COMPARATIVE RESULTS WITH THE ST. JUDE MEDICAL AND MEDTRONIC HALL MECHANICAL VALVES

This study compared the clinical performance of the St. Jude Medical and Medtronic Hall mechanical valves in isolated aortic or mitral valve replacement. From 1984 to 1993, 349 St. Jude Medical valves (aortic 237, mitral 112) and 465 Medtronic Hall valves (aortic 272, mitral 193) were implanted in 814 patients at the University of Ottawa Heart Institute. The patients had similar preoperative characteristics. The hospital mortality rate for aortic valve replacement was 3.4% with the St. Jude Medical valve and 5.8% with the Medtronic Hall valve ($p = 0.26$) and the rate for mitral valve replacement was 8.9% with the St. Jude Medical valve and 11.9% with the Medtronic Hall valve ($p = 0.54$). Actuarial estimates of survival and freedom from complications were calculated. At 5 years the actuarial probability of survival (including hospital deaths) for aortic valve replacement was $86\% \pm 3\%$ with the St. Jude Medical valve and $68\% \pm 4\%$ with the Medtronic Hall valve ($p = 0.0001$) and for mitral valve replacement was $75\% \pm 7\%$ with the St. Jude Medical valve and $70\% \pm 4\%$ with the Medtronic Hall valve ($p = 0.54$). The most common cause of late death was cardiac failure and no deaths were caused by structural failure. The 5-year probability of freedom from bleeding after aortic valve replacement was $99\% \pm 1\%$ with the St. Jude Medical valve and $95\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.06$) and after mitral valve replacement $99\% \pm 1\%$ with the St. Jude Medical valve and $97\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.37$). The 5-year probability of freedom from thromboembolism after aortic valve replacement was $88\% \pm 4\%$ with the St. Jude Medical valve and $81\% \pm 3\%$ with the Medtronic Hall valve ($p = 0.08$) and after mitral valve replacement was $85\% \pm 7\%$ with the St. Jude Medical valve and $77\% \pm 5\%$ with the Medtronic Hall valve ($p = 0.17$). Reoperation was uncommon and there were no cases of structural valve failure. The 5-year actuarial estimate of freedom from reoperation therefore for aortic valve replacement was $99\% \pm 1\%$ with the St. Jude Medical valve and $96\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.09$) and for mitral valve replacement was $98\% \pm 2\%$ with the St. Jude Medical valve and $95\% \pm 3\%$ with the Medtronic Hall valve ($p = 0.40$). We concluded that the St. Jude Medical and Medtronic Hall mechanical valves offered similar clinical performance in isolated aortic or mitral valve replacement. (J THORAC CARDIOVASC SURG 1995;110:663-71)

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The St. Jude Medical and Medtronic Hall mechanical heart valves (St. Jude Medical, Inc., St. Paul, Minn.; Medtronic, Inc., Minneapolis, Minn.) were introduced for clinical use in 1977 and 1978, respec-

tively. The bileaflet construction of the former and the tilting-disc assembly of the latter purportedly offer specific hemodynamic advantages. Although controversy exists as to the relative merits of each clinically, there are few studies from a single center that compare these two prostheses. We report a study of the relative clinical performances of these two mechanical valves in the setting of isolated aortic valve replacement (AVR) or mitral valve replacement (MVR).

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Patients and methods

From May 1984 to December 1993, 349 St. Jude Medical and 465 Medtronic Hall mechanical valves were implanted in 814 patients at the University of Ottawa Heart Institute. There were 509 single valve replacements in the aortic position of which 237 were done with the St. Jude Medical valve and 272 were done with the Medtronic Hall valve. There were 305 single valve replacements in the mitral position of which 112 were done with the St. Jude Medical valve and 193 were done with the Medtronic Hall valve.

