

2年後の時点で経皮的僧帽弁修復術の有益性は認められなかった

MITRA-FR試験:心不全患者における二次性僧帽弁閉鎖不全症は2年後の転帰を改善しない

MITRA-FR: Reducing secondary mitral regurgitation in heart failure does not improve two-year outcomes

心不全患者における二次性僧帽弁閉鎖不全症に対する経皮的修復術は、標準的な医療と比較し、2年後の時点で死亡および入院を減少させない、との MITRA-FR 試験の結果が ESC Congress 2019 で発表され、*European Journal of Heart Failure* に掲載された。総死亡および心不全による予定外入院は、弁修復術を施行された患者の63.8% および弁修復術を施行されなかった患者の67.1% に発現し、2群間で有意差はなかった。これらの転帰を列々に解析しても、有意差は認められなかった。

Full Text

Percutaneous reduction of secondary mitral regurgitation in patients with heart failure does not lower death and hospitalization at two years compared to standard medical care, according to late breaking results from the MITRA-FR study presented in a Hot Line Session at ESC Congress 2019 together with the World Congress of Cardiology and published in the *European Journal of Heart Failure*.

The benefits of percutaneous correction of secondary mitral regurgitation in patients with heart failure is controversial. One-year results of MITRA-FR, first reported at ESC Congress 2018 and published in the *New England Journal of Medicine*, showed no significant impact of mitral valve repair on death and heart failure hospitalization compared to standard medical treatment. In contrast, the COAPT study found that valve repair significantly reduced heart failure rehospitalization and death after two years of follow-up.

"Many hypotheses have been suggested to explain the different outcomes between the two randomized trials," said MITRA-FR principal investigator Professor Jean-Francois Obadia of Civil Hospices of Lyon, France. "One theory is the longer duration of COAPT. We therefore conducted a two-year follow-up of patients in MITRA-FR."

The two-year results show that the combined outcome of all-cause death and unplanned hospitalization for heart failure occurred in 63.8% of patients who underwent valve repair and 67.1% in those who did not, with no significant difference between groups. There were no significant differences between groups when each outcome was analyzed separately. Rates of all-cause mortality were 34.9% and 34.2% in the intervention and control groups, respectively. Rates of unplanned hospitalization for heart failure were 55.9% and 61.8% in the intervention and control groups, respectively.

"This analysis confirms the absence of a significant difference in the rate of the composite outcome of death from any cause or unplanned hospitalization for heart failure in symptomatic patients with severe secondary mitral regurgitation treated by percutaneous mitral valve repair plus medical treatment as compared with those receiving medical treatment alone," said Prof. Obadia. "Percutaneous repair remained safe – there was a very small number of prespecified serious adverse events."

An exploratory analysis of events occurring between 12 and 24 months suggested a lower rate of first hospitalization for heart failure in the intervention group. This was consistent with a divergence in the curves of recurrent hospitalizations for heart failure for each group.

"This repeat event analysis was used as the main endpoint in the COAPT trial and tends to amplify differences compared to the analysis of time to first event, which was the main endpoint in MITRA-FR," said Prof Obadia. "As for any exploratory analysis of secondary endpoints, the interpretation of such an isolated finding should be viewed cautiously and only considered hypothesis generating."

Regarding the differing results between the two trials, Prof Obadia said: "In our view, one of the main reasons is patient selection. Differences in inclusion criteria led to more severe mitral regurgitation, less pronounced left ventricular remodeling, lower pulmonary pressure, and better right ventricular function in COAPT compared to MITRA-FR. In addition, the run-in period assessed by a central eligibility committee was likely to result in more optimized guideline-directed medical therapy in COAPT than in MITRA-FR. However, this set-up may be difficult to implement in everyday practice which rarely achieves optimized therapy."

Prof Obadia said that medical treatment should remain the first line of treatment for heart failure patients with secondary mitral regurgitation. "MITRA-FR and COAPT provide answers but also more questions," he said. "The definition of secondary mitral regurgitation has to be revisited taking into account the dynamic function of the heart. More studies are needed to clarify understanding of this complex disease."

This was an academic study supported by the French Ministry of Health.

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