

SAFETY AND EFFICACY OF PARENTERAL IRON SUCROSE COMPLEX THERAPY IN IRON DEFICIENCY ANEMIA IN ANTENATAL AND POSTNATAL WOMEN

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ABSTRACT

Background: Iron deficiency anaemia (IDA) is one of the common medical disorders in pregnancy in the developing world, which affect both the mother and the newborn and subsequent child and later adult.

Aims & Objective: This study is undertaken to evaluate the safety and efficacy of parenteral iron sucrose complex therapy in iron deficiency anaemia in antenatal and postnatal women.

Material and Methods: 110 consecutive pregnant women between 16-36 weeks of gestation and postnatal women, diagnosed as cases of Iron deficiency anaemia with Hb level 5-8 gm%, who were seen from May 2009 to April 2011 in our Hospital, were included in the study. All the patients received Iron Sucrose Complex in infusion form with the aim to correct the iron deficiency as well as to replenish the iron stores. The aim was to bring her Hb level to 10gm%. Result were analyzed in terms of the safety & efficacy,

Results: Intravenous iron sucrose is effective in achieving target Hb of 10g/dl in 80% of patients. It shows that of IV iron sucrose significantly ($P < 0.001$) increase Hb levels within 4 weeks. There were no major adverse reactions. All women stated that they found the treatment acceptable to them. Iron Sucrose Injection is relatively safe and well tolerated.

Conclusion: Iron sucrose (intravenous) therapy is safe, more effective and well tolerated in the treatment of iron deficiency anaemia during pregnancy. Overall, iron sucrose appears to be a treatment of choice with no serious side effect indicated in the rapid correction of anaemia in pregnancy or restoring maternal iron stores, especially because the total dose can be administered over a shorter period of time. If used in time, this treatment will certainly help to reduce the risk of maternal and foetal complications as well as it also reduce the risk of blood transfusion during peripartum period.

KEY-WORDS: Pregnancy, Iron Deficiency Anaemia; Iron Sucrose Complex

Introduction

Anaemia is the most common problem encountered during pregnancy. Overall prevalence is 40% of world's population. Prevalence is 3-4 times higher in developing countries. Average prevalence is 56%. In India alone the prevalence of anaemia in pregnancy is as high as 88% (WHO Global Database 1997). The existence of IDA generally precedes the pregnancy, the causes being diet poor in iron content coupled with menstrual losses and a rapid succession of pregnancies in which supplemental iron was not provided. 20% of all maternal deaths are contributed to Anaemia.^[1] In underdeveloped countries, anaemia is a major contributory factor to maternal morbidity and mortality.^[2]

Cut off point for diagnosis of anaemia in pregnancy is Hb < 11 gm% according to WHO Criteria, accompanied by depleted iron stores and sign of compromised supply of Iron to tissues.^[3]

Oral iron treatment has been shown to be effective in correcting Iron Deficiency Anaemia. Parenteral Iron Sucrose therapy promises faster, effective, and safe management of iron deficiency anaemia in pregnancy, post-partum and during planned surgeries when time is a constraint

Various modalities of management of IDA like oral, intramuscular and intravenous preparations of iron have been used in the pregnant patients^[4-6] but efficacy of oral iron therapy may be limited in many patients because of dose dependent side-effects, non-compliance, and poor absorption and not possible to achieve the target rise in Hb level

in a limited time-period when patient is approaching the term. Iron sucrose complex (ISC) is a relatively new drug, which is used intravenously for the correction of IDA.^[5,6] The drug has been able to raise the Hb to satisfactory level when used in severely anemic iron deficient pregnant women.^[7,8] The aim of this study was to assess the safety & efficacy of ISC in antenatal and postnatal women with IDA seen at our institution.

Materials and Methods

110 consecutive consenting pregnant women between 16-36 weeks of gestation and postnatal women, diagnosed as cases of Iron deficiency anaemia with Hb level 5-8 gm%, which were seen from May 2009 to April 2011 at our institute were recruited in study.

After admission in hospital wards (antenatal, post natal) and written informed consent was taken prior to screening enrolment. After excluding other causes of anaemia e.g. Thalassemia, Haemolytic anaemia, hypersplenism, infection, inflammation, liver or renal disease subjects were administered Parenteral Iron Sucrose therapy. All the patients received ISC in infusion form with the aim to correct the iron deficiency as well as to replenish the iron stores. The aim was to bring her Hb level to 10gm%.

Formulae were used to calculate the iron requirement of the patient to fulfill the deficit as well as to replenish the iron stores and were calculated as follows: Amount of iron deficit (mg) = Body wt (Kg) × Hb deficit (gm%) × 0.24 + 500

ISC was administered as 200 mg elemental iron in 100 ml 0.9% Normal Saline infusion over 1 hour on alternate days up to the total calculated dose. A test dose of one ml of Iron Sucrose infusion was given and followed by a 15 minutes window period, during which no infusion was given and patient was observed for any allergic reactions. If no reactions occurred, the rest of the infusion was given. Hemoglobin level was done on 14th post treatment day and 1 month post treatment day.

Monitoring during infusion: A set of observations (BP, pulse, temperature) were taken before the

start of the infusion, after 15 minutes and at the end of the infusion. Similar clinical observations were taken as and when required during blood transfusion i.e. looking for symptoms or signs of an adverse reaction. The subjects were allowed to go home four hours after the infusion if all observations were stable. Mild allergic reactions were managed by stopping the administration of ISC and giving Injection Chlorpheniramine 10 mg IV slowly. The infusion was then be restarted at a slower rate and the women observed closely. ISC was not given concomitantly with oral iron preparations.

