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New treatment for severe aortic stenosis shown to save lives, researchers say

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Implantation of a new bioprosthetic-tissue valve into the hearts of patients who have severe aortic stenosis and are too sick or too old for open-heart surgery has been found to both save lives and improve the quality of those lives, according to a new multicenter study, to be published online at 2 p.m. Pacific time today in the *New England Journal of Medicine*.

The study will also be presented at 8 a.m. Pacific time at the Transcatheter Cardiovascular Therapeutics Conference in Washington, D.C. on Sept. 23.

"This is exciting because it does save lives and is a major medical paradigm shift," said D. Craig Miller, MD, the Thelma and Henry Doelger Professor of Cardiovascular Surgery at the Stanford University School of Medicine and one of the manuscript's principal authors. "These patients were really sick with a fatal problem, and now they're feeling better and staying out of the hospital. Before, there was nothing we could really offer them."

Stanford University Medical Center was one of 21 institutions to participate in the study, known as the PARTNER Trial. It is the first randomized clinical trial comparing the efficacy of using a transcatheter heart valve called "TAVI" - which is implanted percutaneously through an artery in the groin directly into the beating heart - with routine medical therapy, which includes aortic balloon valvuloplasty to relieve symptoms. The trial was sponsored by Edwards Lifesciences Corp.,

based in Irvine, Calif., which designs, manufactures and markets tissue heart valves.

A total of 358 patients with severe aortic stenosis, a heart disease characterized by obstruction of the aortic valve due to calcification, participated in the trial. The patients who qualified were debilitated by the disease, which causes shortness of breath, fatigue and congestive heart failure. While the standard of care for most patients with this condition would be open-heart surgery to replace the diseased valve, that was not a realistic option for the specific patients selected for this study, who were too sick or too old to undergo such an operation. For them, the standard of care is medical therapy.

At one year after randomization, 30.7 percent of patients who had received the percutaneous valve replacement had died compared with 50.7 percent of those who received standard medical therapy.

"The most impressive finding in the study is the 20 percent reduction in mortality," said William Fearon, MD, associate professor of cardiovascular medicine at Stanford, who also participated in the study. "This is very dramatic. The effect was so powerful that by just treating five people you can save one life. But beyond just the survival benefit, the improvement in the patients' quality of life based on their symptoms and their ability to exercise is dramatic."

Stanford enrolled more than 80 patients in the PARTNER study, of which 14 were these very sick patients. Jana Pausa, 76, of Atherton, Calif., who had both severe aortic stenosis and lung disease that made her unsuitable for open-heart surgery to replace the diseased heart valve, is one such patient.

"Getting dressed or anything was absolutely debilitating," said Pausa, who was randomized to have the device implanted a year and a half ago.

"Before the surgery, I used a walker. Sleeping was difficult because I didn't feel like I could breathe. I had no energy. When I woke up out of surgery, I immediately felt the difference. I could breathe - for sure it saved my life."

Now she's walking and playing with her grandchildren and planning for her husband's 80th birthday party.

Many patients with severe aortic stenosis come into the hospital in a wheelchair, said Alan Yeung, MD, the Li Ka Shing Professor of Medicine and chief of Stanford's division of cardiovascular medicine, who was also involved in the study. "Nobody thinks they're going to walk out of the hospital. These patients are now able to go shopping, to spend time with their family. People can have a good quality of life."

The study did show though that patients paid a price for the procedure, Miller said. Patients who had the device implanted suffered higher rates of stroke: 5 percent vs. 1 percent. They also had more major vascular complications - 16 percent vs. 1 percent - and bleeding due to the size of the catheter.

Future studies are planned to determine the durability of the TAVI valves and also to determine whether this procedure may be beneficial in other lower-risk and younger patients for whom open-heart surgery is a low-risk and durable option.

The trial used the Edwards SAPIEN valve, which costs about $20,000 but is not yet commercially available in the United States and does not have approval from the U.S. Food and Drug Administration. The valve is made of a stainless-steel stent and cow pericardium.

The procedure, which takes about two hours, involves inserting a catheter (or tube) through the femoral artery in the groin. In this TAVI

approach, the catheter travels up the aorta to the heart and crosses the severely stenotic aortic valve, where the new valve is deployed. The entire concept, starting with patient selection, is a major team effort; the interventional cardiologists and cardiovascular surgeons work together with cardiac anesthesiologists and a cardiologist echocardiographer throughout the procedure using fluoroscopy and transesophageal echocardiography to guide the valve positioning and deployment without cutting the chest open.

The prosthetic heart valve is collapsed down over a balloon over the catheter. After it's been positioned precisely across the diseased aortic valve, the balloon is inflated with saline and the valve expands, crushing the diseased valve and enabling the heart to pump blood to the body much more effectively.

Provided by Stanford University Medical Center