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Research Article

Study of effect of intravenous iron sucrose on different haematological parameters in patients of anaemia in pregnancy

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ABSTRACT

Background: The objective of this study was to evaluate the efficacy of intravenous Iron sucrose by comparing the various hematological parameters before and after infusion of intravenous iron sucrose and also the safety and compliance in cases of pregnancy with anaemia.

Methods: One fifty patients visited in OPD with haemoglobin level <7 gm/dl during 1st and 2nd trimester of pregnancy and all patients of 3rd trimester with mild, moderate or severe anemia after satisfying the inclusion criteria were included. These patients were investigated with different hematological parameters. Patient's hemoglobin, serum iron, total iron binding capacity, peripheral blood smear repeated after the completion of doses after 21 days.

Results: Results were significant with increase in haemoglobin from baseline 6.7 ± 1.2 to 10.2 ± 1.9 after 21 days of treatment. There was significant rise of serum iron levels (93.14 ± 1.9 mcg/dl) post treatment. However repeat TIBC (94.66%) significantly decreased from baseline, mean TIBC was 314.66 ± 1.8 mcg/dl. Significant increase was also noted in MCV, MCH and PCV.

Conclusions: This study showed significant improvement of hemoglobin and iron stores in pregnant women given calculated dose of iron sucrose complex infusion. It was safe for mother and fetus and is well tolerated.

Keywords: Anemia, Intravenous iron sucrose, Hematological parameters

INTRODUCTION

Iron Deficiency Anaemia (IDA) is most common nutritional deficiency in pregnancy. Prophylactic oral iron is recommended during pregnancy to meet the increased demand to overcome physiological haemodilution and in whom oral treatment fails or for whom iron loss exceeds intake that can be met by oral iron therapy. Iron sucrose is reported to be safe and effective for the management of anemia and it can be administered without a test dose.¹⁻³

According to World Health Organization (WHO), the prevalence of IDA is about 18% in developed countries and 35-75 percent (average 56%) in developing countries.⁴ In India the prevalence of anemia ranges

between 33-89%.⁵ About half of global maternal deaths due to anemia occur in South Asian countries; India contributes to about 80% of this mortality ratio.⁶ WHO defines anaemia in pregnancy as haemoglobin level <11 gm%.⁴ In India, the ICMR classification of Iron deficiency anaemia is: 8-11 gm% as mild, 5-8 gm% as moderate and <5 gm% as severe anaemia. Serum ferritin $<12-15$ μ g/l is considered as iron deficiency anemia.⁷

Though the first choice is oral iron supplementation for prevention and treatment of anemia in pregnancy, the intolerance to iron, abnormalities in absorption and non-compliance may make oral iron therapy inadequate and can be benefited from parental iron therapy. Iron therapy during pregnancy may reduce the transfusion rate for the iron deficient women.⁸

Therefore a prospective study was carried out in pregnant women with iron deficiency anemia to evaluate the efficacy of IV iron sucrose complex in terms of improvement of haemoglobin and other various hematological parameters.

METHODS

The prospective study was conducted in department of obstetrics and gynaecology, medical college, Pune. Total 150 women with Iron deficiency anemia with hemoglobin level <7 gm% during 1st and 2nd trimester of pregnancy and of 3rd trimester with mild, moderate or severe anaemia were included in study after meeting inclusion and exclusion criteria. Institutional ethical clearance was obtained before the start of study. Written and informed consent was obtained from all patients. Each patient that came for prenatal visit was screened for iron deficiency anaemia and only those who meet the inclusion criteria were included. Several women with causes of anemia other than iron deficiency anaemia, multiple pregnancy, previous blood transfusion, history of haematological disease, risk of preterm labor, recent administration of iron for the treatment of iron deficiency anaemia were excluded.

Blood samples were taken before the start of the therapy to evaluate levels of haemoglobin, haematocrit, Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC), PBS, serum iron and TIBC. Total iron dose is calculated for the patient.

The formula used for calculation of total dose of Iron Sucrose was, $2.4 * (\text{target Hb gm\%} - \text{actual Hb\%}) * \text{weight} + 500 \text{ mg}$, where weight is patient's weight before pregnancy and target hemoglobin was set at 11gm%. Slow infusion: 100 mg (1 ampoule) of 5 ml was diluted in 100 ml Normal Saline (NS) immediately prior to infusion and infused over 15 min. to 20 min. (A maximum dose infused over 1 hour was 200 mg. Total doses were calculated and given every alternate day for the calculated doses in an infusion form. Patients were followed up regularly and patient was followed up for any adverse reactions of the drug. Laboratory evaluation was performed including haemoglobin, complete blood count, serum iron, TIBC, MCV, MCH, PCV after completion of doses after 21 days. Thus we analyzed 150 women during pregnancy before and after treatment.

