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EXTENDED ABSTRACT

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A single dose of ferric carboxymaltose optimization protocol in the management of anaemic patients presented for postbariatric plastic surgery: a retrospective cohort analysis

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Introduction

Bariatric surgery is currently the most effective treatment for obesity[1] and an increasing number of patients are presented for postbariatric plastic surgery after major weight loss[2]. Nutritional deficiencies, like iron deficiency and anaemia are common in this patients and patient blood management is crucial to reduce the risks of blood transfusion and the associated costs. Intravenous (IV) iron is an effective and recommended treatment where rapid replenishment of iron stores is required, to avoid postoperative depletion iron reserves and to accelerate postoperative recovery of haemoglobin (Hb) levels[3]. The aim of this study was to analyse the dose optimisation protocol of a day-care unit for anaemic patients presented for postbariatric plastic surgery and establish the non-inferiority of a single 1000 mg ferric carboxymaltose (FCM) dose compared with the calculated doses by the simplified method (SM)[4], a simple dosing regimen used to calculate individual iron need for repletion.

Methods

This retrospective cohort study included patients with confirmed anaemia who received a dose of 1000 mg of IV iron in a day-care unit from May 2013 to October 2019 and were proposed to postbariatric plastic surgery. The results of a single 1000 mg FCM dose was examined relative to individually calculated doses by the FCM product information dosing scheme[5] (Table 1).

Table 1 – Determination of the IV iron need, based on simplified dosing method.

Hb	Patient Body Weight	
g/dL	35 kg to 70 kg	≥ 70 kg
< 10	1500 mg	2000 mg
≥ 10	1000 mg	1500 mg

Patients were grouped in two cohorts, according to deviations between administered IV iron and the calculated dose by the SM: whether it did not meet (Cohort A, n = 63) or met (Cohort B, n = 25) the SM scheme. The primary outcome was to compare both cohorts haemoglobin normalization at the reference value for plastic procedures (Hb ≥ 11 g/dL). The secondary outcome was to evaluate the proportion of patients with an Hb level increase by ≥ 2 g/dL at the follow-up visit. In addition, were assessed deviations from the scheduled dose and the transfusion rate for the operated patients (n=65).

Laboratory values were compared at decision time and follow-up visit. After performing a normality test (Shapiro-Wilk Test) and testing the homogeneity of variances (F-test), the differences between quantitative variables were compared using Student's t-test or Wilcoxon-Mann-Whitney test, for those variables in which data fails the normality test. Qualitative data was compared using Fisher's exact test. Fisher's exact test was also used to assess cohort differences in the supplementary doses of IV iron administered to patients and differences between the transfusion rate. Probability of superiority was the chosen effect size measure[6]. A p-value < 0.05 was considered statistically significant for differences

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between cohorts and all tests were two-sided. All statistical analysis of the data was performed using RStudio version 3.6.1 (2019/07/05).

Results

A total of 88 women, aged 20 to 63 years, scheduled for a postbariatric plastic surgery, were considered to the analysis (Table 2).

Table 2 – Patients demographics and baseline characteristics.

	Cohort A (n = 63)	Cohort B (n = 25)	p value
Age (years)	40.6 ± 8.8 (20.0 – 59.0)	43.2 ± 8.0 (29 – 63)	0.17
Weight (kg)	70.6 ± 8.6 (52.0 – 89.0)	61.6 ± 4.9 (51 – 69)	<0.001
Oral Iron	36 (57%)	17 (68%)	0.47
Baseline Hb (g/dL)	9.3 ± 1.0 (6.8 – 11.8)	10.6 ± 0.4 (10.0 – 11.3)	<0.001
Follow-up visit (weeks)	3.8 ± 1.9 (1 – 10)	3.4 ± 1.5 (2 – 8)	0.10

All values are mean ± standard deviation (range), except for oral iron where values are expressed as numbers of patients (percentage).

