

To Assess the Efficacy and Impact of Intravenous Iron Sucrose Therapy Administered to Pregnant Women Diagnosed with IDA

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Abstract

Background: Iron deficiency anaemia (IDA) is highly prevalent in pregnancy, representing the most common nutritional deficiency. To address the increased iron demands during pregnancy, prophylactic oral iron supplementation is recommended. However, in India, many women begin pregnancy with low haemoglobin levels, leading to a high incidence of moderate to severe anaemia that oral iron therapy alone may not adequately address. For pregnant women with moderate anaemia, parenteral iron therapy is recommended.

This study aims to assess the efficacy and impact of intravenous iron sucrose therapy administered to pregnant women diagnosed with IDA.

Methods: The study enrolled fifty patients diagnosed with iron deficiency anaemia, characterized by haemoglobin levels between 8-10 g/dL visiting Vardhaman Mahavir Medical College and Safdarjung Hospital, Delhi, India. The total iron deficit was calculated using a standard formula. The target haemoglobin level aimed for was 11 g/dL. Intravenous iron sucrose was administered in divided doses via infusion. Haemoglobin levels were reassessed three weeks after the completion of the intravenous iron sucrose treatment. Gestational age and socioeconomic distribution were calculated as percentages. Pre- and post-treatment haemoglobin levels were analysed using mean and standard deviation, and p-values were assessed.

Results: The majority of patients (60%) were in the gestational age range of 32-34 weeks, with 30% between 29-31 weeks, and 10% between 26-28 weeks. The mean gestational age was 32.4 ± 2.7 weeks. Socioeconomic distribution revealed 40% from the lower class, 32% from the middle class, and 28% from the upper class. Intravenous iron sucrose therapy proved effective in 90% of patients without any reported side effects or allergic reactions.

Conclusion: This study demonstrated significant improvement in haemoglobin levels among patients receiving intravenous iron sucrose infusion, achieving the target haemoglobin level of 11 g/dL. The treatment was well tolerated and deemed safe for use in pregnant women with iron deficiency anaemia.

Keywords: anaemia, pregnancy, iron deficiency

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Introduction

WHO defines anaemia as haemoglobin (Hb) <11 g %1 In India, the ICMR classification of iron deficiency anaemia is: 8-11 g% as mild, 5-8 g % as moderate and <5 g% as severe anaemia. In absence of interfering factors, serum ferritin $<12-15$ μ g/l is considered as iron deficiency [1]. Anaemia during pregnancy is associated with complications such as post-partum haemorrhage, low birth weight, premature births, stillbirths, and maternal deaths [2].

The World Health Organization (WHO) estimates that nearly 40% of pregnant women and one-third of all women of reproductive age worldwide are

anaemic [3]. In India, the National Family Health Survey, 2019-2021 (NFHS-5) reported that 52.2% of pregnant women in India were anaemic, the prevalence being higher in rural areas (54.3%) than in urban areas (45.7%). The study was conducted in the Faridabad district of Haryana state, where the reported prevalence of anaemia among pregnant women was 55% [4].

Iron deficiency is the most common cause of anaemia and is estimated to contribute to approximately 50% of all cases of anaemia among non-pregnant and pregnant women worldwide [5].

The first choice for prophylaxis and treatment of mild iron deficiency anaemia in pregnancy is oral iron therapy. But in patients with moderate and severe anaemia, oral therapy takes long time and compliance is a big issue in our country. Thus, pregnant women with moderate anaemia should be better treated with parenteral iron therapy and/or blood transfusion depending upon individual basis (degree of anaemia, haemodynamic status, period of gestation, etc.) [6].

Various parenteral iron preparations are available in the market which can be given either intravenously or intramuscularly. Initially, iron dextran and iron sorbitol citrate was started. But test dose was required to be given before these injections as severe anaphylactic reactions were reported with intravenous iron dextran. Iron sucrose has been reported to be safe and effective during pregnancy [6]. The injection can be given without test dose [7]. Intravenous iron sucrose (IVIS) has been reported to be safe and efficacious in rapidly raising the haemoglobin (Hb) level among pregnant women [8-10].

Methods

It was a retrospective study carried out at Vardhaman Mahavir Medical College and Safdarjung Hospital, Delhi in the Department of Obstetrics/Gynaecology for 6 months. Fifty cases fulfilling inclusion and exclusion criteria were considered in this study. Fifty consecutive patients coming to the antenatal OPD, within the age of 20 to 38 years, having singleton foetus with gestational age of 26 to 34 weeks on ultrasound, with confirmed diagnosis of hypochromic microcytic anaemia on blood examination by peripheral smear and serum ferritin levels, and women who were intolerant to oral iron were included in the study.

The patients with other causes of anaemia like thalassemia, megaloblastic anaemia etc., having

liver, kidney or cardiovascular disease, or having history of iron therapy by any route or blood transfusion during present pregnancy were excluded in the study.

Demographic information including name, age and gestational age was taken from the patients. The beneficial effects as well as side effects of iron sucrose were explained to each eligible patient or her relatives and informed consent was taken from each patient. Total iron deficit was calculated by a standard formula. $0.3 \times W (100-Hb\%)$ mg of elemental Iron. W means Patients weight in pounds. Hb% is observed Hb concentration in % and Additional 50% was added for replenishing iron stores. Target Hb was 11gm/dl. Iron sucrose was given by intravenous injection in divided doses on alternate day according to the iron deficit calculated for each individual patient, 200mg elemental iron diluted in 200ml of 0.9% normal saline infusion, initially first 50ml was given at 8-12 drops/ min for 15-30 minutes and patient was monitored for any symptoms and signs of allergic reaction. Later rest of infusion was given at 36 drops/ minute. Haemoglobin was repeated 3 weeks after the last dose of intravenous iron and reticulocyte count was monitored. Gestational age, socio economic class distribution was calculated in percentage and pre and post treatment Hb% was calculated by mean and standard deviation and P-value was assessed.

