

Baylor Implants Synthetic Heart Valve in Patients for Global Trial

Investigational device could give new options to the 4 million people with “leaky mitral valve”

Two Baylor patients were the first in Texas to receive an investigational transcatheter mitral valve replacement (TMVR). Physicians at Baylor’s Jack and Jane Heart and Vascular Hospital implanted the Tendyne Bioprosthetic Mitral Valve System as part of an [international clinical trial](#) that could someday give new options to the 4 million people in the U.S. with mitral regurgitation, otherwise known as a “leaky mitral valve.”

The research physicians implanted the heart valve to study its effectiveness and safety in replacing the heart’s mitral valve—marking a pivotal point following successes seen with transcatheter aortic valve replacement (TAVR). Similar to those procedures, TMVR aims to replace the abnormal mitral valve in patients who are not candidates for traditional open heart surgery.

“It’s exciting to be able to offer a new technology to patients who otherwise wouldn’t have any options,” said Robert Stoler, MD. Paul Grayburn, MD, the principal investigator for this trial, said, “There are a number of transcatheter valves under development and we’re currently using one that has been shown to be effective in previous cases.”

“What we’ve learned so far is encouraging,” added Dr. Grayburn.

An Improved Quality of Life

Both Baylor patients suffered from mitral regurgitation, which prevents the mitral valve from closing as the heart pumps. A healthy mitral valve serves as a one-way gateway through the heart, channeling blood from the left atrium into the left ventricle. But for patients with regurgitation, a faulty mitral valve may not close entirely, allowing blood to leak back into the atrium.

Typically, symptoms can range from fatigue to shortness of breath and heart palpitations. In severe cases, the condition can lead to heart failure or even death.

“Many of my patients just would like to be able to get off the couch and go to the dinner table, and they can’t do it without being completely breathless,” Dr. Grayburn said. “So this is an opportunity to improve the quality of life for these patients.”

A Less-Invasive Approach

Since valve disease can involve a natural “wearing away” of the valve, risk increases with age: Mitral valve regurgitation affects about one in 10 people over age 75.

That’s partially why Abbott’s Tendyne device could meet a substantial need for less-invasive options. Often, treatment requires open-heart procedures to repair or replace the damaged valve, which may not always be the best choice for older individuals. The Tendyne device instead involves a small chest incision and an implantation that is done on a beating heart without the need for a cardiopulmonary bypass machine. [See video of the device in action here: <http://www.tendyne.com/>]

“Many people, when they hit that age [over 75], have a lot of other medical conditions that make surgery a poor option for them,” Dr. Grayburn said. “For a person 25 or 30, surgery is a great treatment for mitral regurgitation, but in older, sicker folks, they need a percutaneous option (via needle puncture of the skin).”

In addition to age, other risk factors for mitral valve regurgitation include a history of heart problems (such as heart disease, heart attack or mitral valve prolapse/stenosis), or infections (endocarditis and rheumatic fever).

A Toolbox of New Options

Currently, alternative options for these patients can include other types of devices and approaches, in addition to the one studied.

“It’s like putting together a toolbox to treat mitral valve disease,” Dr. Stoler said. “We have the MitraClip, a repair device approved by the FDA for certain patients that is being tested in a clinical trial for other patients. There are also technologies that repair the cords from the mitral valve without opening the patient’s chest entirely. And then there are these new TMVR devices that completely replace the mitral valve.

“We will have different types of all three of those technologies, and that’s not to say that one type is going to be the answer—but the better the toolbox we have, the more likely we can fix our patients’ problems.”

Leading the Charge

Baylor is one of 10 centers to participate in the TMVR research that includes a global participant pool of up to 30 patients. To continue with the study and implant more patients in need of mitral valve replacement, investigators seek adult patients with severe mitral regurgitation due to a damaged or non-functioning valve. Participants will receive follow-up monitoring for two years post-implantation.

Official results likely won't surface until the next few years.

"We're very excited," Dr. Grayburn said. "We feel honored to have a chance to get a hand on these valves, to put them in our patients, to improve their quality of life. We're continuing to lead the charge across the nation in bringing new devices to structural heart disease, including mitral regurgitation."

For more information about the "Early Feasibility Study of the Tendyne Mitral Valve System" clinical trial, contact Susan Aston, RN, at 214-820-7358.