

# Study backs new heart valve without cracking chest

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Dr. Martin Leon, a professor at Columbia University Medical Center, holds a model of minimally invasive heart valve by Edwards Lifesciences in Washington, Tuesday, Sept. 21, 2010. (AP Photo/Jacquelyn Martin)

(AP) -- Thousands of older Americans who need new heart valves but are too frail to survive the surgery might soon get a chance at an easier option - a way to thread in an artificial aortic valve without cracking their chests.

The [aortic valve](#) is the heart's main doorway, and a major new study found that snaking a new one in through an artery significantly improved the chances that patients with no other treatment options would survive at least a year.

Not yet known is whether easier-to-implant valves might work for the

less sick who'd like to try the new technology rather than undergo the open-heart surgery required for standard valve replacements that can last 20 years.

That question still is being studied, but two competing types of these "transcatheter aortic valves" already are sold in Europe - and manufacturer Edwards Lifesciences Corp. hopes to win U.S. [Food and Drug Administration](#) approval to sell its version for inoperable patients in about a year.

"This opens the door to a new treatment," said lead researcher Dr. Martin Leon of Columbia University Medical Center and New York-Presbyterian Hospital.

He reported the results in Thursday's [New England Journal of Medicine](#) and at the annual Transcatheter Cardiovascular Therapeutics conference. Edwards paid for the study at 21 hospitals, and many of the researchers have received fees from that company or competing heart device makers.

The valves aren't a cure-all, they come with a risk of stroke, and no one knows how long they'll last. Still, specialists say they're a step to transforming care for a problem on the rise as the population grays.

Some 300,000 Americans already have a seriously diseased aortic valve, a gate that essentially rusts with age until it can't open properly, forcing the heart to work ever harder to squeeze blood through. More than 50,000 people a year undergo open-heart surgery to replace that valve, and thousands more are turned away, deemed too old or ill to survive the arduous operation.

The less invasive option will "possibly be a game-changer," said Dr. Robert Bonow of Northwestern University's Feinberg School in

Medicine in Chicago, who monitors the valves' development for the American Heart Association and has consulted for Edwards. "In the future, this may be the way many patients get their valves replaced."

Patients marvel at how quickly they can bounce back.

"It's like they jacked me up and put a new motor in," said Herbert Rose, 81, of New York City. He couldn't climb a few stairs without pain and shortness of breath before his April implant, but said now he swims 11 to 14 laps in the local pool every other day.

Traditionally, surgeons saw a person's breastbone in half, stop the heart, cut out the old, hardened valve and sew in a new one. Even the best patients spend a week in the hospital and require a few months to recuperate, but people can live well with these valves for decades.

Transcatheter valves, made by Edwards and competitor Medtronic, are threaded through a leg artery up to the heart - and don't require removing the old valve. Instead, it's propped open and the new valve is wedged into that doorway.

In the new study, 358 patients deemed inoperable were randomly assigned to receive either the Edwards transcatheter valve or essentially comfort care. In the first month, 5 percent of the valve recipients died, compared with 2.8 percent of the control group, showing the risk of any procedure in these sickest-of-the-sick.

But a year later, half of the patients who didn't get a new valve had died of various causes, compared with just 30 percent of the valve recipients. Columbia's Leon said doctors saved a life for every five patients treated - and most patients felt better and moved better, enjoying more quality of life.

That's a meaningful survival difference, said Dr. Andrew Wang of Duke University, who called the results exciting. Duke is among the centers soon to begin testing Medtronic's valve.

However, 5 percent of valve recipients suffered strokes, compared with 1 percent of the control group.

While the results are promising, the strokes are a worry, said Dr. James McClurken of Temple University in Philadelphia: "We don't want to have people stop having heart failure and be debilitated by having strokes."

Doctors had seen similar stroke rates in Europe and are working on smaller valves and better techniques to lower that risk.

Study patients will be tracked for five years, but how long these wedged-in valves will last is a huge question if they're ever to be used by lower-risk patients, cautioned Dr. John Conte of Johns Hopkins University, a spokesman for the Society of Thoracic Surgeons. He said potential patients should be evaluated by both an interventional cardiologist and a cardiac surgeon to decide if the new method or the old is the best option.

Standard heart valve replacement costs upward of \$50,000, most from surgical and hospitalization fees. Transcatheter valves are anticipated to cost \$20,000 to \$30,000 but to bring lower hospital bills.

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