

Single-Center Outcome Analysis of 1,161 Patients with St. Jude Medical and ATS Open Pivot Mechanical Heart Valves

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Background and aim of the study: The clinical performance of mechanical heart valves and valve-related complications are important safety endpoints in patients after heart valve replacement. In this retrospective analysis, the mid- to long-term clinical outcomes of two similar bileaflet heart valves, routinely implanted at the authors' institution over an 11-year period, were compared.

Methods: Between January 1993 and December 2003, a total of 1,161 patients (758 males, 403 females) received either a St. Jude Medical (SJM) or ATS mechanical heart valve. Follow up was obtained via an in-house Quality Management Database, ascertained by telephone questionnaire of the patients and/or family physicians. Follow up was 98.9% complete; the median follow up was 4.6 years; total follow up was 5,624 patient-years (pt-yr).

Results: A total of 604 SJM and 601 ATS prostheses was implanted as isolated (n = 669) or combined (n = 492) procedures. The overall 30-day mortality for SJM and ATS was 4.1% and 3.4%, respectively (p =

0.45). Cumulative survival and freedom from valve-related mortality at 10 years for SJM and ATS valves were $66 \pm 3\%$ versus $68 \pm 5\%$ (p = 0.84) and $96 \pm 1\%$ versus $97 \pm 1\%$ (p = 0.36), respectively. No structural valve failure was encountered for both valve types. Freedom from overall valve-related complications at 10 years was $79 \pm 4\%$ for SJM and $66 \pm 6\%$ for ATS (p = 0.08). The linearized rates for valve-related adverse events for SJM and ATS valves, respectively, were: thromboembolism 0.9 and 1.1%/pt-yr; major bleeding requiring transfusion 0.3 and 0.5%/pt-yr; prosthetic endocarditis 0.03 and 0.1%/pt-yr; paravalvular leak 0.1 and 0.6%/pt-yr.

Conclusion: On the basis of an 11-year experience, both bileaflet valves showed very good clinical results, with low incidences of adverse events during the mid-term outcome. Gender and/or concomitant coronary artery disease were not predictors for reduced life expectancy.

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The bileaflet cardiac valve prosthesis design was first introduced in 1977 by Nicoloff and colleagues (1) and, during the following decades, became the most widely implanted mechanical heart valve type. Normally, postoperative mortality and valve-related morbidity are evaluated to underline the safety of bileaflet valves, while hemodynamic data obtained by echocardiography and improvements in NYHA class are used to address their efficacy and clinical utility.

Despite continuous progress in heart valve technology, the risk of thromboembolism and anticoagulant-

related bleeding continue to account for 75% of all complications after mechanical valve replacement (2,3). However, the risk of thromboembolism after valve replacement is multifactorial, and cannot be attributed entirely to the prosthetic heart valve, or to its type and design (4,5). Additionally, in order to avoid high anticoagulation variability as an independent predictor for reduced survival, a consistent management of the International Normalized Ratio (INR) is mandatory in order to minimize anticoagulation-related bleeding (6,7).

The St. Jude Medical (SJM, Minneapolis, MN, USA) bileaflet heart valve prosthesis has been in clinical use for almost three decades, and in large, homogeneous series, long-term follow up data are available in several clinical studies, with good results (8-12). The ATS Open Pivot® Heart Valve (ATS Medical, Minneapolis, MN, USA) was first introduced in 1992. The structural characteristics of this full pyrolytic carbon valve differ

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from those of the SJM in that the hinge mechanism is convex, thus eliminating cavities in the valve ring and pivot guards. Based on this design, less thrombogenicity was anticipated, and low anticoagulation regimens have been proposed by several authors for this valve model (13-16).

The aim of the present study was to compare the clinical outcomes of patients who underwent valve replacement with either SJM or ATS prostheses, in order to detect and determine differences in the mid- to long-term performance between these valve models.