RESULTS

The prevalence of anemia was highest between the age group of 20-30 years and was 87.4%. Lower socioeconomic group accounted for 52% of cases of iron deficiency anaemia. Iron deficiency anaemia was seen more in late second and third trimesters i.e. 93.3%. Maximum cases of moderate iron deficiency anaemia were seen in third trimester accounting 46.15%. Gravida 2 and above affected around 80%. In this study, cases of

severe anaemia were 69.33%, moderate and mild accounted for 21.30% and 6% respectively. Pre-treatment PCV between groups 24-36 was seen in 39.30% cases, serum iron level below normal was seen in 92.67% patients pretreatment. Pretreatment mean serum TIBC levels were 314.66 ± 1.8 , MCV level below normal was seen in 92%, MCH levels below normal was seen in 90.70% and MCHC levels below normal was seen in 90%.

Around 90% cases achieved haemoglobin between 9-11 gm% post treatment (Figure1, Table 1) where mean rise of haemoglobin was from 6.7 ± 1.2 to 10.2 ± 1.9 gm%. Repeat serum iron post treatment above normal was seen in 90.04%. Mean rise of serum iron levels were 93.14 ± 1.9 mcg/dl (Table 2). Repeat serum TIBC post treatment after 21 days above normal were in 94.66%. Mean levels of serum TIBC were significantly reduced. In pretreatment Sr. TIBC was >400 in 67.30% and post treatment repeat TIBC was between 300-399 in 57.33% and 200-299 in 33.33% patients (Figure 2, Table 3).

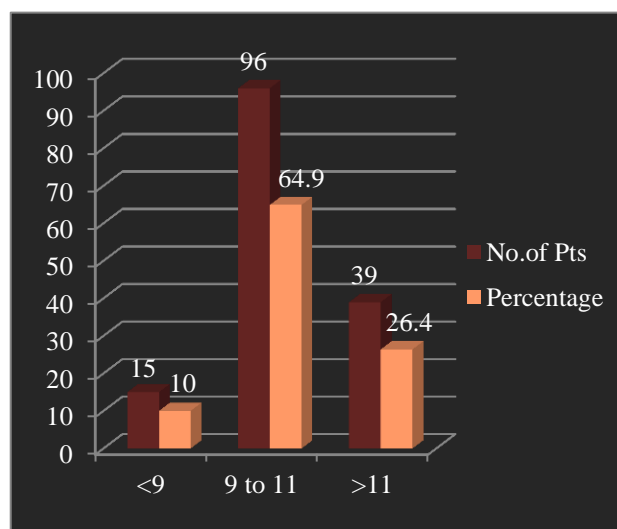


Figure 1: Repeat serum haemoglobin level.

Table 1: Repeat serum haemoglobin level.

Repeat Hb	No. of pts	Percentage	Cum percentage
<9	15	10.00%	10.00%
9 to 11	96	64.00%	74.00%
>11	39	26.00%	100%
Total	150	100.00%	

Table 2: Repeat serum iron level.

Repeat iron	No. of pts	Percentage
>100	17	11.33%
61-100	54	36.00%
41-60	69	46.00%
20-40	10	6.67%
Total	150	100.00%

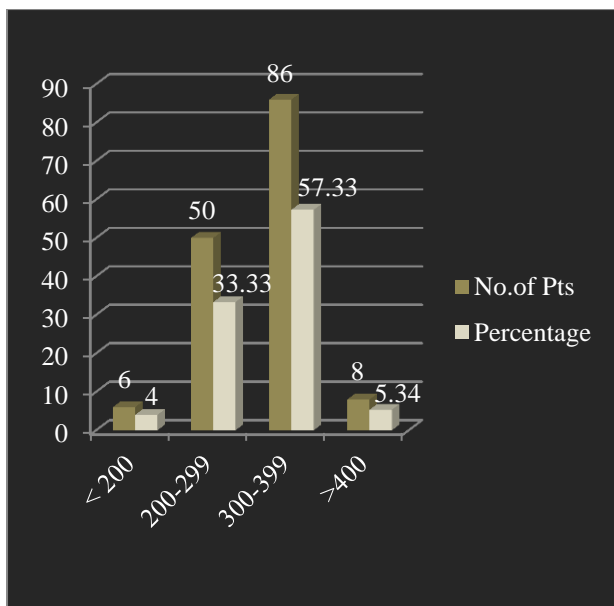


Figure 2: Repeat total iron binding capacity.

