Comparative Study of Oral Iron and Intravenous Iron Sucrose for Anaemia Prophylaxis in Pregnancy

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ABSTRACT

Introduction: According to WHO it is estimated that ~56 million pregnant women are anaemic, among which 75-80 % have iron deficiency anaemia. Even the most optimal diet is not sufficient to meet the increased iron demands in pregnancy, therefore iron supplementation is a must during pregnancy. The first choice in the treatment is oral iron because of its effectiveness, safety, and lower cost. However there are problems with oral intake such as poor compliance. Hence a predetermined dose of parental iron given intermittently may have an advantage. Keeping this in mind, this study has been designed to compare the efficacy of daily oral iron supplementation and fixed schedule of intravenous iron sucrose given in pregnancy for anaemia prophylaxis.

Material and methods: 200 patients between 16 – 20 weeks of gestation with singleton pregnancy and Hb level 8-11 gm/dl attending antenatal OPD were recruited and devided in two groups. Group A was given oral iron tablets containing100mg of elemental iron. Group B was given a total of 1000 mg of intravenous iron sucrose divided into five doses of 200 mg each at weekly intervals. Estimation of haemoglobin was started 4 weeks after commencement of iron therapy and then repeated every 4 weeks till 36 weeks of gestation, pre-delivery and postpartum.

Results: Haemoglobin repeated at term and postpartum did not show significant difference in the two groups. In group A incidence of nausea and vomiting was significant while in group B incidence of superficial thrombophlebitis was significant.

Conclusion: The increment in haemoglobin with iron sucrose was comparable with oral iron. No significant differences were found in immediate postpartum maternal haemoglobin levels. Side effects noted in the study were minimal.

Keywords: Oral iron, intravenous iron, anaemia prophylaxis

INTRODUCTION

Iron deficiency anaemia is the most common nutritional deficiency anaemia world wide with prevalence maximum among pregnant and postpartum women.[1] the prevalence of iron deficiency anaemia in developing countries is approximately 52%.[2] Iron requirement is not evenly distributed throughout pregnancy. In first trimester there is saving of iron due to caesation of menstruation (0.56 mg/day), with the requirements maximum during the latter half of pregnancy.[3] Degree to which iron deficiency anaemia develops depends upon the pre-pregnancy iron stores and physiological changes of iron metabolism during pregnancy. Haemodynamic changes include generalized vasodilatation, plasma volume expansion, increase in red cell mass.[4] Some studies suggest that during early pregnancy there is some decrease in erythropoietic activity, reticulocyte count.[5] A rise of serum ferritin may be observed.[4,6] In the latter half of pregnancy iron demand and oxygen consumption increases progressively. Although iron requirement decreases during the first trimester it increases to 4 to 6 mg during the second and third trimester.[7] Maximum haematological changes- red blood cell expansion occurs during the later half of pregnancy[8], therefore during the last 6-8 weeks of pregnancy iron demand may go upto 10 mg/d.[9] Even the most optimal diet is not sufficient to meet the increased iron demands in pregnancy[7], therefore iron supplementation is a must during pregnancy

According to WHO it is estimated that ~56 million pregnant women are anaemic, among which 75-80 % have iron deficiency anaemia.[10]

The Government of India in the National Nutritional Anaemia Control Programme has recommended that all pregnant women should be given one tablet of iron and folic acid containing 100mg elementary iron and 0.5mg folic acid in the second half of pregnancy for at least 100 days. Intravenous iron therapy is reserved for a small number of patients in whom oral treatment fails. Severe systemic adverse effects associated with iron dextran and iron-sorbitol-citric acid complex limited the use of intramuscular iron. However, iron sucrose is reported to be safe and effective for the management of anemia, and it can be administered without a test dose.

Compliance and absorption of drug is an issue with oral iron. Hence a predetermined dose of parental iron given intermittently may have an advantage.This study was designed to compare the efficacy of daily oral iron supplementation and fixed schedule of intravenous iron sucrose given in pregnancy for anaemia prophylaxis.

Aims and objectives of the research were to compare oral iron tablets and intravenous iron sucrose for anaemia prophylaxis in pregnancy, to look for any significant side effects resulting from respective iron intake and to evaluate whether a limited dose schedule parenteral iron sucrose can be an alternative to daily oral iron throughout pregnancy for anaemia prophylaxis.

MATERIAL AND METHODS

A prospective interventional study was conducted in Dr. D.Y.Patil Medical College, Hospital and Research Center,

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Pimpri, Pune for the period of August 2013 to September 2015.

Study was conducted on 200 patients attending antenatal OPD of Dr D.Y. Patil Medical College Hospital and Research Center, Pimpri, Pune

Inclusion Criteria

1. Singleton pregnancy between 16 – 20 weeks of gestation.
2. Hemoglobin level 8-11 gm/dl.

Exclusion Criteria

1. Pregnant women with hemoglobin level < 8gm/dl and >11 gm/dl
2. Any medical disorder like tuberculosis, thyroid disease, diabetes, liver or kidney disease.
3. Multiple gestation.
4. Any obstetrical complicating factors like pre-eclampsia/ eclampsia.

Methodology

A prospective interventional study was carried out at a tertiary care teaching hospital between August 2013 to September 2015. Ethical committee clearance was obtained before commencing the study. All patients were enrolled after a duely signed informed consent. 200 patients between 16 – 20 weeks of gestation with singleton pregnancy and Hb level 8-11 gm/dl attending antenatal OPD were recruited based on inclusion and exclusion criteria. Medical disorder like tuberculosis, thyroid disease, diabetes, liver or kidney disease were excluded.