Clinical material and methods

Patient data

Between January 1993 and December 2003, a total of 1,161 patients (758 males, 403 females) underwent mechanical valve replacement at the authors' institution with either SJM or ATS bileaflet prostheses.

Among these patients, 579 received a total of 604 SJM valves, and 581 patients received a total of 601 ATS prostheses. Overall, 487 patients underwent aortic valve replacement (AVR) with SJM prostheses, and 393 with ATS; by comparison, 67 mitral valve replacements (MVR) were performed with SJM and 168 with ATS. Double (aortic and mitral) valve replacement (DVR) was carried out with SJM valves in 25 patients, and with ATS valves in 20 patients. One patient was excluded from the study as he received an SJM prosthesis in the mitral position, and an ATS in the aortic position. The patient demographics and baseline characteristics are listed in Table I.

The mean patient age was 62.3 years (range: 15 to 85 years) in the SJM group, and 63.7 years (range: 18 to 89 years) in the ATS group. The preoperative NYHA class did not differ significantly between valve types and implantation site (Table I). A concomitant coronary artery disease with significant stenosis of at least one

Table I: Patient demographics and baseline characteristics.

Parameter	Valve location					
	AVR		MVR		DVR	
	ATS (n = 393)	SJM (n = 487)	ATS (n = 168)	SJM (n = 67)	ATS (n = 20)	SJM (n = 25)
Age (years)*	64.0 ± 12.8	62.9 ± 12.2	63.9 ± 11.4	60.8 ± 14.1	55.3 ± 15.0	55.6 ± 17.3
Gender						
Male	254 (64.6)	333 (68.4)	112 (66.7)	37 (55.2)	11 (55.0)	10 (40.0)
Female	139 (35.4)	154 (31.6)	56 (33.3)	30 (44.8)	15 (45.0)	9 (60.0)
Body surface area (m ²)*	1.87 ± 0.19	1.87 ± 0.19	1.84 ± 0.20	1.79 ± 0.17	1.75 ± 0.20	1.72 ± 0.15
Ejection fraction (%)*	58.8 ± 16.4	57.3 ± 15.9	58.6 ± 14.3	61.9 ± 13.6	64.1 ± 11.4	60.8 ± 11.9
LVEDP (mmHg)*	22.7 ± 9.6	23.0 ± 11.1	15.8 ± 8.8	15.8 ± 7.7	17.9 ± 9.5	13.2 ± 6.9
Preop. cardiac rhythm						
Sinus rhythm	269 (87.1)	334 (86.3)	64 (46.7)	22 (46.9)	8 (57.1)	10 (50.0)
Atrial fibrillation	38 (12.3)	47 (12.1)	71 (51.8)	22 (46.9)	6 (42.9)	9 (45.0)
Pacemaker	2 (0.7)	6 (1.6)	2 (1.5)	1 (2.2)	0 (0.0)	1 (5.0)
Reoperation	18 (4.6)	17 (3.5)	19 (11.3)	11 (16.4)	5 (25.0)	3 (12.0)
Reoperation (same position)	9 (2.3)	4 (0.8)	1 (0.6)	1 (1.5)	0 (0.0)	0 (0.0)
NYHA class						
I	32 (8.1)	20 (4.1)	2 (1.2)	1 (1.5)	0 (0.0)	0 (0.0)
II	177 (45.0)	223 (45.8)	38 (22.6)	16 (23.9)	1 (5.0)	4 (16.0)
III	162 (41.2)	227 (46.6)	99 (58.9)	38 (56.7)	14 (70.0)	16 (64.0)
IV	22 (5.6)	17 (3.5)	29 (17.3)	12 (17.9)	5 (25.0)	5 (20.0)
CAD	123 (31.3)	166 (34.1)	39 (23.2)	14 (20.9)	5 (25.0)	3 (12.0)
Risk factors						
COPD	20 (5.1)	41 (8.4)	10 (5.9)	7 (10.5)	0 (0.0)	0 (0.0)
CVD	1 (0.3)	2 (0.4)	1 (0.6)	1 (1.5)	0 (0.0)	1 (4.0)
Renal failure	5 (1.3)	17 (3.5)	4 (2.4)	1 (1.5)	2 (1.0)	0 (0.0)
Diabetes mellitus	51 (13.0)	56 (11.5)	15 (8.9)	5 (4.5)	6 (30.0)	2 (8.0)
Emergency	8 (2.3)	14 (3.0)	10 (6.9)	7 (11.7)	0 (0.0)	0 (0.0)

*Values are mean ± SD.

