

# Effectiveness and safety of ferric carboxymaltose treatment in patients with inflammatory bowel diseases

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## BACKGROUND

Patients with inflammatory bowel disease (IBD) are at risk for iron deficiency. Absorption of orally given iron may be impaired by intestinal inflammation and treatment with oral iron may aggravate intestinal inflammation. The treatment of iron deficiency anemia with IBD is a particular challenge and often insufficient.

## PURPOSE

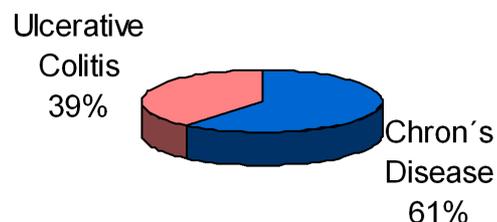
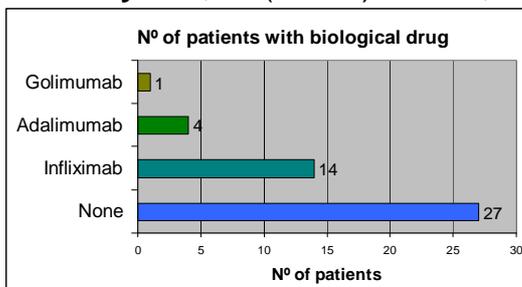
To describe the effectiveness and safety of intravenous ferric carboxymaltose (FCM) in IBD adult patients.

## MATERIALS AND METHODS

Observational-retrospective study in two general hospitals. IBD adult patients who had received at least one dose of FCM from August-2013 to August-2015 for up to 3 months were analyzed. Data collection from clinical records: age, gender, IBD (Crohn's Disease - CD- or Ulcerative Colitis -UC-), FCM dosage, biological drug-treatment, hemoglobine (g/dL), haematocrit (%), mean corpuscular Hb concentration -MCHC-(g/dL), serum-ferritine level -SFL-(ng/mL), all of them pre-FCM and post-FCM infusion. -. The safety profile was evaluated on the basis of the proportion of patients who experienced any adverse drug reaction (ADRs). Statistical analysis powered by SPSS®15.0 (paired T-test).

## RESULTS

- In total, **46 IBD patients** had been treated for concomitant iron deficiency anemia, mean age **49.3±6.6 years**, 22 (47.8%) women,



- The mean cumulative dose was 978±103.2 mg iron.
- Correction of iron deficiency anemia was observed with improved (within 12 weeks):
  - **mean hemoglobin levels:** 11.7±1.4 g/dL vs. 13.6±0.9g/dL ( $p < 0.001$ )
  - **mean haematocrit:** 36.1±4.7% vs. 41.0±3.1% ( $p < 0.001$ )
  - **mean MCHC:** 27.9±3.2 g/dL vs. 30.2±2.4 g/dL ( $p < 0.001$ )
  - **mean MCHC:** 27.9±3.2 g/dL vs. 30.2±2.4 g/dL ( $p < 0.001$ )
  - **mean SFL:** 49.9±84.5 ng/mL vs. 205.2±194.4 ng/mL ( $p < 0.001$ )
- Six (13.1%) subjects reported mild ADRs related to FCM: 4 (8.7%) of these were considered to be potentially related to long duration of administration and to high volume of saline solution for dilution.

## CONCLUSIONS

- Overall FCM was well tolerated in this population and appeared to be effective in correcting iron deficiency anemia.
- We cannot exclude that the correction of iron deficiency anaemia is in some part due to the treatment of the underlying disease and not related to the iron supplementation only.