Study begins of minimally invasive treatment for blocked heart valves

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(Medical Xpress) -- Heart experts at Johns Hopkins have begun testing a new device designed to replace blocked aortic valves in patients for whom traditional open-heart surgery is considered too risky, such as elderly patients and those with other serious medical conditions. The testing is part of a nationwide study to evaluate the device, which is deployed in a minimally invasive way. The first two Maryland patients to receive the device had it put in place by Johns Hopkins doctors on July 8, 2011.

The new device, known as CoreValve, is a self-expanding valve made of a compressed metal scaffold with three flexible tissue leaflets attached. It is put in place inside the patient's damaged valve through a catheter that is threaded through a leg artery to the aorta, the heart's main blood vessel.

Once the device is in place, a process that can take up to two hours, a sheath covering the valve is removed via the same catheter, allowing the leaflets to open and close, directing blood flow to the rest of the body and the brain.

The device is already approved for use in Europe. During the European tests, patients experienced a more than doubling of blood flow, in some cases showing ejection fractions – a measure of blood pumped – rising from 20 percent to between 50 percent and 60 percent.

"The people most likely to benefit from this approach are incredibly

weak, often bedridden because of their severely narrowed, aortic valve," says interventional cardiologist Jon Resar, M.D., who along with cardiac surgeon John Conte, M.D., is leading the Johns Hopkins portion of the study. Hopkins is among 40 medical centers that are participating in the Medtronic CoreValve U.S. Pivotal trial. Medtronic, of Minneapolis, Minn., is the device manufacturer and is funding the tests.

"For many of our patients, this procedure is their only hope," says Resar, an associate professor and director of the adult cardiac catheterization laboratory at the Johns Hopkins University School of Medicine and its Heart and Vascular Institute.

Because it doesn't involve open heart surgery, the approach is known as transcatheter aortic valve implantation, or TAVI for short. Even though it is a minimally invasive procedure, Resar cautions that the device is not a cure-all, noting that about 30 percent of patients who have the procedure may die within a year from disease-related complications in the kidneys, liver or lungs. But for patients whose only treatment option is medication to manage their aortic disease, up to half may die within a year.

Resar adds that many TAVI patients in Europe are living longer than five years after placement of the device, and says the potential risks are far less than with conventional surgery.

About 1,200 participants are expected to be enrolled nationwide in the two-year study. All will have severe aortic valve narrowing and be at high risk or extremely risk of death from traditional, open-heart surgery. Some of the high-risk patients will get the CoreValve TAVI, and others will have traditional open-heart valve surgery. Those at extreme risk will have either TAVI or drug therapy alone to manage their disease.

According to Conte, more treatment options are needed to manage the increasingly severe cardiovascular and other health issues faced by the growing population of Americans over the age of 80. He estimates that more than 300,000 elderly Americans have severe aortic stenosis, or narrowing, and are at high risk of death if open-heart surgery is used to repair the valve.

Conte, a professor of surgery at Johns Hopkins, says possible complications from the TAVI procedure are few. They include bleeding from insertion of the catheter, which can be managed with blood transfusions if needed, and stroke from arterial debris breaking off and lodging in the brain. Surgical filters are being designed to deflect debris away from arteries leading to the brain. Some 15 percent of TAVI patients may also need a pacemaker, as the device sits close to the electrical pathway responsible for regulating the heartbeat. For most patients, a temporary pacemaker is sufficient.

If the CoreValve Pivotal trial is successful and the device is approved, Conte says CoreValve could add to the number of treatment options for his patients. Another TAVI device that is also being studied in the U.S. is the so-called Sapien valve, manufactured by Edwards Lifesciences.

Physicians and potential study participants interested in knowing more about the Medtronic CoreValve U.S. Pivotal trial can visit the website: www.clinicaltrials.gov/ct2/sho … e+replacement&rank=7

Provided by Johns Hopkins University