Values in parentheses are percentages.

CAD: Coronary artery disease; COPD: Chronic obstructive pulmonary disease; CVD: Cerebrovascular disease; LVEDP: Left ventricular end-diastolic pressure.

vessel was diagnosed in 183 SJM patients (31.6%) and in 167 ATS patients (28.7%). Details of further concomitant diseases and preoperative risk factors are also listed in Table I. A predominant aortic stenosis (AS) was diagnosed in 70% of AVR patients in the SJM group, and in 72% in those in the ATS group. Isolated aortic regurgitation was observed in 25% of SJM patients and 23% of ATS patients. Mitral regurgitation was encountered in 85% of the SJM group and 91% of the ATS group, while a predominant mitral stenosis was present in 6% of the SJM group and 5% of the ATS group (Table II).

Surgical procedure

Surgery was performed through a midline sternotomy with cardiopulmonary bypass under normothermic or mild hypothermic conditions (36°C and 32°C, respectively). Heparin (350 U/kg body weight) was administered for intravenous anticoagulation. Blood oxygenation was carried out with a hollow-fiber oxygenator. For myocardial preservation, antegrade cold crystalloid (Bretschneider HTK) or blood (Buckberg) cardioplegia with topical surface cooling was administered. For AVR, the valves were placed intra-annularly, and the sewing technique used was either non-everting interrupted mattress with pledgets on the ventricular side or everting non-pledgetted simple interrupted sutures. MVR was carried out in standard fashion through a transatrial or trans-septal approach, preserving as many of the anterior and posterior chordal structures and leaflet tissues as possible. Everting interrupted mattress sutures with pledgets on the atrial side were used for prosthesis fixation. The left atrial appendix was excluded routinely. Intraoperative transesophageal echocardiography was

used to provide information regarding prosthesis positioning and function. Postoperatively, 15,000 U of heparin were administered per 24-h period, and phenprocoumon (Marcoumar®) was administered orally from the first postoperative day. The target INR range was 2.0-3.0 for AVR, and 2.5-3.5 for MVR.

Patient follow up

The mean follow up was 4.8 ± 2.9 years (range: 0.1 to 11.8 years). Follow up was 98.9% complete, with a total of 5,624 patient-years (pt-yr) registered.

Patient analysis and clinical results presented in this study were in accordance with the guidelines for reporting morbidity and mortality after cardiac valvular operations, as requested by the Councils of The Society of Thoracic Surgeons (STS) and the American Association for Thoracic Surgery (AATS) and revised by Edmunds et al. (17).

Information relating to patient health status and outcome events were collected on a routine basis through an in-house Quality Management Database (BQS, Germany; PATS, Dendrite, UK) or, if necessary, via telephone contact with the patients and/or their family physicians. A standardized data collection instrument for patient self-reporting of adverse events and quality of life was used. Additional information concerning patients who had re-located from the area and/or who had died was provided by the Swiss Federal Bureau of Statistics. Only 13 patients (1.12%) were lost to follow up.

Statistical analysis

Scores and quantitative variables were summarized as mean ± SD, and comparisons between groups were made using the Wilcoxon-Mann-Whitney test.

Table II: Pathology of the native valves.

