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Original Research Article

Study of outcome of the treatment with intravenous iron sucrose in moderately anaemic pregnant women

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ABSTRACT

Background: Moderate anaemia seen in about 15-20% of pregnant women. Iron sucrose complex which is used intravenously for the correction of Iron deficiency anaemia. The drug has been able to raise the haemoglobin to satisfactory level when used in moderately anaemic iron deficient pregnant women. The objective of this study was to study the improvement of Hb% after treatment with intravenous Iron sucrose complex in moderately anaemic pregnant women belonging to 24-32 weeks of gestational age.
Methods: 50 antenatal patients between gestational age 24-32 weeks with hemoglobin between 8-9.5g/dl were selected and included in this study. They were subjected to blood hemoglobin estimation, hematocrit and peripheral smear study. In each infusion, the maximum total dose administered was 200 mg iron sucrose in 100 ml of normal saline, slow IV infused over 30 minutes. Monitoring was done throughout the infusion to observe for any side effects.
Results: Mean hemoglobin among the 50 patients before starting the therapy was 8.172g/dl and the mean hemoglobin at the end of one month of completing the therapy was 11.066g/dl. The rise in mean hemoglobin i.e. the difference in the mean hemoglobin before and after treatment was 2.894g/dl. The p value is 0.0001 which is statistically significant. The mean hematocrit of the 50 patients studied before starting the treatment was 26.772% with a standard deviation of 1.914. The mean hematocrit after completing the therapy was 33.872% with a standard deviation of 1.321. The difference in the mean hematocrit was 7.100% with a p value of 0.0001 which is statistically significant.
Conclusions: Intravenous iron sucrose complex is well tolerated and highly efficacious in improving hemoglobin, hematocrit in the treatment of iron deficiency anaemia in antenatal women.

Keywords: Haemoglobin, Hematocrit, Intravenous iron sucrose, Iron deficiency anaemia, Iron sucrose complex, Moderate anaemia

INTRODUCTION

Anaemia is defined by WHO as a haemoglobin concentration of less than 11 g/dl of venous blood. It is the major indirect cause of maternal mortality (20-40% of maternal deaths).[1] During pregnancy, there is a great demand for iron to meet the requirement of RBC mass expansion in the mother, fetal and placental blood and blood loss at delivery.

In pregnancy, iron deficiency is exaggerated because of the ability of fetus to extract its requirement in obligatory one way direction even from iron deficient mother.[2] This is aggravated by poor absorption of iron due to adverse effects of pregnancy on the gastro intestinal tract, which include nausea and vomiting, motility disorder with reflux esophagitis and indigestion.

Moderate anaemia seen in about 15-20% of pregnant women.[3]

Over the past year, various oral, intra muscular and intravenous preparations of iron have been used for correction of iron deficiency anaemia in the pregnant patients. However, they are associated with significant side effects and it is not possible to achieve the target rise in Hb level in a limited time period when the patient is approaching term.

Iron sucrose complex is which is used intravenously for the correction of Iron deficiency anaemia. The drug has been able to raise the haemoglobin to satisfactory level when used in moderately anaemic iron deficient pregnant women.

The objective of this study was to study the improvement of Hb% after treatment with intravenous Iron sucrose complex in moderately anaemic pregnant women belonging to 24-32 weeks of gestational age.

METHODS

Study was conducted in department of obstetrics and gynaecology, saveetha medical college hospital, chennai during the period of 1 year. Fifty antenatal patients with moderate iron deficiency anaemia with hemoglobin between 8-9.5g/dl were selected and included in this study.

Inclusion criteria

- Primi and multi gravida between 24-32 weeks of pregnancy
- Pregnant women with hemoglobin between 8-9.5g/dl
- Women with established iron deficiency anemia
- Singleton pregnancy.

Exclusion criteria

- Women with history of blood transfusion
- Women who are on other parenteral iron therapies
- Anemia due to causes other than iron deficiency anemia
- Women with gestational diabetes and pregnancy induced hypertension
- Medical disorders complicating pregnancy.

The 50 pregnant women, between gestational age 24-36 weeks were subjected to blood hemoglobin estimation, hematocrit and peripheral smear study.

Iron requirement is calculated by the formula.[4]

[2.4x (Target Hb% - patient's Hb%) x weight in Kg] + 1000 mg (for iron stores)

In the formula, weight represented the patient's weight before pregnancy in kilograms, target haemoglobin was set at 11g/dl.

In each infusion, the maximum total dose administered was 200 mg iron sucrose in 100 ml of normal saline, slow IV infused over 30 minutes. Monitoring was done throughout the infusion to observe for any side effects.

