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Mitral valve disease: if the mitral valve is not reparable/failed repair, is bioprosthesis suitable for replacement?☆

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Abstract

Objective: The durability of mitral bioprostheses has long been known to be inferior to aortic bioprostheses. Mitral valve reconstruction/repair is currently recommended for most mitral valve procedures. The choice of prostheses for non-reparable or failed mitral valve repairs has not been specified or given appropriate attention within the literature. The objective of this study is to address the role of bioprostheses in the specific subset of non-reparable or failed repair patients by using the knowledge of the general durability of mitral porcine bioprostheses, inclusive of the Carpentier-Edwards mitral porcine bioprosthesis. **Methods:** The CE-SAV was implanted in 1135 patients (1175 operations) for mitral valve replacement (MVR) from 1982 to 2000. The mean age was 65.0 ± 12.1 years (range 13–86 years). The mean follow-up was 6.4 ± 4.5 years, 7555.9 patient-years and 98.3% complete. The evaluation considered freedom from structural valve deterioration (SVD) and freedom from composites of complications, as well as risk assessment. **Results:** For the 51–60 year age group, the actual and actuarial freedom from SVD was, at 18 years, 56.0 ± 4.1% and 14.7 ± 5.8%; for the 61–70 year age group was, at 18 years, 69.6 ± 2.6% and 26.5 ± 5.9%, respectively. For the >70 group, at 15 years was 92.2 ± 2.0% and 69.0 ± 9.7%, respectively. There were a total of 256 SVD events with 31 fatalities and 226 reoperations with 10 fatalities (4.42%). The predictors of SVD were age (hazard ratio [HR] 0.98, $p = 0.0002$), concomitant CAB (HR 0.66, $p = 0.020$) and valve size (HR 1.08, $p = 0.034$). The overall actual freedom, at 15–18 years, for >70 age group was, for valve-related reoperation, 94.3 ± 1.5%; and for valve-related mortality was 87.8 ± 2.3%. **Conclusions:** The CE-SAV mitral porcine bioprosthesis cannot be recommended as representative of prosthesis-type of choice for non-reparable or failed repair of native mitral valves for ages ≤70 years. The CE-SAV mitral porcine bioprosthesis is satisfactory for implantation >70 years of age. The clinical performance of the CE-SAV is similar to other mitral bioprostheses.

Keywords: Valve disease; Mitral valve

1. Introduction

The repairability of mitral valve pathology has been reported in large published series to be well greater than 90% [1–3]. However, the Society of Thoracic Surgeons National Database reported the reparable rate to be 40.5% in 2000 and increased to only 58% in 2006.[1] It is due to this data that the prosthesis-type choices for non-reparable and failed repairs of mitral valves require consideration.

The Carpentier-Edwards supra-annular (CE-SAV, Edwards Lifesciences, Irvine, California) porcine bioprosthesis was introduced in 1981. This second generation porcine bioprosthesis has the tissue fixed with glutaraldehyde at 2 mmHg, and treated with calcium mitigation agents, polysorbate 80 and ethanol. The most extensive worldwide experience with this bioprosthesis, in the aortic position, has been documented from the University of British Columbia [4–6].

This report extends the experience with the CE-SAV in mitral valve replacement (MVR). In 1999, from a multi-center study, Jamieson et al. [7] reported on structural valve deterioration (SVD), diagnosed at reoperation, between the CE-PERIMOUNT (CE-P) mitral pericardial bioprosthesis and the CE-SAV mitral porcine bioprosthesis. This study identified an inherent superiority of the CE-P but the failure modes of the two bioprostheses, necessitating intervention, were not taken into consideration; predominantly calcific stenosis of the CE-P and regurgitant failure of the CE-SAV. The authors had previously reported on the early failure mode of stent

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[1] Society of Thoracic Surgeons. Executive Summary – STS Spring 2007 Report. Available at http://www.sts.org/documents/pdf/Spring2007ExecutiveSummary.pdf (last accessed September 10, 2007).

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dehiscence, which was controlled by a manufacturing process change in 1986 and 1987 [4].

The purpose of this study is to address the role of bioprostheses in the specific subset of non-reparable or failed repair patients by using the knowledge of the general durability of mitral porcine bioprostheses, inclusive of the Carpentier-Edwards mitral porcine bioprosthesis. The study was not designed to evaluate the indications for mitral valve replacement in the study population (inclusive of non-repair indications), rather to use the mitral valve replacement population to address the purpose of the study.

