Long-Term Comparison of Three Types of Aortic St. Jude Medical Mechanical Prosthesis in Japanese Patients

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Background: The long-term results achieved with aortic St. Jude Medical (SJM) mechanical prostheses in various age groups of Japanese patients have not been previously compared or reported.

Methods and Results: Since 1981, a total of 240 SJM valves were implanted in 79 patients using the Standard model, in 58 patients with the Hemodynamic Plus model, and in 103 patients with the Regent model for aortic valve replacement (AVR). Follow-up was completed for 2,397 patient-years in 97.5% of the patients, among whom the effect of age was compared, and the subjects were divided into younger (<65 years) and older (≥65 years) groups. Hospital mortality rate was 2.5%. No structural valve deterioration was observed during the follow-up period. Additionally, no significant differences were observed in long-term survival between the 3 models. In contrast, significantly better rates of freedom from all-cause death (P<0.0001), valve-related death (P=0.0018) and valve-related morbidity (P=0.0021), including bleeding events (P=0.0007), were observed in the younger group (n=157, 50.6±1.0 years old) than in the older group (n=83, 72.5±0.7 years old).

Conclusions: All types of SJM valve used for single AVR achieved satisfactory early and long-term results in each age group even 25 years after surgery. When selecting this prosthesis for elderly patients, however, relatively worse performance may be expected compared with that observed in younger patients. (Circ J 2015; 79: 2193–2200)

Key Words: Aortic valve replacement; Valve; Warfarin

The use of bioprostheses has been increasing along with improvements in durability, but mechanical valves continue to be useful prostheses, especially for younger patients, due to their excellent long-term durability and low risk of reoperation. Both in vitro and in vivo data indicate excellent hemodynamic performance associated with a low incidence of valve-related morbidity for St. Jude Medical (SJM; Minneapolis, MN, USA) mechanical prostheses. Therefore, at Kyushu University Hospital we have used 3 serial types of SJM bi-leaflet mechanical heart valve for aortic valve replacement (AVR) since 1981.

The sewing ring in the original SJM standard (ST) model was modified, without changing the pivotal design or blood-contact surface area, to produce the Hemodynamic Plus (HP) model, in which the bulk of the sewing ring has been reduced. The latest Regent (RE) model has a modified external profile that achieves a larger geometric orifice area. This modification allows for the implantation of a larger device, approximately 1.5 sizes larger than the original ST model.

Although SJM mechanical prostheses implanted in relatively younger patients are, in general, expected to be reliable and durable, without the need for additional surgery in the long term (>25 years after surgery), anti-coagulation-related complications may still cause significant problems. Moreover, the long-term results of the 3 types of SJM prosthesis have not yet been reported or compared in Japanese patients. In particular, the differences in the rates of thromboembolic and hemorrhagic complications in various age groups of patients implanted with SJM valves are not currently well described in the literature. We herein analyzed >25 years of clinical experience with SJM valves in order to evaluate the reliability of these second-generation bi-leaflet valves in Japanese patients, based on prosthesis model and patient age.

Methods

This study involved human subjects and was reviewed and approved by the Institutional Review Board at Kyushu University. Two hundred and sixty-six patients underwent AVR with SJM prostheses between November 1981 and December 2014. Among these patients, 26 patients who underwent aortic root replacement (Bentall operation) were excluded to ensure simplicity of analysis. Therefore, a total of 240 patients implanted with aortic SJM prostheses were included in this study. We divided all patients into 2 groups: younger (≤65 years old, n=157) and older (≥65 years old, n=83; Table 1). Mean

Table 1
patient age was 50.6±1.0 years in the younger group and 72.5±0.7 years in the older group. The predominant cause of valve disease was rheumatic or degenerative heart disease in all groups (Table 1). Preceding AVR and bicuspid aortic valves were observed in 14 (8.9%) and 25 patients (15.9%) in the younger group, and in 5 (7.7%) and 11 patients (16.9%) in the older group, respectively (Table 1). The ST, HP and RE models were used in 67, 32 and 58 patients in the younger group, compared with in 12, 26 and 45 patients in the older group, respectively (Table 1).

