



CLINICAL INSIGHTS

EPIC™ MITRAL
STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY



Epic Mitral – Ten Year Clinical Outcomes of SMVR in a Medicare Population¹

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.

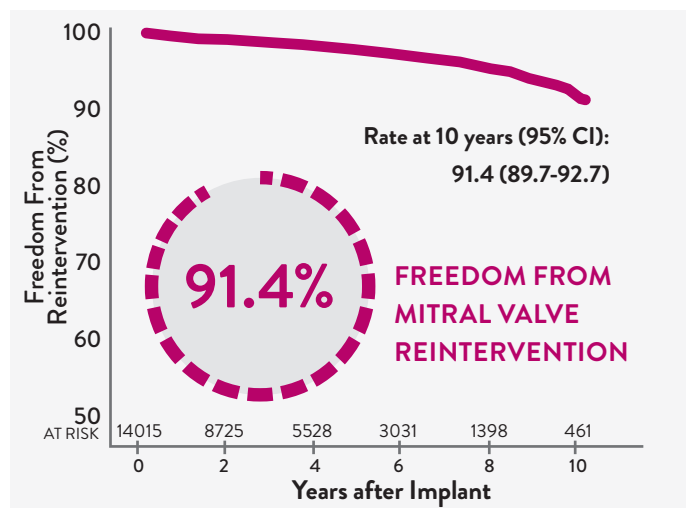
FINDINGS

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 mitral Epic 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 data³ 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 data publications.



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

REFERENCES

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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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