### INTRAVENOUS IRON-SUCROSE COMPLEX THERAPY IN PREGNANT WOMEN WITH IRON DEFICIENCY ANAEMIA- A STUDY IN TERTIARY CENTRE

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#### ABSTRACT

#### BACKGROUND

Anaemia in pregnancy continues to be a major public health problem with 54.96% of the pregnant population suffering from it in our setup. Despite the National Anaemia Prophylaxis Programme, anaemia complicating pregnancy continues to be a widespread problem with adverse effects on maternal and foetal outcome.

The aim of the study is to find out an alternate iron therapy in the form of intravenous iron-sucrose and to determine its therapeutic effectiveness, safety and compliance in the management of anaemic expectant mother and to compare it with that of conventional oral iron therapy.

#### MATERIALS AND METHODS

The study was a randomised controlled clinical trial carried out in the Department of Obstetrics and Gynaecology in collaboration with the Department of Biochemistry, Regional Institute of Medical Sciences (RIMS), Imphal. 100 pregnant women in second or third trimester with mild or moderate anaemia were selected, 50 as study group (intravenous iron) and 50 as controls (oral iron). Initial evaluation included complete blood count and serum ferritin level and reevaluated on the 14<sup>th</sup> and 28<sup>th</sup> day of initiation of therapy.

#### RESULTS

Majority of patients (42%) in the study as well as control group were between 26-30 years of age. The mean  $\pm$  SD increase in haemoglobin and ferritin levels on 28<sup>th</sup> day were 2.66  $\pm$  0.34 gm/dL and 27.65  $\pm$  1.80 ng/mL in study group and 1.55  $\pm$  0.23 gm/dL and 16.89  $\pm$  0.76 ng/mL in control group respectively, both of which were statistically significant.

#### CONCLUSION

The mean haemoglobin and serum ferritin levels throughout the treatment were significantly higher in the intravenous ironsucrose group than in the orally administered iron group and significantly higher number of patients achieved the target haemoglobin of 11.0 gm/dL after 28 days of treatment. This reduces the blood transfusion rates in pregnant women with severe anaemia near term.

#### **KEYWORDS**

Anaemia in Pregnancy, Iron Deficiency Anaemia, Oral Iron Therapy, Parenteral Iron Therapy, Intravenous Iron-Sucrose.

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#### BACKGROUND

Anaemia is the commonest and often neglected disorder complicating pregnancy.<sup>1,2</sup> It is a global public health problem affecting both developing and developed countries

Financial or Other, Competing Interest: None. Submission 17-10-2017, Peer Review 25-10-2017, Acceptance 07-11-2017, Published 14-11-2017. Corresponding Author: Dr. Helen Kamei, Majorkhul, MG Avenue, Imphal West - 795001. E-mail: helendrkamei@yahoo.in DOI: 10.18410/jebmh/2017/1066 with major consequences for human health as well as social and economic development. It is more prevalent in pregnant women and young children. Iron deficiency anaemia of pregnancy prevalence in the developing world is 56% vs. 18% in the developed world.<sup>3</sup> In India, it is estimated to be 65-75%. World Health Organization estimated that about 40-60 percent of women of fertile age have iron deficiency anaemia.<sup>2,4</sup>

Anaemia in pregnancy in the Indian population is mainly nutritional- iron and folic acid deficiency. Indian women during pregnancy are susceptible because of increased iron demand, pre-existing iron balance, poor bioavailability of iron, poverty, malnutrition, early marriage and early childbearing, frequent and poorly-spaced pregnancies, malaria and worm infestations and infections in the antenatal and postnatal periods.<sup>5</sup>

The WHO defines anaemia in pregnancy as haemoglobin <11.0 gm/dL, while the CDC criterion is <11.0 gm/dL in the first and third trimesters and <10.5 gm/dL in the second trimester.<sup>1</sup> WHO classifies anaemia as mild (10.0-10.9 gm/dL), moderate (7.0-9.9 gm/dL) and severe (<7.0 gm/dL).<sup>2</sup>

Iron status is evaluated with parameters like haemoglobin concentration, serum iron concentration, serum ferritin and transferrin saturation. The gold standard for evaluation of iron deficiency is serum ferritin level. Iron deficiency anaemia is diagnosed, if the level is <12 ng/mL.