We also divided all patients into 3 groups according to SJM model (Table 2). The average age of the entire patient cohort was 58.2±1.0 years, although the subgroup mean age was significantly younger in the ST model group (50.4±1.6 years) than in the HP (63.3±1.8 years) and RE model groups (60.8±1.4 years; P<0.0001; Table 2). The predominant cause of valve disease was rheumatic or degenerative heart disease in all 3 groups (Table 2). Preceding AVR and bicuspid aortic valve were observed in 11 (13.9%) and 4 patients (5.1%) in the ST group, in 2 (3.4%) and 10 (17.2%) in the HP group, and in 6 (5.8%) and 22 (21.4%) in the RE group, respectively. A relatively larger prosthesis (median, 23 mm) was implanted in the ST group, whereas a relatively smaller prosthesis (median, 19 mm) was implanted in both the HP and RE groups (Table 2).

Details of the surgery and patient care have been described previously.3,6 In brief, all patients underwent surgery using standard cardiopulmonary bypass with moderate hypothermia (at 28–34°C). Either cold crystalloid or blood cardioplegia, associated with ice slush topical cooling, was delivered, antegrade, retrograde or both. Evertting mattress suture technique with 2-0 braided polyester sutures reinforced with polytetrafluoroethylene (Teflon) felt pledgets was the predominant method used to suture the valves.7 The horizontal mattress suture technique, single suture technique or annular enlargement technique was used in AVR of the small aortic annulus. In the ST, HP and RE groups, concomitant coronary artery bypass grafting (CABG) was performed in 9, 5 and 13 patients, respectively.

Either s.c. heparin calcium at 5,000 or 7,500 units every 12 h or i.v. heparin at 300–500 units/h was administered, starting on the first postoperative day, until the international normalized ratio of the prothrombin time (PT-INR) reached the therapeutic range with oral warfarin. After discharge from hospital, PT-INR was measured at least every 4 weeks and maintained between 1.8 and 2.8.

Early postoperative follow-up, followed by monthly or annual follow-up, was performed by us for most of the patients at the outpatient clinic. For patients with interrupted visits, we directly contacted either them, the family members or their physicians via mail or telephone questionnaire. When the questionnaire response reported a patient death, we directly contacted the physician in charge in order to reconfirm the cause of death and/or related complications.

Six patients could not be contacted, and the follow-up was thus completed in 97.5% of patients. The mean follow-up period was 10.0±0.5 years (11.8±0.7 years in the younger group and 6.5±0.6 in the older group) for a total of 2,397 patient-years (Table 3). The cumulative follow-up period consisted of 1,855 patient-years in the younger group and 542 patient-years in the

| Table 1. Patient Characteristics |
|---------------------------------|
| Groups                          | Total | Younger (<65) | Older (≥65) | P-value |
| n                               | 240   | 157           | 83          |         |
| Male                            | 112   | 78            | 34          | 0.0468  |
| Age (years)                     | 58.1±1.0 | 50.6±1.0   | 72.5±0.7*   | <0.0001 |
| Etiology of valve disease       |       |               |             |         |
| Rheumatic/Degeneration          | 197   | 120           | 76          | 0.0047  |
| Active IE                       | 8     | 8             | 0           | 0.0534  |
| Healed IE                       | 10    | 8             | 2           | 0.5088  |
| Active PVE                      | 1     | 1             | 0           | 1.0000  |
| Healed PVE                      | 1     | 1             | 0           | 1.0000  |
| Takayasu arteritis              | 11    | 11            | 0           | 0.0180  |
| Para-valvular leakage           | 4     | 1             | 3           | 0.1206  |
| Pannus formation                | 1     | 1             | 0           | 1.0000  |
| SVD of previous bioprostheses   | 13    | 11            | 2           | 0.2288  |
| Bicuspid valve                  | 36    | 25            | 11          | 0.7047  |
| Prosthesis used                 |       |               |             |         |
| Standard                        | 79    | 67            | 12          | <0.0001 |
| Hemodynamic Plus                | 58    | 32            | 26          | 0.0806  |
| Regent                          | 103   | 58            | 45          | 0.0134  |
| Concomitant procedures          |       |               |             |         |
| Ascending aorta replacement     | 5     | 5             | 0           | 0.1670  |
| Wapping of the ascending aorta  | 14    | 10            | 4           | 0.7761  |
| MVP or OMC                      | 20    | 17            | 3           | 0.0831  |
| TAP                             | 11    | 4             | 7           | 0.0515  |
| CABG                            | 27    | 15            | 12          | 0.4802  |
| Maze                            | 8     | 5             | 3           | 1.0000  |

