

Study finds treatment fails to improve common form of heart failure

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A medication used for high blood pressure does not improve a common form of heart failure, according to new results from a large, international study.

The study, which included researchers at Wake Forest University Baptist Medical Center in key leadership positions, appears in this week's issue of the *New England Journal of Medicine*, published today.

The findings are disappointing to researchers, who continue to study other medications in search of a successful treatment for the condition, which predominantly affects older individuals, particularly women.

"Heart failure is the only cardiovascular disease on the rise," said Dalane Kitzman, M.D., a cardiologist and professor in the Department of Internal Medicine at Wake Forest Baptist, principal investigator for the Wake Forest Baptist trial site and the national coordinator for the study. "And this newer form of the disease is increasing fastest of all. That's what makes it disconcerting – that we don't have a proven effective treatment. We sort of have to go back to the drawing board."

Doctors long believed that most heart failure was caused by a weakening of the heart muscle that kept it from pumping enough blood out to the body (systolic heart failure). In recent years, however, they have recognized a second and more common form of the disorder in which the heart can empty normally, but does not fill with enough blood (diastolic heart failure). The result is the same – the body does not get

enough oxygen-rich blood for its needs. The most common symptom is shortness of breath. Other symptoms include fatigue, swelling around the ankles and high blood pressure.

Few drugs have been tested as treatment strategies in randomized studies of patients with diastolic heart failure – largely because the condition wasn't recognized as a separate form of heart failure until the past decade. To date, no effective treatments have been found.

Wake Forest Baptist researchers and colleagues, both internationally and within the United States, altogether recruited 4,128 patients with the condition from 25 countries. The patients, all of whom were at least 60 years old, were randomly placed into two groups. One group received 300 milligrams of irbesartan, an anti-hypertensive medication marketed as Avapro™. The other group was given a placebo. Doctors tracked the patients for five years, documenting their progress and outcomes.

The study showed treatment with irbesartan did not reduce the risk of death or hospitalization for cardiovascular causes among patients who had diastolic heart failure, nor did it improve any of the secondary clinical outcomes, including quality of life.

Researchers chose irbesartan for the study because previous, smaller studies in humans with diastolic heart failure indicated that the drug may have had a potential benefit, Kitzman said.

While irbesartan was not successful in treating diastolic heart failure, the study showed the medication, though powerful, was found to be safe for patients with the condition, he said.

There were fewer bad outcomes than predicted, Kitzman added. This may have been partly because blood pressure was well controlled from the start of the study by design. While the results were not positive,

Kitzman said, the study does provide helpful clues to treatment of the disease. "If you have the disease but can control blood pressure with medication, the patient is likely to do pretty well," he said.

Because the disease is so common, researchers are continuing work to find effective treatments. Kitzman and colleagues at Wake Forest Baptist are collaborating in another ongoing trial called TOPCAT (Treatment of Preserved Cardiac function heart failure with an Aldosterone antagonist), testing another medication for treatment of this condition. The study is being funded by the National Institutes of Health. Patients interested in participating can contact (336) 713-4702.

Source: Wake Forest University Baptist Medical Center

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