

Effect of MitraClip therapy on mitral regurgitation

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The percutaneous catheter-based treatment of mitral regurgitation with the MitraClip system improves symptoms and cardiac function at one-year, according to results of a prospective observational study presented here today at ESC Congress 2012.

ACCESS-EUROPE (ACCESS-EU) was a multicentre study of the MitraClip system in a commercial setting in 567 patients enrolled at 14 European sites, the largest group of patients evaluated to date. The results were presented by the study's co-principal investigator Professor Wolfgang Schillinger of the Universitätsmedizin Göttingen in Germany.

"ACCESS-EU provides further confirmation of clinical and functional benefits of the MitraClip system in a real-world setting at one year," said Professor Schillinger. "The results are consistent with those from controlled clinical trials, although patients in ACCESS-EU were older and sicker."

Patients enrolled in ACCESS-EU were elderly (mean age 74 ± 10 years) with significant baseline co-morbidities, including [coronary artery disease](#) in 63% and moderate to severe [renal disease](#) in 42%. At baseline, 85% were in NYHA Functional Class III/IV, and 53% had left ventricular [ejection fraction](#) less than 40%. Seventy-seven percent had functional mitral regurgitation, and many patients were considered at high risk for [mitral valve surgery](#), with an average logistic EuroSCORE of $23 \pm 18\%$.

At one year 82% of patients treated with the MitraClip system were free from death, 79% free from mitral regurgitation grade above 2+, and 94% free from mitral valve surgery. Following treatment, the majority of patients showed significant clinical improvements, with 72% now classified in NYHA Class I/II. In addition, results reflected an improved [functional capacity](#), with a median improvement of 60.5 meters for six-minute walk distance. Improvements in quality of life were also recorded, as shown in a median improvement of 14.0 points between baseline and one-year scores on the Minnesota Living with [Heart Failure](#) Questionnaire.

"Where the benefits of surgery do not outweigh the surgical risks, the MitraClip treatment is an important alternative for patients with mitral regurgitation," said Professor Schillinger.

As background to the study he added that mitral valve regurgitation is the most commonly diagnosed type of valvular insufficiency, affecting more than one in ten people over the age of 75 – approximately 4 million people in Europe alone. Significant mitral regurgitation is a debilitating condition in which the heart's ability to function continues to deteriorate over time and may lead to heart failure, atrial fibrillation, stroke, or death. The condition has traditionally been managed with medications, which can temporarily relieve symptoms but do not address the underlying cause of the condition, or with open-heart surgery. Approximately 50% of patients are considered high risk for complications from surgery because of advanced age, significant ventricular dysfunction, or other serious co-morbidities and are denied surgery.

The MitraClip system includes a [catheter](#)-based device that is delivered to the heart through the femoral vein. The system is designed to reduce significant [mitral regurgitation](#) by clipping together the leaflets of the mitral valve.

Provided by European Society of Cardiology

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