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Long-term hemodynamic performance of bileaflet prostheses versus tilting-disc prostheses in the aortic position

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ABSTRACT

Background: The aim of this study was to compare the long-term hemodynamic performances of Medtronic-Hall (MH) and ATS medical bileaflet (ATS) valves in the aortic position.
Methods: We reviewed 249 patients that underwent AVR using MH or ATS valves between October 1994 and February 2004. MH valves were implanted in 117 patients (the MH group) and ATS valves in 132 patients (the ATS group). Serial changes in echocardiographic findings and clinical outcomes were analyzed.
Results: No early mortality occurred, and the late valve-related mortality was 11.2% (28/249). The transaortic mean pressure gradient (TMPG) in the MH group increased more rapidly than that in the ATS group during follow-up. Concomitant mitral valve replacement (double valve replacement, DVR) and placement of small aortic prostheses (indexed effective orifice area less than 0.85 cm^2/m^2) were found to contribute to a postoperative increase in TMPG. No inter-group difference in cumulative survival was observed at 10 years ($88.2 \pm 3.1\%$ vs. $84.7 \pm 3.1\%$, $p = 0.847$). Cox regression analysis revealed that old age and DVR were predictors of late death, and that female gender, inclusion in the MH group and DVR were predictive of major adverse valve-related events (MAVREs).
Conclusions: The MH group showed higher MAVREs than the ATS group and a relatively rapid increase in TMPG. Furthermore, DVR and placement of small prostheses were related to a late increase in TMPG irrespective of valve type.

1. Introduction

Many different mechanical prostheses have been used for aortic valve replacement (AVR), and the majority of commercially available mechanical heart valves have acceptable durability and thrombogenicity. However, mechanical valves differ in terms of hemodynamic performance, and considerable effort continues to be directed toward the enhancement of the hemodynamic performance of mechanical valves. In particular, several design modifications have been made to reduce the transaortic mean pressure gradient (TMPG) related to patient-prosthesis mismatch. The bileaflet valve is currently more popular than the tilting-disc valve, mainly because the newer prosthetic device is generally perceived to have better clinical performance. However, a few reports have claimed that tilting-disc valves are inferior to bileaflet valves in terms of long-term clinical outcome or hemodynamic performance, and although tilting-disc valves are not often used today, many patients still possess tilting-disc valves.

The Medtronic-Hall (MH) tilting-disc valve (Medtronic, Inc, Minneapolis, MN) was introduced to clinical practice in 1977, after a great deal of research and development [1]. Compared to previous tilting-disc valves, the size of the minor orifice was increased, and the disc was made to lift out of its housing and rotate to cause the larger orifice to face the greater curvature of the ascending aorta, thereby creating an optimal flow pattern [2]. The ATS Medical open-pivot bileaflet (ATS) heart valve (Medtronic, Inc, Minneapolis, MN) was introduced in 1992. This full pyrolytic carbon valve has a hinge mechanism that is constructed without a cavity in the valve ring and contains pivot guards [3], with the aim of improving hemodynamic performance and reducing thrombogenicity. We previously reported that MH valves have lower TMPGs than similarly sized ATS valves in the aortic position during the immediate postoperative period [4]. The aim of the present study was to compare the long-term clinical outcomes of MH and ATS valves used for AVR and to identify long-term hemodynamic performance differences between these valves.

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2. Materials and methods

2.1. Patients

A total of 249 patients who underwent AVR with the MH or ATS valves as their first cardiac surgery at the Samsung Medical Center from October 1994 to February 2004 were enrolled in this retrospective, nonrandomized study. ATS valves were used from October 1994 to May 2001 and MH valves from August 1997 to January 2004. Valves were chosen based on surgeon discretion. Our institutional review board approved this study and waived the need for individual consent.

2.2. Operative technique

The basic surgical procedures and principles of AVR have been previously described and were maintained throughout this study [4]. The ATS valve was used preferentially before August 1997, and the MH valve was used subsequently since it is believed that even-sized MH valves have better hemodynamic performance than similarly-sized ATS valves. This assumption is based on the increased relative size of the minor orifice in MH valves compared to those in previous tilting-disc valves and the design of the disc to lift out of the housing and rotate the opening, such that the larger orifice faces the greater curvature of the ascending aorta to create an optimal flow pattern. The 20-mm MH valve was preferred in patients with a small aortic annulus. When MH valves were implanted, the larger valve opening was oriented toward the right coronary cusp; with the exception of one patient, all MH valves were the same size. For ATS valve implantations, the pivot axes of valves were oriented perpendicular to the interventricular septum. Bileaflet valves were implanted in all cases of concomitant mitral valve replacement. All patients received warfarin from the first postoperative day. The target INR (International Normalized Ratio) ranged from 1.8 to 2.5, according to the presence of risk factors of thromboembolism such as atrial fibrillation or a history of cerebral infarction.

2.3. Follow-up

Standard guidelines were used to define mortality and morbidity [5]. An *early event* was defined as an event that occurred within the first 30 postoperative days, and all later events were defined as *late* events. Major adverse valve related events (MAVREs) included any structural or nonstructural prosthesis dysfunction, valve thrombosis, embolism, bleeding event, and prosthetic valve endocarditis. Postoperative outcomes and events after discharge were acquired by reviewing medical records, by direct telephone interviews with patients or their families, and from the National Registry of Births and Deaths.

Follow-up was completed in all 249 patients. Most ($n = 181$, 72.7%) were followed regularly at our institution, and mean overall follow-up duration was 112.1 ± 35.9 months (maximum 177 months, a total of 2326 patient-years). Telephone or outpatient interviews were conducted with patients ($n = 48$, 19.3%) or first-degree relatives to confirm mortality and morbidity. Mortalities and causes of death among the remaining patients ($n = 20$, 8%) were determined using national registry death and survival data.

