Original Research Article

Evaluation of the efficacy, tolerability and safety of multiple dose intravenous iron sucrose v/s intravenous ferric carboxymaltose in iron deficiency anaemia in postnatal women

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Abstract

Background: Among various parentral iron preparation, intravenous iron sucrose is most commonly used drug. In postpartum cases single dose intravenous (FCM) ferric carboxymaltose is an effective to cure anaemia. The primary objective of this study was to describe benefits of single dose FCM in postnatal anaemic women. **Methods:** This was an observational prospective non randomized study of post natal anaemic women, who receive i/v iron sucrose and i/v iron FCM. Data was recorded in predesigned coded case report forms and statistical analysis was performed. **Results:** In present study mean haemoglobin level achieved in intravenous ferric corboxymaltose group was significantly higher and rate of increase in haemoglobin level was also significantly higher in carboxy maltose group then intravenous iron sucrose group. Ferric carboxy maltose elevate serum ferritin and restore iron faster than intravenous iron sucrose. **Conclusions:** Single dose i/v FCM is effective for the treatment of postpartum anaemic women. When compared with i/v iron sucrose, i/v FCM is well tolerated, prompts a rapid Hb response, demands less number of doses and less hospital stay, hence less number of adverse effects.

Key Word: Haemoglobin, ferric carboxymaltose, iron sucrose.

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INTRODUCTION

Anaemia is one of major contributing factor in maternal mortality and morbidity in third world countries and according to WHO it contributes to 20% maternal death. Postpartum anaemia is observed in up to 27% of women. Postpartum anaemia arises frequently[1], affects low socio-economics women disproportionately. it imposes a substantial disease burden during a critical period of mother-child interaction[2] and may give rise to lasting developmental deficits in infants of affected mother[3]. infants born to mother , who are anaemic at 10 week postpartum, show evidence of developmental delay, which are irreversible even after subsequent treatment of anaemia in mother. In postpartum women, iron deficiency is the most common cause of anaemia[4]. Although iron therapy is indicated in anaemic women both oral iron agents and parentral iron preparation, can not achieve optimal , effective iron replacement. Oral preparation is limited by GI upset and patient nonadherence[3-5], whereas treatment with i/v iron either risks anaphylaxis when using iron dextran[5] or require multiple injection of low dose of available non dextran containing agents[6-7]. Ferric carboxymaltose complex is a non dextran containing investigational iv iron agent designed to be administered in large doses by rapid i/v injection. The ability to safety inject a single dose as large as 1000 mg is as inject a

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single dose as large as 1000mg is as little time as 15 min and there by reduce the need for multiple i/v iron infusion, which makes this agent an ideal iron therapy for the treatment of postpartum anaemia. To determine whether large dose i/v iron administration is an effective iron therapy. We conducted a randomized controlled trial to compare the efficiency of single large dose iron with that of multiple doses of i/v iron sucrose, in the management of patient with postpartum anaemia.

METHODS

This was a hospital based prospective comparative study conducted in a tertiary level hospital, department of obstetrics and gynecology, m.g.m. medical college and m.y. hospital indore (m.p.)., after institutional ethical committee approval. We screened patients for potential eligibility, after vaginal and caesarean delivery at 24-48 hour post delivery up to 6 weeks. They were enrolled and randomly assigned to receive either i/v FCM or i/v iron sucrose. The amount of iron needed was calculated by the following formula: body weight (kg) × 2.3 × (15 – patients Hb g/dl) + 500 or 1000 mg (for stores). The study was comprised of 200 cases which were distributed randomly in two groups consisting of 100 cases in each group. Group A receive iron FCM therapy while Group B receive iron sucrose therapy. Inclusion criteria – Postpartum women after vaginal or caesarean delivery with diagnosis of IDA on blood picture. Hb % 6- 10 gm post natal from 24 hr to 6 weeks. Exclusion criteria were anaemia other than IDA, H/O allergy to intravenous iron infusion, vitamine B 12 or folate deficiency, chronic bleeding, previous blood transfusion, haematologic disease, liver disease or renal disease. A detailed clinical history (antenatal, intranatal and postnatal), previous treatment history including iron therapy, compliance with oral iron and chronic medical illness was taken. Detailed examination including general physical examination and obstetric examination was done. Investigation specific to anaemia included haemogram, reticulocyte count and peripheral blood smear, red cell indices including mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), RDW, Hb electrophoresis and serum feritin level, serum iron, Total iron binding capacity (TIBC) and transferin saturation were done. Iron requirement was calculated according to Ganzoni's formula[5] Iron required (mg) = total iron deficit [mg] = body weight [kg] × (target Hb (14 gm/Dl) - actual Hb) ×0.24+storage iron (500 or 1000) mg.

