Selection of Prosthetic Valve and Evidence—Need for the Development of Japan’s Own Guidelines

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Purpose: In 2014, the American Heart Association (AHA)/American College of Cardiology (ACC) guidelines were largely revised with regard to the selection of prosthetic valves. (1) A mechanical prosthesis is reasonable for aortic valve replacement (AVR) or mitral valve replacement (MVR) in patients less than 60 years of age, (2) A bioprosthesis is reasonable in patients more than 70 years of age, and (3) Either a bioprosthetic or mechanical valve is reasonable in patients between 60 and 70 years of age.

Japan faces the unprecedented population aging, and moreover, the average life expectancy is longer among the Japanese than the Westerners. In Japan, whether this choice is appropriate seems questionable.

Methods: This time, with the revision of the AHA/ACC guidelines, it might be necessary to take into consideration the average life expectancy of Japanese people and revise the Japanese guidelines accordingly.

Results: We should consider whether 60–70 years should be set as a gray zone regarding the age criteria for choosing biological valves, or if the age should be set higher relative to that specified in the western guidelines, given the longer Japanese life expectancy.

Conclusion: We believe that the development of unique, Japanese guidelines for the selection of prosthetic valves will allow us to provide appropriate selection and treatment for each patient.

Keywords: prosthetic valve, valve replacement

Introduction

In recent years, valvuloplasty has been actively performed in surgical treatment of valvular diseases. In the 1950s, however, the introduction of prosthetic valves dramatically improved the prognoses of patients with valvular diseases, and even today, prosthetic valves are essential in the treatment of valvular disease. In 1952, Hufnagel transplanted a ball-type prosthetic valve in the descending aorta, and in 1960, Braunwald, Harken, and Starr et al. performed replacement surgery using prosthetic valves that they developed uniquely. Among those, the Starr-Edwards ball valve was the most popular prosthetic valve at the time. Later, mechanical valves such as tilting valve and bileaflet valve, and biological valves have also been improved with anti-calcification processing and refined stents, and 60 years have passed since the introduction of prosthetic valves. At present, the bileaflet valve and stented valve are the most frequently used mechanical valve and biological valve, respectively; these valves feature the durability and anti-thrombogenicity superior to any prosthetic valves in the past, and with anticoagulant therapy fully established, both valves have been reported to show favorable long-term follow-up results.
Today, a wide selection of prosthetic valves is available depending on age, sex, and lifestyle. The present report addresses the selection of prosthetic valves, along with bibliographical consideration.

Long-Term Follow-Up Results for Prosthetic Valves

Mechanical valves

Currently, the most internationally used mechanical valve is the bileaflet valve. Almost 40 years have passed since Nicoloff et al. used the St. Jude Medical (SJM) valve for the first time in 1977, and in Japan, our department was the first to use it in 1978. Today, the bileaflet valve, SJM valve, CarboMedics valve, ATS valve, Bicarbon valve, and On-X valve are available for use in Japan, and each has been reported to show favorable long-term follow-up results. The bileaflet valve exhibits satisfactory durability, and today, with fully established anti-coagulant therapy, remarkable improvements have been observed compared to before in valve-related complications such as thromboembolism and bleeding. With regard to the SJM valve, Emery et al. reported long-term follow-up results over 25 years, with a thromboembolism-free rate of 86% in aortic valve replacement (AVR) cases and 81% in mitral valve replacement (MVR) cases, and a bleeding-free rate of 81% in AVR cases and 81% in MVR cases. In our department, the SJM valve has also demonstrated a stable valve function, with similar valve-related complications (e.g., thromboembolism, bleeding) compared to the ATS valve, which is the same bileaflet valve. With regard to the ATS valve, Van Nooten et al. reported 15-year long-term follow-up results, with a 10-year thromboembolism-free rate of 91% in AVR cases and 85% in MVR cases, and a 10-year bleeding-free rate of 91% in AVR cases and 90% in MVR cases. The ATS valve is a mechanical valve characterized by its quiet valve sound, and our department has obtained favorable 15-year long-term follow-up results, as follows: the 15-year thromboembolism-free rate was 98.0% ± 1.4% in AVR cases and 98.0% ± 1.4% in MVR cases; the 5-year thromboembolism-free rate was 93.3% ± 4.6% in double valve replacement (DVR) cases; and the 15-year bleeding-free rate was 98.0% ± 1.4% in AVR cases, 75.0% ± 2.2% in MVR cases, and 100% in DVR cases. In particular, the reason for less bleeding was likely due to the control levels of INR, which were classified according to patient condition (patients in sinus rhythm following AVR: 1.6–2.0; MVR cases: 1.8–2.5; DVR cases, patients with atrial fibrillation complication, and those with left atrial dimension of ≥50 mm, 2.0–2.5), and were controlled lower than international normalized ratio (INR) set internationally.

