Trial Investigates Heart Valve Replacement Without Opening The Chest

A new approach for implanting an aortic heart valve without open-heart surgery is being offered at Rush University Medical Center to patients with severe aortic stenosis who are at high-risk or not suitable candidates for open heart valve replacement surgery.

Aortic valve stenosis (AS) affects nearly 1.5 million Americans, causing the hardening or thickening of the aortic valve leaflets, which limits leaflet motion and obstructs oxygen-rich blood flow from the heart to the rest of the body. Although AS typically progresses slowly without symptoms, once symptoms occur, treatment is required. Fifty percent of patients may not survive beyond one to three years. Traditionally, patients with symptomatic AS undergo aortic valve replacement during an open-heart surgery to alleviate symptoms, improve survival and improve quality of life. However, many patients who are at very high risk for surgery are considered inoperable.

The PARTNER II trial will compare a pioneering technology called the Edwards SAPIEN XT valve, which is made of bovine pericardial tissue leaflets hand-sewn onto a metal frame, and a new catheter delivery system called the Edwards NovaFlex delivery system, which navigates the heart from a small incision to the femoral artery in a patient’s leg or through a small incision between the ribs and snaked up into the left ventricle. The Edwards NovaFlex delivery system positions the catheter inside the patient's original, collapsed valve, using a balloon to deploy the frame, which holds the artificial valve in place in order to restore normal blood flow. Both procedures are performed on a beating heart, without the need for open, cardiopulmonary bypass and its associated risks.

Results from the first phase of the PARTNER trial showed that the rate of death from any cause at one year was 50.7 percent in the patients who received standard therapy, as compared to 30.7 percent of patients treated with transcatheter aortic valve replacement (TAVR). The transcatheter valve procedures take about 90 minutes, compared with four to six hours for open-heart surgery. In open-heart surgery, the surgeon cuts through the breastbone, stops the heart, removes the valve and replaces it. Open-heart surgery can require a two to three month recovery period, compared to only a few days for the transcatheter approach.

The next generation Edwards SAPIEN XT valve in The PARTNER II trial was engineered to provide a better valve patterned after surgical heart valves and to potentially decrease treatment complications. The PARTNER trial is the world's first randomized, controlled trial of a transcatheter aortic heart valve. In this clinical phase, patients are randomized to receive either the new Edwards Sapien XT valve using the NovaFlex delivery system or the Edwards SAPIEN Transcatheter Heart

Valve.

The PARTNER II trial is one of the three latest, nationwide clinical trials for minimally invasive heart valve replacement being offered through the Rush Valve Clinic, where a team of cardiac surgical and interventional experts address diseases of the aortic, mitral and pulmonary valves. The three clinical trials include:

- PARTNER II trial for patients with aortic stenosis.
- COMPASSION trial for patients with a dysfunctional conduit – a phase II clinical trial using the SAPIEN Transcatheter Heart Valve in patients who have a dysfunctional conduit between the right ventricle and the pulmonary artery.
- EVEREST II trial for patients with mitral regurgitation – a continued access trial using the eValve MitraClip to treat a mitral valve leak.

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