心不全患者の鉄欠乏を補正することにより症状が改善する

FAIR-HF：慢性心不全患者において鉄欠乏を治療することにより症状、心機能分類およびQOLが改善する

FAIR-HF: Treatment for iron deficiency improves symptoms, functional capacity and quality of life in chronic heart failure patients

慢性心不全（CHF）患者に鉄剤（ferric carboxymaltose）を静脈内注射し鉄欠乏を改善することにより症状、運動耐容能およびQOLが改善すると2009年American Heart Association学会のレイトブレイキング臨床試験のセッションで発表され、New England Journal of Medicineに掲載された。研究者らは鉄欠乏を有する心不全患者459人を調査した。3分の2の患者は鉄欠乏が回復するまで鉄剤の静脈内注射を毎週の後月に1回施行され、3分の1はプラセボを投与された。鉄剤を静注された群の患者は、スタディの2つの一次エンドポイント（24時間後の自己申告によるPatient Global Assessment[PGA]、P<0.0001およびNew York Heart Association[NYHA]クラススコア、P<0.0001）の有意な改善を示した。PGAのエンドポイントに関しては、鉄剤に振り分けられた患者の50%が24週後に"非常に改善"または"中等度改善"と報告したのに対し、プラセボ群においてはこの種の改善を示した者は28%に過ぎなかった。トライアルの結果によると、鉄剤群の患者の47%が24週後にNYHAクラスIまたはIIであったのに対し、プラセボ群ではわずか30%であった。PGAとNYHAクラスの結果はあらかじめ定義された全てのサブグループにおいて同等であった。

Full Text

Intravenous (IV) iron treatment with ferric carboxymaltose to reverse iron deficiency can significantly improve symptoms, exercise tolerance and quality of life for chronic heart failure (CHF) patients, researchers said in a late-breaking clinical trial presentation at the American Heart Association's Scientific Sessions 2009.

"Our study shows that treating iron deficiency for 24 weeks with iron in the form of I.V. ferric carboxymaltose safely improves symptoms in patients with chronic heart failure with anemia," said Stefan D. Anker, M.D., Ph.D., Professor of Cardiology and Cachexia Research, Department of Cardiology, Charité Medical School in Berlin, Germany. Anker is lead investigator of the FAIR-HF (Ferinject® Assessment in patients with IRon deficiency and chronic Heart Failure) study.

Anker added, "This is the first fully successful phase 3 trial of a drug for chronic heart failure to improve symptoms in many years. Besides symptoms, our treatment also improved functional exercise capacity as measured by the 6-minute walking test and quality of life and it was very well tolerated."

The researchers studied 459 heart failure patients with iron deficiency in 75 study sites, mainly in Europe and Argentina. Researchers randomized two-thirds of the patients to receive weekly I.V. injections of iron until the iron deficiency was reversed, with monthly treatment thereafter. The other one-third received a placebo (saline).

The group treated with I.V. iron showed significant improvements in both of the study's two primary endpoints: 1) self-reported Patient Global Assessment (PGA) score after 24 weeks (P<0.0001) and 2) a measure of CHF severity called New York Heart Association (NYHA) class (P<0.0001). To illustrate the results, for the PGA endpoint, 50 percent of patients assigned to ferric carboxymaltose were either "much improved" or "moderately improved" at week 24 compared to only 28 percent of patients showing this kind of improvement in the placebo group. For NYHA class, the study showed that 47 percent of patients assigned to ferric carboxymaltose were in NYHA class I or II at week 24, compared to only 30 percent of patients on placebo therapy.

The results for PGA and NYHA class were very similar in all predefined subgroups, regardless of whether they were defined by hemoglobin or ferritin level, age, or gender. "It is important that the benefits of I.V. iron were observed in patients regardless of a diagnosis of anemia, suggesting that iron deficiency itself is an important therapeutic target in heart failure patients, independent of presence of anemia." said Anker.

Furthermore, researchers found significant improvements in the secondary endpoints. After 24 weeks, patients receiving I.V. iron injections undergoing the six-minute walk test were able to walk 39.1 meters further than at baseline, compared with just 8.6 meters further in the placebo group.

From as early as week 4 of the study, and throughout the study, I.V. iron improved quality of life assessments compared with placebo (P<0.001). There was no significant difference in mortality or rates of adverse events, including hospitalizations, between the treatment and placebo groups.

Sponsor: Vifor Pharma Ltd., Switzerland.

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Disclosures: Stefan D. Anker is a member of the Executive Committee of FAIR-HF and a consultant to Vifor Pharma Ltd. and Amgen Inc. He has received honoraria for speaking for the companies.

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