Two-dimensional and Doppler echocardiography was attempted before discharge and at 1, 3, and 5 years after surgery. Left ventricular end-systolic and diastolic dimensions were obtained in the parasternal view based on American Society of Echocardiography guidelines [6]. Left ventricular ejection fractions were calculated using Simpson's biplane method. Peak and mean pressure gradients across aortic valves were calculated using the Bernoulli equation. The left ventricular mass was calculated using Devereux and Reichek's formula [7]. The left ventricular mass index (LVMI, in g/m^2) was defined as the left ventricular mass/body surface area. Estimates of the prosthetic effective orifice area were obtained from the manufacturer's specifications for each size valve. Indexed effective orifice area (EOAI) was defined as the effective orifice area/body surface area. The degree of tricuspid regurgitation (TR) was assessed using the vena contracta width and the ratio of the maximal jet area to the corresponding right atrial area averaged in the parasternal and apical views. For statistical analysis, TR was graded from "0" to "4." Complete echocardiographic data at 1 year after surgery were available for 224 of 249 patients (90.0%) and at 5-year follow-up for 172 (74.7%) of the 230 patients who survived for longer than 5 years.

2.4. Statistical analysis

Results were expressed as mean ± standard deviation or as frequency and proportion. The *t*-test and the Chi-square test were used to assess inter-group differences. Serial TMPG values were analyzed using repeated-measure analysis of variance. The within-subject factor was time after surgery, and the between-subject factors were valve type, valve size based on EOAI and concomitant MVR (double valve replacement, DVR). Multivariable Cox proportional hazard analysis was employed to identify independent predictors of mortality and cardiovascular events. Survival curves were constructed using the Kaplan–Meier method, and inter-group comparisons were performed using the log-rank test. Probability (p) values < 0.05 were considered statistically significant, and statistical analysis was carried out using SPSS version 17.0 (SPSS, Chicago, IL).

3. Results

3.1. Patient characteristics

Of the total 249 patients, 115 were female. The average age at time of surgery was 52.4 ± 11.8 years (range, 20 to 76). The types of prosthesis used were the MH valve in 117 patients (47%, the MH group) and the ATS valve in 132 patients (53%, the ATS group). Atrial fibrillation was present before operation in 95 patients (38.2%). Underlying diseases were defined as rheumatic in 141 patients (56.6%), degenerative in 86 (34.5%), endocarditis in 19 (7.6%), and other in 3 (1.2%) (Table 1).

3.2. Clinical outcomes

No early mortality was recorded among the 249 patients, but there were 15 late mortalities (12.8%) in the MH group and 26 (19.7%) in the ATS group, which was not a significant difference. In the MH group, causes of death were sudden aortic prosthesis dysfunction in 2 patients, an unknown etiology in 2, cerebral infarction in 6, septic shock related to prosthetic valve endocarditis in 1, pneumonia in 2, and unexplained sudden death in 2. In the ATS group, causes of death were infective endocarditis in 4, pneumonia in 3, intracranial hemorrhage in 5, embolic infarct in 4, malignancy in 7 and unknown sudden death in 3. The various serious complications and their rates are listed in Table 2. No intergroup differences were observed in terms of incidence of prosthetic valve failure, endocarditis, thromboembolism, bleeding, or heart valve reoperation. Incidences of thromboembolic events were 0.8%/patient-year in the MH group and 0.5%/patient-year in the ATS group.

Seven patients (6%) underwent redo AVR in the MH group, and one of these required a reoperation for prosthetic valve endocarditis. In the other 6, reoperations were related to aortic valve pannus formation. In 3 of these 6 patients, TMPGs increased (range, 34 to 40 mm Hg), and all 3 had symptoms related to aortic stenosis. Two of the remaining 3 patients underwent emergency repeat AVR after requiring cardiopulmonary resuscitation or extracorporeal membrane oxygenator support caused by acute aortic regurgitation or obstruction by subaortic pannus. In the remaining patient, the primary surgical indication for repeat surgery was severe tricuspid regurgitation; however, during surgery, we found subaortic stenosis with pannus

Table 1
Patient characteristics.

Variable	MH group ($n = 117$)	ATS group ($n = 132$)	p value
Age, y	51.2 ± 10.4	53.5 ± 12.9	0.121
Sex (female), n (%)	67 (57.3)	48 (36.4)	0.001
Body surface area, m^2	1.62 ± 0.15	1.62 ± 0.17	0.670
NYHA functional class ≥ III, n (%)	29 (24.8)	11 (8.3)	0.244
Atrial fibrillation, n (%)	50 (42.7)	45 (34.1)	0.161
Bicuspid, n (%)	23 (19.7)	29 (22.0)	0.654
Etiology, n (%)			
Rheumatic	66 (50.0)	75 (64.1)	0.948
Degenerative	41 (31.1)	45 (38.5)	0.078
Endocarditis	7 (6.0)	12 (9.1)	0.357
Acute	7 (6.1)	9 (6.8)	
Healed	0	3 (2.6)	
Size of aortic prosthesis, n (%)			
≤21 mm	39 (33.3)	60 (45.5)	0.053
Concomitant procedures			
MVR	62 (53.0)	55 (41.7)	0.074
TVP	33 (28.2)	11 (8.3)	0.001
Maze procedure	18 (15.4)	0 (0)	0.001
Aortic annular reconstruction	9 (7.7)	9 (6.8)	0.790
Ascending aorta procedures	6 (5.1)	2 (1.5)	0.107

MH, Medtronic-Hall valve; *ATS*, ATS valve; *NYHA*, New York Heart Association; EOAI, indexed effective orifice area; *MVR*, mitral valve replacement; *TVP*, tricuspid valvuloplasty.