

Twenty-Year Experience With the St. Jude Medical Biocor Bioprosthesis in the Aortic Position

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Background. The purpose of this study was to evaluate the long-term performance of the St. Jude Medical Biocor stented porcine prosthesis in the aortic position.

Methods. From January 1985 to December 1996, 455 patients admitted for aortic valve replacement were consecutively enrolled in this study. The mean age was 72.5 ± 9 years, 18 patients (3.5%) had had previous cardiac surgery, and coronary artery bypass grafting was performed in 171 patients (37.6%). Follow-up was complete in 99.6%; up to 21 years were covered. Actuarial event-free rates are given as mean \pm standard error and adverse events were classified according to the guidelines for reporting morbidity and mortality after cardiac valvular operations.

Results. Cumulative follow-up time was 3,321 patient-years with a mean follow-up of 8.2 years. The actuarial

survival rate after 20 years was $9.4\% \pm 2.8\%$. The actuarial rates for freedom from structural valve deterioration were $93.1\% \pm 1.7\%$ at 10 years, $88.4\% \pm 3.5\%$ at 15 years, and $70.3\% \pm 10.9\%$ at 20 years. The actuarial rates for freedom from reoperation due to structural valve deterioration were $91.9\% \pm 1.6\%$ at 10 years, $90.6\% \pm 2.1\%$ at 15 years, and $86.5\% \pm 4.5\%$ at 20 years.

Conclusions. This study presents one of the largest series of St. Jude Medical Biocor aortic valves in the world. Results indicate an age-dependent risk of structural valve degeneration beginning as soon as 7 years postoperatively for patients below the age of 65 years, but show a low overall incidence of valve-related complications and excellent durability.

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Bioprostheses are prone to continuous degeneration and this may lead to structural valve deterioration (SVD) requiring reoperation [1–3]. Improvements in valve design and conservation methods have extended the lifetime of bioprostheses [4, 5]. Therefore, long-term data concerning valve dysfunction and the risk of reoperation are of particular interest.

The St. Jude Medical (SJM) Biocor valve (St. Jude Medical, Inc., St Paul, MN) is a triple composite porcine bioprosthesis that was first introduced in 1982 in Brazil [5]. The Biocor valve is preserved at low pressure in glutaraldehyde. During a 12-year period, from January 1985 to December 1996, the Biocor prosthesis was implanted in a series of 455 consecutive patients. This study aims to provide 21-year outcome data in patients who received a SJM Biocor bioprosthesis in the aortic position.

Material and Methods

Patients

This study includes data on all 455 patients who received a SJM Biocor bioprosthesis in the aortic position at our center between January 1985 and December 1996. This study was approved by the local Ethics Committee of the Technical University of Munich (number 1546/06). The

need for an individual consent for the study was waived by the Ethics Committee as in this retrospective study individual patients were not identified.

Follow-Up

The follow-up was conducted by questionnaires and telephone contacts with the patients in 2003 and 2006. The questionnaire was designed to answer the questions regarding clinical outcome [6]; telephone contact was made by two persons using standardized questions including a complete patient history. All possible valve-related complications were checked. Additionally, all available medical reports were obtained from the patients' cardiologists or home physicians. Causes of death were determined from hospital records and the governmental registration office. The latest follow-up was accomplished from January 2006 to July 2006.

Valve Selection

Patients older than 65 years received a bioprosthesis. The decision to implant a Biocor was made by the surgeon according to his (her) preferences. All implanted Biocor valves were standard Biocor tissue valves.

Operative Techniques

Operations were performed using standard cardiopulmonary bypass with moderate hypothermia. The valves were secured to the annulus with interrupted pledgeted

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Table 1. Demographics and Valve Size Distribution

Variable	
Age	72.5 ± 9 years
Gender (m/f)	239/216
NYHA (preop)	
II	14 (3%)
III	155 (34%)
IV	49 (10.8%)
Unknown	237 (52%)
Concomitant procedure	
CABG	171 (37.6%)
Other	26 (5.7%)
Valve size	
21	60 (13.2%)
23	182 (40%)
25	160 (35.2%)
27	43 (9.5%)
29	10 (2.2%)

CABG = coronary artery bypass grafting; NYHA = New York Heart Association.

mattress sutures. All implanted valves were standard Biocor tissue valves.

