

Clinical Summary of On-X[®] Mitral Heart Valve

Survival Data



ARTIVION™

On-X[®]
Mitral Heart Valve

Clinical Summary

New Survival Data: The On-X Mitral Heart Valve Demonstrates Excellent Survival in Large Landmark Study for Mechanical Mitral Valves

The Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) Mitral Trial¹ is one of the largest studies ever conducted with mechanical mitral valves involving 401 patients (mean age 55 y/o) at 44 North American centers.

PROACT Mitral represents the most contemporary evidence on performance and anticoagulation for any mechanical mitral valve. Due to its size and scope, a similar study is likely to never be repeated.

Key Takeaways

- The PROACT Mitral Study data showed patients with standard-dose anticoagulation had excellent survival rates of 99.5% at 1 year, 94% at 3 years and 91% at 5 years (Figure 1)
- These results also complement other large-scale analysis such as Goldstone et al.² that show in patients up to 70 years of age, mechanical mitral valves have a survival benefit at 15 years over tissue valves. (Figure 2)
- This evidence continues to support the 2020 AHA/ACC and 2021 ESC/EACTS Guidelines,^{3,4} which recommend the use of a mechanical mitral prosthesis for patients < 65 y/o.

Conclusion

The On-X Mitral Heart Valve, which is engineered for exceptional clinical performance, now has the most robust body of evidence supporting its use as demonstrated by the low mortality rates in PROACT Mitral.

On-X Heart Mitral Valves should be managed at current guideline recommendations of 2.5–3.5 INR.

References

1. Chu M.W.A., et al. (2023). Low-Dose Vs Standard Warfarin After Mechanical Mitral Valve Replacement: A Randomized Trial. *Ann Thorac Surg*, S0003-4975 (23)00005-X. 2. Goldstone AB, et al. (2017). Mechanical or biologic prostheses for aortic-valve and mitral-valve replacement. *N Engl J Med*;377:1847–57. 3. Otto CM, et al. (2021). 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circ*,143(5). doi: 10.1161/CIR.0000000000000932. 4. Vahanian A, et al. (2022). 2021 ESC/EACTS Guidelines for the management of valvular heart Disease. *Eur Heart J*.43(7):561-632.

Figure 1

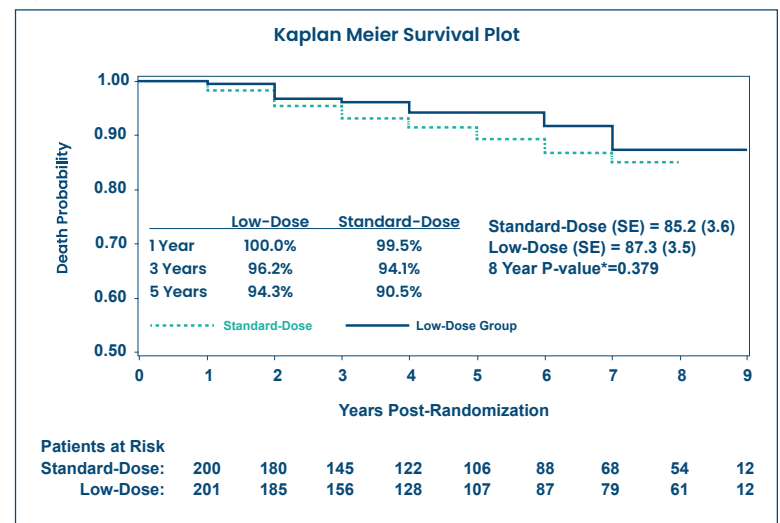
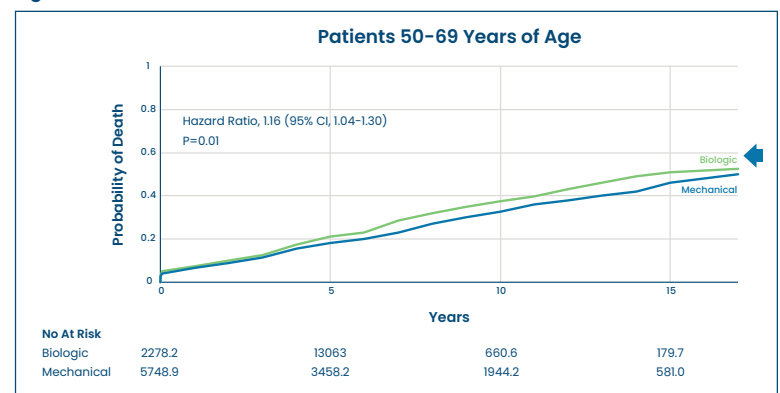


Figure 2



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