

'Cow valve' heart implant hailed as breakthrough

April 3 2011, by Kerry Sheridan

A new type of heart valve made with cow tissue and inserted by catheter was hailed on Sunday as a major breakthrough that could eliminate the need for open heart surgery in some patients, US doctors said Sunday.

The method is aimed at high-risk patients who suffer from severe aortic stenosis, a clogged valve that impedes the pathway of oxygen-rich blood by making the heart work harder to pump blood through a narrowing opening.

The condition affects nine percent of Americans over 65. Without treatment, up to half of patients die within two years.

The technique of inserting the bioprosthetic valve through a tube in the artery is less invasive than conventional surgery and showed similar survival rates to conventional surgery, but also raised the risk of stroke and other major heart complications.

The research was part of the multi-year PARTNER study, the world's first randomized trial comparing the two methods, and was showcased at the American College of Cardiology conference in New Orleans.

"The progress has been quite dramatic over several years," said Craig Smith, chair of the Columbia University College of Physicians and co-principal investigator on the study.

The method lowered costs involved with rehospitalization in frail,

elderly patients and was found to increase life expectancy by as much as 1.9 years, said the research.

The process is already being done in Europe but has yet to gain Food and Drug Administration approval in the United States, where the valve is considered an investigational device.

"You are all witnessing history in the making," said David Moliterno, professor of medicine at the University of Kentucky.

"This probably will be seen as one of the biggest steps in cardiovascular medicine, as far as intervention is concerned, potentially in our lifetime," said Moliterno, who was not involved in the study.

After balloon angioplasty and the invention of stents, "this will be seen as the next major turning point," he said.

The study compared results among 699 patients with a median age of 84, who were randomly assigned to either transcatheter aortic valve replacement (TAVR) or open heart surgery to replace the aortic valve (AVR).

The TAVR process involves taking a wire mesh stent that holds three stitched-in valve flaps made of cow tissue, and inserting that into the heart via a catheter in a leg artery or under the rib cage.

The bioprosthesis, called the Edwards SAPIEN heart valve, is made by Edwards Lifesciences in California.

The valve is treated with an anti-calcium building agent that helps cut back on the causes of stenosis. It is not yet available on the US market.

Early results from the study at the 30-day mark favored the catheter

insertion of the bioprosthesis, showing a death rate of 3.4 percent compared to 6.4 percent for the open heart surgery method.

Death rates evened out over time and were similar at one year.

Those in the catheter-group also saw lower risk of major bleeding (9.3 percent compared to 19.3 percent in surgery patients) and irregular heart rhythm (8.6 percent compared to 16 percent in the other group).

"These results clearly show that TAVR is an excellent alternative to surgical AVR in high-risk patients," said Smith.

However, the new method carried significantly higher risk of "major vascular complications," at a rate of 11 percent after TAVR compared to 3.2 percent in patients who underwent conventional surgery.

Major stroke risk was also higher in TAVR patients -- 3.8 percent versus 2.1 percent at the 30-day mark and 5.1 percent versus 2.4 percent after one year.

Smith declined to elaborate about the suspected causes of stroke in patients who underwent TAVR, but said the subject was being studied and would be addressed at a future conference on thoracic surgery.

Both the valves typically used in open heart surgery and the type used in the TAVR method are made with cow tissue, or bovine flaps, but the open heart surgery valves are bulkier, Smith said.

The catheter-inserted valves are smaller in size but have a slightly larger opening than the heart surgery valves.

A next-generation device is being formulated that includes some improvements to the design and can be inserted through a smaller

catheter, researchers said.

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