Anticoagulation Management

There was no routine postoperative anticoagulation, except in patients with atrial fibrillation or other indications for continuous anticoagulant therapy. The target international normalized ratio (INR) for patients who received anticoagulant therapy was 2.0 to 2.5 at our center, INR analysis being available since the end of the 1990s.

Outcomes

Predefined study outcomes included survival and adverse events. We assessed all adverse events related to the heart valve prosthesis, such as bleeding, endocarditis, embolism, leak, tear, valve degeneration, and reoperation that occurred during the follow-up time interval.

Valve-related death was defined as death caused by structural valvular deterioration, nonstructural dysfunction, valve thrombosis, embolism, bleeding events, valvular endocarditis, or death related to operative replacement of a dysfunctional prosthesis. Sudden, unexplained deaths of patients were counted as valve related deaths [6]. Adverse events data were collected in accordance with the standards described by Edmunds and colleagues [6] and the US Food and Drug Administration document "Replacement of Heart Valve Guidance" 1996 [7].

Statistical Analysis

Statistical evaluation was performed with the Statistical Package for Social Sciences, version 13 (SPSS, Inc, Chicago, IL). Categorical variables were reported using the number and percent of observations. Continuous variables were reported as mean ± standard deviations. Complication rates and survival rates were calculated using a nonparametric actuarial Kaplan-Meier product-

limit estimator [8]. To compare the survival and the complications patients were grouped into the following age-classes: less than or equal to 65 years, 66 to 74 years inclusive, and 75 years or above. A *p* value less than 0.05 was considered statistically significant.

Results

Patient Population

Over a 12-year period all the 455 patients who underwent aortic valve replacement with the Biocor valve at our center were included. The follow-up covered up to 21 years and was 99.6% complete for the endpoint "death"; cumulative follow-up time was 3,321 patient-years. Mean follow-up time was 8.2 years. Distributions of valve sizes and patient characteristics at the time of implantation are shown in Table 1.

Patient Survival

The overall 30-day mortality was 5.3% (24 of 455). Twelve of those patients had concomitant coronary artery bypass

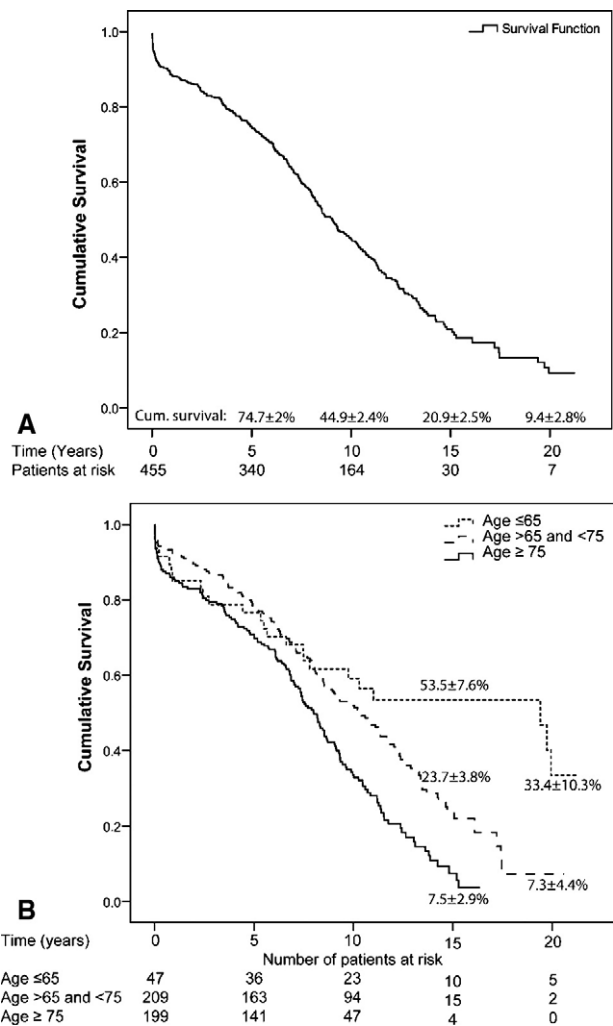


Fig 1. Survival rates for all patients (A) and for patients divided by age groups (B).

