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Research Article

A COMPARATIVE STUDY BETWEEN ORAL IRON AND INTRAVENOUS IRON (FCM) THERAPY IN POSTPARTUM ANAEMIA

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ABSTRACT

Background: Iron deficiency anaemia is a common cause of nutritional deficiency anaemia among the women of child bearing age in both developed and developing countries. Post partum anaemia is very common and it affects 5-50% of parturients.
Objectives: The objectives of this study is to compare the effects of oral iron and intravenous (i.v) Ferric Carboxymaltose (FCM) injection by rise in haemoglobin and other haematological parameters level in post partum anaemia and compare any major and minor drug effects involved with the therapy.
Materials And Methods: It was a 2 year prospective study on post partum anaemic patients from January 2018 to December 2019 at CSS Hospital, Kolkata. Total 200 post partum women with haemoglobin (7-10 g/dl) and peripheral smear showing microcytic hypochromic anaemia on the 2nd post partum day were randomised in 1:1 ratio to receive either oral iron or FCM .Oral iron was given in the dose of 65 mg elemental iron thrice daily and followed up on day 7 and day 42 with haemoglobin, haematocrit, serum ferritin and red cell indices.
Results: Anaemia is one of the most common causes of morbidity affecting post partum women. The prevalence of post partum iron deficiency anaemia calculated in this study was about 65-70%. Majority of such women are young and their age lies between 20-25 years. The severity of anaemia increases with degree of parity and illiteracy. Demographic characteristic are directly related with the degree of anaemia.FCM causes prompt restoration of iron stores than oral iron as shown by increase in serum ferritin level on 7th and 42nd day. The rise in all the red cell indices or parameters (MCV, MCHC, MCH, haematocrit and reticulocyte count are significantly more in the FCM group than the oral iron group ($p<0.05$). Besides the total side effects were higher with oral group than iv FCM group.
Conclusion: IV FCM is better option in early restoration of Hb% level and maintenance of iron stores within a short span of time.

INTRODUCTION

anaemia is the commonest medical disorder during pregnancy, in which iron deficiency anaemia (IDA) is the commonest. It is a world health problem that affects 20% of women in Western world and 56% in developed countries[4,5]. Antepartum anaemia continues in post partum period if timely intervention is not done. Such post partum anaemia affects 48% of delivered mothers. Approximately 30%of women in post partum period have haemoglobin level<8 gm/dl. According to WHO the postpartum anaemia is defined as haemoglobin level <10gm/dl. As per CDC Hb level is <11gm% is considered as anaemia. Post partum anaemia has the following symptoms – easy fatigueability, tiredness, breathlessness, palpitation, depression , stress and affected cognitive function.

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This may complicate the mother child interactions.Thus the IDA needs comprehensive treatment from the various treatment modalities . In this respect the obstetrician is faced with dilemma regarding which treatment option will be more beneficial considering new drug formulations available in the market. Several comparative study between oral iron and iv FCM (Ferric carboxymaltose) was conducted to help the obstetrician to find out the best option for clinical practise.

MATERIALS AND METHODS

This was a two year prospective study from January 18 to December 19 at CSS Hospital with the mothers of haemoglobin level between 7-10 gm/dl and peripheral smear showing microcytic hypochromic anaemia on the 2nd postpartum day. The 200 patients were randomised in 1:1 ratio to receive either iv FCM (Single dose 1000 mg) or oral iron Ferrous sulphate thrice a day (65 mg elemental iron thrice

daily for 6 weeks). One hundred patients with iron deficiency anaemia received i.v FCM . The required doses were adjusted in such a way that on a single day 15mg/kg of FCM was given not exceeding 1000mg. Total dose was calculated from Ganzoni formula. If total dose exceeded 1000 mg then the subsequent doses were given weekly up to maximum total dose 2500mg. Required dose of FCM was diluted in 250 ml normal saline and was transfused over 15 minutes with all preparations to manage anaphylactic reactions if required. Clinical condition of patient like pulse rate, blood pressure, respiratory rate were recorded for 24 hours before, during and after administration of FCM . Local injection site reactions and systemic side effects were noted. All patients underwent ultrasound examination for lower abdomen and pelvis to exclude pelvic tumour i.e fibroid uterus .

