

# Parenteral Iron Sucrose Therapy for Moderate and Severe Iron-Deficiency Anemia in Pregnancy

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## Abstract

**Introduction:** In India, women become pregnant with low baseline hemoglobin levels resulting in high incidence of moderate to severe anemia in pregnancy where oral iron therapy cannot meet the requirement. Pregnant women with moderate to severe anemia are to be treated with parenteral iron therapy. This study was done to evaluate the effect and response of intravenous iron sucrose given to pregnant women with iron deficiency anemia (IDA). **Subjects and Methods:** A prospective observational study was conducted in 60 pregnant women with documented IDA with Hb between 6-9 gms % were given intravenous iron sucrose 200 mg thrice weekly after calculating the dose requirement. Analysis of data was done by using paired T test. **Results:** The mean Hb raised from  $7.82 \pm 0.93$  to  $10.8 \pm 1.2$  after 8 weeks of therapy. There was significant increase in serum ferritin levels from  $12.4 \pm 0.54$  to  $66.35 \pm 18.5$ . Other parameters including hematocrit, serum iron, TIBC were also improved significantly. No major anaphylactic reactions were observed during the study period. **Conclusion:** Intravenous iron sucrose therapy was effective in increasing Hb, S.Ferritin and other hematological parameters in pregnant women with moderate anemia.

**Keywords:** Anemia, IDA, Iron Sucrose, Serum Ferritin, Hb, Parenteral Iron Therapy

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## Introduction

Anemia is one of the most commonly encountered medical disorder during pregnancy. Prevalence of anemia in India is highest in the world. IDA is the most common nutritional anemia in pregnant women. Increased requirement of iron during pregnancy and most of women become pregnant with low Hb level, resulting in higher incidence of moderate to severe anemia in pregnancy. According to WHO, the prevalence of IDA is about 18% in developed countries and 56%(35-75) in developing countries.<sup>[1]</sup> In India the prevalence ranges from 33-89%.<sup>[2]</sup>

Maternal anemia can have serious deleterious effects in mother and fetus such as poor intrauterine growth of fetus, increased risk of preterm birth and low birth weight babies. This intern results in higher perinatal morbidity, mortality and infant mortality rates. In India IDA is directly or indirectly responsible for 40% of maternal deaths.<sup>[3]</sup>

WHO defines anemia as  $Hb < 7$  gms %.<sup>[4]</sup> The relative prevalence of mild, moderate, severe anemia are 13%, 57%

and 12% respectively in India (ICMR data).<sup>[5]</sup> In India the ICMR classification of anemia is 10-10.9 gms% as mild, 7-10 gms% as moderate, severe is  $< 7$  and very severe is  $< 4$  gm% . serum ferritin  $< 12-15 \mu\text{g/l}$  is considered as iron deficiency.

The treatment of choice for prophylaxis and mild anemia in pregnancy are oral iron therapy. But oral therapy takes long time in patients with moderate to severe anemia, and decreased compliance due to GI side effects, poor bioavailability and malabsorption. So oral iron therapy cannot meet the requirement in moderate to severe anemia in pregnancy. Thus pregnant women with moderate anemia should be better treated with parenteral iron therapy and or blood transfusion depending upon the individual basis (Hemodynamic status and period of gestation).

The parenteral iron preparations available are iron dextran, iron sorbitol citrate, iron sucrose, ferric carboxy maltose, sodium ferric gluconate and sodium isomaltoside. Test dose is necessary before giving intravenous iron dextran as severe anaphylactic reactions were reported with it.<sup>[4,5]</sup>

Iron sucrose can be given without test dose and it has a favorable safety profile and it is an alternative to other forms of parenteral iron therapy in correction of iron store depletion and correction of anemia during pregnancy.<sup>[6]</sup> Hence intravenous iron sucrose is widely used for the treatment of IDA, when oral iron is poorly tolerated.

