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The Initial United States Experience With the ATS Mechanical Cardiac Valve Prosthesis

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ABSTRACT

From January 1, 1997 through June 30, 2000, 224 patients underwent valve replacement with the ATS Medical cardiac valve prosthesis under a USFDA-approved investigational device exemption study. Aortic valve replacement (AVR) was conducted in 152 patients (39 with coronary bypass) and mitral replacement (MVR) in 72 patients (18 with coronary bypass). Overall operative mortality was 1.8% (AVR = 2.8%, MVR = 0%), with only one valve-related death. In 372 patient-years of follow-up, there were an additional four patient deaths, two of which were valve related following a stroke. Valve-related complications included: thromboembolism (linearized rate = 3.8% per patient year), of which 3/11 had chronic deficits (0.8% per patient year); thrombosis (1 MVR = 0.8% per patient year); paravalvular leak (1 AVR = 0.4% per patient year); anticoagulant-related hemorrhage (1 AVR and 5 MVR = 1.6% per patient year) with no patient mortality; prosthetic valve endocarditis (1 MVR = 0.8% per patient year); and valve dysfunction (0%). Echocardiographic gradients were proportional to valve size and did not significantly change over the follow-up period. This study documented the ATS Medical prosthesis to be a valuable addition to the surgeon's armamentarium in the treatment of cardiac valvular disease.

INTRODUCTION

Since its worldwide introduction nearly 24 years ago, the all-pyrolytic bileaflet design of prosthetic mechanical heart valves has become the dominant model being implanted [Emery 1979]. In spite of the mechanical valve's global acceptance, problems such as thromboembolism and valve thrombosis remain, requiring therapeutic life-long anticoagulation. To address these and other problems, the ATS Open Pivot‰ Mechanical Valve Prosthesis (ATS Medical, Inc., Minneapolis, MN) was introduced. Taking advantage of developments in pyrolytic carbon coating technology, the ATS valve differs from other bileaflet models in that there are no cavities in the valve ring in which stasis or eddy currents may develop (Figure 1, ◎); rather, the valve leaflets hinge on convex pivot guides on the pyrolytic carbon orifice ring. This allows a low profile with no cavities in the region of the pivot area. The sewing cuff is mounted on a titanium ring, which allows rotation during implantation and radiopacity for easy visualization by x-ray. Valve noise, a bothersome problem for some patients, is also reduced by this design [Sezai 2000]. Phonocardiographic studies have indicated less valve noise in the ATS Medical prosthesis than in other bileaflet mechanical valve prostheses. Theoretical flow models indicate a potential for reduced valve-related complications [Van Nooten 1996, Westaby 1996]. The ATS valve was introduced outside the United States in May of 1992. After a significant accumulation of world-wide experience, the United States studies began with the first implant on January 1997, under an investigational device exemption from the U.S. Food and Drug Administration (FDA).

METHODS

After approval by two institutional review boards in the Twin Cities metropolitan area (Abbott Northwestern Hospital, Minneapolis, MN and United Hospital, Inc., St. Paul, MN), the ATS valve study was initiated in January 1997. This prospective, non-randomized study involved consecutive patient implants from January 1, 1997 through June 30, 2000 and reports the results of a single-practice experience. The primary objective is to discuss and document valve-related events (VREs) with a secondary focus on echocardiographic valve gradient changes from the time of implant to one year following the procedure. Patient candidates for elective isolated valve replacement with or without other cardiac operations were invited to participate in this study. After review of current medical history for compliance with inclusion and

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Table 1. Demographics by Type of Operation

Variable	Total	AVR	AVR+CAB	AVR+Other	MVR	MVR+CAB	MVR + Other
# Patients	224	108	39	5	47	18	7
Mean Age (±SD)	62 ± 14	58 ± 15	71 ± 9.5	66 ± 17	62 ± 13	64 ± 10	65 ± 15
Gender:							
Male	136 (61%)	72 (66%)	25 (64%)	3 (60%)	23 (49%)	10 (56%)	3 (43%)
Female	88 (39%)	36 (33%)	14 (36%)	2 (40%)	24 (49%)	8 (44%)	4 (57%)
Pre-Op NYHA:							
II	117 (52%)	70 (65%)	11 (28%)	2 (40%)	26 (55%)	3 (17%)	4 (57%)
III	98 (43%)	33 (28%)	27 (69%)	3 (60%)	17 (36%)	15 (83%)	3 (43%)
% First Op	192 (86%)	92 (85%)	35 (90%)	3 (60%)	40 (85%)	16 (89%)	6 (86%)
Lesion:							
Regurgitation	80 (36%)	28 (26%)	3 (8%)	1 (20%)	35 (74%)	8 (44%)	5 (72%)
Stenosis	84 (37%)	52 (48%)	22 (56%)	4 (80%)	1 (2%)	4 (22%)	1 (14%)
Combined	60 (27%)	28 (26%)	14 (36%)	–	11 (23%)	6 (33%)	1 (14%)