2. Patients and methods

The CE-SAV was implanted in 1135 patients (1175 operations) for mitral valve replacement from 1982 to 2000 at the affiliated teaching hospitals of the University of British Columbia, namely St. Paul's Hospital, Vancouver General Hospital and Royal Columbian Hospital. The mean age was 65.0 ± 12.1 years (range 13–86 years). Of the total population (1135 patients), 7.4% (84) had previous valve replacements, 6.8% (77) had previous valve repairs [rheumatic disease (69), myxomatous degenerative disease (7), ischemic disease (1)] and 2.0% (23) other cardiac procedures. Of the total procedures (1175) performed, the indications were: rheumatic valve disease, 54.3% (638); degenerative disease, 23.6% (277); ischemic disease, 7.0% (82); native valve endocarditis, 2.9% (34); miscellaneous, 2.0% (23); and prosthetic valve disease, 10.3% (131). Concomitant coronary artery bypass (CABG) was performed in 39.8% (452).

The patient population was evaluated as an overall procedure cohort (1175 operations) and by age distribution: 50 years or less, 151 procedures (12.9%); 51–60 years, 180 (15.3%); 61–70 years, 404 (34.4%) and more than 70 years, 440 (37.4%) procedures.

The total cumulative follow-up was 7555.9 patient-years, with a mean ± SD of 6.7 ± 4.7 years. The follow-up (calculated from 1135 patients) by age categories was as follows: 50 years or less, 1296.3 patient-years; 51–60 years, 1461.3 patient-years; 61–70 years, 2667.1 patient-years; and more than 70 years, 2131.2 patient-years. The mean follow-up by age categories was: 50 years or less, 8.7 ± 4.8 years; 51–60 years, 8.4 ± 4.7 years; 61–70 years, 6.7 ± 4.9 years; and >70 years, 5.1 ± 3.7 years ($p = 0.00002$). The total follow-up was 98.3% complete during a six-month closing interval in 2004; 19 of 1135 patients were lost to follow-up.

The guidelines for reporting morbidity and mortality after cardiac valvular operations were used to define valve-related complications and served as a basis for our methodology [8]. Multivariate proportional hazard regression analysis was used to assess risk factors [age (continuous and age categories ≤50, 51–60, 61–70 and >70 years), gender, rhythm, previous CAB, previous valve procedure, concomitant CAB and valve size] as independent predictors of structural valve deterioration, prosthetic valve endocarditis (PVE), non-structural dysfunction (NSD), valve-related reoperation (VR-REOP), valve-related residual morbidity (permanent functional or neurological impairment) (VR-MORB) and valve-related mortality (VR-MORT). The composites of valve-related complications are inclusive of structural valve deterioration, non-structural dysfunction, thromboembolism (TE), hemorrhage (ATH-antithromboembolic related hemorrhage) and prosthetic valve endocarditis.

Patient survival was assessed by Kaplan–Meier actuarial methodology. Structural valve deterioration and composites of valve-related complications were evaluated by both actual (cumulative incidence) and actuarial methodology. The actual cumulative incidence, risk probabilities were determined by an analogue of the Kaplan–Meier methodology.

The overall longitudinal evaluation was conducted periodically between 1982 and 1998, and repeated in 2004. The operative and pathological reports were evaluated to summarize the morphology of the structural failure of the documented failed prostheses. The reports facilitated classification as calcification without leaflet tears, calcification with leaflet tears, primary tears and stent post dehiscence. The sites of the primary tears were classified as commissural, middle and belly of the leaflet, basal portion of the leaflet and free margin of the leaflet.

This article has been formulated from the University of British Columbia cardiac valve database and the investigators have maintained University of British Columbia clinical research ethics board approval throughout the years, which is currently effective to December 2008. The approval incorporates an informed consenting process.

3. Results

The early mortality was 10.0% (114/1135 patients). The early mortality with CABG was 13.5% (61/452 patients) and without CABG was 7.8% (53/683 patients). By procedure, the early mortality was 9.7% (114/1175 procedures). The early mortality with CABG was 13.2% (61/461 procedures) and without CABG was 7.4% (53/714 procedures).

The late mortality (>30 days) was 7.9%/patient-year (595/1021 patients). The overall survival was 17.5 ± 1.7% at 15 years, 10.7 ± 1.8% at 18 years and 5.2 ± 2.1% at 20 years. The overall fatality rate was 9.38% per patient-year (709), from any cause. The predictors of overall mortality were age (hazard ratio [HR], 1.04 (1.03–1.05), $p < 0.001$); previous valve procedure (HR 1.75 (1.32–2.32), $p = 0.001$), and concomitant CABG (HR 1.38 (1.17–1.63), $p = 0.00012$).