Results

Regarding age distribution, majority of the patients i.e., 48.5% were between 26-30 years while minimum patients 10% were > 35 years of age with mean age of 32.3 ± 3.1 years. Most of the patients 30 (60%) had gestational age between 32-34 weeks, 15 patients (30%) had 29-30 weeks of gestational age while 5 patients (10%) were between 26-28 weeks of gestation (Table 1).

Table 1: Distribution of patients by duration of pregnancy (N=50)

| Gestational age (in weeks) | No. Of patients | % |
|----------------------------|-----------------|------|
| 26-28 | 5 | 10% |
| 29-31 | 15 | 30% |
| 32-34 | 30 | 60% |
| Total | 50 | 100% |

Distribution of cases by socio economic status shows 20 patients (40%) belonged to lower class (monthly income < Rs.5000), 16 patients (32%) belonged to middle class (monthly income Rs.5000-10000) and 14 patients (28%) were of upper class (monthly income Rs.>10000) (Table 2).

Table 2: Distribution by socio economic status

| Socio economic status | No. Of patients | % |
|-----------------------|-----------------|------|
| Upper class | 14 | 28% |
| Middle class | 16 | 32% |
| Lower class | 20 | 40% |
| Total | 50 | 100% |

Therapy was effective in 45 patients (90%) while in 5 patients (10%) therapy was ineffective. Mean Hb level before iron sucrose therapy was 8.5 ± 1.2 while it was increased up to 11.2 ± 1.8 after the therapy (Table 3) and was found significant ($p < 0.001$).

Discussion

Maternal iron deficiency is very common in India causes being poverty, poor literacy rate, early marriage, increased parity, less use of contraception and hence poor spacing of births so they are potentially associated with maternal malnutrition and intrauterine growth retardation. Anaemia is estimated to affect nearly two third of pregnant women in the developing countries [11]. Iron deficiency is responsible for 95% of anaemia during pregnancy [12]. The responsible factors producing iron deficiency anaemia generally precedes the pregnancy, including diet poor in iron content coupled with menstrual losses and a rapid succession of pregnancies in which supplemental iron was not provided. Most women begin their pregnancy with partially or completely depleted iron reserves. Thus, the severity of the anaemia is inversely related to the amount of iron reserves [12].

During pregnancy, there is a great demand for iron to meet the requirement of red cell mass expansion in the mother, foetal and placental blood and blood loss at delivery [13]. In pregnancy, iron deficiency is exaggerated because of the ability of foetus to extract its requirement even from iron deficient mother [13].

This is aggravated by poor absorption of iron due to adverse effect of pregnancy on the gastrointestinal tract which includes nausea and vomiting, motility disorder with reflux esophagitis and indigestion. In underdeveloped countries, anaemia is a major contributory factor to maternal morbidity and mortality [14]. Inadequate antenatal care along with lack of knowledge of dietary needs of pregnant woman, and overall poor socioeconomic conditions are all responsible for increased maternal mortality rates in our country [15].

Other Asian countries like Indonesia also report high prevalence of iron deficiency anaemia in pregnancy and associated maternal and foetal loss. It is also associated with high perinatal mortality rate [16]. In the developed world it has long been documented that intravenous iron supplementation is highly effective in treating iron deficiency anaemia in a variety of settings, including pregnancy. There is irrefutable evidence that compared to oral iron, intra venous iron sucrose results in a much more rapid resolution of iron deficiency anaemia [17], has minimal side-effects, and since it is administered intravenously, it circumvents the problems of compliance. Unlike intravenous iron dextran,

anaphylactic reactions are virtually unknown with iron sucrose [18].

Present study showed that intra venous iron sucrose significantly ($P < 0.001$) increase Hb levels within 4 weeks. There were no major complications, and none of women experienced any adverse reaction. All women stated that they found the treatment acceptable to them. A random, prospective, open study conducted in France by Bayomeu et al, involving 50 patients at 6 month of gestation to compare intravenous iron sucrose versus oral route showed an increase in haemoglobin from 9.6 ± 0.7 g/dl to 11.11 ± 1.3 g/dl after 4 weeks of treatment with intra venous iron sucrose ($P < 0.001$) [17]. These results are comparable to current study. In a study conducted at Aga Khan Hospital for women and children in Karachi on 60 pregnant women at 12-34 weeks gestation with iron deficiency anaemia. Intra venous iron sucrose was compared to iron sorbital. Mean increase of 2.6g/dl Hb was seen in iron sucrose group [19].

In another study carried out by Raja et al on intravenous iron sucrose complex therapy in iron deficiency anaemia in pregnant women. Fifty pregnant women between 16-32 weeks of gestation with haemoglobin of 8gm/dl were included. Results showed mean Hb level increased from 7.5 to 11gm/dl [20]. In the present study mean Hb before therapy was 8.5 ± 1.2 and after therapy 11.2 ± 1.8 ($P < 0.001$) which was significant. Our results were consistent with the study of Raja et al [21]. Like most of the other studies there were no major adverse reactions noted in any patient in our study.

Conclusion

Iron sucrose complex has been able to raise the haemoglobin to satisfactory level when used in severely anaemic iron deficient pregnant women. It is safe and well tolerated. We would like to recommend total dose infusions of iron sucrose in divided doses prophylactically in the mid trimester to avoid untoward catastrophes that can happen to the mother and the foetus due to iron deficiency anaemia.

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