Pathology	AVR		MVR		DVR	
	ATS (n = 393)	SJM (n = 487)	ATS (n = 168)	SJM (n = 67)	ATS (n = 20)	SJM (n = 25)
Etiology						
Valve calcification	344 (87.5)	442 (90.8)	105 (62.5)	31 (46.3)	4 (20.0)	6 (24.0)
Rheumatic	3 (0.8)	5 (1.0)	24 (14.3)	13 (19.4)	9 (45.0)	10 (40.0)
Endocarditis	23 (5.9)	22 (4.5)	8 (4.8)	5 (7.5)	5 (25.0)	5 (20.0)
Ischemic	0 (0.0)	0 (0.0)	5 (3.0)	1 (1.5)	0 (0.0)	0 (0.0)
Prosthetic	9 (2.3)	17 (3.5)	19 (11.3)	11 (16.4)	5 (25.0)	3 (12.0)
Others/unknown	23 (5.9)	18 (11.2)	26 (15.5)	17 (25.4)	2 (10.0)	4 (16.0)
Dysfunction						
Stenosis	277 (71.6)	339 (70.3)	8 (4.9)	4 (6.0)	2 (10.5)	6 (26.1)
Regurgitation	87 (22.5)	121 (25.1)	150 (90.9)	57 (85.1)	8 (42.1)	13 (56.5)
Combined	23 (5.9)	22 (4.6)	7 (4.2)	6 (9.0)	9 (47.4)	4 (17.4)

Values in parentheses are percentages.

AVR: Aortic valve replacement; DVR: Double valve replacement; MVR: Mitral valve replacement

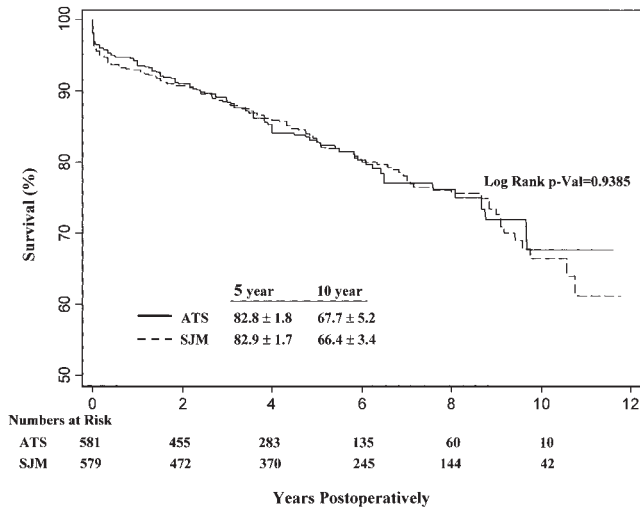


Figure 1: Actuarial survival of patients who received a SJM or ATS bileaflet mechanical heart valve.

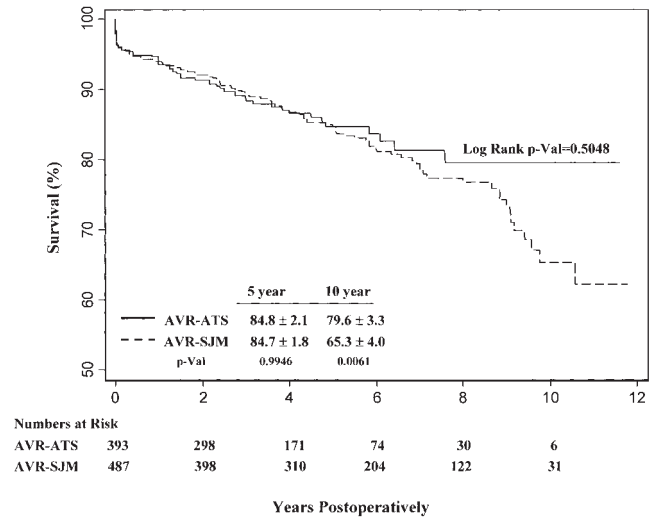


Figure 2: Actuarial survival at 5 and 10 years of patients undergoing aortic valve replacement (AVR) with SJM and ATS bileaflet mechanical heart valves.

