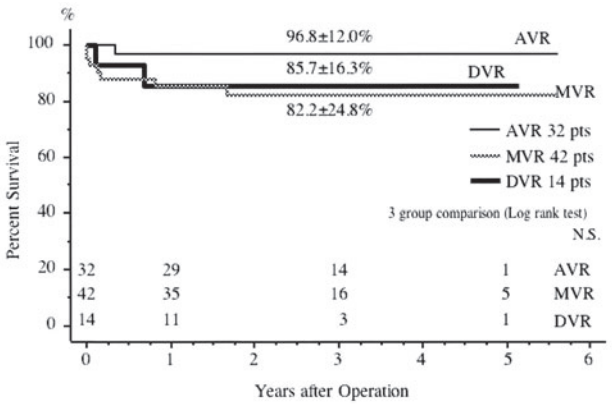

Figure 1, Probability of Survival
AVR; aortic valve replacement, MVR; mitral valve replacement,
DVR; aortic and mitral valve replacement

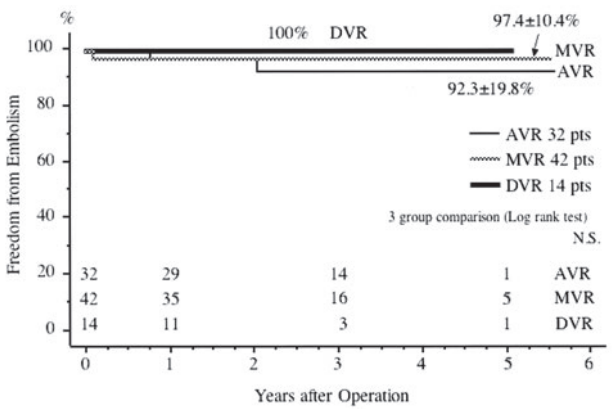

Figure 2, Freedom from Embolism
AVR; aortic valve replacement, MVR; mitral valve replacement,
DVR; aortic and mitral valve replacement

in the MVR group, and 85.7 ± 33.9 % in the DVR group（Fig.1）. Preoperatively, 96% of the patients were in the New York Heart Association（NYHA）functional classes II, III or IV. At follow up, 81% were in class I.

b）Embolic events

Two patients in the AVR group and1in the MVR suffered strokes. Freedom from embolic episodes at 5 years was 92.3 ± 19.8 % in the AVR group, 97.4 ± 10.4 % in the MVR, and 100% in the DVR（Fig.2）.

c）Thrombosis

No thrombotic episodes occurred in this study.

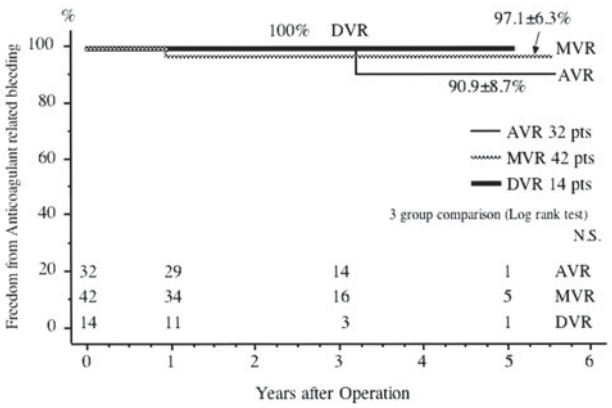

Figure 3, Freedom from Anticoagulant related bleeding
AVR; aortic valve replacement, MVR; mitral valve replacement,
DVR; aortic and mitral valve replacement

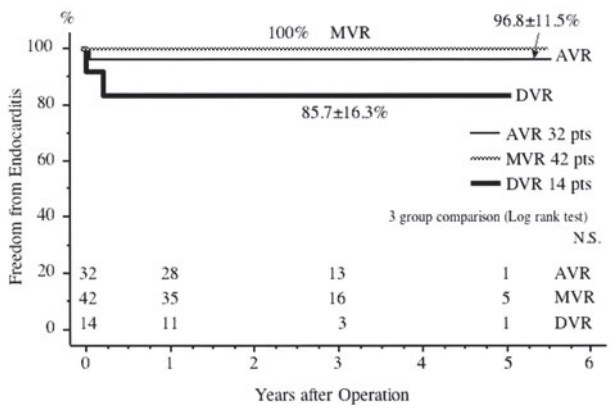

Figure 4, Freedom from Endocarditis
AVR; aortic valve replacement, MVR; mitral valve replacement,
DVR; aortic and mitral valve replacement

d）Anticoagulant related bleeding

There were two bleeding episodes; 1 gastric hemorrhage in the AVR group, and 1 cerebral hemorrhage in the MVR. Freedom from anticoagulant related bleeding at 5 years was 90.9±8.7 % in the AVR group, 97.1±6.3 % in the MVR, and 100% in the DVR（Fig.3）.