Biological valve

Biological valves come in stented or stent-less, made of bovine or porcine material, and preserved in glutaraldehyde or formaldehyde solution. Since stentless valves have been reported to show questionable long-term follow-up results, stented valves represent biological valves that are most frequently used today. The first generation porcine biological valves have been observed to show calcification and structural valve deterioration (SVD) during a long-term follow-up period. Subsequently, there has been a remarkable improvement in long-term follow-up results due to processing to suppress calcification and improved stents.

Currently, stented biological valves available in Japan include the Carpentier-Edward (CEP) valve, Trifecta valve, and Mitroflow valve, which are all made of bovine heart sac membrane, and the Mosaic valve and the Epic valve, which are made of porcine valve. When evaluating the durability of biological valves, follow-up of more than 15 years is necessary. Forcillo et al. reported 25-year long-term follow-up results regarding the CEP valve in the aortic position. In this study, 10-, 15-, and 20-year freedom from reoperation due to SVD were 90% ± 3%, 60% ± 6%, and 30% ± 8%, respectively, in patients aged less than 60 years. On the other hand, in patients in their 60s, 10- and 15-year rates were 95% ± 1% and 90% ± 3%, respectively, and in patients aged 70 years or older, the 10-year rate was 99% ± 0.5%, showing that the outcomes were more favorable in patients aged 60 years and older. McClure et al. reported 25-year long-term follow-up results regarding the CEP valve in the aortic position, with a 34.7% 15-year freedom from reoperation due to SVD in patients aged less than 65 years, 89.4% in patients aged between 65 and 75 years, and 99.5% in patients aged 75 years or older. With regard to the CEP in the mitral position, Bourguignon et al. reported 25-year long-term follow-up results, with a 20-year SVD-free rate of 23.7% ± 6.9%; in terms of the durability, they reported 11.4 years in patients aged less than 60 years, 16.6 years in those aged between 60 and 70 years, and 19.4 years in those aged 70 years or older.

Selection of Prosthetic Valves at Our Facility

The 2006 American Heart Association (AHA)/American College of Cardiology (ACC) guidelines recommend...
biological valves for the aortic valve in patients aged 65 years and older with no risk of thromboembolism (Class IIa).22) However, the Society of Thoracic Surgeons (STS) guidelines established in 2013 downgraded the application, recommending the use of biological valves in Class IIb cases for patients less than 65 years of age.23) In 2014, the AHA/ACC guidelines were largely revised with regard to the selection of prosthetic valves.24) The revised points are as follows: for Class I, (1) The choice of valve intervention, that is, repair or replacement, as well as type of prosthetic valve, should be a shared decision-making process that accounts for the patient’s values and preferences, with full disclosure of the indications for and risks of anticoagulant therapy and the potential need for and risk of reoperation (Level of Evidence: C), and (2) A bioprosthesis is recommended in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired (Level of Evidence: C); for Class IIa, (1) A mechanical prosthesis is reasonable for AVR or MVR in patients less than 60 years of age who do not have a contraindication to anticoagulation (Level of Evidence: B), (2) A bioprosthesis is reasonable in patients more than 70 years of age (Level of Evidence: B), and (3) Either a bioprosthetic or mechanical valve is reasonable in patients between 60 and 70 years of age (Level of Evidence: B).25)

