

## Effect of oral versus parenteral therapy to improve the Hb level among antenatal women with iron deficiency anaemia: A randomized controlled trial

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**Abstract: Objective:** To evaluate the effect of oral versus parenteral therapy to improve the Hb level among antenatal women with iron deficiency anaemia.

**Methods:** This was a randomized controlled study conducted in northern India among antenatal women with iron deficiency anaemia. The inclusion criteria were Hb concentration less than 11 gm/dl and gestational age 21-36 weeks. A total of 230 women were included in the study and divided randomly into 2 groups: Group A was given 240 mg elemental iron as ferrous sulphate for 8 weeks. Group B was given parenteral iron at the same interval as in Group A.

**Results:** The Hb level was significantly ( $p=0.0001$ ) increased in both the groups from before (Group A= $8.56\pm 1.18$ , Group B= $8.31\pm 1.03$ ) supplementation to after supplementation (Group A= $11.77\pm 1.20$ , Group B= $12.20\pm 1.70$ ). The increase was lower among the women of Group A (27.3%) as compared to Group B (31.9%). There was no association between age & gestational age of women and percentage increase in Hb in both the groups. About one third of the women of both Group A (32.2%) and Group B (31.3%) women experienced constipation.

### CONCLUSION

We found that the parenteral iron therapy in the form of iron sucrose was better choice to reduce iron deficiency anaemia as compared to oral therapy. Early supplementation will help to decrease the risk of blood transfusion during the peripartum period.

**Key words:** Iron sucrose, antenatal women, Hb, anaemia

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### I. Introduction

Anaemia affects nearly half of all the pregnant women in the world, these figures are 52% in the developing and 23% in the developed world<sup>1</sup>. The high prevalence of iron deficiency anaemia among women during pregnancy in developing countries is of concern and a cause of considerable morbidity and mortality<sup>2</sup>. Anaemia is defined by World Health Organisation as a state where haemoglobin (Hb) is less than 11 gm/dl and haematocrit less than 33%. The most common cause of anaemia is iron and folate deficiency. Iron deficiency anaemia accounts for 75-95% cases of anaemia in pregnancy. It can occur as a result of poor nutrition, malaria, hook worm infestation and closely spaced pregnancies. Anaemia results in an increased number of preterm, low birth weight, impaired cognitive development of children, postpartum haemorrhage, postpartum depression and reduced adult work productivity<sup>3</sup>.

Severe anemia in pregnancy results in relatively poor maternal and fetal outcome. Maternal effects are preterm labor, preeclampsia, sepsis and postpartum hemorrhage and increase need of blood transfusion<sup>4</sup>. A study reported a fetal mortality rate of 50% at 7 months, 28% at 8 months and 24% at 9 months of gestation<sup>5</sup>. Mild to moderate degrees of iron-deficiency anemia can impact motor and mental development in children and adolescents<sup>6,7</sup>. Apart from maintaining balanced diet, general treatment includes iron supplementation by either oral or intramuscular or intravenous routes. Interventions to control IDA include iron supplementation and iron fortification, health and nutrition education, control of parasitic infections and improvement of sanitation<sup>8</sup>.

Though, the National Nutritional Anemia Control Program (NNACP) in India was launched in 1970, anemia continues to be a major public health problem. The program was unsuccessful due to the lack of effective health education and supervision<sup>9</sup>. In most developing countries like India, the decision to recommend appropriate supplementation for IDA in pregnant women is left to the health care personnel and is based on the individual maternal condition<sup>10</sup>.

Oral iron supplementation is usually enough for most of the antenatal women. But intolerance to iron, abnormalities in absorption and non-compliance may make oral iron therapy in some women inadequate and

these can be benefited from parenteral iron therapy. Iron sucrose is a suitable alternative source of iron; It can be administered by intra venous infusion. It is well tolerated and safe but may cause hypotension, nausea and low back pain<sup>11,12</sup>.

The aim of the present study was to evaluate the effect of oral versus parenteral therapy to improve the Hb level among antenatal women with iron deficiency anaemia.

## **II. Material And Methods**

This was a randomized controlled study conducted in a tertiary care hospital in northern India among antenatal women with iron deficiency anaemia. The study was approved by the ethical committee of the hospital and consent was taken from each of the women before enrolling in the study. The inclusion criteria were Hb concentration less than 11 gm/dl and gestational age 21-36 weeks. Exclusion criteria were anaemia due to any other disease and history of intravenous iron therapy.

