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Mitral Valve Replacement and Long-term Prognosis

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ABSTRACT :

Objective. We assessed the long-term risk of mortality associated with mechanical and biological mitral valve replacement (MVR).

Methods. We reviewed articles published during the last decade, with emphasis on large series reporting mortality data and follow-up of 5 years or longer. The latest editions of textbooks on cardiology and cardiac surgery were also reviewed.

We used mortality analysis methodology, comparing the observed mortality in these series to the expected mortality calculated from country-specific life tables, to calculate the risk of mortality expressed as the mortality ratio (MR), values above 100% traducing the excess risk of mortality compared to the general population.

Results. After MVR, the MR at 10 years of follow-up varied from 182% to 437% (mean: 278%) for mechanical valve prostheses, and from 237% to 637% (mean: 298%) for bioprosthetic valves. A MR above 700% was associated with MVR before the age of 50 years. Duration of follow-up, age at surgery, gender, and New York Heart Association functional class at time of surgery, variability in anticoagulation, concomitant coronary artery bypass grafting and type of valve implanted were all independent prognostic factors after MVR.

Conclusion. Different from aortic valves replacement (AVR), mechanical MVR has a better prognosis than biological MVR. As with AVR, the MR is very high after mechanical and biological MVR, under the age of 50 years.

Key words : Mitral valve replacement, mechanical valves, bioprosthesis, long-term survival.

Mitral valve replacement (MVR) by mechanical or bioprosthetic valves revolutionized the care of patients with severe mitral valve disease. A number of advanced lesions of the mitral valve still require MVR with reliable devices. Improved valve design and development of better biomaterials will eventually improve clinical results further. Worldwide, mechanical MVR is more common today than bioprosthetic MVR. Indications to choose one type of mechanical valve or another vary primarily by surgeon preference and occasionally depend on the state of the annulus and whether or not there have been multiple previous operations.¹⁾

Mitral valve repair is a preferred method for mitral regurgitation. The results of a recent study by Suri et al.²⁾ demonstrate the clear advantage of mitral valve repair over valve replacement, and the improving durability of valvuloplasty, which is now comparable to or better than mechanical valve replacement. Mitral valve repair is the first-choice approach for mitral regurgitation, because of the associated preservation of left ventricular function. In mitral valve stenosis, open commissurotomy has been replaced by mitral balloon valvuloplasty.³⁾ We will restrict our topic to MVR leaving mitral valve repair, mitral valve annuloplasty and mitral valve balloon valvuloplasty for another article.

Patients in any age group in sinus rhythm who wish to avoid anticoagulation may prefer a bioprosthetic valve. This is especially true for patients in who anticoagulation is contraindicated.⁴⁾ A bioprosthetic valve is preferred in patients over age 70 years and in sinus rhythm, since these valves deteriorate more slowly in older subjects. In addition, as also observed by Grunkemeier et al.,⁵⁾ some 60-year-olds may not outlive their prosthetic valves

because of comorbid disease.^{6),7)} Specifically, patients who require combined MVR and coronary artery bypass grafting (CABG) for ischemic mitral regurgitation and coronary artery disease have significantly reduced long-term survival compared to patients who do not have concomitant coronary artery disease.^{7),8)}

As long-term results have become available for various bioprostheses, it appears that the incidence of structural valve degeneration is a drawback of these valves,^{9),10)} and is more frequent in mitral than in aortic bioprosthesis.¹¹⁾ Furthermore the durability of porcine bioprostheses is better than that of pericardial mitral bioprostheses.¹²⁾

Published studies of mortality after valve replacement have significant limitations. Many of them have reported a single large center's experience over an extended period of time, often more than 10 years.¹³⁾ Although these reports are necessary to assess long-term valve survival and the incidence of valve-related complications, and post-operative findings may represent world class centre experience, the data may not be representative of current practice and may not be generalized to other centers. Underwriting manuals from different companies recommend very different ratings for patients with MVR; this might reflect the companies' experience in such cases. However, as underwriting recommendations are so different, we favoured an evidence-based approach and assessed long-term risk mortality after MVR, based on studies from varying centers during the last decade.