Data given as mean±SEM or n. *vs. younger group. CABG, coronary artery bypass grafting; IE, infective endocarditis; MVP, mitral valve plasty; OMC, open mitral commissurotomy; PVE, prosthetic valve endocarditis; SVD, structural valve deterioration; TAP, tricuspid annuloplasty.
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Hospital and late deaths, as well as all valve-related mortality and complications, were strictly defined according to the published guidelines of the American Association of Thoracic Surgery/Society of Thoracic Surgeons.\(^8\)

older group (Table 3). The mean follow-up period in each group was 16.9±1.0 years (1,337 patient-years) in the ST group, 10.9±0.6 years (630 patient-years) in the HP group and 4.2±0.3 years (431 patient-years) in the RE group (Table 2).

### Table 2. Results vs. SJM Mechanical Prosthesis Type

| Series          | Standard | Hemodynamic Plus | Regent |
|-----------------|----------|------------------|--------|
| n               | 79       | 58               | 103    |
| Male            | 41       | 19               | 52     |
| Age (years)     | 50.4±1.6* | 63.3±1.8        | 60.8±1.4 |
| Etiology of valve disease | | | |
| Rheumatic/Degeneration | 57       | 53               | 86     |
| Active IE       | 4        | 1                | 3      |
| Healed IE       | 4        | 1                | 5      |
| Active PVE      | 1        | 0                | 0      |
| Healed PVE      | 1        | 0                | 0      |
| Takayasu arteritis | 7        | 0                | 4      |
| Para-valvular leakage | 0        | 0                | 4      |
| Pannus formation | 0        | 1                | 0      |
| SVD of previous bioprostheses | 9        | 2                | 2      |
| Bicuspid valve  | 4        | 10               | 22     |
| Valve size      |          |                  |        |
| 17              | 0        | 0                | 28*    |
| 19              | 9*       | 43               | 40     |
| 21              | 21       | 15               | 26     |
| 23              | 16*      | 0                | 9      |
| 25              | 20*      | 0                | 0      |
| 27              | 12*      | 0                | 0      |
| 29              | 1        | 0                | 0      |
| Hospital death (%) | 3.8  | 3.4             | 1.0    |
| Mean follow up period (years) | 16.9±1.0 | 10.9±0.6 | 4.2±3.0* |
| Maximum follow-up period (years) | 30     | 17.7            | 9.4    |
| Total patient-years | 1,336.9 | 629.5         | 430.8  |
| Valve-related morbidity (%) | 34 (43.0) | 13 (22.4) | 12 (11.6) |
| Valve-related morbidity at 5 years | 92.0±2.9 | 98.1±1.8 | 88.2±3.5 |
| 10 years | 85.0±4.2 | 80.7±5.7 | 74.9±9.3 (9 years) |
| 15 years | 79.6±4.9 | 71.0±7.5 |  |
| 20 years | 70.8±6.1 | 65.1±8.9 |  |
| Bleeding events (%) | 7 (8.9) | 8 (13.8) | 8 (7.8) |
| Thromboembolism (%) | 14 (17.7) | 4 (6.9) | 4 (3.9) |
| Fatal anticoagulation events (%) | 6 (7.6) | 5 (8.6) | 2 (1.9) |
| Valve thrombosis (%) | 0.45 | 0.79 | 0.46 |
| PVE (%) | 5 (6.3) | 0 | 0 |
| Para-valvular leakage (%) | 2 (2.5) | 0 | 0 |
| Pannus formation (%) | 1 (1.3) | 0 | 0 |
| Re-AVR (%) | 6 (7.6) | 0 | 0 |

*P<0.05 vs. others. Data given as mean±SEM or as specified. AVR, aortic valve replacement; SJM, St. Jude Medical. Other abbreviations as in Table 1.
Statistical Analysis
All continuous variables are presented as mean±SEM. Fisher’s exact test and Student’s t-test were used for univariate analysis. The incidences of death and events are expressed in linearized form (%/patient-years). The actuarial survival rates and freedom from valve-related morbidity were calculated using the actuarial life table (Kaplan-Meier) method and reported with SEM. Comparisons of these estimates were made using the log-rank test. P<0.05 was considered to be significant.

