

Intravenous Iron Sucrose: Safety and Effectiveness in Pregnant Women with Moderate to Severe Anemia.

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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 safety and effectiveness of intravenous iron sucrose given to pregnant women with proven iron deficiency anemia.

Materials And Methods:- A prospective observational study was conducted in 98 pregnant women attending antenatal checkup at primary health center with documented low Hb levels between 6-9 gmsHb. They were treated with intravenous iron sucrose 200mg thrice weekly calculating the dose required. Statistical analysis of the data was done by using paired T TEST.

Results:- Mean Hb raised from 7.9-11.5 after 8 weeks of iron infusion therapy. A significant rise in serum ferritin values is noted. Other parameters including Serum Iron, TIBC, Reticulocyte Count and MCV were also improved significantly without any Adverse drug reactions.

Conclusion:- Intravenous iron sucrose therapy was effective in measuring Hb, S.Ferritin and other hematological parameters in pregnant women with moderate anemia.

Key Words:- Anemia, IDA, Iron sucrose, Hb, Parenteral iron therapy.

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I. Introduction

Anemia is one of the most commonly encountered medical disorder during pregnancy. Prevalence of anemia in India is highest in the world, Iron deficiency anemia 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 Iron deficiency anemia in India ranges from 65-90% [1].

Maternal anemia can have serious deleterious effects in mother and fetus such as IUGR, increased risk of preterm labour and low birth weight. This in turn results in higher perinatal morbidity, mortality and infant mortality rates. In India Iron deficiency anemia is directly or indirectly responsible for 42% of maternal deaths [2]. In India the ICMR classification of anemia is 10-10.9gms% as Mild,

7-10gms% as Moderate,

< 7 gms % as Severe [4],

< 4 gms% as Very severe.

The management of anemia in pregnancy with oral iron supplements takes long time to improve and decreased compliance due to gastrointestinal side effects, poor absorption and lesser bioavailability. So oral iron supplements cannot fulfill the requirement in pregnancy. Thus pregnant women with severe anemia is better treated with parenteral iron therapy. Available parenteral iron preparations are IRON DEXTRAN, IRON SORBITROL CITRATE, IRON SUCROSE, SODIUM FERRI GLUCONATE.

IRON SUCROSE INJECTION approved in November 2000 by FDA. Iron sucrose is an hydroxide sucrose complex in water. The molecular mass of iron sucrose is 34,000-60,000 daltons. Iron sucrose is administered by intravenous injection or infusion. The recommended schedule is to administer 100mg IV over 5 min, 1-3 times weekly until 1,000mg has been administered. The rate of administration should not exceed 20mg per minute. Optimal doses of iron sucrose 200-300mg IV over two hours were well tolerated and found safe.

II. Material And Methods

A prospective observational study was conducted among 98 pregnant women with Iron deficiency anemia at primary health center in ANANTHAPUR district.

The studies was conducted in KORRAPADU PHC AT ANANTHAPURAM district from MARCH 2016-APRIL 2017.

98 pregnant women with documentation IDA with Hb between 6-9 Hb% were included in this study. Pregnant women with multiple pregnancy, high risk, preterm labour, anemia other than IDA were excluded. Informed written consent was obtained from all the patients before starting the therapy. All the pregnant women were given anti-helminthic therapy with ALBENDAZOLE 400mg stat, Folic acid were given to all the women during the therapy. Baseline investigations including complete blood picture, LFT, RFT, Urine routine, microscopy and culture and stool examination (ova and cyst) were done.

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

Required elemental iron in mg = $2.4 \times (\text{normal Hb} - \text{patients actual Hb}) \times \text{pregnancy weight in kgs} + 1000$.

Here 2.4 is standard co-efficient. Normal Hb is taken as 14 gms. To the value calculated value by the above formula, 1000mg is added for replenishment of stores.

The required elemental iron dose varied depending on index Hb and pre pregnancy weight of patient. The dose requirement was 1600 -2200mg. The duration to complete the total therapy was 2.5 to 4.5 weeks.

The iron sucrose was given as outpatient basis, in the dose of 200mg intravenously, 3 times a week, in 200ml of NS over a period of 15 to 20 min. Patients were observed during transfusion and one hour post transfusion for side effects. FHR was assessed before and after transfusion. Blood samples were collected to measure Hb, serum ferritin and red cell indices prior to transfusion and again 3 weeks, 6 weeks and 8 weeks. During the study Hb concentration, serum ferritin levels were drastically increased again after 4 weeks blood samples were measured for improvement in serum iron level, reticulocyte count, TIBC, MCV.

