

Original Article

IRON DEFICIENCY ANEMIA IN PREGNANCY: INTRAVENOUS VERSUS ORAL ROUTE

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ABSTRACT

Background: The aim of this prospective, randomized, controlled study was to compare the efficacy of intravenous iron sucrose versus oral iron in the treatment of iron deficiency anemia during pregnancy.

Methodology: One hundred fifty pregnant women with gestational age less than 34 weeks with iron deficiency anemia were selected. The women in group A received IV iron sucrose. The drug was administered by IV infusion. The women in the group B received ferrous sulphate as oral iron in the dose of two tablets three times a day. Repeat laboratory estimations were done after six weeks. Results were analyzed by t test and Z-test of preparation using SPSS 15 and Microsoft excel.

Results: Mean gestational age in group A and group B were 26.13 ± 5.15 weeks and 26.27 ± 4.71 weeks, respectively. Mean Hb level was 6.71 ± 0.65 g/dl in group A which was raised to 10.64 ± 0.71 g/dl. Mean Hb level was 6.72 ± 0.67 g/dl in group B which was raised to 10.17 ± 0.54 . The target Hb level of 10 g/dl was achieved in 88% cases in group A and in 76% cases in group B ($P = 0.055$).

Conclusion: Intravenous iron sucrose therapy is safe and as effective as oral iron in the treatment of iron deficiency anemia during pregnancy.

Key words: Iron deficiency anemia, iron sucrose complex, anemia in pregnancy, oral iron.

INTRODUCTION

60-80% of pregnant women suffer from anemia in India.^{1, 2} Iron deficiency is responsible for 90-95% cases.³ Despite the existence of the national anemia prevention program over the last 20 years, the prevalence of anemia in pregnancy still continues to be high.^{1, 2} Oral iron therapy is certainly very appropriate and first line for most cases. But a large proportion of women do not show the desired response because of various reasons.² Many studies have shown that iron deficiency anemia can be effectively treated by iron sucrose.¹⁻¹⁵ Also, iron stores are replenished better than oral route¹⁴.

The aim of this prospective, randomized, controlled study was to compare the efficacy of intravenous iron sucrose versus oral iron in the treatment of iron deficiency anemia during pregnancy.

MATERIALS AND METHODS

This study was conducted in the department of Obstetrics and Gynecology, Surat Municipal Institute of Medical Education and Research (SMIMER) from

April 2011 to December 2012. Approval from the Institutional Ethics Committee was obtained prior to conducting the study. Any financial assistance was not taken for conducting this study.

Pregnant women with gestational age less than 34 weeks with moderate to severe iron deficiency anemia (Hb less than 8 g/dl) who gave informed consent were selected from ANC clinic. We set the target Hb level of 10 g/dl. Multivitamin supplementation was given to all women as a part of standard prenatal care.

Inclusion criteria

Ante natal women with iron deficiency anemia with Hb less than 8 g/dl. Features of iron deficiency were evidenced by: hypochromic microcytic anemia, low MCV, MCH and MCHC values, increased RDW and low serum iron.

Exclusion criteria

The Pregnant women with gestational age less than 12 weeks and more than 34 weeks, anemia due to causes other than iron deficiency, any other medical or obstetric complicating factors like hypertension, diabetes

mellitus, malaria, infective hepatitis etc. are excluded from the study.

One hundred fifty pregnant women matching the above criteria, allocated to either group A (IV iron sucrose) (n=75) or group B (oral iron) (n=75) by sequentially numbered opaque envelope.

The women in group A received IV iron sucrose. The dose of iron sucrose was calculated as follows: $2.4 \times \text{Body weight (in kg)} \times (\text{target Hb} - \text{actual Hb}) + 500$ mg for iron stores. The drug was administered as 100 mg (two ampoules) in 100 ml normal saline by slow IV infusion. No any specific brand of iron sucrose was selected during the study. The dose was repeated on alternate day basis. No test dose was given. The women in the group B received ferrous sulphate as oral iron in the dose of two tablets three times a day. Each tablet contained 200 mg as salt (60 mg elemental iron). Women were instructed to take the tablets on an empty stomach either two hour before or after meal. The dose was started one tablet a day and then gradually increased.

All women were followed regularly and assessed for side effects, compliance, clinical and laboratory response. Repeat laboratory estimations were done after six weeks. Results were analyzed by t test and Z- test of preparation using SPSS 15 and Microsoft excel.

RESULTS

As shown in table 1, women had similar characteristics in both groups. Mean age of women in group A and group B were 24.49 ± 4.10 years and 24.49 ± 3.74 years, respectively. Mean gestational age in group A and group B were 26.13 ± 5.15 weeks and 26.27 ± 4.71 weeks, respectively.