The overall linearized occurrence rate of valve-related complications was 9.73% (9.06–10.40) per patient-year (735). The linearized occurrence rates for valve-related complications were as follows: PVE, 0.62% (0.44–0.80) per patient-year (47); NSD, 0.67% (0.49–0.86) per patient-year (51); ATH, 0.91% (0.70–1.13) per patient-year (69); overall TE (inclusive of thrombosis), 3.34% (2.93–3.74) per patient-year (252); overall TE without thrombosis 3.19% (2.79–3.59) per patient-year (241); and major thromboembolism, 1.81% (1.51–2.11) per patient-year (137).

Composites of valve-related complications were as follows: valve-related reoperation, 3.48% (3.07–3.89) per patient-year (263); valve-related residual morbidity, 1.55% (1.27–1.83) per patient-year (117); and valve-related mortality, 1.58% (1.29–1.86) per patient-year (119).

The freedoms from SVD, both actual and actuarial, are designated in Fig. 1a and b. There were 252 events for the

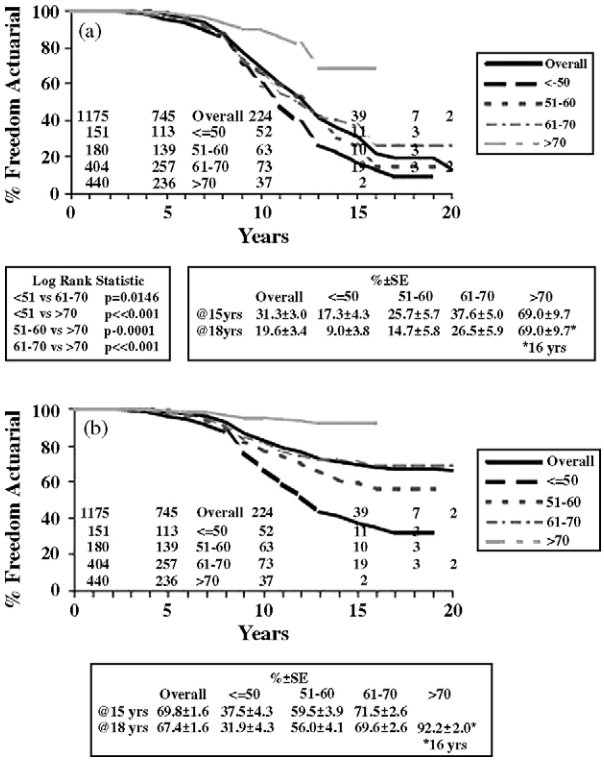

Fig. 1. (a) Freedom from structural valve deterioration (actuarial); overall and by age groups, (b) freedom from structural valve deterioration (actual); overall and by age groups.

overall cohort. Actual and actuarial freedom, overall, at 18 years was $67.4 \pm 1.6\%$ ($69.8 \pm 1.6\%$ at 15 years) and $19.6 \pm 3.4\%$ ($31.3 \pm 3.0\%$ at 15 years), respectively. The actual and actuarial freedoms from SVD for age groups 51–60 years and 61–70 years are detailed in Fig. 1a and b. The freedom from SVD at 15 years for the greater than 70 year age group was $92.2 \pm 2.0\%$ and $69.0 \pm 9.7\%$, respectively.

The cumulative incidence (hazard function) of SVD by age groups and actual risk of SVD by the age groups ($\leq$50, 51–60, 61–70 and >70 years) was evaluated, with inclusion and exclusion of stent dehiscence. In the 51–60 years group, the actual exclusion risk for SVD over 18 years was $37.7 \pm 4.3\%$; for 61–70 years, $26.8 \pm 2.6\%$ over 18 years; and for >70 years, $7.0 \pm 2.0\%$. Of the 39 stent dehiscence cases; 10 were $\leq$50 years; 13, 51–60 years; 13, 61–70 years; and 3 were >70 years. For the group >70 years, the freedom (actual) of SVD exclusive of stent dehiscence was $93.0 \pm 2.0\%$ at 18 years and SVD inclusive of stent dehiscence, $92.2 \pm 2.0\%$ at 18 years [by actuarial analysis, >70 years greater than 51–60 years ($p = 0.001$) and greater than 61–70 years ($p = 0.0001$)].