Total body iron deficit of a patient was calculated using the Ganzoni formula (iron deficit=weight in kg x (target haemoglobin – patients baseline haemoglobin) x 2.4+1000). Target haemoglobin was 12gm%, 2.4 is a unit less conversion constant and 1000 is the target iron stores in mg. patient's baseline haemoglobin was estimated within 2 days postpartum. All the patients were followed on day seven and day 42 with the following investigations likes haemoglobin (g/dl), haematocrit (%), serum ferritin (microgram/ml), red cell indices and reticulocyte count. The various parameters were compared between the two groups at the end of the study using chi-square test. P-value <0.05 was considered significant. Complications or adverse effects if any during transfusion of FCM or during intake of oral iron were recorded.

RESULTS

Anaemia is one of the most common disorder affecting the post partum woman. Prevalence of post partum iron deficiency anaemia calculated in the study was as high as 65-70%. About two third of post partum patients are young and their age lies between 20-25 years and they have poor iron stores at conception. About half of the women had normal BMI (18-25) but a significant percentage of patients (30%)in oral iron and 33%in FCM had lower BMI (<18). Anaemia may be associated with low BMI and poor nutritional status. For post partum anaemia maternal malnutrition is a major factor. The severity of post partum anaemia increases with increasing parity, illiteracy and poor socio-economic status. Statistically significant difference in haemoglobin rise was noted at day seven in iv FCM group than oral iron group, but at 42ndday of treatment both groups achieved almost similar increase in haemoglobin level.Fig 1

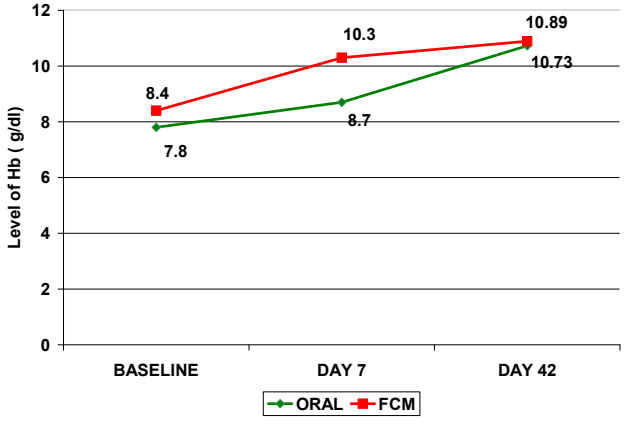

Figure 1 Comparison of Hb (g/dl) rise in two groups after iron therapy

FCM iron preparation caused prompt statistically significant restoration (p<0.05) of iron store than oral iron as shown by increase in serum ferritin level at both day7 and day 42 Fig 2

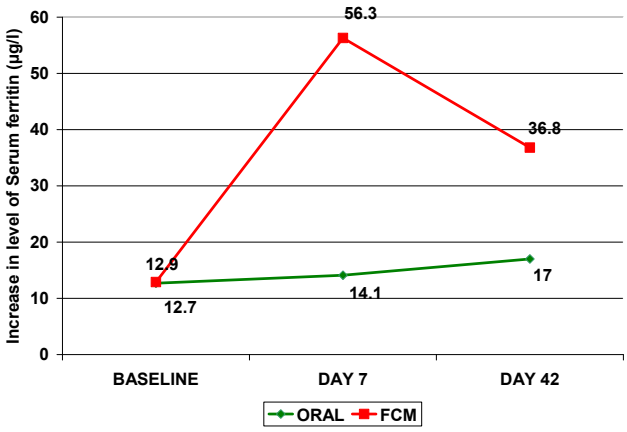

Figure 2 Comparison of increase in serum ferritin (µg/l) in two groups

The rise in MCV, MCH, MCHC, haematocrit, reticulocyte count were significantly more in the FCM group (p<0.05) than in oral iron group (table 1,2,3,fig 3 &4)

Observation Increase in MCHC (g/dl) in Two Groups

Mchc(dl)		Iron Group	Fcm Group	P-Value
Baseline		32.5	30.7	P>0.05
Day 7	Level (g/dl)	32.8	32.5	P<0.05
	Difference of Increase (g/dl)	0.3	1.8	P<0.05
Day 42	Level(g/dl)	33.2	32.7	
	Difference of increase (g/dl)	0.7	2.0	

Observation of Increase in MCV in Two Groups

Mcv(fl)		Oral Iron	Fcm Group	P-Value
Baseline		74.6	74.2	P>0.05
Day 7	Level(fl)	75.05	76.5	P<0.05
	Difference of Increase (fl)	0.45	2.4	P<0.05
Day 42	Level(fl)	76.24	76.6	P<0.05
	Difference of Increase (fl)	1.64	5.4	P<0.05

