



CLINICAL INSIGHTS

EPIC™ MITRAL AND EPIC™ SUPRA STENTED TISSUE VALVES



Three-Year Outcomes of Valve-in-Valve Intervention within the Epic™ Supra and Epic™ Mitral Valves in a Medicare Population

INTRODUCTION

There has been an increase in utilization of transcatheter valve-in-valve (ViV) intervention in patients with structural valve deterioration of their bioprosthetic valves. Real-world outcomes of ViV beyond one-year are not well characterized due to limited prospective follow-up studies. Gaining insights into the **real-world** outcomes of ViV would be informative to heart teams counseling patients on valve choice for both the surgical implant as well as the transcatheter ViV implant.

STUDY METHOD

- This study was a single-arm observational study using Medicare claims data.
- Deidentified patients undergoing SAVR or SMVR in the U.S. between 1/1/2008-12/31/2019 were selected by ICD-9/10 procedure codes and then linked to a manufacturer registration database of Epic™ Supra and Epic™ Mitral valves.
- Patients undergoing subsequent ViV were identified. 3-year outcomes of survival, valve reintervention, and heart failure (HF) rehospitalization post-ViV until 6/30/2021 were assessed using the Kaplan Meier (KM) method.

DEMOGRAPHICS

- N=253 (SAVR: 128, SMVR: 125)
- Average age at ViV reintervention was 78.3 years
- Baseline HF present in 45% of SAVR and 76% of SMVR patients.

KEY FINDINGS

- ViV intervention was feasible in all valve sizes, including the 19mm Epic™ Supra (n=15) and the 25mm Epic™ Mitral (n=13) valves
- 3-year KM freedom from valve reintervention after ViV was >95% for both valve positions
- Freedom from HF rehospitalization was 73% and 70% for Aortic and Mitral positions, respectively at 3 years
- Survival at 3 years post ViV was 66% and 58% for Aortic and Mitral, respectively. This was comparable to contemporary findings at three years from the VIVID and Partner 2 Registries.^{2,3}

CONCLUSIONS

This real-world nationwide study of U.S. Medicare patients implanted with an Epic™ valve in the aortic and mitral positions demonstrates the feasibility of ViV in all valve sizes and **>95% freedom from reintervention** at 3-years.

FREEDOM FROM VALVE REINTERVENTION AFTER VIV AT 3 YEARS



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

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REFERENCES

1. Fang, K. et. al. (2022, June). Three-Year Outcomes of Valve-in-Valve Intervention within the Epic™ Supra and Epic™ Mitral Valves in a Medicare Population. Poster presented at the TVT Annual Meeting, Chicago.
2. Simonato, Matheus, et al. “Transcatheter mitral valve replacement after surgical repair or replacement: comprehensive midterm evaluation of valve-in-valve and valve-in-ring implantation from the VIVID registry.” *Circulation* 143.2 (2021): 104-116.
3. Webb, John G., et al. “3-year outcomes after valve-in-valve transcatheter aortic valve replacement for degenerated bioprostheses: the PARTNER 2 registry.” *Journal of the American College of Cardiology* 73.21 (2019): 2647-2655.

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