The choice of valve was made at the surgeon's discretion and the surgical technique and follow-up were similar for all patients. In general each surgeon used one brand throughout the study period. Operative technique included cardiopulmonary bypass with moderate hypothermia, topical cooling with saline solution, and cold crystalloid cardioplegic solution administered in the antegrade fashion. The implantation technique consisted of the use of interrupted horizontal mattress sutures reinforced with Teflon pledgets. Warfarin sodium administration was started within 72 hours after operation. During the initial years of the study the target prothrombin time ratio was 1.5 to 2.0 and most recently the target International Normalized Ratio (INR) was set at 2.5 to 3.5. Regulation of anticoagulation therapy after discharge from the hospital was by the patient's family physician or cardiologist after initial stabilization of the therapeutic results by the surgeon.

Follow-up. All patients who underwent valve replacement were registered with the Valve Clinic of the Ottawa Heart Institute. Survivors were evaluated annually and the closure date for this study was March 1, 1994. Of the 814 patients, 12% were considered lost to follow-up. There were 1172 patient-years of follow-up for the AVR group and 599 patient-years of follow-up for the MVR group.

Statistical analysis. Data are presented in strict accordance with the Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations.¹ In addition we further defined major bleeding according to these Guidelines (as bleeding that caused death, stroke, operation, or hospitalization or that necessitated transfusion) and all other bleeding as minor.

Comparisons between the preoperative characteristics of the patient groups were made by the χ^2 test or Fisher's exact test where appropriate for discrete variables and Student's *t* test for continuous variables. Late survival (freedom from death) and event-free probabilities were calculated by means of the life-table technique with SPSS statistical data analysis software (SPSS Inc., Chicago, Ill.) and are reported with 95% confidence limits. Comparisons between groups were made with the formula

$$z = \frac{P_x - P'_x}{\sqrt{(SE[P_x])^2 + (SE[P'_x])^2}}$$

which is defined in Colton.² Results were considered statistically significant at the $p < 0.05$ level.

Results

Clinical characteristics. In both the AVR and MVR groups the average age of the patients at the time of implantation was similar: in the AVR group it was 58.5 ± 0.9 years in patients with the St. Jude Medical valve and 57.8 ± 0.8 years in patients with the Medtronic Hall valve ($p = 0.31$) and in the MVR group it was 58.2 ± 1.2 years in patients with the St. Jude Medical valve and 57.9 ± 0.9 years in patients with for the Medtronic Hall valve ($p = 0.49$). In the AVR group the proportion of male patients was 70% for the St. Jude Medical valve and 68% for the Medtronic Hall valve ($p = 0.70$), whereas in the MVR group there was a greater proportion of female patients in the Medtronic Hall valve group (67%) than in the St. Jude Medical valve group (56%) ($p = 0.04$). In the AVR group previous valve operations had been done in 23% of patients who received the St. Jude Medical valve and 34% of the patients who received the Medtronic Hall valve ($p = 0.005$), whereas in the MVR group previous operations had been done in 30% of the St. Jude Medical valve group and 32% of the Medtronic Hall valve group ($p = 0.80$).

Concomitant operations were done in 22% of patients: in the AVR group in 27% of patients receiving the St. Jude Medical valve and 21% receiving the Medtronic Hall valve ($p = 0.19$) and in the MVR group in 22% of patients receiving the St. Jude Medical valve and 16% receiving the Medtronic Hall valve ($p = 0.22$). Coronary artery bypass was the most common associated procedure, being and it was done in 93% of patients with a similar distribution among all four groups.

Before operation most patients were in New York Heart Association functional class III or IV. For AVR this included 60% and 66% ($p = 0.17$) and for MVR 68% and 68% ($p = 0.99$) of patients with the St. Jude Medical valve and Medtronic Hall valve, respectively. After operation, however, few were in class III or IV. For AVR this included 7% and 8% ($p = 0.81$) and for MVR 9% and 9% ($p = 0.84$) of patients with the St. Jude Medical valve and Medtronic Hall valve, respectively (Table I).

