

Evaluation of safety and efficacy of intravenous iron sucrose therapy for moderate anaemia in antenatal women

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ABSTRACT

Background: Prevalence of iron deficiency anaemia is high in developing countries like India. Treatment of iron deficiency anaemia in pregnancy is very important to bring down maternal mortality rate as blood loss during delivery can lead to death of the patient. The aim and objective of our study is to evaluate the efficacy and safety of intravenous iron sucrose infusions in antenatal women admitted in hospital suffering from moderate iron deficiency anaemia. Special emphasis was given to observe adverse drug effects.

Methods: This was a prospective observational study conducted in Obstetrics and Gynaecology department, Government General Hospital, Rangaraya Medical College, Kakinada, Andhra Pradesh. Study period was two months and study population included antenatal women with gestational age less than 37 weeks with moderate iron deficiency anaemia. Peripheral smear was examined for microcytic hypochromic anaemia and they were treated with intravenous infusion of iron sucrose. Haemoglobin levels were checked before and 5 weeks after iron infusions. Monitoring was done for adverse reactions.

Results: Out of 322 admissions, 95% were found to be anaemic. 72 patients were suffering from moderate anaemia from which 25 have been included and treated with intravenous iron sucrose infusions. They were observed for efficacy and safety parameters. Two minor adverse events were reported (fever with chills and angioedema of lips) and they were excluded from study. Mean haemoglobin concentration was found to be raised from 7.08 ± 0.73 (SD) to 11.33 ± 0.48 (SD) within 5 weeks for 23 patients.

Conclusions: Iron sucrose infusion is safe and effective for anaemia in pregnancy.

Keywords: Pregnant women, Iron deficiency anaemia, Iron sucrose infusions

INTRODUCTION

Anaemia is a reduction in red cell mass. It is often described as a decrease in the number of red blood cells per cubic millimetre (mm^3) or as decrease in the haemoglobin concentration in blood to a level below the normal physiologic requirement for adequate tissue oxygenation.¹ This decrease in the oxygen carrying capacity of blood is very important in pregnancy. According to National Family Health Survey-3, prevalence of anaemia in pregnancy is 58.7%.² Iron deficiency anaemia (IDA) is the most common nutritional deficiency in pregnant women. IDA during pregnancy is

extremely serious public health problem in India.³ Study done by Toteja et al showed that 84.9% of pregnant women were anaemic.⁴ In India, anaemia begins at infancy and childhood, increases in severity during adolescence in girls and gets aggravated during pregnancy. Indian Council of Medical Research classified IDA as- mild (8-11%), moderate (5-8%) and severe (<5%).⁵ Choice of therapy depends on severity of anaemia and the period of gestation. High prevalence of anaemia during pregnancy is due to combined effect of haemodilution and increased demand of iron. Mild IDA in pregnancy can be treated with oral iron therapy whereas moderate and severe anaemia are to be treated with parenteral iron therapy or blood transfusion

depending upon individual basis⁵. Percentage of pregnant women (15-49 years aged) with anaemia in Andhra Pradesh is 68.1%.⁶

Drawbacks of oral iron therapy include intolerance, unpredictable absorption rate and there maybe difficulty in replenishing the iron stores.⁷ Advantage of parenteral therapy is certainty of its administration to correct haemoglobin deficit and to fix iron store. Expected rise in haemoglobin level after parenteral therapy is 0.7-1 gm/100 ml per week. Intravenous iron sucrose is mostly suitable during 30-36 weeks of pregnancy. Parenteral iron therapy should be used only when clearly indicated because acute hypersensitivity, including anaphylactic and anaphylactoid reactions, can occur in 0.2-3% of patients. Other reactions to intravenous iron include headache, malaise, fever, generalized lymphadenopathy, arthralgias, urticaria and in some patients with rheumatoid arthritis, exacerbation of the disease.⁸ Parenteral preparations available in India are iron sucrose, iron dextran, ferric carboxymaltose and sodium ferric gluconate. The intent of the study is to check effectiveness of the preparation with least side effects. The objectives of our study were to evaluate the efficacy and safety of intravenous iron sucrose infusions in antenatal women with moderate iron deficiency anaemia admitted in the hospital. Special emphasis was given to observe adverse drug effects.