We also estimated the discriminative age indicative of better SJM valve results with regard to long-term survival and valve-related adverse event rates. We subsequently evaluated the discriminative age between the 2 age groups. Both the likelihood ratio and P-value were repeatedly calculated using Cox regression modeling. The age with the highest likelihood ratio at P<0.05 was defined as the discriminative age (Table 4).

Results
Early Mortality
In total, 6 death occurred either within 30 days of surgery or in hospital at any time interval after surgery. The early mortality rate was 2.5% (6/240) for all patients, 1.3% (2/157) in the younger group and 4.8% (4/83) in the older group, respectively (Table 3). The early mortality rate was 3.8% (3/79) in the ST group, 3.4% (2/58) in the HP group, and 1.0% (1/103) in the

Table 3. Early and Valve-Related Morbidity vs. Patient Age

| Groups                      | Total | Younger (<65 years) | Older (≥65 years) |
|-----------------------------|-------|---------------------|-------------------|
| n                           | 240   | 157                 | 83                |
| Hospital death (%)          | 2.5   | 1.3                 | 4.8               |
| Mean follow-up period (years)| 10.0±0.5 | 11.8±0.7          | 6.5±0.6*          |
| Maximum follow-up period (years)| 30.0 | 30.0                 | 23.2              |
| Total patient-years         | 2,397.1 | 1,855.3           | 541.8             |
| Valve-related morbidity (%) | 33 (41.8) | 13 (22.4)          | 12 (11.7)         |
| %/patient-year              | 2.5   | 2.1                 | 2.8               |
| Freedom from valve-related morbidity at 5 years | 91.8±1.9 | 94.9±1.9           | 85.7±4.2          |
| 10 years                    | 80.5±3.2 | 86.3±3.3           | 67.3±7.5          |
| 15 years                    | 75.9±3.8 | 78.8±4.4           | 58.6±8.7          |
| 20 years                    | 67.6±5.2 | 72.1±5.5           | 29.3±21           |
| Bleeding events (%)         | 23 (9.6) | 12 (7.6)           | 11 (13.2)         |
| %/patient-year              | 0.96   | 0.65                | 2.03              |
| Thromboembolism (%)         | 22 (9.2) | 16 (10.2)          | 6 (7.2)           |
| %/patient-year              | 0.92   | 0.86                | 1.11              |
| Fatal anticoagulation events (%) | 13 (5.4) | 9 (5.7)            | 4 (4.8)           |
| %/patient-year              | 0.54   | 0.49                | 0.74              |
| Valve thrombosis (%)        | 1 (0.42) | 0                   | 1 (1.2)           |
| %/patient-year              | 0.04   | 0                   | 0.18              |
| PVE (%)                     | 5 (2.1) | 3 (1.9)             | 2 (2.4)           |
| %/patient-year              | 0.21   | 0.16                | 0.37              |
| Para-valvular leakage (%)   | 2 (0.8) | 2 (1.3)             | 0                 |
| %/patient-year              | 0.08   | 0.11                | 0                 |
| Pannus formation            | 1 (0.42) | 1 (0.7)            | 0                 |
| %/patient-year              | 0.04   | 0.05                | 0                 |
| Re-AVR (%)                  | 6 (2.5) | 5 (3.2)             | 1 (1.2)           |
| %/patient-year              | 0.25   | 0.27                | 0.18              |

*P<0.0001. Abbreviations as in Tables 1,2. Data given as mean±SEM or as specified.