Table 3: Repeat total iron binding capacity.

Repeat TIBC	No. of pts	Percentage	Cum percentage
<200	6	4	4%
200-299	50	33.33	37.33%
300-399	86	57.33	94.66%
>400	8	5.34	100%
Total	150	100.00%	

The compliance of patients according to their willingness to continue the treatment was good among 96.67%. Minimal side effects 8.70% were seen with IV iron sucrose. Out of those bradycardia was seen in 2.70% cases while nausea, flushing, dizziness were seen in 1.33% cases each while vomiting in 0.67% (Figure 3). Superficial thrombophlebitis was seen in maximum 3% cases while fever with chills were seen in 0.7% and no anaphylactic reaction was seen in any case.

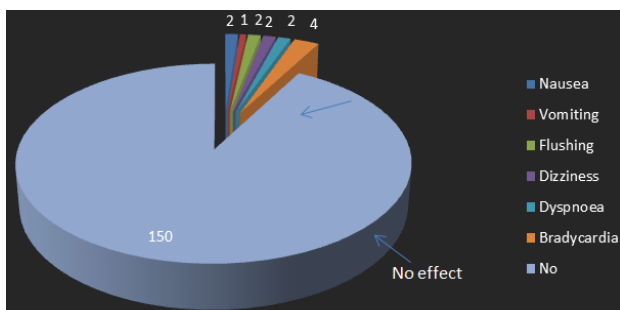


Figure 3: Adverse effects of the drug: No. of pts.

DISCUSSION

The total requirement of iron during pregnancy is approximately 1000 mg. Usually this iron is mobilized

from iron stores. However women with poor iron stores become iron deficient during pregnancy. Studies have shown that Hb levels less than <8 gm% in pregnancy are associated with higher maternal morbidity.^{6,9,10} Severe anemia is associated with cardiac failure and pulmonary edema. Indian females need 100 mg of elemental iron per day for anaemia prophylaxis in pregnancy and for treatment of anemia dose recommended is 200 mg of elemental iron per day.¹¹

Intravenous iron sucrose produces more rapid increase in haemoglobin concentration than oral iron and intramuscular iron dextran.¹² Two studies compared iron sucrose with orally administered iron in the treatment of iron deficiency anaemia in pregnancy.^{13,14}

The present study confirmed that IV administered iron sucrose elevates haemoglobin and restores iron stores during the treatment of mild iron deficiency anaemia in pregnancy. The mean hemoglobin, mean serum iron and other blood indices were significantly increased in intravenously administered from baseline. Iron sucrose is well tolerated with no serious adverse effects. It has a lower incidence of adverse allergic reactions and they are mild one. Major disadvantage of IV iron sucrose is cost, need for hospitalization and invasive nature. However it may be considered as an alternative to oral iron in the treatment of pregnant women with sever iron deficiency anaemia during the third trimester. Since iron tablets induce a high concentration of free radicals in the intestinal milieu, which may damage the intestinal epithelium, the minimal essential iron dose is to be recommended.¹⁵ In the case of a poor compliance or non-efficiency with oral iron supplementation, intravenous iron prophylaxis can be useful.

Systematic iron prophylaxis during pregnancy has been debated.¹⁶ The first choice in the prophylaxis of iron deficiency anaemia for almost all women is oral iron replacement because of its effectiveness, safety, and low cost. But long-term oral prophylaxis can produce side effects, in particular on the digestion.¹⁷ Coupled with digestive side effects and with the attention needed for daily self-dosing, poor compliance often results. However, Milman et al. showed that a supplement of 80 mg of ferrous iron or less does not have documented side effects.¹⁸ On the other hand, although iron absorption may be adequate in healthy, iron-replete women, it is far below the iron requirement of iron-depleted or iron deficient pregnant women.^{17,19} In addition, even women who respond well to oral supplementation require a period of months to reach target Hb.

CONCLUSION

In conclusion, our study showed that intravenous iron sucrose significantly causes improvement in haemoglobin and iron stores. It was safe and well tolerated. In our country where incidence of IDA is more commonly

found in pregnant females, this type of treatment will be helpful in the management of these patients.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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