Group A: intravenous FCM . single dose of FCM was injected (500 mg/10 ml or 1000mg / 20 ml) in 250 ml of 0.9% normal saline over 15 minute period.

Group B:- intravenous iron sucrose injection. It was given as 200mg elemental iron (2 ampoules of 5ml) in 100 ml of 0.9 % normal saline infusion, over a period of 30 minute period alternate days up to 5 doses or as calculated deficit. Stastical analysis: for comparision between two groups independent student t test was applied. To examine efficacy, we defined the primary efficacy endpoint as the proportion of patient with a Hb increase at 2 weeks. 4 weeks and 6 week after starting of therapy. Secondary measure of efficacy included the proportion of patient attaining a Hb more than 10 gm/Dl. maximum increase in ferritin level at 2weeks and 6 weeks after therapy. We defined secondary end point as the proportion of patients with achievement of target haemoglobin (11 and > 11 gm/dl) at 2, 4 and 6 weeks of therapy. We closely moniterd blood pressure and all adverse events were recorded in all patients, before, during and after administration of i/v iron. we recorded adverse events from the day of consent through the completion of the study(day 42). We used computerized random number generation to prepare random treatment assignments.

RESULTS

In our study in group A 35% cases were primiparous and 65% cases were multiparous and in group B 49% cases were primiparous and 51% cases were multiparous. Most of patient in both groups are illiterates and belongs to lower socioeconomics status. Table 1 In present study we found that mean level of before starting therapy were 7.28 and 7.82 in group A and group B respectively. There were increase of 2.02 gm/dl in Hb level after two week in group A and 1.14 gm/dl increase of Hb level in group B. After 4 week there were rise of 3.18 in group A and 2.13 in group B and after 6 week these difference further increase, 4.22 n group A while 3.45nin group B. Table 2 In present study 83% cases achieved the targeted haemoglobin after 6 weeks of therapy in Group A while 73% cases achieved targeted haemoglobin in group B. Table 3. The mean ferritin level at start of therapy in group A was 43.299 and group B was 44.759. the mean ferritin level after treatment with FCM and IS was 212.854 and 179.032 respectively, which is also statistically significant. Table 4 MCHC at start of therapy in group A was 29.642 gm/dl and 29.808 gm/dl in group B, after 6 weeks there is statistically significant change in its value. MCHC was 32.527 gm/dl in group A and 31.504 gm/dl in group B after 6 weeks. MCV value also increase after 6 weeks of therapy which is statistically significant in FCM group. Table 5. In both groups most of the patients were normally delivered. In FCM group 9% cases had undergone caesarean section while in group B 12% cases undergone caesarean section. In group A 2%

patients were suffered from shivering while in group B, 2% patients were suffered from rashes and % suffered from shivering. In present study apart from few minor reactions like rashes and shivering, no major adverse reaction were seen, no anaphylactic reaction was detected and not any venous thrombosis seen which were comparable to other studied. All patients made uneventful recovery.

DISCUSSION

In India iron deficiency in pregnancy and postpartum period is a major health issue , our study indicate that postpartum anaemia can be treated effectively by ferric corboxymaltose as compared to iron sucrose with additional advantage and less side effects and with better compliance. Illiteracy and poverty causes poor maternal health because of poor nutrition, refusal for taking nutritional and health services provided by government due to superstition it all compromises quality of female life. The rise in mean haemoglobin level after two week of therapy in Nalini Sharma *et al*[8] was 2.94 in FCM group while 1.7 in IS group which is correspond with present study. The rise in mean haemoglobin level after four week of therapy in Ruchika Garg *et al*[9] was 3.95 in FCM group while 3.32 in IS group which is correspond with present study. Breymann *et al* reported the mean Hb rise was 3.37 in FCM group and 3.29 in IS group after 12 week of therapy. In a study conducted by Seid *et al*[10], the rise in haemoglobin after 6 weeks of therapy were higher in FCM group compare to iron sucrose group which is correspond with present study. Hussain *et al*[11] compared FCM and iron dextron in iron deficiency anaemia and showed FCM had greater efficacy will favourable safety profile in the same study mean increase in serum ferritin was 543.2 and 319.7 hg/ml in FCM and iron dextran groups. In present study mean haematological parameter (MCHC & MCV) increase statistically significantly in group A as compare to group B after 6 weeks of therapy which is correspond with study conducted by Ruchika Garg *et al*[12].

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