Comparison of categorical variables between groups was performed with Fisher's exact test and the chi-square test. Linearized rates were expressed in % per pt-yr. Kaplan-Meier statistics were used for a description of time to event variables with censored values, and differences between groups assessed with the log-rank test or by proportional-hazards models adjusted by gender and age. All analyses were performed using SAS version 8.2 (18).

Results

Mortality

The overall 30-day mortality was 4.1% (n = 24; AVR 3.7%, MVR 7.4%, DVR 4.0%) in the SJM group, and 3.4% (n = 20; AVR 3.8%, MVR 1.8%, DVR 10.0%) in the ATS group (p = 0.54). Early deaths occurred in 18 AVR, five MVR and one DVR patients in the SJM group, and in 15 AVR, three MVR and two DVR patients in the ATS group. In none of the patients was any valve-related cause of early death observed. The actuarial survival is shown graphically in Figure 1. The 10-year survival was 66 ± 3% for SJM patients, and 68 ± 5% for ATS. In total, 97 late deaths were reported in the SJM group and 78 in the ATS group; these occurred in 78 AVR, 14 MVR and five DVR patients in the SJM group, and in 38 AVR, 37 MVR and three DVR patients in the ATS group. With respect to implantation sites, actuarial survival at 10 years after AVR showed a significant difference between SJM and ATS valves, with 65% for SJM and 80% for ATS (p = 0.006) (Fig. 2). After MVR, the first five years of follow up showed a significant difference in survival rate between SJM (74%) and ATS (80%) (Fig. 3) (p = 0.038). Freedom from valve-related

death at 10 years was 96 ± 1% for SJM prostheses and 97 ± 1% for ATS prostheses (p = 0.36) (Fig. 4).

Thromboembolic events

Thromboembolic events occurred in 30 patients (5.2%; 22 AVR, five MVR, three DVR) in the SJM group, with neurological impairment in four cases (three transient, one permanent). Two patients died after severe stroke following valve thrombosis due to insufficient anticoagulation management. Early thromboembolism occurred in one patient, and late events in 29 patients. The linearized rate for thromboembolic events was 0.9%/pt-yr (0.8%/pt-yr for AVR, 1.4%/pt-yr for MVR, 2.3%/pt-yr for DVR).

In the ATS group, late thromboembolism was observed in 28 patients (4.8%; 17 AVR, 11 MVR), leading to a transient neurological impairment in two patients and a permanent neurological deficit in one patient. Another patient died following valve thrombosis and stroke. The linearized rate for thromboembolic events was 1.1%/pt-yr (1.1%/pt-yr for AVR, 1.3%/pt-yr for MVR). Freedom from thromboembolism at 10 years was 89% for SJM and 81% for ATS (Fig. 5).

Bleeding events

There were 10 bleeding events in the SJM group (1.7%; nine AVR, one DVR), resulting in a linearized rate of 0.3%/pt-yr (0.3%/pt-yr for AVR, 0.8%/pt-yr for DVR). Three late deaths occurred after a severe bleeding event (cerebral in two cases, bleeding of the intestine in one case).

There were 12 bleeding events in the ATS group (2.1%; five AVR, five MVR, two DVR), resulting in a