Hospital mortality. Among the patients having AVR there were 8 hospital deaths in patients with the St. Jude Medical valve (3.4%) and 16 hospital deaths in patients with the Medtronic Hall valve (5.8%) ($p = 0.26$). In the MVR group there were 10 deaths in patients with the St. Jude Medical valve (8.9%) and 23 in patients with the Medtronic Hall valve (11.9%) ($p = 0.53$). In the AVR group a

Table I. Preoperative characteristics of the patient groups

	AVR			MVR		
	St. Jude Medical	Medtronic Hall	<i>p</i> Value	St. Jude Medical	Medtronic Hall	<i>p</i> Value
No. of patients	237	272		112	193	
Mean age (yr)	58.5 ± 0.9	57.8 ± 0.8	0.31	58.2 ± 1.2	57.9 ± 0.9	0.49
Sex ratio (male/female)	165/72	184/88	0.70	49/63	63/130	0.04
Previous valve operation	54 (23%)	93 (34%)	0.005	34 (32%)	61 (32%)	0.80
Concomitant operation	63 (27%)	58 (21%)	0.19	25 (22%)	31 (16%)	0.22
NYHA functional class III/IV	142 (60%)	180 (66%)	0.17	76 (68%)	131 (68%)	0.99

NYHA, New York Heart Association.

previous operation did not affect hospital survival. Patients having a first operation had a mortality rate of 3.6% compared with 7.4% for those having previous operations ($p = 0.10$). Similarly in the MVR group gender did not influence early survival. Male patients had a mortality rate of 13.4% compared with 8.6% for female patients ($p = 0.26$). No deaths in either group were directly attributable to prosthetic valve failure. Autopsy was done in 61% of deaths in patients who received a St. Jude Medical valve and 67% of deaths in patients who received a Medtronic Hall valve. Major causes of death included myocardial dysfunction (St. Jude Medical valve 8, 44%; Medtronic Hall valve 15, 38%), bleeding (St. Jude Medical valve 1, 6%; Medtronic Hall valve 7, 18%), multiorgan failure (St. Jude Medical valve 3, 17%; Medtronic Hall valve 3, 8%), sudden death (arrhythmia) (St. Jude Medical valve 0; Medtronic Hall valve 4, 10%), and stroke (St. Jude Medical valve 0; Medtronic Hall valve 2, 5%). In addition two patients (11%) having MVR with the St. Jude Medical valve died primarily of technical problems at the time of operation, including one patient with left ventricular rupture and one with atrioventricular disruption. Technical problems caused death in six patients (15%) who received the Medtronic Hall valve including left ventricle-to-right atrium fistula in three patients having MVR, aortic dissection in two patients having AVR, and ventricular septal defect in one patient having AVR.

Late survival. There were a total of 51 late deaths recorded after AVR: 12 in patients receiving the St. Jude Medical valve and 39 in patients receiving the Medtronic Hall valve. Cardiac failure, not related to prosthetic valve dysfunction, was the most common cause of these late deaths, accounting for 33% and 41%, respectively, of these late deaths. Valve-related deaths accounted for three late deaths in the group having AVR with the St. Jude Medical valve and six late deaths in the group having AVR with

the Medtronic Hall valve. These included death from thromboembolism, endocarditis, or hemorrhage. The actuarial probability of survival to 5 years after AVR with the St. Jude Medical valve was $86\% \pm 3\%$ and $68\% \pm 4\%$ after AVR with the Medtronic Hall valve ($p = 0.0001$) (Fig. 1).

After MVR there were a total of 28 late deaths, 8 in patients with the St. Jude Medical valve and 20 in patients with the Medtronic Hall valve. Deaths as a result of cardiac failure accounted for 25% and 50%, respectively, of these late deaths. There was 1 valve-related late death in the former group and 2 in the latter. Therefore the actuarial probability of survival to 5 years after MVR with the St. Jude Medical valve was $75\% \pm 7\%$ and $70\% \pm 4\%$ with the Medtronic Hall valve ($p = 0.54$) (Fig. 2).