Therefore, a prospective study was conducted in pregnant women with IDA (Hb between 6-9 gms%) to evaluate the response and effect of intravenous iron sucrose in terms of improvement in hemoglobin and other red cell indices.

**Objective:** In this study, we aimed to analyze the effectiveness of parenteral iron sucrose use in our pregnant patient population.

## Subjects and Methods

This study was conducted in civil hospital from September 2020 to June 2021. 50 pregnant women with documented IDA with Hb between 6-9 gms% were included in this prospective study. Patients having hemoglobin levels below 6 gr/dL or symptomatic (severe fatigue, palpitations, tachycardia, shortness of breath) patients with hemoglobin levels greater than 6 gr/dL and women with multiple pregnancy, high risk for preterm labour, history of recent blood transfusion and other causes of anemia other than IDA were excluded from this study. Informed consent for intravenous iron therapy was taken. All the pregnant women were given antihelminthic therapy with albendazole 400mg single dose. Folic acid were given to all women during the therapy. Baseline investigations including blood (LFT, RFT), Urine (routine, microscopy and culture) were done.

The iron sucrose dose was calculated by using the formula as follows

Required elemental iron in mg =  $2.4 \times (\text{normal Hb} - \text{patients actual Hb}) \times \text{Prepregnancy weight in kg} + 500$ .

Here 2.4 is standard coefficient. Normal Hb is taken as 14 gms. To the value calculated by above formula 500 mg is added for replenishment of stores.

The iron sucrose was given as outpatient basis, in a dose of 200 mg intravenously, three times a week, in 200 ml of NS over a period of 15-20 minutes. The duration to complete total therapy was 2.5 to 4.5 weeks.

Patients were observed during transfusion and one hour post transfusion for side effects. FHR was assessed before and after transfusion. In order to investigate the effect of iron sucrose therapy on hemoglobin and hematocrit levels, serum ferritin levels before iron sucrose administration and at 3 and 7 weeks were measured.

## Results

A total of 60 pregnant women were available for the analysis. Fifteen (25%) and 45 (75%) patients were in the second and third trimester of the pregnancy, respectively. Four (6.6%) of the patients had severe and 56 (93.3%) of the patients had moderate anemia. The mean age of women was  $25.6 \pm 5.2$  (19-32 years). The mean period of gestation at the time of diagnosis was 31.1 weeks (26.8-34.3). Prior to iron transfusion mean Hb was  $7.82 \pm 0.93$  gms. After completion of therapy mean Hb raised to  $10.8 \pm 1.2$  gms%.

Out of 60 pregnant women, 5 (11%) were delivered before 37 weeks, the remaining 55 (88.8%) women were delivered at term (> 37 weeks). Of these 45(75%) were delivered vaginally, 15(25%) were delivered by LSCS (elective or emergency). Mean period of gestation at delivery  $38.75 \pm 1.2$  (37.2-40.3) weeks. The median birth weight was 2.950kg (2.550-3.230) and the median duration from iron sucrose administration to delivery was 7.4 (4.1-10.4) weeks. Five patients (8.3%) reported mild hypersensitivity reaction to intravenous iron in the form of mild itching at the infusion site. No severe or life-threatening hypersensitivity reaction was reported.

## Discussion

Iron therapy is the mainstay of iron-deficiency anemia treatment and intravenous iron is increasingly used when oral therapy is not tolerated. In this study, we found that intravenous iron therapy is effective in iron restoration and anemia treatment with few side effects.

Iron requirements are greater in pregnancy than in non pregnant state. Although iron requirement is reduced in the first trimester because of absence of menstruation, they rise steadily thereafter. In the first trimester the daily iron requirement is 0.8 mg, 4-5 mg in second trimester and 6-8 mg in the third trimester. The total iron requirement during pregnancy is about 1000-1200mg. (for growing fetus- 270 mg, Placenta – 90 mg, for expansion of RBC mass – 450 mg and blood loss during delivery – 150 mg).<sup>[1]</sup> Usually this iron is mobilized from iron stores. However women with poor iron stores become iron deficient during pregnancy.