Observation of Increase in MCH in Two Groups

Mch(pg)		Oral Iron Group	Fcm Group	P-value
Baseline		25.2	25.1	p>0.05
Day 7	Level (pg)	25.3	6.6	P<0.05
	Difference of Increase (pg)	0.1	1.5	p<0.05
Day 42	Level (pg)	26.1	27	P<0.05
	Difference of Increase(pg)	0.9	2.5	P<0.05

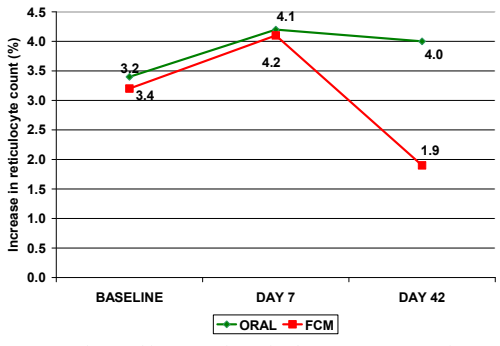

Figure 3 Comparison of increase in reticulocyte count (%) in two groups

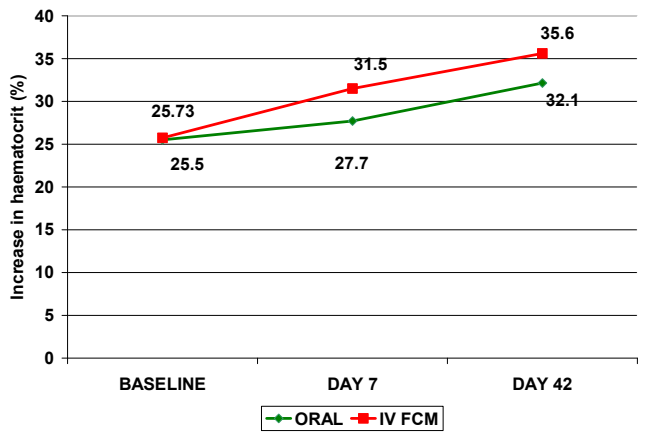

Figure 4 Comparison of increase in haematocrit (%) in two groups

In respect of adverse effects the oral iron group as more adverse effects than iv FCM group .oral iron therapy was more associated with prolonged GI disorder like constipation, diarrhoea , upper abdominal pain , nausea and vomiting leading to non compliance as seen in 30% of patients as compared to 1% in FCM group. FCM group was more commonly associated with injection site reaction (as mild rashes to systemic reactions)

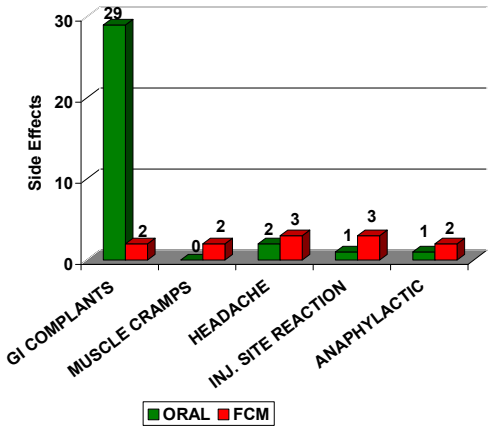

Figure 5 Comparison of side effects in two groups

DISCUSSIONS

Post partum anaemia is a very important medical disorder that needs aggressive attention to treat and build up iron reserves in the puerperium so as to ensure minimal incidence of anaemia for future pregnancy. The preferred modality of treatment is still to be explored for best compliance and least side effects. It is a challenging issue till now for the governmental policies and practicing doctors.

The prevalence of post partum iron deficiency anaemia calculated in the study was approximately 70%, out of 200 post partum women including both post delivery and post caesarean 140 patients had haemoglobin less than 10gm/dl with feature of peripheral smear of iron deficiency anaemia in complete hemogram.

The finding was in accordance with the study done by Somdutta *et al* in 2009 who also found a similarly high prevalence of post partum anaemia in North Indian region[3,4,8]. About 70% of the study participants were anaemic in this study and more than half of the patients in the two groups (approx 50%)had normal BMI and one third had low BMI.

The mean BMI of patients in each group were 22.31+/- 4.3 and 21.93+/- 4.3 kg/m^2 respectively with no statistical significance (p=0.6047) [p>.60]

Holland *et al* (1996) studied association of anaemia with BMI and found a significant association of postpartum anaemia with low BMI.

The mean initial haemoglobin in oral iron group and FCM group were 8.2+/-0.4 and 7.8+/-.04 gm/dl respectively which was statistically comparable (p>0.05). At day 7 there was only 0.7gm% increase in haemoglobin in patients receiving oral iron while FCM groups shows a comparable higher increase in haemoglobin ie 2.1gm%.