e）Endocarditis

Fatal endocarditis occurred in 2 patients in the DVR group and 1 required re-operation for endocarditis in the AVR. Freedom from endocarditis at5years was 96.8±11.5 % in the AVR group, 100 % in the MVR, and 85.7±16.3 % in the DVR（Fig.4）.

f）Non-structural prosthetic valve dysfunction

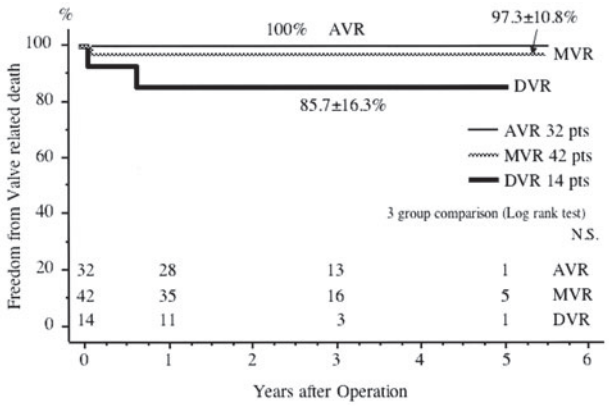

Figure 5, Freedom from Valve related death
AVR; aortic valve replacement, MVR; mitral valve replacement,
DVR; aortic and mitral valve replacement

One late transitional hemolysis, which healed in 2 months, occurred in the MVR group.

g）Re-operation

One patient in the AVR group required re-operation for prosthetic valve endocarditis.

h）Valve related death

Three（2 in the DVR group, 1 in the MVR）valve related deaths occurred. Freedom from valve related death at 5 years was 100 % in the AVR group, 97.3 ± 10.8 % in the MVR, and 85.7 ± 16.3 % in the DVR（Fig.5）.

2. Linearized rates［95% confidence interval］of events（Table 2）

Overall linearized and 95% confidence rates for each event were 1.3［-0.2, 2.9］%/patient-year for embolic events, 1.9［0.1, 3.7］%/patient-year for bleeding, 0.2［-0.4, 1.3］%/patient-year for prosthetic valve endocarditis, and 0.4［-0.4, 1.3］%/patient-year for valve related deaths. The linearized and 95% confidence rates of the AVR group were 1.29［-0.2, 2.8］%/patient-year for embolic events, 1.5［-0.1, 3.0］%/patient-year for bleeding and 0.05［-0.2, 0.3］%/patient-year for endocarditis. The linearized and 95% confidence rates of the MVR group were 0.05［-0.2, 0.3］%/patient-year for embolic events, 0.4［-0.4, 1.3］%/patient-year for bleeding and 0.07［-0.4, 0.3］%/patient-year for valve related deaths. Those of the DVR group were 0.16［-0.4, 0.7］%/patient-year for endocarditis and 0.36［-0.4, 1.1］%/patient-year for valve related deaths.

Discussion

The mechanical heart valves currently manufactured are durable and so structural valve dysfunction is rarely observed. However, non-structural mechanical valve dysfunction and thrombo-embolic events or hemorrhagic episodes still lead to complications after valve surgery. Some patients need re-operation because of prosthetic valve dysfunction caused by prosthetic valve function being restricted with throm-

bosis or pannus formation, and peri-prosthetic valvular leaks with or without infective endocarditis [4, 5]. Therefore, lowering thrombo-embolic episodes after implantation is critical for success after a mechanical valve is implanted.