Although a number of comparative studies have reported on mechanical versus biological heart valves over a long-term follow-up period, a few reports have attained a high evidence level (Table I). Brennan et al. compared long-term clinical outcomes of AVR patients aged between 65 and 80 years registered in the STS database (mechanical valves: 14789 patients; biological valves: 24410 patients), and reported that the survival rate increased after nine years with biological valves, and that while no difference was found between the two valve types regarding thromboembolism, bleeding was significantly higher with mechanical valves (12 years: mechanical valves, 21.8%; biological valves, 15.5%), and reoperation was significantly higher with biological valves (12 years: mechanical valves, 2.3%; biological valves; 5.2%). Among these, there were three times more patients aged between 65 and 69 years who had biological valves compared to those aged between 75 and 80 years.26) Stassano et al. conducted a randomized study on mechanical and biological valves in 310 AVR patients aged between 55 and 70 years, and reported that while there were no differences between the two valve types in terms of survival, thromboembolism, bleeding, prosthetic valve infection, or major prosthesis-related adverse events, significantly higher SVD and reoperation rates were observed with biological valves. In this report, it is also mentioned that controlling INR levels low at 2.0–2.5 had led to the prevention of bleeding complications in patients with mechanical valves.26) Weber et al., compared AVR between 103 patients with mechanical valves and 103 patients with biological valves, who were matched by background and were aged less than 60 years. They reported that survival was higher in those with mechanical valves than with biological valves, and that although no differences were found in valve-related complications between the two valve types, the valve function of mechanical valves was hemodynamically superior. Furthermore, they proposed, “the transcatheter valve-in-valve intervention as potential treatment of tissue valve degeneration should not be considered the sole bailout strategy for younger patients because no evidence is available that this would improve the outcome.”27) The valve-in-valve treatment still has a high mortality rate, and although the treatment is promising in terms of the future results, the use of biological valves with consideration for valve-in-valve treatment in young patients is likely inappropriate at the moment. McClure et al. examined propensity-matched AVR patients aged 65 years or younger (361 with mechanical valves, 361 with biological valves), and reported that 14-year survival rates were 75% with mechanical valves and 65% with biological valves, and 14-year thromboembolism-free rates were 95% with mechanical valves and 91% with biological valves, showing no significant differences. The 14-year bleeding-free rate was significantly higher with biological valves, at 98% compared to 89% with mechanical valves. The 14-year operation-free rate was significantly higher with mechanical valves, at 95% compared to 81% with biological valves.28)

Only a few comparative studies have examined mechanical valves and biological valves in the mitral valve position over a long-term follow-up period. Kaneko et al. compared background-matched patients at ages less than 65 years who had a mechanical valve (125 cases) or biological valve (125 cases) in the Brigham and Women’s Hospital in the United States, and reported that patients with biological valves had a low reoperation-free rate (15 years: mechanical valve, 96.1%; biological valve, 75.3%) and low survival rate (15 years: mechanical valve, 62.6%; biological valve, 40.0%), while there were no differences in thromboembolism and bleeding events between the two valve types. These results suggest the safety of mechanical valves in patients aged less than 65 years.29)
Table 1  Comparison studies of mechanical and biological valve

