ICU
MANAGEMENT & PRACTICE

Fast, Simple Treatment Option For Patients Too Sick For Open-heart Surgery?

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 ($p<0.001$). Similarly, the average size of the leaky opening between the mitral valve flaps was reduced from 0.25 cm2 before the procedure to 0.17 cm2 after 1 and 6 months ($p<0.001$).
In the 18 patients who could not be treated with the CARILLON device, the heart's veins were too small, the device did not adequately reduce the backflow of blood through the mitral valve, or the device pressed on nearby coronary arteries and reduced blood flow to the heart muscle. However, when the coronary arteries are squeezed in this way, it is possible to successfully reposition the device almost half of the time, Dr. Siminiak said.

One patient died as a result of kidney failure, which was related to toxicity from the contrast dye used during interventional procedures. Three patients suffered an access-related puncture of the cardiac vein, but all of the blood vessels healed on their own. In three patients, abnormal lab tests hinted that the heart muscle might have been injured, but further investigation showed no problems.
"These are very intriguing clinical results that, I hope, will create enthusiasm among interventional cardiologists," Dr. Siminiak said. "This system might become a true breakthrough for a large group of patients who really have had no other treatment option."

Dr. Siminiak is continuing to follow-up patients to determine whether the improvements in mitral valve function are long-lasting.

With these results, AMADEUS has demonstrated the safety of this coronary sinus approach and provided early feasibility data on the efficacy of the device in reducing functional mitral regurgitation and improving patient function and quality of life. Researchers have begun discussions with the FDA concerning investigational device exemption status for the CARILLON Mitral Contour System. If approved, this would enable a pivotal randomized clinical trial to be launched later this year. The Carillon Mitral Contour System was recently granted CE Mark approval, which allows the device to be sold in Europe.

The AMADEUS study was funded by Cardiac Dimensions, the manufacturer of the CARILLON Mitral Contour System. Dr. Siminiak was reimbursed for the costs of the study but receives no other financial support from the company.

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