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Original Research Article

A comparative study of oral iron and intravenous iron in iron deficient antenatal mothers

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ABSTRACT

Background: The aim of the study is to compare the efficacy, tolerance and compliance between oral iron and intravenous infusion of iron in iron deficient antenatal mother.

Methods: This is a prospective randomised clinical and interventional study in the department of Obstetrics and Gynaecology in Vinayaka Mission Kirupananda Variyar Medical College and Hospital. The antenatal women attending the antenatal op were screened for Hb status. Those antenatal women of gestational age 16-34 weeks with Hb level between 7-10g% and diagnosed to have iron deficiency anemia by peripheral smear and serum ferritin were included in this study after getting informed consent. The total numbers of 100 mothers were allotted into two major groups, group A and group B of 50 subjects each. Group A: 50 pregnant women given oral iron supplementation (carbonyl iron 100 mg twice a day). Group B: 50 pregnant women given intravenous iron sucrose therapy after calculating the total iron requirement. The rise in hemoglobin in both the groups were compared

Results: In this study the mean rise of hemoglobin in carbonyl iron was 0.914 ± 0.20 gm% whereas in iron sucrose group was 2.43 ± 0.20 gm%. This showed that iron sucrose (i.v) had better rise in Hb than carbonyl iron (oral).

Conclusions: The present study revealed that intravenous iron sucrose therapy was better tolerated with higher increase in mean haemoglobin compared to oral iron therapy. There were no serious side effects with intravenous iron sucrose therapy. Intravenous iron sucrose is a good substitute to oral iron therapy in moderate anaemia.

Keywords: Antenatal mothers, Intravenous iron, Oral iron

INTRODUCTION

Anemia is estimated to affect 20-50% of the world's population and pregnancy is one of the most risk factors. The centre for disease control and prevention defines anemia when hemoglobin and hematocrit values are less than 11g/dl and 33% in the first and third trimester and 10.5g/dl and 32% in second trimester.¹ Anemia is one of the world's leading problem.

Iron deficiency anemia is one of the common nutritional deficiency affecting pregnant females. According to national family health survey, incidence of anemia in

pregnant women in India is 54% in urban and 59% in rural areas. It is responsible for adverse obstetric and perinatal outcome in a large number of women in developing countries.

Anemia is major public health concern in economically disadvantaged segments of population especially in developing countries. In a country like India, anemia is frequently severe and contributes to maternal mortality and morbidity. It deserves more attention than what it is currently receiving. Apart from economic backwardness, gender discrimination is more prevalent in India and other Asian countries.

The girl child right from birth is neglected with regard to nutrition and education thereby leading to anaemia problem during school going age and pre pregnancy state itself.

There is increased incidence of blood transfusion and its risks in a woman in whom the anemia is not diagnosed in time and corrected properly. The incidence of anemia in India is 40-90%. According to WHO anemia contributes to 40% of maternal deaths in third world countries. In India Maternal death due to anaemia is 10-15%.²

METHODS

This is a prospective randomised clinical and interventional study done in the Department of Obstetrics and Gynaecology, Vinayaka Missions Kirupananda Variyar Medical College and Hospitals, Salem, Tamilnadu for a period of 1 year from April 2016 to March 2017.

The antenatal women attending the antenatal OP were screened for Haemoglobin status. Those antenatal women of gestational age 16-34 weeks with haemoglobin between 7-10 gm% were recruited in this study with informed consent. A total of hundred women were allotted into two major groups of 50 subjects each.

Inclusion criteria

Pregnant women with

- Iron deficiency anaemia with Hb values between 7-10 gm%
- Gestational age 16-34 weeks.
- Single viable fetus with no anomalies.

Exclusion criteria

Pregnant women with

- Hb less than 7 gm% or more than 10 gm%
- Gestational age less than 16 weeks and more than 34 weeks.
- Anaemia due to causes other than iron deficiency.
- History of blood transfusion and erythropoietin treatment in present pregnancy
- Other medical disorders complicating pregnancy or h/o haematological diseases
- Multiple pregnancy
- Specific allergy to iron derivatives.

Patient analysis

Complete general physical examination was carried out along with examination of the cardiovascular system and respiratory system. Abdominal examination was carried out. Apart from routine antenatal profile, stools for ova, cyst and occult blood, serum ferritin (CLIA) were done

and diagnosis of Iron deficiency anaemia confirmed. Haematological parameters were analysed. Initial blood examination was done between 16 and 34 weeks.

Following specific haematological investigations were done at the first visit other than routine investigations:

- Haemoglobin (Hb)
- Peripheral smear

The recruited pregnant women (100) were divided into two major groups and to make a. Comparative study with oral and parenteral iron therapy.

