Study finds new drug may hold promise for hospitalized heart failure patients

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Hospitalized heart failure patients given an investigational drug had improved symptoms and other clinical benefits including fewer deaths, than those given standard of care plus a placebo, according to late-breaking clinical trial research presented at the American Heart Association's Scientific Sessions 2012.

The full manuscript for RELAXin in Acute Heart Failure (RELAX-AHF) Trial, is published in *Lancet*.

Compared to those given a placebo, patients given serelaxin experienced a significant reduction in heart failure symptoms including a 20 percent reduction in a measure of shortness of breath. Additionally, patients receiving serelaxin:

- experienced over 45 percent fewer episodes of worsening heart failure symptoms during hospitalization;
- Spent almost half a day less time in the intensive care units;
- Had almost a full day shorter hospital stay.

There were 37 percent fewer deaths from any cause at six months among the serelaxin group, including significantly fewer cardiovascular-related deaths (7.3 percent in serelaxin patients versus 11.3 percent with placebo).

Serelaxin did not reduce rehospitalizations among heart failure patients.

Serelaxin is a peptide hormone or a chain of molecules that relax blood vessels and improve blood flow to organs, potentially protecting them from acute injury.

"Current therapy for acute heart failure has remained unchanged for decades," said John R. Teerlink, M.D., co-principal investigator of the trial and professor of medicine at the University of California in San Francisco. "Acute heart failure is a major public health problem and an expensive one due to repeat hospitalizations since patients' worsening symptoms keep coming back."

"Our findings suggest serelaxin holds promise as the first evidence-based therapy for acute heart failure to substantially improve patients' symptoms and clinical outcomes, including death," said Teerlink, who is director of the heart failure program at the San Francisco Veterans Affairs Medical Center.

The multicenter phase III, conducted October 2009-February 2012, included 1,161 patients at 96 sites in 11 countries.

Researchers randomly assigned patients to receive 30 mcg/kg per day of serelaxin or a placebo through a 48-hour intravenous infusion. Patients received the medication within 16 hours of hospitalization for heart failure-related symptoms of shortness of breath with evidence of decline in kidney function. They also received standard therapy with diuretics to help flush fluid or congestion from the body and reduce swelling.

Nearly two-thirds of the patients were men, most were Caucasian and average age was 72 years. Most patients had multiple diseases: 87 percent had high blood pressure; 53 percent high cholesterol; 52 percent ischemic heart disease; 52 percent atrial fibrillation; 48 percent diabetes; and 14 percent had suffered a stroke.

"We are pleased with the results," said Marco Metra, M.D., co-principal investigator of the trial, professor of cardiology at the University of Brescia and head of the Cardiology Institute of the Civil Hospital of Brescia, Italy. "While we did not see a reduction in rehospitalizations in this trial, the significant reductions in worsening of heart failure and death are encouraging signals that we can change the course of this devastating disease."

Provided by American Heart Association