僧帽弁閉鎖不全症に対するMitraClipの有望なデータ

ACCESS-EU:実地臨床を対象としたヨーロッパのスタディにおいてMitraClip治療は治療後1年の有意な有益性を示した

ACCESS-EU: MitraClip therapy demonstrates significant benefits one year following treatment in real-world European study

僧帽弁閉鎖不全に対するMitraClipシステムを用いた経皮的カテーテル治療は1年後の症状および心機能を改善したとの前向き観察研究の結果が2012年European Society of Cardiology学会で発表された。ACCESS-EUROPE（ACCESS-EU）は、ヨーロッパの14施設で登録された567人の患者に対するMitraClipシステムの多施設スタディであり、これまでに評価された中で最大規模のものである。患者は、冠動脈疾患（63%）、中等度から重度の腎疾患（42%）、NYHA心機能分類クラスIII/IV（85%）、および左室駆出率<40%（53%）などの基礎疾患を有する高齢者（平均年齢74±10歳）であった。77%が機能性僧帽弁閉鎖不全を有し、平均ロジスティックEuroSCOREは23±18%であり、多くの患者は僧帽弁手術がハイリスクと考えられた。1年後に、MitraClipシステムで治療された患者の82%が生存しており、79%は僧帽弁閉鎖不全が2度以下であり、94%は僧帽弁手術を受けていなかった。多くの患者が臨床的に改善を認め（現在72%がNYHAクラスI/IIIに分類された）、機能的能力が改善し（6分間歩行距離の改善の中央値60.5m）、QOLが改善した（Minnesota Living with Heart Failure Questionnaireで14.0点の改善）。

Full Text

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 at ESC Congress 2012.

ACCESS-EUROPE (ACCESS-EU) was a multicenter 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 ±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. 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.

Conference News