Operating without interrupting warfarin reduces risk of bleeding after cardiac device surgery

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A new Canadian study shows that operating without interrupting warfarin treatment at the time of cardiac device surgery is safe and markedly reduces the incidence of clinically significant hematomas compared to the current standard of care. The new findings were released today at Heart Rhythm 2013, the Heart Rhythm Society's 34th Annual Scientific Sessions, and will be published online today in The *New England Journal of Medicine* (*NEJM*).

At least a quarter of patients that require pacemaker or implantable defibrillator surgery are taking warfarin to reduce the risk of a stroke. Current guidelines recommend bridging many of these patients to heparin treatment and stopping anticoagulation therapy in the days leading up to surgery which can put a patient at risk of a stroke. The Bruise Control trial is the largest randomized clinical trial to compare continuing warfarin to temporary cessation with heparin bridging in patients before and after device surgery.

"We hope that Bruise Control will change how we are treating patients around the world," said lead author David Birnie, MD, Director of the Arrhythmia Service at the University of Ottawa Heart Institute, Canada. "Our study conclusively shows that treating patients with a high risk of stroke with continued warfarin instead of heparin bridging will improve patient outcomes, decrease complications and reduce hospitalization."

Bruise Control randomized 681 patients at 17 Canadian and 1 Brazilian center with a less than 5 percent annual risk of thrombo-embolic events. One group received continued warfarin, while the other patients were bridged to therapeutic doses of either intravenous heparin or subcutaneous low-molecular-weight heparin starting three days before the procedure and resuming 24 hours after surgery. Patients were evaluated after surgery and the study found that clinically significant hematomas were 80 percent less frequent in patients that received uninterrupted warfarin. Compared to the heparin arm of the trial, patients receiving warfarin had fewer prolonged hospital stays (1.2 percent vs. 4.8 percent), less re-interruption of anticoagulation (3.3 percent vs. 14.5 percent) and fewer re-operations (0.6 percent vs. 2.4 percent). Patients in the continued warfarin arm also had greater satisfaction with their peri-operative anticoagulation management.

Co-Principal Investigator Vidal Essebag, MD, PhD, Director of Cardiac Electrophysiology, McGill University Health Center, Montreal, stated, "To many, the substantial reduction in pocket hematoma that we observed with continued warfarin may be counterintuitive. One explanation that has been proposed is the concept of an 'anticoagulant stress test.' That is, if patients undergo surgery while fully anticoagulated, any excessive bleeding will be detectable and appropriately managed while the wound is still open. In contrast, when surgery is performed with heparin bridging, such bleeding may remain latent, and appear only when full anticoagulation is resumed postoperatively."

The Bruise Control trial was funded by the Canadian Institutes of Health Research (CIHR).

"This randomized clinical trial eliminates a dilemma faced by physicians throughout the world," said Dr. Jean Rouleau, Scientific Director of the CIHR Institute of Circulatory and Respiratory Health. "The study shows

that patients requiring cardiac arrhythmia device surgery can remain on their current blood thinners, thus reducing the chance of stroke and hematoma. CIHR is pleased to support Dr. Birnie and his team. Our hope is that this research evidence will soon be brought to the point of care, so it can benefit patients around the world."

Provided by University of Ottawa