Material and methods

Selected articles

Of 279 articles identified by "PUBMED" search, using the terms "mitral valve replace-

ment AND long-term survival", restricted to abstracts and articles published in English from January 1995 to June 2006. 15 were selected according to the following criteria: large series including more than 400 patients, and reporting survival at 5 years or more, with separate results for mechanical and bioprosthetic MVR or combined results. Nine additional papers were found by consulting the bibliography and related references from the selected articles, for a total of 24 publications meeting our selection criteria. All were reports of consecutive cases in 1 center, several centers, or reports in several papers.

Mortality analysis

The usual mortality analysis methodology¹⁴⁾ was used to calculate the risk of mortality, expressed as the mortality ratio (MR), comparing the observed mortality calculated from actuarial survival in each study with the expected mortality calculated from life tables for the general population from corresponding countries, and according to length of follow-up.

Observed mortality was expressed as the geometric average annual mortality rate (\check{q}), derived from the observed cumulative survival rate (P), as $\check{q} = [1 - P^{1/\Delta t}]$, Δt being the length of follow-up.

Expected mortality (also expressed as the geometric average annual rate, weighted for gender, and adjusted to the duration of study follow-up) was calculated from life tables for the general population of each country in the Human Mortality Database, available at: <http://www.mortality.org>.

We chose to use expected mortality from population life tables rather than actuarial life tables because the studies were not randomized and reported the mortality of consecutive cases. The extra mortality associated with

valve replacement in these cohorts was, therefore, better reflected by comparison with population tables as discussed in a previous paper.¹⁵⁾

From each life table, we calculated the cumulative mortality rate (Q'): the expected cumulative survival rate (P') was calculated as its complement (i.e. $P' = 1 - Q'$), and the expected geometric average annual mortality (\check{q}') rate was derived from P' as above, i.e. ($\check{q}' = [1 - P'^{1/\Delta t}]$).

Results

Selected articles

From a total of 24 publications meeting our selection criteria, 9 reported results on MVR with mechanical valves only,^{16) 24)} 9 with bioprosthetic valves only,^{25) 23)} and 6 with combined valves.^{31) 39)}

The selected articles totaled 22,009 patients from 11 countries (USA, Canada, France, Italy, Spain, the Netherlands, Sweden, UK, Israel, Japan and Taiwan) and 1 multicenter study. Mean age at operation in these studies varied from 40 to 69 years (with an average mean age of 58 years): 45% of patients were men. Mean reported survival was 53% for an average follow-up of 12 years. The average mortality ratio comparing the observed mortality to the corresponding expected mortality from life tables for each country was 275% overall.

Surprisingly, mean age at surgery was similar in patients with mechanical and biological MVR (57 and 58 years, respectively). However, patients from series with combined valves were older than series with separate mechanical and bioprosthetic valves (average mean age 62 years). Follow-up varied from 5 to 20 years.

Demographic characteristics, type of valve

(mechanical valves, bioprosthesis and combined), the percentage of men, and overall survival according to follow-up for each study

are summarized in Tables 1, 2, and 3. In Table 2, the same group (Jamieson et al.) reported results with the Carpentier-Edwards

Table 1 Mechanical mitral valve replacement: studies, baseline characteristics of patients, follow-up and overall survival

	Setting	Patients (N)	Men (%)	Age (years)	Overall survival %		
					5-yr	10-yr	15-yr
Aris et al. 1996 ⁶⁴	SPA	2,806	52	53	90.7		
Carrier et al. 2006 ¹⁷¹	CDN	1,043	34	59	76	59	40
Gao et al. 2004 ¹⁸⁰	USA	1,406	74	56		51	23 (20 Y)
Bondo et al. 2003 ¹⁹⁰	JPN	812	41	58	91.9	88.4	85.4
Kallewaard et al. 2000 ²⁰⁰	NL	800	62	55			41
Butchart et al. 2001 ²¹⁰	UK	796	26	57		59.2	
Borman and De Riberolles 2003 ²²⁰	ISR	656	60	58		75.1	
Remadi et al. 1998 ²³⁰	FRA	616	43	56			60
Ruel et al. 2004 ²⁴⁰	CDN	493	38	59	86		
Total patients and mean values		9,428	48	57	86	67	50

Table 2 Bioprosthetic mitral valve replacement: studies, demographic characteristics of patients, follow-up and overall survival

