



A PROSPECTIVE STUDY TO ASSESS THE EFFECTIVENESS AND SAFETY OF INTRAVENOUS IRON SUCROSE THERAPY IN IRON DEFICIENCY ANEMIA IN ANTENATAL PATIENTS IN A DISTRICT HOSPITAL

Gynaecology

Sonika Gupta*

Consultant Gynaecologist and Obstetrician, District Hospital, Udhampur, Jammu
*Corresponding Author

Poonam Sharma

Lecturer, Department of Pathology, Government Medical College, Jammu

ABSTRACT

Introduction: Iron deficiency anemia is the commonest nutritional deficiency in pregnancy. It is particularly common in developing countries and is aggravated due to increased demand of iron during pregnancy and blood loss during delivery. Though there are different methods for correcting iron deficiency anemia, iron sucrose infusion is commonly used because of minimal side effects. This study was undertaken to evaluate the response and effect of intravenous iron sucrose in antenatal patients with iron deficiency anemia.

Methods: This prospective study included 100 antenatal patients with iron deficiency anemia. After performing relevant investigations and calculating appropriate dose, injection iron sucrose was administered to the patients under proper monitoring and supervision. Patients were evaluated again at end of 4 weeks.

Results: Iron sucrose therapy was effective in achieving mean hemoglobin rise of 2.72 ± 0.06 gm%. Further intravenous iron sucrose significantly increased ($P < 0.00001$) hemoglobin level within 4 weeks of therapy without any major adverse effects.

Conclusions: This study establishes the safety and efficacy of iron sucrose therapy in correcting anemia in antenatal patients.

KEYWORDS

Antenatal patients, Iron deficiency Anemia, Intravenous iron sucrose

INTRODUCTION

Anemia is a major health problem in the entire world, particularly in developing countries. In the developing countries, anemia directly or indirectly contributes to about 20% of maternal deaths and predisposes to postpartum hemorrhage, sepsis and preeclampsia. Maternal anemia is associated with intrauterine growth retardation, preterm births and low birth weight children [1,2].

According to World Health Organization (WHO), anemia in pregnancy is present when the Haemoglobin (Hb) concentration in peripheral blood is 11gm/100ml or less. According to WHO, prevalence of anemia in pregnancy in developing countries ranges between 35-75% (average 56%) [2]. According to Indian council of medical research (ICMR), prevalence of anemia in pregnant women in India ranges between 50% and 90%. As per ICMR classification, Iron deficiency anemia (IDA) is graded as mild, moderate and severe anemia with levels of 8-11gm%, 5-8gm% and <5gm% of Hb respectively. Cause of high prevalence of anemia in India is multifactorial.

The treatment of anemia in pregnancy depends on severity of anemia and associated obstetrical and medical complications. In mild degree of Iron deficiency anemia, first choice of treatment is oral iron therapy. But in moderate to severe degrees of anemia, parenteral iron is a better alternative as endogenous iron stores are usually depleted and less iron is provided for erythropoiesis [3]. Parenteral iron is also a better alternative to the oral iron in women who are non-compliant or cannot tolerate oral therapy. It is superior to the oral therapy as there is no need for constant motivation and the critical time is saved in non-responders in the late gestation, thereby decreasing the need for blood transfusion which carries its own risks.

Conventional parenteral iron like iron dextran and iron gluconate require test dose as they are known to cause anaphylactic reactions and accumulation of these compounds in liver parenchyma is much higher compared to iron sucrose [4,5]. Iron sucrose therapy is effective in increasing Hb and serum ferritin in pregnant women with less incidence of minor and no incidence of serious side effects as per recent studies [5,6].

So the study was undertaken to evaluate the response and effect of parenteral iron sucrose complex therapy in IDA in pregnancy.

METHODS:

This was a prospective hospital based study conducted in District hospital, Udhampur, Jammu. 100 antenatal patients in the OPD and maternity ward of the hospital with Hb level between 6-9gm% were included in the study after taking informed consent.

Inclusion Criteria-

- Antepartum singleton pregnancy with anemia.

- Hb concentration between 6-9 gm%

Exclusion Criteria-

- Patients with Hb >9gm% or < 6gm%
- Anemia other than IDA
- With history of hypersensitivity reaction to Injectable iron sucrose
- Multiple Gestation
- Women with medical disorders and co-morbidities other than anemia like Tuberculosis, Diabetes Mellitus, Renal and Hepatic disorder, Thromboembolism, DVT, Cardiovascular dysfunction, COPD and Asthma

Fresh Blood sample was taken in each patient and complete hemogram with blood indices obtained. Serum Ferritin Levels were also obtained. Peripheral blood smears (stained with leishman's stain) were evaluated to study morphology of RBC's. Baseline tests for renal and liver functions, urine for routine microscopic examination and culture sensitivity and stool examination for ova and cyst were done.

Deficit of iron was calculated by the following formula:

Total iron dose (mg) = weight (kg) x (target Hb in gm% – present Hb in gm%) x 2.4 + 500 mg for replenishment of stores.

Target Hb was kept at 11gm%. Calculated dose of iron sucrose was given in divided dose on alternate days. 200 mg of iron sucrose was mixed in 100ml of normal saline solution and given intravenously. First 10ml of the solution was infused over a period of 15 minutes to look for any adverse reaction. If there was no adverse reaction, the remaining portion was infused over next 30 minutes. Patients were closely monitored during the entire procedure for adverse drug reactions. Emergency drugs were kept ready for anaphylactic reactions. Effect of iron sucrose was evaluated by improvement in clinical features of patients, rise in Hb level, blood reticulocyte count and blood indices and results tabulated.

