Early and Mid-Term Outcome of Valve Replacement With Porcine Bioprosthesis in the Aortic Positions

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Objective

The porcine bioprosthesis is used for the replacement of malfunctioning native or prosthetic aortic and/or mitral heart valves. This study aimed to retrospectively analyze the early and mid-term clinical results of porcine bioprosthesis in the aortic position among the Chinese population.

Methodology

Study design

- Patients who underwent aortic valve replacement (AVR) with the porcine bioprosthesis at two tertiary care centers from April 2017 to October 2021 were included. The ethics review board of each participating center reviewed and approved the study.
- The medical records were retrospectively reviewed to evaluate the clinical characteristics, operative findings, and early and mid-term postoperative outcomes in these patients.

Case Report Form → Patient baseline characteristics / Operative information / Early and mid-term postoperative outcomes

Statistical analysis

- Continuous variables were presented as mean ± SD and categorical variables as frequency and percentage.
- The major adverse event rate was calculated as a percentage of the number of adverse events divided by the total number of person-years of follow-up.
- Freedom from death was calculated using Kaplan-Meier analysis. The analyses of age groups (≥65 years vs. <65 years) were conducted according to the recommendations for prosthesis type by the American College of Cardiology (ACC) and American Heart Association (AHA) guidelines. Comparisons between groups were performed using the log-rank test. All tests were 2-sided, and P<0.05 was considered statistically significant.

Results

The study population consisted of 127 patients (78 males, mean age 64 ± 9 years), with a mean preoperative New York Heart Association (NYHA) class of 2.8 ± 0.6 (**Table 1**).

Table 1. Baseline characteristics of patients included in the study

| Variables	N = 127
Age (years)	
Mean ± SD	64 ± 9
Sex, n (%)	
Female	49 (38.6)
Male	78 (61.4)
NYHA, n (%)	
I	4 (3.2)
II	23 (18.1)
III	94 (74.0)
IV	6 (4.7)
Aortic valve lesion, n (%)	
Stenosis	5 (3.9)
Regurgitation	76 (59.8)
Mixed	46 (36.2)

➤ **Perioperative period**

There were no valve-related reoperations or deaths during the perioperative period.