AVR = aortic valve replacement, MVR = mitral valve replacement, CAB = coronary artery bypass, Other = miscellaneous cardiac procedure

exclusion criteria, informed consent was obtained and 224 patients underwent a mitral (n = 72) or aortic (n = 152) valve replacement (MVR and AVR respectively). Of the 152 aortic valve implant procedures, 103 used the newer Advanced Performance (AP) valve series. In this modification, materials used in the primary design and manufacture of the standard valve was unchanged, but the device had been redesigned to reduce the external sewing cuff bulk, permitting a valve of larger size with a greater geometric orifice area to be implanted into any given annulus diameter. This translates into an increase in effective orifice area and theoretically lower pressure gradients across the valve. The patient benefits from the internal orifice area of a valve that is one full size larger (AP 20 mm size translates to Standard 23 mm size).

Table 2. Valve Size Distribution

	AVR Positions		
Size[1]	Standard (n = 49)	AP (n = 103)	MVR Positions (n = 72)
16	–	2 (1.55)	–
18	–	4 (2.02)	–
19	1 (1.55)	–	–
20	–	34 (2.56)	–
21	3 (2.02)	–	–
22	–	40 (3.17)	–
23	12 (2.56)	–	–
24	–	21 (3.84)	–
25	23 (3.17)	–	1 (3.17)
26	–	2 (4.59)	–
27	10 (3.84)	–	2 (3.84)
29	–	–	24 (4.59)
31	–	–	30 (5.35)
33	–	–	15 (5.35)

[1]Note: ( ) Geometric orifice area (cm^2) from ATS Open Pivot Heart Valve, ATS Medical, Inc., Minneapolis, MN. Size is tissue annulus area. AP = Standard valve tissue annulus diameter minus 3

Reasons for excluding patients from consideration included multi-valve operations, emergency status, contraindication for anticoagulation, expected survival of less than five years, history of drug or alcohol abuse within 12 months of surgery, having a current replacement valve in another position, or anticipation of additional cardiac surgery within 12 months of the procedure. Patients were followed per protocol with physical examination and laboratory hematologic studies performed at discharge and at follow-up of six months and annually. Two-dimensional echocardiograph and Doppler studies were performed at discharge and one-year follow-up intervals. All perioperative data collated is in accordance with standards described by Edmunds et al. [Edmunds 1988]. Long-term anticoagulant management was under the direction of a primary physician or cardiologist using targeted international normalization ratios (INR) of 1.8-2.5 for AVR and 2.5-3.5 for MVR.

Echocardiographic Evaluation

All patients were examined by transthoracic two-dimensional color, spectral, and continuous wave Doppler echocardiography prior to hospital discharge and at one year (range of 11-14 months post-implant) using Hewlett Packard 5000 and 5500 Imaging Systems. One hundred seventy-eight of the 224 patients (78%) have completed this follow-up. All echocardiograms were performed by the same certified sonographer using standard protocols and calculation packages, and read by a core group of experienced echocardiographers to minimize interpretation variability. The interrogation of the ATS valve was done from the apical five chamber, the right sternal border, and the supra-sternal notch views. Transvalvular velocity (V2) for the aortic and mitral valves was obtained using continuous wave Doppler. The peak gradients were calculated using the Simplified Bernoulli Equation $4(V_2^2)$. In patients with left ventricular outflow tract (LVOT) velocities (V1) greater than 1.0 meters per second, the full Bernoulli Equation was used $4(V_2^2-V_1^2)$ [Griffin 1994]. Mean gradients were measured using the Hewlett Packard calculation package. Color Doppler assessment was

