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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 surgical aortic valve replacement (SAVR) or surgical mitral valve replacement (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. Three-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.

RESULTS

- ViV intervention was feasible in all valve sizes, including the 19 mm Epic™ Supra (n = 15) and the 25 mm Epic™ Mitral (n = 13) Valves.
- Three-year KM freedom from valve reintevention after ViV was > 95% for both valve positions.
- Freedom from HF rehospitalization was 73% and 70% for aortic and mitral positions, respectively at three years.
- Survival at three years post ViV was 66% and 58% for aortic and mitral, respectively. This was comparable to contemporary findings at three years from the Valve-in-Valve International Data Registry and Partner 2 Registries.[1,2]

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 three years.[3]

> 95.0%

FREEDOM FROM VALVE REINTERVENTION AFTER VIV AT THREE YEARS

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™ PLUS/EPIC™ PLUS SUPRA STENTED 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; valve thrombosis. It is possible that these complications could lead to: reoperation; explantation; permanent disability; death.

References

1. 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.
2. 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.
3. 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.

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