Low-dose anticoagulation therapy used with new design mechanical heart valve lowers bleeding risk

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For more than 40 years, patients under 65 years of age requiring heart valve replacement have had to choose between a mechanical valve that offers life-long durability but requires aggressive warfarin anticoagulation or a biological (cow or pig) valve that will wear out in 10-20 years but does not require anticoagulation. Aggressive warfarin anticoagulation is accompanied by significant annual risk of bleeding, while inadequate anticoagulation of a mechanical artificial valve has been associated with high risk of clotting problems that can cause strokes.

A newer generation mechanical heart valve, manufactured by On-X Life Technologies, Austin, TX, has several design features that make it more efficient and less likely to clot. The FDA is allowing a randomized trial to be conducted to determine whether it is safe and effective to treat patients with an On-X mechanical aortic valve with less aggressive anticoagulation than has previously been recommended by the American Heart Association and American College of Cardiology.

In an interim report to be presented at the 93rd AATS Annual Meeting in Minneapolis on May 6, 2013, John D. Puskas, MD, Professor and Associate Chief of the Division of Cardiothoracic Surgery, Emory University School of Medicine, Athens, GA, and his co-investigators show that lower dose anticoagulation therapy, combined with low-dose aspirin, resulted in a reduction of 55 to 60% of the incidence of adverse

bleeding events without significant increases in stroke, transient ischemic attack or total neurological events when used in conjunction with the On-X mechanical aortic valve.

As part of the Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT), a control group of patients received standard treatment of warfarin administered to maintain a target range of the International Normalized Ratio (INR) of 2.0-3.0. The second treatment group received low-dose warfarin, targeting an INR of 1.5-2.0.

From June 2006 until October 2009, 375 Aortic Valve Replacement (AVR) patients were randomized into control (190) and treatment (185) groups three months after surgery. All patients had received standard therapy for the first 3 months including aspirin 81 mg daily. Mean age was 55.8 years in the control group and 54.1 years in the treatment group. Approximately 80% of the patients were male and 93% were in sinus rhythm before valve replacement. Patients were followed for an average of 3.82 years.

Dr. Puskas concludes that "Anticoagulation may be safely reduced in AVR patients after implantation of this approved bileaflet mechanical prosthesis. In combination with low-dose aspirin, this therapy resulted in significantly lower risk of bleeding than customary aggressive anticoagulation, without significant increase in clots or strokes."

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