

Mitra Clip: Looking at its chance in developing country

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Looking at developed countries data on valvular heart diseases, mitral regurgitation is one of the most commonly encountered valvular lesions. Moderate to severe regurgitation present in up to 30% of patients with various clinical subsets. Mitral regurgitation severity has been positively correlated with the subsequent development of heart failure and death.¹⁻⁴

The 2008 ACC/AHA guidelines describe three types of MV operations: (i) MV repair; (ii) MV replacement with chordal preservation; and (iii) MV replacement with removal of the mitral apparatus. The ACC/AHA guidelines support MV surgery for patients with severe (3– 4+) MR who are symptomatic with preserved LV size and function, asymptomatic with LV dysfunction or increased LV size, who have recent onset atrial fibrillation or evidence of pulmonary hypertension, or in symptomatic patients with severe LV dysfunction (LVEF \leq 30%) despite optimal medical therapy.

Currently, a new percutaneous approach for treating mitral regurgitation (so called MitraClip) which involves mechanical edge-to-edge coaptation of the mitral leaflets has been developed. The device mechanism is analogous to the surgical Alfieri technique. MitraClip (Abbott Vascular, Abbott Park, Illinois, USA; formerly manufactured by Evalve Inc, Menlo Park, California, USA) has been approved by

FDA last year.⁵ Since 2008 almost 4000 MitraClip have been implanted all over the world (Figure 1).⁶ Overall, the procedure has proven to be safe with exceedingly low rates of fatal or life-threatening complications. Additionally, significant improvements in functional capacity and quality of life have been reported following MitraClip implantation. However, apart from these encouraging results, open questions remain to be addressed, particularly about long term durability and clinical efficacy, and the selection of the most appropriate candidates for MitraClip implantation. As the experience with this procedure continues to expand, larger studies are expected that will help to further define the role of the MitraClip procedure among established therapies.⁶

Patient selection is utmost important to gain procedural success. Two main criteria of Endovascular Valve Edge-to-Edge Repair Study (EVEREST) for patient selection are clinical and anatomical criteria. Clinical criteria comprise of moderate-to-severe (3+) and severe (4+) mitral regurgitation, meeting class I indications for intervention (MVR or mitral valve replacement) by the ACC/AHA or ESC guidelines, mitral regurgitation aetiology limited to degenerative or functional, non-rheumatic or -endocarditic origin, and high surgical risk by EuroSCORE or STS scores. Anatomical criteria comprise of mitral regurgitation originating from the central 2/3 of the valve, mitral orifice area \geq 4 cm², meeting criteria for degenerative mitral regurgitation (i.e. flail gap $<$ 10 mm, flail width $<$ 15 mm), meeting criteria for functional mitral regurgitation (i.e. coaptation depth \leq 11 mm, coaptation length \geq 2 mm).^{7,8}

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Recently published paper of a 4-year follow-up shows no differences in the primary end point between the MitraClip procedure and surgery. The clip group had significantly more follow-up surgeries for residual mitral regurgitation.⁹The study shows the comparison of the procedures in a surgical population favors surgery as compare to clip, however it provides useful information about the long-term durability of the device. Treatment with the MitraClip was associated with mortality rates similar to surgery at one year, but the degree of MR reduction was less with percutaneous repair. At one year, approximately 20% of MitraClip patients required mitral-valve surgery to treat moderate or severe MR compared with only 2.2% of patients treated with surgery.

Reynolds et al.¹⁰ analyze 12-month data cost-effectiveness on the MitraClip from EVEREST II and estimated indexed admission costs, costs for follow-up hospitalizations, and resource-based costs including rehabilitative and long-term care services. These were compared with expenses associated with conventional mitral valve surgery. Researchers used the assumed price of the MitraClip (18,000 USD) in the United States, where the system is still not commercially available, and the European sales price of about 26,200 USD. At the U.S. price, use of the system reduced overall costs by 2,200 USD per patient, indicating that this method is economically dominant. However, at the European price, overall costs were 6,192 USD higher than

conventional surgery with a cost >400,000 USD per quality-adjusted life year (QALY) gained. In Indonesia, MitraClip price is even higher (up to 33,000 USD) while the surgical cost is lower compare to Europe. This situations make clip procedure far more costly.

In some developing countries, such as Indonesia, where universal coverage of health insurance conducted and manage by government only best proven and affordable medical technologies will allowed to be implemented. In other hand surgical valves procedure considered to be at its lowest cost making clip only cost-effective when surgical repair is contraindicated. Furthermore, in developing countries significant number of mitral regurgitation is related to rheumatic heart disease. Unfortunately, currently MitraClip is contraindicated for use in Rheumatic mitral disease.⁵

As a conclusion we can cite the EVEREST II author Dr. Mauri's saying⁹: "In a patient where surgical risk is very high, it may make sense to avoid the up-front risk if a good result can be achieved with a less invasive procedure. In good surgical candidates, where more complete treatment can be achieved with surgery with minimal risk, up-front surgery makes more sense." In our setting at developing country concerning of all mentioned studies results, MitraClip should be limited for whom surgery is not desired due to its very high risk. Nowadays, surgical repair must still be the procedure of choice for mitral regurgitation treatment.

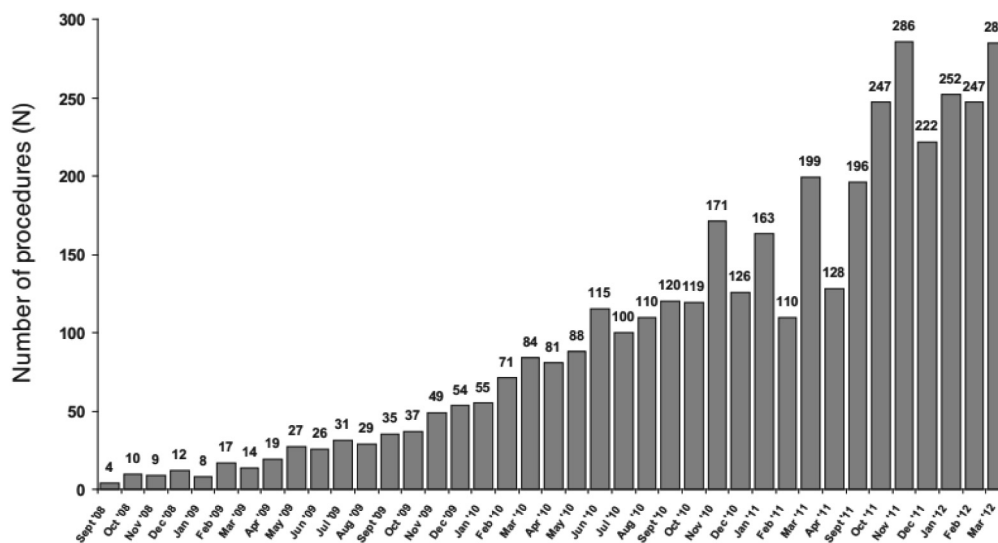


Figure 1. Number of MitraClip procedures in Europe after CE mark approval 2008. Note that between April and September 2011, MitraClip implantations were interrupted as a result of a technical defect in the delivery system.⁶

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