Procedure of study

Visit I

Information regarding patient's name, address, age and history of amenorrhea was obtained and results of general and obstetric examination were noted, maternal weight was noted.

Investigation include estimation of hemoglobin value, hematocrit and peripheral smear examination to note the type of anemia.

The patients were given 200 mg of iron sucrose diluted in 100 ml of 0.9% normal saline and infused over 15-20 minutes every alternate day until the required dosage is infused.[4] For the infusion of iron sucrose, test dose is not needed.[5]

Patient was advised to avoid oral iron during iron sucrose therapy. They were advised to report any adverse effects immediately. They were explained about repeating investigations during follow-up visits after a period of 4 weeks.

Visit II

After a period of 4 weeks, the pregnant women were examined clinically and maternal weight was noted. Hemoglobin and hematocrit were done in both groups to note the improvement in values.

The side effects volunteered by the women were noted.

Hemoglobin estimation was done by automated hematology analyzer method, which is most practical, cost effective and commonly used method.

RESULTS

Fifty antenatal women after confirming iron deficiency anemia were included in this study and the required dosage of iron was infused intravenously in the form of iron sucrose complex.

Demographical data particulars

No. of patients	50
Mean age±SD range	25.88±3.305
Mean gestational age	28.42±2.75
Mean BMI	21.58±2.52

In this study, age of cases were ranging from 20-32 years with mean age of 25.88±3.305 and mean BMI was

21.58±2.52. This was found to be statistically insignificant.

Characteristics of the class studied

Table 1: Age distribution.

Age	Number	Percentage
≤20	2	4%
21-25	22	44%
26-30	21	42%
>30	5	10%
Total	**50**	**100%**

Among 50 women studied, 4% were less than or equal to 20 years, 44% of the patients belong to the age group between 21-25 years, 42% of the patients belong to the age group between 26-30 years and 10% belong to age group above 30 years. The mean age group in our study was 25.88±3.305 years.

Table 2: Socio economic class.

Socio economic class	Number	Percentage
Class I	-	-
Class II	-	-
Class III	-	-
Class IV	12	24%
Class V	38	76%
Total	**50**	**100%**

Among the 50 patients 38 women belongs to class V and 12 women belongs to class IV socio economic status and none belonged to the class I, II and class III.

Table 3: Obstetric code.

Gravida	Number	Percentage
Primi	15	30%
Multi	35	70%
Total	**50**	**100%**

Among the 50 antenatal patients included in our study 30% were primi gravida and 70% were multi gravida who are prone for iron deficiency due to successive pregnancies.

Table 4: Mean haemoglobin.

	Number	Mean Hb g/dl	Standard deviation
Before treatment	50	8.172	0.4704
After treatment	50	11.066	0.7383
Change in Hb%		2.894	

Mean hemoglobin among the 50 patients before starting the therapy was 8.172g/dl and the mean hemoglobin at the end of one month of completing the therapy was 11.066g/dl. The rise in mean hemoglobin i.e. the difference in the mean hemoglobin before and after treatment was 2.894g/dl. The p value is 0.0001 which is statistically significant.

Table 5: Change in hematocrit.

	Number	Mean PCV %	Standard deviation
Before treatment	50	26.772	1.914
After treatment	50	33.872	1.321
Change in mean PCV		7.100	

P value: 0.0001

The mean haematocrit (Hct) of the 50 patients studied before starting the treatment was 26.772% with a standard deviation of 1.914. The mean hematocrit after completing the therapy was 33.872% with a standard deviation of 1.321. The difference in the mean hematocrit was 7.100% with a p value of 0.0001 which is statistically significant.

Table 6: Adverse effects of the drug.

Sr. no.	Adverse reactions	Number	Percentage
1	Head ache	-	-
2	Nausea/ vomiting	1	2%
3	Abdominal pain	-	-
4	Chills and rigors	1	2%
5	Joint pain	-	-
6	Thrombophlebitis	-	-
7	Pain at injection site	-	-
8	Anaphylactic reaction	-	-
9	No side effects	48	96%

Among the 50 antenatal patients in this study, the side effects were very minimal and seen in only 4%. They were nausea/vomiting in 2% patients and chills and rigors in 2%. There were no anaphylactic reactions noted in the study group. There were no adverse effects noted in 96% of the patients.

DISCUSSION

In our study 50 antenatal patients with iron deficiency anemia were selected according to the inclusion and exclusion criteria stated in the methodology. The iron required is calculated and given intravenously in the form of iron sucrose complex and followed up after 30 days and the results are analyzed.

