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Patients receive heart valve replacements without surgery using high-tech device

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Interventional cardiologists at Rush University Medical Center now offer a minimally-invasive transcatheter valve replacement procedure for patients with congenital heart disease that doesn't involve open heart surgery.

Rush is one of three sites taking part in the investigational device exemption (IDE) feasibility study of minimally-invasive pulmonic valves and successfully implanted the first three patients enrolled in the trial on Thursday, April 17.

"We were able to successfully implant the Edwards SAPIEN transcatheter heart valve percutaneously in the first three patients treated in this trial. All of the patients are recovering and are expected to go home today," said Dr. Ziyad M. Hijazi, director of the Rush Center for Congenital and Structural Heart Disease, chief of the section of pediatric cardiology and professor in the departments of pediatrics and internal medicine at Rush University, Chicago. "Patients with congenital right ventricular outflow tract problems typically face the burden of multiple open-heart surgeries throughout their lives, either to replace their 'native' diseased valves or, as they age, their bioprosthetic replacement valves."

Hijazi, an interventional cardiologist and pioneer in nonsurgical repair of the heart, and his colleagues, Dr. Clifford J. Kavinsky and Dr. Zahid Amin, used a bovine pericardial heart valve that can be compressed onto a balloon to the approximate diameter of a pencil, threaded from the leg into the circulatory system and deployed across the patient's pulmonary

valve. The valve replacement is accomplished as a “beating heart” procedure, without requiring cardiopulmonary bypass or an open-chest incision.

Edwards Lifesciences Corporation of Irvine, Calif., makes the Edwards SAPIEN transcatheter valve that was implanted.

“We can replace heart valves in high-risk patients with severe pulmonary stenosis (abnormal narrowing in a blood vessel) who might not be candidates for conventional valve replacement surgery. Instead, these patients can benefit from a transcatheter valve replacement procedure done minimally-invasively, without cardio-pulmonary bypass, that has the potential to shorten recovery time,” said Hijazi.

“Patients with congenital right ventricular outflow tract problems typically face the burden of multiple open-heart surgeries throughout their lives, either to replace their ‘native’ diseased valves or, as they age, their bioprosthetic valves. This clinical study will enable physicians to offer a minimally-invasive alternative to symptomatic patients with a regurgitant, or leaky, pulmonary valve conduit, giving them the opportunity to recover and resume their normal activities."

“My team is proud to be able to address this serious unmet patient need and to offer the chance to take one or more surgeries out of the treatment course for these patients,” said Hijazi.

The U.S. Food and Drug Administration (FDA) conditionally approved the investigational device exemption (IDE) clinical trial in late 2007. The study of 30 patients at three hospitals will enable the collection of safety and effectiveness data, ultimately in support of a commercial approval application.

Source: Rush University Medical Center