JOURNAL OF INSURANCE MEDICINE

ORIGINAL ARTICLE

Outcome of Patients Treated With a St. Jude Prosthetic Heart Valve

Robert J. Pokorski

Background. Long-term outcome of patients treated with a St. Jude prosthetic heart valve was reported by investigators in Lausanne, Switzerland. This article quantifies the mortality and morbidity implications of single or multiple heart valve replacement.

Results. After hospital discharge, mortality ratios were highest for duration 5-10 years, roughly comparable in patients who received a single valve, and generally higher in those who received both an aortic and a mitral valve prosthesis. Outcome varied with preoperative myocardial function, but there was no survival difference among subjects with a history of stenotic, regurgitant, or mixed lesions. Postoperative complications included embolism, anticoagulant-related hemorrhage, stroke, prosthesis thrombosis, endocarditis, prosthesis dysfunction, hemolytic anemia, and reoperation.

Conclusions. This study indicated that overall mortality experience was fairly comparable in patients who received a single St. Jude prosthetic heart valve and less favorable in those who received multiple valves. Long-term morbidity rates following insertion of a St. Jude prosthetic heart valve were high.

Address: Cologne Life Reinsurance Company, 30 Oak Street, Stamford, CT 06905

Correspondence: Robert J. Pokorski, MD, FACP
Vice President, Worldwide Medical Research & Development
Telephone: (203) 356-4003,
Facsimile: (203) 356-4038
E-mail: pokorski@colognere.com

Keywords: Prosthetic valve, valve prosthesis, aortic stenosis, aortic insufficiency, mitral stenosis, mitral insufficiency.

Received: Nov. 7, 1997

Accepted: Dec. 31, 1997

Journal of Insurance Medicine, 1997, 29:240-243

Synopsis

Long-term outcome of patients treated with a St. Jude prosthetic heart valve between 1979 and 1984 was reported in a study from Lausanne, Switzerland.[1] The cohort consisted of 321 patients (59% male, 41% female) who received 354 valve prostheses: 194 aortic (mean age 58±13 years), 94 mitral (mean age 57±11 years), 1 tricuspid (age 68 years), and 32 multiple valves[2], (mean age 52±14 years). Follow-up was 96% complete (2967 patient-years, mean follow-up 9.5 years). Valve surgery had been performed previously in 34 patients (11%). Etiology of the valvular heart disease varied depending on whether the aortic or mitral valve was affected, with most cases overall due to rheumatic, congenital, myxomatous, endocarditic, or degenerative causes. The most common indications for valve surgery were heart failure in 226 cases (70.4%), syncope in 20 (6.2%), chest pain in 16 (5%), and two or more symptoms in 50 patients (15.6%). Combined coronary artery bypass graft surgery and prosthetic valve replacement were done in 44 patients (14%). There were 10 deaths within the first 30 days of surgery and an additional 125 deaths during the remainder of the study. Late mortality was classified as valve-related (15%), sudden death (19%), cardiac non-valve related (31%). noncardiac (29%), and unknown (6%). Expected mortality rates were determined from Switzerland Population Table 1988-1993. Additional data were obtained from the author.

Analysis

Average annual mortality experience is displayed for all patients combined (Table 1), aortic valve replacement (Table 2), mitral valve replacement (Table 3), and multiple valve replacement (Table 4), and summarized in the Figure.

- After hospital discharge (0-30 days), mortality ratios were highest for duration 5-10 years for all four groups.
- When comparing aortic (Table 2) vs.

mitral (Table 3) valve results, experience was more favorable for mitral valve replacement for duration 30 days-5 years, more favorable for aortic valve replacement for 5-10 years, and essentially the same for duration 10-13 years.

- Mortality ratios for durations 5-10 years and 10-13 years were much higher in patients who received both an aortic and mitral valve (Table 4).

- Data provided by the author indicated that year 1 expected mortality rate (mean q') for the entire cohort (Table 1) corresponded to what would be expected in 65-year-old individuals, and comparative experience was calculated on that basis. Mortality ratios would be significantly higher for younger individuals and lower for older patients.

Debetez et al.[1] reported other parameters which affected long-term survival.

- Outcome was better in patients with good pre-operative myocardial function compared to those with clinical or laboratory evidence of cardiac failure.

- Co-morbid coronary heart disease was not an independent risk factor for mortality after adjusting for age and the presence or absence of heart failure.

- There was no survival difference among subjects with a history of stenotic, regurgitant, or mixed lesions.

- Valve-related deaths were more common in patients who received small prostheses (≤23 mm).

