CLINICAL INSIGHTS

EPIC™ MITRAL
STENTED TISSUE VALVE WITH LINX AC TECHNOLOGY

Long-Term Outcomes and Freedom from Calcification

INTRODUCTION

The Quebec Heart and Lung Institute at Laval University has a long history with surgical mitral valve replacement (SMVR) with bioprosthetic heart valves[1]. Therefore, a study was conducted to evaluate the long-term clinical and echocardiographic outcomes of the Epic™ Mitral stented tissue valve with Linx™ Anti-Calcification technology.

Pre-clinical animal studies demonstrate that Linx™ Anti-Calcification Technology reduces tissue calcification in four ways[2-5]:

- Reduces free aldehydes
- Extracts lipids
- Minimizes uptake of cholesterol
- Stabilizes leaflet collagen

STUDY METHOD

- Retrospective design using a prospective single-center registry
- Between 2007 and 2021, n=1,397 consecutive adult patients underwent MVR with the Epic Mitral
  - Exclusion: adult congenital heart disease
- Valve hemodynamics and Structural Valve Deterioration (SVD) were evaluated
- Chart review was performed to identify the mechanism of bioprosthetic failure
- Cox regression analysis was performed to identify the independent risk factors of late mortality and prosthetic mitral valve reoperation
- Follow-up was 100% complete up to maximum 13.6 years post initial MVR

DEMOGRAPHICS

- n=1,397
- Average patient age at implant was 72 years
- 46% female
- Concomitant CABG was performed in 46% of cases and concomitant valve surgery was performed in 46% of cases.

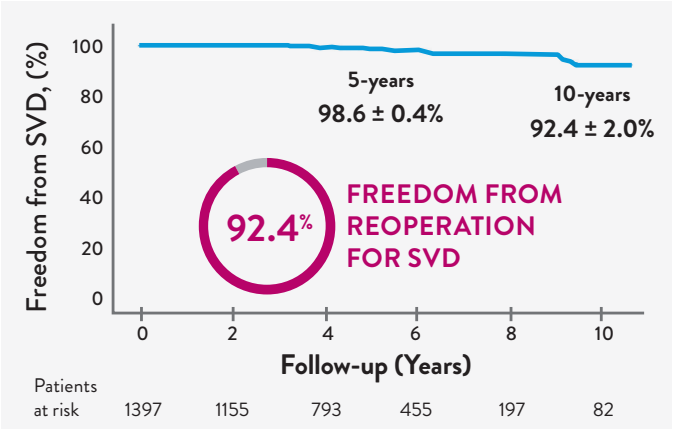
FINDINGS

A key finding from this study was that at 10 years post implant the **freedom from mitral valve reintervention due to SVD was 92.4% and the freedom from all-cause reintervention was 88.9%**. This finding is comparable to the 91.4% freedom from all-cause Epic Mitral valve reintervention at 10 years post-implant in an all-comer real-world population in the USA[6].

A recent study showed that valves that fail with calcification tend to result in a higher stroke rate after reintervention[7]. The Quebec Heart and Lung Institute experience shows no cases of leaflet calcification (100% freedom from calcification) at the ten year timepoint. The primary mechanism of SVD was regurgitation related to leaflet tear. Epic Mitral with Linx Anti-Calcification Technology's leaflets are engineered to allow for the lowest leaflet profile and prevent calcification, which may provide a stroke risk advantage in Valve-in-Valve cases*.

CONCLUSIONS

The Quebec Heart and Lung Institute study of the Epic Mitral valve once again confirms excellent long-term durability of the valve with a 92.4% freedom from reintervention due to SVD at 10 years post implant, as well as 88.9% freedom from all-cause reintervention. These long-term study results remain consistent with prior published data[6]. The study showed 100% freedom from calcification, which is in line with literature demonstrating less calcification in porcine valves[7]. Less leaflet calcification in porcine valves may offer an advantage at the time of valve reintervention against stroke risk.



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

See Important Safety Information referenced within.

Epic™/Epic™ Supra Stented Porcine Tissue Valves
Rx Only
Important Safety Information

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

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