Transcript Details

This is a transcript of an educational program accessible on the ReachMD network. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/global-heart-failure-academy/affirm-ahf-key-takeaways/12005/

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AFFIRM-AHF: Key Takeaways

Hospitalizations due to acute heart failure (AHF) represent a growing healthcare problem and a large economic burden. Iron deficiency is highly prevalent in patients with AHF who represent a high-risk population for increased mortality and recurrent hospitalizations. Previous clinical trials have shown that intravenous ferric carboxymaltose (FCM) improves symptoms, exercise capacity, and quality of life in ambulatory patients with heart failure with reduced ejection fraction (HFrEF) and comorbid iron deficiency. AFFIRM-AHF is a first-in-kind prospective, randomized (1:1), double-blind, placebo-controlled trial designed to evaluate the effect of FCM compared with placebo in patients with AHF (ejection fraction <50%) and iron deficiency. The primary endpoint was the combined assessment of cardiovascular (CV) death and recurrent hospitalizations during the 52-week follow-up period after randomization. A total of 1108 subjects from 121 sites located in Europe, South America, Israel, Lebanon, and Singapore included in the modified intention-to-treat population for whom study treatment was started and at least one post-randomization value was available. Findings showed a primary endpoint rate ratio (RR) of 0.79 (95% CI, 0.62–1.01; P = 0.059) when correction of iron deficiency was initiated prior to hospital discharge. RR for total HF hospitalizations was 0.74 (95% CI, 0.58–0.94; P = 0.013). The secondary endpoint of combined first HF hospitalization or CV death had a hazard ratio of 0.80 (95% CI, 0.66–0.98; P = 0.030). AFFIRM-AHF results were potentially affected by the COVID-19 pandemic. A prespecified COVID-19 sensitivity analysis, where patients were censored in each country at the date when the first COVID-19 patient was reported, showed a primary endpoint RR of 0.75 (95% CI, 0.59–0.96; P = 0.024). Therefore, it is plausible that factors related to COVID-19 may have diluted the treatment effect. The results support the recommendation for treatment with FCM in patients with iron deficiency and HFrEF (<50%) who have been stabilized after an episode of AHF in order to prevent recurrent hospitalizations. Data also support the use of a prespecified COVID-19 analysis for ongoing clinical trials during the current pandemic. For more information on the AFFIRM-AHF trial and the role of iron deficiency in HF, the audience is invited to visit the related resources section on the webpage of this activity.