Twenty-Five–Year Experience With the Medtronic-Hall Valve Prosthesis in the Aortic Position

A Follow-Up Cohort Study of 816 Consecutive Patients

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Background—The Medtronic-Hall valve was developed and for the first time implanted in Oslo, Norway, in 1977. A total of 1104 patients received this valve at Rikshospitalet from 1977 to 1987. In the present study, we followed up on all 816 patients undergoing aortic valve replacement over a 25-year period.

Methods and Results—This is a retrospective cohort analysis of 816 consecutive patients undergoing aortic valve replacement with the Medtronic-Hall valve at Rikshospitalet, Oslo, Norway, from 1977 to 1987. All patients were contacted by means of questionnaires or telephone. Data were checked against hospital databases and medical records. Date of death was verified by the Norwegian civil registry. Follow-up was 99.6% complete. Survival analysis included operative deaths as well as late deaths. Survival at 25 years was 24.9%. No mechanical failures were found. Valve thrombosis was seen in 4 patients, in 1 case combined with pannus formation. Small valves (20 mm to 21 mm) were associated with reduced survival; however, when controlled for the confounding effects of age and gender, valve size did not remain a significant risk factor. Patient-related factors were important: Older age, female gender, and the need for concomitant coronary artery bypass surgery significantly reduced survival, whereas surgery of the ascending aorta did not. Linearized rates of thromboembolic complications, warfarin-related bleeding, and endocarditis were 1.5%, 0.7%, and 0.16%/patient-year, respectively. At follow-up, 79% of the patients were in New York Heart Association classes I to II.

Conclusions—This study confirms the excellent long-term outcome for patients with Medtronic-Hall valves in the aortic position.

Key Words: heart diseases ▪ prosthesis ▪ heart valves

The Medtronic-Hall (MH) tilting valve disk was first implanted in Oslo, Norway, in June 1977. From 1977 to 1987, the valve was used as the only valve of choice and was inserted in a total of 1104 consecutive patients at our department.

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The MH valve is made of a single piece of titanium with no welds. The disk is made of tungsten-impregnated graphite with a carbon pyrolytic coating. The tungsten renders the disk radiopaque. In the aortic position, the maximal opening is 75°. A central aperture in the disk allows free rotation. The valve is rotatable in the sewing ring. The sewing ring is made of Teflon. Aortic sizes are 20 to 31 mm (outer diameter).

The initial clinical results were published in 1979. The cohort of patients has been followed up and analyzed at 5, 10, and 15 years. In the present study we report our 25-year follow-up data for the 816 patients undergoing aortic valve replacement (AVR) with special reference to survival, functional status, valve-related complications, and the impact of concomitant surgery.

Methods

Of the total cohort of 1104 patients, 816 underwent AVR. The inclusion criteria for the requirement of AVR followed the generally accepted criteria at that time: aortic stenosis with transvalvular pressure gradient >50 mm Hg with or without regurgitation or pure aortic regurgitation of hemodynamic importance. The study included 577 male and 239 female subjects, with mean ages of 54.3±13.6 and 58.7±11.5 years, respectively. Age range was 6.3 to 77.2 years. Figure 1 gives the age distribution at the time of operation, showing that the large majority of patients were aged >50 years. A total of 216 underwent concomitant major cardiac surgery, including aorto-coronary bypass in 139 patients, aortic surgery in 46 patients (conduits, grafts, or transannular patches), resection of subaortic stenosis in 17 patients, resection of a left ventricular aneurysm in 10 patients, and various other procedures in 4 patients. These patients have been included in the actuarial survival analysis.
In addition, patients who underwent repair of 1 valve in addition to AVR were included in this analysis. Of the 816 operations, 35 had undergone previous heart surgery. Closing date was May 1, 2005. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript as written.