METHODS

This was a prospective observational study conducted in Obstetrics and Gynaecology department, Government General Hospital, Rangaraya Medical College, Kakinada, Andhra Pradesh. Study period was two months from 1st June 2015 to 31st July 2015.

The current study has been approved by Institutional ethics committee. Informed consent was taken from patients. All the patients who were admitted in antenatal ward were categorised into mild, moderate and severe anaemia and percentages were taken.

Inclusion criteria

Study population included antenatal women with gestational age less than 37 weeks and haemoglobin values between 5 and 9 gram%. Peripheral smear was examined and it was found to be microcytic hypochromic anaemia. The required administrative iron sucrose dose has been determined based on formula: $2.3 \times (\text{target Hb} - \text{actual Hb}) \times \text{body weight} + 500 \text{ mg}^3$. This value varied depending on individual haemoglobin values and their body weights. Twenty five patients suffering from moderate anaemia have been treated with iron sucrose, (Iron S: ferric hydroxide in complex with sucrose equivalent to 100 mg of elemental iron) added to normal saline and given as intravenous infusion on alternate days over a period of 30 minutes till calculated dose is completed. Haemoglobin values were recorded at

baseline, iron sucrose infusion was given and haemoglobin was checked after 5 weeks. Each patient was observed for development of any adverse effects or anaphylactic reactions. Minor adverse events were observed only in 2 cases (fever with chills and angioedema of lips) and the iron therapy was discontinued for them. They were managed by blood transfusion.

Statistical analysis

Haemoglobin values before and after treatment with iron sucrose were compared using paired t-test. P value less than 0.05 was taken as significant.

RESULTS

Percentage of anaemic patients is represented in figures. Out of 322 admissions, 95% patients were suffering from anaemia. 72 patients were suffering from moderate anaemia from which 25 patients were treated with intravenous iron sucrose.

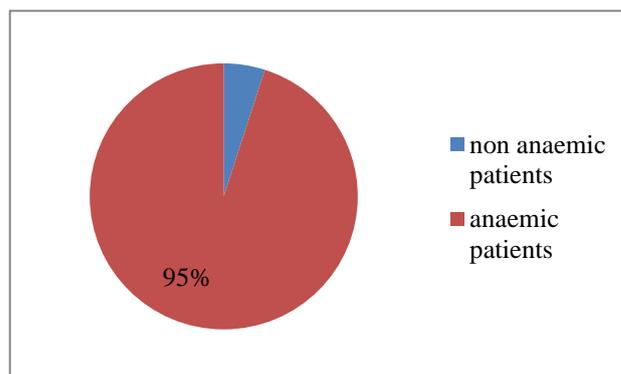


Figure 1: Prevalence of IDA.

Efficacy and safety parameters were monitored. Mean haemoglobin concentration found to be raised from 7.08 ± 0.73 to 11.33 ± 0.48 within 5 weeks. Paired Student t-test was done and the study was found to be significant with p value less than 0.001.

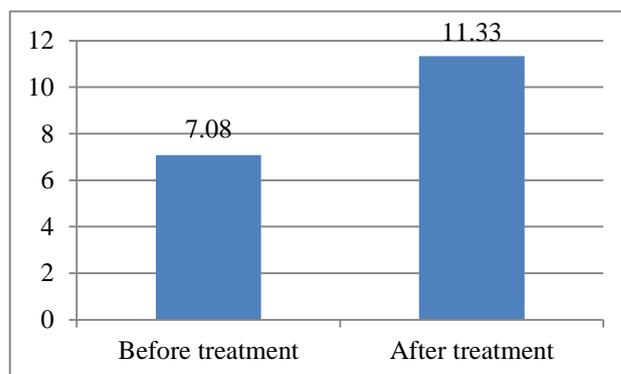


Figure 2: Change in mean haemoglobin concentration with intravenous iron sucrose infusion.

Two adverse events were recorded. One of the patients developed fever with chills and another patient developed angioedema of lips.