- Group A: 50 pregnant women given oral iron supplementation (carbonyl iron 100mg of elemental iron/day).
- Group B: 50 pregnant women given parenteral iron (iron sucrose) therapy after calculating iron requirement

Calculation of patient's iron deficit

Total iron dose required (mg) = 2.4 x weight in kg x target Hb – actual Hb of patient) g/dl + 500

Final tests were done after 4 weeks of iron supplements in both groups.

RESULTS

In the age group 18-20yrs, 4, 1, 7 pregnant women had Hb rise of 0 -0.9, 1-1.9 and 2-2.9 gm% respectively. In the age group 21-25 yrs, 14, 06, 20 pregnant women had a rise of Hb of 0-0.9, 1-1.9, 2-2.9 gm% respectively. In the age group 26-30 yrs, 17, 8, 21 pregnant women had Hb rise of 0-0.9, 1-1.9, 2-2.9 gm% respectively. Above 30 yrs of age, pregnant women had a Hb rise of 2-2.9 gm% respectively.

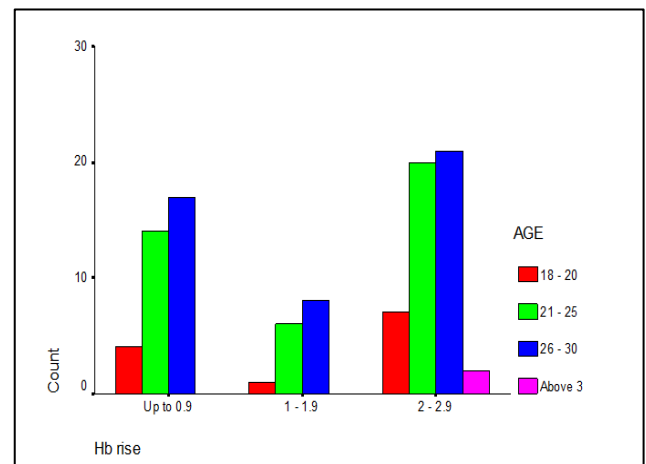


Figure 1: Comparison of rise in HB with distribution of age.

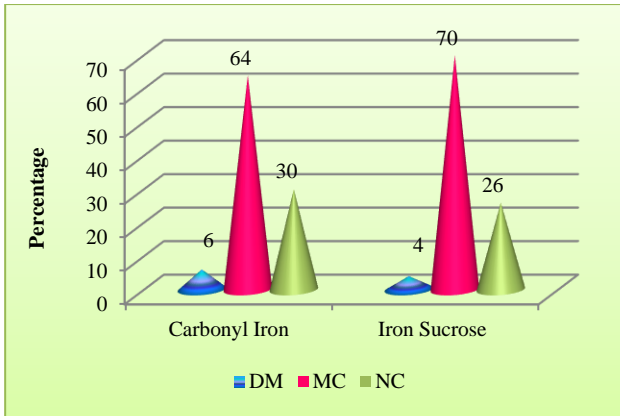


Figure 2: Distribution of patients according to type of peripheral smear (PS).

Figure 2 showing distribution of patients according to peripheral smear. Among these 64 to 70% were microcytic hypochromic, 26 to 30 % showed normocytic normochromic and the 2-3% patients showed dimorphic anaemia which was found to be statistically insignificant between the groups.

Table 1: Adverse reactions.

Adverse reactions	IV group	Oral group
Nausea/vomiting	1	5
Epigastric pain	0	0
Constipation	0	2
Staining	0	0
Thrombophlebitis	0	0
Rashes	2	0
Myalgia	0	0
Fever	0	0
Hypotension	0	0
Total	3	7

Comparing both groups minimal adverse reactions are noted in oral group than intravenous group (IV). Tolerance and compliance are better with IV Group.

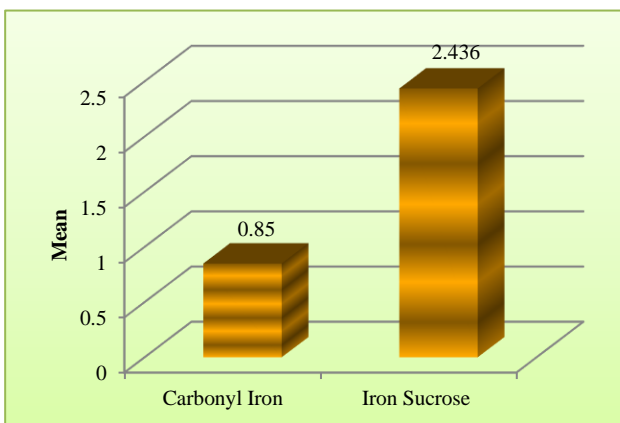


Figure 3: Comparison of carbonyl iron versus iron sucrose in rise of haemoglobin (Hb).

