新薬は心不全治療において有望である（LBCT-19921）

RELAX-AHF-1:Serelaxinは急性心不全で入院した患者の治療において期待できそうである

RELAX-AHF-1: Serelaxin may hold promise for patients hospitalized for acute heart failure

入院中の心不全患者に治験薬serelaxinを投与したことにより症状が改善し、死亡が減少するなどの有益性が認められたとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表され*Lancet*に掲載された。この多施設第3相RELAXin in Acute Heart Failure（RELAX-AHF）トライアルでは、心不全患者1,161人を1日30mcg/kgのserelaxinまたはプラセボを48時間静脈内投与される群に無作為に割り付けた。患者は、心不全症状による呼吸困難と腎機能低下所見を伴い入院し、入院後16時間以内に薬物を投与された。また、利尿薬を用いた標準治療も受けた。Serelaxin群においては呼吸困難指標の20%低下や入院中の心不全症状増悪エピソードの45%を超える減少などの、心不全症状の有意な軽減が認められた。集中治療室滞在期間はserelaxin群でほぼ半日短く、入院期間はほぼ1日短かった。Serelaxinは6か月時点の心血管死亡率（HR 0.62, 95%CI 0.40-0.95; *P* =0.03）および総死亡率（HR 0.62, 95%CI 0.40-0.95; *P* =0.03）を低下させた。Serelaxinは再入院は減少させなかった。

Full Text

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 dyspnea. 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

Serelaxin reduced cardiovascular mortality (HR 0.62, 95%CI 0.40-0.95; *P* =0.03) and all-cause mortality (HR 0.63, 95% CI 0.43-0.93; *P* =0.02) at six months. Serelaxin did not reduce rehospitalizations for heart failure or renal failure.

"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 dyspnea 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."

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Corthera, Inc., a Novartis affiliate company, funded the study.

Cardiology特集

AHA2012 (第85回米国心臓病協会)

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