➤ **Follow-up period**

- The follow-up rate was 98.4%, with a cumulative follow-up duration of 308 person-years.
- During follow-up, the incidence of prosthetic valve dysfunction and perivalvular leakage events was both 0.32%/patient-year, with no reoperations required. Other observed adverse events included arrhythmias (1.62%/patient-year), cerebral hemorrhage (0.32%/patient-year), cerebral embolism (0.32%/patient-year), and cerebral infarction (0.32%/patient-year).
- Nine deaths were recorded, and the cumulative survival rate at four years was $90.1\% \pm 3.6\%$ (**Figure 1A**). The causes of death included cerebral hemorrhage (2 cases), tumor metastasis (1 case), other cerebrovascular causes (1 case), renal failure (1 case), hypertension (1 case), and unknown etiology (2 cases). Subgroup analysis showed a four-year cumulative survival rate of $97.7\% \pm 2.3\%$ for patients under 65 years and $83.6\% \pm 6.1\%$ for those aged 65 years or older (P > 0.05) (**Figure 1B**).
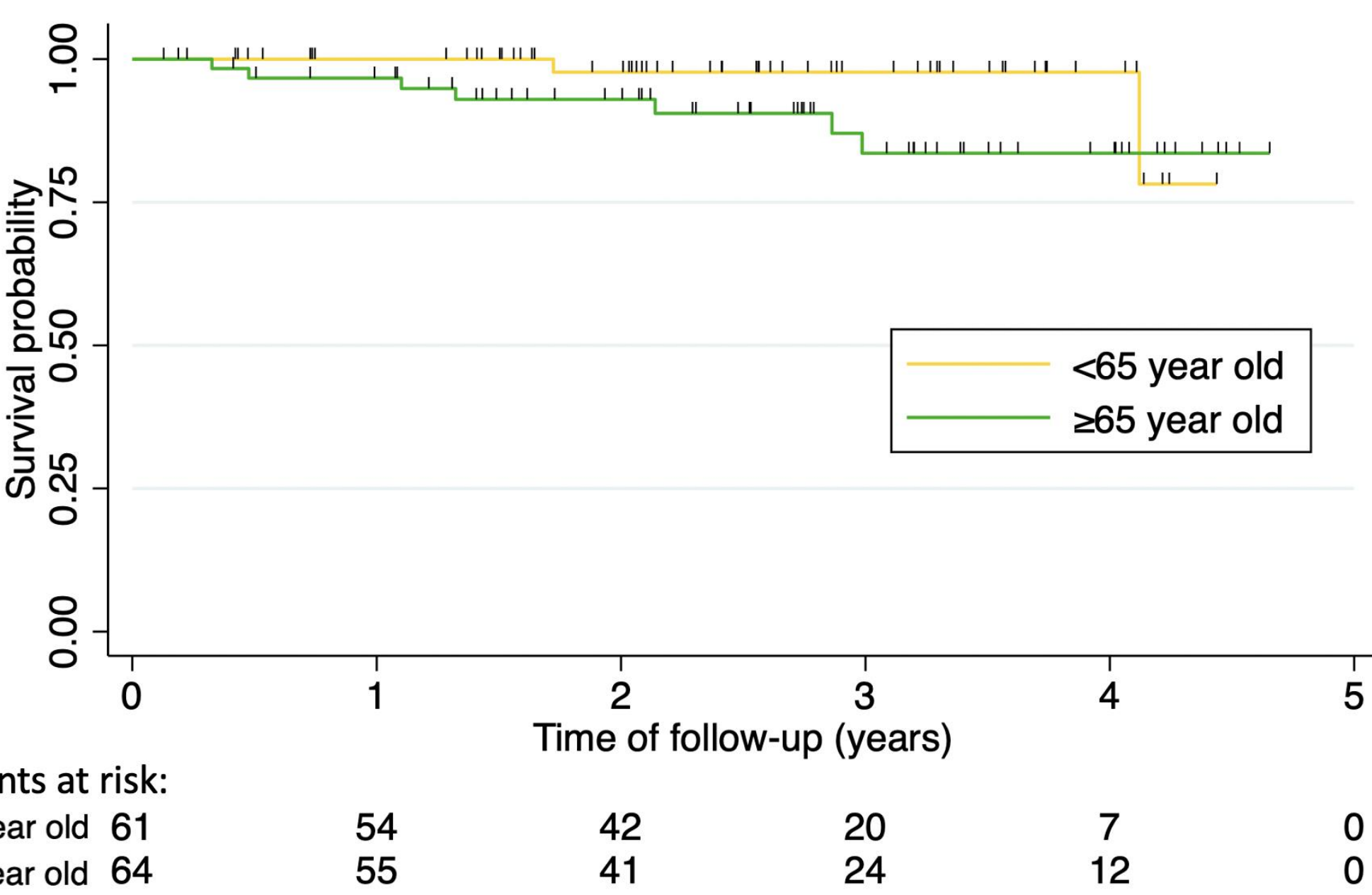
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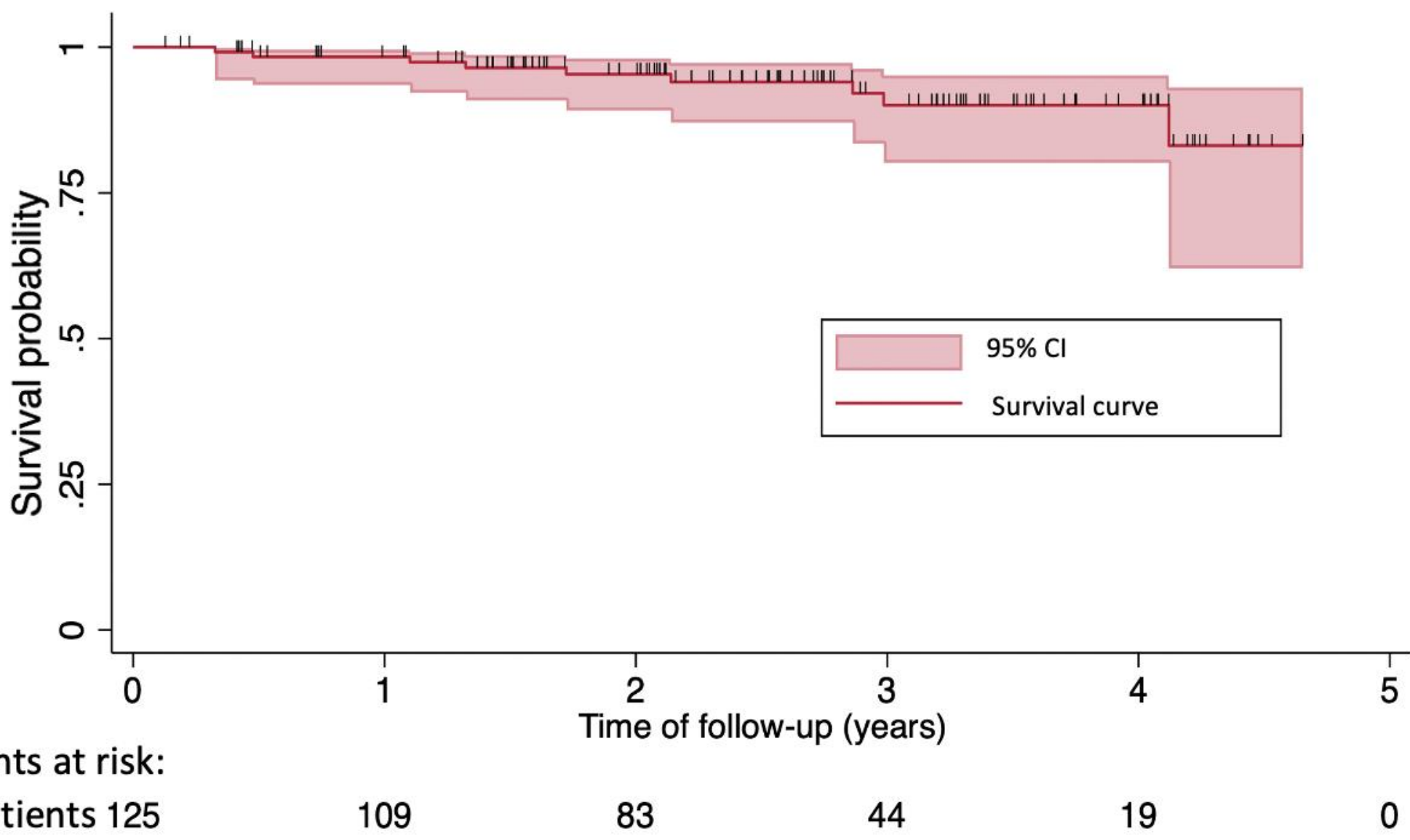
Figure 1. Kaplan-Meier curves for (A) overall survival and (B) overall survival by age group: ≥65 years vs. <65 years.

Conclusion

The porcine bioprosthesis demonstrated favorable early and mid-term clinical outcomes with a minimal incidence of valve degeneration and adverse events. It is one of the reliable options for patients undergoing heart valve replacement.

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