Internal bleeding higher with popular heart device than earlier model

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The incidence of internal bleeding was higher in the most commonly implanted heart device than in an earlier model, according to two studies at Henry Ford Hospital in Detroit.

The HeartMate II, a left ventricular assist device (LVAD) is a continuous-flow mechanical pump connected to the patient's heart that takes over the pumping of the weakened heart's left ventricle.

"Although there were more instances of bleeding in the skull and gastrointestinal track with the HeartMate II, as opposed to the earlier model, there was no increase in mortality," says lead author Jeffrey A. Morgan, M.D., associate director of Mechanical Circulatory Support in the Edith and Benson Ford Heart &Vascular Institute at Henry Ford.

Dr. Morgan will present the studies on June 11 at the annual conference of the American Society of Artificial Internal Organs in Washington, D.C.

From March 2006 through May 2010, 64 patients with chronic heart failure underwent implantation of a HeartMate II LVAD as a bridge to transplant or a permanent therapy for those ineligible for transplants.

The incidence of gastrointestinal bleeding or adverse neurological events (ANE) was evaluated to determine their impact on survival and identify predictors of occurrence.

The overall incidence of gastrointestinal bleeding was nearly 22 percent, and the incidence of major ANEs was eight percent. Patients with an ANE were significantly older, with a higher incidence of chronic renal insufficiency. They also had higher International Normalized Ratios (INRs), a lab test that measures the time it takes for blood to clot, and compares it to an average, at the time of the event. The higher the INR, the longer it takes blood to clot.

No complications due to blood clots occurred in those with gastrointestinal bleeding, but for patients with an ANE, there were four intracranial hemorrhages and one thromboembolic stroke.

There was no significant difference in gender, race, cause of heart failure, diabetes, or body mass index (BMI) between patients who had post-operative bleeding and those who did not.

Study co-author Robert J. Brewer, M.D., surgical director of the Mechanical Circulatory Support Program at Henry Ford, believes that as data accumulates on the relatively low incidence of thromboembolic events with the HeartMate II for patients on low-dose or no anticoagulation, it may be prudent to lower the goal INR, with the intent of lowering bleeding complications.

The HeartMate II is smaller, with fewer moving parts, than the previous model, the HeartMate I XVE, and requires less invasive surgery. Its size makes it available to a larger number of advanced-stage heart failure patients, and it has been predicted to greatly increase patients' quality of life. The device can cover the full output of a healthy heart. Studies have shown that continuous-flow pumps last much longer than pulsing pumps before they must be replaced.

Usage of LVADs has increased in the United States, where heart failure affects five million people, but there are less than 3,000 donor organs

available annually worldwide. Last year, nearly 2500 patients were implanted with the device in the United States, which is used chiefly for those waiting for a heart transplant due to the chronic donor shortage. In other cases, it is used for long-term support in patients who are not candidates for a heart transplant.

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