The number of events of age categories is detailed by age groups in Table 1, documenting linearized rates, related fatalities and reoperations. There were a total of 256 events with 31 fatalities and 226 reoperations with 10 fatalities (4.42%). The linearized occurrence rates of SVD for patients $\leq$70 years were exceptionally high: 4.67%/patient-year for 51–60 years and 3.43%/patient-year for 61–70 years. It was only in the age group >70 years that the rate dropped to 0.86%/patient-year. There were 30 documented events that did not have reoperations, with 21 fatalities attributed

Table 1
Structural valve deterioration overall and by age groups by linearized rates, events alive and fatal, and reoperation and no reoperation, alive and fatal.

Age groups	Rates, %/patient-year	Total vents	Events		REOP	No REOP
			Alive	Fatal		
≤50	6.21	79	77	2	79 (2)*	0 (0)*
51–60	4.67	68	62	6	64 (3)	4 (3)
61–70	3.43	90	70	20	71 (5)	19 (15)
>70	0.86	19	16	3	12 (0)	7 (3)
Total	3.39	256	225	31	226 (10)	30 (21)

* () Fatal.

primarily to SVD. The fatalities were contributed to by congestive heart failure, myocardial infarction, cardiac arrest, cancer, left ventricular dysfunction and mitral regurgitation, renal failure, chronic obstructive pulmonary disease, gastrointestinal hemorrhage and non-valve-related cerebrovascular accident.

The actual freedom, at 18 years, from other valve-related complications was as follows: PVE, $94.4 \pm 1.1\%$ (actuarial, $83.3 \pm 5.9\%$); NSD, $96.4 \pm 0.7\%$ (actuarial, $92.8 \pm 2.0\%$); ATH, $93.7 \pm 1.1\%$ (actuarial, $81.8 \pm 7.7\%$); overall thromboembolism, $82.4 \pm 1.3\%$ (actuarial, $71.8 \pm 2.6\%$); and major TE, $87.4 \pm 1.2\%$ (actuarial, $78.0 \pm 2.7\%$).

There were 109 mortalities (exclusive of 10 sudden unexpected deaths) from valve-related complications and 263 reoperations with 15 fatalities. Of the total 119 valve-related mortalities, 31 were due to SVD, 14 were due to PVE, 9 were due to NSD, 14 were due to ATH, 37 were due to

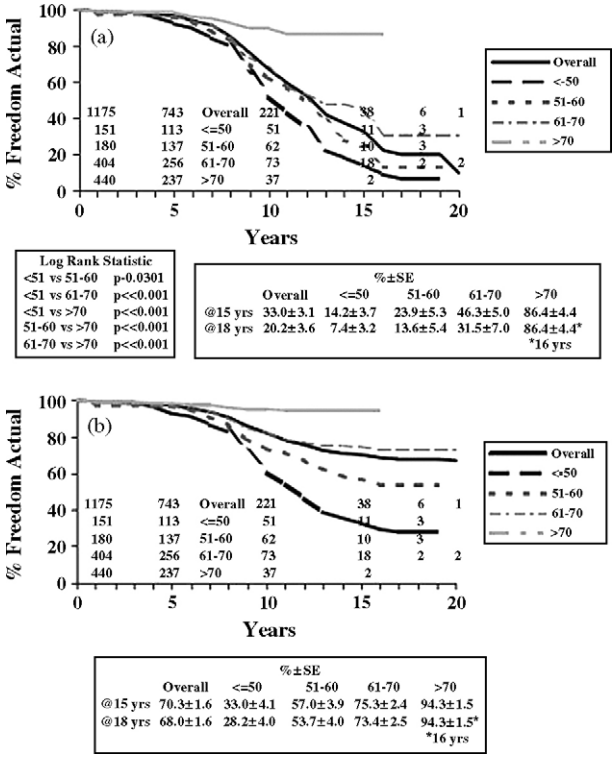

Fig. 2. (a) Freedom from valve-related reoperation (actuarial); overall and by age groups, (b) freedom from valve-related reoperation (actual); overall and by age groups.