grafting (CABG), one patient had concomitant CABG and replacement of the ascending aorta, and one patient had concomitant repair of the ascending aorta. All other patients who died within 30 days had isolated aortic valve replacement. The most frequent cause of death was congestive heart failure (2.8%; 13 of 455). There were two valve-related early deaths. One patient with defect of one cusp in combination with a hemorrhagic pericarditis, and one patient with unclear cause of death, which was classified as valve-related in line with the guidelines [6].

Actuarial survival rates at 5, 10, 15, and 20 years were $74.7\% \pm 2.0\%$, $44.9\% \pm 2.4\%$, $20.9\% \pm 2.5\%$, and $9.4\% \pm 2.8\%$, respectively (Fig 1A). Survival was significantly superior in younger patients; ie, aged less than 65 years (as shown in Fig 1B). Freedom from valve-related death at 5, 10, 15, and 20 years was $94.3\% \pm 1.2\%$, $90.9\% \pm 1.5\%$, $87.8\% \pm 2.6\%$, and $87.8\% \pm 2.6\%$, respectively, and was comparable in all age groups.

Hemorrhage

Major bleeding occurred in 28 patients. Of those with a major bleeding event 7 patients had atrial fibrillation; all 7 patients were under permanent anticoagulation with Coumadin (Marcumar; Roche Pharma AG, Grenzach-Wyhlen, Germany) with a target INR between 2.0 and 2.5. The exact INR values at the time of the bleeding events were unknown. Three further patients died of an intracerebral hemorrhagic event; the anticoagulation status of those patients at the time of the event was also unknown. The other 18 patients had major bleeding events without further sequelae.

The actuarial freedom from hemorrhagic complications at 5, 10, 15, and 20 years was $96.6\% \pm 1.0\%$, $93.0\% \pm 1.6\%$, $92.2\% \pm 1.8\%$, and $76.8\% \pm 14.1\%$, respectively. Freedom from hemorrhage was comparable in all age groups.

Endocarditis

A total of 18 patients suffered from prosthetic valve endocarditis (PVE). Three patients received antibiotic treatment without reoperation, 8 patients required reoperation due to PVE, and 7 patients died. Actuarial freedom from PVE after 5, 10, 15, or 20 years was $96.1\% \pm 1.0\%$, $95.0\% \pm 1.2\%$, $95.0 \pm 1.2\%$, and $95.0 \pm 1.2\%$, respectively. The risk of postoperative PVE was significantly higher ($p < 0.005$) in patients younger than 65 years than in patients aged 65 years or more. In patients younger than 65 years the incidence of preoperative endocarditis was higher (3 of 49 patients; 6.1%) compared with patients aged between 65 and 75 years (4 of 221 patients; 1.8%) and patients older than or equal to 75 years (1 of 184 patients; 0.5%).

Structural Valve Deterioration

Structural valve deterioration was defined according to the guidelines published in 1996 [6] as a decrease of one New York Heart Association (NYHA) functional class resulting from an intrinsic abnormality of the valve that causes stenosis or regurgitation. Additionally, a mean pressure gradient exceeding 40 mm Hg was defined as