<table>
<thead>
<tr>
<th>Author</th>
<th>Numbers</th>
<th>Age (y.o)</th>
<th>Follow-up period</th>
<th>Survival</th>
<th>TE</th>
<th>Bleeding</th>
<th>SVD</th>
<th>Reoperation</th>
<th>Valve-related complication</th>
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<td></td>
<td>B: 24410</td>
<td>Max. 17 years</td>
<td>(12 years)</td>
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<td></td>
<td>B: 105</td>
<td>Max. 16 months</td>
<td>(13 years)</td>
<td>(13 years)</td>
<td>(13 years)</td>
<td>(13 years)</td>
<td>(13 years)</td>
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<tr>
<td>Weber (2012)27</td>
<td>M: 103</td>
<td>&gt;60</td>
<td>33 months</td>
<td>M &gt; B</td>
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<td>M = B</td>
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<td></td>
<td>B: 103</td>
<td>Max. 10 years</td>
<td>–</td>
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<td>–</td>
<td>–</td>
<td>M = B</td>
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<tr>
<td>McClure (2014)28</td>
<td>M: 361</td>
<td>&gt;65</td>
<td>8 years</td>
<td>M = B</td>
<td>M = B</td>
<td>M &gt; B</td>
<td>–</td>
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<td></td>
<td>B: 361</td>
<td>(14 years)</td>
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<td>(14 years)</td>
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<tr>
<td>Brown (2008)29</td>
<td>M: 220</td>
<td>50–70</td>
<td>M: 9.1 years (Max. 11.9 years)</td>
<td>M &gt; B</td>
<td>M = B</td>
<td>M &gt; B</td>
<td>–</td>
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<td>M = B</td>
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<tr>
<td></td>
<td>B: 220</td>
<td>Max. 6.2 years (Max. 9.6 years)</td>
<td>(10 years)</td>
<td>(10 years)</td>
<td>–</td>
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<tr>
<td>Nishida (2014)30</td>
<td>M: 36</td>
<td>&gt;70</td>
<td>M: 7.3 years (Max. 23.2 years)</td>
<td>M &lt; B</td>
<td>M = B</td>
<td>M &gt; B</td>
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<td>M &gt; B</td>
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<td></td>
<td>B: 111</td>
<td>Max. 4.6 years (Max. 21 years)</td>
<td>(14 years)</td>
<td>(14 years)</td>
<td>(14 years)</td>
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<td>(14 years)</td>
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<td></td>
<td>M: 67</td>
<td>60–69</td>
<td>M: 9.8 years (Max. 25.5 years)</td>
<td>M = B</td>
<td>M &gt; B</td>
<td>M = B</td>
<td>M &lt; B</td>
<td>M = B</td>
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<td></td>
<td>B: 52</td>
<td>Max. 6.7 years (Max. 25.7 years)</td>
<td>(10 years)</td>
<td>(10 years)</td>
<td>–</td>
<td>–</td>
<td>–</td>
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<td></td>
<td>M: 140</td>
<td>60&gt;</td>
<td>M: 13.3 years (Max. 28.8 years)</td>
<td>M &gt; B</td>
<td>M = B</td>
<td>M = B</td>
<td>M &lt; B</td>
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<td></td>
<td>B: 37</td>
<td>Max. 9.0 years (Max. 25.5 years)</td>
<td>(15 years)</td>
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<tr>
<td>Sezai (2015)31</td>
<td>M: 117</td>
<td>&gt;65</td>
<td>M: 6.2 ± 4.3 years (Max. 18.5 years)</td>
<td>M = B</td>
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<td>M &lt; B</td>
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<td></td>
<td>B: 201</td>
<td>Max. 4.3 ± 3.6 years (Max. 13.7 years)</td>
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<td>Mitral valve</td>
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<td></td>
<td>B: 125</td>
<td>Max. 3 years</td>
<td>(15 years)</td>
<td>(20 years)</td>
<td>(15 years)</td>
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<td>(15 years)</td>
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<tr>
<td>Sezai (2015)33</td>
<td>M: 59</td>
<td>&gt;65</td>
<td>M: 6.2 years (Max. 18.5 years)</td>
<td>M = B</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>M &lt; B</td>
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<tr>
<td></td>
<td>B: 81</td>
<td>Max. 4.3 years (Max. 13.7 years)</td>
<td>–</td>
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TE: thromboembolism; SVD: structural valve deterioration; M: mechanical valve; B: biological valve
Japanese guidelines were revised in 2012 (www.jcirc.or.jp/guideline/pdf/JCS2012_ookita_h.pdf), as follows: as for Class I regarding the indications for biological valves, (1) patients who cannot receive or reject receiving administration of warfarin due to complications with hemorrhagic disease or other conditions, and (2) patients at the age of 65 years or older who require AVR, who do not have risk factors for thromboembolism. As for Class IIa, (1) patients who are considered to have issues with compliance to treatment with warfarin, (2) young women who wish to become pregnant, (3) AVR with the same type of valve in patients who require AVR due to active infectious endocarditis, and (4) patients who require tricuspid valve replacement (TVR). As for Class IIa, (1) patients aged 70 years or older who require MVR, who do not have risk factors for thromboembolism, (2) valve replacement for the mechanical valve due to thrombus formation, (3) AVR with the autologous pulmonary valve in patients with growth potential, and (4) patients in sinus rhythm who chose a biological valve after discussing in detail the risks of anticoagulant therapy, as well as the risk of requiring reoperation in the future, even if the patient is aged less than 65 years old. These are in accordance with the guidelines in the United States and Europe from before 2012. Few reports exist regarding long-term follow-up results concerning prosthetic valves in Japanese patients, and thus Japanese guidelines were created with references mostly comprising of the literature from the United States and Europe. Given that the average life expectancy of Japanese people is 3–5 years longer than that of Western people, there appears to be an urgent need for many studies reporting long-term follow-up results regarding prosthetic valves in Japanese patients.

