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Original Research Article

Comparative study of oral iron and intravenous iron sucrose for the treatment of iron deficiency anemia in pregnancy

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ABSTRACT

Background: The aim of this study was to compare the efficacy and safety of iron sucrose with oral iron in the treatment of iron deficiency anemia of pregnancy.

Methods: An interventional comparative study was conducted at Jhalawar Medical College, Jhalawar involving 80 pregnant women with iron deficiency anemia from March 2016 to August 2016. Inclusion criteria were gestational age between 24-32 weeks with established iron deficiency anemia, with hemoglobin between 7-10g/dl. Target Hemoglobin was 11 g/dl. In intravenous iron sucrose group iron sucrose dose was calculated from following formula: total iron dose required (mg) = 2.4 x body weight in Kg x (target Hb – Patient's Hb g/dl) + 500. In oral iron, group patient received ferrous-sulphate 335 mg daily BD. Hb level were reviewed at 2, 4, 6 weeks. **Results:** Change in Hemoglobin level from baseline significantly higher in IV iron group than oral iron group. In IV

Results: Change in Hemoglobin level from baseline significantly higher in IV iron group than oral iron group. In IV iron, group mean value of baseline Hb was 8.07 ± 0.610 g/dl and in oral iron group was 8.48 ± 0.741 g/dl. At the end of 6-week mean hemoglobin in IV iron sucrose was 10.66 ± 0.743 g/dl and in oral iron group was 10.08 ± 0.860 g/dl. **Conclusions:** Intravenous iron sucrose elevates more Hb than oral iron, with less adverse effects.

Keywords: Hemoglobin, Iron sucrose, Iron deficiency anemia, Oral Ferrous Sulphate

INTRODUCTION

Anemia is a major public health problem worldwide. The global prevalence of anemia during pregnancy is estimated by World Health Organization to be 47.4%.¹ According to recent WHO figures, India is included in the list of countries with high prevalence of anemia in pregnant women (>40%).¹ The prevalence of anemia among all age groups is high in India. Every second woman is anemic (55%).² Iron deficiency starts in childhood, worsens in adolescence and gets aggravated in pregnancy. The WHO defines anemia in pregnant women as hemoglobin level below 11 g/dl.

The Centers for Disease Control (CDC) recommends that hemoglobin in pregnant women should not be allowed to fall below 10.5 g/dl in the second trimester, taking into account the physiological changes of pregnancy.³ The most common causes of anemia are poor nutrition, iron deficiency, malaria, hook worm infestation, HIV infection and hemoglobinopathies.^{4,5} Anemia is responsible for adverse obstetric outcome like cardiac failure, pre-eclampsia, antepartum hemorrhage, post-partum hemorrhage, puerperal sepsis, lactation failure, delayed wound healing.⁶ Anemia is a major cause of maternal mortality. Anemia accounts for 20% direct and 20% of indirect maternal deaths.⁷ Anemia leads to increased risk of blood transfusion during postpartum period. Iron therapy before delivery may reduce the transfusion rate for iron deficient women.

The aim of this study was to compare the efficacy and safety of iron sucrose with ferrous sulphate in treatment of iron deficiency anemia of pregnancy.

METHODS

A interventional comparative study was conducted at OBG Dept. Jhalawar Medical College and hospital, Jhalawar from March 2016 - August 2016. All women attending antenatal clinic were screened for anemia between 24-32 weeks of gestation with sample size of 80 pregnant women.

Iron deficiency anemia was diagnosed on basis of peripheral blood film, complete blood count.

Inclusion criteria

- Singleton and uncomplicated pregnancy
- Gestational age between 24-32 weeks
- Hb between 7-10 g/dl
- Willing for enrolment in study
- Likely to come for follow up

Exclusion criteria

- Allergic to parenteral iron
- Patient with Hb <7g/dl > 10g/dl
- Patient with obstetrical complications
- Patient with acute and chronic infections

Ethical committee clearance was obtained. After taking consent, detailed history and examination of patient was done. Iron deficiency anemia was diagnosed. The women were divided into 2 groups.

Oral group: Oral iron Ferrous Sulphate 335 mg containing 100 mg of elemental iron BD was given to the patients for 4 weeks.

IV group: Parenteral iron sucrose was given to patients.

Oral group: Patients received Ferrous Sulphate 335 mg containing 100 mg elemental iron BD orally for 4 weeks. Patients were instructed to take the tablets with empty stomach and not to take coffee or tea after taking tablet. Hb was repeated at 2, 4 and 6 weeks after beginning of oral treatment.

Total iron dose was calculated by following formula:-

Body weight (kg) x (target Hb – pt's Hb)g/dl x 2.4 + 500 mg

Target Hb was 11 g/dl and weight is patient's prepregnany weight in Kg.

Calculated dose of iron sucrose was given in divided doses thrice weekly. 200 mg of iron sucrose was mixed in 100 ml of normal saline, the first few ml was infused intravenously over a period of 15 min, if there was no adverse reaction remaining amount was infused over 30 min period. Oral iron was stopped during study. Patients were closely monitored for any adverse reaction and emergency drugs like steroid, antihistamines were kept ready. If there was any adverse reaction, drip was stopped immediately and treated accordingly. Hb was repeated after 2, 4, 6 weeks of beginning of iron therapy.

At first visit:

Detailed history, physical examination and obstetrics examination was done. Following investigations were done for each patient:

- CBC
- Peripheral blood film
- Urine examination

All women were given 500 ug folic acid daily. Deworming was done with Albendazole 400 mg. Patients were advised to take high protein diet.

During follow up visit:

- Patients were enquired about adverse reaction.
- CBC was repeated

RESULTS

Table 1: Distribution of Hb in different time in oraliron.