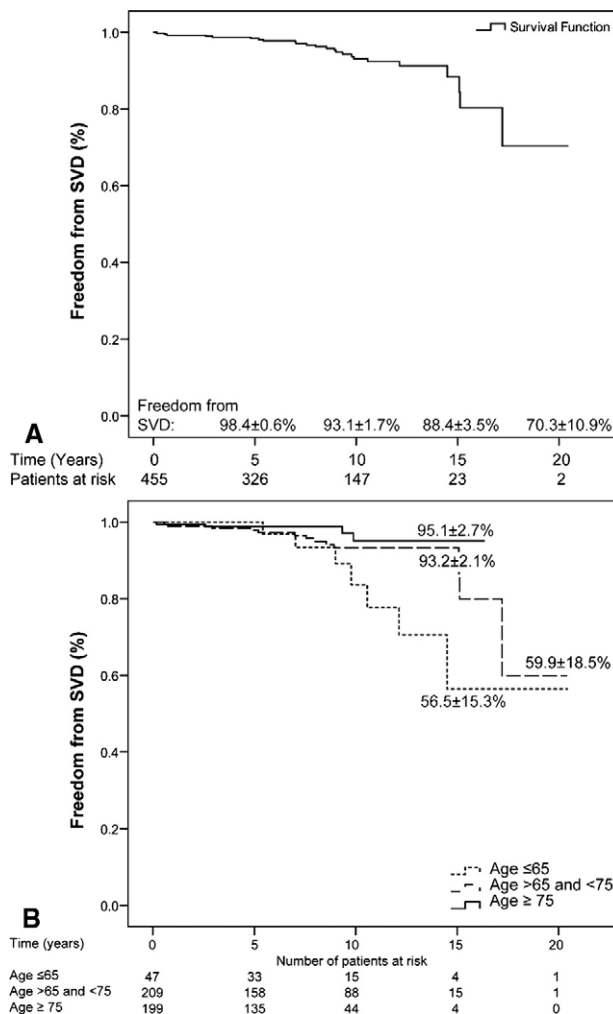


Fig 2. Freedom from structural valve deterioration (SVD) for all patients (A) and for patients divided by age groups (B).

structural valve deterioration. In total, 23 patients suffered from structural valve deterioration (SVD); of those, 16 required reoperation. Four patients were not referred by their general practitioners or refused reoperation and were treated conservatively (NYHA I, III – 1 patient each; NYHA II – 2 patients), 2 patients were too old for a reoperation (NYHA I and II). One patient was mentally retarded and the custodian refused reoperation (NYHA IV). Overall mortality of the reoperated patients was 37.5% (6 of 16) and 28.6% (2 of 7) for non-reoperated patients. There was no early death in the group of the reoperated patients (mean days to death: 995 days ± 964.4 days; range: 71 days to 2,141 days). Causes for deaths in the reoperated group were chronic heart failure (2), acute nonvalved-related death (2), valve-related death (1), and death due to other causes (1). In the group of patients who did not undergo reoperation both deaths were due to unknown causes. The actuarial freedom from SVD after 5, 10, 15, and 20 years was $98.4\% \pm 0.6\%$, $93.1\% \pm 1.7\%$, $88.4\% \pm 3.5\%$, and $70.3\% \pm 10.9\%$ (Fig 2A).