In our study, 4% (2/50) were less than or equal to 20 years, 44% (22/50) of the patients belong to the age group between 21-25 years, 42% (21/50) of the patients belong to the age group between 26-30 years and 10%

(5/50) belong to age group above 30 years. The mean age group in our study was 25.88±3.305 years.

In our study, 76% (38/50) belonged to the class V socio economic status who were more prone for nutritional deprivation and 24% (12/50) belonged to the class IV socio economic status and none belonged to the class I, II and class III. Hence all were in the low socio economic status.

In our study, 30% were primi gravida and 70% were multi gravida. Majority of study group were multi gravida.

Comparison of outcome parameters

Change in Hb%

Most studies had measured Hb level when the interval between last dose of IVIS, and Hb measurement was atleast 4 weeks.[6]

In our study which included 50 antenatal patients, the mean Hb before starting treatment was 8.172 g/dl and after 4 weeks of treatment was 11.066 g/dl with a p value of 0.0001 ($p<0.05$) which was statistically significant. The average rise in the Hb in the 4 weeks time was 2.894g/dl with a p value <0.05 which was statistically significant.

According to a study by Khurshid SR et al, journal of Pakistan medical association, which included 50 pregnant women with iron deficiency anemia (Hb <8g/dl), the mean of hemoglobin, MCV and serum ferritin values before and after treatment was compared and concluded that p value is statistically significant.[7] Our study was comparable to this study.

Our study could be compared to a study by A Dede, D Uygut et al at the Zakai Tahi Burak women's health education and research hospital, division of perinatology, Turkey, which included seventy five (75) postnatal women with hemoglobin <9 g/dl after delivery whether vaginal or cesarean and compared the effect of intravenous iron sucrose complex versus oral ferrous sulphate and compared the results at the end of 28 days.[8] The mean hemoglobin at the start of treatment was 8.2±0.6g/dl in both the groups. But the mean rise in hemoglobin at the end of 28 days was 12.5±1.6g/dl and 11.8±0.7g/dl in the intravenous and oral group respectively. P value was 0.200 which was not significant. However the rise in mean hemoglobin in the intravenous group was 4.3.g/dl.

Change in hematocrit

In our study which included 50 antenatal patients, the mean hematocrit (Hct) before starting treatment was 26.772% and after 4 weeks of treatment was 33.872% with a p value of 0.0001 ($p<0.05$) which was statistically significant. The average rise in the hematocrit in the 4 weeks time was 7.100 with a p value <0.05 which was statistically significant.

Adverse reactions

In our study, the side effects were very minimal and seen in only 4% (2/50). They were nausea/ vomiting in 2% (1/50) patients and chills and rigors in 2% (1/50). There were no anaphylactic reactions noted in the study group. There were no adverse effects noted in 96% (48/50) of the patients.

In a study by Bhandal N, Russel R et al, at department of anaesthesia, oxford, UK, a prospective randomized control trial which included forty four (44) post natal women with hemoglobin <9g/dl at 24-48 hours post delivery.[9] There were no serious adverse effects were reported. Five women (23%) complained of metallic taste during the infusion of the drug which is not noted in our study. Four women (18%) complained of facial flushing, describing it as warm tingling sensation, this was reported as 'not unpleasant'. There was no hemodynamic disturbance observed either during infusion or after infusion.

In another study by Khurshid SR et al, published in, which included 50 pregnant women with iron deficiency (Hb <8g/dl), who were treated with iron sucrose complex, only 2 patients had mild reactions. One had pain in the epigastrium and the other had restlessness. No patient had reactions of severe nature, threatening to patient's life and requiring discontinuation of infusion. Iron sucrose complex was well tolerated and safe for both mother and fetus.[10]

CONCLUSION

In our study Intravenous iron sucrose complex found to be highly efficacious and resulted in hemoglobin rise of 2.89gm, and hematocrit rise of 7.1% after 4 weeks of treatment in iron deficiency anemia in 50 antenatal women. Iron sucrose complex infusion was well tolerated and safe both to the mother and the fetus since it produced nausea and vomiting in 1 woman and chills and rigors in 1 woman among the 50 antenatal women of treatment group. There were no major adverse reactions.

To conclude intravenous iron sucrose complex is safe, convenient and more effective mode of treatment of iron deficiency anemia in antenatal women. It could be used to reduce the number of blood transfusion in the antenatal period in asymptomatic women with hemoglobin between 8-9.5g/dl.

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