# New heart valve shows high survival rates in study

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Loyola University Medical Center is the only Chicago hospital participating in a landmark clinical trial of an artificial aortic heart valve that does not require open heart surgery.

First results from the trial were announced at the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco. Results were positive, with high survival rates and low rates of stroke.

"This is a major breakthrough," said Fred Leya, MD, co-principal investigator at the Loyola site. "Not only did patients live longer, but their quality of life improved substantially." The other co-investigator at Loyola is Mamdouh Bakhos, MD.

The heart valve is called the Medtronic CoreValve® System. It is deployed with a catheter, which is inserted into an artery in the groin and guided up to the heart. Once in place, the artificial valve takes over the function of a diseased valve.

"It saved me a great deal of pain and suffering from not having to have my chest cracked open," said Loyola patient Martin Rogus, who participated in the clinical trial. While recovering from the valve placement, he said, "It almost felt like they didn't do anything."

Rogus said that before receiving the new valve, he could not walk a single block without having to stop and catch his breath. Now he can

walk a mile slowly, without stopping. "It's been a great gift," he said.

The valve is being studied in patients with severe aortic stenosis. This condition occurs when the heart's aortic valve is narrowed, restricting blood flow from the heart to the body. The valve doesn't open properly, forcing the heart to work harder to pump blood.

Symptoms include fatigue, dizziness, chest pain/pressure, heart murmur, shortness of breath during activity, heart palpitations and fainting. Aortic stenosis can lead to heart failure and death. About 100,000 people in the United States have aortic stenosis. Currently in the United States, the standard treatment is to replace the aortic valve through open-heart surgery.

The initial phase of the trial included 471 patients at 40 centers who were extremely frail and had complex medical problems that made them too sick for open heart surgery.

One year after implantation, 76 percent of the patients were still alive, a remarkable result considering how ill they were. And only 4.1 percent had experienced major strokes within that first year, which was significantly lower than expected.

The valves worked well, with strong blood flow and low leakage rates.

There was a huge improvement in patients' quality of life, as measured on a 100 point scale. The scores of patients who had their implant for one year improved 27.4 points on the KCCQ scale. (By comparison, 5 points is considered important and 20 points is considered a very large improvement.)

Investigators are expected to report on the trial's other study of patients who are not as frail as those in the initial group. Half of these new

patients have been randomly assigned to receive CoreValve and half have been assigned to conventional open heart surgery.

More than 45,000 patients in more than 60 countries have received the CoreValve System. In the United States, use of the device is limited to clinical trials.

Leya is a professor of medicine and director of Interventional Cardiology, and Bakhos is professor and chair of Thoracic and Cardiovascular Surgery at Loyola University Chicago Stritch School of Medicine. J. Michael Tuchek, DO, worked with Leya in implanting the device. Tuchek is a clinical assistant professor in the Department of Thoracic and Cardiovascular Surgery.

Provided by Loyola University Health System