Morbidity. Bleeding was identified in 5 patients after AVR with the St. Jude Medical valve and in 19 patients after AVR with the Medtronic Hall valve. Major bleeding after AVR with the St. Jude Medical valve was seen in 1 patient who died and in 8 after AVR with the Medtronic Hall valve, 2 of whom died. The actuarial freedom from major bleeding at 5 years therefore for AVR was $99\% \pm 1\%$ with the St. Jude Medical valve and $95\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.06$). Bleeding after MVR was seen in 3 patients with the St. Jude Medical valve and 9 patients with the Medtronic Hall valve. Major bleeding was seen in 1 of the former and 4 of the latter patients, with no deaths. The 5-year actuarial freedom from major bleeding after MVR therefore was $99\% \pm 1\%$ with the St. Jude Medical valve and $97\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.37$). Thromboembolism was noted in 13 patients (15 events) after AVR with the St. Jude Medical valve and in 34 (42 events) after AVR with the Medtronic Hall valve. After AVR with the St. Jude Medical valve there were 14 neurologic events, consisting of a transient ischemic attack (TIA) in 10 patients (12 events) and a stroke

Fig. 1. Actuarial survival (freedom from death): AVR. *SJM-AVR*, AVR with the St. Jude Medical valve; *MH-AVR*, AVR with the Medtronic Hall valve.

Fig. 2. Actuarial survival (freedom from death): MVR. *SJM-MVR*, MVR with the St. Jude Medical valve; *MH-MVR*, MVR with the Medtronic Hall valve.

(CVA) in 2 patients. Peripheral embolism occurred in 1 patient. There were no deaths as a result of these complications in this group. After AVR with the Medtronic Hall valve 21 patients had TIA (29 events) and 12 a stroke (12 events). One patient had a myocardial infarction thought to be embolic in origin. Death occurred in 2 of these patients as a result of stroke. The 5-year actuarial freedom from

thromboembolism after AVR was $88\% \pm 4\%$ with the St. Jude Medical valve and $81\% \pm 3\%$ with the Medtronic Hall valve ($p = 0.08$) (Fig. 3). Of the patients having AVR with the St. Jude Medical valve who had emboli 78% (10) were in sinus rhythm, whereas 85% (29) of the patients having AVR with the Medtronic Hall valve were in sinus rhythm.

Fig. 3. Actuarial freedom from thromboembolism: AVR. *SJM-AVR*, AVR with the St. Jude Medical valve; *MH-AVR*, AVR with the Medtronic Hall valve.

Fig. 4. Actuarial freedom from thromboembolism: MVR. *SJM-MVR*, MVR with the St. Jude Medical valve; *MH-MVR*, MVR with the Medtronic Hall valve.

Thromboembolism was seen after MVR in 6 patients (7 events) with the St. Jude Medical valve and 22 patients (32 events) with the Medtronic Hall valve. In the former this consisted of TIA alone in 3 patients (3 events) and a CVA in 2 patients (2 events). One patient had a TIA followed by a CVA. There was 1 death that occurred after a stroke. After MVR with the Medtronic Hall valve 15 patients had TIA alone (20 events) and 3 patients had CVA

alone (5 events). Three patients had TIA followed by CVA and 1 patient had a peripheral embolism. There were no deaths in this group caused by thromboembolism. The 5-year actuarial freedom from thromboembolism after MVR therefore was $85\% \pm 7\%$ with the St. Jude Medical valve and $77\% \pm 5\%$ with the Medtronic Hall valve ($p = 0.17$) (Fig. 4). Of the patients having MVR with the St. Jude Medical valve who had emboli none (0%) were

Fig. 5. Actuarial freedom from reoperation: AVR. *SJM-AVR*, AVR with the St. Jude Medical valve; *MH-AVR*, AVR with the Medtronic Hall valve.

in sinus rhythm, whereas of the patients having MVR with the Medtronic Hall valve who had emboli only 36% (8) were in sinus rhythm.