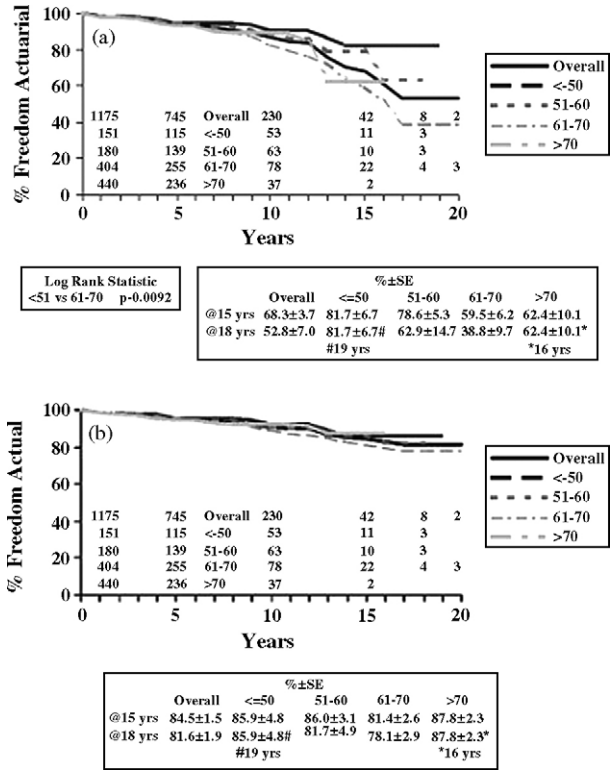

Fig. 3. (a) Freedom from valve-related mortality (actuarial); overall and by age groups, (b) freedom from valve-related mortality (actual); overall and by age groups.

thromboembolism and 4 due to thrombosis, and 10 due to sudden unexpected death. Of the 263 valve-related reoperations, there were 225 due to SVD, 14 due to PVE, 19 due to NSD and 5 due to thrombosis, with 10, 0, 3 and 2 fatalities, respectively. The freedom from valve-related reoperation (actual and actuarial) overall and by age groups is illustrated in Fig. 2a and b. The freedom from valve-related mortality (actual and actuarial), likewise, is presented in Fig. 3a and b. The actual freedom from valve-related reoperation was 94.3 ± 1.5% for age group >70 years at 16 years (actuarial 86.4 ± 4.4%) (Fig. 2a and b). The actual freedom from valve-related mortality for >70 years was 81.6 ± 1.9%, overall, with no clinical difference between age groups (Fig. 3a and b).

The univariate predictors of SVD, valve-related reoperation and valve-related mortality are detailed in Table 2. The multivariate predictors of SVD, valve-related reoperation, valve-related mortality and valve-related morbidity are presented in Table 3. The predictors of SVD were age, concomitant CABG and valve size. The predictors of valve-related reoperation were age and concomitant CABG. The predictors of valve-related mortality were age and previous valve procedure. The only predictor of valve-related morbidity was valve size.

The mean time from implantation to reoperation for SVD was 9.59 ± 3.01 years and by age categories: 50 years or less, 9.96 ± 3.01 years; 51–60 years, 10.16 ± 3.14 years; 61–70 years, 9.07 ± 2.78 years; and more than 70 years, 7.06 ± 1.98 years.

The pathology of the cases of SVD was reviewed. Of the 252 cases of structural valve deterioration, 221 came to reoperation or the valve was examined at autopsy, and 31 were confirmed by echocardiogram only; 233/252 (92.5%) presented with mitral insufficiency, 19/252 (7.5%) presented with stenosis. Reoperation and/or autopsy of the 221 cases of structural valve deterioration revealed the following findings: calcification with leaflet tear 113 (51.1%), calcification without accompanying leaflet tear 10 (4.5%), primary tears 59 (26.7%) and stent post dehiscence 39 (17.6%). In the population of 113 showing calcification with tears the degree of calcification was graded as trivial/mild in 46, mild/

Table 2
Univariate predictors of SVD, valve-related reoperation and valve-related mortality.

