

Clinical Safety of Intravenous (I/V) Infusion of Iron Sucrose Complex for Treatment of Iron Deficiency Anemia in Pregnancy

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ABSTRACT

Background: Anemia is a common nutritional disorder occurring in about 48 to 52% of population. This becomes even more prevalent amongst pregnant women due to already existing deficiency for various reasons coupled with pregnancy induced stresses requiring not only prophylactic oral iron & folic acid but also injectable iron & blood transfusions

Aim: To find safety profile and tolerability of injectable iron sucrose in pregnant patients as a substitute to more conventional oral iron therapy.

Methods: This prospective study was conducted in the Department of Obstetrics & Gynecology at Pak Red Crescent Medical College on 130 pregnant patients with singleton pregnancy who had hemoglobin between 6 to 11 gm/dl. They were given injectable iron sucrose in pre-calculated dose and results were noted.

Results: Minimum side effects were seen along with rise in hemoglobin upto 2 gm/dl

Conclusion: Iron sucrose complex is safe and effective in patients who cannot take oral iron due to any reason. It results in better and quicker elevation in hemoglobin levels among these women.

Keywords: Iron deficiency anemia, iron sucrose complex, hb (haemoglobin).

INTRODUCTION

WHO has defined anemia in pregnancy as hemoglobin (hb) <11gm/dl in the first and third trimester of pregnancy and less than 10.5gm/dl in second trimester of pregnancy^{1,2}. The prevalence of anemia in developed countries is 14% but in our country it is nearly 51%^{3,4}. Anemia can be due to many causes such as decreased nutritional intake of iron, other nutritional deficiencies, worm infestation, increased blood loss and increased requirements. (2) In pregnancy iron deficiency due to both increased requirements and decreased intake is the leading cause of anemia^{1,5,6,7}. The body needs about 1240 mg during pregnancy. Woman saves some due to amenorrhea but still needs about an added requirement of 1000mg¹. The supplement is usually given in the form of oral iron but many a times it results in treatment failure due to side effects (nausea, flatulence, diarrhea, constipation black tarry stools etc.) or non-adherence further resulting in decreased physical, mental and cognitive performance^{8,9}. It results in increased maternal and fetal morbidity as anemic mothers can have increased susceptibility to infection, cardiac failure, venous thromboembolism and premature delivery. The baby can suffer the consequences of premature delivery, low birth weight as well as anemia in the first year of life^{10,11,12,13,14,15}. Though Iron deficiency anemia is a major nutritional and health problem due to its morbidity and mortality in both mother and fetus but it is a potentially preventable disease^{14,15}. Many researches are going on to find out other safer ways to give iron to patients who cannot take oral iron due to any reason and our study is also one of the similar efforts which is further discussed in our objectives.

The objectives of this study were to evaluate maternal safety and tolerability to iron sucrose and to see an alternative to oral iron with better efficacy.

METHODOLOGY

We conducted Randomized controlled trials and prospective study in the department of obstetrics and gynecology from

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October 2018 to March 2019 for 6 months at Pak Red Crescent Teaching Hospital Dina Nath.

Inclusion Criteria: We screened the woman attending antenatal clinic for anemia. We picked 130 women having singleton pregnancy with hb less than 11g/dl with decreased mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and mean corpuscular hemoglobin concentration (MCHC).

Exclusion Criteria: We excluded the patients fulfilling above criteria but having any hemoglobinopathies, hypersensitivity to parenteral iron preparations, history of cirrhosis of liver, acute or chronic infections patients with history of severe asthma, eczema, or other atopic allergies.

We took permission from ethical committee of the hospital and informed written consent from every patient. The total dose was calculated by applying the following formula
(Target hb-patient hb) x body weight in kg
 $\times 2.4 + 500 \text{mg} = \text{elemental iron required}$.

