



Ten-Year Outcomes of a Contemporary Supra-annular Porcine Aortic Bioprosthesis in a Medicare Population¹

INTRODUCTION

Bioprosthetic surgical aortic valve replacement (SAVR) remains an important treatment option for older patients with aortic valve disease in the era of transcatheter valve interventions. Gaining insights into the **real-world** long-term clinical outcomes of SAVR and the impact of underlying comorbidities and concomitant procedures would be informative to surgeons counseling patients needing to undergo an aortic valve replacement.

STUDY METHOD

- This study was a single-arm observational study using Medicare fee-for-service (FFS) claims data.
- Deidentified patients undergoing SAVR in the U.S. between 1/1/2008-12/31/2019 were selected by ICD-9/10 procedure codes and then probabilistically linked to a manufacturer registration database using implant date, date of birth, gender, and implant hospital.
- Western Institutional Review Board approval was received with a waiver of informed consent for utilizing a deidentified database.

All-cause mortality, aortic valve reintervention (surgical replacement or transcatheter valve-in-valve* implantation) and heart failure rehospitalization were evaluated at 10-years using the Kaplan Meier method, and a multivariable Cox regression was used to identify predictors of mortality following SAVR. 10-year survival was also stratified based on underlying HF and concomitant procedures.

DEMOGRAPHICS

- **N=11,685**
- Average patient age at implant was 76.3 years
- 39.5% female
- 51.6% with a history of heart failure
- Concomitant CABG was performed in 44.9% of cases and concomitant valve surgery was performed in 11.2% of cases.

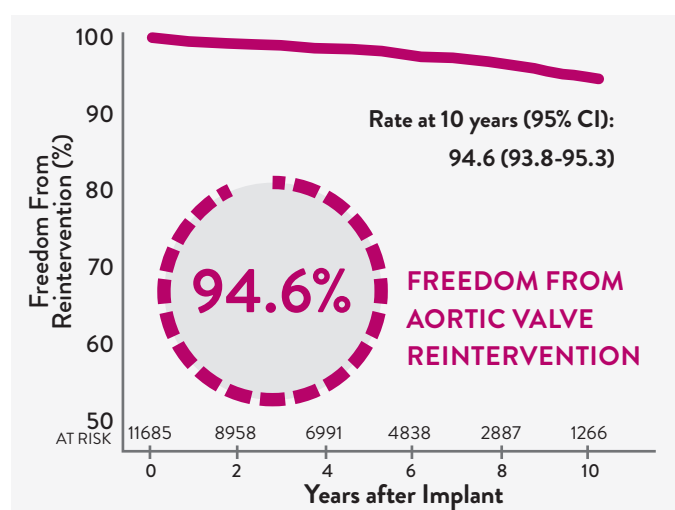
FINDINGS

A key finding from this study was that at 10 years post implant the **freedom from all-cause aortic valve reintervention 94.6%**. This finding is comparable to the 97.3% Epic Aortic valve freedom from reintervention due to SVD for all patient ages at 10 years post-implant reported from Leipzig University.²

Freedom from HF hospitalization was 64%. The 10-year survival for the study population was 33.5% representing a survival rate greater than that of a contemporary population of 2.3 million Medicare beneficiaries (16.7%).

CONCLUSIONS

This real-world study of the Epic Supra valve demonstrates at 10-years a **94.6% freedom from valve reintervention** and freedom from HF hospitalization of 64%. The long-term survival was found to be impacted by baseline comorbidities and the need for concomitant procedures. Overall, these results exhibit excellent outcomes and are in-line with existing Epic Supra data publications.



*Note: The safety and effectiveness of valve-in-valve procedures in an Epic™ or Epic™ Supra valve have not been established.

REFERENCES

1. Wiechmann, R. et. al. (2022, May). Ten-Year Outcomes of a Contemporary Supra-annular Porcine Aortic Bioprosthesis in a Medicare Population. Poster presented at the AATS Annual Meeting, Boston.
2. Jawad, Khalil, Sven Lehmann, Alex Koziarz, Maja Dieterlen, Stefan Feder, Martin Misfeld, Jens Garbade, Vivek Rao, and Michael Borger. "Midterm results after St Jude Medical Epic porcine xenograft for aortic, mitral, and double valve replacement." Journal of Cardiac Surgery 35, no. 8 (2020): 1769-1777.

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