Figure 3 comparing the above two drugs, the mean difference in Hb rise between Iron sucrose and Carbonyl iron is 1.586. The mean Hb rise for Iron sucrose and Carbonyl iron being 2.436 ± 0.23 and 0.850 ± 0.16 respectively. P value calculated <0.001 which is significant. Independent sample t-test is used.

DISCUSSION

Pregnant women (gestational age 16-34weeks) with moderate iron deficiency anaemia only (Hb 7-10gm%) were recruited into the present study so as to ensure prevention of severe anaemia in these women at term by oral and intravenous therapy. Our study illustrates clearly that intravenous iron sucrose complex is effective with better compliance in efficacy and has a rapid and profound response in improving anaemia as compared to carbonyl Iron (oral therapy).

According to Malviya et al 2003, Singh et al 1998⁴ suggest a connection between age and the occurrence of anaemia since other studies have reported that young women (<18 or <20 years) showed a higher tendency to be anaemic.¹⁻³ In present study, the most affected (56 out of 100 women), by IDA in pregnancy were in the age group of 21-25 yrs.

There was no study conducted to report the Hb rise with only carbonyl iron in pregnant women. In our study, the mean haemoglobin rise was $0.91 \pm 0.20 \text{ gm\%}$ with carbonyl iron. In present study, the mean rise of Hb in carbonyl iron was $0.914 \pm 0.20 \text{ gm\%}$ whereas in iron sucrose group was $2.43 \pm 0.20 \text{ gm\%}$. This showed that iron sucrose (i.v) had better rise in Hb than carbonyl iron (oral).

A study was available - Wali A et al reported a better rise of Hb in iron sucrose group when compared to iron sorbitol. This showed that iron sucrose (i.v) therapy is better than iron sorbitol (i.m) therapy in treating IDA in pregnancy.

In present study, while correlating the Hb rise, with types of iron preparations given, showed Hb rise with, carbonyl Iron and iron sucrose were 0.914 ± 0.20 , $2.43 \pm 0.20 \text{ gm\%}$ respectively, thus, clearly demonstrating the superiority of iron sucrose over the oral therapy (P value <0.001 , significant).

In the developed world, it has long been documented that intravenous iron supplementation is highly effective in treating IDA in pregnancy. There is irrefutable evidence that compared to oral iron, iv iron sucrose results in a much more rapid resolution of IDA, with minimal side-effects, and also because it is administered intravenously, it circumvents the problems of compliance and absorption.

In present study also, there were minimal side effects with iron sucrose which were self-limiting. Anaphylaxis

is highly unlikely as the complexes contain no biological polymers.

In this study, the side effects of iron sucrose could be completely avoided by dividing the total dose into smaller doses (100-200 mg/day) and by slow administration as seen in some studies by Al-Momen et al, Danielson BG and Hoigne et al.⁴⁻⁶

With regard to the mean haemoglobin rise, dramatic response was found in iron sucrose group as compared to oral iron group (both ferrous sulphate and carbonyl iron) as concluded by Al - Momen et al, that intravenous iron sucrose is safe, convenient and effective in pregnant women with IDA as compared to other oral iron preparation. Ample amount of data exists in India to show that supervised oral administration of upto 240 mg iron has not been able to raise the Hb levels above 11gm/dl in pregnant women if their initial Hb levels was between 5.0 and 7.9 gm/dl.

In present study, compliance with oral treatment was surprisingly good similar to a study conducted by Bayoumeu F et al in contrast to the findings described in some other studies.⁷ Gastrointestinal troubles, with a frequency of up to 30% as described by Al-Momen et al have been reported in patients groups treated with oral iron (carbonyl iron). Carbonyl iron showed a better rise in haemoglobin more than ferrous sulphate in a study conducted by Gordeuk et al.⁸

According to Kochchar PK et al, response to therapy with parenteral iron is similar to that with oral iron.⁹ The haemoglobin rises at a similar rate, although stores will be replenished more efficiently with parenteral iron (iron sucrose). The main advantage of parenteral therapy (iron sucrose) is the certainty of its administration to correct anaemia and build up the stores.

According to Perewusnyk G et al with his 8 years of experience with iron sucrose complex in twenty five countries indicated that Fe-sucrose complex therapy is a valid first-line option for safe and rapid reversal of Fe-deficiency anaemia.¹⁰

CONCLUSION

The present study revealed that intravenous iron sucrose therapy was better tolerated with higher increase in mean haemoglobin when compared to oral iron therapy. There were no serious side effects with intravenous iron sucrose therapy. Intravenous iron sucrose is a good substitute to oral iron therapy in moderate anaemia.

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Ethical approval: Not required

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