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Original Research Article

Comparative study to evaluate intravenous iron sucrose with oral ferrous sulphate for treatment of anaemia in pregnancy

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ABSTRACT

Background: This study aimed to compare the efficacy of oral iron and intravenous iron in improving haemoglobin in iron deficiency anemia.

Methods: This was randomised controlled trial conducted on 100 pregnant women who attended Gynaecology & Obstetrics OPD for antenatal check-up in June 2019 to May 2020 in the Department of Obstetrics and Gynaecology at Hindu Rao Hospital and associated NDMC Medical College, New Delhi. All pregnant women at gestation age 20 to 32 weeks with confirmed diagnosis of iron deficiency anemia were divided into two groups. In the group A, oral iron was given and in the group B, intravenous iron sucrose was given in divided doses. Haemoglobin was checked after 2 weeks, 4 weeks and 6 weeks. For both groups paired sample test is applied and comparison (in term of rise in haemoglobin from pre to post) of both groups was found to be significant. The results were analyzed by student's t-test and chi-square test.

Results: Haemoglobin values were found to be increased in both the groups at 2nd 4th and 6th weeks. When both the groups were compared the rise in the values was higher in the IV iron sucrose group 1.6gm than oral iron 0.8gm after two weeks of treatment.

Conclusions: Intravenous iron sucrose treated iron deficiency anemia of pregnancy faster and more effectively than oral iron without serious side effects.

Keywords: Iron deficiency anemia, Iron sucrose, Oral iron therapy

INTRODUCTION

Anemia is defined as a group of conditions that result from an inability of erythropoietin tissue to maintain normal haemoglobin concentration in the body.¹ Haemoglobin is the protein in our RBC that is responsible for carrying oxygen to our tissues. In India more than 90% of anemia cases are due to iron deficiency anemia.^{2,3} globally it is estimated that 37% of pregnant women are anemic.⁴ The prevalence of anemia in pregnant women is 52.5% according to NFHS 5 (2019 to 2021).⁵ The prevalence of iron deficiency anemia is much higher in developing countries than developed world due to malnutrition and

lack of prenatal iron supplements in under developed countries.⁶ The centre for diseases control and prevention defines anemia when haemoglobin and haematocrit values are less than 11gm and 33% in the 1st and 3rd trimester.^{7,8} Anemia occurs when our body does not have enough iron. Most common cause of iron deficiency anemia in females is loss of iron in the body due to heavy menstruation, poor diet, intestinal diseases that interfere with iron absorption internal bleeding because of stomach ulcer, and polyps in the colon or intestine, multiple pregnancies.⁹ Iron deficiency anemia gets aggravated by increase requirements during pregnancy.¹⁰ There is great demand for iron to meet the requirements of red blood cell mass

expansion in the mother, fetal and placental blood and blood loss at delivery.¹¹ The adverse effects of anemia include low birth weight, preterm delivery, infections, reduce immune-competence, poor cognitive development, reduces work capacity and increase maternal mortality.¹² The provision of iron supplements to pregnant women in the form of oral/parental iron for prevention and treatment of iron deficiency anemia is considered which can also reduce the need for blood transfusion.¹³ Oral iron is associated with side effects, non-compliance and takes a long time to correct anemia. Parental iron therapy is therefore considered an alternative for oral iron defaulters.¹⁴ The present study was aimed to compare the efficacy safety of iron sucrose and oral iron for treatment of iron deficiency anemia in pregnancy.

METHODS

All pregnant women who attended antenatal check-up at Hindu Rao Hospital New Delhi over a period of one year from June 2019 to May 2020 screened for anaemia with gestation age between 20 to 32 weeks. Women with established iron deficiency anemia with HB 6-8 gm/dl were enrolled for study. This was a prospective study where 100 anemic antenatal women were randomized into two groups. Iron deficiency anemia was diagnosed on the basis of peripheral blood film and complete blood count.

Inclusion criteria

Singleton and uncomplicated pregnancy, gestation age between 20 to 32 weeks, HB between 6-8 gm/dl, willing for enrolment in study and likely to come for follows up were included.

Exclusion criteria

Allergic to parental iron, patient with HB <6 gm/dl >10 gm/dl, patient with acute or chronic infections, patient with medical complications like severe hypertension, diabetes, asthma, hepatitis, fever at the time of visit were excluded.

Total iron dose requirement is calculated by weight in kg x [target HB - initial HB] x 2.4 + 500 mg.

Ethical committee clearance was obtained after taking consent, detailed history and examination was done. The women were divided into 2 groups.

Oral group: oral iron ferrous sulphate 100 mg BD was given to the patients for 6 weeks. Patients were instructed to not to take coffee or tea after taking iron tablet. HB was repeated at 2, 4 and 6 weeks after beginning of oral treatment.

IV sucrose iron group: Parental iron sucrose was given to patients after calculating the total dose required to the patient in divided dose thrice weekly. 200mg of iron sucrose was mixed in 100 ml of normal saline, first few ml was infused intravenously over a period of 15 minutes, if

there was no adverse reaction remaining amount was infused over 30 minutes. Oral iron was stopped during this period. Patients were closely monitored for any adverse reactions. HB was repeated after 2, 4 and 6 weeks of beginning of iron therapy.

RESULTS

Majority of pregnant women enrolled in the study group were between 26 to 30 years (65%) followed by 31 to 34 years (23%), 22 to 25 years (10%) and 2% were in the age group 18 to 21 years (Table 1).

Table 1: Distribution of pregnant women on the basis of age.