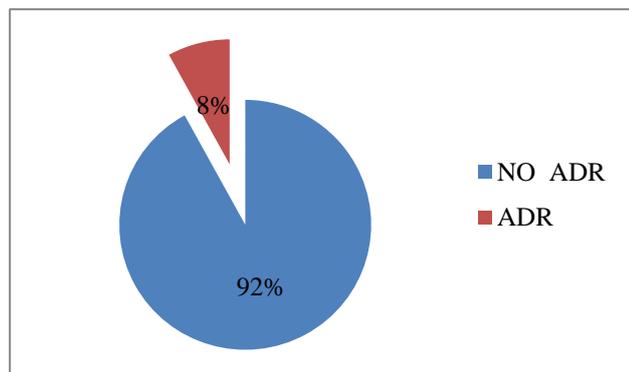


Figure 3: Occurrence of adverse reactions.

DISCUSSION

In a typical gestation with single foetus, the maternal need for iron induced by pregnancy averages close to 800 mg and 200 mg are shed through the gut, urine and skin. This total amount, 1000 mg considerably exceeds the iron stores of most women.⁹ The amount of iron diverted to the foetus from an iron-deficient mother is not much different from the amount normally transferred; the new born infant of severely anaemic mother does not suffer from iron-deficiency anaemia.

Iron sucrose is complex of polynuclear iron (III)-hydroxide in sucrose. Following intravenous injection, the complex is taken up by the reticuloendothelial system, where it dissociates into iron and sucrose. Iron sucrose is generally administered in daily amounts of 100-200 mg within a 14-day period to a total cumulative dose of 1000 mg.⁸

Iron sucrose appears to be better tolerated and causes fewer adverse events when compared to iron dextran.⁸ Anaphylactoid reactions can occur in less than 1% of patients treated with parenteral iron therapy. This reaction is more commonly associated with iron dextran than with ferric gluconate and iron sucrose.¹

Kriplani et al conducted a prospective study in the department of Obstetrics and Gynaecology, All India Institute of Medical Sciences (AIIMS), New Delhi, India.⁵ They evaluated the response and effect of intravenous iron sucrose complex in terms of improvement in haemoglobin status and safety parameters in 100 antenatal women suffering from iron deficiency anemia. The mean Hb raised from 7.63 ± 0.61 g% to 11.20 ± 0.73 g% after therapy and there were no major side effects and no allergic or anaphylactic reaction. In the present study also similar results were obtained.

Panchal et al conducted prospective observational study in Ahmedabad.¹⁰ They included patients of anaemia in pregnancy and also patients suffering from chronic kidney disease in their study. The patients were divided into 3 groups and each group was given one formulation of iron. The formulations used in the study were iron sucrose, oral ferrous ascorbate and oral ferrous sulphate. This study was conducted to evaluate efficacy and safety of ferrous ascorbate and iron sucrose in patients with iron deficiency anemia. They observed a significant increase in mean hemoglobin and anemia indices in patients treated with iron sucrose as compared to ferrous ascorbate at end of treatment. They concluded that intravenous iron sucrose causes faster replenishment of iron store and more improvement in clinical symptomatology and laboratory parameters with better safety profile. The present study was done only in antenatal women and the efficacy of iron sucrose was not compared with any other iron formulations.

A study conducted in USA by Morales-Borges concluded that iron sucrose as well as iron dextran is an effective treatment for anemia in pregnancy. They are safe, efficacious, fast and cost effective as an alternative in the management of anemia in pregnant women at third trimester. They also quoted that as per the majority of studies, iron sucrose is the preferred drug as it demonstrated a high success rate, better compliance and a decrease in the rate of transfusion in the postpartum period.¹¹

Limitations

The limitations of the present study included lack of investigation for serum ferritin levels and long term effects of iron sucrose on haemoglobin levels were not observed.

CONCLUSION

In our study most of the antenatal women admitted were suffering from IDA. Iron sucrose infusions were given to them based on their requirement. Most of them did not suffer from any major adverse reaction. Raise in haemoglobin level was observed within expected time period. In conclusion iron sucrose infusions can be given to pregnant women safely.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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