Endocarditis was identified in 13 patients after AVR: 4 in the St. Jude Medical valve group and 9 in the Medtronic Hall valve group. There were 2 deaths in each group as a result of this complication. The 5-year actuarial freedom from endocarditis after AVR was $97\% \pm 1\%$ with the St. Jude Medical valve and $94\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.09$). Endocarditis was identified in 6 patients after MVR: 2 in the St. Jude Medical valve group and 4 in the Medtronic Hall valve group. There were 2 deaths as a result of this complication, both in the latter group. At 5 years the actuarial freedom from endocarditis after MVR was $97\% \pm 2\%$ with the St. Jude Medical valve and $96\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.72$).

Reoperation after discharge was uncommon with either valve in either position. There were no cases of structural dysfunction in this study. Reoperation was required for two patients having AVR with the St. Jude Medical valve and seven patients having AVR with the Medtronic Hall valve. Both patients in the former group required reoperation because of prosthetic valve endocarditis and there was one resultant death. In the latter group reoperation was required because of endocarditis in three patients, nonstructural failure (paravalvular leaks) in two, and iatrogenic ventricular septal defect in one case

and in one patient where there was thought to be a high transvalvular gradient. There was only one death among these patients, and it occurred in the patient with a ventricular septal defect in whom multiorgan failure developed after-operation. The 5-year actuarial freedom from reoperation in patients having AVR was $99\% \pm 1\%$ with the St. Jude Medical valve and $96\% \pm 2\%$ with the Medtronic Hall valve ($p = 0.09$) (Fig. 5).

Reoperation was required in one patient receiving MVR with the St. Jude Medical valve and in six patients receiving MVR with the Medtronic Hall valve. The former patient required reoperation because of endocarditis and survived. In the latter group three patients required reoperation because of endocarditis, one because of nonstructural failure, and one because of recurrent TIAs and one required transplantation because of terminal heart failure. Death occurred in two of the patients who had reoperation because of endocarditis. The 5-year actuarial freedom from reoperation after MVR therefore was $98\% \pm 2\%$ with the St. Jude Medical valve and $95\% \pm 3\%$ with the Medtronic Hall valve ($p = 0.40$) (Fig. 6).

Discussion

The St. Jude Medical and the Medtronic Hall prosthetic valves remain the most widely used mechanical valves in North America. Although a number of authors have reported their experience with

Fig. 6. Actuarial freedom from reoperation: MVR. *SJM-MVR*, MVR with the St. Jude Medical valve; *MH-MVR*, MVR with the Medtronic Hall valve.

one of these valves, there are few studies from a single center that compare the relative efficacy of both. This may be important because referral patterns may vary from one institution to another, as may operative techniques and postoperative management, which often makes comparisons difficult.

Though the hospital mortality reported here was lower for AVR with the St. Jude Medical valve this difference did not reach statistical significance. Before operation both groups of patients having AVR were similar though there was a greater proportion of reoperations in the group having AVR with the Medtronic Hall valve. In this study previous operation was not a risk factor for hospital mortality after AVR. Factors that have previously been noted as independent determinants of survival for AVR have included the urgency of operation, the presence of endocarditis, previous valve operation, concurrent coronary artery disease, and patient age.^{3,4} Previously reported hospital mortality rates for AVR with the St. Jude Medical valve have been 2.4%,⁴ 3.2%,⁵ 3.6%,⁶ 5.2%,⁷ 5.8%,⁸ and 7%.⁹ For AVR with the Medtronic Hall valve early mortality rates of 1.7%,¹⁰ 3.8%,¹¹ 4.2%,¹² and 9.3%¹³ have been reported. The hospital mortality rate reported here was lower for MVR with the St. Jude Medical valve but again this did not reach statistical significance. In this study there was a greater proportion of female patients in the group having MVR with the Medtronic Hall valve; however, this was not a risk factor for early