A total of 230 women were included in the study and divided randomly into 2 groups: Group-A was given 240 mg elemental iron as ferrous sulphate for 8 weeks at the interval of 15 days. They were given a simple calendar to tick mark whenever they took their daily dose to maintain compliance. Group B was given parenteral iron at the same interval as in Group A. The total iron dose was calculated by formula, rounded to nearest multiple of 100:

$$\text{Total Iron Dose} = \text{Weight (kg)} \times [\text{Target Hb (gm/l)} - \text{Actual Hb (gm/dl)}] \times 0.24 + 500\text{mg}^{13}$$

The target Hb was taken as 12 gm/dl because of physiological haemodilution during pregnancy<sup>6</sup>. Actual Hb was Hb at the time of inclusion, 0.24 was correction factor and 500 mg is average stored iron in adults<sup>13</sup>. Each ampoule of iron sucrose contains 100 mg iron. It was given in 100 ml normal saline over a period of 30 to 40 minutes. Initial few drops were given very slowly and the patient was kept under observation for any adverse reaction. No oral iron was given to Group B patients during the study period. The patients were asked to come on day 30 to enquire about any side effects and at day 60 for Hb levels.

## **III. Results**

The average age of the women and gestational age was similar in both the groups, thus both the groups were comparable (Table-1).

The Hb level was significantly ( $p=0.0001$ ) increased in both the groups from before (Group A= $8.56\pm 1.18$ , Group B= $8.31\pm 1.03$ ) supplementation to after supplementation (Group A= $11.77\pm 1.20$ , Group B= $12.20\pm 1.70$ ). The increase was lower among the women of Group A (27.3%) as compared to Group B (31.9%) (Table-2). There was no association between age & gestational age of women and percentage increase in Hb in both the groups (Fig.1).

About one third of the women of both Group A (32.2%) and Group B (31.3%) women experienced constipation while 24.3% of Group A and 22.6% of Group B women faced the problem of nausea during the supplementation (Fig.2).

## **IV. Discussion**

Anaemia is a global public health problem affecting both developing and developed countries with major consequences for human health as well as social and economic development. It occurs at all stages of life cycle, but is more prevalent in pregnant women and young children. It occurs when the concentration of haemoglobin falls below what is normal for a person's age, gender and environment, resulting in the oxygen carrying capacity of the blood being reduced. Prevalence of anaemia in all the groups is higher in India as compared to other developing countries<sup>14</sup>. Prevalence of anaemia in South Asian countries is among the highest in the world. WHO estimates that even among the South Asian countries, India has the highest prevalence of anaemia. What is even more Important is the fact that about half of the global maternal deaths due to anaemia occur in South Asian countries; India contributes to about 80 percent of the maternal deaths due to anaemia in South Asia<sup>15</sup>.

The present study was aimed to evaluate the effect of oral versus parenteral therapy to improve the Hb level among antenatal women with iron deficiency anaemia. In our study, we found highly significant rise in haemoglobin concentration in Group B than Group A patients which was consistent with the findings of Françoise et al<sup>13</sup> who gave iron at weekly interval. Our finding was contrary to the study by Al-Memon et al<sup>16</sup> who reported no significant difference in the effectiveness of iron sucrose over oral iron for elevating Hb concentration during pregnancy. The adverse effect of parenteral iron therapy was better than the findings of the study by Reveiz et al<sup>17</sup>. We found no association between age and gestational age of women with increase in Hb.

Physicians often face poor compliance with oral therapy because of digestive side effects which can lead to worsening of anaemia. In these cases, parenteral forms of supplementation are indicated as well as in those patients in whom oral treatment is ineffective<sup>18</sup>, like in those suffering from inflammatory bowel disease

many of whom are iron deficient and show digestive intolerance to ferrous salt<sup>19</sup>. Wali et al<sup>20</sup> reported that the intravenous iron therapy was found safe, convenient and more effective than intramuscular iron therapy in treatment of iron deficiency anaemia during pregnancy.

We recommend that the effects of parenteral iron therapy on the baby should be investigated in further studies.

## V. Conclusion

We found that the parenteral iron therapy in the form of iron sucrose was better choice to reduce iron deficiency anaemia as compared to oral therapy. Early supplementation will help to decrease the risk of blood transfusion during the peripartum period.