	SVD	VR-REOP	VR-MORT
Gender	M 18.2%, F 23.6%, $p = 0.033$	M 18.6, F 24.9%, $p = 0.014$	M 9.3%, F 10.7%, $p = 0.515$
Age (years)	No 67.7 ± 10.8 years, yes 56.0 ± 12.3 years, $p < 0.001$	No 68.2 ± 10.1, yes 54.8 ± 12.6, $p < 0.001$	No 65.2 ± 12.3, yes 65.4 ± 9.8, $p = 0.806$
Pre-CABG	No 2.0%, yes 20.0%, $p = 0.015$	No 22.9%, yes 7.3%, $p = 0.030$	No 10.2%, yes 7.3%, $p = 0.792$
Pre-valve	No 1.6%, yes 4.9%, $p = 0.841$	No 22.7%, yes 18.8%, $p = 0.495$	No 9.8%, yes 14.1%, $p = 0.280$
Pre-repair	No 20.1%, yes 36.5%, $p = 0.0003$	No 21.1%, yes 36.5%, $p = 0.001$	No 9.9%, yes 12.5%, $p = 0.530$
Pre-cardiac	No 21.5%, yes 16.7%, $p = 0.802$	No 22.5%, yes 16.7%, $p = 0.666$	No 10.3%, yes 4.2%, $p = 0.502$
OP-CABG	No 29.1%, yes 9.5%, $p < 0.001$	No 30.8%, yes 9.3%, $p < 0.001$	No 11.8%, yes 7.6%, $p = 0.027$
Size	No 28.2 ± 2.2, yes 28.9 ± 2.1, $p = 0.000004$	No 28.2 ± 2.2, yes 28.8 ± 2.2, $p < 0.0001$	No 28.4 ± 2.2, yes 28.6 ± 2.2, $p = 0.312$

Table 3
Multivariate predictors of SVD, valve-related reoperation and valve-related mortality.

	SVD	VR-REOP	VR-MORT	VR-MORB
Gender	–	–	–	–
Age	HR 0.98 (0.97–0.99), **$p = 0.0002$**	HR 0.97 (0.96–0.98), **$p < 0.001$**	HR 1.03 (1.01–1.05), **$p = 0.001$**	–
Pre-CABG	–	–	–	–
Pre-valve	–	–	HR 1.96 (1.05–3.64), **$p = 0.034$**	–
Pre-repair	–	–	–	–
Pre-cardiac	–	–	–	–
OP-CABG	HR 0.656 (0.46–0.94), **$p = 0.020$**	HR 0.691 (0.48–0.99), **$p = 0.043$**	–	–
Valve size	HR 1.08 (1.01–1.15), **$p = 0.034$**	–	–	HR 1.12 (1.02–1.24), **$p = 0.019$**

moderate 20, moderate/severe 23 and unknown in 24. The location of the tears was at the commissures in 59, free margins 32, middle/belly 7 and fracture of wire stent 1, as known in 79 patients, with more than one location often affected.

The presentation of deterioration in the 221 valves confirmed by reoperation/autopsy changed throughout the age groups $\leq$50 years (78), 51—60 (63), 61—70 (69) and >70 (11) as follows: calcification with tears, 60%, 51%, 44% and 36%, respectively; calcification without tears, 6%, 5%, 3% and 0%, respectively; primary tears, 21%, 24%, 35% and 36%, respectively; and stent post dehiscence, 13%, 21%, 20% and 27%.

In the population of 10 with calcification and no tears, 5 out of 7 with reports showed moderate/severe degree of calcification. Of the 59 primary tears, the location of the lesions were commissural 12, free margin 7, basal 6, and unknown 34. One case of stent post dehiscence actually involved dehiscence at two posts, not just one.

Of the 31 structural valve deteriorations diagnosed by echocardiography only, the echocardiograms showed two with moderate and severe stenosis, and 29 with moderate/severe and severe mitral regurgitation.

4. Discussion

The reparability of mitral valve pathology has been reported in large published series to be well greater than 90% [1—3].

However, the Society of Thoracic Surgeons national database reported the reparable rate to be 40.5% in 2000 and increased to only 58% in 2006.[1] It is due to this data that the prosthesis-type choices for non-reparable and failed repairs of mitral valves requires consideration.

The Carpentier-Edwards SAV porcine bioprosthesis was introduced in the early 1980s with both the aortic and mitral versions. The University of British Columbia and its affiliated teaching hospitals has provided periodic documentation on both the aortic and mitral prostheses but particularly the aortic prosthesis [4—6]. The clinical performance and durability of the aortic prosthesis was reported in 2005 [5]. In 2006, the Vancouver experience with the CE-SAV AVR was compared to the Tours, France experience with the CE-PERIMOUNT AVR and similar clinical performance was documented [9].

The last report on the CE-SAV MVR was in 1999 when Jamieson and international colleagues [7] compared the Vancouver CE-SAV MVR experience to the worldwide experience with the CE-PERIMOUNT MVR. The durability, at 10 years, was different with freedom from SVD diagnosed at reoperation being in favor of CE-P for age groups 51—60, 61—70 and >70 years, as documented in Table 4. The comparison was performed on SVD diagnosed at reoperation, but the failure modes of the two bioprostheses were not appreciated and were not taken into consideration; predominantly calcific stenosis of the CE-P and regurgitant failure of the CE-SAV.