Operative Technique
The patients were operated on under conditions of moderate hypothermia, local cooling, and St Thomas Hospital cardioplegia. The prosthesis was in most cases implanted with interrupted Dacron sutures with the large valvular opening oriented toward the noncoronary cusp. The largest valve size possible was preferably implanted. In 700 patients it was possible to use the larger valve sizes, with external diameter varying from 23 to 31 mm, and in 116 patients the smallest valve sizes were used, with external diameter varying from 20 to 21 mm. The former group of patients were younger than the latter, with mean age 54.8±13.0 years versus 60.2±13.2 years, and had a higher male-to-female ratio (79% versus 21%).

Anticoagulation Therapy
Anticoagulation therapy was initiated on the first postoperative day by parenteral administration of warfarin and was continued lifelong by parenteral administration of warfarin and was continued lifelong. Anticoagulation therapy was controlled by the TT method (Nycomed, Oslo, Norway), with the ideal target being 12% to 7%, corresponding to an international normalized ratio of 2.5 to 3.5.

Follow-Up
The standardized questionnaire on quality of life previously used in connection with the 1-, 5-, 10-, and 15-year follow-up studies was sent to all patients. Hospital records were scrutinized for valve-related complications.

Thromboembolism was defined as any sudden, focal neurological deficit persisting for >1 hour or the occurrence of any sudden symptoms related to obstruction of a systemic artery. Thrombotic obstruction of the prosthesis was defined as any thrombotic material impeding free movement of the disk. Anticoagulation-related hemorrhage included any nontraumatic bleeding necessitating hospital admission or blood transfusions. Periprosthetic leak included all paravalvular fistulas that necessitated reoperation. Mechanical valve failure was defined as any case of mechanical rupture of the valve. Prosthetic valve endocarditis was defined as any infection of the prosthesis documented by blood cultures, reoperation, or autopsy.

Statistical Analysis
Survival analysis was performed by the Kaplan-Meier method. Survival analysis included operative deaths as well as late deaths. Comparison of our cohort of AVR patients with the mortality of the total Norwegian population matched by age, gender, and time period was performed with the standard mortality ratio method. Comparison of survival was done with the use of Breslow and Mantel-Cox test statistics. Independent risk factors of mortality were estimated by the Cox regression model. Complications were expressed as linear rates. Comparison of linear rates was completed with a likelihood ratio test.

Study Limitation
Because this study began many years before the guidelines for reporting on valve mortality and morbidity were defined, our original definitions may deviate to some degree from the present definitions. During the first 10 years of our study, all incidents of morbidity (eg, thromboembolism, valve, thrombosis, bleeding, leak, endocarditis) were counted; however, the date of the incidents was not always stored. For this reason, only linear rates of mortality are given. Because of older age and the mental condition or physical handicap of patients (such as hip arthrosis), the functional class could not be assessed in 15 of 227 patients still alive at follow-up.

Strength of the Study
All patients have been operated on at our department and have been followed up for 25 years by the same group. Death dates could be verified from the Norwegian civil registry. A standard questionnaire was sent to the patients 1, 3, 5, 10, 15, 20, and 25 years after surgery. In the case of lack of a response, telephone interviews were performed. Collection of data ended on May 1, 2005. Three patients were lost to follow-up, and therefore follow-up was 99.6% complete and included a total of 10 805 patient-years. Average follow-up time was 13.2±8.2 years.

Results
Survival
Early mortality was 5.6%. The number of patients alive gradually decreased during the time of observation (Figure 2). A total of 227 patients were alive at follow-up. Cumulative survival at 25 years was 24.9%. During follow-up, 395 male patients and 190 female patients died. The expected numbers of deaths, based on Norwegian population statistics for an age- and gender-matched population, were 167 and 49, respectively. The standard mortality ratio was 2.36±0.12 for men and 3.93±0.28 for women. The observed rates of death were higher than expected for all age groups. Further analysis showed that several factors were important for the long-term prognosis.

Age
Survival was related to age at the time of operation (Figure 3). The youngest age group was characterized by a 94% survival for the first 15 years of follow-up, whereas the middle-aged
and elderly patients showed a gradual decrease in survival recognizable during the whole observation period. The difference between the 3 age groups was significant during the whole observation period.

