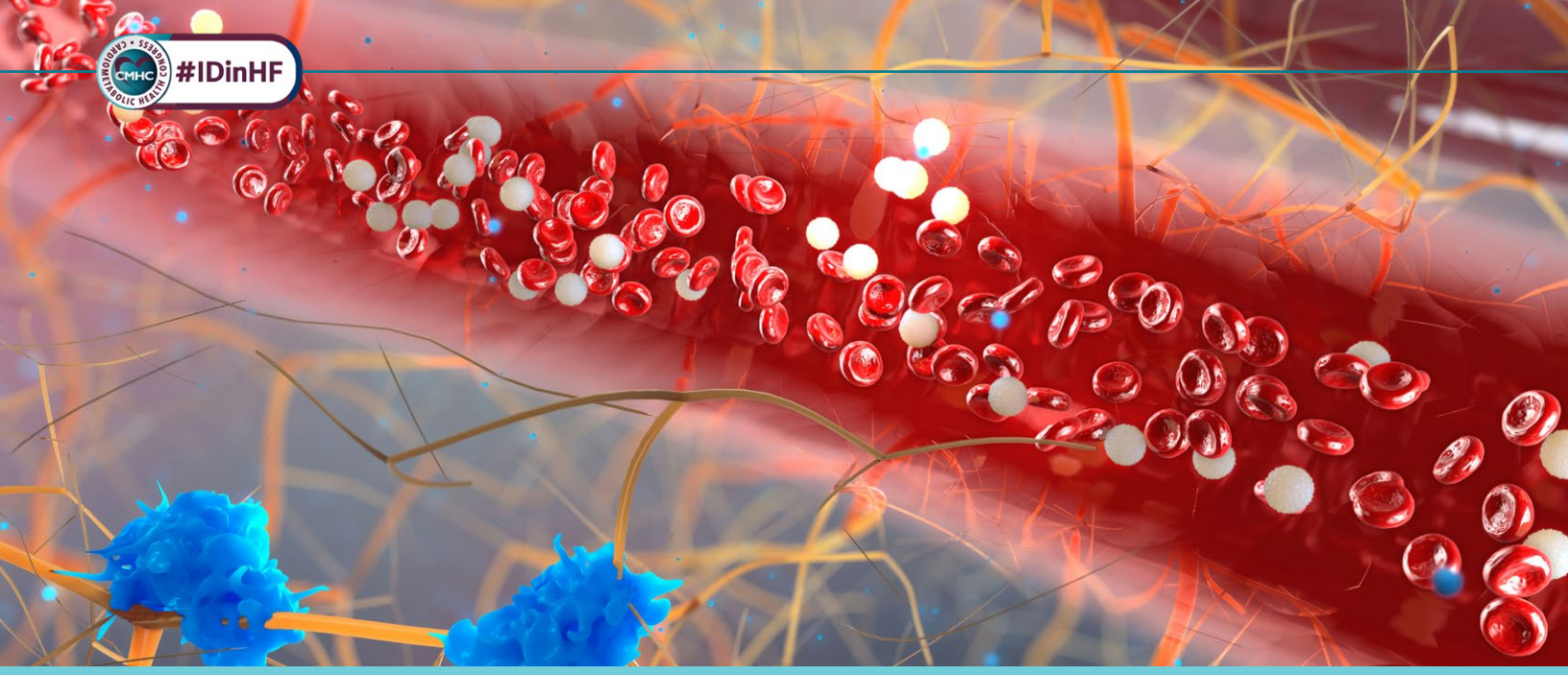

AFFIRM-AHF Study Demonstrates Benefits of Iron Repletion in Improving Quality of Life in Iron Deficient Patients with Acute HF

BACKGROUND

As a sub-analysis of the AFFIRM-AHF trial, researchers at the Wroclaw Medical University in Poland aimed to determine the benefit of intravenous ferric carboxymaltose (FCM) on health-related quality of life (HRQoL) in patients with heart failure (HF) and iron deficiency (ID) after an acute cardiac episode. The main results of this trial showed that treatment with FCM can reduce the risk of HF hospitalizations. Given that improvement of quality of life is one of the major goals of HF therapy, authors aimed to further explore whether FCM therapy can improve HRQoL in this setting, an outcome that has not been extensively studied in these high-risk patients.

They cited previous analyses' findings that intravenous iron is one of a limited number of treatments for HF that results in HRQoL improvement, thus warranting an objective measure of said improvement. Moreover, recent trials in acute HF patients, such as EVEREST and SOLOIST-WHF, seemed to support that intervening after an episode of acute HF can significantly improve HRQoL.

OBJECTIVE

Because patients with HF and ID experience poorer HRQoL compared to those with normal iron levels, the AFFIRM-AHF study, as an important secondary endpoint, sought to identify if intravenous FCM can improve HRQoL in acute HF patients with ID.

DESIGN

Investigators set out to evaluate the effect of intravenous FCM compared with saline placebo when administered before discharge in hospitalized patients with acute HF and ID. Study participants who were to receive FCM had their dose calculated based on body weight and baseline iron levels. Intravenous FCM (or saline placebo) was administered at discharge and at week 6, and again at week 12 or 24 if participant was still presenting with ID.

Assessment of HRQoL was based on the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ-12), a self-reported and validated tool that was completed at hospital discharge and again at weeks 2, 4, 6, 12, 36, and 52. Note that the KCCQ-12 reporting period of 52 weeks goes beyond the maximum treatment window of 24; this extended phase of data collection was to account for long-term effects on HRQoL and the possible reoccurrence of ID in participants who received FCM.

PARTICIPANTS

Researchers initially identified 1108 eligible participants who were hospitalized with acute HF and comorbid ID. Criteria for participation were that patients were: older than 18 years of age; currently hospitalized with clinical symptoms, signs and biomarkers of HF; receiving furosemide for LVEF function of less than 50% in the 12 months prior to hospitalization; ID defined by ferritin levels below 100ng/mL (or up to 299ng/mL if transferrin saturation was less than 20%).

Prior to discharge, 1058 participants were randomly assigned to the intravenous FCM study group (n=535) or the saline placebo group (n=523), and by the study's conclusion after 52 weeks there were 380 living participants in the study group and 388 in the placebo group.

RESULTS

All participants' KCCQ-12 scores were similar and showing impaired HRQoL at study baseline. At 2 weeks post-discharge, scores from both the control and study groups improved but there was no statistical difference between groups. From week 4 to 24, however, the participants who received FCM showed statistically meaningful improvements in self-reported HRQoL compared to the participants who received saline placebo.

DISCUSSION

A target of all HF therapies is to improve patients' symptoms and heart function, however, improving quality of life is also an important standalone objective. ID is known to increase symptom burden, impair exercise capacity, and negatively impact quality of life in patients with HF. Demonstrating a significantly better KCCQ-12 score in patients who underwent intravenous FCM therapy, the authors of the AFFIRM-AHF study report a likely avenue to reduce hospital readmittance and improve HRQoL for HF patients.

The authors acknowledge limitations of the study; the KCCQ-12 is a self-reported measure which is subject to reporter (participant) bias. Also, this study notably took place during the COVID-19 pandemic, for which a change in HRQoL can be attributed, although it is not possible to determine how much. Future studies should include physiological markers of HF to determine if FCM iron supplementation also improves cardiac function, in addition to improving HRQoL as demonstrated by the present study.

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