

Serious adverse events associated with ferric carboxymaltose administration in patients with inflammatory bowel disease treated with anti-TNF drugs

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INTRODUCTION

Iron deficiency anemia is very common among the patients with a chronic illness. The prevalence among the inflammatory bowel disease (IBD) patients is up to 75%. About 20–30% patients present with iron deficiency without anemia. Both conditions are an important cause of chronic fatigue syndrome in IBD patients. International guidelines recommend parenteral iron replacement for treating iron deficiency anemia in IBD patients. However there are more adverse events documented with parenteral iron compared to oral supplements especially in patients with an active disease. Ferric carboxymaltose (FCM) is considered a safe drug.

METHODS

The medical records of 62 patients who received parenteral ferric carboxymaltose during the period from 1.1.2011 to 2.2.2013 were analysed. Data included the underlying disease, serum iron levels, CRP, treatment with biologic drugs (anti-tumor necrosis factor alpha (anti-TNF)) and any observed adverse events associated with biologic therapy or FCM application. Serious adverse events were described as: low blood pressure, chest pain, dyspnea, tachycardia, nausea, generalized urticarial (hives), excessive sweating and flushing.

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RESULTS

The underlying disease distribution is displayed in a pie chart 1. 25 patients were male and 37 were female.

Of 53 patients with IBD 32 (60,4 %) were treated with anti-TNF drugs, 16 were receiving infliximab and 16 patients adalimumab.

Of 62 patients in the study group the adverse events were observed in 4 (6,5 %) patients (3 female and 1 male). **All of the affected individuals had an inflammatory bowel disease and were receiving anti-TNF therapy.** Three patients had Crohn's disease and one ulcerative colitis. Two patients were receiving adalimumab and two infliximab. Both individuals on adalimumab were previously treated with infliximab. One individual had a documented allergic reaction to infliximab. The severity of the underlying disease at the time of the adverse event is unfortunately not available.

The exact mechanism causing the adverse events is unclear. Possible mechanism is IgG mediated reaction between the FCM and the anti-TNF drug (IgG antibody) or between the FCM and antibodies developed against the biologic drug. Currently there is a lack of evidence to classify this reaction as anaphylaxis.

CONCLUSION

Serious adverse events associated with ferric carboxymaltose (FCM) were only observed in IBD patients receiving anti-TNF drugs. All events occurred after the first administration of FCM. Possible mechanism is cross reaction between FCM and anti-TNF drug (IgG antibody) or FCM and antibodies developed against the biologic drug. Caution is advised administering FCM to IBD patients treated with anti-TNF drugs.