The two cohorts presented no significantly statistical differences (p = 0,06) in haemoglobin normalization (Table 3), with a small effect size (PS = 0,62). The mean Hb improved from 9,3 ± 1,0 to 11,5 ± 0,8 g/dL in Cohort A and from 10,6 ± 0,4 to 12,0 ± 1,0 g/dL in Cohort B. At the follow-up visit an Hb increase of at least 2 g/dL was achieved by 54% (n = 34) and by 20% (n = 5) patients in Cohort A and B (p = 0,75), respectively. For those the mean increase in Hb was 3,03 g/dL in Cohort A and 2,9 g/dL in Cohort B. By that time, 78% (n = 49) patients in Cohort A and 96% (n = 24) in Cohort B had reached a Hb ≥ 11 g/dL. When analysing the Hb increase by age group, there are no statistically significant differences in any of the groups. The largest effect size occurred for patients aged 45 years and older (PS = 0,68), followed by patients under 35 years (PS = 0,64) and those between 35 and 44 years (PS = 0,58).

The blood transfusions rate was the same in both cohorts (5%, p = 1) for the 65 patients already submitted to postbariatric plastic surgery.

Table 3 – Laboratory values at decision time and follow-up visit.

	Reference Range	Cohort A (n = 63)	Cohort B (n = 25)	p value[a]
Before FE IV Session				
Hb (g/dL)	12.0 – 16.0	9.3 ± 1.0 (6.8 – 11.8)	10.6 ± 0.4 (10.0 – 11.3)	< 0.001
Hct (%)	36.00 – 46.00	30.2 ± 2.7 (20.9 – 30.6)	33.2 ± 1.1 (31.1 – 35.6)	< 0.001
MCV (fL)	80.0 – 100.0	74.2 ± 7.6 (57.3 – 102.4)	79.5 ± 6.9 (67.9 – 91.0)	0.002
MCH (pg)	26.0 – 34.0	22.7 ± 3.1 (15.4 – 33.7)	25.3 ± 2.6 (20.7 – 30.0)	0.000
MCHC (g/dL)	31.0 – 37.0	30.5 ± 1.4 (26.9 – 33.3)	31.8 ± 0.8 (30.4 – 33.5)	0.001
RDW (%)	11.60 – 14.00	16.8 ± 2.9 (12.5 – 30.0)	15.4 ± 1.6 (13.0 – 20.0)	0.019
After FE IV Session				
Hb (g/dL)	12.0 – 16.0	11.5 ± 0.8 (9.2 – 13.4)	12.0 ± 1.0 (10.6 – 14.9)	0.057
Hct (%)	36.00 – 46.00	36.4 ± 2.3 (30.5 – 41.4)	39.0 ± 8.7 (32.6 – 78.3)	0.345
MCV (fL)	80.0 – 100.0	81.3 ± 8.7 (32.3 – 103.9)	84.8 ± 5.8 (74.4 – 97.4)	0.023
MCH (pg)	26.0 – 34.0	26.1 ± 3.0 (20.2 – 37.6)	27.2 ± 1.9 (23.7 – 30.0)	0.017
MCHC (g/dL)	31.0 – 37.0	31.6 ± 3.0 (28.6 – 34.7)	32.2 ± 1.9 (30.5 – 33.5)	0.004
RDW (%)	11.60 – 14.00	22.4 ± 5.0 (11.0 – 31.6)	19.1 ± 3.4 (13.0 – 26.0)	0.004

[a]Exact test for differences between Cohort A and B with respect to each value: Wilcoxon-Mann-Whitney test.
Hb: Haemoglobin; Hct: Erythrocytes; MCV: Mean Corpuscular Volume; MCH: Mean Corpuscular Haemoglobin; MCHC: Mean Corpuscular Haemoglobin Concentration.

Conclusions

Our data demonstrate the non-inferiority of the adopted protocol for anaemia optimization since the same clinical outcomes can be obtained, in terms of morbi-mortality and transfusion rate, using a single 1000 mg FCM dose, when compared with the calculated doses by the simplified method. A decrease in dose administered to patients is beneficial for the hospital as it would allow monetary savings, without increasing patient health complications associated with blood loss.

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