Table 4. Discriminative Age Indicative of Better Post-AVR Results

| Age (years) | LR   | P-value |
|-------------|------|---------|
| Valve-related death | 71   | 8.6338  | 0.0033 |
| Cardiac death     | 65   | 9.3429  | 0.0022 |
| All-cause death   | 64   | 8.2837  | 0.0040 |
| Valve-related morbidity | 68   | 10.8361 | 0.0010 |
| Bleeding events   | 67   | 14.0138 | 0.0002 |
| Thromboembolism   | None | 0.4661  | 0.4948 |
| Bleeding or thromboembolic events | 63   | 10.1525 | 0.0014 |
| Re-AVR            | None | 1.2043  | 0.2725 |

AVR, aortic valve replacement; LR, likelihood ratio.
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ized ratios for the ST, HP and RE models were 3.1, 4.4, 2.8%/patient-years for all-cause death; 1.3, 1.8, 1.3%/patient-years for cardiac death; and 0.8, 1.1, 0.7%/patient-years for valve-related death, respectively. Regarding other causes of late death, no significant differences were observed in the incidences of thromboembolism, bleeding events, valve thrombosis or PVE among the 3 groups.

Valve-Related Morbidity

Age Comparison  Figure 1 shows significantly better actuarial survival (P<0.0001; Figure 1A), freedom from cardiac death (P=0.0007; Figure 1B) and freedom from valve-related death (P=0.0018; Figure 1C) in the younger group compared with the older group. The linearized ratios for the younger and elderly patients were 2.5 and 6.6%/patient-years for all-cause death, 1.1 and 2.2%/patient-years for cardiac death, 0.6 and 1.5%/patient-years for valve-related death, respectively. The predominant cause of valve-related late death was sudden/unexpected death (n=8) and bleeding events (n=7) in 20 patients; that of non-valve-related late cardiac death was chronic heart failure (n=8) in 13 patients; and that of non-cardiac late death was cancer (n=9) in 41 patients. Regarding other causes of valve-related death, no significant differences were observed in the incidences of thromboembolism, valve thrombosis or prosthetic valve endocarditis (PVE), except for bleeding events between the 2 groups.

Model Comparison  No significant differences were observed in either the actuarial survival (Figure 2A), freedom from cardiac death (Figure 2B) or freedom from valve-related death (Figure 2C) between the ST, HP and RE groups. The linearized ratios for the ST, HP and RE models were 3.1, 4.4, 2.8%/patient-years for all-cause death; 1.3, 1.8, 1.3%/patient-years for cardiac death; and 0.8, 1.1, 0.7%/patient-years for valve-related death, respectively. Regarding other causes of late death, no significant differences were observed in the incidences of thromboembolism, bleeding events, valve thrombosis or PVE among the 3 groups.

Late Mortality

Age Comparison  Figure 1 shows significantly better actuarial survival (P<0.0001; Figure 1A), freedom from cardiac death (P=0.0007; Figure 1B) and freedom from valve-related death (P=0.0018; Figure 1C) in the younger group compared with the older group. The linearized ratios for the younger and elderly patients were 2.5 and 6.6%/patient-years for all-cause death, 1.1 and 2.2%/patient-years for cardiac death, 0.6 and 1.5%/patient-years for valve-related death, respectively. The predominant cause of valve-related late death was sudden/unexpected death (n=8) and bleeding events (n=7) in 20 patients; that of non-valve-related late cardiac death was chronic heart failure (n=8) in 13 patients; and that of non-cardiac late death was cancer (n=9) in 41 patients. Regarding other causes of valve-related death, no significant differences were observed in the incidences of thromboembolism, valve thrombosis or prosthetic valve endocarditis (PVE), except for bleeding events between the 2 groups.

Model Comparison  No significant differences were observed in either the actuarial survival (Figure 2A), freedom from cardiac death (Figure 2B) or freedom from valve-related death (Figure 2C) between the ST, HP and RE groups. The linearized ratios for the ST, HP and RE models were 3.1, 4.4, 2.8%/patient-years for all-cause death; 1.3, 1.8, 1.3%/patient-years for cardiac death; and 0.8, 1.1, 0.7%/patient-years for valve-related death, respectively. Regarding other causes of late death, no significant differences were observed in the incidences of thromboembolism, bleeding events, valve thrombosis or PVE among the 3 groups.

