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Ferric carboxymaltose-A novel formulation of iron in treatment of postpartum iron deficiency anaemia

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Abstract
Aims and Objectives: Compare the efficacy and safety of FCM with oral iron in improvement of haematological parameter and iron store in post partum iron deficient women.
Methods: Postpartum women were screened for IDA. 70 women in each group were randomized. One group received FCM as per calculated dose with folic acid and other 70 women received oral ferrous sulphate 200 mg TDS + folic acid. Both groups were followed up for 6 wks. Any adverse effects were noted. Hb level, Red cell indices & Iron stores were monitored.
Results: At 6 wk, Mean Hb rise 3.3+/- 0.8 in FCM group, Where as 2.2+/- 1.0 in oral group(P=0.00, Highly significant), MCV increases by 13.0+/-8.1 in FCM group(77 to 90 fl) where as 4.5+/-6.9 in oral group, P=0.00. TIBC decreases by 416 mcg/dl to 325 mcg/dl in FCM group. Whereas 422 to 388 mcg/dl in oral group (P=0.00), Sr ferritin rises by 138.1+/-30.8 ng/ml in FCM group. Whereas 2.2+/- 1.8 in oral group (P=0.00).
Conclusions: FCM is more efficacious than oral iron in improving haematological parameters and restoring iron stores with comparable side effects, convenient dosing schedule and no need of test dose

Keywords: ferric carboxymaltose, postpartum iron, anaemia

Introduction

In a typical singleton pregnancy, the maternal need of iron averages 1000-1400 mg. Which exceeds the iron stores of most women and result in marked iron deficiency. In our population due to lack of antenatal care anaemia is very common and it persist in postpartum period also because of added blood loss during delivery. Since many patients are coming for institutional delivery now a days because of NRHM-Janani Suraksha Yojna and monitory incentives. We can get hold most of these patients in the postpartum period and this is the time to detect and adequately treat iron deficiency before she goes back and get lost to follow up.

Postpartum anaemia increase the morbidity of mother like it aggravates puerperal sepsis, causes delayed wound healing, sub involution of uterus etc. In baby it causes poor growth trajectory, reduced adult height & delayed psychomotor development. In our scenario pregnancy occurs at very short interval. Women conceive even prior to replenishment of iron stores which gets depleted in previous pregnancy. This aggravates pregnancy complication like pre-eclampsia, APH.

Therefore the role of single shot intravenous iron replenishment becomes most important in our situations and this can be effectively done during postpartum period, When the patient is in our care. iron therapy is the definitive treatment of iron deficiency anaemia. Noncompliance and intolerance to oral iron limits its efficacy. Then Parenteral iron therapy comes in picture. Multiple injections reduces the compliance of Iron sucrose complex in comparison to FCM. Our aim of study was to assess efficacy and safety profile of FCM in postpartum deficiency anaemia.

Material and Methods

The study was carried out in the dept. of obstetrics & gynaecology PMCH, Patna BIHAR from nov.2013 to April 2015. 140 women within 10 days of delivery having moderate anaemia (7-10 mg/dl) were included in the study. all women were randomized in to two groups. Group -1 received intravenous FCM and Group-2 received oral ferrous sulphate. Total dose of iron required was calculated by GANZONI FORMULA.

Total dose of iron =Body wt. (in kg) x (14-baseline Hb) x 2.4 + 500

Where 14-target Hb (in gm/dl), 2.4-unitless conversion constant. 500 = target iron store in mg.