Table 3. Intraoperative Data and Mortality

	Total (n = 224)	AVR (n = 108)	AVR + CAB (n = 39)	AVR + Other (n = 5)	MVR (n = 47)	MVR + CAB (n = 18)	MVR + Other (n = 7)
Perfusion (min)	99 ± 42	86 ± 30	114 ± 82	126 ± 28	95 ± 37	127 ± 87	157 ± 122
Cross-Clamp (min)	69 ± 25	56 ± 21	36 ± 21	79 ± 21	62 ± 24	35 ± 22	53 ± 30
Mortality							
Early Death	4 (1.8%)	3 (2.8%)	1 (2.6%)	0	0	0	0
Late Death	4 (1.8%)	2 (1.8%)	1 (2.6%)	0	0	1 (5.9%)	0

performed in multiple views for assessment of valvular and paravalvular insufficiency (grades 1-4).

Surgical Techniques

Operative procedures were conducted on cardiopulmonary bypass (CPB) via midline sternotomy using a centrifugal pump and membrane oxygenation (Medtronic, Inc., Minneapolis, MN). Cardioplegia was used in all cases, and the choice of blood or crystalloid solution was surgeon-specific. In coronary bypass (CABG) patients, vein grafts were performed first, followed by valve replacement, and IMA grafting was conducted last. The aortic valve was replaced with the axis perpendicular to the septum and the mitral valve anatomic; the interrupted mattress suture technique with braided suture was used to implant all valves. The subvalvular apparatus of the posterior leaflet of the mitral valve was preserved when possible. Subcutaneous heparin (5,000 units q8hr) was administered to all patients starting on postoperative day (POD) 1 and continued until the INR on oral anticoagulation reached therapeutic levels. Oral anticoagulation therapy with Warfarin sodium was initiated on POD 1. Patients with coronary artery bypass received aspirin as part of standard postoperative treatment.

Statistical Analysis

Continuous variables are reported as the mean ± standard deviations. Survival rates were calculated using non-parametric actuarial Kaplan-Meier calculations. Linearized rates are expressed in percent per patient year (% per pt/yr).

Results

Over the 41 months of the study, 224 patients (136 male and 88 female) were enrolled with a total follow-up of 372 years. Aortic valve replacement was performed in 152 or 68% of the total group, and 72 patients (32%) had mitral valve replacement. The male/female ratio, ages, study group demographics, and etiology of valve disease are shown in Table 1 (◎). The size distribution of valves implanted is shown in Table 2 (◎). Combined procedures were conducted that included CABG (n = 57, 25%) and others (n = 12, 5%). The myocardial ischemic times were 64 ± 24 min. for the AVR group and 67 ± 26 min. for the MVR group. Cardiopulmonary bypass (CPB) times were 95 ± 34 min. and 108 ± 53 min. in the AVR and MVR groups, respectively. Complete operative data is shown in Table 3 (◎).

Mortality

The operative mortality (Table 4, ◎) for the total group was 1.8%, distributed as follows: AVR = 2.8% (n = 3/108), AVR/CAB = 2.6% (n = 1/39), MVR = 0% (n = 0/47), and MVR/CAB = 0% (n = 0/18). Four patients died late in the study period, with a mean for all eight deaths of 73 days from operation to death. Three of the eight total deaths were attributed to valve-related events: the first (AVR) of cardiac tamponade and cerebrovascular accident (CVA) with subsequent multi-system organ failure (MSOF); the second (MVR) following a major CVA and bleed with MSOF; and the third (AVR) of MSOF following reoperative surgery for a paravalvular leak. All other mortalities were due to cardiac or other causes. Kaplan-Meier actuarial survival curves are shown in Figure 2 (◎) for AVR, MVR, and the total cohort.

Table 4. Summary of Patient Mortality

	Days to Death	Death Cause	Valve Related Event
Early Valve Deaths			
Aortic valve	1	Aortic rupture	No
Aortic valve	2	Massive MI 2 days after port-access implant of valve with post-op cardiogenic shock	No
Aortic valve	5	Cardiac tamponade	No
Aortic valve + CAB	57	PVL 20 days after implant, sepsis	Yes (PVL)
Late Valve Death			
Mitral valve + CAB	98	Permanent stroke after major bleed	Yes (CVA)
Aortic valve	104	Elective surgery for pericardial effusion, major CVA post-op with exsanguination from CT, MSOF	Yes (CVA)
Aortic valve	121	Massive MI with perforated colon and peritonitis	No
Aortic valve + CAB	199	Failure to thrive 6 months after implant, developed staph sepsis	No