Age distribution (years)	No. of women	% age
18-21	2	2
22-25	10	10
26-30	65	65
31-34	23	23
Total=100		100

Majority of pregnant women enrolled in the study group were gravid 3 - gravid 4 (72%), followed by gravid 2 (18%) and Gravid 5 (10%) (Table 2).

Table 2: Distribution of pregnant women based on parity.

Parity	No. of women	% age
G2	18	18
G3-G4	72	72
G5	10	10
Total=100		100

Majority of pregnant women enrolled in the study group were 52% 7gm HB, 39% with HB 6gm and 9% with HB 8gm (Table 3).

Table 3: Distribution of pregnant women based on haemoglobin concentration.

Haemoglobin in gm	No. of women	% age
8	9	9
7	52	52
6	39	39
Total=100		100

Table 4: Distribution of pregnant women based on fetal growth retardation.

FGR in gm	No. of women	% age
8	0	0
7	7	7
6	9	9
Total=100		100

At HB 6gm 9% of the babies were having fetal growth retardation, at HB 7gm 7% of babies were having fetal growth retardation and at HB 8gm no fetal growth retardation seen (Table 4).

At HB 6gm 7% of pregnant women had pre term deliveries, at HB 7gm 3% of pregnant women had pre term deliveries and at HB 8gm no pre term delivery occurred (Table 5).

Table 5: Distribution of pregnant women based on pre term delivery.

Haemoglobin in gm	No. of women PTD	% age
8	0	0
7	3	3
6	7	7
Total=100		100

At HB 6gm 9% of pregnant women had intrauterine fetal death, at HB 7gm 1% of pregnant women had intrauterine fetal death and at HB 8gm no intrauterine fetal death occurred (Table 6).

At HB 6gm 18% of pregnant women had gestational hypertension and 1% women had preeclampsia, at HB 7gm 11% of pregnant women had gestational hypertension

and at HB 8gm no gestational hypertension occurred (Table 7).

Table 6: Distribution of pregnant women based on intrauterine fetal death.

Haemoglobin in gm	No. of IUD	% age
8	0	0
7	1	1
6	9	9
Total=100		100

Table 7: Distribution of pregnant women based on preeclampsia and gestational hypertension.

Haemoglobin in gm	No. of PE-GHTN	% age
8	0	0
7	11 GHTN	11
6	18 GHTN and 1PE	18 and 1
Total=100		100

Pregnant women with anemia HB 8gm, 7gm and 6gm were randomly divided into two groups: Group 1 received oral iron and Group 2 received IV iron. In group 1 HB rise after 2 weeks, 4 weeks and 6 weeks was 0.8gm, 1.6gm and 2.4gm. and in group 2 HB rise after 2 weeks, 4 weeks and 6 weeks was 1.6gm, 2.12gm and 3.72gm (Table 8).

Table 8: Distribution of pregnant women based on haemoglobin rise after treatment with oral iron and intravenous iron therapy.

Study groups	Iron therapy	Hb at the time of recruitment (gm)	After 2 week Hb rise (gm)	After 4 week Hb rise (gm)	After 6 week Hb rise (gm)
Group 1 (9 women)	Oral iron	8	8.8	9.6	10.4
	IV iron	8	9.6	10.12	11.72
Group 2 (52 women)	Oral iron	7	7.8	8.6	9.4
	IV iron	7	8.6	9.12	10.72
Group 3 (39 women)	Oral iron	6	6.8	7.6	8.4
	IV iron	6	7.5	8.12	9.73

DISCUSSION

In this study we demonstrated improvement in haemoglobin concentration at all time points after initiation of iron treatment (6 weeks after start of therapy) the rise in haemoglobin is more with IV group 3.72 gm after 6 weeks of start of treatment than with oral Iron 2.4 gm after 6 weeks of treatment which is similar to Froessler et al.¹⁵ Another research that agreed with our current study was conducted by Kriplani et al in which pregnant women were enrolled for 200 mg iron sucrose twice weekly no significant side effects or anaphylactic reaction occurred.¹⁶ When analyzed across time it was found that intravenously administered iron sucrose was significantly more likely to have higher haemoglobin from base line than those patients with orally administered iron at every

point measurement [2 weeks, 4 weeks and 6 weeks] during the course of study similar to Ragip et al and Al-Momen et al.^{17,18} Prenatal iron supplementation improves iron store in neonates.¹⁹ The first choice treatment of iron deficiency anemia is oral iron replacement because of its effectiveness, safety and low cost. Oral iron supplementation is adequate in most clinical conditions and in absence of inflammation, significant ongoing blood loss can correct anemia.²⁰ Intravenous iron sucrose reduced the requirement of blood transfusion among pregnant women with severe anemia. Blood transfusion is mandatory in severe anemia (Hb <5 gm /dl any time in pregnancy and Hb <6 gm/dl if women present after 36 weeks of gestation). Blood transfusion is also indicated in case of abnormal fetal oxygenation, post-partum anemia with shock, severe acute blood loss in APH, and anemia

with sepsis. Iron deficiency is associated with preterm labour, peripartum haemorrhage and a small but measurable increment in maternal mortality. Oral iron, the current front line therapy for iron deficiency of pregnancy is associated with gastrointestinal adverse events in the majority of women, with resultant poor adherence, in forming on a need for IV Iron.²¹ While Iron sucrose, the time-honoured standard for iv iron repletion in pregnancy is effective and safe, require 4 to 7 visits, each requiring the placement of an iv access device. Intravenous iron is superior to oral iron with respect to faster increase in haemoglobin and faster replenishment of body iron stores.

CONCLUSION

In view of the failure of oral iron in the correction of anemia to significant extent in pregnant women with moderate anemia. Intravenous administration of iron sucrose therapy is more effective in achieving the optimum result because of better compliance and absorption.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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