INNOVATIONS

Key Points

- Mitral valve regurgitation, or leaky mitral valve, is a common valve disorder in which the leaflets of the mitral valve fail to seal effectively, resulting in some blood flowing back in the left atrium every time the left ventricle contracts. This condition has been traditionally addressed with open heart surgery.
- We use the latest imaging techniques both to ensure that each patient is a good candidate for the procedure, and to monitor their progress once the device is implanted.
- The Mount Sinai Hospital is studying outcomes for this MitraClip® device compared with outcomes for high risk surgical and medical approaches.
- Unlike traditional mitral valve surgery, which requires opening the chest and temporarily stopping the heart, the MitraClip procedure is performed through a small incision in the groin.
- In our experienced center, the procedure itself can take from one to three hours. Sometimes it can be longer depending on the complexity of the case.

Selecting Candidates for Transcatheter Mitral Valve Repair

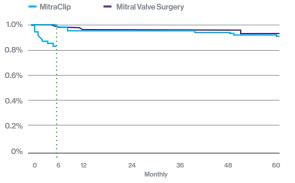
Annapoorna S. Kini, MD

Samin K. Sharma, MD

Mitral valve regurgitation is a common valve disorder that causes blood to leak backward through the mitral valve and into the left atrium as the heart muscle contracts. Mitral regurgitation can originate from degenerative or structural defects due to aging, infection, or congenital anomalies. In contrast, functional mitral regurgitation occurs when coronary artery disease or events such as a heart attack change the size and shape of the heart muscle, preventing the mitral valve from opening and closing properly. In people with moderate to severe mitral regurgitation, the left ventricle works harder to keep up with the body's demand for oxygenated blood. Over time, this dysfunction can lead to enlargement of the left ventricle, weakening of the myocardium and pulmonary hypertension.

Surgery—either to repair or replace a leaky mitral valve—has been the principal therapeutic option for patients with chronic, severe mitral regurgitation that is not controlled with medication. A less invasive option, which involves transcatheter implantation of a device that essentially sutures the valve leaflets and increases their coaptation, is indicated for patients with severe degenerative mitral regurgitation who are at high risk for conventional heart surgery.

EVEREST Trial: Freedom from Death or MV Surgery Beyond 6 Months



The EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II Trial was a randomized study comparing the transcatheter approach using MitraClip®—a tiny cobalt chromium clip that sutures the anterior and posterior mitral valve leaflets—with surgery in patients with moderate to severe mitral regurgitation who are candidates for either procedure.

After five years, the study has demonstrated that MitraClip was associated with a similar risk of death compared with mitral valve surgery after excluding patients who required surgery within six months. However, patients who were treated with the MitraClip had a significantly higher rate of residual mitral regurgitation at five years after the procedure compared with those who had surgery (14 percent versus 3 percent).

Another clinical trial, COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation), is now getting underway in 100 U.S. sites. The study will compare transcatheter mitral valve repair with standard therapy—medications, pacemaker implantation, or other treatments—and standard therapy alone in approximately 610 patients

COAPT Trial Design

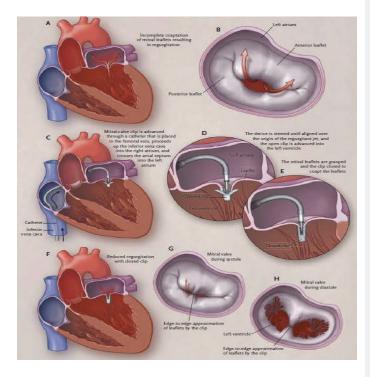
~610 Patients Enrolled at Up to 100 Sites Symptomatic HF treated with maximally tolerated guideline directed medical therapySignificant FMR (≥3+ by Echo Core Lab) Not appropriate for MV surgery as determined by site's Local Heart Team Valve anatomy eligible for MitraClip treatment

Randomize 1:1



Clinical and TTE follow-up: Baseline, treatment, 1-week (phone), 1, 6, 12, 18, 24, 36, 48, 60 months Primary Endpoint: Hospitalization for heart failure within 2 years

Cardiac Catheterization Laboratory



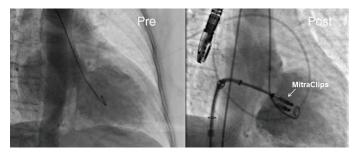
with significant functional mitral regurgitation who are not candidates for cardiac surgery.

At The Mount Sinai Hospital, we employ a variety of sophisticated imaging techniques to select patients who are most likely to benefit from transcatheter mitral valve repair. Three-dimensional transesophageal echocardiography (3D TEE) allows us to assess the location and size of the gap and identify structural abnormalities that could reduce the effectiveness of the transcatheter approach.

Reference:

Randomized comparison of percutaneous repair and surgery for mitral regurgitation: *JAM Coll Cardiology* 2015; 66:2844-54.

Pre and Post MitraClip Implant





PATIENT: Teresa Kukura, 89-year-old female **DIAGNOSIS:** MV insufficiency **TREATMENT:** Transcatheter mitral valve repair using MitraClip®

"Everyone at Mount Sinai Hospital was very good and very caring, especially Dr. Sharma."

"I have spent time at the hospital for heart failure, and it seemed my condition was getting worse. I was having trouble breathing and could hardly walk around the neighborhood, or even around my home. My valves were the problem, but I was afraid to have a major operation to fix them. During one of my follow-up visits to my cardiologist, he told me they were getting too bad, and he said the doctor to see was Dr. Sharma.

"When I met with Dr. Sharma, he immediately set me at ease. He could see the problem and offered a clear solution. Since I was a high-risk case for surgery, he recommended a tiny clip that would stop the leakage in my mitral valve. The procedure went smoothly and I was out in two weeks—by that time, everyone at the hospital didn't realize there had been anything wrong with me! This past Christmas Eve, I was able to walk up two flights of stairs at my family's house and then down those stairs on Christmas Day. I walked even more that day to visit family, and my granddaughter said I was walking better than her 60-year-old father—and I'm almost 90! Everyone at Mount Sinai Hospital was very good and very caring, especially Dr. Sharma. Thank God I have great doctors."