The risk for SVD was significantly ($p < 0.05$) different

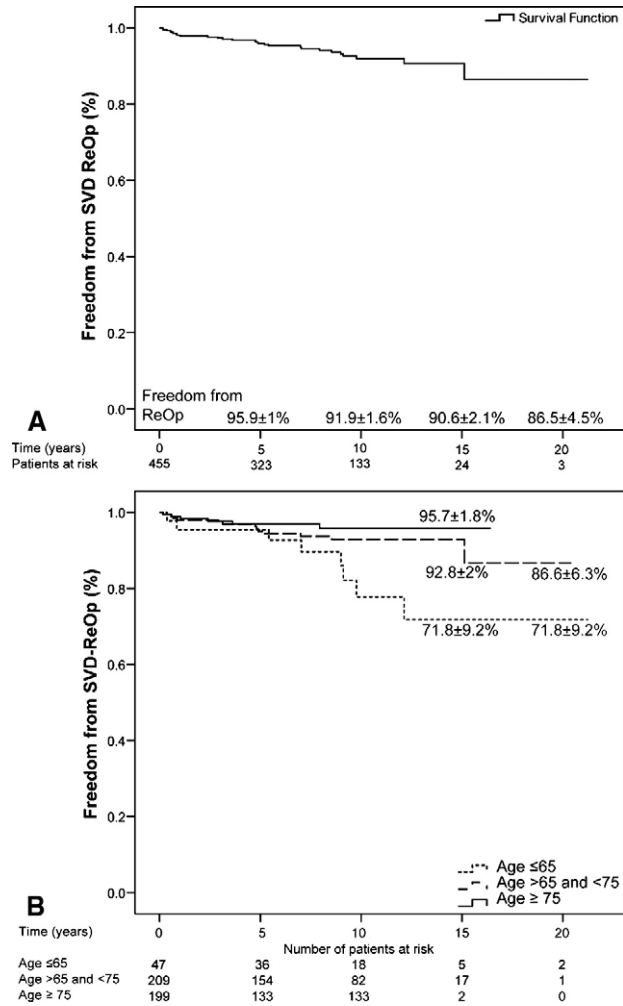


Fig 3. Freedom from reoperation due to structural valve deterioration (SVD) for all patients (A) and for patients divided by age groups (B).

for the different age groups (as shown in Fig 2B). In patients under 65 years of age the risk for SVD began to increase 7 years postoperatively (Fig B).

Nonstructural Valve Dysfunction

The actuarial freedom from nonstructural valve dysfunction (NSVD) at 5, 10, 15, and 20 years was 97.5% ± 0.8%, 97.5% ± 0.8%, 97.5% ± 0.8%, and 97.5% ± 0.8% and was similar in all age groups. Nonstructural valve dysfunction occurred in 10 patients. All patients suffered from a paravalvular leakage.

Reoperation

Reoperation was defined according to Edmunds and colleagues [6] as any operation that repaired, altered, or replaced a previously operated valve. During the 20-year follow-up period, 32 patients required reoperation. Reasons for reoperation were SVD in 16 patients, PVE in 7 patients, and paravalvular leakage in 4 patients. (A further group of 6 patients exhibited paravalvular leakage without the need for reoperation; all 10 patients with

paravalvular leakage survived.) One patient suffered from valve dysfunction due to thrombotic material on the leaflets, 2 patients were reoperated due to an aneurysm of the ascending aorta, and 1 patient had a coronary artery bypass operation. One patient had a reoperation without the cause being known. Actuarial freedom from reoperation after 5, 10, 15, and 20 years was 95.4% ± 1.1%, 90.6% ± 1.8%, 88.2% ± 2.4%, and 84.0% ± 4.7%. The risk for reoperation within 5 years after implantation of the prosthesis was significantly increased ($p < 0.005$) in patients aged up to 65 years, compared with patients aged over 65 years.

The actuarial freedom from reoperation due to SVD at 5, 10, 15, and 20 years was 95.9% ± 1%, 91.9% ± 1.6%, 90.6% ± 2.1%, 86.5% ± 4.5% (Fig 3A) and was significantly increased ($p < 0.05$) in patients younger than 65 years (Fig 3B). Survival after reoperation at 5 and 10 years was 51.6 ± 9.8% and 25.1 ± 10.8%, respectively.

