New way to fix leaking mitral heart valves safe in initial testing

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A new nonsurgical technique to repair leaking mitral valves in heart failure patients was safe in a study reported in *Circulation: Cardiovascular Interventions*.

In a small study that focused on feasibility and safety, researchers observed improvements in mitral regurgitation in patients successfully treated with a reversible implant called the Percutaneous Transvenous Mitral Annuloplasty (PTMA®) system.

"Heart failure prevalence is worsening, and we know that the outcome of congestive heart failure is worse when mitral regurgitation is present," said Stefan Sack, M.D., Ph.D., lead author of the study and chief of cardiology, pneumology and intensive care at Schwabing Hospital in Munich, Germany.

The mitral valve controls the flow of blood from the heart's upper left chamber (left atrium) into the lower left chamber (left ventricle). If the mitral valve leaks, a condition known as mitral regurgitation occurs where small to large quantities of blood flow back into the left atrium rather than to the aorta and subsequently on to the rest of the body. This common condition can lead to congestive heart failure or worsen existing heart failure. Prior studies have clearly demonstrated the relationship of mitral regurgitation with illness and death in heart failure patients.

The PTMA® system consists of a repair device contained inside a

catheter. The catheter is threaded through a vein into the coronary sinus, which rests at the back of the heart and collects most of the blood returning from the heart. The catheter is pushed up to the mitral annulus, a fibrous ring encircling the mitral valve, and anchors the device in place.

Tiny, shaped metal rods made of a nickel-titanium alloy are inserted into the catheter. The combination changes the shape of the mitral annulus and allows the valve's two leaflets to close more tightly and prevent blood leakage.

In the study, Sack and colleagues at one Canadian and four European centers evaluated 27 patients divided into four groups between April 2006 and November 2007. The patients' average age was 70. Researchers made device improvements and refined their diagnostic and implantation techniques between each successive group.

Nine patients received PTMA® implants, but researchers removed four devices — one due to fracture and three because they had shifted position.

No deaths, heart attacks, strokes or emergency surgeries occurred among the 27 patients. Four patients suffered at least one major adverse event — including pneumonia, temporary kidney dysfunction or an abnormal accumulation of fluid around the heart.

If proven effective, the PTMA® system could significantly reduce risks associated with surgical repair of the mitral valve. Today, the operation requires opening the chest and putting the patient on a heart-lung machine, which carries some risk of heart attack and stroke during surgery, and infection, lung problems and irregular heart beats afterward.

However, the study showed that the PTMA® system does not work with

all patients due to a variety of anatomic and disease specific causes.

Researchers said it's too soon to gauge the clinical impact of the device.

The international research team is engaged in Ptolemy-2, a larger follow-up trial assessing the PTMA® system's efficacy and further confirming its safety.

Heart failure is a condition in which the heart can't pump enough blood to meet the body's needs. It caused or contributed to more than 292,000 deaths in the United States in 2005, according to the American Heart Association. At age 40, men and women have a 20 percent lifetime risk of developing heart failure. The risk doubles for those with a blood pressure of 160/90 milligrams of mercury (mm Hg) or higher.

Source: American Heart Association (news : web)