



P62. THE COMPARATIVE EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE WITH IRON SUCROSE FOR THE TREATMENT OF PREOPERATIVE ANEMIA WITH MENORRHAGIA: AN OPEN-LABEL, MULTICENTER, RANDOMIZED STUDY

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Objective: To compare intravenous ferric carboxymaltose (FCM) with iron sucrose (IS) for the effectively and timely treatment of preoperative iron deficiency anemia (IDA) in women with menorrhagia.

Methods: This open-label, multicenter, two-arm study randomized patients with menorrhagia and preoperative IDA (Hb level <10 g/dL and serum ferritin level <30 ng/mL) to receive intravenous FCM as a single-dose (?1,000 mg iron) or multiple-doses of IS (?200 mg iron; maximum 600 mg iron/week).

Patients: In total, 101 patients (FCM n=52; IS n=49) were randomized to study treatment.

Interventions: Intravenous FCM as a single-dose (?1,000 mg iron) vs. multiple-doses of IS (?200 mg iron; maximum 600 mg iron/week)

Main Outcome Measures: Primary endpoint was proportion of patients that achieved hemoglobin (Hb) levels ?10 g/dL (surgery eligibility criterion) 2 weeks after the first administration of study drug. Secondary endpoints included mean Hb levels 2 weeks after first administration, time to reach Hb ?10 g/dL, and quality of life (QoL).

Results: Mean total doses were similar for both treatments (FCM: 923.1 \pm 207.3 mg; IS: 939.6 \pm 352.3 mg; P=0.774) yet the total dose for FCM was always administered in one hospital visit while IS was administered over 3–8 visits. FCM was as effective as IS in achieving Hb ?10 g/dL 2 weeks after first administration in patients (FCM: 78.8%; IS: 72.3%; P=0.452). However, time to reach Hb ?10 g/dL was significantly shorter in the FCM than the IS group (7.7 vs 10.5 days; P=0.013). Furthermore, mean Hb levels 2 weeks after first administration was higher in FCM treated patients than IS patients, though this was not significant (P=0.079). QoL scores were not significantly different between the treatment groups and both treatments were well tolerated.

Conclusion: FCM is as effective as IS in correcting preoperative IDA in patients with menorrhagia. The added benefits of FCM over IS were significant rapid correction of IDA, and replenishment of iron stores, as well as reduced hospital visits. FCM could allow for earlier surgical intervention as an effective alternative to IS for these patients.

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