On-X® | Aortic Heart Valve
STEP AHEAD

FAQs for Anticoagulation Clinics: Lowered INR 1.5–2.0* for On-X Aortic Heart Valve Patients

Q: What is the recommended anticoagulation regimen for On-X Aortic Valve patients?

A: Warfarin anticoagulation with INR of 2.0–3.0 for the first 3 months after surgery, after which INR should be reduced to 1.5–2.0. The addition of a daily aspirin at a dose from 75 to 100 mg is also recommended for patients, unless there is a contraindication to the use of aspirin.[1]

Q. Is the 1.5–2.0 INR* for the On-X Aortic Valve FDA and CE approved and supported by the AHA/ACC Guidelines?

A: Yes, the On-X Aortic Valve is FDA and CE approved for the INR 1.5–2.0.*,[1] The 2017 AHA/ACC Valvular Heart Guidelines includes the INR 1.5–2.0* for the On-X Aortic Valve (IIb, B-R recommendation).[2]

Q: Does the 1.5–2.0 INR* for the On- X Aortic Valve result in an increased thromboembolic (TE) and stroke rate?

A: No, the evidence of the multicenter, prospective, randomized clinical trial (PROACT) with On-X Aortic Valve patients with 1.5–2.0 INR* had a >60% reduction in bleeding rates without an increase in TE and stroke rate compared to those with 2.0–3.0 INR.[1,3]

Q: Do co-morbidities impact the 1.5–2.0 INR* for the On-X Aortic Valve?

A: Selection of an anticoagulant or anticoagulant/antiplatelet regimen is based on the particular needs of the patient and the clinical situation. Patients with co-morbidities that require an INR range higher than 1.5-2.0* should not reduce their INR. The 2017 AHA/ACC Guidelines recommend an INR of 1.5-2.0* in patients without a risk of thromboembolism.[1,2]

Q: How should On-X Aortic Valve patients with Atrial Fibrillation (A-Fib) manage their anticoagulation?

A: Any On-X Aortic Valve patients with Atrial Fibrillation (A-Fib) that require an INR range higher than 2.0 should not reduce their INR to 1.5–2.0.* For On-X Aortic Valve patients with A-Fib who do not require a higher anticoagulation treatment for their A-Fib (above 2.0) may continue with the 1.5–2.0 INR.*,[1]

Q: Which heart valve patients are excluded from the 1.5–2.0 INR* for the On-X Aortic Valve?

A: Right-sided valve replacement, mitral valve replacement, double (aortic plus mitral) valve replacement, and patients with any other brand of mechanical heart valve.[1]

Q: Do patients need to be on home monitoring with the On-X Aortic Valve?

A: The use of home monitoring to accomplish stable INR control is recommended, but not required.[1]

Q: What is the difference between anticoagulation requirements for the On-X Aortic Valve and other mechanical valves from different manufacturers?

A: The On-X Aortic Valve is the only mechanical valve with FDA and CE approval clinically proven safe with less blood thinner (warfarin).[1] The American Heart Association guidelines state that less blood thinner may be reasonable for patients with the mechanical On-X Aortic Valve.[2] In a prospective randomized clinical trial, On-X Aortic Valve patients with a reduced blood thinner dose had >60% fewer bleeding events without an increase in risk of stroke.[1] The On-X Aortic Valve, as a mechanical heart valve, has a much lower risk of reoperation than tissue valves with the additional benefit of less bleeding risk than other mechanical aortic valves because of the lower amount of anticoagulation required. All other aortic mechanical valve anticoagulation should be managed at an INR of 2.0-3.0.[2]

Q. What is the recommended anticoagulation for patients with the On-X Mitral Valve?

A. The warfarin anticoagulation for patients with the On-X Mitral Valve is 2.5–3.5 INR, which is the same for all other mitral mechanical valves.[1,2] The addition of a daily aspirin at a dose from 75 to 100 mg is also recommended for patients, unless there is a contraindication to the use of aspirin.[1]

*After 3 months standard therapy. **1.** On-X Prosthetic Valve Instructions for Use. **2.** Nishimura RA et al., 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. 2017;135:e1159-95. **3.** Puskas J, Gerdisch M, Nichols D, et al. Reduced anticoagulation after mechanical aortic valve replacement: interim results from the Prospective Randomized On-X Valve Anticoagulation Clinical Trial randomized Food and Drug Administration investigational device exemption trial. J Thorac Cardiovasc Surg. 2014;147(4):1202-1211.

On-X Life Technologies, Inc.
1300 East Anderson Lane, Bldg. B
Austin, Texas 78752 USA
Phone: (512) 339-8000
Fax: (512) 339-3636
Email: onx@onxlti.com

CryoLife, Inc.
1655 Roberts Boulevard, NW,
Kennesaw, Georgia 30144 USA
Phone: 888-427-9654
Fax: 770-590-3753
Email: CUSTSVC@cryolife.com

CryoLife Europa, Ltd.
Bramley House, The Guildway
Old Portsmouth Road
Guildford, Surrey, GU3 1LR, United Kingdom
Phone: +44 (0) 1483 441030
Fax: +44 (0) 1483 452860
Email: europaorders@cryolife.com

CryoLife Asia Pacific, Pte, Ltd.
1 Marina Boulevard, #28-00
One Marina Boulevard, Singapore (018989)
Phone: +65 (0) 9784 9820
Email: CUSTSVC@cryolife.com

CryoLife® Life Restoring Technologies®