FCM was given as slow intravenous infusion. maximum single dose not exceeding 15 mg/kg or 1000 mg per dose in 250 ml of 0.9 % normal saline over 15 min. during infusion subject was kept under strict observation with resuscitative measures available in the ward. FCM was repeated weekly up to calculated dose or maximum 2500 mg. second group was instructed to take ferrous sulphate tablet 200mg(containing 60mg elemental iron) 3 times daily 1 hr before meals for 6 weeks. Both the groups were given deworming therapy along with folic acid 5 mg tablet once a day. All subjects were followed at 3 wks & 6 wks. CBC, Red cell indices and serum iron parameters were done at the time of recruitment and at 6 wks. only CBC repeated at 3 wks also. subject in oral group have higher incidence of gastrointestinal

side effects. Urticaria, muscle cramps, headache were present in parenteral group. No patients in parenteral group have post treatment injection site pain. Coulter haematology analyzer was used for Hb & MCV determination. Serum ferritin was detected by using ferritin ELISA KIT. P value <0.05 was considered to be significant.

Results

The total no. of selected patients during the study period was 140. Demographic profile were comparable in both the groups. mean age was 23.03 & 24.84 yr. in Gr.1 & 2 respectively majority of women were para-2.mean G.A was 38 wks at the time of delivery

Table 1: Baseline haematological parameter

Parameters	Group 1 N=70 Mean+/-SD	Group 2 N=70 Mean+/-SD	P Value
HB (gm/dl)	8.6+/-1.0	8.6+/-0.9	0.790
MCV (fl)	77+/-8.9	76.3+/-9.2	0.422
Serum iron (mcg/dl)	51.4+/-26.3	55.7+/-21.2	0.199
TIBC (mcg/dl)	416.7+/-37.8	422.5+/-37.1	0.549
Transferrin saturation (%)	12.4+/-5.3	13.2+/-4.6	0.530
Ferritin (ng/dl)	13.1+/-7.0	13.3+/-7.2	0.849
MCH (pg)	24.5+/-3.7	24.4+/-3.9	0.793
MCHC (g/dl)	30.8+/-2.7	31.1+/-2.3	0.492

Table 2: Post treatment haematological parameter

Parameters	Group1 N=70 Mean+/-SD	Group2 N=70 Mean+/-SD	P Value
HB (gm/dl)	11.9+/-1.2	10.5+/-1.3	0.000
MCV (fl)	90.3+/-40.5	80.2+/-6.5	0.000
Serum iron (mcg/dl)	115.8+/-19.9	90.4+/-30.4	0.000
TIBC (mcg/dl)	325.7+/-44.6	388.4+/-47.3	0.000
Transferrin saturation (%)	24.4+/-5.4	17.1+/-6.8	0.000
Ferritin (ng/dl)	152.7+/-32.6	18.4+/-6.8	0.000
MCH (pg)	29.8+/-1.8	27.1+/-3.2	0.000
MCHC (g/dl)	33.6+/-1.4	31.6+/-4.0	0.000

Oral group has higher no. of lost to follow up compare to parenteral group.68 subject in parenteral group and 53 subject in oral group completed the study.

Discussion

In our study both groups were comparable in all haematological parameter at the time of recruitment. At 3 wks and 6 wks of therapy FCM showed better and earlier response than oral iron. correction of anaemia (Hb>11 gm/dl) was 73% in FCM received women whereas only 44% in women taking oral iron, this difference was highly significant (p=0.001).VAN WYCK *et al* showed more subject in parenteral group achieved Hb level >12 gm/dl than oral group. Mean Hb rise was 3.3 gm/dl in FCM group whereas 2 gm/dl in oral group ((p=0.000). serum ferritin which indicates iron stores of the body it increased markedly in FCM group (shown in table -2). so replenishment of iron store by FCM is clinically useful and it will prevent recurrence of Iron deficiency anaemia. serum transferrin saturation, serum iron level, red cell indices was more improved in cases of FCM. Greater fall in total iron binding capacity in FCM group than oral iron group. 100% compliance in patients of FCM group only 90% in oral group.

Conclusion

FCM is more efficacious in improving haemoglobin levels, more Earlier and significantly restores other haematological parameter including iron stores.it has comparable side effect profile and convenient dosing schedule with no need of test dose.

Thus it shows us a ray hope to curb the evil of anaemia which is highly rampant in Indian post-partum women.

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