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“The St. Jude Medical Cardiac Valve Prosthesis: A 25-Year Experience with Single Valve Replacement”

Emery RW, Krogh CC, Arom KV, et al. A long-term retrospective study, 4,480 patients - 2982 aortic, 1498 mitral implants in patients between 1977- 2002 32,190 patient years of total follow-up.



Study objective:

- Document patient survival and Valve Related Events (VREs) in up to a 25-year experience.

Key findings:

- Proven clinical performance:
 - Only 1.6% (71/4480) of patients during the course of 25 year follow-up needed their SJM valve replaced or repaired. Actual freedom from reoperation at 20 years was 97% AVR and 96% MVR.
 - The study notes an exceedingly low reoperation incidence for pannus formation or entrapment at .1% AVR and 0% MVR.
- Low complication rates:
 - Table 1 re-confirms the very low complication rates with the St. Jude Medical® mechanical heart valves.
 - Table 2 shows the percentage of patients free from valve-related mortality and late mortality during the study period.
 - According to the authors, “Valve-related events were low, most commonly caused by patient-related factors as opposed to the presence of a prosthetic valve.”

“Of the more than 70 mechanical valves that have been introduced clinically, the SJM has been the most successful.”
p.776

“This retrospective study represents the longest [32,190 patient years], largest [4,480 patients], and most complete report [95% follow-up] on a bileaflet mechanical valve.”
p.780

Table 1

Linearized Rates VREs (% pt-py.)		
	AVR	MVR
Valve thrombosis	0.06	0.18
Thromboembolism	1.9	2.8
Bleeding	2.7	2.7

“The SJM valve can be recommended to patients as a prosthesis that will last their lifetime.” p.781

Table 2

Percentage of Patients		
Free From:	AVR	MVR
Valve-Related Mortality	93%	91%
Late Mortality	61%	63%

Study Implications for Valve Selection:

- **Life Expectancy:**

Patients are living longer with their prosthetic valves: In this study, 28% of patients followed-up were older than 80 years.¹

“Because there is a risk of bioprosthetic valve loss as early as 6 to 8 years after implant, mean time to biologic repeat replacement may be short.” p.781

- **Reoperation:**

The study showed that reoperative mortality risk is significant at 10%.¹

- Other studies have shown operative morbidity and mortality increase with patient age.^{2,3,4,5}
- The annual risk of tissue valve reoperation begins to rise in 6-8 years and increases progressively with time.^{1,6}

- **Anticoagulation:**

Nearly half of all bleeding events occurred in the first year post-op.¹

- Patient self-testing may lower valve related events, although no patients did self-testing in this study.¹
- Up to 1/3 of patients require chronic anticoagulation for the long-term.¹
- Long-term studies have noted up to 1/3 of aortic tissue valve recipients and over half of mitral tissue valve recipients eventually require chronic anticoagulation.⁷

- **Age:**

The authors recommend the following criteria for mechanical valve replacement:¹

- AVR < 70 years of age
- MVR < 75 years of age
- A mechanical valve is recommended also in the more elderly and those who are already taking or are at risk for being placed on anticoagulation.

Conclusion:

Following extensive long-term follow-up over 25 years, the SJM mechanical heart valve demonstrates excellent function in the aortic and mitral positions with low complications rates.

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