death. Independent determinants of survival for MVR from previous studies have included urgency, endocarditis, coronary disease, age, and ventricular function.^{3,4} Gender, however, was also not a risk factor in these studies. Operative mortality rates of 4.3%,³ 4.7%,⁶ 7.4%,⁸ 8%,⁹ 9.9%,⁵ and 11.9%⁷ have been reported for MVR with the St. Jude Medical valve and 7.5%,¹¹ 7.8%,¹³ 8.4%,¹⁰ and 13.1%¹² for MVR with the Medtronic Hall valve.

Anthunes,¹⁴ in 1990, reported the results of a prospective randomized comparison of the St. Jude Medical and Medtronic Hall valves. This study of isolated MVR and AVR did not include patients who had previous valvular operations and it grouped the aortic and mitral valve results together. The hospital mortality rate in that study was 3.2% (3 patients) for the 89 patients receiving the St. Jude Medical valve and 5.7% (5 patients) for the 80 patients receiving the Medtronic Hall valve. Similarly a 1992 prospective randomized study by Fiore and associates¹⁵ compared the results of MVR with the St. Jude Medical and Medtronic Hall valves. The hospital mortality rate in that study, however, was higher for the 55 patients receiving a St. Jude Medical valve than for the 47 patients receiving a Medtronic Hall valve at 14.5% (8 patients) and 10.6% (5 patients), respectively. The early survival differences noted in both of these studies, however, did not reach statistical significance at the 0.05 level possibly because of the study sizes.

We have detected a late survival advantage with the St. Jude Medical valve for isolated AVR or MVR at 5 years; this difference only reaches statistical significance with the former. Beyond 5 years the number of patients at risk in this study is small, which makes comparisons inappropriate. Actuarial 5-year estimates of survival of $71\% \pm 3\%$,⁷ 78% ,⁴ $78\% \pm 4\%$,⁵ and 96% ¹⁶ for AVR with the St. Jude Medical valve and $70\% \pm 6\%$,¹² $72\% \pm 5\%$,¹³ 82% ,¹¹ and 89% ¹⁰ for AVR with the Medtronic Hall valve have previously been reported. Survival estimates of $59\% \pm 4\%$,⁷ $64\% \pm 9\%$,⁵ 78% ,⁴ and 88% ¹⁶ for MVR with the St. Jude Medical valve and $67\% \pm 6\%$,¹² $72\% \pm 5\%$,¹³ 74% ,¹¹ and 79% ¹⁰ for MVR with the Medtronic Hall valve have also been reported. In the study by Fiore and associates¹⁵ the 3-year survival was lower for MVR with the St. Jude Medical valve ($79\% \pm 5\%$) than for MVR with the Medtronic Hall valve ($87\% \pm 5\%$). Anthunes¹⁴ also found a lower 5-year survival with St. Jude Medical valves ($74\% \pm 6\%$) than Medtronic Hall valves ($88\% \pm 5\%$) despite the higher hospital mortality rate with the latter. Late survival is dependent on many factors related to the individual patients' disease and to the complications of the prostheses. Most deaths in our study were a result of cardiac failure and were not related to prosthetic valve dysfunction or failure or its attendant complications.

