



FRONTIERS IN PATIENT MANAGEMENT

Section Editors

Eduardo Marbán, MD, PhD*

Norman E. Lepor, MD, FACC, FAHA, FSCAI†

*Director, Cedars-Sinai Heart Institute; MarbanE@cshs.org

†Attending cardiologist, Cedars-Sinai Heart Institute;

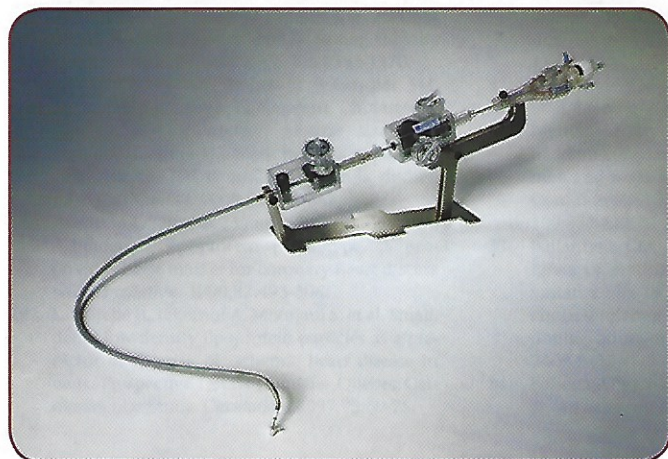
Norman.Lepor@gmail.com

Clinical Conundrum: Mitral Valve Regurgitation in a 76-Year-Old Woman

Norman Lepor, MD, interviewing Saibal Kar, MD, Director of Interventional Cardiac Research at the Cedars-Sinai Heart Institute.

NL: *One of your more interesting cases was a 76-year-old woman with a remote history of myocardial infarction, known coronary artery disease, and diabetes. The patient presented to Cedars-Sinai Heart Institute with history of recurrent episodes of pulmonary edema. Update me on her treatment.*

SK: On further evaluation, she was diagnosed with non-obstructive coronary artery disease and severe functional mitral regurgitation (MR) secondary to papillary muscle displacement. She was found to be a suitable candidate to participate in a clinical trial and she was enrolled in the EVEREST II (Endovascular Valve Edge-to-Edge REpair



The MitraClip.

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Welcome

On behalf of all of us at the Cedars-Sinai Heart Institute, it is my pleasure to present "Frontiers in Patient Management," a quarterly update on the latest developments in treating complex cardiac diseases.



The cardiac tradition at Cedars-Sinai goes back to the time of Prinzmetal, Swan, and Ganz, and continues through the present day. Every issue of *Reviews in Cardiovascular Medicine* will contain a concise Q & A with a Cedars-Sinai Heart Institute physician about treating an intricate condition, instituting a new surgical approach, or detailing the most recent advances that could help all of us in our practices.

I welcome your suggestions and comments and look forward to hearing from you as to other ways in which the Cedars-Sinai Heart Institute might be helpful to your practice.

Eduardo Marbán, MD, PhD

STudy), designed to evaluate the safety and efficacy of percutaneous mitral valve repair with the MitraClip® system in patients with Grade 3-4 MR compared to conventional mitral valve surgery. She underwent successful mitral valve repair using a single MitraClip device, and was discharged home in 24 hours. She has been followed for more than three years, and on follow-up echocardiography has only mild to moderate MR, with no further episodes of acute heart failure.

NL: *This case example appears to demonstrate the potential for a novel percutaneous treatment for MR, obviating the need for open heart mitral valve repair/replacement, which in her case based on her comorbidities and age would be of significant risk.*

SK: Data from the High Risk Registry of the EVEREST II clinical trial recently presented in Barcelona at the annual European Association of Percutaneous Cardiovascular Interventions indicate that the MitraClip procedure may be suitable in selected patients with MR who were at high risk for mitral valve surgery. In the future, this percutaneous therapy may be particularly suitable for high surgical risk or for younger patients with MR who are seeking a less invasive alternative. As the science of

percutaneous mitral valve repair advances, we expect to have other devices that will be evaluated here at the Cedars-Sinai Heart Institute.

NL: *So let's talk about percutaneous repairs.*

SK: We started our first EVEREST II cases in October 2005. The Cedars-Sinai Heart Institute was the first heart center in California to offer this investigational procedure. Since then, we have become one of the leading centers of percutaneous mitral valve repair in the world. We have the largest number of patients randomized in the EVEREST II study at 32 patients, with 22 patients undergoing the percutaneous valve repair with the MitraClip device, with an implant success rate over 90 percent. In all, we have enrolled over 50 patients in EVEREST II. Currently, we are actively enrolling patients in the REALISM continuous access registry. Both low and high surgical risk patients with significant MR are being treated with the MitraClip procedure in this registry.

NL: *So in terms of patients who come in, let's say, New York Heart Association (NYHA) class III or IV, what kind of clinical improvements are you seeing?*

SK: We have seen improvement in functional class and a reduction in the incidence of hospitalizations for congestive heart failure. In recent data from the High Risk Registry that I presented at the American College of Cardiology Scientific Session, we demonstrated a reduction in NYHA class III and IV from 91 percent at presentation to only 26 percent at one-year post MitraClip therapy.

NL: *Are all patients with severe mitral insufficiency good candidates for this procedure?*

On Call: Saibal Kar, MD

An interventional cardiologist with a special expertise in valvuloplasty and congenital heart disease, Dr. Kar's research interests are focused on coronary restenosis, device development, and the advancement of percutaneous techniques in the treatment of congenital and valvular heart diseases.



Dr. Kar is leading the Heart Institute's participation in 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.

"As the science of percutaneous mitral valve repair advances, we expect to have other devices that will be evaluated here at the Cedars-Sinai Heart Institute."

Saibal Kar, MD

SK: No, in the clinical trial there are some important inclusion/exclusion criteria; only patients who have grade 3 to grade 4 MR originating from the central portion of the mitral valve may be enrolled. It may be either degenerative, such as a flail or prolapse of the mitral valve, or functional MR where the actual leaflets are normal but because of distortion of the ventricle secondary to cardiomyopathy or ischemic heart disease, there is malcoaptation of the leaflets leading to MR. This technology could be applicable to both categories of mitral valve disease.

Controversies and Advances in the Treatment of Cardiovascular Disease

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