MitraClip in Patients With Severe Mitral Regurgitation and Severe Left Ventricular Systolic Dysfunction

To the Editor:

Kaneko et al have reported the safety and efficacy of MitraClip® (Abbott, Menlo Park, CA, USA) in treating patients with severe mitral regurgitation (MR) and left ventricular ejection fraction (LVEF) <30% in Germany. However, there is a unique limitation to therapeutic attempts using MitraClip in patients with LVEF <30% in Japan, because those patients were excluded in the pivotal domestic study. Such restriction is not apparent in other countries, nor in Taiwan, where we performed our first MitraClip procedure on May 1, 2016. We have demonstrated similar safety and efficacy to Western countries. With regard to this specific issue, we retrospectively reviewed our MitraClip cohort. A total of 10 of 61 consecutive cases (16%) had baseline LVEF <30%, 9 of whom had functional MR. All the patients with LVEF <30% experienced significant improvements in New York Heart functional class, 6-minute walk distance, and rehospitalization rate for heart failure. The LVEF in our cohort wasn’t related to mortality (odds ratio and 95% confidence interval: 1.02, 0.94–1.10).

Compared with the findings from Kaneko et al, our preliminary data also encouraged use of the MitraClip in selected patients with severe MR and poor LV systolic function for whom there are limited therapeutic options. Although heart transplantation would be the destination therapy, the lack of donors remains a major barrier even when LV assist devices can be used as a bridge therapy. MitraClip has been purposed as a treatment in patients with medical refractory functional MR in the European guideline. Evidence supports MitraClip as an effective procedure in bridging or even remitting heart transplantation. From the national reimbursement perspective, every cost should be weighed to improve public health as well as waiving the disease impact. The utilization of therapy across the national population is highly correlated with the national reimbursement policy. Not surprisingly, higher national economic index and specific reimbursement systems are associated with higher utilization of this therapy. The financial barrier of every individual to access the therapy should be evaluated by a health-economy approach. Compared with conservative medical treatment alone, the average treatment effect of MitraClip in subjects with severe MR was decreasing 9.5% the probability of dying in 12 months, decreasing 50% the probability of rehospitalization for heart failure at 12 months, and 3.01 incremental quality-adjusted life years. The incremental cost-effectiveness ratio is €7,908, which is taken as cost-effective treatment in Europe. In Taiwan, the MitraClip procedure isn’t reimbursed yet, and underutilization is inevitable. We therefore need more evidence to negotiate with policy makers and general practitioners. Unlike in the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (COAPT) trial, the lower limit of LVEF is 15% in the MITRA-FR study. The results of both trials will be announced soon in the near future. Until then, we may be able to elucidate the clinical impact of MitraClip in this group of patients.

References


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