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News | April 2, 2015

FDA Approval: On-X Aortic Valves With Less Warfarin

Thousands With On-X Aortic Implant May Be Able to Reduce Medication Regimen

Thousands of Americans with On-X Aortic Heart Valves may be able to reduce their regular blood-thinning medication regimen, thanks to an expanded labeling claim just granted by the U.S. Food and Drug Administration (FDA) to On-X Life Technologies Inc., the company announced recently.

Approximately 200,000 patients have received the company's On-X replacement heart valves, which are bileaflet prosthetic valves made of pure pyrolytic carbon. While all mechanical heart valve patients must continuously take blood-thinning ("anticoagulant") medications such as warfarin, the FDA's new labeling expansion makes the On-XAortic Heart Valve the only one in the world that allows patients to be managed, starting three months after their surgery, at an INR (International Normalized Ratio) level of 1.5 to 2.0, which is closer to an unmedicated INR. An INR blood test measures the length of time required for a patient's blood to clot.

"On-X valves have a long history of excellent clinical performance and are especially appealing to patients who seek a single, life-long solution to their aortic heart valve problems," said John Puskas, M.D., Chair of Cardiothoracic Surgery at Mount Sinai Beth Israel Hospital in New York City. "While anticoagulation therapy remains a necessity for mechanical valve recipients, the FDA's new approval of a significantly lower INR for On-X Aortic Heart Valves should really change the clinical landscape for many patients."

Data published in 2014 in the Journal of Thoracic and Cardiovascular Surgery on On-X's PROACT (Prospective Randomized On-X Anticoagulation Clinical Trial) study affirmed that high-risk trial patients with On-X Aortic Heart Valves who reduced their regular blood-thinning medication dosage to maintain a lower INR of 1.5 to 2.0 and took a low-dose aspirin experienced a 65% overall reduction in bleeding events with no increase in stroke rate.

AHA-ACC Guidelines Recommend Mechanical Valves for Younger Patients

Official clinical guidelines published jointly by the American Heart Association (AHA) and the American College of Cardiology (ACC) suggest that mechanical heart valves are the "standard of

care" for patients younger than 60 years of age who require an aortic valve replacement. The guidelines, which focused on furnishing recommendations for optimal medical therapy for the first time, also indicated that mechanical valves were considered "reasonable" for patients between 60-70 years of age.

"The AHA-ACC guidelines affirm that mechanical valves are preferred for many younger patients with valvular heart disease," says Blase Carabello, M.D., Chair of the Cardiology Department at Mount Sinai Beth Israel Hospital in New York. "While the AHA-ACC guidelines generally recommend an INR target in the range of 2.0 to 3.0, patients who receive On-X Aortic Heart Valves with reduced anticoagulation medication levels should experience the added benefits of an enhanced quality of life along with diminished overall risk of medication-related bleeding complications."

According to Clyde Baker, CEO for On-X Life Technologies, some people choose animal tissue replacement valves in an attempt to avoid potential side effects associated with the blood-thinning medication warfarin, which is often marketed under the brand name Coumadin. He notes, however, that tissue valves are known to have a limited lifespan, with most structurally failing in less than 15 years in patients under 60 years of age. Tissue valve failure requires patients to undergo the risk, pain and expense of subsequent reoperation for new replacements. Additionally, many tissue valve patients also require warfarin in order to manage other conditions.

"Our newly approved expanded labeling, which lowers the recommended INR rates for On-X aortic valves, reinforces how our technology represents a single, life-long clinical solution that frees patients of worries of potential reoperation due to tissue valve failure," Baker says. He adds that, because the FDA's reduced INR guidance applies only to individuals with an On-X aortic mechanical valve, all patients should check with their doctor to determine whether changes to any medical regimen are appropriate.

On-X Valve's Documented Durability, Safety

According to Jack Bokros, Ph.D., founder of On-X LTI, a combination of unique product features and characteristics led to the FDA granting the label expansion for a lower INR rate exclusively for On-X mechanical aortic valves. The prosthetic valve's pure pyrolytic carbon material provides a thromboresistant surface, while its proprietary design is intended to mimic the performance of a patient's native valve in the bloodstream.

"On-X valves have been shown to cause less turbulence or blood damage than commonly seen in other mechanical heart valves," Dr. Bokros says, noting that a comprehensive 50-year retrospective study of mechanical heart valves presented in 2014 indicated that On-X's valves had the lowest documented rate of valve thrombosis (clot formation) when compared to eight other competitive mechanical heart valves.

"Our On-X Aortic Heart Valve is the next evolution in implantable heart valves, representing a durable therapeutic solution that also improves patient safety by lowering the risk of bleeding events," Baker concluded. "We look forward to making this important technology available to heart valve patients across the U.S. who want safe, reliable therapeutic solutions that are intended to last their entire lifetimes."

About On-X LTI

On-X Life Technologies develops mechanical heart valve replacements that are designed to dramatically improve patients' quality of life. Headquartered in Austin, Texas, ON-X LTI is a privately held company.

SOURCE: On-X LTI