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A comparative randomized study to observe the effect of parentral iron sucrose and oral iron in the treatment of iron deficiency anaemia in pregnancy

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Abstract
Objective: Iron deficiency anaemia is a common problem in obstetrics throughout the developing World, despite the fact that this problem is largely preventable & easily treatable. The aim of this study was to compare the efficacy of intravenous iron sucrose versus oral iron in the treatment of iron deficiency anemia during pregnancy.
Methods: 100 pregnant women with gestational age between 26 to 34 weeks with mild to moderate iron deficiency anemia (Hb 7-10 g/dl) were selected. The target Hb level was 11 g/dl. Selected patients were divided in two equal group, Group-A received IV iron sucrose. The drug was administered by IV infusion. The group B received ferrous sulphate as oral iron. Repeat laboratory estimations were done after six weeks. Data were analyzed using SYSTAT 7.0 (SPSS Inc. USA). Differences between mean percentages were analyzed by independent -'t' test.
Results: Rise in haemoglobin concentration was observed from 8.41±0.13 to 11.63±0.14 g/dl in Group A and from 8.43±0.15 to 10.09±0.16 g/dl in group B after six weeks.
Conclusion: The present study revealed that intravenous iron sucrose is a safe and effective alternative to oral iron in treatment of iron deficiency anaemia of pregnancy.

Keywords: Pregnancy, anaemia, iron deficiency, oral iron, parenteral iron

Introduction
Anaemia during pregnancy is a major public health problem throughout the world, particularly in developing countries. According to WHO anaemia affects nearly half of all the pregnant women in the world, these figures are 52% in the developing and 23% in the developed world, due to malnutrition and lack of prenatal iron supplement programmes [1]. The Centre for Disease Control and Prevention defines anaemia when haemoglobin and haematocrit values are less than 11g/dL and 33% in the first and third trimester and 10.5 g/dL and 32% in the second trimester.
The most common cause of anemia is iron and folate deficiency. In pregnancy75-95% cases of anaemia is due to iron deficiency. It can occur as a result of poor nutrition, malaria, hook worm infestation and closely spaced pregnancies. Anaemia results in an increased number of preterm, low birth weight, impaired cognitive development of children, postpartum haemorrhage, postpartum depression and reduced adult work productivity [2].
During pregnancy average requirements are: basal iron (280 mg), expansion of red cell mass (570 mg), transfer to fetus (200-350 mg), for placenta (50-150 mg), blood loss at delivery (100-250 mg). After deducting iron conserved by amenorrhoea (240-480 mg), an additional 500-600 mg is required in pregnancy or 4-6 mg/ day of absorbed iron. As absorption is less than 10% (3-4% in low bio-availability diets), for a minimum of 4-6 mg absorption, at least 40-60 mg of iron should be available in the diet [3]. Diet alone cannot supply such amounts of iron in non-industrialized countries making iron supplementation a necessity in all pregnant women [4]. Iron can be supplemented by mouth, intramuscular or intravenous injection. Alternatively, blood transfusion and recombinant erythropoietin are used. Oral iron is associated with side effects, non-compliance and takes a long time to correct anaemia. Parenteral preparations like iron dextran, iron sorbitol are associated with anaphylactic reactions and blood transfusions are associated with cross reactions and viral infections. Recently there is increasing interest on alternative therapeutic options like intravenous iron sucrose and human recombinant erythropoietin. Iron sucrose has been shown to have several advantages like low incidence of side effects, high availability for erythropoiesis, little renal excretion and low tissue accumulation and toxicity [5].

In recent years, very few studies have been designed to compare intravenous iron sucrose treatment with oral iron in pregnancy [6, 7]. However, some controversies exist between these studies. Therefore the present study was under taken to compare the efficacy and safety of iron sucrose and oral iron for the treatment of iron deficiency anaemia in pregnancy.

Materials and Methods

Study design

This was a, prospective, randomized, comparative study conducted in the department of Obstetrics and Gynecology, Jawahar Lal Nehru Hospital, Bhilai from August 2008 to February 2010, after approval from the Institutional Ethics Committee. Any financial assistance was not taken for conducting this study.

Sample size

This study was done in 100 patients in duration of 18 months.

Inclusion criteria

Pregnant women with gestational age between 26 to 34 weeks with mild to moderate iron deficiency anemia (Hb 7-10 g/dl) who gave informed consent were selected from ANC clinic. We set the target Hb level of 11 g/dl. The initial iron status of the woman was assessed by the clinical and laboratory examinations. Features of iron deficiency were evidenced by: low red cell count, MCHC, reticulocyte count, serum ferritin and serum iron and increased TIBC.