Morbidity rates were high. Complications included embolism (2.3% per patient-year), anticoagulant-related hemorrhage (3.3% per patient-year), stroke (2.6% per patient-year), prosthesis thrombosis (0.1% per patient-year), endocarditis (0.4% par patient-year), prosthesis dysfunction (0.4% per patient-year), hemolytic anemia (0.1% per patient-year), and reoperation (0.4% per patient-year). Eighty subjects were not retired at the end of follow-up, and the degree of activity was known for 65 of these patients: 40 (62%) were working full-time, 10 (15%) were partially active, and 15 (23%) were not working and received complete disability compensation. The reason for complete or partial disability was valve-related in 5 cases, cardiac-related in 11, and non-cardiac in 9.

In conclusion, this study indicated that overall mortality experience was roughly comparable in patients who received a single St. Jude prosthetic heart valve and less favorable in those who received multiple valves. Mortality ratios in Tables 1-4 are most applicable to 65-year-old patients. Long-term morbidity rates following insertion of a St. Jude prosthetic heart valve were high.

References

1. Debetaz LF, et al. St. Jude medical valve prosthesis; An analysis of long-term outcome and prognostic factors. J Thorac Cardiovasc Surg 1997; 113:134-48.
2. With a single exception, multiple valve surgery referred to both aortic and mitral valve replacement.

Table 1

Mortality Experience Following Insertion of a St. Jude Prosthetic Heart Valve, All Patients Combined, by Duration since Surgery

Duration t to +△t	Entrants**	Mortality Rate* Observed q	Mortality Rate* Expected q′	Comparative Experience* Mortality Ratio 100q/q′	Comparative Experience* Excess Death Rate 1000 (q-q′)
0-30 d	321	0.315	0.01348	2,340	302
30 d-5 yr	311	0.028	0.01532	183	13
5-10 yr	265	0.055	0.02325	237	32
10-13 yr	197	0.042	0.02921	144	13

* Mortality rates are average annual values. Mortality ratios and excess death rates represent average annual experience.
**Entrants are the number of subjects alive at the beginning of the interval.

Table 2

Mortality Experience Following Insertion of a St. Jude Prosthetic Heart Valve, Aortic Valve Replacement, by Duration since Surgery

Duration t to +△t	Entrants**	Mortality Rate* Observed q	Mortality Rate* Expected q′	Comparative Experience* Mortality Ratio 100q/q′	Comparative Experience* Excess Death Rate 1000 (q-q′)
0-30 d	194	0.271	0.01596	1,700	255
30 d-5 yr	189	0.035	0.01808	194	17
5-10 yr	157	0.061	0.02726	224	34
10-13 yr	114	0.048	0.03500	137	13

* Mortality rates are average annual values. Mortality ratios and excess death rates represent average annual experience.
**Entrants are the number of subjects alive at the beginning of the interval.

Table 3

Mortality Experience Following Insertion of a St. Jude Prosthetic Heart Valve, Mitral Valve Replacement, by Duration since Surgery

Duration t to +△t	Entrants**	Mortality Rate* Observed q	Mortality Rate* Expected q′	Comparative Experience* Mortality Ratio 100q/q′	Comparative Experience* Excess Death Rate 1000 (q-q′)
0-30 d	94	0.402	0.01051	3,820	391
30 d-5 yr	90	0.017	0.01219	139	5
5-10 yr	81	0.046	0.01772	260	28
10-13 yr	62	0.031	0.02420	128	7

* Mortality rates are average annual values. Mortality ratios and excess death rates represent average annual experience.
**Entrants are the number of subjects alive at the beginning of the interval.

Table 4

Mortality Experience Following Insertion of a St. Jude Prosthetic Heart Valve, Multiple Valve Replacement, by Duration since Surgery

Duration t to +△t	Entrants**	Mortality Rate* Observed q	Mortality Rate* Expected q′	Comparative Experience* Mortality Ratio 100q/q′	Comparative Experience* Excess Death Rate 1000 (q-q′)
0-30 d	32	0.315	0.00908	3,470	306
30 d-5 yr	31	0.015	0.01062	141	4
5-10 yr	26	0.051	0.01569	325	35
10-13 yr	20	0.050	0.01962	255	30

* Mortality rates are average annual values. Mortality ratios and excess death rates represent average annual experience.
**Entrants are the number of subjects alive at the beginning of the interval.

Figure

Average Annual Mortality Ratios Following Insertion of a St. Jude Prosthetic Heart Valve