III. Statistical Analysis

Hb CALCULATION:

$$\text{Desired Hb} - \text{Actual Hb} \times 150 + 500 = \text{No. of ampoules}$$

100

- For Pregnant with 6 gms of Hb% -14 ampoules
- For Pregnant with 7 gms of Hb% -13 ampoules
- For Pregnant with 8 gms of Hb% -11 ampoules
- For pregnant with 9 gms of Hb% - 10 ampoules
- For pregnant with 10 gms of Hb% -9 ampoules
- For pregnant with 11 gms of Hb% -8 ampoules

	Baseline Value	4 Weeks	6 weeks	8 weeks	Statistical significance
Hb g%	7.82 ± 0.93	8.14 ± 0.84	9.8 ± 0.80	11.34 ± 0.82	P < 0.0005
S.Iron µg/dl	30.8 ± 5.84	39.92 ± 8.96	58.17 ± 13.0	80.45 ± 11.8	P < 0.0005
TIBC µg/dl	360.4 ± 39.9	347 ± 16.3	328.8 ± 13.0	311.7 ± 12.0	P < 0.0005
S.Ferritin µg/l	12.1 ± 5.1	16.8 ± 9.9	26.7 ± 112.4	67.34 ± 20.5	P < 0.0005
Reticulocyte count %	1.38 ± 0.54	3.8 ± 0.72	4.5 ± 2.6	5.5 ± 2.0	P < 0.0005
MCV fl	65.3 ± 5.8	76.4 ± 5.0	80.4 ± 3.6	86.6 ± 2.8	P < 0.0005

TABLE:- Shows the baseline hematological parameters and changes in haemogram after Iron sucrose IV infusion

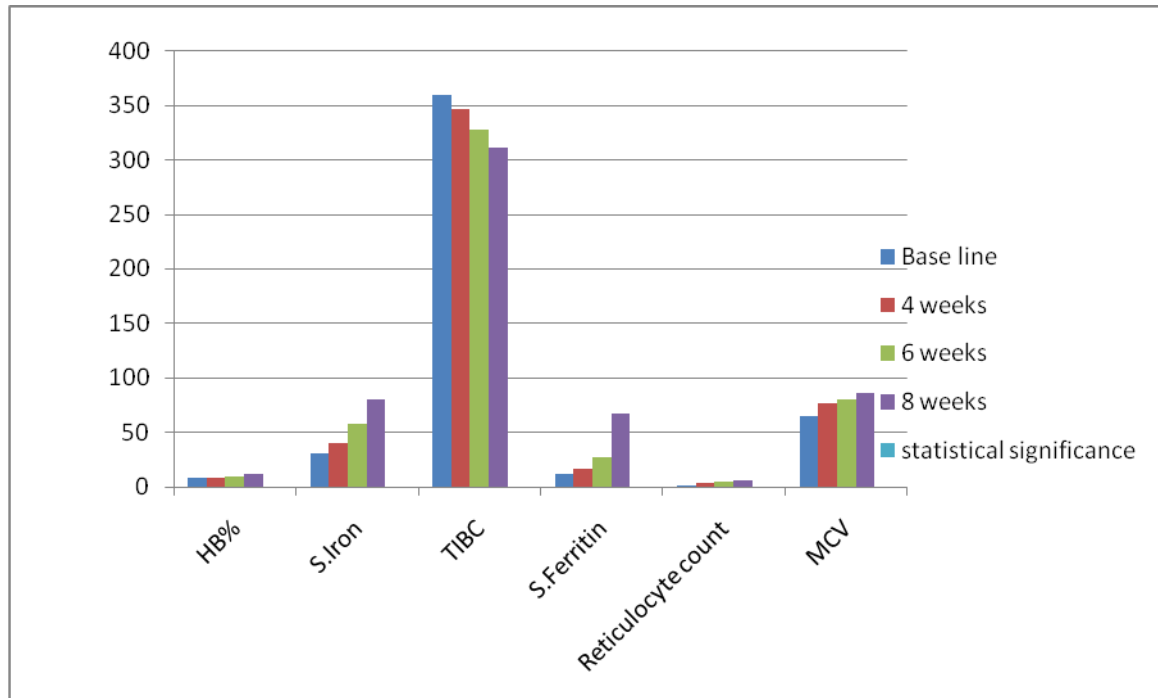


Fig: Bar diagram showing change in Haematological parameters.