	Setting	Patients (Number)	Men (%)	Age (years)	Overall survival %		
					5-yr	10-yr	15-yr
Fann et al. 1996 ²⁵⁰	USA	1,285	30	58	70	50	32
Jamieson et al. 1995 ²⁶⁰	CDN	938	53	64			35 (12 Y)
Bortolotti et al. 1995 ²⁷⁰	ITA	603	36	50		62 (8 Y)	
Borger et al. 2006 ²⁸⁰	CDN	559	47	40		50	
Yu et al. 2003 ²⁹⁰	TAIW	523	46	67		84	
Jamieson et al. 1995 ³⁰⁰	CDN	501	54	56		51.7	24.4
Glower et al. 1998 ³¹⁰	USA	492	41	59	69	44	23
Rizzoli et al. 2006 ³²⁰	ITA	484	42	65			39.7
Marchand et al. 2001 ³³⁰	MC*	435	41	61	76	56.8	37.1
Total patients and mean values		5,820	43	58	72	56	31

*Multicenter

Table 3 Combined mitral valves: studies, demographic characteristics of patients, follow-up and overall survival

	Setting	Patients (Number)	Men (%)	Age (years)	Overall survival %		
					5-yr	10-yr	15-yr
Tourani et al. 2000 ³⁴⁰	USA	1,844	40	58		64.5	
Grunkemeier et al. 1999 ³⁵⁰	USA	1,579	38	56		50	
Cen et al. 2001 ³⁶⁰	USA	1,139	37	61		47.6	
Khan et al. 2001 ³⁷⁰	USA	915	44	69			43
Hellgren et al. 2004 ³⁸⁰	SWE	784	48	64	75	55.9	36.5
Stahle et al. 1997 ³⁹⁰	SWE	500	57	65		55.1	
Total patients and mean values		6,761	45	62	75	52	40

Table 4 Mechanical mitral valve replacement: observed and expected mortality and mortality ratio at 5, 10, and 15 years

	Observed mortality (\hat{q})			Expected mortality (\hat{q}')			Mortality ratio MR (%)		
	5-yr	10-yr	15-yr	5-yr	10-yr	15-yr	5-yr	10-yr	15-yr
Aris et al. 1996 ^{16a}	0.0193			0.0083			232		
Carrier et al. 2006 ^{27a}	0.0534	0.0514	0.0592	0.0126	0.0171	0.0250	423	300	236
Gao et al. 2004 ^{18a}		0.0651	0.0708		0.0195	0.0437		334	162
Bondo et al. 2003 ^{19a}	0.0185	0.0122	0.0105	0.0060	0.0067	0.0099	308	182	106
Kallewaard et al. 2000 ^{20a}			0.058			0.0262			221
Butchart et al. 2001 ^{21a}		0.0634			0.0145			437	
Borman et al. 2003 ^{22a}		0.0351			0.0154			227	
Remadi et al. 1998 ^{23a}			0.034			0.0222			153
Ruel et al. 2004 ^{24a}	0.0297	0.0241	0.0231	0.0102	0.0129	0.0167	290	185	138
Mean values	0.0302	0.0419	0.0426	0.0093	0.0143	0.0239	313	278	169

Table 5 Bioprosthetic mitral valve replacement: observed and expected mortality and mortality ratio at 5, 10, and 15 years

	Observed mortality (\hat{q})			Expected mortality (\hat{q}')			Mortality ratio MR (%)		
	5-yr	10-yr	15-yr	5-yr	10-yr	15-yr	5-yr	10-yr	15-yr
Fann et al. 1996 ^{25a}	0.0688	0.0669	0.0732	0.0144	0.0173	0.0235	478	386	311
Jamieson et al. 1995 ^{26a}			0.0833			0.0342			245
Bortolotti et al. 1995 ^{27a}		0.0589			0.0091			637	
Borger et al. 2006 ^{28a}		0.0669			0.0382			237	
Yu et al. 2003 ^{29a}		0.0171			0.0031			550	
Jamieson et al. 1995 ^{30a}		0.0638	0.0897		0.0156	0.0204		410	440
Glower et al. 1998 ^{31a}	0.0715	0.0788	0.0933	0.0184	0.0248	0.0363	388	317	257
Rizzoli et al. 2006 ^{32a}			0.0597			0.0304			196
Marchand et al. 2001 ^{33a}	0.0534	0.0549	0.0684	0.0159	0.0221	0.0305	335	248	225
Mean values	0.0645	0.0581	0.0779	0.0162	0.0186	0.0292	400	397	279

