

Study offers less complex, minimally invasive procedure to treat heart valve leak

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Cardiac experts at Rush University Medical Center are studying a new, minimally invasive procedure to treat leaky heart valves. Instead of open heart surgery, patients will undergo a less complex catheter-based procedure to treat mitral regurgitation, a serious heart disorder where blood leaks backwards toward the lungs with each heart beat.

The researchers at Rush are taking part in the national EVEREST II REALISM trial, a prospective, multi-center, phase II clinical study comparing the effectiveness of the eValve MitraClip device to standard open [heart surgery](#). The tiny clip, which is placed using a catheter, holds the flaps of the mitral valve together to prevent leaking.

In normal hearts, the flaps of the valve between the left atrium and the left ventricle come back together after each heartbeat. With mitral regurgitation, the valve does not seal completely and blood leaks back into the left atrium. This reverse flow forces the heart to work harder to circulate the blood and can result in shortness of breath, fainting, [low blood pressure](#), fluid retention, fatigue, loss of appetite, and a hacking cough that worsens when lying down.

If left untreated, patients with mitral regurgitation can suffer serious complications.

"Patients can develop heart rhythm disorders which can cause blood clots and strokes. The heart muscle gets worse and worse function, so by the time symptoms develop, patients have lost critical [heart function](#),"

said Dr. Ziyad M. Hijazi, study investigator and director of the Center for Congenital and Structural Heart Disease at Rush.

This new procedure is performed under [general anesthesia](#) and is far less complex than the standard method of correcting mitral regurgitation - open heart surgery, which requires a sternum splitting operation, use of a heart-lung machine and stopping the heart to repair or replace the valve.

"Until now, open heart surgery was the only option for patients with severe mitral regurgitation," said Cliff Kavinsky, MD, study co-investigator and a cardiologist in the Center for Congenital and Structural Heart Disease at Rush. "Instead, we can use a catheter to reach the heart valve."

With a small puncture in the groin area of the leg, a catheter is threaded through the leg vein up into the heart. This allows doctors to manipulate a tiny clip, which can bring the mitral leaflets together to help control or cure the mitral regurgitation and stop the leak.

Because the procedure is minimally invasive, patients usually spend one night in the hospital compared to about five nights with [open heart surgery](#).

Preliminary results from the phase I trial, known as EVEREST I, show that the vast majority of mitral regurgitation patients who had successful results with the MitraClip device did not need mitral valve surgery three years after their procedure and many benefited from significantly improved function of the left ventricle. At 36-months follow-up, 82 percent of patients who had a successful result with the MitraClip device remain free from surgery. Seventy-four percent of patients with one or more clips implanted experienced significant improvement in the leak. Also, 12 months after the procedure, the shape of the left ventricle has improved. This was based on five echocardiographic measures, including

left ventricular end-systolic dimension.

"There are no drugs that specifically treat or cure mitral regurgitation," said Hijazi. "This procedure may allow us to stave surgery safely and manage patients' symptoms effectively."

Source: Rush University Medical Center ([news](#) : [web](#))

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