Valve-Related Morbidity

Age Comparison  No structural valve deterioration was observed in any of the SJM prosthesis groups during the follow-up period. Para-valvular leakage, bleeding events, thromboembolism, valve thrombosis, PVE, pannus formation and further AVR were associated with valve-related morbidity. The linearized ratios for each event are listed in Table 3. Figure 1 shows a significantly better rate of freedom from valve-related morbidity (P=0.0021; Figure 1D) in association with a better rate of freedom from bleeding events (P=0.0007; Figure 1F) in the younger patient group, although freedom from thromboembolism was equivalent between the younger and older groups (P=0.4983; Figure 1E). The rates of freedom from valve-related morbidity in the younger and older patient groups at 10 and 20 years were 86.3±3.3% and 72.1±5.5%, compared with 67.3±7.5% and 29.3±21%, respectively (P=0.0021; Figure 1D), whereas the rates of freedom from bleeding in the younger and older patient groups at 10 and 20 years were 95.4±2.1% and 86.7±4.6%, compared with 83.2±5.6% and 74.7±7.7%, respectively (P=0.0007; Figure 1F). A total of 23
between the ST, HP, and RE model groups, but a significantly higher rate of freedom from bleeding events was observed in the ST group compared with the HP and RE groups ($P=0.0089$; Figure 2F). Given that the average age at AVR in the ST group was significantly younger than in the other 2 groups, the higher freedom from bleeding events observed in the ST group might have been due to this, because the incidence of bleeding events was significantly lower in the younger group compared with the older group in the present series. It should be noted, however, that bleeding events occurred at 17 years after AVR even in the ST group. This suggests that the incidence of anticoagulation-related bleeding events is associated with patient age, and will increase as patient age increases.

**Discriminative Age for Better SJM Prosthesis Results**

Based on the aforementioned results, patients under a certain age seemed to have better results than the patients over that age when using the SJM prostheses. Therefore, we further calculated the discriminative age indicative of better SJM valve results (Table 4). The discriminative ages for valve-related death, cardiac death, all-cause death, valve-related morbidity, bleeding events and bleeding plus thromboembolic events were 71, 65, 64, 68, 67 and 63 years, respectively. No discriminative age was observed for thromboembolic events or re-AVR. The patients under these ages had better results than the patients over these ages (Figures 1A–D,F).

**Figure 2.** Actuarial rates of freedom from (A) all-cause, (B) cardiac and (C) valve-related death, (D) valve-related morbidity, (E) thromboembolism (TE) and (F) bleeding events associated with the 3 types of St. Jude Medical (SJM) mechanical prostheses. No significant differences were observed in (A–C) long-term survival or (D,E) valve-related morbidity, except for (F) bleeding events, between the 3 groups. AVR, aortic valve replacement; HP, SJM Hemodynamic Plus; RE, SJM Regent; ST, SJM Standard.
Discussion

In this report, we found generally satisfactory early and late results following valve replacement with 3 different models (ST, HP and RE) of SJM aortic prostheses in both younger (<65 years) and older (≥65 years) patients. No significant differences in hospital mortality were observed between the 3 SJM prosthesis models or between the younger and older patient groups. In contrast, the long-term survival rates were significantly better in the younger group than in the older group for the 3 SJM prosthesis models. Furthermore, the incidence of valve-related morbidity was significantly higher in the older group due to the higher incidence of bleeding events. Comparing the 3 models of SJM prosthesis, only bleeding events were less frequent in the ST group, in which the average patient age was significantly younger compared with that in the HP and RE group.

