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Catheter repair of mitral valve improves heart size, symptoms

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A catheter-mounted device that acts like a clothespin to clip together the flaps of a leaky heart valve is not only reducing the abnormal backflow of blood from the left ventricle to the left atrium, it is helping to shrink the enlarged, overworked heart and relieving symptoms of fluid overload—all without open-chest surgery. These are the one-year findings in a small group of patients enrolled in the Endovascular Valve Edge-to-Edge Repair Study (EVEREST), which is evaluating the use of the MitraClip for the treatment of mitral regurgitation (MR).

The sub-analysis is being reported today in a Late-Breaking Clinical Trials session at the SCAI Annual Scientific Sessions in Partnership with ACC i2 Summit (SCAI-ACCi2) in Chicago. SCAI-ACCi2 is a scientific meeting for practicing cardiovascular interventionalists sponsored by the Society for Cardiovascular Angiography and Interventions (SCAI) in partnership with the American College of Cardiology (ACC).

“One trouble with mitral regurgitation is that the heart has to work harder, and over time, it dilates and enlarges,” said James Hermiller, MD, director of the interventional fellowship at St. Vincent Heart Center of Indiana in Indianapolis. “Demonstrating that the left ventricular enlargement is actually reversing itself is important objective evidence that the heart is responding favorably. It confirms that there’s something real here.”

Mounted on the end of a catheter, the MitraClip is threaded through the femoral vein in the groin and into the right atrium. A needle puncture in

the wall separating the upper chambers of the heart enables the catheter to pass into the left atrium, where the clip is opened up like a clothespin. It is then passed through the mitral valve into the left ventricle. When the heart contracts, the flaps of the mitral valve are grasped by the clip, which is then closed, securing the edges of the valve flaps together at their centers. The result is a bow-tie-shaped opening that permits blood flow from the left atrium to the left ventricle during relaxation of the heart, and enables the valve flaps to close more effectively during contraction, rather than allowing leakage of blood backward into the left atrium.

The study by Dr. Hermiller and his colleagues focused on 23 patients treated at 15 medical centers either during the EVEREST I study or during the “roll-in” phase of the ongoing EVEREST II study, which is comparing MitraClip therapy to open-chest surgery. All of the patients in the new analysis had functional MR, which results not from a defect in the valve leaflets but from enlargement of the valve opening as a result of heart attack or heart failure. Of the quarter-million people newly diagnosed with mitral regurgitation in the United States each year, as many as two-thirds have the functional form, but it hasn’t been clear whether the MitraClip would work as well in functional MR as in degenerative MR.

Before the procedure, all patients had moderately severe or severe mitral regurgitation, and 83 percent of patients had heart failure ranked as New York Heart Association (NYHA) functional class III or IV, which is characterized by lung congestion, shortness of breath, fatigue, swelling of the legs, and difficulty with light-to-moderate physical activity. After the procedure, mitral regurgitation was mild to modest in 19 of 22 patients (83 percent) treated with the MitraClip.

After one year, 12 patients had completed follow-up and had matched data from both baseline and follow-up. Ten of the 12 patients (83

percent) continued to have only mild to modest mitral regurgitation and nine of 12 (75 percent) continued to enjoy an improvement in symptoms and daily function of at least one NYHA class. In addition, heart size was significantly smaller. For example, the left ventricular internal diameter during relaxation, or diastole, fell from an average of 6.0 cm at baseline to 5.4 cm at 12 months (p=0.037), and left ventricular end-diastolic volume fell from an average of 208 mL at baseline to 178 mL at 12 months (p=0.037).

“This is a small study, but it demonstrates a proof of principle that the MitraClip can reduce mitral regurgitation and improve heart function in patients with functional MR,” Dr. Hermiller said. “These findings are promising and interesting, but clearly we need a lot more data.”

Source: Weber Shandwick Worldwide

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