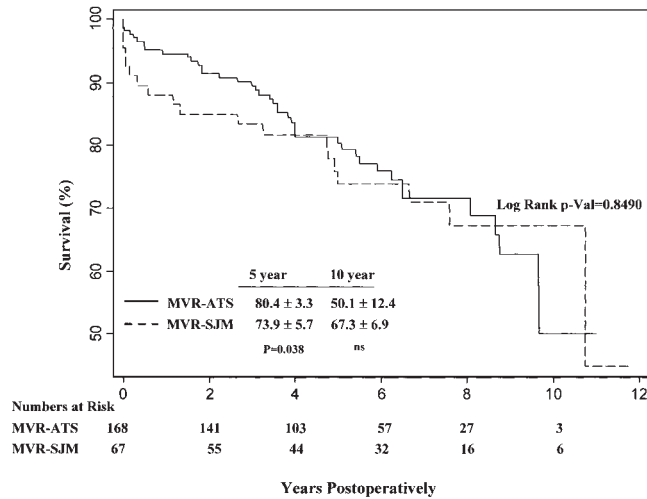


Figure 3: Actuarial survival at 5 and 10 years of patients undergoing mitral valve replacement (MVR) with SJM and ATS bileaflet mechanical heart valves.

linearized rate of 0.5%/pt-yr for the entire group, and 0.3%/pt-yr for AVR, 0.6%/pt-yr for MVR, and 2.3%/pt-yr for DVR. Two late deaths were observed following severe cerebral bleeding. The subsequent autopsy of one of these patients revealed the rupture of an intracranial aneurysm as the main cause of bleeding. Freedom from major bleeding events at 10 years was 96% for SJM and 95% for ATS (Fig. 6).

Structural valve deterioration

No structural valve deterioration was encountered among 1,205 implanted valves,

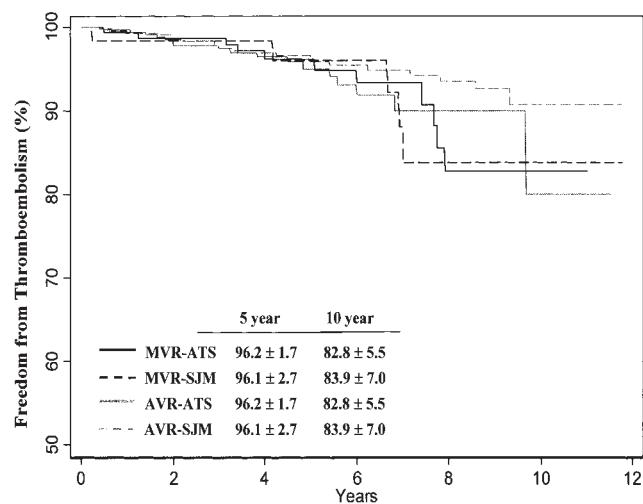


Figure 5: Actuarial freedom from thromboembolism (TE) in patients with SJM or ATS valves.

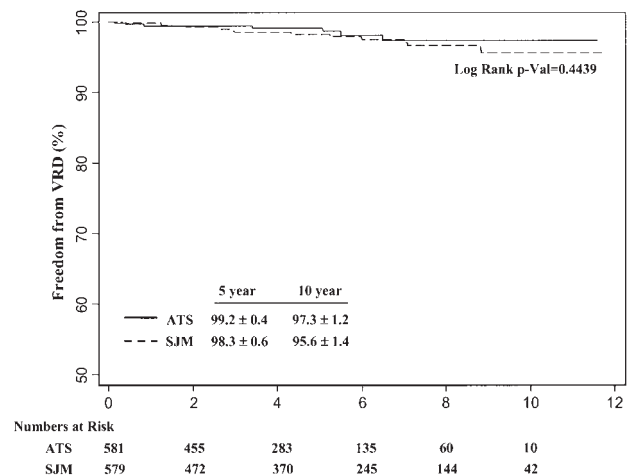


Figure 4: Actuarial freedom from valve-related death (VRD) in patients receiving a SJM or ATS bileaflet mechanical heart valve.

Non-structural dysfunction

Paravalvular leak was observed in 14 (2.4%) patients (13 AVR, one MVR) in the SJM group. The linearized rate for paravalvular leak was 0.5%/pt-yr for the SJM group (0.5%/pt-yr for AVR, 0.3%/pt-yr for MVR). Five patients required reoperation (four AVR, one MVR). In four patients, the prostheses had to be exchanged. One late death was observed after surgical repair of a paravalvular leak in the aortic position.