**Gender**
A comparison between male versus female patient survival showed the same pattern of a gradual decrease in survival with time but with a significantly better survival in the male population: 25.4±2.3% versus 16.3±2.8% at 25-year follow-up (Figure 4).

**Valve Size**
During the whole observation period, significantly better survival was seen in patients with the largest valve sizes of 22 to 31 compared with the smallest valve sizes of 20 to 21, with a 26.8±1.9% survival in the former group at 25-year follow-up compared with a 13.9±3.5% survival in the latter (Figure 5). However, patients receiving small valves were more often female and were older. When age and gender were controlled for their confounding effect by the Cox regression model, valve size did not remain a significant risk factor for survival. Thereby, the risk ratio for the smaller valve sizes was reduced from risk ratio=1.48 (95% confidence interval, 1.2 to 1.9; \( P=0.0001 \)) to risk ratio=1.02 (95% confidence interval, 0.8 to 1.3; \( P=0.83 \)).

**Concomitant Coronary Artery Bypass Graft**
Survival was significantly better in those who did not receive coronary artery bypass graft (CABG) surgery versus the 140 patients who needed CABG surgery at the time of valve prosthesis insertion: 27.7±1.9% versus 11.0±3.1% at 25-year follow-up (Figure 6).

**Ascending Aortic Surgery**
Twenty-four patients received a Dacron graft to replace the ascending aorta, and 22 patients underwent enlargement of the aortic annulus. The 20-year survival for these 2 groups (37.5±9.0% and 48.2±9.6%, respectively) did not differ significantly from the rest of the population (not enough patients were at risk for a 25-year analysis).

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**Functional Class**
On the basis of the questionnaires, we were able to estimate New York Heart Association (NYHA) functional class in 212 of the 227 patients alive at follow-up (Figure 7). A total of 121 patients (57%) were without dyspnea or angina pectoris at rest or during exercise (NYHA class I); another 56 (22%) had dyspnea or angina pectoris during more strenuous exercise (NYHA class II), and the remaining 17% had significant symptoms during moderate exercise or at rest (NYHA class III to IV).

**Morbidity**
Various serious complications are shown in Figure 8.

No incidents of mechanical valve failure occurred. A total of 159 thromboembolic events were reported (1.5 events per 100 patient-years). Valve thrombosis was seen in 4 patients...
Age

Age at the time of the operation is the strongest predictor of long-term survival. As might be expected, the older the patients are at the time of implantation, the less 25-year survival is to be expected. The relatively small group of patients aged <18 years at the time of operation had almost no mortality for the first 15 years after operation, with a drop in survival to 88% after 20 years. For patients aged >18 years at the time of operation, survival curves show a gradual decline, recognizable within 5 years after operation and continuing for the whole observation period. This decline was more pronounced in those aged >70 years at the time of operation than in those in the group aged 16 to 70 years. One reason for this is of course the length of normal life (ie, “the more years one has lived, the shorter time is left”). Obviously, factors other than those related to age are also of importance for the long-term outcome. Older patients are more likely to have clinically significant associated comorbid conditions at the time of operation that are known to adversely affect survival after AVR failure. Thus, previous studies indicate that patient characteristics at baseline are of more importance as determinants of late mortality after valve replacement than the choice of prosthesis. Some of these factors are also elucidated in the present study.

Gender

During the whole observation study, male patients had better survival rates than female patients; the difference was significant with cumulative survival of 25% versus 16%, respectively, up to 25 years after operation. Some previous studies did not reveal gender to be of significance, and in 1 study male gender appeared to be a risk factor.