CAB = coronary artery bypass, CVA = cerebrovascular accident, PVL = perivalvular leak

Table 5. Valve-Related Complications and Linearized Rates

Complication	Total N = 224	All AVR N = 152	All MVR N = 72
Total patient days	135,459	90,801	44,658
Total patient years	372.1	249.4	122.68
TE [n (ppy)]	14 (3.76)	10 (4.01)	4 (3.26)
Mean INR for TE event	1.7 ± .57	1.8 ± 0.64	1.4 ± 0.13
Chronic	3 (0.81)	2 (0.80)	1 (0.81)
Transient	11 (2.96)	8 (3.21)	3 (2.44)
Thrombosis [n (ppy)]	1 (0.27)	0	1 (0.81)
Mean INR for Thrombosis event	1.8		1.8
Bleed [n (ppy)]	10 (2.68)	4 (1.60)	6 (4.89)
Mean INR for Bleed event	3.4 ± 2.3	1.7 ± 0.46	4.3 ± 2.4
Major	6 (1.61)	1 (0.40)	5 (4.07)
Minor	4 (1.07)	2 (0.8)	2 (1.63)
PVL [n (ppy)])	4 (1.07)	1 (0.40)	3 (2.44)
Major	1 (0.27)	1 (0.40)	0
Minor	3 (0.81)	0	3 (2.44)
SBE [n (ppy)])	1 (0.27)	0	1 (0.81)

*ppy = percent per patient year, TE = thromboembolism, INR = international normalization ratios, PVL = perivalvular leak, SBE = subacute bacterial endocarditis

Valve-Related Complications

Valve-related complications for each group, including length of patient follow-up (years), events (number), event incident (per patient year), and INR levels at the time of event are shown in Table 5 (◎).

A. Thromboembolism (TE)

Fourteen patients (6.3%, linearized rate of 3.8% per pt/yr) developed evidence of a major or minor thromboembolic event. Three of these patients (2 AVR and 1 MVR) were left with chronic deficits while the remaining patients' deficits were transient in nature, consisting of visual/speech disturbances (n = 8) or paresis (n = 3) with complete resolution. These events are further detailed in Table 6 (◎). The mortality rate due to TE events was 0.6% for AVR and 1.4% for MVR. Freedom from valve thromboembolism is shown in Figure 3 (◎). The linearized rate of major thromboembolism events was 0.81% per pt/yr. Interestingly, there were fewer events in patients after MVR than AVR.

B. Valve Thrombosis

One patient developed a valve thrombosis in the mitral position one year after implant; the patient's INR at the time of the event was sub-therapeutic at 1.8. The patient had a history of preoperative and postoperative atrial fibrillation with consistent sub-therapeutic INR levels. Echocardiography at 12-month follow-up revealed a normally functioning valve. Seventeen days after this echocardiogram the patient presented at the physician's office with cessation of valve sounds. The patient survived explantation on POD 396 and had no residual effects. Freedom from valve thrombosis is shown in Figure 4 (◎).

C. Paravalvular Leaks (PVL)

Four patients had echocardiographically demonstrated paravalvular leaks. One patient (AVR/CAB) experienced a major PVL that required reoperation for repair at 20 days post-procedure. The patient expired from complications related to multi-system organ failure at 57 days from the primary implant. Three other minor PVL events were reported (AVR = 0, MVR = 3) on follow-up echocardiography, with a mean interval of 194 days from implant. These events did not require surgical intervention, and all were shown by echocardiography at a later follow-up examination to have been resolved. Freedom from paravalvular leak is shown in Figure 5 (◎).

D. Anticoagulant-Related Hemorrhage (ARH)

There were 10 total bleeding events, of which six were major (1 AVR, 5 MVR), requiring hospitalization and/or

Table 6. Thromboembolic Events: (n = 14)