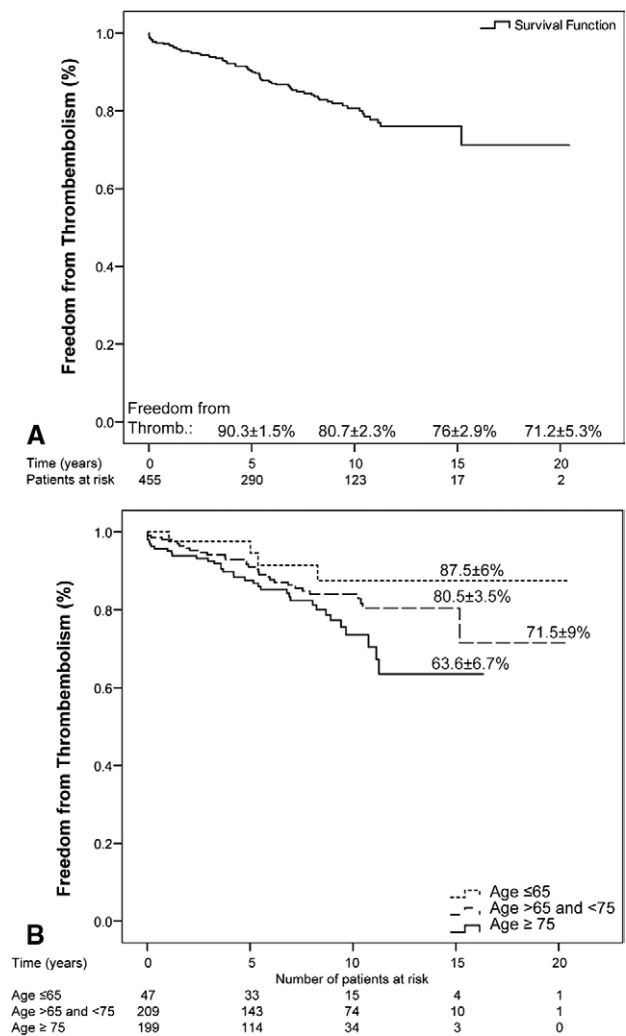


Fig 4. Freedom from thromboembolism for all patients (A) and for patients divided by age groups (B).

Thromboembolism

Thromboembolism occurred in 70 patients. Of those, 41 patients suffered from major cerebral thromboembolism, 1 patient from minor cerebral thromboembolism, and 19 patients from a reversible ischemic neurologic deficit. In 9 patients thromboembolism of the extremities occurred. Of the 41 patients with major stroke, 8 had atrial fibrillation and were under anticoagulation. Sixteen patients died after the acute event and 25 patients had residual neurologic deficits. Coagulation status of the patients with sinus rhythm was unknown. Overall freedom from thromboembolism after 5, 10, 15, and 20 years was $90.3\% \pm 1.5\%$, $80.7\% \pm 2.3\%$, $76.0\% \pm 2.9\%$, and $71.2\% \pm 5.3\%$ (Fig 4A). Older patients had an increased risk of thromboembolism (as shown in Fig 4B).

Comment

From 1999 to 2002 there was an increase in the implantation of bioprostheses from 50% to 65% [2]. Thus, at a time when the majority of patients request biologic valve prostheses, complete long-term follow-up studies are of special importance to advise patients concerning their individual risk after valve replacement. The main focus of long-term biologic valve studies lies on the incidence of SVD, thromboembolism, and major bleeding events compared with patients with mechanical prostheses.

The present study is one of the longest and largest follow-up studies of a bioprosthetic heart valve worldwide. Our study does not evaluate the hemodynamic performance, as there are several papers concerning the reliable hemodynamic function of the Biocor porcine prosthesis [9, 10].

Survival

Up to now the longest follow-up study for the Biocor includes a 17-year follow-up of around 1,500 patients, published by Mykén [11]. The group reported an actuarial survival of $28.2\% \pm 3.7\%$ at 17 years for patients receiving the valve in the aortic position (mean age, 70 ± 11 years). We observed a survival rate of $9.4\% \pm 2.8\%$ at 20 years, and calculated a freedom from death after 17 years of $17.4\% \pm 2.7\%$ in the present study.

Valve-Related Mortality

The incidence of valve-related mortality in our patient group was 7.9% (36 of 455 patients) and was higher than in the Gothenburg population after 17 years (2.7%; 35 of 1,283).

Reoperation

Freedom from reoperation in our population was $84.0\% \pm 4.7\%$ after 20 years. These results are comparable with published outcomes describing other bioprosthetic valves. Recipients of the Biocor prosthesis ($n = 254$) at the Karolinska Institute, Stockholm were reported to have about 87% freedom from reoperation after 11 years

(mean age, 78.5 ± 5 years) [12]. For the Carpentier-Edwards pericardial valve Jamieson and colleagues published a freedom from valve-related reoperation of $62.3 \pm 3.5\%$ at 18 years (mean age, 68.9 ± 10.9 years) [13].

Structural Valve Deterioration

Overall freedom from SVD was $70.3\% \pm 10.9\%$ after 20 years in this population, but patients aged up to 65 years were at a significantly higher ($p < 0.05$) risk of SVD than patients aged over 65 years. Kaplan-Meier calculations also showed significant differences regarding the time of occurrence of SVD for patients younger than 65 years, starting about 7 years postoperatively. After 20 years freedom from SVD was $56.5\% \pm 15.3\%$, $59.9\% \pm 18.5\%$, and $95.1\% \pm 2.7\%$ for patients aged 65 or less, 66 to 74, and 75 or greater years, respectively. Similar age-related differences in valve degeneration for the Biocor prosthesis have been reported previously in both the aortic and mitral positions [10, 14].