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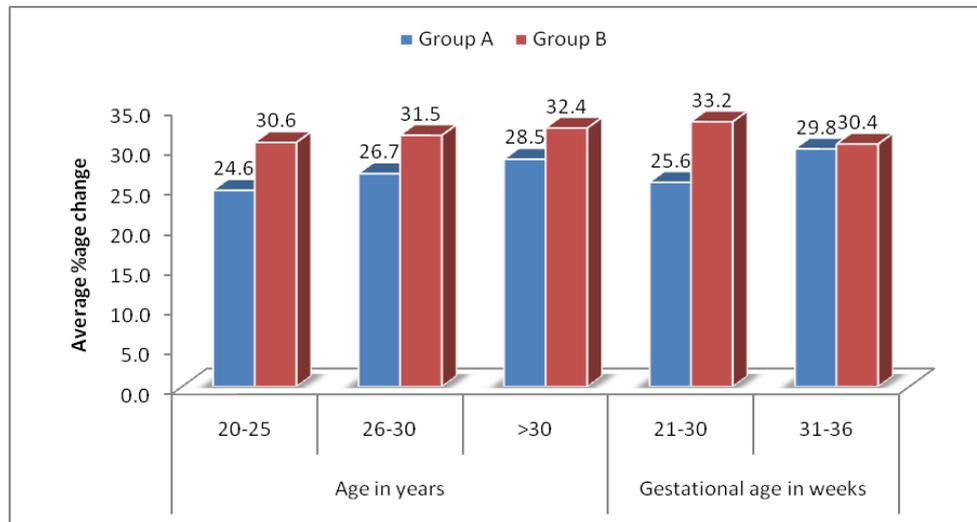
**Table-1: Distribution of women in both the groups**

	Group A (n=115)		Group B (n=115)		p-value
	No.	%	No.	%	
<b>Age in years</b>					
20-25	60	52.2	65	56.5	
26-30	30	26.1	25	21.7	0.71
>30	25	21.7	25	21.7	
Mean±sd	25.78±5.41		26.43±5.16		
<b>Gestational age in weeks</b>					
21-30	66	57.4	65	56.5	0.89
31-36	49	42.6	50	43.5	

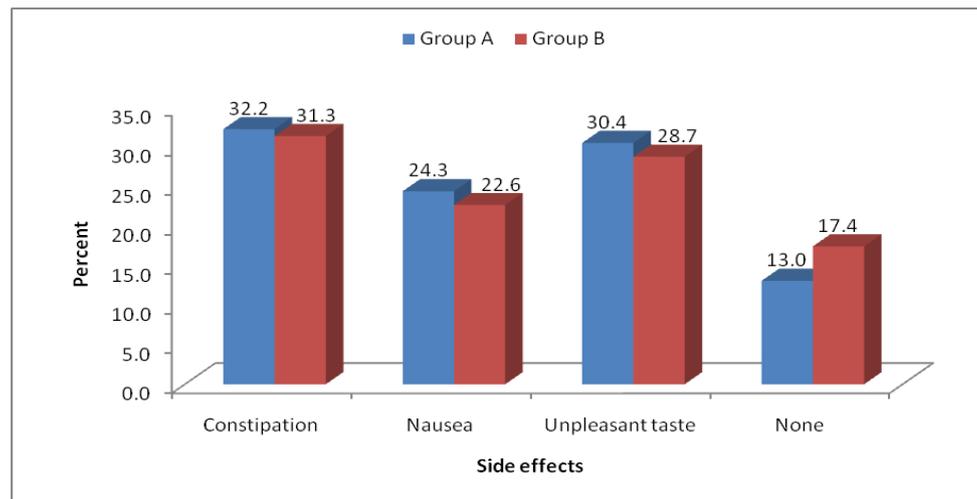
**Table-2: Haemoglobin concentration before and after iron therapy by oral and intravenous routes**

Hb (gm/dl)	Group A (n=115)	Group B (n=115)	p-value <sup>1</sup>
Before	8.56±1.18	8.31±1.03	0.09
After	11.77±1.20	12.20±1.70	0.003*
p-value <sup>2</sup>	0.0001*	0.0001*	
Average %age change	27.3%	31.9%	

<sup>1</sup>Unpaired t-test, <sup>2</sup>Paired t-test



**Fig.1: Average %age change in haemoglobin concentration before and after iron therapy by oral and intravenous routes according to age (p>0.05) and gestational age (p>0.05)**



**Fig.2: Distribution of side effect during the supplementation in both the groups**