Number of Events	Days to Event	Event Description	Event Rhythm	INR at time of Event
		Visual/Speech Disturbance		
11 (Transient)	1. (AVR)–5 days to event	1. Amaurosis	1. Atrial Fibrillation	1. 2.3
8 AVR	2. (AVR)–4 days to event	2. Blurred Vision	2. Sinus Rhythm	2. 2.4
3 MVR	3. (AVR)–91 days to event	3. Slurred Speech	3. Atrial Fibrillation	3. 1.3
	4. (AVR)–99 days to event	4. Amaurosis	4. Atrial Fibrillation	4. 1.3
	5. (AVR)–817 days to event	5. Field Loss–Optic Neuropathy	5. Sinus Rhythm	5. 1.1
	6. (AVR)–957 days to event	6. Acute Visual Changes	6. Sinus Rhythm	6. 1.2
	7. (MVR)–22 days to event	7. Blurred Vision	7. Atrial Fibrillation	7. 2.1
	8. (MVR)–233 days to event	8. TIA	8. Atrial Fibrillation	8. 1.6
		Paralysis and weakness		
	1. (MVR)–149 days to event	1. Balance	1. Atrial Fibrillation	1. 1.4
	2. (AVR)–126 days to event	2. Left Hemi. Paresis	2. Sinus Rhythm	2. 2.4
	3. (AVR)–141 days to event	3. Peripheral Emboli	3. Sinus Rhythm	3. 1.2
3 (Chronic)	1. (AVR)–1day to event	1. Left Hemiparesis	1. Sinus Rhythm	1. 1.2
2 AVR	2. (AVR)–98 days to event	2. CVA	2. Sinus Rhythm	2. 2.7
1 MVR	3. (MVR)–5 days to event	3. CVA	3. Sinus Rhythm	3. 1.3

Table 7. Anticoagulant-Related Hemorrhage Events: (n = 10)

Number of Events	Days to Event	Event Description	INR at Time of Event
4 (minor GI Bleed)	GI Bleeds		
2 AVR	1. (AVR)–5 days to event	1. Guaiac Stools–Gastritis	1. 1.0
2 MVR	2. (AVR)–789 days to event	2. G.I. Bleed	2. 4.5
	3. (MVR)–23 days to event	3. Hematuria	3. 1.7
	4. (MVR)–524 days to event	4. Rectal Bleeding	4. 3.2
6 (major)			
1 AVR	1. (AVR)–353 days to event	1. Subdural Hematoma	1. 2.0
5 MVR	2. (MVR)–5 days to event	2. G.I. Bleed	2. 8.6
	3. (MVR)–6 days to event	3. G.I. Bleed	3. 1.6
	4. (MVR)–25 days to event	4. G.I. Bleed	4. 6.4
	5. (MVR)–355 days to event	5. G.I. Bleed	5. 2.7
	6. (MVR)–663 days to event	6. Retroperitoneal Bleed	6. 3.4

transfusion. Two of these patients died, but the etiology of these deaths was related to an initial thromboembolic event. The bleeding events are delineated in Table 7 (◎), and freedom from anticoagulant-related bleeding is shown in Figure 6 (◎). The linearized rate for major anticoagulant-related bleeding was 1.6% per pt/yr. The mortality for ARH complication was 0% in both groups. Of the patients having ARH events, the INR was subtherapeutic in three, therapeutic in four, and supra-therapeutic in three.

E. *Prosthetic Valve Endocarditis*
One patient was diagnosed as having culture-negative endocarditis (MVR) at 489 days from implant and was successfully treated with a course of antibiotics. After the antibiotic regimen, no recurrence was discovered. Freedom from prosthetic valve endocarditis is shown in Figure 7 (◎).

F. *Valve Dysfunction*
There was no structural valve dysfunction for AVR or MVR patients.

Echocardiographic Follow-up

Echocardiographic follow-up results are shown in Table 8 (◎) for aortic standard valves, aortic AP valves, and mitral valves by size. At the one-year follow-up exam, the peak aortic valve gradient average was 18.4 mm Hg (range of 2.3 to 62 mm Hg) with a mean aortic gradient of 10.6 (range 1.3 to 34 mm Hg). Although there was a trend towards decreased mean and peak gradients at one year, the difference was not statistically significant. The mitral valve peak gradient averaged 9.5 mm Hg (range of 1 to 16.9 mm Hg) with a mean mitral gradient of 4.1 mm Hg (range of 1.6 to 12 mm Hg). Peak and mean gradients were inversely related to the valve size.