**Studies in Our Facility**

Our facility was the first to use the SJM valve and the ATS valves in 1978 and 1993, respectively. Based on these experiences, we have been using mechanical valves in many cases. With regard to selection criteria for prosthetic valves, we choose the type of prosthesis based on a thorough discussion with each patient according to the following references: mechanical valves for patients aged less than 70 years; biological valves for patients aged 75 years or older; and either type of valves for patients aged between 70 and 75 years depending on patient characteristics (activity level, living with family, complication with atrial fibrillation, with or without aortic annulus enlargement, etc.). If patients choose a mechanical valve, they are supposed to undergo postoperative outpatient follow-up by a cardiologist or cardiac surgeon who are familiar with warfarin treatment once a month, and should their values deviate from the target levels, they are required to receive outpatient examination once a week until the values fall under the target range.

In our facility, we have performed valve replacement in 401 patients aged 65 years or older since 1993 (mechanical valve: 157 cases; biological valve: 244 cases), and examined their long-term follow-up outcomes including prosthesis-related complications. The mean age was 69.6 ± 3.7 years in those with mechanical valves, and 76.3 ± 4.8 years in those with biological valves; among patients aged 70 years and older, 71 patients chose mechanical valves. Valve-related complications were observed in nine patients with mechanical valves (5.7%; cerebral infarction, three cases of sudden death, cerebral hemorrhage, prosthetic valve infection, one case of paravalvular leakage (PVL)) and in 21 patients with biological valves (8.6%; six cases of cerebral infarction, cerebral hemorrhage, four cases of sudden death, PVL, SVD, two cases of gastrointestinal bleeding, one case of prosthetic valve infection). No significant differences were observed in the cumulative survival rate and major Adverse Cardiac and Cerebrovascular event (MACCE)-free rate, but freedom from prosthesis-related complications was significantly higher with mechanical valves (p = 0.0431). In particular, AVR outcomes were favorable, and only one patient developed prosthesis-related complications (Figs. 1 and 2).

Based on our experience, in patients aged 65 years or older, those with mechanical valves had satisfactory outcomes with a low rate of valve-related complications.
Japan is facing the aging of the population that no other countries in the world have ever experienced. In Japan, people make regular outpatient visits and properly take medications; given such national traits, our results suggest that for the Japanese, mechanical valves can be selected without any issues even at a higher age (especially in the aortic valve position), as long as the environment is such that elderly patients are well supported.

**Need for Japan’s Own Prosthetic Valve Selection Guidelines**

Japan faces the unprecedented population aging, and moreover, the average life expectancy is longer among the Japanese than the Westerners (Fig. 3). According to the 2013 abridged life table, the average remaining lifespan at ages 70, 65, and 60 years are 15.28 years in men and 19.59 years in women, 19.08 years in men and 23.97 years in women, and 23.14 years in men and 28.47 years in women, respectively (Fig. 4). It might be reasonable to select biological valves for patients aged 65 years or older in Western countries, but in Japan, whether this choice is appropriate seems questionable. According to reports from the United States and Europe, reoperation-free rates are rapidly declining with biological valves passed 15 years or longer. This time, with the revision of the AHA/ACC guidelines, it might be necessary to take into consideration the average life expectancy of Japanese people and revise the Japanese guidelines accordingly.

