New medicine reduced risk for heart failure emergencies, hospital visits

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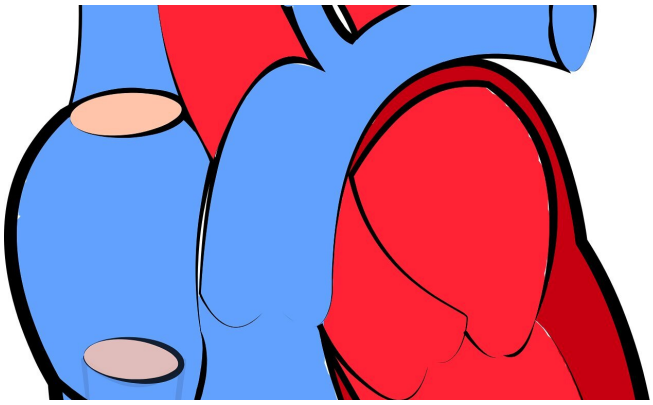

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Omecamtiv mecarbil, a new, investigational heart medication, reduced the risk of heart failure-related events in patients with heart failure with reduced ejection fraction, according to late-breaking research presented today at the American Heart Association's Scientific Sessions 2020. The virtual meeting is Friday, November 13—Tuesday, November 17, 2020. The manuscript of this study is simultaneously published today in *The New England Journal of Medicine*.

Ejection fraction is a measurement of the proportion of blood the heart pumps out with each contraction. Heart failure with reduced ejection fraction, or HFrEF, occurs when the left ventricle, the heart's largest pumping chamber, loses its ability to contract normally. The heart can't pump with enough force to push blood into circulation. An ejection fraction of 40% or less is used to define HFrEF. For this study, an EF of ? 35% was required.

The GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure) study assessed omecamtiv mecarbil, an investigational medication that was granted "fast track" designation as a new heart failure treatment option by the U.S. Food and Drug Administration in May 2020.

Omecamtiv mecarbil binds to cardiac myosin, the protein in the heart that transforms chemical energy into mechanical work, thus powering muscle contraction. In previous studies, it was found to improve cardiac function by increasing the effectiveness by which myosin interacts with actin, another protein involved in heart muscle contraction.

"Omecamtiv mecarbil is the first in a class of heart medicines called myotropes that selectively target cardiac muscle to improve cardiac performance," said John R. Teerlink, M.D., lead author of the study, director of heart failure and of the Echocardiography Laboratory at the San Francisco Veterans Affairs Medical Center and professor of medicine at the University of California San Francisco. "In the phase 2 study that led to GALACTIC-HF, omecamtiv mecarbil increased measures of cardiac performance and function. GALACTIC-HF focused on evaluating the effect of this potential medication on outcomes in patients with chronic heart failure."

GALACTIC-HF was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial. The study enrolled more than 8,000 patients in 35 countries with chronic heart failure who were either currently hospitalized for heart failure or with a recent history of hospitalization or emergency department visit for heart failure within one year prior to screening.

Participants were predominantly male (79%) and white* (78%), with an average age of 66 years and average ejection fraction of 27%. In addition:

- 62% had coronary artery disease;
- 40% had Type 2 diabetes;
- 70% had high blood pressure;

- 36% had chronic kidney disease; and
- 25% were hospitalized at the time of enrollment.

* While only 7% of participants self-reported as Black, more Black patients were enrolled in GALACTIC-HF than in any contemporary, international heart failure trial.

Patients were randomized to receive either an oral placebo or omecamtiv mecarbil. The study investigated how much time passed before the first heart failure event such as hospitalization, an urgent visit requiring intravenous therapy for heart failure or cardiovascular death.

The study found that patients receiving omecamtiv mecarbil had less risk of experiencing a heart failure event or cardiovascular death. The medicine had a greater effect for patients with lower ejection fraction (ejection fraction ?28%), an indicator of more advanced heart failure. In addition, the concentration in the blood of N-terminal B-type natriuretic peptide, a hormone that is increased with worsening heart failure, was reduced in patients treated with omecamtiv mecarbil. There were no significant imbalances in adverse events between patients randomized to treatment or placebo. In addition, side effects that typically limit the use of current heart failure therapies, such as adverse effects on blood pressure, heart rate, potassium levels or kidney function, were not observed.

"This study provides substantial evidence characterizing the efficacy and safety of this novel therapy," said Teerlink. "The trial included a wide range of patients from both the inpatient and outpatient settings, and these findings will inform potential future implementation of omecamtiv mecarbil to treat chronic heart failure."

More information: Session: LBS.01. Heart Failure and Atrial Fibrillation: Vitamins, Minerals, Nutrients, and More, www.abstractsonline.com/pp8/?_ … 4/presentation/40148

Provided by American Heart Association

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