Exclusion criteria

The Pregnant women with gestational age less than 26 weeks and more than 34 weeks, anemia due to causes other than iron deficiency, any other medical or obstetric complicating factors like hypertension, diabetes, reaction to IV iron sucrose are excluded from the study.

Methodology

After careful history analysis, clinical examination and minimal investigations, other cause of anaemia was ruled out. Two groups were made and in each group 50 patients were included.

The women in group A received IV iron sucrose. The dose of iron sucrose was calculated as follows: 2.4×Body weight (in kg) × (target Hb- actual Hb). To replenish iron stores 10 mg/kg of iron sucrose was added. Total calculated dose was given in divided doses either on alternate day or twice weekly. Maximum dose is 200 mg per dose infused IV over 1 h. The stability of iron sucrose in normal saline has been shown in studies at concentration of 0.5 to 2 mg/ ml for a period of 24 h. So 100 mg iron sucrose diluted in 100 ml saline (1 mg/ml) is stable and should be given in 15-20 min. So the dilutions and administration were: 5 ml iron sucrose (100 mg iron) in 100 ml of 0.9% NaCl infused over at least 15 min. No test dose was given.

The women in the group B received ferrous sulphate as oral iron BD for 6 weeks. Women were instructed to take the tablets on an empty stomach either two hour before or after meal. Each tablet contained 200 mg as salt (60 mg elemental iron).

The each and every patient of these two groups was followed up every week for six weeks. At the end of six weeks all the initial investigation viz: haemoglobin, red blood cell count, reticulocyte count, PCV, MCHC, serum iron, serum ferritin and total iron binding capacity of serum were estimated. All the haematological parameters were repeated at the time of delivery and one week after delivery.

Statistical Analysis

Data were analyzed using SYSTAT 7.0 (SPSS Inc. USA). Differences between mean percentages were analyzed by independent -'t' test. A value of $P<0.05$ was considered to be statistically significant. All means have been expressed as mean ± standard error.

Results

In this prospective study, 100 pregnant women were included according to selection criteria and randomly assigned in the one of the two groups, i.e. iron sucrose (group A, $n = 50$) or ferrous sulfate (group B, $n = 50$). At 6 weeks, 48 pregnant women from the iron sucrose group (two develops hypersensitivity reaction) and 35 pregnant women from the ferrous sulfate group (Fifteen patients did not take tablet regularly) could be included for the analysis. Majority of the patients were in the age group of 25 to 29 years in both oral and intravenous group. Mean age of the patients in oral group was 29.1+1.0 and in the intravenous group it was 27.9+0.95 years.

To compare the haematological parameters of two groups (Group- A and Group- B), independent sample t-test was performed. There was significant differences ($p<0.05$) was observed in Hb, serum iron level and total iron binding capacity, whereas other parameters were found to be non-significant ($p<0.05$) (Table 1 and Table 2).

Table 1: Haemoglobin level before and after treatment

Group	Hb level (g/dl)		Differences
	Before treatment	After treatment	
Group A	8.41±0.13	11.63±0.14	3.22
Group B	8.43±0.15	10.09±0.16	1.66

Table 2: Change in various Haematological parameters

Sr. No.	Haematological parameters	Change in haematological parameters after treatment		P value
		Group- A	Group- B	
1.	Haemoglobin level (g/dl)	3.22	1.66	0.0012
2.	Red cell count (million/ mm^3)	0.98	1.02	4.2021
3.	Packed cell volume (%)	9.94	11.74	4.9721
4.	Mean corpuscular haemoglobin concentration (%)	4.97	4.34	3.5412
5.	Reticulocyte counts (%)	0.74	0.59	2.1210
6.	Serum iron level (µg %)	69.1	41.2	0.0471
7.	Serum ferritin (µg/l)	64.73	14.28	0.0012
8.	Total iron binding capacity (µg %)	-310.22	-150.09	0.0012

To compare the weekly change in haemoglobin level in two groups, independent sample t-test was performed. Two group differ significantly (p<0.05) change in haemoglobin per cent in all the weeks (Table 3, Figure 1).

