LOWER IS BETTER

Real World Outcomes

ARTIVION™ | On-X® Aortic Heart Valve

On-X Aortic Heart Valve Post Approval Study (PAS)

One-Year Outcomes

Multinational, Prospective, Observational Study

Objective: Assess the occurrence of major bleeding (MB), valve-related thromboembolism (TE), and valve thrombosis (VT) with the On-X Aortic Heart Valve when targeted at an International Normalized Ratio (INR) level range of **1.5 – 2.0**.

510

Patients

Real World Representation of INR Monitoring

Clinic
N = 440

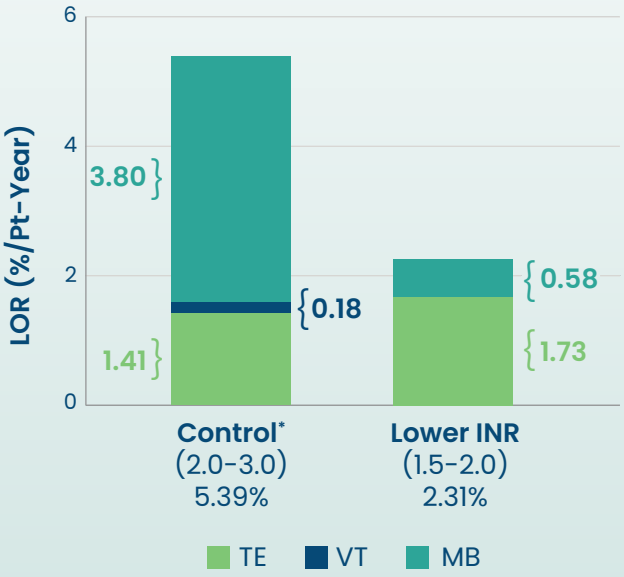
Home
N = 70

Primary Endpoint

The Linearized Occurrence Rate (LOR) for the lowered INR group is **significantly lower** compared to the control.*

Composite Primary Endpoint

5.39% vs. 2.31%, p<0.0001



Conclusion

Real world data shows that On-X at low INR (1.5-2.0) **reduces risk of major bleeding by >84%**, proving safe for the patient with **no significant increase in thromboembolic events and no valve thrombosis**.

A Valve for Life.

Oo AY, Loubani M, Gerdisch MW, Zacharias J, Tsang GM, Perchinsky MJ, Hagberg RC, Joseph M, Sathyamoorthy M. Presented at the European Association for Cardio-Thoracic Surgery Annual Meeting, October 2023.

*Artivion data on file, weighted average of control groups from FDA Premarket Approval P000037 S030 and IDE trial G050208.

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