Table 1: Demographic profile

Parameter	Group A (n=75)	Group B (n=75)
Age of women		
< 20 yrs	12 (16%)	13 (17%)
21-30 yrs	58 (77%)	60 (80%)
> 30 yrs	5 (7%)	2 (3%)
Parity of women		
Nullipara	32 (42%)	34 (45%)
Multipara	43 (58%)	41 (55%)
Gestational age		
12-20 weeks	16 (21%)	15 (20%)
20-28 weeks	34 (45%)	36 (48%)
28-34 weeks	25 (34%)	24 (32%)

Table 2: Hemoglobin level before and after treatment

Group	Hb level (g/dl) before treatment	Difference after treatment (g/dl)	
Group A(n=75)	6.71 ± 0.65	10.64 ± 0.71	3.93 ± 0.60
Group B (n=75)	6.72 ± 0.67	10.17 ± 0.54	3.45 ± 0.68

All figures are in mean \pm SD; P value= 0.284 using t-test

As shown in table 2, mean Hb level was 6.71 ± 0.65 g/dl in group A which was raised to 10.64 ± 0.71 g/dl after six weeks. Mean Hb level was 6.72 ± 0.67 g/dl in group B which was raised to 10.17 ± 0.54 after six weeks. The rise in Hb level was 3.93 ± 0.60 g/dl in group A and 3.45 ± 0.68 g/dl in group B ($P=0.284$). As shown in table 3, the target Hb level of 10 g/dl was achieved in 66 (88%) cases in group A and in 57 (76%) cases in group B. This difference was non significant ($P =0.055$). As shown in table 4, 39% of women had suffered GIT side effects like Epigastric discomfort, nausea, constipation etc. in oral iron group. No serious side effects were observed in group A. 20% of women had suffered from pain at injection site and 5% had suffered from phlebitis. Strong motivation and regular follow up were required to ensure ingestion of oral tablets. The back count of tablets collected from women in group B showed that only 87% of women took more than 90% of their supplements, suggesting poor compliance, while all women in group A had received full doses of injectable iron within a short period of time.

Table 3: Proportion of women getting the target hemoglobin level **

Group	Women with Hb > 10 g/dl	Women with Hb < 10 g/dl
Group A(n=75)	66 (88%)	9 (12%)
Group B(n=75)	57 (76%)	18 (24%)

**P=0.055, Non significant (Z- test of preparation)

Table 4: Side effects

Side effects	Group A	Group B
Epigastric discomfort / Nausea / Vomiting	0	16 (22%)
Constipation/ Diarrhea	0	13 (17%)
Metallic taste	0	6 (8%)
Pain at injection site	15 (20%)	0
Phlebitis	6 (8%)	0
Fever	5 (7%)	0

DISCUSSION

Anemia is responsible for 20% cases of maternal mortality.² Perinatal outcome is also poor in women with anemia. Women suffering from anemia are at risk of development of heart failure, postpartum collapse and shock and low birth weight babies.

Three parenteral iron preparations are available for use: iron dextran, iron sorbitol citric acid complex and iron sucrose.² Due to low molecular weight, adverse reactions with iron sucrose are much less than other two preparations. The best recommended way to administer iron sucrose is 100-200 mg IV three times weekly. Test dose is not required.^{2,3,4,9,12} It can not be given by IM route and as total dose infusion. It can be given as slow IV injection undiluted over a period of two to five minutes or IV infusion (100 mg to be diluted in 100 ml of normal saline immediately prior to

infusion and is to be infused over a period of at least 15 minutes).

In the study done by Bayoumeu et al¹⁰ involving 50 women, intravenous iron sucrose was compared with oral ferrous sulphate. Rise of Hb was similar in both the groups on day 30, which is comparable to our study. Bencaiova G et al¹⁴ assessed and compared the efficacy and safety of IV iron sucrose to oral ferrous sulphate. There was non significant increase in Hb in the iron sucrose group but the iron stores were better replaced in IV group. In the studies conducted by Shafi D et al², Al RA⁸ and al-Momen et al⁹, they concluded that IV iron sucrose group achieved significantly higher Hb levels in a shorter period of time. In our study, 39% of women in oral iron group had suffered GIT side effects which was similar to study by Shafi D et al² (37%) which is a common reason for non compliance.

CONCLUSION

Iron deficiency anemia in pregnancy can be effectively treated by oral iron or intravenous iron sucrose. Oral therapy has disadvantages of long therapy, GIT side effects and poor compliance. Intravenous iron sucrose therapy is safe and as effective as oral iron.

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