Haemoglobin level, MCV and serum ferritin level were done fortnightly. Coulter haematology analyser was used for Hb and MCV determinations. Serum ferritin levels were measured using standard laboratory techniques.

Allergic Reactions were graded as grade I and grade II and they are described as following. Grade I reaction was mild to moderate in nature, settled with an anti-allergic drug but not requiring discontinuation of the infusion and Grade II reaction was severe in nature, threatening the patient's life and requiring discontinuing of infusion.

Mean values of Hb, MCV and ferritin were used to compare pre and post treatment parameters. A p value of less than 0.5 was considered to be significant.

The data was compiled and standard tests of significance (p- value) were applied.

Results

The total number of selected patients during the study period was 110 among them 61 were antenatal & 49 were postnatal. The age of subjects ranged from 18 to 35 years. The mean age was 25years. Most of the patients were multigravida. The average gestational age was 30 weeks. 21 (19.26%) subjects had symptoms like weakness, fatigue, pedal edema and fever. However 89 (80.73%) study subjects were asymptomatic. Forty six out of 110 (42.2 %) subjects had taken haematinics of which regular iron tablets had been taken by only 9 out of 110 (8.25%) subjects.

Thirty seven out of 110 (33.94%) subjects admitted having 'irregular' in their iron ingestion. Sixty four out of 110 subjects (57.78%) had not taken any form of oral iron therapy. Among antenatal subjects the mean pre-treatment Hb was 7.01 gm% and it was 7.25 gm% among post natal subjects. In present study, dose of ISC required ranged between 600-1200 mg with mean of 744.44mg.

Among antenatal subjects, mean 14th post treatment day Hb and 1 month post treatment day Hb were 9.1 gm% and 10.34 gm% respectively with rise of 2.21 gm% on 14th post treatment day and 3.33 gm% on 1 month post treatment day (p-value <0.001).

Among postnatal subjects, mean 14th post treatment day Hb and 1 month post treatment day Hb were 9.47 gm% and 10.48 gm% respectively with rise of 2.22 gm% on 14th post treatment day and 3.23 gm% on 1 month post treatment day (p-value <0.001).

The three antenatal subgroups (16-24, 24-32, 32-36 weeks) did not show a statistically significant difference in rate of Hb rise on the 14th and 30th post treatment days i.e. the Hb rise was independent of gestational age at administration of ISC.

In present study, out of 61 antenatal subjects 57 were delivered during study period. Among them, 51 (91.07%) subjects were delivered at term, only 6 (10.07%) subjects were delivered before gestational age of 37 weeks and had interval of > 2 weeks after completion of ISC therapy indicating there is no association of ISC and Preterm labour.

After the test dose of ISC infusion, only two patients had grade I allergic reaction. One had pain in the epigastrium and the other had restlessness. No patient had grade II allergic reaction. The mean duration to achieve the target Hb level of 11 gm/dl was five weeks.

Before ISC infusion, the mean Hb level was 7.5 gm/dl, mean MCV was 65 fl and mean serum ferritin level was 9.6 ug/l. After ISC infusion, the mean Hb level rose to 11 gm/dl, mean MCV became 75 fl and mean serum ferritin level was

16.4 ug/l. The differences in values were statistically significant (p<0.05).

Discussion

Our study showed that iron sucrose complex can be used in the pregnant patients with iron deficiency anaemia not only for correction of deficit in the haemoglobin but also for restitution of iron stores as seen by significant improvement of ferritin level. The mean duration of the period to achieve the target Hb in the present study was 5 weeks as compared to 6.9 ± 1.85 weeks in a previous study.^[6]

We used Hb, MCV and ferritin levels to monitor response of hemopoietic system to iron sucrose complex because of their relative importance in the haemodynamic of the pregnant lady. Due to dilution effect of pregnancy on plasma volume, there is a decrease in Hb, haematocrit and red blood cell count but MCV remains unaffected.^[9] Thus, serial evaluation is useful in differentiating dilutional anaemia from progressive IDA during pregnancy. Except for bone marrow biopsy, serum ferritin is best indicator for assessment of iron stores in the non-pregnant women.^[9-11] In pregnancy, it falls dramatically in second and third trimester, presumably because of hemo-dilution effect.^[10]

Treatment of IDA has included oral iron, intramuscular iron, iron dextran, ISC, recombinant erythropoietin and blood transfusion.^[9] However, most of these have their disadvantages. Even patients who respond well to oral iron therapy require a long time (months) to reach target Hb compared with weeks required in case of treatment with ISC. The compliance is always a problem and to improve this, even iron-rich natural mineral water has been tried to treat IDA in pregnant women.^[12] The use of intramuscular iron preparations in IDA is discouraged because of pain, irregular absorption and staining. Up to 30% of patients who were given iron dextran suffer from adverse effects, which include arthritis, fever, urticaria and anaphylaxis.^[9] In present study, only few subjects had mild side effects and none had anaphylaxis, thus showing the safety of the drug in the pregnant women. Side effects were limited in the present study because the total dose

of ISC was administered at intervals and it was given in diluted form and slowly.

Conclusion

This study showed significant improvement of Hb and iron stores in pregnant women given calculated dose of ISC infusion. It is safe and well tolerated. In our country with high prevalence of IDA during in pregnancy, this type of treatment may be helpful in management of these patients.

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