Hb (g/dl)	Mean (g/dl)	Std. dev.	F value	P value
Base line Hb	8.4833	0.7418		
2nd week Hb	8.7333	0.7396	23.743	< 0.0001*
4th week Hb	9.2033	0.825		
6th week Hb	10.0867	0.8609		

Table 2: Distribution of Hb in different time in IViron.

Hb (g/dl)	Mean (g/dl)	Std. dev.	F value	P value
Base line Hb	8.0767	0.6100		
2nd week Hb	8.8167	0.6164	82.351	< 0.0001*
4th week Hb	9.7900	0.7406		
6th week Hb	10.660	0.7430		

80 women were included in the study. At the end of study, we had complete data of 60 patients (30 in each group). 12 patient dropped out from oral iron group and 8 patients dropped out from IV iron group.

Initial demographic and clinical characteristic were similar in both groups. In oral group mean baseline Hb was 8.48 ± 0.741 g/dl and in IV group mean baseline Hb was 8.07 ± 0.610 g/dl. An increase in Hb was observed from baseline to 6 weeks in each group, but the increase in IV group is more than oral group.

Mean Hb was 8.733 ± 0.739 g/dl at 2 weeks, 9.20 ± 0.825 g/dl at 4 weeks, $10.08\pm.860$ g/dl at 6 weeks compared to IV iron which was 8.81 ± 0.616 g/dl at 2 weeks, 9.79 ± 0.740 g/dl at 4 weeks, 10.66 ± 0.743 g/dl at 6 weeks. There is a significant variation (p<0.005) in Hb in

different times in oral and IV iron groups but according to mean Hb levels were increased in succeed time. Rise of mean Hb from baseline to 6 weeks in oral group is 1.6 g/dl where is in IV group it is 2.59 g/dl. Target Hb achieved by patients in oral iron group was 16.66% while in IV iron group was 36.66%.

Table 3: Comparison of Hb in IV and Oral Iron in	n different time period.
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Hb (g/dl)	Group	Mean (g/dl)	Std. dev.	T value	P value
Base line Hb	IV iron	8.0767	0.61008	1.7483	0.0857
	Oral iron	8.4833	0.74189		
2nd week Hb	IV iron	8.8167	0.61649	0.474	0.637
	Oral iron	8.7333	0.73968		
4th week Hb	IV iron	9.7900	0.74062	2.897	0.005*
	Oral iron	9.2033	0.82566		
6th week Hb	IV iron	10.6600	0.74306	2.761	0.008*
	Oral iron	10.0867	0.86093		

Table 4: Adverse reactions with oral and IV iron.

Symptoms	Oral iron	IV iron
Nausea, vomiting	8	0
Constipation	6	0
Fever/chills	0	1
Rashes	0	0
Dizziness	0	3
Thrombophlebitis	0	1
Total	14	5

There is no significant difference in Hb level between iron sucrose and oral iron group (p>0.05) in baseline and 2nd week. But found significant difference in 4th and 6th week (p<0.005) (Table 3).

In oral iron group 46.66% show adverse reaction while in IV group 16.66% show adverse reaction. None major anaphylactic reaction noted with iron sucrose.

DISCUSSION

Iron deficiency anemia is a major public health problem worldwide. Increased requirements aggravate IDA during pregnancy. There is a great demand for iron to meet the requirement of red blood cell mass expansion in the mother, fetal and placental blood and blood loss at delivery.^{8,9} This is aggravated by poor absorption of iron due to pregnancy induced nausea, vomiting, motility disorder with indigestion and phytate rich Indian diet.^{8,9} Other factors responsible for high incidence of IDA in India include early marriage, teenage pregnancy, multiple pregnancies, less birth spacing, low iron and folic acid intake and high incidence of hookworm infestation in Indian population.¹⁰

In view of high prevalence of anemia in pregnancy and serious adverse consequence in both mother and baby, management of anemia in pregnancy was accorded a very high priority. There are various forms of treatment for IDA. Over the past years, various oral, intramuscular and intravenous preparations of iron have been used for correction of IDA in the pregnant patients.¹¹⁻¹³

The study confirmed that parenteral administered iron sucrose elevated hemoglobin more than oral iron.

Al Momenet al¹³, in their study compared 52 women treated with intravenous iron sucrose and 59 women treated with 300 mg oral iron sulfate. Intravenous iron sucrose complex achieved significantly higher hemoglobin levels 128.5 ± 6.6 versus 111.4 ± 12.4 g/l in the oral iron group (p<0.001) in a shorter period 6.9 ± 1.8 versus 14.9 ± 3.1 weeks in control group (p≤0.001). Iron sucrose complex showed no major side effects while 4 (6%) of the ferrous sulphate could not tolerate ferrous sulphate, 30% complained of gastro intestinal symptoms. These results are similar to our study.

Deeba S et al¹⁴, in their study concluded that difference in Hb from baseline in IV group was 1.72 ± 0.484 at 2 weeks, 2.18 ± 0.865 at 4 weeks, 2.89 ± 0.5989 at 6 weeks compared to oral iron, which was 0.5550 ± 0.456 at 2 weeks, 1.39 ± 0.4402 at 4 weeks, and 1.9 ± 0.3020 at 6 weeks. P value was 0.000 which was clinically significant and showed that Hb levels were increased more in intravenous group. These results are similar to our study.

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 under supervision is a better alternative for women with moderate anemia. To conclude, intravenous administration of iron sucrose is safe, highly efficacious with better compliance for the treatment of iron deficiency anemia. Iron sucrose therapy is more effective in achieving the optimum results because of better compliance, better absorption.

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