Dietary source cannot meet the demands of iron required during the pregnancy. Supplementary source is essential to avoid iron depletion of maternal reserve. The ability of the foetus to extract its iron requirement in obligatory one way direction even from iron deficient mothers exaggerates the iron deficiency in pregnant women.<sup>1</sup>

Anaemia during pregnancy is considerable risk factor of both mother and foetus. Maternal complications include cardiovascular symptoms, pre-eclampsia, reduced physical, mental and cognitive performance, reduced immune function, infection, reduced blood reserves, delayed involution, postpartum haemorrhage, increased risk of blood transfusion<sup>1,4,6</sup> mortality.1,6 and maternal Foetal complications include intrauterine growth retardation, premature delivery, premature rupture of membrane, infections, intrauterine death, perinatal morbidity and mortality, low birth weight and sometimes irreversible damage to the central nervous system with impairment of psychomotor development.1,3,4,6

In India, despite the National Nutritional Anaemia Control Programme (NNACP) providing free Iron-Folic Acid (IFA) supplementation to pregnant women commencing from second trimester until 3rd month of lactation, the prevalence of anaemia appears to be rising.<sup>5,7</sup> Oral iron, though, is the first choice of treatment for iron deficiency anaemia because of its safety and lower cost, it showed limited effectiveness due to various factors, viz. side effects, lack of compliance, limited bioavailability and inability to achieve the target rise in haemoglobin level in a limited time period. So, various parenteral iron preparations, recombinant human erythropoietin and blood transfusion have been used for correction of iron deficiency anaemia in pregnancy. Intramuscular iron preparation causes pain, staining, irregularly absorbed, arthralgia, fever, urticaria and severe anaphylactic reactions. Blood transfusion carries a considerable transfusion risks. Iron-sucrose was first clinically used by Nissim in 1947. Intravenous iron-sucrose is generally well tolerated, but may cause a variety of adverse effects, including temporary changes in taste, fever, shivering, injection site reactions and nausea. Cost and need for hospitalisation are the disadvantages of iron-sucrose.<sup>1,3,7</sup>

Several authors concluded that iron-sucrose is effective, but it carries a minimal risk of allergic accident and iron

overload.<sup>1,4,8</sup> This study compares the effect of intravenous iron-sucrose therapy to oral iron therapy.

#### Aims and Objectives

To evaluate and compare the therapeutic effectiveness, safety and compliance of intravenous iron-sucrose complex to oral iron in pregnant women with iron deficiency anaemia attending RIMS Hospital, Imphal, Manipur.

#### MATERIALS AND METHODS

The study was a randomised controlled clinical trial carried out in the Department of Obstetrics and Gynaecology, in collaboration with the Department of Biochemistry, Regional Institute of Medical Sciences, Imphal, Manipur.

One hundred pregnant women with anaemia who gave informed consent were included in the study.

**Inclusion Criteria**- Pregnant women in second or third trimester with singleton pregnancy with haemoglobin level less than 10.5 gm% attending RIMS for ANC were included in the study.

**Exclusion Criteria**- Pregnant women diagnosed with other causes of anaemia, intolerance to iron derivatives, multiple pregnancy, antepartum haemorrhage or history of asthma, eczema or other atopic disease were excluded from the study. Those who had history of recent blood transfusion or with risk of preterm labour were also excluded from the study.

All were randomly assigned- 50 in intravenous iron as study group and 50 in oral iron group as controls. A specially designed pro forma was used to collect the data for the study.

In the study group, the women were hospitalised and the required dose was calculated from the following formulaweight x (target haemoglobin - actual haemoglobin) x 0.24 + 500 mg.<sup>4</sup> Target haemoglobin level was 11 gm/dL. Ironsucrose (Inj. Noripol containing ferric hydroxide complex with sucrose equivalent to elemental iron 50 mg in 2.5 mL) was given by intravenous infusion on alternate day. In each infusion, the maximum total dose administered was 400 mg elemental iron in 400 mL of 0.9% NaCl (1:1) initially given at 8-12 drops/minute for 15-30 minutes and patient was monitored for any sign of allergic reaction. Later, rest of the infusion was given at 36 drops/minute. No test dose was given.