Table 8. Peak and Mean Valve Gradients for Standard, AP, and Mitral Valve Positions by Size, as Shown by Echocardiogram upon Discharge and One-Year Follow-up

	Aortic Standard Position (n = 41)				Aortic AP Position (n = 78)				MVR Positions (n = 56)			
	Discharge		1 Year		Discharge		1 Year		Discharge		1 Year	
Size	Mean (± SD)	Peak (± SD)	Mean (± SD)	Peak (± SD)	Mean (± SD)	Peak (± SD)	Mean (± SD)	Peak (± SD)	Mean (± SD)	Peak (± SD)	Mean (± SD)	Peak (± SD)
16	–	–	–	–								
18	–	–	–	–	19 ± 9	31 ± 12	18 ± 11	28 ± 15				
19	28	51	34	62								
20		–	–	–	11.6 ± 3	20 ± 6	11 ± 4	20 ± 8				
21	17 ± 11	30 ± 18	16 ± 6	28 ± 8								
22	–	–	–	–	11 ± 5	19 ± 8	9 ± 4	16 ± 7				
23	18 ± 5	32 ± 8	16 ± 6	24 ± 11								
24		–	–	–	9 ± 3	16 ± 5	7 ± 2	12 ± 4				
25	14 ± 5	24 ± 7	12 ± 4	21 ± 7					10	16	7.8	12
26		–	–	–	11 ± 2	19 ± 4	7 ± 4	13 ± 7				
27	11 ± 3	19 ± 5	11 ± 5	18 ± 8					3	13	5	15
29	–	–	–	–					4 ± 2	10 ± 4	6 ± 5	11 ± 5
31	–	–	–	–					5 ± 2	11 ± 4	4 ± 2	8 ± 4
33	–	–	–	–					3 ± 1	7 ± 3	3 ± 1	7 ± 2

DISCUSSION

The ATS Medical mechanical valve prosthesis represents an alternative bileaflet heart valve design that incorporates advances in the technology of pyrolytic carbon coating. Because the valve leaflet rests on convexities coated on the valve housing, there are no concavities in which stasis or turbulence may develop. Because of this design, other investigators have reported that modification of accepted anticoagulant target INR levels to a lower tolerance is possible [Westaby 1996]. This design also offers quieter valve closure, which has been documented phonocardiographically. Although historically the St. Jude Medical prosthesis has scored the lowest decibel readings, it has been demonstrated that the ATS valve has an even lower closing sound [Blome-Eberwein 1996, Sezai 2000].

Mechanical valve prostheses offer the advantage of longevity following native valve replacement, but there is a life-long need for therapeutic anticoagulation. The incidence of prostheses-related complications is similar for modern bileaflet valves but varies with the patient population, the intensity of follow-up, and the recommended level of anticoagulation [Akins 95, Bernal 98]. In our population, for instance, anticoagulant-related hemorrhage (ARH) does not differ with patient age [Arom 96]. It is therefore difficult to compare results between demographically and geographically different studies. The current study was conducted with a closely followed population, with follow-up only totaling 372 patient years. Events are similar to those we reported with a mechanical prosthesis of another bileaflet design. [Arom 1996]. Importantly, most thromboembolic (TE) events were minimal, with 11 of 14 (79%) being minor. Mortality and disability were very low. Additionally, the incidence of ARH was similar to TE, but the fact that there were only four minor as opposed to six major ARH events indicates that there is room for continued improvement in reducing INR levels, particularly in patients without risk factors for TE such as regional wall motion abnormalities, depressed ejection fraction, or atrial fibrillation. Two patients having TE also had later ARH complications.

To further the argument in favor of reducing target INR, it should be observed that all patients in atrial fibrillation had only minor TE events (n = 6) that were completely resolved. Regarding the ARH events, there was, as expected, a higher incidence in MVR patients that was probably related to the higher recommended level of INR (2.5-3.5 vs. 1.8-2.5 for AVR). The one incident of mitral valve thrombosis occurred in a patient in atrial fibrillation with a low INR rate after implantation.

Prior studies completed outside of the United States revealed similar low rates of valve-related complications [Shiono 1996, Westaby 1996]. Valve-related complications are more common during the first year of patient follow-up [Bernal 1998]. Therefore, given the limited follow-up of this study, a relatively higher incidence of events could be expected. The mean mitral gradient seen in our patient group with valves of 27-33 mm is similar to that reported previously in several earlier series that evaluated the ATS, St. Jude Medical, and Medtronic Hall mechanical valve prostheses [Van Nooten 1996, Westaby 1996]. Similarly, our aortic gradients are consistent with those reported previously for the St. Jude prosthesis [Reisner 1988, Van Nooten 1996]. More data is needed with regard to the smallest valve sizes (Aortic 18AP, Standard 19, and Mitral 25 mm) to determine normal values for these groups. Echocardiographically determined gradients showed a decreasing trend over the first year and were similar to those reported for other bileaflet mechanical valve prostheses [Akins 1995]. Although patients in the current report are older than those in prior, non-United States study reports, the incidence of valve-related complications is similar [Autschbach 2000, Georgiadis 2001].