A thorough history followed by clinical examination of all cases was carried out and antenatal investigations as per our institution protocol were undertaken. The cases were randomly divided into two groups of 100 each by randomly generated numbers.

Group A was given oral iron tablets containing100mg of elemental iron and 500 microgram folic acid daily throughout pregnancy.

Group B was given a total of 1000 mg of intravenous iron sucrose divided into five doses of 200 mg each at weekly intervals.

These patients continued taking 5 mg folic acid tablets daily throughout pregnancy. All adverse events after each infusion of iron sucrose were identified. Patients on oral iron therapy were asked regarding compliance, tolerance and side effects. Compliance was ensured in the oral iron group by history taking and enquiring colour of stools. Suitable dietary advise was given to both the groups. Estimation of haemoglobin was started 4 weeks after commencement of iron therapy and then repeated every 4 weeks till 36 weeks of gestation. Haemoglobin levels in both the groups were compared and requirement of additional therapy if any was also assessed. After this haemoglobin level was investigated at the time of admission for delivery and 48 hours after delivery unless indicated earlier for intrapartum/postpartum complications.

STATISTICAL ANALYSIS

Tables were generated with the help of Microsoft office software. Results were tabulated and statistically analysed according to chi-square test and Z test.

RESULTS

Both groups were matched for age, parity and dietary history. On comparing haemoglobin level between group A and group B at recruitment, successive follow up and at term and delivery, it was found that haemoglobin at recruitment between group A and group B did not show any significant difference and haemoglobin compared at successive visits showed significant improvement in both groups.

Haemoglobin repeated at 28-32 weeks and 35-36 weeks in group A and group B showed some statistical significance with improvement greater in grou p B with P value <0.05 and Z value of 2.02. However there was no clinical difference in between the two groups. but haemoglobin repeated at term and postpartum did not show significant difference (P >0.05) between the two groups.

The results of haemoglobin comparison are tabulated below in table 1.

No major adverse effects were noted in the study. In group A incidence of nausea and vomiting was significant while in group B incidence of superficial thrombophlebitis was significant. In group A 2 patients complaints of giddiness, 1 patient complaint of headache and 1 patient complained of pain in abdomen. Headache and pain was on and off. In group B 3 patients complained of fever and 2 patients complained of chills as tabulated in table 2. All side effects were conservatively managed.

DISCUSSION

Oral iron is the first choice for anaemia prophylaxis and treatment in mild iron deficiency anaemia, however compliance is an issue. In such cases injectable iron therapy may have its place.

Iron sucrose has been reported to be safe and effective during pregnancy.[11] In this study mean haemoglobin at recruitment did not show any significant difference between group A and group B.. Haemoglobin in both group at successive visits showed significant improvement with a slight edge in group B at 28-36 weeks. The result of this study was in accord-

Hb. (gm%) at	Group A (n=100)		Group B (n=100)		Z Value	P Value
	Mean	SD	Mean	SD		
Recruitment	10.19	0.64	10.16	0.44	0.33	>0.05
20 – 24wks	10.45	0.69	10.42	0.50	0.38	>0.05
28 – 32wks	10.48	0.67	10.64	0.38	2.01	<0.05
35 – 36wks	10.59	0.55	10.73	0.49	1.99	<0.05
Term	10.76	0.58	10.89	0.61	1.51	>0.05
Post partum	9.73	1.09	9.83	0.64	0.77	>0.05

Table-1: Comparison of Haemoglobin level in group A and group B

Side effects	Group A (n=100)	Group B (n=100)	Z Value	P Value
Nausea	5	0	2.29	<0.05
Vomiting	4	0	2.04	<0.05
Chills	0	2	1.43	>0.05
Fever	0	3	1.76	>0.05
Giddiness	2	0	1.43	>0.05
Headache	1	0	1.01	>0.05
Pain in abdomen	1	0	1.01	>0.05
Superficial thrombophlebitis	0	8	2.95	<0.005

Table-2: Side effects wise distribution of cases in A and group B

ance with a study conducted by Bayoumeu in 2002.[12] and by Gabriela et al in 2009.[13] However a study conducted by AL RA (2005) to compare the efficacy of intravenous iron to oral iron in the treatment of anemia in pregnancy showed that hemoglobin from baseline was significantly higher in the intravenous group compared to the oral group at each measurement.

Side effects noted in this study were minimal. The high tolerance of iron sucrose has been partly attributed to slow release of iron from the complex and also due to the low allergenicity of sucrose. Till date, one death has been reported with intravenous iron sucrose injection.[14] The explanation given for this was because of very slow infusion (1-2 h) free radicals released from the iron sucrose may have caused the death. The injection should be given within 15-20 min or up to 200 mg can be given as slow IV bolus over 2-3 min.

The cost of therapy of injectable iron sucrose is known to be higher when compared to oral iron tablets. Moreover iron tablets with folic acid are provided free of cost to antenatal mothers under the national family welfare program of the government. Therefore cost is an important limiting factor in using iron sucrose injection for anaemia prophylaxis in pregnancy not withstanding its advantages in the long run.

CONCLUSION

The increment in haemoglobin with iron sucrose was comparable with oral iron. No significant differences were found in immediate postpartum maternal haemoglobin levels, birthweight and Apgar score of neonates.Side effects noted in the study were minimal. Compliance can be ensured with the injectable iron group, however the cost of injectable iron is more compared to iron tablets. If cost is not a limiting factor limited dosage schedule of iron sucrose as prescribed in the study is a safe and effective alternative to daily oral iron taken throughout pregnancy for anaemia prophylaxis in pregnancy.

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