経皮的僧帽弁修復術の可能性

プレリミナリーなEVOLUTIONスタディの結果、経皮的僧帽弁修復術は一部の選択された僧帽弁閉鎖不全患者に実用的となる可能性がある

Preliminary EVOLUTION study results suggest that percutaneous mitral valve repair may become practical for selected patients with mitral regurgitation

スタディの結果、経皮的僧帽弁修復術の改良により一部の選択された僧帽弁閉鎖不全患者に有益で安全となる可能性があることが示唆された、とESCで発表された。EuroHeart Surveyにより、僧帽弁閉鎖不全は多く認められるが（自己弁疾患症例の30%）、患者の50%しか外科的形成術を施行されていないことが確認された。今回の研究は、2つの経皮的アプローチ法（edge-to-edge techniqueおよび僧帽弁輪形成術）が更なる評価に値することを示した。開発中のデバイスは冠動脈洞の遠位部および近位部に固定部位がありこの固定部分の間にブリッジを有する。弁輪形成術の方が冠動脈洞のカテーテル挿入のみでよいため、簡単である。EVOLUTIONのプレリミナリーな結果（患者60人）によると、施行可能率は高く（90%）安全性も優れていた。約80%の患者が90日後の時点で合併症を有さなかった。非常にプレリミナリーな結果からは、逆流の程度が軽減したことが示唆された。

Full Text

Preliminary results from studies such as EVOLUTION suggest that percutaneous mitral repair may be beneficial and safe for selected patients with mitral regurgitation who are not currently being treated surgically, according to a presentation at the annual meeting of the European Society of Cardiology.

Based on EuroHeart Survey results, mitral regurgitation represents the second most important native valve disease in Europe (30 percent). The same survey suggests that mitral valve repair is performed only 50 percent of the time. This shortfall is mostly due to a lack of expertise in performing the procedure. Finally, survey data highlight the fact that half of the patients, despite the presence of severe symptoms and severe mitral regurgitation, are not considered for surgery by their physicians. Thus, there is a need for treatment other than surgery for high-risk patients or those denied surgery.

Percutaneous mitral valve repair was introduced only a few years ago. There are two different approaches to percutaneous mitral valve repair.

The first approach is the edge-to-edge technique, which creates a double mitral valve orifice replicating the surgical intervention pioneered by Professor Alfieri. This technique is very demanding because it requires trans-septal catheterization and sophisticated collaboration between the echocardiographist and interventionist to catch the valve at the appropriate moment and location.

Preliminary clinical results obtained in over 100 patients suggest that in expert hands the feasibility of the technique is high (80-90 percent) and the degree of mitral regurgitation can be reduced to mild in two thirds of cases. In addition, the risk is low, once again, in experienced centers. In patients where the procedure was successful, two thirds remained event free after three years. Thus these data, even if only preliminary, are encouraging.

The second possible approach is mitral annuloplasty, which is achieved by introducing a constraining device in the coronary sinus located in the vicinity of the mitral annulus. The rationale here is that ring annuloplasty is almost always combined with other procedures during surgical interventions on the mitral valve. More than ten devices have been designed and three are currently being studied. They share common technical features: distal fixation and proximal fixation in the coronary sinus and a bridge between the two fixating elements.

Annuloplasty is easier because it only requires catheterization of the coronary sinus. Preliminary results from the EVOLUTION study in 60 patients show high feasibility (90 percent) and good safety profiles: Almost 80 percent of patients experienced no complications within 90 days. Very preliminary efficacy data suggest a reduction in the degree of regurgitation.

Clearly at the present stage these two approaches do not yet reach the standard of the multiple surgical techniques that make the success of surgical mitral valve repair.

The annuloplasty technique could be potentially used in patients with functional mitral regurgitation, while the edge-to-edge technique could be used in selected patients with degenerative mitral regurgitation. The potential clinical indications of the new percutaneous techniques are represented by the vast group of patients with contraindications or judged to be at very high risk for surgery.

Many devices are currently being studied or are at the experimental stage: suture-based direct annuloplasty, percutaneous mitral valve replacement, or transpericardial left ventricular remodeling.

Further research should be carefully evaluated in comparison with surgery and standard contemporary medical treatment including cardiac resynchronization. Trials such as EVEREST II, EVOLUTION II, and AMADEUS are underway.

Development of such new techniques will require close collaboration between engineers, interventionalists, imaging specialists, and surgeons.