The ATS valve is a pylolytic carbon, open-pivot, low-profile cardiac valve prosthesis. Its two leaflets are constructed to rotate on spheres projecting into the orifice. The hinge mechanism has no cavities in the valve housing that might cause stasis or turbulence of blood flow. The mechanism is completely washed out by blood moving through the valve orifice. Excellent early and midterm clinical results have been reported for the ATS valve. A multi-center study on the ATS valve with a mean follow-up of 1.8 ± 1.3 years showed just 2.1% early deaths, while the 5-year actuarial freedom from valve related death was 96% in the AVR and 94% in the MVR groups [6]. The linearized incidence of embolic episodes was 1.85 %/patient-year in the AVR group, and 3.19 %/patient-year in the MVR. The incidence of valve thrombosis was 0.07 %/patient-years in the AVR group, and 0.64 %/patient-year in the MVR. Bleeding complications occurred at the rate of 1.23 %/patient-year in the AVR group, and 0.80 %/patient-year in the MVR. Baykut and colleagues reported their 11 years of experience; linearized rates of embolism, thrombosis, bleeding complications, endocarditis, and non-structural valve dysfunction were 1.1%, 0.04%, 0.5%, 0.1%, and 0.6%, respectively, per patient-year for the entire group [7]. Freedom from valve related death at 10 years was 99.2% 94.6%, and 100% for AVR, MVR, and DVR groups, respectively.

Long-term clinical experience with St. Jude Medical and Carbomedics bileaflet mechanical valves for AVR and MVR have shown that the rates of thrombosis were between 0.73 and 3.4%/patient-year, and that the 10-year freedom from thrombosis was between 77 and 94.2% [8-14]. As well, the rates of bleeding in those studies were between 0.52 and 2.7%/patient-year, and the 10-year freedom from bleeding between 77 and 96.4%. This means that these bileaflet mechanical valves, including ATS valves, work well and do not show different clinical performances. The present follow-up study provides additional evidence of the low rates of valve-related complications for ATS valve use.

Thrombo-embolic complications occurred in patients in the AVR and MVR groups, though anticoagulant therapy for all patients was well controlled. All patients received warfarin potassium and anti-platelet agents. An INR between 1.3 and 1.8 was our standard for patients who had AVR before 2000. We previously reported that AVR patients tend to show higher incidences of lethal hemorrhagic complications [15]. Thus, INR for these patients was lower than INR for patients who had MVR or DVR. However, our earlier study implies that INR should be maintained at between 1.8 and 3.3 for all patients having mechanical valve replacement [16]. Hemorrhagic complications occurred in2patients, with AVR and MVR, including1case with cerebral bleeding. As anticoagulant therapy was well controlled in these 2 cases, this might indicate an adverse influence of this particular anticoagulant therapy on patients' prognosis in cases of complications. Therefore, we believe that not only careful anticoagulant therapy but also adequate control of risk factors such as hypertension and diabetes mellitus is required to prevent lethal complications. DVR cases were considered more complicated when compared to AVR or MVR; however, neither thrombo-embolic complications nor bleeding were identified in the DVR group. The limitation of our study was the small number of patients prospectively enrolled.

Non-structural prosthetic valve dysfunction because of late transitional hemolysis was observed in one MVR patient, who had no peri-valvular leakage. Postoperative NYHA clinical functional improvement was satisfactory in all groups. Low cardiac output syndrome with ischemic heart disease led to lethal

complications with 3 early deaths in patients with advanced stage III or IV NYHA classification. Two of these patients simultaneously had coronary artery bypass grafting. To obtain better clinical outcomes, an operation before advancing clinical function should be considered. As well, more intensive peri-operative management may be necessary for patients with ischemic heart disease.

Conclusion

We analyzed the clinical courses of 88 patients who received ATS prosthetic heart valve implantation at the mitral and/or aortic position. Our mid-term single center study found excellent results associated with low incidences of valve-related mortality and morbidity.

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自治医科大学附属病院における ATS 機械弁の中期成績

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要　約

【方法】大動脈弁置換術（AVR）32例，僧帽弁置換術（MVR）42例，僧帽弁兼大動脈弁位人工弁置換術（DVR）14例に ATS 弁を用いた。平均年齢は61.1±9.9歳，追跡期間は平均2.5±1.5年，累積224.2患者 / 年であった。

【結果】早期死亡は MVR 3 例，遠隔期死亡 7 例（0.25％患者 / 年）で，うち弁関連死亡 3 例，非弁関連死亡 4 例であった。3 年の生存率は AVR 96.8％，MVR 82.2％，DVR 85.7％であった。血栓性合併症は AVR 3 例（0.45％患者 / 年），出血性合併症は 2 例（0.94％患者 / 年；AVR 1 例，MVR 1 例），人工弁感染が 3 例（0.07％患者 / 年；DVR 2 例，AVR 1 例），溶血が MVR 1 例（2.07％患者 / 年）で AVR 後感染に対して再手術を 1 例（0.15％患者 / 年）に施行した。

【結論】ATS 弁は弁関連合併症が少なく，他の弁種と比較しても良好な中期成績であった。

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