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Device approved for use in heart failure patients with mitral regurgitation

The MitraClip® transcatheter mitral repair procedure was initially approved in 2013 by the Food and Drug Administration (FDA) to treat patients with degenerative — or primary — mitral valve disease who are not good candidates for traditional surgery. The approval has now been expanded to include heart failure patients with functional — or secondary — mitral regurgitation whose symptoms have failed to improve with guideline-directed therapy.

Physical changes to the heart brought about by congestive heart failure can distort the mitral valve to the point of malcoaptation, where the valve leaflets no longer seal and blood flows backward from the left ventricle into the left atrium. Mitral valve regurgitation makes it even harder for the weak, dilated heart to circulate blood throughout the body. Because most heart failure patients with functional mitral regurgitation are in very poor health, they are usually not candidates for surgical mitral valve repair.

Treatment options for heart failure patients

Patients who have advanced heart failure are at increased risk for recurrent hospitalizations, decreased quality of life and high mortality. Heart failure patients with functional mitral regurgitation have significantly more severe heart failure symptoms and a worse prognosis.

Treatment option for a challenging group of patients

The newly approved indication for MitraClip use is a significant development for advanced heart failure patients. "Results of the COAPT trial will likely lead to updated treatment guidelines for use of MitraClip in advanced heart failure patients with mitral regurgitation who remain symptomatic despite guideline-directed medical therapy," says Marcella Calfon Press, MD, PhD, assistant professor in the Division of Cardiology. "MitraClip offers an exciting new therapy that can improve symptoms and potentially prolong life for many of our heart failure patients.

"The extended indications for the Mitraclip is another example of successful innovation and research bringing advanced technology and treatment to patients," says Richard J. Shemin, MD, Chief of Cardiac Surgery.

"These study results highlight the importance of a multidisciplinary approach to care and an advanced heart failure program that works closely with interventional cardiologists and cardiac surgeons to ensure patients receive optimal care," states Dr. Calfon Press.

Current therapies for advanced heart failure include guideline-directed medical therapy and, in many cases, cardiac resynchronization. Both have been shown to significantly improve heart function and patients' heart failure class based on symptoms and physical assessment. Despite these care options, the prognosis for heart failure patients with mitral regurgitation remains limited.

In March 2019, the FDA approved use of the MitraClip procedure in heart failure patients with functional mitral valve regurgitation. Approval of this new indication for use of the device was supported by results of the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial — a large, multicenter study that enrolled 614 heart failure patients with advanced mitral regurgitation who remained symptomatic despite receiving guideline-directed medical therapy. The study participants were randomized into a control group, which continued to receive maximally tolerated medical therapy, and a device group that underwent MitraClip transcatheter mitral valve repair in addition to medical therapy.

The COAPT study revealed that use of MitraClip in addition to guideline-directed medical therapy was superior to guideline-directed medical therapy alone in reducing heart failure re-hospitalization and mortality in symptomatic patients. Re-hospitalizations for heart failure symptoms among the device group were 35.8 percent per year, compared to 67.9 percent for the control group. The 24-month mortality rate for the device group was significantly lower than that of the control group: 29.1 percent versus 46.1 percent. The MitraClip procedure also proved to be very safe among this high-risk population, with 96.6 percent freedom from device-related complications at 12 months.

Percutaneous mitral valve repair

While patients with advanced heart failure and mitral regurgitation are generally not surgical candidates, the COAPT trial showed that they can significantly benefit from the MitraClip transcatheter procedure.

Aided by state-of-the-art cardiac imaging, the MitraClip is delivered via catheter to the patient's heart and mitral valve through the femoral vein. Once positioned and implanted, the tiny clothespin-like device works by permanently clipping together a portion of the leaflets of the valve. The backflow of blood is reduced or eliminated, allowing the heart to pump more efficiently.

Team approach provides comprehensive care

UCLA's dedicated mitral valve team includes interventional cardiologists, cardiac surgeons, advanced heart failure specialists, advanced imaging echocardiographers, anesthesiologists, nurse practitioners and catheterization lab staff, all working in close partnership with patients, their families and referring physicians to coordinate a care plan designed to offer the best outcomes.

Regularly scheduled conferences conducted in the Cardiovascular Center allow access to the entire mitral valve team to discuss each patient's case and provide individualized recommendations using a multidisciplinary approach.

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