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FACT SHEET

Cedars-Sinai Heart Institute and the Evalve MitraClip: Clinical trial of non-surgical repair for severe mitral valve regurgitation

Cedars-Sinai is the lead enroller in the world in the Everest II Clinical Trial

The Cedars-Sinai Heart Institute is the lead enroller in the world for the Everest II Clinical Trial – a study comparing non-surgical repair for severe mitral valve regurgitation with conventional surgery. In 2005, a team of doctors at the Institute implanted the first Evalve MitraClip™ in California, and was also first on the West Coast to insert two clips during a single procedure. Cedars-Sinai is believed to be the most experienced center in the nation with any form of percutaneous mitral valve repair.

About four million Americans have significant mitral valve regurgitation, with 250,000 new patients diagnosed each year.

The mitral valve consists of two “leaflets” that act as swinging doors between the left atrium and the left ventricle. If the valve fails to close properly, blood flows backward into the atrium (regurgitation), leaving the left ventricle, the heart’s primary pumping chamber, with too little blood. To compensate, the ventricle stretches and overworks. Over time, it undergoes a process called remodeling, becoming enlarged, distorted and weak.

The MitraClip procedure is performed in a cardiac catheterization laboratory with the patient under general anesthesia. A thin, flexible tube (catheter) is inserted through a small incision in the groin and guided through the femoral vein to the affected area of the heart. A smaller catheter holding the clip is slipped through the first catheter. After the clip is attached to the valve leaflets, the catheters are removed. The patient is released from the hospital within a day or two.

While the procedure is complex and challenging, requiring a coordinated effort among echocardiographers, interventional cardiologists, anesthesiologists and other team members, it is also somewhat forgiving. If the clip is not placed ideally on the first attempt, it can be reset. If it does not sufficiently correct the regurgitation, surgical repair or replacement of the valve remains an option.

Results from studies so far show that the MitraClip can provide successful reduction of mitral regurgitation for up to 36 months. Also, studies showed that with resumption of proper valve function, left ventricular remodeling was significantly improved at 12-month follow-up.

Traditional surgery is still the best option in extremely difficult cases or when the annulus, the ring-shaped structure to which the leaflets are attached, needs repair. Cedars-Sinai’s Center for Valvular Intervention, one of the largest heart valve programs in the western United States, combines the expertise of cardiologists and cardiothoracic surgeons to offer a wide range of surgical and non-surgical repair and replacement procedures.