The present results, including those for hospital mortality, are similar to our previous results for CarboMedics (CM) valves18 and to those of others for various bi-leaflet mechanical valves such as SJM valves,11–14 CM valves14–16 and ATS valves.20–22 Because of the relatively younger patient age and the relatively fewer concomitant operations, such as CABG, in the present series, it may not be possible to compare these results directly with those obtained at other institutes. In this study, the hospital mortality rates were similar between the older and younger patient groups, although a higher age itself is a well-known risk factor for increased patient mortality. The present actuarial freedom rates from valve-related, cardiac and all-cause death after implantation of SJM valves are similar to our previous results for CM valves18 and to those of others for bi-leaflet mechanical valves.11–14,20,21,23

The present incidence of bleeding events or thromboembolism is similar to that for other current era devices, including SJM valves21,23 and ATS valves.22 In contrast, the incidence of transient ischemic attacks was lower than in other studies.11,13 Because we could not follow up all the patients every month or even every year after surgery, some non-fatal incidents, including transient ischemic attacks, may have been missed during the follow-up period. No structural valve deterioration was observed during the 30-year study period after AVR. Only 1 case of valve thrombosis, which was treated with tissue-plasminogen activator alone and did not require re-AVR, was observed in the HP group at 8.6 years after AVR (0.04%/patient-years). The present incidence of valve thrombosis is similar to that reported by Emery et al (0.06%/patient-years).11 Baudet et al., however, reported a higher incidence of valve thrombosis (0.25%/patient-years) and indicated that patients who are not given appropriate anti-coagulant therapy tend to suffer from valve thrombosis, although their heart beats showed sinus rhythm.23

Among the valve-related morbidities evaluated in this study, a significantly higher incidence of bleeding events was observed after AVR in the older patient group (P=0.0007; Figure 1F). Consistent with the Emery et al study,11 we found that the half of the bleeding events (5 of 11 events) occurred early in the first year after AVR in the older patient group. In contrast, such bleeding events occurred later after AVR in the younger patient group (average interval, 13.7 years for 12 events). Based on these data, we recently used a slightly lower PT-INR for the early phase after AVR in the elderly patients, although the 2014 AHA/ACC guidelines recommend a target PT-INR of around 2.5–3.0 for patients with mechanical aortic prostheses.24 In this context, it might be reasonable to use the lower target PT-INR in Japanese elderly patients with valve replacement with mechanical prostheses, because Asian people have been shown to have a substantially higher risk (2–4-fold) of warfarin-related intracranial hemorrhage than white people,25 and because elderly patients have a higher risk of bleeding complications after anti-coagulant therapy.26 In fact, Kimura et al reported that low-intensity warfarin therapy (PT-INR, 1.5–2.0) prevents both thromboembolism and bleeding events in patients with left atrial thrombosis.27 Moreover, a target PT-INR range of 1.5–2.5 was associated with prevention of thromboembolism or bleeding complications in both Japanese patients with mitral mechanical valves28 and in European patients with mechanical aortic valves.22 Therefore, we would like to propose a somewhat lower target PT-INR of 1.5–2.5 for elderly patients who have undergone AVR with mechanical prostheses. This policy may be useful for Japanese patients as well as for those of other races.

With regard to the present elderly patients aged >65 years old, a relatively worse performance of SJM prosthesis is expected compared with that seen in the younger patients. Based on Cox regression modeling, we identified the discriminative age for several factors. The discriminative ages for long-term survival, valve-related morbidity, bleeding events except for the thromboembolic events and re-AVR, were determined, and the patients aged <63–71 years of age had better results after AVR than those above these ages. In patients above this age range, bioprostheses may be an alternative treatment of choice.

The relatively smaller effective orifice area (EOA) of the smallest SJM prosthesis might induce patient-prosthesis mismatch. In this series, we used a 17-mm SJM prosthesis in 28 patients, and the EOA on echocardiography at discharge was 1.0±0.4 (n=26), and patient–prosthesis mismatch (EOA/body surface area <0.85) was observed in 22 patients. Further analysis is necessary to clarify the relationship between patient-prosthesis mismatch and >10-year results after AVR for the smallest SJM prosthesis.

Conclusions

All types of SJM valve used for single AVR are associated with satisfactory early and long-term results in any age group of patients, even 25 years after surgery. Extreme care should be taken to prevent bleeding complications in elderly patients after AVR.

Study Limitations

In this report, we could not compare the hemodynamics data for the 3 types of SJM valve because the echocardiographic data for many of the patients, especially those who underwent AVR with the ST or HP models, were not available.

Disclosures

None.

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