

## 軽度心不全においてアルドステロン拮抗薬は多大な有益性を示した

EMPHASIS-HF: エブレレノン は軽度症状を有する収縮期心不全患者の生存率を有意に改善する

EMPHASIS-HF: Eplerenone significantly improves survival in systolic heart failure patients with mild symptoms

収縮期心不全及び軽度症状を有する患者にアルドステロン拮抗薬エブレレノンを投与したところ、プラセボを投与された患者と比較し死亡および入院のリスクが37%低下したとのレイトブレイキング臨床試験の結果が2010年AHA学会で発表され、New England Journal of Medicine オンライン版に掲載された。軽症心不全患者にエブレレノンを投与した際の入院および生存率に関するスタディ（Eplerenone in Mild Patients Hospitalization And Survival Study in Heart Failure: EMPHASIS-HF）において、軽症心不全患者2,737人（平均年齢69歳、男性78%、白人82%）を、標準的な心不全治療に加えエブレレノン（25～50mg）またはプラセボを投与する群に無作為に割り付けた。対象となった患者のほとんどが心不全を数年間（平均5年間近く）患っていた。平均追跡期間は21ヵ月であった。3分の2の患者が動脈硬化症を有していた。エブレレノンを投与された患者のうち死亡または入院したのは249人であったのに対しプラセボ群では356人であった—統計学的に有意な差であった。エブレレノンはまた、プラセボと比較し、総死亡率と入院を3分の1以上減少させた。心不全死および入院減少におけるエブレレノンの有益性が圧倒的であったため、被検者の組み入れは予定された2010年5月よりも前に終了された。

### Full Text

Patients with systolic heart failure and mild symptoms given eplerenone had a 37 percent reduced combined risk of death and hospitalization than patients who received a placebo, according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2010.

In the Eplerenone in Mild Patients Hospitalization And Survival Study in Heart Failure (EMPHASIS-HF), 2,737 patients with mild heart failure were randomized to receive eplerenone (25-50 milligrams) or placebo, as well as standard heart failure therapy. Among patients taking eplerenone, 249 deaths or hospitalizations occurred, compared to 356 in the placebo group - a statistically significant difference.

Eplerenone is an aldosterone antagonist. These medications improve the remodeling of the failing heart by blocking the action of aldosterone, a naturally occurring hormone that was initially found to help maintain appropriate amounts of salt and water in the body. However, aldosterone can also have a number of direct harmful effects on the cardiovascular system. Aldosterone concentrations are abnormally high in people with heart failure.

Under current guidelines, aldosterone antagonists, including eplerenone and the older spironolactone, are recommended only for patients with moderate to severe heart failure and reduced heart function or for patients with heart failure following a recent heart attack. Until this study, their effects in patients with mild disease were unclear.

"This treatment is certainly going to change the guidelines for mild heart failure," said Faiez Zannad, M.D., Ph.D., the study's lead author and professor of therapeutics and director of the Clinical Investigation Center at the Nancy University Hospital Center in Nancy, France. "Now patients with all kinds of severity of systolic heart failure, whether it is post-myocardial infarction, with mild or severe symptoms, are potentially eligible for some kind of aldosterone blockade, and, certainly, for eplerenone."

In the study, eplerenone also decreased the rate of a number of other complications. It's also important that eplerenone reduced the number of deaths due to any cause and hospitalizations for any reason, by one-third compared to placebo, Zannad said.

"What was impressive was that we also hit all the secondary endpoints, including mortality from all causes," he said.

Study participants' average age was 69 years, 78 percent were male, and 82 percent were white. Most had suffered from heart failure for several years, with an average duration of nearly five years. Two-thirds had a history of atherosclerosis.

Patient enrollment began in March 2006 at 270 centers in 29 countries. Average follow-up was 21 months. Enrollment ended before the scheduled end of the study, in May 2010, because eplerenone showed an overwhelming benefit in reducing heart-failure deaths and hospitalizations.

Co-authors are John J.V. McMurray, M.D.; Henry Krum, Ph.D.; Dirk J. van Veldhuisen, M.D., Ph.D.; Karl Swedberg, M.D., Ph.D.; Harry Shi, M.S.; John Vincent, M.B., Ph.D.; Stuart J Pocock, Ph.D.; and Bertram Pitt, M.D. Author disclosures are on the abstract. Pfizer, Inc. funded the study.

## Cardiology特集

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