In the control group, two 100 mg iron tablets per day (cap RUBIRED containing ferrous ascorbate equivalent to elemental iron 100 mg) were given for 28 days. Patients were instructed to take the tablets in an empty stomach 2 hours before or after their meals. Deworming was done for all patients.

Laboratory evaluation (complete blood count and serum ferritin level) was performed at the time of inclusion in the study and on the 14<sup>th</sup> and 28<sup>th</sup> day.

All patients were seen every 2 weeks. During each visit, all adverse events related to the drugs were recorded after physical examinations and direct enquiries of the patients.

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Adherence to oral treatment was assessed by the number of returned tablets and asking the colour of the stool.

### **RESULTS AND OBSERVATIONS**

In the present study, 100 anaemic pregnant women were recruited. Maximum cases in the study and control groups were in the age group 26-30 years constituting 42% each followed by those aged between 20-25 years constituting 34% and 26% in the study and control groups, respectively. Primigravidas accounted for 70% and 48% in study and control groups, respectively. Majority in the study group were of 31-34 weeks period of gestation constituting 64%,

while in control group, 21-25 weeks period of gestation constituted maximum with 48%. Mean period of gestation was 30.84 weeks (215.92 days) and 25.19 weeks (173.3 days) in study and control group, respectively, which was statistically significant (p-value <0.001). In this study, the mean weight of the study group was 55.96  $\pm$  6.77 kg and that of control group was 55.94  $\pm$  6.24 kg. 50% of pregnant anaemic women in study group and 56% in control group belonged to lower socioeconomic class (<Rs. 5000/month) forming the majority.

Parameter	Group	Mean ± SD	t-value	d.f	p-value	
Hb0( before treatment (am/dL)	Case	8.33 ± 0.44	9.038	98	<0.001	
Hb% before treatment (gm/dL)	Control	9.16 ± 0.47	9.038			
Comum formitin before treatment (ng/ml)	Case	9.70 ± 1.84	4 670	98	-0.001	
Serum ferritin before treatment (ng/mL)	$\begin{array}{c c} \text{Control} & 11.56 \pm 2.10 \end{array}$		4.679	98	<0.001	
Table 1. Comparison of Pretreatment Haemoglobin and Serum Ferritin Level between the Study and Control Group						

As shown in Table 1, pretreatment mean  $\pm$  SD haemoglobin levels in study and control group were 8.33  $\pm$  0.44 gm/dL and 9.16  $\pm$  0.47 gm/dL respectively, which was found to be statistically highly significant (p-value <0.001). Pretreatment mean  $\pm$  SD serum ferritin levels in the study and control group were 9.70  $\pm$  1.84 ng/mL and 11.56  $\pm$  2.10 ng/mL, respectively, which also was found to be statistically highly significant (p-value <0.001).

Parameter	Group	Mean ± SD	t-value	d.f	p-value
Hb% after 14 days of treatment (gm/dL)	Case	9.37 ± 0.37	3.590	98	0.001
HD% after 14 days of treatment (gin/uL)	Control	9.67 ± 0.47	5.590		
LIPO/ after 20 days of treatment (am/dL)	Case	$10.99 \pm 0.26$	3.712	98	<0.001
Hb% after 28 days of treatment (gm/dL)	Control	10.72 ± 0.44	3./12		
Table 2. Comparison of Haemoglobin Level between Cases and Controls after 14 and 28 Days of Treatment					

d.f = degree of freedom.

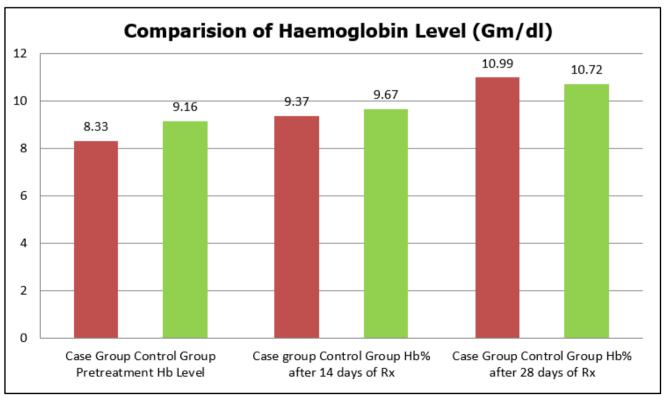


Figure 1. Comparison of Haemoglobin Level (gm/dL)

