

Heart patients do better with non-surgical valve replacement than standard medical therapy

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Patients diagnosed with aortic stenosis who are too sick for open-heart surgery have better survival rates and an improved quality of life after undergoing catheter-based heart valve replacement than if the patients had been treated with standard medical therapy, according to a study authored by a Cedars-Sinai Heart Institute physician based on results from a multicenter clinical trial.

The study, published online today by the [New England Journal of Medicine](#), will appear in the May 3 print edition of the journal.

"This study shows that this minimally invasive procedure adds years to life and life to years," said Raj Makkar, MD, associate director of the Cedars-Sinai [Heart](#) Institute and the Stephen R. Corday, MD, Chair in Interventional Cardiology.

[Aortic stenosis](#), a stiffening of the aortic valve's three flaps, restricts the flow of blood from the heart to the rest of the body. It forces the heart to work harder and deprives the organs of sufficient oxygen-rich blood. Aortic stenosis affects an estimated 2 to 9 percent of U.S. adults 65 and older. The condition can cause chest pains, shortness of breath, dizziness and fainting.

Before catheter-based heart valve procedures were developed in the last decade, patients diagnosed with aortic stenosis would have just one

option to repair a malfunctioning valve: Open-heart surgery.

However, about a third of patients are too frail for open heart surgery. And without it, patients with aortic stenosis can expect to die from [heart failure](#) within five years and often much sooner.

In percutaneous or minimally invasive heart valve procedures, physicians use the vascular system's network of "highways" -- the arteries -- to reach the heart instead.

Physicians insert a thin tube, or catheter, through a small incision in the groin or the side of the chest. The catheter, which contains a compressed artificial [aortic valve](#), is threaded along the arteries all the way to the heart. Once the valve is precisely positioned in the heart, a balloon nestled inside the valve – similar to the kind used for angioplasties -- is inflated. The balloon pops the valve open, like an umbrella, to its full diameter.

Cedars-Sinai's Heart Institute is a global leader in seeking nonsurgical solutions for malfunctioning heart valves. Physicians at the Heart Institute, in conducting multiple clinical trials, have performed more of these catheter-based valve procedures than doctors at any other U.S. medical center.

In the clinical trial, which was funded by valve manufacturer Edwards Lifesciences, 358 patients at 21 medical centers were randomized into two groups. One group underwent percutaneous procedures. The other group received standard medical treatment, including prescription drugs. Both groups were followed for two years.

Results include:

- Two years after being diagnosed, 68 percent of patients receiving standard medical therapy had died, compared to just 43 percent of patients who received the minimally invasive procedure.
- 33 percent of patients who received the minimally [invasive procedure](#) were readmitted to the hospital at some point during the two years of follow up, compared to 72 percent of patients who received medical therapy.
- Patients who underwent the procedure did have a higher risk of stroke, with 14 percent suffering a stroke, compared to just 5 percent of standard therapy patients.

Other than reimbursement for travel to medical centers participating in the clinical trial, Makkar has received no payment from Edwards Lifesciences.

Open-heart surgery to repair or replace heart valves is still the "gold standard," says Eduardo Marbán, director of the Cedars-Sinai Heart Institute and the Mark S. Siegel Family Professor, who adds that demand for catheter-based procedures is growing.

"The heart's valves wear out as you age," Marbán said. "And the older you are generally makes you a less attractive candidate for [open heart surgery](#). This new, less-invasive option will become more and more important to patients as the Baby Boom Generation ages."

Provided by Cedars-Sinai Medical Center

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