Table 6 Combined mitral valve replacement: observed and expected mortality and mortality ratio at 5, 10, and 15 years

	Observed mortality (\hat{q})			Expected mortality (\hat{q}')			Mortality ratio MR (%)		
	5-yr	10-yr	15-yr	5-yr	10-yr	15-yr	5-yr	10-yr	15-yr
Tourani et al. 2000 ^{34a}		0.0429			0.0188			228	
Grunkemeier et al. 1999 ^{35a}		0.0669			0.0174			385	
Cen et al. 2001 ^{36a}		0.0725			0.0298			243	
Khan et al. 2001 ^{37a}			0.0809			0.0434			186
Hellgren et al. 2004 ^{38a}	0.0559	0.0565	0.0649	0.0152	0.0215	0.0340	367	363	190
Stable et al. 1997 ^{39a}		0.0578			0.0315			183	
Mean values	0.0559	0.0593	0.0729	0.0152	0.0238	0.0387	367	280	188

porcine valve before 1982 (Standard valve)³⁰⁾ and after 1982 (Supra-annular valve).²⁶⁾

Mortality ratios

Observed and expected geometric average annual mortality rates, according to follow-up and the MR for each study are summarized in Tables 4, 5, and 6.

In patients with mechanical valves, the MR varied from 232% to 423% (average: 313%) in studies reporting survival at 5 years, from 182% to 437% (average 278%) in studies reporting survival at 10 years, and from 106% to 236% (average 169%) in those reporting survival at 15 years and more.

In patients with bioprosthetic valves, the MRs were higher and varied from 335% to 478% at 5 years, 237% to 637% at 10 years, and 196% to 440% at 15 years (average values of 400%, 397% and 279%, respectively).

The MRs of series with combined mechanical and biological valves are reported in Table 6, with MR values intermediate between MRs of mechanical and biological MVRs.

The biological MVRs were placed in relatively young patients, with an average age for implantation close to the series with mechanical valves; propensity of biological valves to deteriorate faster in younger patients (less than 60 years of age), is a possible explanation for such differences in MRs in series with mechanical versus biological valves.

Reading the selected articles, made it clear that duration of follow-up, age at implantation, preoperative clinical status (New York Heart Association (NYHA) class), gender, variability of anticoagulation and the nature of the implanted valve (mechanical vs. bioprosthesis) all influenced long-term mortality after MVR.

Factors influencing mortality

Duration of follow-up

Overall survival rates for all MVRs decreased with the duration of follow-up. The average cumulative survival rate was 79% at 5 years, 61% at 10 years, and 43% at 15 years or more, a manifestation of increased mortality rate in population aging more in the longest follow-up series. However averaged MRs decreased from 353% at 5 years to 219% at 15 years or more, as the extra mortality associated with a medical condition, lessens as age progresses. For mechanical MVRs the MRs (averaged between all studies) declined at 5, 10 and 15 years, and were 313%, 278% and 169%. Similarly the averaged MRs of bioprosthetic valves decreased respectively at 5, 10 and 15 years: 400%, 397%, and 279%.

Influence of age

Glower et al.³¹⁾ reported survival by age group in a series of 492 bioprosthetic MVRs. Mortality rates derived from survival at 10 years increased with age (from 0.0450 for age <50 years to 0.1808 for age over 70 years), but when compared to the expected mortality for the same age group from the US life table, the risk of mortality expressed as the MR decreased with age, from 8-fold in age group <50 to 2-fold for age group over 70 years (the MR was 789% for age group <50 years, 560% for age group 50-59 years, 284% for age group 60-69 years, and 198% for age over 70 years).

The same pattern was noted in a series from Sweden reported by Hellgren et al.³²⁾ including 784 patients with combined mechanical and bioprosthetic MVR followed for 8 years. The MR was 872% for age group <50, 325% for age group 50-60 years, 220% for age group 61-70 years, and 189% for age over 70 years.