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Table 2 and Figure 1 shows the comparison of haemoglobin level between the study and control group after 14 and 28 days of treatment. On  $14^{th}$  day, mean  $\pm$  SD haemoglobin levels were  $9.37 \pm 0.37$  gm/dL and  $9.67 \pm 0.47$  gm/dL in the study and control groups, respectively which was found to be statistically significant with p value = 0.001. On  $28^{th}$  day, the study group had mean  $\pm$  SD haemoglobin level of  $10.99 \pm 0.26$  gm/dL, while control group had 10.72

 $\pm$  0.44 gm/dL. This was also found to be statistically highly significant with p value <0.001. The mean  $\pm$  SD increase in haemoglobin levels on 14<sup>th</sup> day were 1.04  $\pm$  0.15 gm/dL and 0.52  $\pm$  0.12 gm/dL in the study and control group, respectively, while on 28<sup>th</sup> day, the increase was 2.66  $\pm$  0.34 gm/dL in the study group and 1.55  $\pm$  0.23 gm/dL in control group. This was found to be statistically highly significant with p value = <0.001.

Parameter	Type of Study	Mean ± SD	t-value	d.f	p-value
Corrum formitin after 28 days of treatment (ng/dl)	Case	27.65 ± 1.80	- 38.811	98	<0.001
Serum ferritin after 28 days of treatment (ng/dL)	Control	16.89 ± 0.76			
Table 3. Comparison of Serum Ferritin Level between Cases and Controls after 28 Days of Treatment					

d.f = degree of freedom.

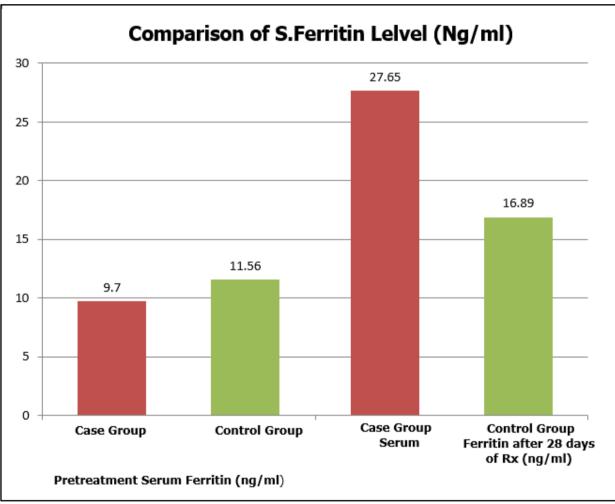


Figure 2. Showing Increase in Serum Ferritin Level

As shown in the Table 3 and Figure 2, serum ferritin levels in both the study and control group were higher than the baseline levels after 28 days of treatment. Mean  $\pm$  SD serum ferritin levels were 27.65  $\pm$  1.80 ng/mL and 16.89  $\pm$  0.76 ng/mL in the study and control groups, respectively and this was found to be statistically highly significant with p-value <0.001. Mean  $\pm$  SD increase were 17.92  $\pm$  3.34 ng/mL and 5.33  $\pm$  1.59 ng/mL in the study and control groups, respectively, which also was found to be statistically highly significant (p-value =<0.001).

This study found that the Mean  $\pm$  SD costs were Rs. 1505.90  $\pm$  221.87 and Rs. 293.60  $\pm$  59.47 in the study and control groups, respectively and was found to be statistically highly significant (p-value <0.001). In the study group, 8% (4 patients) had mild side effects/reactions, while 92% (46 patients) did not have any side effect. In control group, 24% (12 patients) experienced minor side effects, while no side effects were encountered in 76% (38 patients). The study group needed hospitalisation for infusion of iron sucrose with an average stay of 3.96  $\pm$  0.96 days, whereas control group did not require hospitalisation.

Group	Number of Patient who Achieved the Target Hb	% of Patient who Achieved the Target Hb	Target Haemoglobin Achieved (11.0 g/dL)		
Case (50)	39	78	78%		
Control (50)	28	56	56%		
Table 4. Comparison of Target Haemoglobin Achieved in Cases and Controls After 28 Days of Treatment					

As shown in Table 4 in this study, 78% of patients (39 patients) in intravenous iron-sucrose group and 56% (28 patients) in oral iron group achieved the target haemoglobin of 11 gm%.