RESULTS:

60% of women were seen in the age group of 20 – 29 years group (Table 1). The mean age of pregnant women was 25.6 ± 1.92 years. 40 % women had period of gestation between 28–36 weeks and 26% had period of gestation between 13-20 weeks.

Among all patients, 69% women had Hb level < 8 gm% before infusion. Following infusion of iron sucrose, 73% women achieved Hb level of 10 gm% or more after infusion (Table 1). 15% of women had Hb level <7 gm% before infusion and 27% of patients had Hb <10 gm% post infusion. The mean hemoglobin raised from 7.58 ± 0.4 gm% to 10.3 ± 0.46 gm% after completed 4 weeks of therapy ($P < 0.00001$) (Table 2)

Adverse Effects after infusion were observed in 12% patients, with

fever and injection site pain being the commonest ones. Solitary patient in our study had anaphylactic reaction and was managed with hydrocortisone and adrenaline. Rest if the patients had uneventful post infusion period.

DISCUSSION:

Iron deficiency anemia (IDA) is a major health problem worldwide and responds well to iron supplementation. In pregnancy, the total amount of extra iron requirement ranges from 700 to 1400 mg with an average of 1000 mg. This amount cannot be provided by diet, so there is a need for iron supplementation during pregnancy to overcome the deficit [6]. Pregnant women are commonly prescribed oral iron agents because of convenience and low cost. However, the efficiency of these agents is limited by their inadequate absorption rate and gastrointestinal side effects and compliance. Second generation intravenous iron formulations, including iron sucrose and ferric gluconate have proven efficacy in the management of IDA and are not associated with the serious allergic reactions encountered with first generation iron formulation like iron dextran.

In this study, out of the 100 patients, 60% patients were between 20 to 29 years. Thakor N et al [7] observed maximum patients (48%) in the age group of 20–24 years in their study. Our study observed a higher prevalence of anemia in 3rd trimester as compared to 1st and 2nd trimester. The findings collaborate with study by Singh R et al [8].

69% of patients in our study had Hb levels < 8gm% before iron sucrose infusion. After treatment, 73% women achieved Hb levels of 10 gm% or more. Pre-treatment mean Hb level in our study was $7.58 \pm 0.46\text{gm\%}$ and it rose to $10.3 \pm 0.46\text{gm\%}$ after infusion with P value <0.0001. Thakor N et al [7] in their study observed that 40% of women had Hb < 8gm% and 65.4% women achieved Hb of 10gm % after treatment. The mean hemoglobin in their study raised from $7.8 \pm 0.61\text{gm\%}$ to $10.1 \pm 0.73\text{gm\%}$ (P < 0.001) after six weeks of therapy. In study by Kriplani A et al [9], mean Hb level at the beginning of infusion was $7.63 \pm 0.61\text{gm\%}$ with 32% women having mild and 68% having moderate anemia. After completion of therapy, mean Hb in their study rose to $11.20 \pm 0.73\text{gm\%}$ and 67% women achieved Hb > 11gm%. The results of our study were comparable to those of Kriplani A et al [9].

Out of 100 patients, 4 had fever with chills and 3 patients developed injection site pain. Only single patient in our study had severe anaphylactic reaction. Shafi D et al [10] also conducted study on efficiency and safety of intravenous iron sucrose versus oral iron (ferrous ascorbate) in pregnancy and found that there were no serious adverse drug reactions, anaphylaxis or shock.

Limitations of this study were that the sample size was smaller and it was a non-randomized trial without any control group, so we cannot generalize the obtained results

CONCLUSIONS:

Intravenous iron sucrose transfusion is an effective treatment strategy in pregnant patients with IDA. Intravenous iron sucrose was associated with negligible side effects. Intravenous iron causes rapid rise in hemoglobin level with faster replacement of iron. Other advantages of iron sucrose infusion are that it can be used in peripheral level hospital where blood bank facilities are not available or are inadequate. It causes rapid correction of anemia which ultimately improves maternal and fetal outcome.

Conflicts of interest: Nil

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Tables:

Table1: Rise in Hemoglobin Level in Pregnant Women (n=100)

Pre infusion Hb		Post infusion Hb	
Hb (gm%)	No. of pts (%)	Hb (gm %)	No of pts (%)
6.0 - 6.9	15 (15%)	9.0-9.9	27(27%)
7.0 – 7.9	54 (54%)	10.0 – 10.9	62 (62%)
8.0 – 8.9	31 (31%)	11.0 – 11.9	11 (11%)
Total	100	Total	100

Table 2: Mean rise in hemoglobin and mean Hb levels in pregnant women before and after treatment (n=100)

Mean Hb pretreatment	Mean Hb post treatment	Mean rise in hemoglobin
$7.58 \pm 0.46\text{gm\%}$	$10.3 \pm 0.46\text{gm\%}$	$2.72 \pm 0.06\text{gm\%}$

Table 3: Adverse Reactions (n=12)

Types of Adverse Reactions	Number of Patients
Injection site pain	3
Phlebitis	1
Headache	1
Fever with chills	4
Arthralgia	2
Anaphylactic reaction	1
Total	12

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