Iron Repletion Aids Heart Failure in Phase III Investigation

BY MITCHEL L. ZOLER

ORLANDO — The clinical benefits from intravenous iron in chronic heart failure seen in a placebo-controlled study of 459 patients abruptly made iron repletion a new, plausible treatment for a sizeable fraction of heart failure patients.

“This is a new therapeutic concept. When patients [with heart failure] are symptomatic, physicians should think about iron deficiency,” Dr. Stefan D. Anker said at the annual scientific sessions of the American Heart Association.

The study results also showed that the boost from iron occurred regardless of whether patients were anemic before starting treatment, a finding that suggests iron helps patients by a mechanism that does not involve hemoglobin.

The study findings “are very intriguing. Iron deficiency hasn’t been on our radar screen,” commented Dr. Marcel L. Jessup, professor of medicine and associate chief of clinical affairs in the division of cardiovascular medicine at the University of Pennsylvania in Philadelphia. “I think this is something that people will start to act on quickly.”

Iron deficiency is extremely common in this population,” commented Dr. John G.F. Cleland, professor and chairman of cardiology at the University of Hull, England.

Despite the promising results, the study was not powered to address safety or efficacy end points.

Dr. ANKER

Major Finding: At 24 weeks, Patient Global Assessment scores improved in 50% of the 304 heart failure patients receiving intravenous iron and in 28% of the 155 patients on placebo.

Data Source: FAIR-HF, placebo-controlled phase III study of 459 patients, from 75 sites in 11 countries, randomized to iron or placebo.

Disclosures: The study was sponsored by Vifor Pharma, a Swiss company that markets Ferinject in Europe. Dr. Anker has received fees from Vifor; he also has received fees from Roche and Amgen.

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The average age was 79 years among the cases and 77 years among the controls. Both the cases and controls were evenly split among men and women. Identification of gout relied on hospitalization, a physician visit, or a diagnostic code in the medical record.

During an average follow-up of 2 years, the rate of death or new heart failure hospitalization was 63% higher in the patients with gout than in those without gout.

The rate of death or new heart failure hospitalization was even higher in patients who had acute gout, with a twofold higher risk in the adjusted analysis. The researchers defined acute gout as hospitalization or a physician visit for gout within 60 days of the index heart failure event.

Another pair of analyses looked at the impact of allopurinol treatment. Among patients with an index heart failure event who also had gout treatment with allopurinol, there was a significant 31% reduction in the subsequent rate of death or heart failure hospitalization in the adjusted analysis. This benefit was limited to the patients on chronic allopurinol treatment for more than 30 days. Patients on allopurinol for 30 days or less showed no significant reduction in mortality or new heart failure hospitalizations.

‘The Effect Occurs So Quickly’

This is a remarkable result. I am especially impressed that the separation in the primary end points between the patients receiving iron and those on placebo began to be statistically significant after the first 4 weeks on treatment and then continued to separate further. The effect occurs so quickly. This is probably the fastest separation we’ve seen in a clinical trial in heart failure.

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Data Source: The analysis used administrative health record data from residents of the province of Quebec; 14,327 cases of people hospitalized for heart failure were compared with 143,255 controls.

Disclosures: None