At 5 years we could not detect large differences between these two valves in freedom from complications. In all cases, however, the actuarial estimate was higher with the St. Jude Medical valve for either AVR or MVR, though the differences were not significant statistically. The actuarial freedom from thromboembolism was higher for the St. Jude Medical valve in both the aortic and mitral positions in this study. The 5-year freedom from thromboembolism after AVR with the St. Jude Medical valve has previously been reported at $88\% \pm 3\%$,⁷ 92% ,⁴ $92\% \pm 4\%$,⁵ and $97\% \pm 6\%$ ⁸ and after AVR with the Medtronic Hall valve at $82\% \pm 4\%$,¹³ $92\% \pm 3\%$,¹² and 95% .¹⁰ After MVR with the St. Jude Medical valve 5-year actuarial estimates have been reported at 85% ,⁴ $89\% \pm 5\%$,⁵ $92\% \pm 2\%$,⁷ and $99\% \pm 1\%$ ⁸ and after MVR with the Medtronic Hall valve at $85\% \pm 8\%$,¹² $89\% \pm 3\%$,¹³ and 94% .¹⁰ Clearly the occurrence of thromboemboli and bleeding after heart valve replacement is related to the level of anticoagulation, which varies among studies. In our study the target levels of anticoagulation were the same for both the St. Jude Medical and Medtronic Hall valves. However, beyond the

initial few weeks required for stabilization, control of anticoagulation was not centralized. Further, we do not have complete records of the actual level of prothrombin time or INR at the time of thromboembolism. Current recommendations are for a target INR of 2.5 to 3.5 for all mechanical valves.¹⁷ The comparative study by Anthunes¹⁴ did not detect a statistically significant difference in freedom from thromboembolism at 5 years between the St. Jude Medical valve ($92\% \pm 4\%$) and the Medtronic Hall valve ($89\% \pm 4\%$) with a prothrombin index of 35% to 45%. Similarly although there was an apparent advantage with the St. Jude Medical valve in the rate of thromboembolism at 3 years in the study of Fiore and associates¹⁵ ($98\% \pm 2\%$ versus $88\% \pm 6\%$) in which a prothrombin ratio of 1.5 was used this did not reach statistical significance.

Serious bleeding was uncommon in our study with less bleeding noted with St. Jude Medical valves in both aortic and mitral positions. Previous studies have reported the freedom from hemorrhage after AVR with the St. Jude Medical valve to be $89\% \pm 2\%$,⁷ 94% ,⁴ and $98\% \pm 2\%$ ⁵ and that after AVR with the Medtronic Hall valve to be 100% .¹² After MVR with the St. Jude Medical valve freedom from hemorrhage has been reported as 87% ,⁴ $97\% \pm 3\%$,⁵ and $92\% \pm 2\%$ ⁷ and after MVR with the Medtronic Hall valve 100% .¹² One study grouped AVR and MVR with the Medtronic Hall valve and reported a combined 5-year estimate of $98\% \pm 1\%$.¹³ Anthunes¹⁴ did not find any cases of serious bleeding with either valve in either position, whereas Fiore and associates¹⁵ did not detect any large differences in bleeding between MVR with the St. Jude Medical valve and the Medtronic Hall valve ($91\% \pm 5\%$ versus $94\% \pm 4\%$) with a target prothrombin ratio of 1.5.

As in most previous reports we noted a low rate of endocarditis with little difference between the two valves. Arom and colleagues⁵ reported a 6-year actuarial freedom from endocarditis of $99\% \pm 2\%$ for AVR with the St. Jude Medical valve and $99\% \pm 1\%$ for MVR with the Medtronic Hall valve. Similarly Keenan and associates¹² reported 5-year estimates of $96\% \pm 2\%$ for AVR with the Medtronic Hall valve and $99\% \pm 2\%$ for MVR with the Medtronic Hall valve. Reoperation in our short-term follow-up study was also uncommon, which attests to the similar durability of these valves. Of note, there were no cases of structural failure in our series.

In summary, the results obtained from this study indicate that the St. Jude Medical and the Medtronic

Hall prostheses offer similar excellent clinical performance for both AVR and MVR. Although our results suggest an advantage in favor of the St. Jude Medical valve both in terms of survival and complications these differences await further clarification with more patients followed up for a longer period of time.

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