From survival at 15 years, by age groups (<65 years and \geq 65 years) in a series of 513 mechanical and 402 bioprosthetic MVR by Khan et al.,³⁷ calculated MR comparing observed mortality derived from survival rates with expected mortality from life table US, 1989-1991, decreased with advanced age in patients with bioprosthetic MVR (300% in patients under age 65 versus 258% in patients aged 65 years or more); this was probably due to increased structural deterioration rate of the biological valves in the younger group; however, in this series the MRs, increased slightly (180% vs. 211%) with advanced age in those with mechanical MVR.

Influence of gender

From the series of Hellgren et al.,³⁸ we calculated MRs of 390% for 361 women followed for 8 years, and 194% for 347 men followed for 7 years. This denotes that the risk of mortality was almost twice higher in women compared to men.

Preoperative NYHA functional class

Patients with advanced preoperative symptoms have reduced long-term survival. In the study by Hellgren et al.,³⁸ survival at 5 years decreased with NYHA functional class (84% with NYHA class I/II, 79% with class IIIA, and 70% with NYHA class IIIB/IV). The risk of mortality increased with functional class, with calculated MRs of 225%, 300% and 435% in these 3 groups respectively.

Influence of anticoagulation variability

Butchart et al.,⁴⁰ in a series of Medtronic-Hall valves included in reference 21, reported that anticoagulation variability influenced mortality after mechanical MVR. In 647 patients (27% men), with mean age 57 years, mortality at 15 years was compared to expected mortality in the UK general population of the same age. The risk was 3-fold higher in

patients with high anticoagulation variability than in those with low anticoagulation variability. The calculated MRs were respectively 165%, 245%, and 395% in patients with low, intermediate and high anticoagulation variability, respectively.

Concomitant CABG

In a series of 1844 patients (mean age 58 years) reported by Tourani et al.,⁴¹ survival at 10 years was higher in patients (n=1418) without concomitant CABG versus patients (n=426) with concomitant CABG (70% vs. 48%). The risk of mortality, expressed as MR calculated according to life table USA was higher in the group without CABG (242% vs. 180%). This MR took into consideration the fact that patients without concomitant CABG were younger (55 years vs. 65 years) with more women in this group (64% vs. 46%).

We have to mention, however, that inverse results were obtained in a smaller series of 784 patients aged 64 years, reported by Hellgren et al.³⁸ At 5 years, the calculated MR was 500% in patients with concomitant CABG vs. 300% in those without.

Biological versus mechanical mitral valves

The advantages and disadvantages of mechanical valve prostheses and bioprostheses is now better known after years of follow-up. Because of the risk of thromboembolism and the hazards of continuous anticoagulation associated with mechanical valves prostheses, tissue valves were widely used for MVR from the 1970s until the early 1980s. However, one disadvantage of the bioprostheses was their predictable structural failure, often leading to reoperation, whereas mechanical valves provided durability.

Cen et al.³⁶ concluded that valve type did not influence survival in young or older patients. However, from this study of 495 pa-

tients with bioprostheses as well as 644 patients with mechanical MVR and similar demographic characteristics, we calculated MRs of 218% with mechanical valve replacement and 279% with bioprostheses at 10 years of follow-up. This is consistent with our literature review.

In the series by Khan et al.,²⁷⁾ the MR was also higher with biological (MR = 300%) than with mechanical valves (MR = 180%) under age of 65.

Pelletier et al.²³⁾ reported series of 1,593 patients (51% men) who underwent valve replacement from 1976 to 1988 with a porcine (878 patients, mean age: 54 years) or pericardial bioprostheses (715 patients, mean age: 57 years); this study included 678 MVRs. Pericardial valve showed a much higher degree of degeneration in the mitral position, with a freedom rate of deterioration after 6 years of 70% compared with 92% with porcine prostheses. Survival was better after porcine compared with pericardial prostheses valves (78% vs. 71% at 6 years after implantation), and MRs (calculated according to life table Canada 1980-1989) were 270% and 485% respectively. This series published before 1995, did not meet our selection criteria, and was not included in our main review.

Conclusion

Different from AVR, mechanical MVR has a better prognosis than biological MVR. Under the age of 50 years, very high mortality is associated with either mechanical or biological MVR. Furthermore, our medical literature review has shown that duration of follow-up, age at time of surgery, gender, preoperative NYHA functional class, concomitant CABG and variability of anticoagulation should be taken into account when assessing long-term

prognosis after MVR.

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