CLINICAL INSIGHTS

EPIC™ MITRAL STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY

Epic Mitral – Ten Year Clinical Outcomes of SMVR in a Medicare Population[1]

INTRODUCTION

Bioprosthetic surgical mitral valve replacement (SMVR) remains an important treatment option for older patients with mitral valve disease in the era of transcatheter valve interventions. Gaining insights into the **real-world** long-term clinical outcomes of SMVR and the impact of underlying comorbidities and concomitant procedures would be informative to surgeons counseling patients needing to undergo a mitral valve replacement. Thus, a retrospective study was conducted to better understand the outcomes of SMVR.

STUDY METHOD

- This study was a single-arm observational study using Medicare fee-for-service (FFS) claims data.
- Deidentified patients undergoing SMVR 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, mitral 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 SMVR. 10-year survival was also stratified based on underlying HF and concomitant procedures.

DEMOGRAPHICS

- N = 14,051
- Average patient age at implant was 74 years
- 58% female
- 77% with a history of heart failure
- 36% with renal failure (4.2% on dialysis)
- Concomitant CABG was performed in 32% of cases and concomitant valve surgery was performed in 25% of cases.

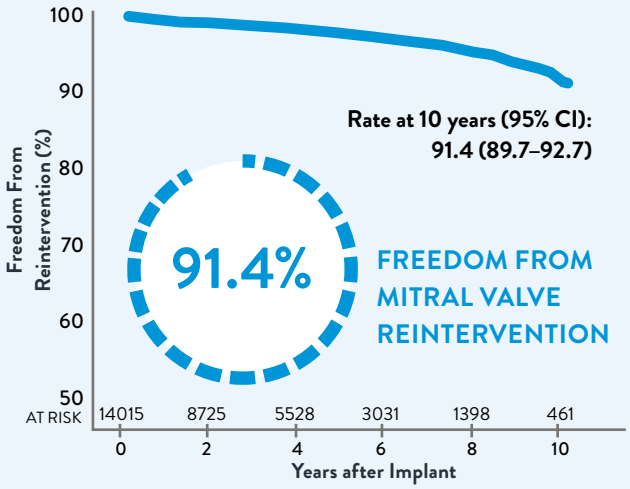
FINDINGS

A key finding from this study was that at 10 years post implant the **freedom from all-cause mitral valve reintervention was 91.4%**. This finding is comparable to the 95.7% freedom from Epic™ Mitral Valve reintervention due to SVD for all patient ages at 10 years post-implant reported from Leipzig University.[2]

Freedom from HF hospitalization was 51.3%, which is impressive in a Medicare patient population where 77% have a heart failure history. The 10-year survival varied from 18% to 40% depending on the presence of a history of heart failure and whether a concomitant CABG and/or valve surgery was performed.

CONCLUSIONS

This real-world study of the Epic Mitral Valve demonstrates at 10-years a **91.4% freedom from valve reintervention and freedom from HF hospitalization of 51.3%**. The long-term survival is consistent with prior published data[3] and 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 Mitral Valve data publications.



***Note:** The safety and effectiveness of valve-in-valve procedures in an Epic™ or Epic™ Supra Valve have 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.

For U.S. audience only

Rx Only
Important Safety Information

EPIC™ /EPIC™ SUPRA STENTED PORCINE TISSUE VALVES

INDICATIONS FOR USE

The Epic™ 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™ 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; valve thrombosis.

It is possible that these complications could lead to: reoperation; explantation; permanent disability; death.

REFERENCES

1. Rodriguez, E. et. al. (2022, January). Ten-Year Outcomes of a Contemporary Generation Low-Profile Porcine Mitral Bioprosthesis in a Medicare Population. Poster presented at the STS Annual Meeting, Virtual.
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.
3. Vassileva C-M et al. Long-term survival of patients undergoing mitral valve repair and replacement: A longitudinal analysis of Medicare Fee-for-Service beneficiaries. Circulation 2013; 127: 1870-1876.

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