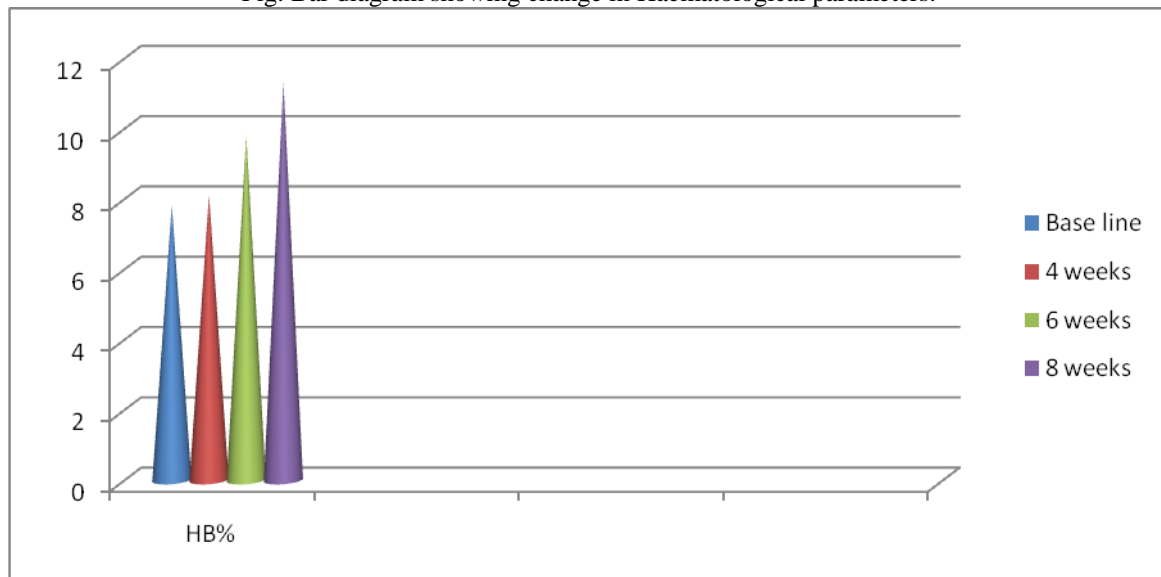


Fig- 2- Bar diagram showing rise in Haemoglobin by 8 weeks.

STATISTICAL ANALYSIS:-

Interpretation and analysis of data was done by using paired T test P < 0.005 was taken as significant.

IV. Results

The mean age of women was 25.5 ± 3.4 (19-32 years), the mean period of gestation at the time of diagnosis was 25 ± 5.12 (18-32) weeks. Prior to iron transfusion mean Hb was 7.82 ± 0.93 gms. Out of 90 pregnant women entered into this study 62 women (68.88%) were defined as having moderate anemia and 28 (31.11%) had severe anemia. After completion of therapy mean Hb raised to 11.34 ± 0.82 gms % (table)

PERINATAL OUTCOME:-

Out of 90 pregnant women, 10 (11%) were delivered before 37 weeks. The remaining 88.88% women were delivered vaginally, 22 (24.4%) were delivered by LSCS (elective /emergency). Mean period of gestation at

delivery 38.75 ± 1.2 (37.2- 40.3) weeks.5 women had PPH and required packed cell transfusion.the mean birth weight of the babies was 2.75 ± 430 gms (2.3-3.2 kg)

V. Discussion

Iron requirements are greater in pregnancy than in non-pregnant state. Although iron requirements are reduced in the 1st trimester because of absence of menstruation, they rise steadily thereafter. In the 1st trimester the daily iron requirement is 0.8mg, 4-5mg in 2nd trimester and 6-8mg in 3rd trimester. The total iron requirement is about 1000-1200mg (for growing fetus-270mg, placenta-90mg, for the expansion of RBC mass-450mg and blood loss during delivery 150mg)[7]. usually this iron is mobilized from iron stores however women with poor iron stores become iron deficient during pregnancy.

Studies have shown that moderate to severe anemia in pregnancy are associated with higher maternal fetal morbidity, severe anemias associated with cardiac decompensation and pulmonary edema. Blood loss even 200ml in 3rd stage of labor can cause shock and death in severe anemia[8]. the stores in Indian women are deficient and they require 100 mg elemental iron per day for prophylaxis. for the treatment of anaemia the recommended dose is 200 mg elemental iron per day[9].

The major challenges in the management of IDA are related to tolerability and side effects of iron therapy in its different forms. Therefore it is crucial to determine the most appropriate form and dose of iron as well as duration of treatment in order to successfully replenish the iron stores.

In a large systemic review and meta analysis involving 75 studies including 10,879 participants in many specialties had shown that intravenous iron was associated with significant increase in standardized mean Hb concentration compared with oral iron or no supplementation.[10]

Alkakriplani, Reetamehay et al[11], evaluated the effect of intravenous 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 6-9gm% Hb was taken as cut-off, the rise in mean Hb was from 7.82 to 11.34 after intravenous iron sucrose therapy.[12]. Parenteral iron therapy in pregnant women reduces the need for blood transfusion[13].

VI. Summary And Conclusion

In prospective observational study our results showed that iv iron sucrose therapy was safe and effective with better compliance to manage moderate to severe anemia in pregnancy with negligible side effects compared to oral iron therapy.

Therefore the use of intravenous iron sucrose has been characterized by reassuring safety profiles and easy administration schedules. nowadays the total desired Hb levels and the required dose to correct iron deficiency anemia are calculated. to restore tissue iron deposits easily administered by a single IV infusion with not more than 15 to 30 min time improving the pharmacokinetic benefits of effective rapid replenishment of iron stores.

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