As described above, the literature referenced in the current Japanese guidelines mostly comprises articles from the United States and Europe. We think that there is a pressing need for many studies that report long-term follow-up results regarding prosthetic valves in Japanese patients. We are starting to see more reports that could be used as references in the future, and among those, some report ≥10-year follow-up results concerning prosthetic valves in Japanese patients. Nishida et al. from Kyushu University compared the mechanical valve and CEP valve in AVR by age. No difference was observed between the two valve types in freedom from valve-related mortality among patients aged 60 years or older; however, among patients aged less than 60 years, outcomes were significantly more favorable with mechanical valves.
(91.1% \pm 2.4\%) than with biological valves (61.2% \pm 19.0\%). Among patients aged 70 years or older, the rate of freedom from valve-related complications was 57.5% \pm 14.0\% with biological valves, which was significantly more favorable compared to 51.2% \pm 11.0\% with mechanical valves. Among patients aged less than 60 years, the rate was 73.3% \pm 3.9\% with mechanical valves, which was significantly more favorable compared to 11.1% \pm 7.3\% with biological valves. In this study, the results concerning SVD were significantly more favorable with mechanical valves in patients aged less than 70 years, and with regard to bleeding and thromboembolic events, patients aged 70 years or older, and patients in their 60s, respectively, showed favorable results with biological valves. It has been suggested that mechanical valves in patients under the age of 60 years, and biological valves in patients over the age of 70 years, are appropriate selections. This report is the only one that has compared long-term follow-up results for mechanical and biological valves in the same facility. Arinaga et al. from Kurume University reported 12-year follow-up results regarding the CEP valve in the aortic valve position, as follows: 5-, 10-, and 12-year freedom from valve-related mortality were 89.8\% \pm 2.4\%, 86.9\% \pm 3.1\%, and 76.1\% \pm 10.2\%, respectively; 10-year freedom from valve-related complications was 82.4\%; the 10-year thromboembolism-free rate was 96.9\%; 10-year bleeding-free rate was 94\%. These results show favorable outcomes over 10 years postoperatively. Minakata et al. reported long-term follow-up results regarding the CEP valve in the aortic position in Kyoto University and its affiliated hospitals; 5-, 10-, and 15-year freedom from reoperation due to SVD were 99.5\%, 96.7\%, and 97.5\%, respectively, and among all, patients aged 65 years and older had a 10-year rate of 94.4\%, whereas patients aged less than 65 years had a rate of 47.2\%, showing a significant difference. Thus, the report suggests that the CEP valve is favorable in the elderly.

There have only been a few studies reporting long-term follow-up results for prosthetic valves in Japanese subjects. Furthermore, few reports exist regarding biologic valves over 15 or more years, or regarding biological valves in the mitral valve position. It is likely that with biological valves, reoperation is rarely performed in many cases where the patient is older than 80 years. In patients aged 80 years or older, there may be cases where reoperation would not be performed even when SVD occurs. Based on our experience, at the time of surgery, 77 years and 76 years were the ages at which selection of a biological valve was considered; SVD occurred 12 years and 9 years after surgery, respectively, and at the onset of SVD, the patients were old (89 years and 85 years old, respectively). No reoperation was performed, and we encountered deaths in MVR cases. It might be necessary to grasp the approximate number of cases where no reoperation is performed despite the occurrence of SVD, and to evaluate these cases as a valve-related complication.

Japanese medical system and patient medication compliance are considered superior to those in the United States and Europe, and this time, with the revision of the AHA/ACC guidelines for the selection of prosthetic valves, we should consider whether 60–70 years should be set as a gray zone regarding the age criteria for choosing biological valves, as in the case of western guidelines, or if the age should be set higher relative to that specified in the western guidelines, given the longer Japanese life expectancy. This requires evaluation according to long-term follow-up results concerning both valve types in Japanese subjects. We believe that the development of unique, Japanese guidelines for the selection of prosthetic valves will allow us to provide appropriate selection and treatment for each patient.

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Conflict of Interest Statement

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References