Valve Size

Although reduction in the natural valve area after valve prosthesis insertion is usually mild to moderate in severity and is regarded of no immediate clinical significance, patients with the largest valve sizes (23 to 31) have been reported to have a better prognosis than those with the smallest valve sizes of 20 to 21. This might indicate that the smallest valve sizes represent a hazard to the life of the patients because of an anticipated higher transvalvular gradient. This, however, is less likely because hemodynamic studies with the MH prosthesis have shown small and hemodynamically acceptable gradients even in the smallest valve sizes, which may represent an alternative to root enlargement. The interpretations of our findings are, however, rather complex because patients with the smallest valve sizes tended to be
older and included more female patients than those with the largest valve sizes. Both factors are known to affect long-term survival. However, when we performed a multivariate analysis correcting for gender and age, the risk ratio for the smaller valve sizes was reduced from risk ratio = 1.48 to risk ratio = 1.02, indicating that the risk of survival was the same in those with the large valve prosthesis as in those with the smallest valve sizes. This also means that the smallest MH valve prosthesis has an effective prosthetic valve area considered comparable to that of a normal human valve when inserted into a patient of appropriate body size and that the poorer survival seen in patients with the smallest valve sizes seen in our study can be attributed to the fact that they were representing a population older than those who received the larger valve sizes. In a randomized study, Fiore et al. could not detect any difference in performance when comparing the St Jude and the MH valves.

Concomitant CABG

The present study shows that associated CABG surgery adversely affected survival. Associated CABG has been shown to represent an independent predictor of mortality. In the study of Connolly et al., the 5-year survival was 69% for patients without coronary artery disease and 39% for those with significant coronary artery disease. Our data at 10 years were 63.7% and 51.3%, respectively (Figure 4).

Concomitant Ascending Aorta Surgery

The good long-term survival for this group of patients was surprising, and we do not find much relevant data in the literature. On the other hand, many patients with a slight dilatation of the ascending aorta that was not dealt with during the aortic valve operation later required reoperation. In many previous studies, patients needing concomitant procedures were excluded from the analysis.

Thromboembolic Complications

Patients who are at the lowest risk of thromboembolism are those with sinus rhythm, normal left ventricular function, and no previous history of thromboembolism. Our report shows that the risk of thromboembolism is very small with the use of the MH valve prosthesis and confirms the previous experiences with this valve prosthesis.

Bleeding Complications

Because of the risk of thromboembolism, the major disadvantage with use of mechanical valves is the need for anticoagulation therapy, bleeding, and its consequences. The linearized rate of bleeding was 0.7 per 100 patient-years. Bleeding is more frequent in mechanical valves than in biological valves. However, bleeding complications can be further reduced by introducing international normalized ratio self-management that permits lower anticoagulation levels.

Valve-Related Complications

Structural deterioration was not seen in this study. This is in agreement with previous studies. Pannus requiring reoperation was seen in 1 case. Hemolysis was only seen secondary to paravalvular leak.

Summary

In summary, this 25-year follow-up study confirms that the MH valve is a durable and reliable valve with a low rate of valve-related complications. The study further demonstrates the significance of patient-related risk factors for survival associated with coronary artery disease.

Source of Funding

This study was supported by the Professor K.V. Hall Fund, Rikshospitalet, Oslo, Norway.

Disclosures

Dr Svennevig is presently (for a 4-year period) an elected member of the Medtronic Medical Advisory Board. The remaining authors report no conflicts.

References

The Medtronic-Hall valve, first implanted in 1977, is a mechanical heart valve made of a single piece of titanium. The disk is made of graphite with a carbon pyrolytic coating. We followed up with 816 patients who received Medtronic-Hall valves in the aortic position over a 25-year period. No mechanical failures had occurred, and the linearized rates of complications were low. The cumulative survival at 25 years, 24.9%, was lower than expected for a matched normal population; however, 79% of the patients were in New York Heart Association functional class I to II. Older age, female gender, and the need for concomitant coronary surgery were associated with reduced survival. This study confirms that the Medtronic-Hall valve is a durable and reliable heart valve with a low rate of valve-related complications. The study further demonstrates the significance of patient-related risk factors for survival.

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