Our results compare favorably with published data on the Carpentier-Edwards porcine valve [13], which showed a freedom from SVD of 64.0% after 18 years (compared with 70.3% after 20 years in the present study). Subdivided into age groups, the authors reported freedom from SVD in 77.6% of the patients aged 61 to 70 years and in 94.6% of the patients older than 70 years [13]. Our age groups (≤ 65 years, 66 to 74 years, ≥ 75 years) are not fully comparable, but our results are slightly superior for patients older than 75 years ($95.1\% \pm 2.7\%$). Nevertheless they seem to be worse for younger patients ($56.5\% \pm 15.3\%$ for patients ≤ 65 years; $59.9\% \pm 18.5\%$ for patients 66 to 74 years).

Structural valve deterioration is an age-dependent phenomenon, which has been demonstrated for all biologic prostheses. However, younger patients request such implants mostly for life style considerations. Although the speed of SVD may be significantly different for specific biologic valves, patients below 65 years of age should be advised, that even with the most durable biologic valve today, they take a chance (of approximately 50%) of having a reoperation for replacement within 20 years.

Reoperations Due to SVD

Structural valve deterioration is a major cause of reoperation, and is generally due to either major calcification or to primary cusp deterioration without significant dystrophic calcification [3, 15, 16], both leading to a partial or total dysfunction of the bioprosthesis. The study of Biocor valves inserted in the aortic position by Mykén [11] reported a freedom from reoperation due to SVD of 73.9% after 17 years [11], which was lower than in the present study (86.5% after 20 years).

The mortality of patients who underwent reoperations due to SVD seems to be considerably higher than the mortality in patients with SVD and no reoperation (37.5% vs 28.6%). Because the groups were very small these results must be interpreted very carefully and do not justify any general statement concerning the indication for reoperation.

Hemorrhage

In the present data the overall freedom from anticoagulant-related hemorrhage (ARH) was 76.8% \pm 14.1% after 20 years and was similar for all age groups. This result seemed surprisingly low and comparable with results for mechanical valves and an aggressive anticoagulant regime. With the SJM mechanical valve, freedom from ARH after 20 years' follow-up was 77.9% (mean age, 62 \pm 14.1 years) [17] compared with 76.8% in our study. In our group there was no routine anticoagulation applied postoperatively, except in patients with atrial fibrillation or other indications for continuous anticoagulant therapy. It is possible, however, that in the present study bleeding was related to age rather than the anticoagulation regime. In our population the mean age was higher than in some other studies [11, 13]. The risk of hemorrhagic events such as gastrointestinal and cerebral bleeding rises in a general population with increasing age, and is further increased by medication such as low-dose aspirin [18].

In our analysis a single hemorrhagic event led to a drop in the freedom from ARH at 17 years from 92.2% to 76.8%. This was a nonpermanent, nonlethal cerebral event in an 89-year-old man. At that time only 5 patients were at risk, so this event had a large impact on the overall result. A more detailed description of the anticoagulation status of the individual patient was not possible as INR analyses were available only since the end of the 1990s, and systematic coagulation profiles were not available in most patients who were receiving chronic anticoagulation.

At 17 years (before the single hemorrhagic event described above) our results (92.2% \pm 1.8%) were comparable with Mykén's data [11] using the Biocor valve (91.4% \pm 2.2% freedom from ARH at 17 years), and Minami and colleagues' [19] experience with the Mitroflow prosthesis at 15 years (94.4% freedom from bleeding, mean age 75.6 years).

Other Complications

Freedom from thromboembolism also decreased with increasing age, and this may be due to the general observation that the incidence of transient ischemic attacks, ischemic stroke, and hemorrhagic stroke rises with advanced age by more than 1% in people aged over 65 years [20]. Mykén [11] published very similar results with the Biocor valve after 17 years of follow-up; freedom from thromboembolic events was 98.8% in patients aged up to 50 years, but fell with increasing age to 73.7% in patients aged over 80 years.

