Epic™
Tissue Heart Valves

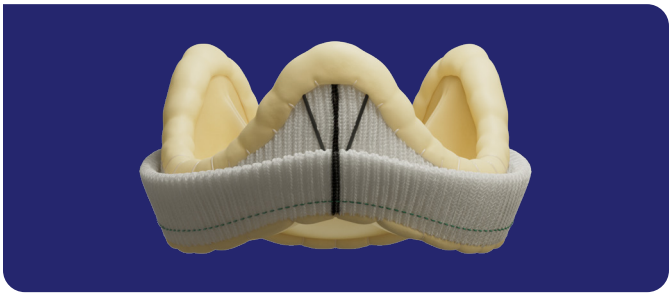
ABBOTT

Epic™ Supra valve – 10-year clinical outcomes of SAVR in a Medicare population[1]

Clinical Insights

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 claims data.
- De-identified patients undergoing SAVR in the United States between January 1, 2008, and December 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 de-identified database.

All-cause mortality, aortic valve reintervention (surgical replacement or transcatheter valve-in-valve implantation) and heart failure (HF) 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 HF
- Concomitant coronary artery bypass grafting was performed in 44.9% of cases, and concomitant valve surgery was performed in 11.2% of cases

Results

A key finding from this study was that, at 10 years post-implant, the **freedom from all-cause aortic valve reintervention was 94.6%**. This finding is comparable to the 97.3% Epic™ Aortic valve freedom from reintervention due to structural valve deterioration 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%).

Note: The safety and effectiveness of valve-in-valve procedures in Epic™ valves has not been established.
For U.S. audience, see Important Safety Information referenced within.
For audiences outside of the U.S., always check the regulatory status of the device in your region.

Conclusions

This real-world study of the Epic™ Supra valve demonstrates, at 10 years, a **94.6% freedom from valve reintervention and 64% freedom from HF hospitalization.** 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.

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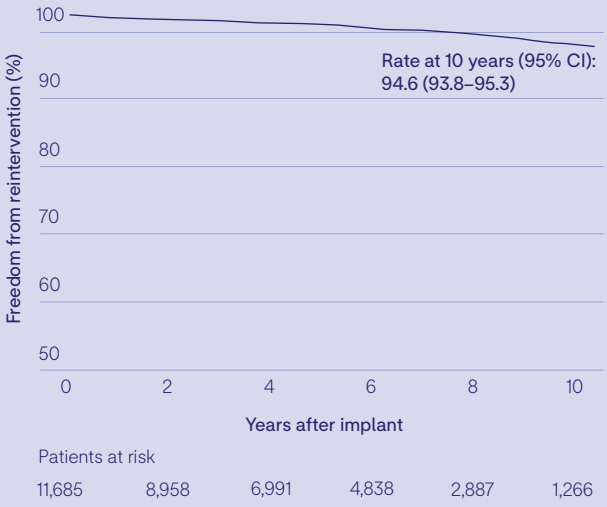
Freedom from aortic valve reintervention



For U.S. audience only

Rx Only
Important Safety Information

Epic™ Plus and Epic™ Plus Supra Porcine Tissue Valves

Indications for Use
The Epic™ Plus valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic™ Plus Supra valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

Contraindications
None known.

Potential Adverse Events
Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include angina; cardiac arrhythmias; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage, anticoagulant/antiplatelet-related; leak, transvalvular or paravalvular; myocardial infarction; nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other); prosthesis regurgitation; stroke; structural deterioration (calcification, leaflet tear or other); thromboembolism and valve thrombosis.

It is possible that these complications could lead to reoperation, explantation, permanent disability and death.

1. Wiechmann, RJ., et. al. Ten-year Outcomes of Surgical Aortic Valve Replacement with a Contemporary Supra Annular Porcine Valve in a Medicare Population. JTCVS Open. 2022, https://doi.org/10.1016/j.xjon.2022.08.002.
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.

Caution: Product(s) intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use inside the product carton (when available) or at www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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