

Lowered Anticoagulation Trial Preliminary Results



The On-X® Prosthetic Heart Valve continues to demonstrate tolerance of low INR that has been seen in worldwide studies.

A unique study of On-X heart valves

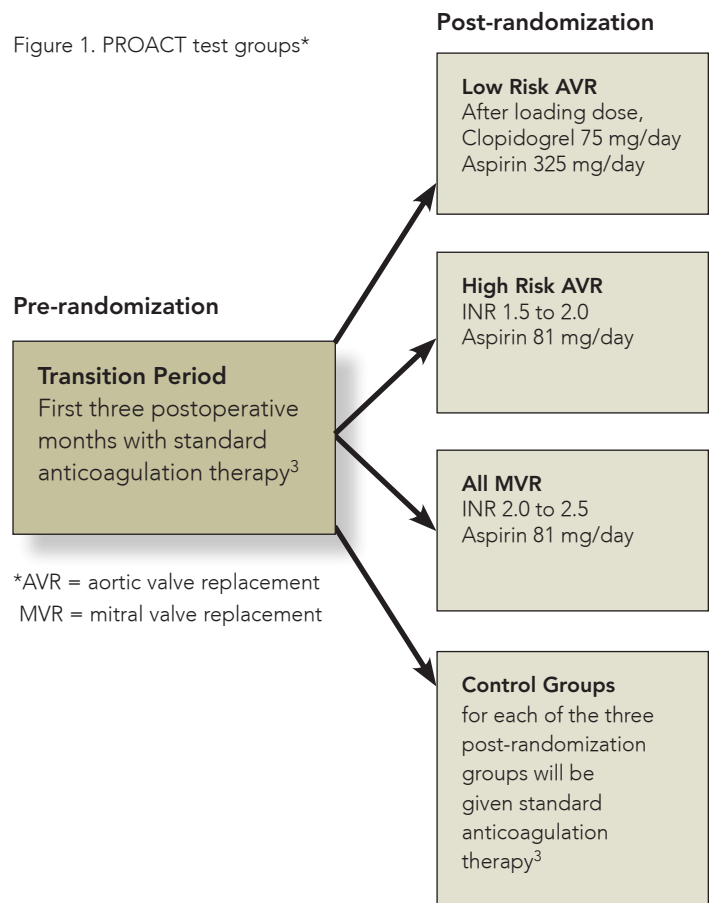
The Prospective Randomized On-X Valve Anticoagulation Trial (PROACT) was initiated in 2006 and is currently ongoing in 36 centers throughout the United States and Canada (Figure 1).¹⁻³ The study groups are presented in Figure 1. This unique study was approved by the FDA for an IDE trial because of the exceptional clinical outcomes seen in trials of the On-X valve since 1996.⁴⁻⁸

Current results

A preliminary report of PROACT trial data for the high risk aortic patient test and control groups was made by John Puskas of Emory University in Atlanta at the American College of Cardiology on April 5, 2011.⁹ As hypothesized, patients in the test group with INR's between 1.5 and 2.0 are currently equal in composite thromboembolic and hemorrhage rates compared to the control group of patients. All patients were participating in home monitoring of INR—a treatment proven to reduce bleeding complications related to anticoagulation therapy.¹⁰

The future of a unique mechanical valve

According to Dr. Puskas, "Our goal is to maintain patients with this type of mechanical valve [On-X] on a safer and more convenient regimen that's closer to the benefits of biological valves. . . The data so far are encouraging and the other study limbs are likely to show similar findings. If final data confirm these early results, the FDA may grant a label for lower doses of anticoagulation drugs. . . One day we may be able to offer a durable mechanical heart valve with no blood thinner to selected patients."¹¹



Consistent results

These results emphasize the ability of the On-X valve to tolerate an inconsistent INR level without an increase in thromboembolic events that are exhibited by other currently available mechanical valves.^{12,13} Table 1 shows composite thromboembolic and hemorrhage rates from the FDA PMA approval studies for current products implanted in the USA.¹⁴⁻²³

Table 1. Comparison of composite bleeding and thromboembolism rates for aortic valves from FDA IDE approval studies¹⁴⁻²³

Mechanical valves		Tissue valves	
On-X	2.4	Magna	2.8
St Jude Regent	4.7	Mitroflow	3.7
ATS	4.1	Mosaic	2.6
Carbomedics	2.7	Biocor	2.8
		Freestyle	4.0
		ATS 3f	3.5

Until the completion and analysis of study data, On-X Life Technologies, Inc., continues to recommend standard anticoagulation therapy as presently prescribed by various professional societies for the On-X valve.³

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On-X aortic and mitral valves are FDA approved.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Refer to the Instructions for Use that accompany each valve for indications, contraindications, warnings, precautions and possible complications. CAUTION: Investigational use of this device in the Prospective Randomized On-X Valve Anticoagulation Trial (PROACT) is limited by federal law to investigational sites. For further information, visit www.onxlti.com.

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