The earlier mode of failure of stent dehiscence of the CE-SAV has been considered corrected by a change in the manufacturing process in 1986 and 1987. The stent dehiscence mode of failure was identified in prostheses implanted between 1982 and 1986 [4] and considered due to the aortic wall being extensively trimmed.

This study evaluation was initially conducted to determine if the 10-year assessment in 1999 of the mitral prosthesis held validity at the 15—18 year interval of observation. The actual cumulative incidence and actual/actuarial freedom was calculated with and without stent dehiscence. Stent dehiscence accounted for 18% of structural valve deterioration while calcification with leaflet tear, 51%; calcification without tear, 4.5%; and primary tears, 27%. Bottio and investigators [10] reported the pathological findings of limited explants of the Hancock II and found failures distributed equally between dystrophic calcification and primary, non-calcium-related tearing and only one case of commissural dehiscence in the combined aortic and mitral explants. The pathology of the CE-PERIMOUNT MVR has been reported by Marchand and colleagues [11,12] to be distinctly different that the CE-SAV MVR-calcification in the majority of cases, 73%; leaflet tear, 20%; and leaflet tear + calcification, 7%.

There remains difficulty in comparing the freedom from structural valve deterioration because of the various reports assessing different age categorizations, the use of actuarial analysis but incomplete use of actual analysis. Actuarial analysis assesses the incidence of structural failure of the prosthesis while actual determines the influence of structural failure on the specific population from the center under review.

The CE-SAV MVR compares reasonably favorably with the Hancock II from studies by David, Rizzoli and colleagues [13—15]. The actual freedom in the current study is 93% at 16 years for the population >70 years. With the Hancock II, David et al. [13] had 89% actual freedom at 15 years for $\geq$65 years while Rizzoli et al. [15] reported 89.5% at 15 years. The Toronto series of the Hancock II was further reported by Borger et al. [16], in 2006, at 10 and 20 years by only actuarial analysis. The report does not support comparison for 15- and 18-year freedoms from structural valve deterioration as the 18-year freedoms were not reported and the 20-year freedoms are not supported by adequate number of patients at risk.

The only MVR prosthesis that seems to be outperforming others with regard to freedom from structural valve deterioration is the St. Jude Medical Biocor [17,18]. In 2005, Myken [18] reported a 17-year actuarial freedom of 96% for patients >60 years (51—60 years, 79%; 61—70 years, 89%; and 71—80 years, 100%) in a limited series. These remarkable results for a mitral bioprosthesis may be related to the tri-composite configuration with stress reduction. This prosthesis has no calcium mitigation therapy while the current generation St. Jude Medical Epic does have calcium retardation therapy.

The Medtronic Mosaic porcine bioprosthesis only has reporting of clinical performance to 6—8 years and consequently the impact on structural valve deterioration requires further extended evaluation [19].

The manufacturer of the CE-SAV, Edwards Lifesciences, had the CE-SAV AVR approved in the United States in 2000 while the CE-SAV MVR was not presented for approval. In the United States, Edwards Lifesciences, through the years, has continued to market the first-generation standard config-

uration as the CE Duraflex, low-pressure mitral bioprosthesis. The CE-SAV mitral bioprosthesis is marketed internationally. The tissue has been treated with calcium mitigation agents, polysorbate-80, and ethanol in the XenologiX process, as with other Edwards bioprostheses.

There are limitations to this study. The accrual time period was predominantly prior to commencement of mitral valve reconstruction in the study center, that is, 70% of the patient population. The remaining mitral valve replacements were performed during the commencement of mitral valve reconstruction as a standard of care. Several determinants of long-term outcome were not included in the risk analysis, namely ventricular dysfunction, preoperative NYHA status, congestive heart failure, hypertension, renal failure and diabetes mellitus, as well as timing of surgery. This study primarily dealt with structural valve deterioration of bioprostheses and previous studies have identified predominantly the risk factors considered.

The reassessment of the Carpentier-Edwards Supra-annular porcine mitral bioprosthesis reveals very acceptable

Table 4
Freedom from structural valve deterioration for mitral bioprostheses.