Then calculated required iron was given in the form of injectable Iron sucrose intravenous (I/V) on alternate days until target was achieved. Two ampoules were diluted in 100ml .9% normal saline. First 25 ml were transfused as test dose over a period of 30 minutes at the rate of 12 drops/min. If no adverse event occurred during this time the remaining 75 ml was given at the rate of 36 drops/min. Clinical safety was evaluated based upon the nature and fatality of adverse effects If any occurred at the end of 2 hours and 4 days of treatment. The response was seen on day 14 by measuring reticulocytes, Hb, MCV, MCH MCHC and hematocrit (hct) and then again on day 28th. The response and tolerability to therapy was recorded on a global assessment of response to therapy on a five point rating scale as; 1=excellent, 2=good, 3=average, 4=poor, 5=very poor at the end of study period. The rating was done independently by the physician and the patient.

Results were analysed by statistical package for social science version 20 for comparison of means. For clinical parameters P value <.05 was taken as significant.

RESULTS

Out of 130 women in the study group 35 were primigravida and rest were multigravida. Maximum (91%) woman were in the

age group of 18-40 with 70% exposure rate of iron deficiency among pregnant woman at 95% confidence interval and 5% margin of error. After consideration of drop out 130 patients were evaluated. Before starting the therapy 75% of the patients had hb% level between 7-9.9g/dl (moderate anemia) and 14% had mild anemia (hb level 10g/dl-11g/dl); 11% patients had severe anemia(<6.9); . Mean hb in the pretreatment group was 7.7g/dl (range 6 to 11). After 14 days of receiving I/V iron therapy mean hb was 8.1 (range 7 to 11). After 28 of treatment mean hb level increased to 9.9g/dl (range 7.7-11.5). After 28 days of treatment none were in severe anemia. And 49% were now having mild to moderate anemia. In 51% anemia was totally corrected. Majority of patients were free of side effects 125(96.15%). Minor side effects were noted in few cases 5(3.84%). Side effects included injection site reaction, metallic taste, hypotension, warm tingling sensation and headache. The response and tolerability to therapy were recorded on 5 point rating scale. Majority of the patients were satisfied with the treatment 73((56.15%) excellent, 45(34.6%) good, 12(9.2%) average and 21.53%) poor.

DISCUSSION

Iron is an important micronutrient essential for building haem part of the haemoglobin. During pregnancy when many woman enter the pregnancy in already iron deficient state due to factors like deficient diet in iron content coupled with menstrual losses, generally a rapid succession of pregnancies and inadequate supplemental iron and are unable to take oral iron due to side effects; i/v iron sucrose is one of the good options to give iron¹⁶. As shown in our study its side effects are few and occur in very few patients. Similar results were shown in Devasenapathy et al study that included 764 patients from 37 centers in India. Minor side effects were seen in 1.2% patient and non-fatal anaphylactic reaction occurred in 0.13% patients where as in our study minor adverse effects occurred in 3.84% patients and there was no anaphylactic reaction¹⁷. Also in our study the hb was built up to 2 gm in one month and there was evident increase in reticulocyte count. Similar results were shown in Alka Kriplani study which showed an increase of 4 gm in hb in 2 months whereas in one of the similar retrospective study conducted in primary health center of rural Haryana rise in hb was about 1.7gm/dl^{18,7}. In comparative study by Shruti B Bhavi and Purushottam B. Jaju iron sucrose therapy showed better results than oral iron (ferrous fumarate)¹⁹. Whereas Harsha Sheila Gaikwad showed in his study that intra muscular iron had much more side effects than intravenous iron sucrose¹⁶.

Despite best efforts to combat anemia in our region, anemia in pregnancy has remained one of the major antenatal problems in our region so we should not only give oral iron but utilize options like iron sucrose whose safety along with efficacy is seen in many studies other than ours.

CONCLUSION

I/v Iron sucrose therapy results in rapid increase of hb level and restore iron stores promptly in pregnant woman. Iron sucrose injection is an effective substitute to oral and intramuscular iron therapy in our country as it is safe, effective and has better compliance. Its use in pregnancy will be helpful in improvement of iron deficiency anemia.

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