In the ATS group, a paravalvular leak was observed in 16 (2.8%) patients (10 AVR, six MVR). Among these patients, three (18.8%) presented with preoperative endocarditis. Six patients required reoperation (three AVR, three MVR). In two patients with AVR, the par-

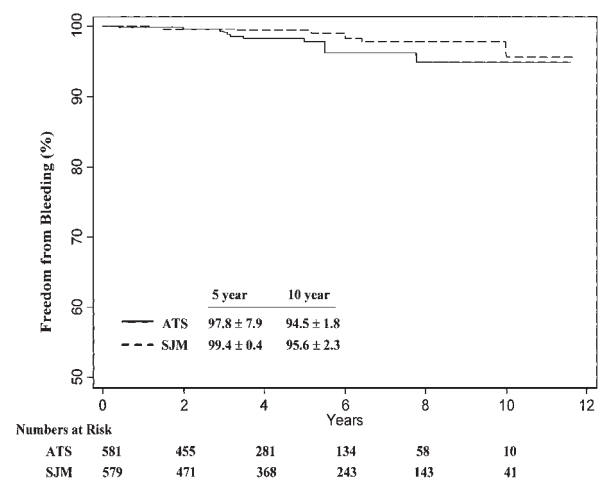


Figure 6: Freedom from bleeding events in patients undergoing mechanical heart valve replacement with SJM or ATS valves.

avalvular leak could be repaired, but in the remainder of this group the prostheses were exchanged. The linearized rate for paravalvular leak was 0.6%/pt-yr (0.6%/pt-yr for AVR, 0.7%/pt-yr for MVR).

Valve thrombosis

A valve thrombosis was observed in two patients with an SJM aortic prosthesis, and both died after an acute cerebral embolization (see 'Thromboembolic events'). Actuarial freedom from valve thrombosis at 10 years was 98% (98% for AVR, 100% for MVR, 100% for DVR).

In the ATS group, a valve thrombosis was observed in an 84-year-old female patient with MVR + coronary artery bypass grafting. For reasons unknown, her family physician had switched from phenprocoumon to aspirin at five years after surgery, and the resultant mitral valve thrombosis led to a severe cerebral embolization. The patient died in hospital four months after the event. Actuarial freedom from valve thrombosis at 10 years was 99.5% (100% for AVR, 99% for MVR, 100% for DVR).

Prosthetic endocarditis

De-novo prosthetic endocarditis occurred at six weeks after surgery in one patient with an SJM valve in the aortic position. Following adequate medical therapy, a redo operation was performed and the prosthesis exchanged successfully. Actuarial freedom from prosthetic endocarditis at 10 years was 99% (99% for AVR, 100% for MVR, 100% for DVR).

Three patients with an ATS valve suffered from prosthetic endocarditis (one patient after AVR, at 31 months postoperatively; two patients after MVR, at four and 55 months after surgery). These patients underwent a redo operation with prosthesis exchange. Actuarial freedom from prosthetic endocarditis at 10 years was 99% (99% for AVR, 98% for MVR, 100% for DVR).

Discussion

Bileaflet mechanical heart valve prostheses have been proven superior to heart valves of other generic design in terms of hemodynamic performance and durability (19). However, the influence of specific design features on transvalvular pressure difference, leakage, loss of energy, turbulence, stasis, or even the design of the sewing cuff, can be limiting factors for the overall success of prosthetic valve replacement (19,20).

