

Intriguing early results for device that reshapes enlarged, leaky heart valve

May 7 2009

An innovative device that acts like a belt to reshape an enlarged, leaky heart valve is providing a minimally invasive treatment option for patients who are too sick for open-heart surgery. According to a Late-Breaking Clinical Trial presented today at the Society for Cardiovascular Angiography and Interventions (SCAI) 32nd Annual Scientific Sessions, the CARILLON Mitral Contour System safely treated leaky mitral valves even in patients with moderate-to-severe heart failure, and was effective in reducing the backward flow of blood from the left ventricle to the left atrium.

The CARILLON Mitral Annuloplasty Device European Union Study (AMADEUS) study also showed that after treatment, patients experienced less shortness of breath and reported a better quality of life.

"This system is an exciting new option for patients and represents a significant improvement over medical management, the current standard of care," said Tomasz Siminiak, MD, PhD, a professor of cardiology at Poznan University of Medical Sciences, Cardiac and Rehabilitation Hospital Kowanowko, Kowanowko, Poland. "The CARILLON procedure is very simple and can be performed in under an hour. This is important for these patients, who are generally very sick."

The AMADEUS study focused on patients with functional mitral regurgitation. This type of leaky valve develops when the heart becomes abnormally enlarged after a heart attack or some other illness that damages the heart muscle. As the heart gets bigger, the valve opening

stretches and the valve flaps, or leaflets, no longer come together to form a tight seal. As a result, when the heart contracts, some of the blood in the left ventricle is propelled backward through the leaky valve into the left atrium, instead of being circulated to the rest of the body. The result is shortness of breath, especially during physical activity.

To implant the CARILLON Mitral Contour System, the interventional cardiologist punctures the jugular vein in the neck and threads a slender tube, or catheter, into the coronary sinus and then the great cardiac vein, a heart vein that passes near the mitral valve. The CARILLON device consists of two anchors connected by a shaping ribbon, made of nitinol, which conforms to the natural contours of the veins.

The device is passed through the catheter and into the great cardiac vein. One of the anchors is locked in place in order to restore the natural shape of the mitral valve and bring the valve flaps together. The second anchor is then locked in place. Imaging studies are used to confirm that the leaky valve is closing properly, and the implant is released. If the results are not satisfactory, the interventional cardiologist can recapture the system.

The AMADEUS study was primarily designed to test the feasibility and safety of the CARILLON system for the repair of leaky mitral valves. The study involved 48 patients with moderate-to-severe functional mitral regurgitation, an enlarged heart, reduced cardiac pumping ability, [heart failure](#), and limited exercise capacity. Researchers were able to implant the CARILLON device in 30 patients. In this group, echocardiography confirmed the improvement in mitral valve function after both 1 and 6 months. For example, the average volume of blood propelled backward through the mitral valve fell from 35 mL before the procedure to 23 mL after 1 month and 24 mL after 6 months (p

Citation: Intriguing early results for device that reshapes enlarged, leaky heart valve (2009, May 7) retrieved 10 April 2024 from

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