Younger patients seemed to have an increased risk of developing PVE postoperatively. This is also consistent with other studies. Minami and colleagues [19] reported a significant reduction in the frequency of PVE with increasing age in their population of Mitroflow valve recipients.

Influence of Patient Age on Outcome

As described above, younger patients had a higher valve degeneration rate (leading to an increased risk of reop-

eration) and an increased risk of PVE compared with older patients. The opposite is true, however, for hemorrhagic and thromboembolic events [18, 20]. With a trend toward the selection of bioprostheses in younger patients, the risk of reoperation due to SVD should be carefully discussed. However, our results for the Biocor valve showed extremely low reoperation rates compared with other bioprostheses in the aortic position [13, 21–23].

Limitations of the Study

As discussed in other studies it is extremely difficult to collect data and to maintain the quality of follow-up over a long timeframe. In particular, we did not obtain systematic echocardiographic data, a fact that could result in an underestimation of SVD rates.

The large number of variables that influence outcome make it difficult to compare results from different studies, and few data are available to guide interpretation of individual factors. In this discussion we tried to select the most appropriate comparators and to avoid potentially misleading "actual" data analyses.

Conclusion

Compared with other bioprostheses with available long-term results, our present 20-year experience demonstrated very satisfying outcomes for the SJM Biocor porcine bioprosthesis in the aortic position. Results indicate an age-dependent risk for SVD beginning as soon as 7 years postoperatively for patients below 65 years of age, but showed a lower overall incidence of valve-related complications and excellent durability, especially for patients aged over 65 years. Thus, our results support the recent changes in the "Guidelines for the Management of Patients with Valvular Heart Disease" from 2006 [2], where bioprostheses are still recommended for patients older than 65 years (class IIa). Additionally, bioprostheses are recommended for patients younger than 65 years for life style considerations (Class IIa). It needs to be stressed that the choice of using a bioprosthesis is driven by logic and discussion with the patient because the second generation tissue valves, porcine or pericardial, provide patients with similar outcomes compared with mechanical valves [24].

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INVITED COMMENTARY

The article by Eichinger and colleagues [1] reports their experience with 20-year longevity of the St. Jude Biocor bioprosthesis (St. Jude Medical, Inc, St. Paul, MN) in terms of the incidence of valve deterioration, thrombogenicity, endocarditis, and related health events (ie, basic information for valve substitute assessment).

These two decades of follow-up represent an era in which biological prostheses generally won the battle against mechanical substitutes. The reason for this trend in cardiosurgery is an expectation of better quality of life and lower risk of morbidity and mortality (especially in older populations) after biological prosthesis implantation.

It should not be forgotten that trends toward the use of bioprostheses in elderly patients are based on the lack of postoperative anticoagulant treatment on the one hand and on the durability of the implants, which are resistant to structural valvular deterioration (SVD), on the other. However, the price for this benefit is the higher reoperation rate, which has to be taken into account.

In the present article, the actual freedom from SVD assessed according to published guidelines for 5, 10, 15,

and 20 years was $98.4 \pm 0.63\%$, $93.1 \pm 1.73\%$, $88.4 \pm 3.53\%$, and $70.3 \pm 10.93\%$, respectively, and the data represent realistic values for the biological prosthesis for today.

The risk for reoperation within 5 years after implantation of the prosthesis was significantly ($p = 0.005$) higher in patients up to 65 years old, which is a well-known phenomenon. The report finds a surprisingly low percentage ($76.8 \pm 14.1\%$) of overall freedom from anticoagulant-related hemorrhage. Advanced age has to be taken into account as an explanation. Evidence-based studies to assess the pathophysiology of older patients are still lacking.

The SVD rises sharply in younger patients (<65 years), as demonstrated, after 10 years, and after 15 years freedom from SVD reached $56.5 \pm 15.3\%$, which is critically low. It should be noted as well that younger patients had a higher risk for developing prosthetic endocarditis compared with older patients (6.1 vs 1.8%, respectively; $p < 0.005$).

In general, reoperation is not necessarily associated with higher mortality rate when the operation is undertaken before severe valve destruction takes place, producing hemodynamic deterioration, and in larger series