The difference of rise of haemoglobin was statistically significant in the two groups with more desirable outcome in FCM group (p<0.05).

When the results were compared in day 42 no difference in the rise of haemoglobin in the two groups were observed .increase in mean haemoglobin in oral iron and FCM at end of study on day 42 was 2.69 and 2.93 gm/dl with no statistical significance. (p>0.05)

Excluding bone marrow biopsy serum ferritin is the best indicator for assessment of iron stores. A woman with insufficient iron stores in post partum period has higher chance of developing anaemia and its complications . In absence of iron stores erythropoiesis is restricted in iron deficiency anaemia. Therefore rapid replenishment of iron stores is important for correction of anaemia. In the present study mean basal serum ferritin level at the onset of study were comparable in two groups with no statistical significance. After giving oral iron therapy oral group showed a slight increase in ferritin level i.e. 14.1microgram/l at day 7and 17.0 mirogram/l at day 42 while iv iron showed marked increase in serum ferritin level i.e. 56.3 microgram/l at day 7 and 36.7microgram/l in FCM group at day 42.

Table 4 Observation in different studies [9,12,13]

Studies	Iron therapy	Results (increase in HB%)
Breymann *et al* (2008)	Oral vs FCM	Oral iron increased HB by 0.8dm/dl while FCM by 2.8gm/dl at one week with no difference in HB levels at fourth week
Van Wyck at al (2007)	Oral vs FCM	Similar rise HB levels at 6 weeks
Quinibi et at (2008)	Oral vs FCM	Significant difference of 0.8gm/dl increase in Hb by oral iron and 1.6gm/dl by FCM at five weeks. (p<0.05)
Rathore *et al* (2014)	Oral iron v/s IV iron sucrose vs FCM	Increase in FCM group was significantly higher (p<0.0001) than conventional iron sucrose and iron group. The mean increase inHb after two weeks was 0.8, 2.4 and 3.2 gl/dl and 2.1, 3.4 and 4.4 gl/dl at sixth week in oral iron, iron sucrose and FCM groups, respectively.
Damineni eat al (2016)	Oral vs FCM	Increase in FCM group was 3.2g/dl and in oral group 2.2g/dl at sixth week
Present study	Oral vs FCM	Increase in FCM and oral group 1.9g/dl and 0.3g/dl at first week and 2.49g/dl and 2.33g/dl at six week respectively.

Table 5 summarizes result of changes inMCV, MCH and MCHC observed in various other studies.[10,11]

Study	Iron modality	MCV (fl)	MCH (pg)	MCHC (g/l)	P Value
Sied at el (2008)	FCM vs Iron oral	1.9 vs 1.1	1.6 vs 0.2	1.2 vs 0.6	<0.05
Van Wyck at al (2007)	FCM vs Iron oral	3 vs 0.3	1.5 vs 0.6	1.8 vs 0.7	<0.05
Present Study	FCM vs Iron oral	5.4 vs 1.64	2.5 vs 0.9	2.0 vs 0.7	<0.05

As noted in the present study, the various other studies also show higher incidence of gastric intolerance with oral iron preparations compared to parenteral preparations.

Table 6 shows the result of side effects between oral iron and FCM seen in different studies. [1,7]

Studies	Oral Iron	FCM
Breymann *et al*; 2008	24%	3.5%
Sled *et al* 2008	16.3%	3.5%
Van wyck *et al*; 2007	22.4%	4.5%
Quinibi *et al*; 2008	26%	3.5%
Present Study	30%	8%

CONCLUSION

The oral iron is very much convenient, affordable preparation of iron therapy but it has certain disadvantages. Bioavailability of different oral iron preparation is variable and is severely affected by presence of phosphates and oxalates in food. In oral iron therapy the associated side effects leads to non adherence or non compliance to oral therapy. Poor patient compliance is a major hindrance in success of oral iron therapy in community basis.

Intravenous iron therapy is proved to be a better option in early restoration of haemoglobin and maintaining stores. In our country there is a high prevalence of anaemia and majority of people are rural people. In this situation the ability to deliver a huge dose of iron within a short time may make iv FCM therapy suitable for patients requiring quicker restoration of iron stores .this study strengthens the clinical trial findings of good safety and efficacy of IV FCM in patients with post partum anaemia in real world clinical practise.

Compliance with Ethical Standards and Conflict of Interest

The author declares that there is no conflict of interest in the manuscript. This study is prospective analysis with informed consent of using data and it was approved by institutional Ethical Committee and all participants gave written informed consent.

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