

EMPHASIS HF: Study shows eplerenone to reduce atrial fibrillation

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The aldosterone antagonist eplerenone (Inspra, Pfizer) significantly reduced the development of new onset atrial fibrillation and flutter (AFF) in patients with class 2 heart failure, concludes a sub-analysis of the EMPHASIS-HF trial, presented at the Heart Failure Congress 2011, organized by the Heart Failure Association of the European Society of Cardiology (ESC). The analysis, presented in Late Breaking Session 1, furthermore showed that the beneficial effects of eplerenone in reducing major CV events were similar in patients with and without AFF at the start of the study.

The Eplerenone in Mild [Patients](#) Hospitalization And Survival Study in Heart Failure study (EMPHASIS-HF) - presented first at the [American Heart Association](#) Meeting in 2010 and published simultaneously on-line in the [New England Journal of Medicine](#)¹ - showed that eplerenone in comparison to placebo produced a 37% reduction in the primary end point of the composite of death from cardiovascular causes or hospitalization for heart failure, a 24% reduction in cardiovascular death, and a 42% reduction in hospitalization for heart failure for patients with class 2 heart failure.

While previous studies had shown that aldosterone blockade delivered significant benefits in patients with class 3-4 heart failure (The RALES study) or in post MI patients with left ventricular dysfunction (The EPHEMUS study), what had been unknown until EMPHASIS-HF was whether the benefits could be extended to the far larger population of patients with mild heart failure (class 1-2). The RALES study used spironolactone, while the EPHEMUS study used the newer, more selective eplerenone.

The EMPHASIS-HF trial - which involved 2737 patients from 278 centres with NYHA class 2 heart failure and ejection fractions of no more than 35% - set out to address the question of whether eplerenone was effective in patients with mild heart failure. Patients were randomized to receive

eplerenone (25mg once daily, up titrated to 50 mg daily if required) or placebo in addition to recommended therapy. The trial was stopped after 21 months due to the significant benefits in the eplerenone group. In the current presentation, the investigators have re-analyzed the original data to explore the development of new onset atrial [fibrillation](#) or flutter (AFF) in patients who had no history of AFF at baseline. The study also set out to determine whether eplerenone worked as well in patients who already had AFF at baseline as those who did not.

Results at an average follow-up of two years showed that new onset AFF occurred in 25/911 (2.7%) of the patients in the group randomized to eplerenone versus 40/883 (4.5%) in the group randomized to placebo (hazard ratio (HR) 0.58 95% CI 0.35-0.96, p=0.034). The analysis also showed that the risk of cardiovascular (CV) death or [hospital](#) admission for worsening heart failure (the primary endpoint of the original study) was not significantly different in patients with and without AFF at baseline (P=0.33).

Commenting on the results study presenter Karl Swedberg, from the University of Gothenburg, Sweden, said, "This latest analysis makes an even stronger case for the use of eplerenone in patients with mild heart failure because in addition to reducing mortality it also reduces the incidence of AF. AF is a condition which both increases morbidity and complicates the care of patients with heart failure."

Use of eplerenone in patients with mild heart failure, he added, will be considered for inclusion in the ESC guidelines when they are updated at the end of 2011.

Eplerenone

Eplerenone, which has been called a "cleaner, safer" version of spironolactone, is approved for

hypertension and for use in addition to optimal medical therapy early after acute MI in patients with congestive heart failure (CHF), on the basis of the Eplerenone Post-AMI [Heart Failure Efficacy and Survival Study \(EPHESUS\)](#) study. It has, however, yet to be approved for patients with mild HF.

While eplerenone is available generically in the US, the drug is still under patent in Europe and Canada.

More information: Zannad F, McMurray JJV, Krum H, et al. Eplerenone in patients with systolic heart failure and mild symptoms. *New Eng J Med* 2011; 364:11-21. Available at: www.nejm.org

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