Author	Prosthesis	Mean age (years)	Freedom from SVD	Duration	
			Actuarial	Actual	Years
Neville et al. [12]	CE-P	63.9 ± 11.5	78		12
		<60	70		12
		>60	100		12
Jamieson et al. [7][a]	CE-SAV	51–60	69.4 ± 4.5%	80.0 ± 3.0%	10
	CE-P		84.3 ± 5.0%	89.8 ± 3.3%	10
	CE-SAV	61–70	75.2 ± 3.7%	87.6 ± 1.9%	10
	CE-P		95.2 ± 2.1%	96.8 ± 1.4%	10
	CE-SAV	>70	91.5 ± 3.2%	96.5 ± 1.3%	10
	CE-P		100%	100%	10
Myken et al. [17][a]	SJM Biocor	63	92.0 ± 4.0%		15
		≤50	71.0 ± 15.0%		15
		51–60	90.0 ± 7.0%		15
		61–70	100%		15
		71–80	100%		15
David et al. [13]	Hancock II	65 ± 11	66.0 ± 6.0%	83.0 ± 3.0%	15
		<65		76.0 ± 5.0%	15
		≥65		89.0 ± 4.0%	15
Marchand et al. [11][a]	CE-P	60.7	68.8 ± 4.7%	83.4 ± 2.3%	14
		<65	62.8 ± 5.7%	75.7 ± 3.6%	14
		≥65	85.9 ± 5.0%	93.8 ± 2.1%	14
		≤60	59.2 ± 6.6%	72.2 ± 4.5%	14
		61–70	76.0 ± 6.3%	87.4 ± 3.1%	14
		>70	100%	100%	10
Rizzoli et al. [14]	Hancock II	<65		82.0 ± 4.2%	15
		≥65		91.8 ± 4.6%	15
Jamieson et al. [17]	Medtronic	70.5 ± 9.5	98.4 ± 1.1%	98.7 ± 0.9%	6
	Mosaic	≤60		100%	6
		61–70		98.0 ± 2.0%	6
		>70		98.7 ± 1.3%	6
Myken [18][a]	SJM Biocor	64 ± 12	81.3 ± 6.0%		17
		≤50	63.8 ± 15.3%		17
		51–60	78.6 ± 12.1%		17
		61–70	89.4 ± 7.1%		17
		71–80	100%		17
		<60	78.6 ± 8.2%		17
		>60	95.8 ± 3.8%		17
Borger et al. [16]	Hancock II	67 ± 11			
		<65	82.0 ± 5.0%		10
		≥65	95.0 ± 2.0%		10
		<65	27.0 ± 9.0%		20
		≥65	59.0 ± 11.0%		20
Rizzoli et al. [15]	Hancock II	<60	70.0 ± 7.5%	77.5 ± 5.3%	15
		≥60	72.0 ± 7.4%	87.8 ± 3.2%	15
		≥65	75.6 ± 9.2%	89.5 ± 3.8%	15
Jamieson et al. (current)	CE-SAV	51–60	24.0 ± 8.1%	62.3 ± 4.3%	18
		61–70	33.8 ± 6.4%	73.2 ± 2.6%	18
		>70	70.4 ± 9.8%	93.0 ± 2.0%	16

[a] Freedom from reoperation for SVD.

freedom from structural valve deterioration for patients greater than 70 years of age (freedom, actuarial 70% and actual 93% at 15—16 years) and compares favorably to major mitral bioprostheses [4,11—18,20—22]. The CE-SAV meets our clinical performance criteria for patients greater than 70 years of age. The CE-SAV performance, being similar to other mitral bioprostheses, does not represent the expectations when non-reparable/repaired mitral valves may be replaced with a bioprosthesis. The Carpentier-Edwards Supra-annular porcine mitral bioprosthesis remains not recommended for patients less than 70 years of age because of the limited durability and increased risk of reoperation for structural valve deterioration. In consideration of this recommendation and the documented clinical performance of other bioprostheses, bioprostheses cannot be the recommended prosthesis-type for non-reparable or failed repairs of the mitral valve (Table 4).

As one considers the risk of reoperation with bioprostheses to replace a non-reparable mitral valve, the choice for mitral valve replacement in the age category at risk is mechanical prostheses [23]. It is only if the age category is above 70 years should one consider bioprostheses. The desired management modality with placement of a prosthesis in a non-reparable mitral valve is that future reoperation is avoided, regardless of the potential safety of that operation [23]. The residual problem with mechanical prostheses is the risk of fatal hemorrhage. This serious complication can be minimized by the use of patient-controlled anticoagulation and the use of current contemporary mechanical prostheses that afford the opportunity for reduction of stasis within the valve components and provide the opportunity for the use of low-dose anticoagulation to prevent both major thromboembolism and major hemorrhage [24,25].

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