The present study was neither prospective nor randomized in design, and represented a retrospective clinical outcome analysis of two structurally comparable prosthetic heart valves implanted at the same insti-

tution during the same time period. There was no significant difference in early mortality rates between the SJM and ATS prostheses, independent of the implantation position, which suggested a similar preoperative risk profile for both groups. The overall early mortality rates of both valves (4.1% for SJM, 3.4% for ATS) were in accordance with previously published data on other bileaflet valves, including On-X®, CarboMedics® or Sorin Bicarbon® (21-24). The actuarial survival after 10 years was not significantly different between SJM and ATS, irrespective of the anatomic position. In the aortic position, actuarial survival at 10 years was significantly different between SJM and ATS valves (65% for SJM, 80% for ATS; $p = 0.006$), a situation which had not been predicted on completion of the first five years of follow up. In a study conducted by Masters et al. (25), the 10-year survival probability of SJM prostheses after implantation in the aortic position was reported as 57.5%, which was similar to the present results with this prosthesis. In contrast, after a follow up of 138 months, Kandemir et al. (26) observed a remarkably higher survival rate for SJM prostheses in the aortic position (75.9%), although these patients were characterized by a low mean age of 46.4 years), which may have influenced the overall survival rate. Based on the present results, it can be assumed that ATS valves would yield a better outcome in the aortic position. Since long-term results of ATS valves (particularly for the aortic position) are insufficiently described in the literature, a propensity score analysis of the present results for the AVR group is ongoing.

In the MVR group, the actuarial survival rate was significantly different during the first five years, with 74% for SJM and 80% for ATS ($p = 0.038$). However, at the end of the 10-year follow up period no significant difference in actuarial survival was observed between the valve models. Freedom from valve-related mortality was 96% for SJM and 97% for ATS, and previous reports have listed values for SJM valves of between 90% and 96% (8,9,12). For ATS prostheses, no comparable mid- to long-term clinical outcome analyses are available. With regards to these studies, the present results are at least equal or better than those of other bileaflet prostheses (24,25).

The incidence of cerebral embolization has been investigated previously by several groups in relation to the determination of intracranial high-intensity transient signals (HITS) (27,28). Neither prosthesis type nor intensity of anticoagulation regimen influenced the HITS counts (29). Due to the low incidence of thromboembolic events with bileaflet prostheses, some authors recommend a lower-intensity regimen of anticoagulation for these models, compared to other mechanical prostheses, especially in the aortic position (30-33). In all of the present patients a target INR range

of 2.0-3.0 in the aortic position and 2.5-3.5 in the mitral position was maintained, as recommended in the European Guidelines (34). Although the addition of antiplatelet drugs (e.g., aspirin) is sometimes recommended to prevent thromboembolic events and further reduce the anticoagulant dose (32), all of the present patients received only phenprocoumon for long-term anticoagulation.

Among the present patients there was no evidence of any valve-related complication originating from a structural defect of the implanted prostheses. Paravalvular leak and prosthetic endocarditis are rare complications with modern bileaflet prostheses, and despite a relatively high proportion of patients being operated on during or immediately after treatment for endocarditis, no recurrent endocarditis was observed. In fact, the linearized rates of these parameters were very low, and comparable with those reported elsewhere (8,12,16,23,24). Between 1997 and 1998, nine SJM Silzone® valves were implanted, with no evidence of paravalvular leak in these patients.

One interesting observation was that, after a relatively high initial morbidity and mortality, the mid-term outcomes of the DVR patients were better than have been reported elsewhere (8,23). Although in the present study the number of DVR patients was low, these findings lead to the conclusion that such patients have a high probability of long-term survival if they survive the high perioperative risk of double-valve implantation. A reliable hypothesis might be that, in Switzerland, where there is a high density of follow up cardiologists, patients with DVR are followed more intensively than others, as a greater number of complications due to anticoagulation are anticipated.

Study limitations

The present study was a retrospective analysis of patients operated on over a period of 11 years, and consequently, by examining the patient files, the possibility of a totally homogeneous evaluation could not be anticipated. In addition, and especially for mechanical prostheses, the decision of which prosthesis should be implanted was always made intraoperatively by the surgeon. Thus, the composition of both groups was influenced by this fact and became more coincidental.

In conclusion, based on the authors' experience between 1993 and 2003, both SJM and ATS bileaflet prostheses provide very low incidences of adverse events and valve-related complications, and both can be recommended for mechanical valve replacement.

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