Table 3: Weekly change in level of haemoglobin

Weeks	Group - A average %	Group - B average %	P - Value
First	13.42 ± 0.74	9.80 ± 0.60	0.0001
Second	18.81 ± 0.83	5.91 ± 0.44	0.0001
Third	4.72 ± 0.31	1.66 ± 0.11	0.0077
Fourth	2.70 ± 0.23	1.17 ± 0.09	0.0047
Fifth	1.33 ± 0.08	0.74 ± 0.07	0.0005
Sixth	0	0.37 ± 0.04	0.0000
At time of delivery	45.60 ± 2.33	27.97 ± 1.29	0.0010
One week after delivery	33.45 ± 2.22	16.40 ± 1.33	0.0140

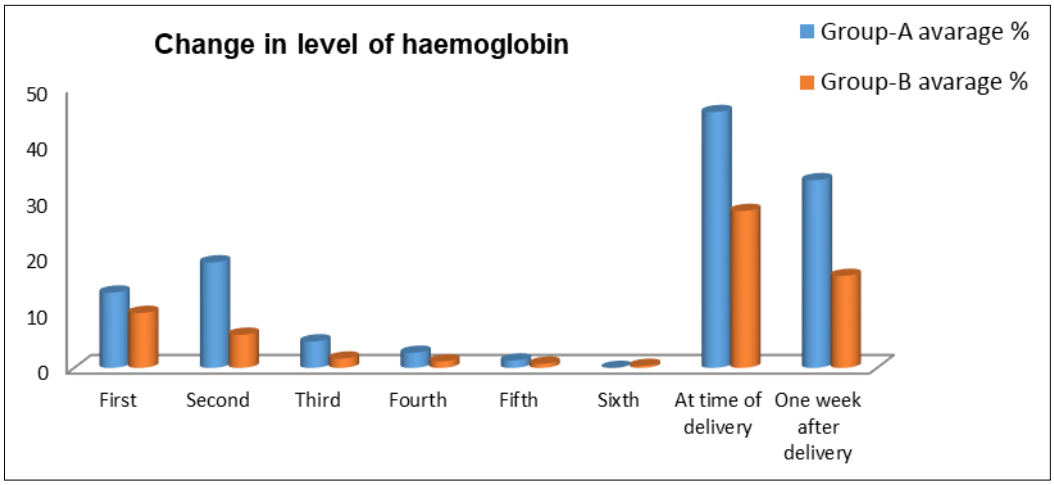

Fig 1: Change in level of haemoglobin of group- A and group- B patients

No significant differences between the two groups in pregnancy outcomes were observed. Systemic side effects were more common in the parenteral iron group, whereas gastrointestinal side effects were more common in the oral iron group.

Discussion

Iron deficiency anemia during pregnancy is the commonest medical disorder in pregnancy in developing world and deserves special attention because of its potential consequences [8, 9, 10].

Although oral iron supplementation is widely used for the treatment of IDA, not all patients respond adequately to oral iron therapy. Previously, the use of intravenous iron had been associated with undesirable and sometimes serious side effects and therefore is under utilised. However, in recent years, new type II and III iron complexes have been developed, which offer better compliance and toleration as well as high efficacy with a good safety profile. There are few studies comparing intravenous iron sucrose versus oral iron iron for the treatment of iron deficiency anaemia in pregnancy [11, 12].

In the present study the baseline mean Hb level in the oral iron therapy group was 8.43 ± 0.15 g/dl and parental iron therapy it was 8.41 ± 0.13 g/dl, which was found to be statistically insignificant between the groups. Six weeks after starting the therapy, there was a high significant change (p<0.05) in the Hb level in both oral and injectable iron group. The mean Hb rise in the injectable iron group was 3.22 g/dl (p <0.05) and in the oral iron group was 1.66 g/dl (p <0.05). The similar findings of increased Hb% in oral and IV group were also reported by earlier workers [13, 14]. The significant difference (p<0.05) in increase in serum iron, serum ferritin and TIBC was also observed in two group A and B in our study, whereas the rise of other haematological parameters i.e. red cell count, packed cell volume, mean corpuscular haemoglobin concentration and reticulocyte counts were non-significant. Indicate that IV group respond better than the oral group (p<0.05). The other workers also reported increase in serum iron in both the groups, but there was no significant difference between oral and IV groups [15, 16].

When analyzed across time it was found that two group differ significantly (p<0.05) change in haemoglobin per cent in all the weeks. Intravenously administered iron sucrose(Group A) was significantly more likely to have higher haemoglobin from baseline than those patients with orally administered iron at every point at measurement (at 1st week, 2nd week and at term) during the course of the study similar to other studies [17, 18].

Conclusion

The present study revealed that intravenous iron sucrose is a safe and effective alternative to oral iron in treatment of iron deficiency anaemia of pregnancy. It may reduce the blood transfusion rates in pregnant women who have severe anaemia near term. Major disadvantages of intravenous treatments are cost, need for hospitalization or an outpatient setting, and the invasive nature of the procedure. However, it may be considered an alternative to oral iron in the treatment of pregnant women with iron deficiency anaemia.

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