Severe iron-deficiency anemia has been associated with an increased risk of low birth weight, maternal mortality, neonatal mortality and preterm birth. Blood loss even 200 ml in third stage of labour can cause shock and death in severe anemia.<sup>[7]</sup> The stores in Indian women are deficient and they require 100 mg elemental iron per day for prophylaxis. For the treatment of anemia the recommended dose is 200 mg elemental iron per day.<sup>[8]</sup> The major challenges in the management of IDA are related to tolerability and side effects of iron therapy. Therefore it is crucial to determine the most appropriate form and dose of iron as well as duration of treatment in order to

**Table 1: General characteristics**

Characteristics	Values
Mean Maternal Age	25.6±5.2
Mean Hemoglobin Levels before Iron Sucrose therapy (g/dL)	7.82±0.93
Characteristics	30.1 (26.8-33.3)
Median Gestational Age Of Delivery	38.75 (37.2-40.2)
Median Birth Weight (grams)	2.950 (2.550-3.230)
Median Duration From Iron Sucrose Administration To Delivery	7.4 (4.1-10.4)

**Table 2: Changes in hemoglobin, hematocrit, S.iron, TIBC and ferritin levels**

Before iron therapy		3 Weeks	7 Weeks
Hemoglobin gr/L (mean±S.D.)	7.82±0.93	8.14 ± 0.84	10.8±1.2
Hematocrit	24.7±1.9	26.8±1.8	32.5±3.8
S. iron µg/dl	30±5.84	39.92± 8.96	76.45±12.8
TIBC µg/dl	360.4±38.9	347 ± 16.3	318.7±11.9
Ferritin µg/L (mean±S.D.)	12.4±0.54	16.8 ± 9.9	66.35±18.5

successfully replenish the iron stores.

Due to the therapeutic challenges of oral iron therapy, intravenous iron emerged as an alternative tool for treatment of iron deficiency. High-molecular-weight iron dextran was the first iron product for intravenous use: however, anaphylactic reactions was associated with it. Recently new intravenous iron products with better safety profiles were launched to the market. Iron sucrose, which is a dextran free product and has a satisfying safety profile without a need for a test dose (unless the patient has a history for drug allergies), has become the leading intravenous iron compound in the market. intravenous iron sucrose resulted in significantly higher mean hemoglobin and ferritin levels and those patients treated with iron sucrose achieved maximum hemoglobin levels in half the time.<sup>[9]</sup>

Alkakriplani et al, evaluated the effect of intra venous iron sucrose complex in 100 pregnant women with moderate to severe anemia and they found that the mean Hb was raised from 7.63 to 11.20 after 8 weeks of therapy. In our study, 6-9 gm% Hb was taken as cut-off, the raise in mean Hb was from 7.82 to 10.8 after intravenous iron sucrose therapy. So the results of our study were similar to their study.<sup>[10]</sup>

In a prospective observational study of 65 anemic pregnant women received ferric carboxy maltose upto 15 mg/kg between 24 – 40 weeks of pregnancy and they found that I.V ferric carboxy maltose infusion significantly increased the Hb above the baseline levels in all women. No serious adverse effects were found, serum ferritin levels increased significantly after the infusion.<sup>[11]</sup>

In Indian women, we took 14 as index Hb. Even with this, maximam mean ferritin after 7 weeks of therapy was within normal range. The reason could be due to severely depleted

iron stores in Indian women.

## Conclusion

Our results showed that intravenous iron sucrose therapy was effective to treat moderate to severe anemia in pregnancy with negligible side effects. Therefore the use of intravenous iron should be considered as an effective, rapid and safe treatment option in pregnant women with IDA and for effective rapid repletion of iron stores.

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