CONCLUSION

The ATS Medical cardiac valve prosthesis is a valuable addition to the armamentarium of the cardiac surgeon. While early overall valve complications with the ATS prosthesis were shown to be similar to other bileaflet prostheses, most complications were of minor significance. The improved design of this device offers the potential for use of a future prosthesis with modified anticoagulation.

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REVIEW AND COMMENTARY

1. Editorial Board Member KK138 writes:

In the Discussion section, the authors should provide a more thorough overview of the results that have so far been presented for the ATS valve. The following recent publications on the ATS may be considered: Circulation 2000 Nov 7;102(19 Suppl 3):III1-4 (Randomized study of ATS vs. SJM vs. Carbomedics valves, 100 each group incl. Clinical FU); Ann Thorac Cardiovasc Surg 2000 Feb;6(1):34-8 (Midterm results); J Thorac Cardiovasc Surg 2001 Jun;121(6):1101-6 (Microembolic events).

Authors' Response by Robert W. Emery, MD:

In regard to the first publication, the purpose of our paper was to report on a consecutive experience that led to FDA approval of particular valve prosthesis; therefore, a comparison with non-US studies did not seem appropriate (Autschbach et al.). We did compare our results to previous studies performed within our group by the same surgeons using the same techniques with other bileaflet valve prostheses in a non-randomized fashion. The second publication was not available at the time the paper was submitted. As to the third publication, the authors note that higher microembolic signal counts cannot be used to predict embolic complications. I only noted the similarity in the incidence of neurologic events as best I could calculate. It is certainly appropriate to include in this paper references to recent reports on this new cardiac valve prosthesis.

2. Editorial Board Member IG23 writes:

There is some information missing:

In Surgical Technique:

1) Preservation of the mitral chordae in view of the excellent results (no operative mortality);
2) Associated treatment of left auricula or enlarged atria.

In Results:

1) Prevalence of preoperative atrial arrhythmias (afib) in order to address the importance of this risk factor, given the sinus rhythm prevalence in patients with embolic complications.
2) In Table 8, for the purpose of having larger numbers to rely on, it would be better to group Standard and AP valves according to their internal size. The internal size could be translated to label size of the standard and AP model in the legend or referencing Table 2.

Authors' Response by Robert W. Emery, MD:

Preservation of the anterior chord was at the surgeon's discretion and not recorded. Similarly, with the left atrial appendage, most surgeons ligate the appendage when enlarged or if atrial fibrillation intervenes, but this data was not gathered as part of the database. Also, the prevalence of preoperative arrhythmias was not recorded in our data collection process.

I have kept Table 8 the way it is because the AP and the standard valves are different sizes, and we believed that a table delineating the echocardiographic follow-up results available for each size valve would be clearer.

3. Editorial Board Member GX21 writes:

Although the amount of clinical material is meager, this is an important paper because it is the initial experience with this new valve.

1) The authors should use confidence intervals for linearized rates.
2) To save space, the authors could eliminate the Total columns in the tables; the information given for the individual positions is sufficient, and pooling heterogeneous groups is not meaningful.
3) Also to save space, the Figures could be eliminated. With so few events and follow-up to only three years, they do not contribute important information. (If the Kaplan-Meier curves are given, they should include confidence intervals, but this would be visually confusing since the lines are so close together.)
4) The last sentence in paragraph A under Valve-Related Complications is not needed (there were also more valves in MVR than AVR).

Authors' Response by Robert W. Emery, MD:

1) We did not use confidence limits for linearized rates because the curves from the graphs overlapped so much that the incidence would become meaningless.
2) The Total columns, to us, indicate that all the numbers are appropriate and add up. I would prefer they stay as part of the manuscript unless space dictates otherwise.
3) We believe that the Figures are important because they depict visually the minimal incidence of complications

suffered with this valve over the course of the study.

4) Finally, the last sentence under paragraph A relating to valve complications is necessary. In most reports, patients with a mitral valve prosthesis with the often-associated high incidence of supraventricular arrhythmias have a higher incidence of thromboembolic complications than patients who had aortic valve replacement. This is not true in this series and is worthy of special note.