### DISCUSSION

Anaemia in pregnancy continues to be a major public health problem with 54.96% of the pregnant population suffering from it in our setup. The present study was, therefore, conducted to find out an alternate iron therapy in the form of intravenous iron-sucrose and to determine its therapeutic effectiveness, safety and compliance in the management of anaemic expectant mother and to compare it with that of conventional oral iron therapy.

In this study, most of the pregnant women in the study and control groups were in the age group 26-30 years constituting 42% each. Similar findings were recorded by Naj F et al<sup>4</sup> where majority of the patients (48.5%) were between 26-30 years of age. Mean age in this study was 27.56  $\pm$  4.57 years in the study group and 28.44  $\pm$  5.06 years in control group, which is similar to mean age of 26.86 years obtained by Lone FW et al<sup>9</sup> and 29  $\pm$  3.7 years in the study group and 28  $\pm$  4.1 years in control groups obtained by Bhandal N et al.<sup>10</sup>

The maximum patients in the study group were primigravidas 70% (35 patients), followed by para 1 with 22% (11 patients) and para 2 with 8% (4 patients), which is similar to the finding reported by Al-Ragip A et al<sup>8</sup> where primigravidas constituted 62.2% of the cases. Bayoumeu F et al<sup>11</sup> also recorded higher incidence in primigravidas than multiparas. High incidence of anaemia in primigravidas maybe because of the fact that most of the pregnancies were unplanned and were started with almost depleted state of iron store, more nausea and vomiting in first pregnancy, which hampers the dietary intake, less antenatal check-up and lack of knowledge regarding iron rich diet.

In the present study, majority of the cases, i.e. 32 patients (64%) were of gestational age 31-34 weeks and 17 patients (34%) in 26-30 weeks in the study group, while in control group, 21-25 weeks period of gestation constituted maximum with 48% (24 patients). This study is similar to that of Naz F et al<sup>4</sup> where 60% of cases had 31-34 weeks and 40% had 26-30 weeks gestational age.

The average body weights of both the study and control groups were almost similar, which were similar to the findings reported by Bayoumeu F et al<sup>11</sup> where the mean weight of the study group was  $53 \pm 18$  kg and that of control group was  $55 \pm 2$  kg.

In this study, distribution of cases by socioeconomic status shows that 25 patients (50%) belonged to lower class (<Rs. 5000/month) and 16 patients (32%) belonged to middle class (5000-10,000/month). Anaemia was least prevalent in the higher income group (Rs. >10,000/month),

seen only in 9 patients (18%). This is in total agreement with many of the studies where it is stated that poor socioeconomic condition is one of the major contributors for iron deficiency anaemia in pregnancy. The findings in this study are similar to findings reported by Naz F et al<sup>4</sup> where 40% belong to lower class, 37% belong to middle class and 23% belong to upper class. According to Agarwal P et al,<sup>12</sup> poverty is directly proportional to anaemia. Idowu O et al,<sup>2</sup> also found it to be more common in unemployed pregnant women with low socioeconomic class.

In this study, the pretreatment mean  $\pm$  SD haemoglobin levels were 8.33  $\pm$  0.44 gm/dL in the study and 9.16  $\pm$  0.47 gm/dL in control groups. In their review, Naz et al<sup>4</sup> reported haemoglobin level of 8.7  $\pm$  1.2 gm/dL in the study group. Bayoumeu F et al<sup>11</sup> reported 9.7  $\pm$  0.5 gm/dL in the study and 9.6  $\pm$  0.8 gm/dL in control groups.

In the present study, pretreatment mean  $\pm$  SD serum ferritin levels were 9.70  $\pm$  1.84 ng/mL and 11.56  $\pm$  2.10 ng/mL in the study and control groups, respectively. Similar findings were reported by Kumar A et al<sup>13</sup> where the serum ferritin level was 11.67  $\pm$  3.48 ng/mL in the study group and 10.93  $\pm$  3.05 ng/mL in control group. Al-Ragip et al<sup>8</sup> in their study recorded a lower serum ferritin level of 4.1  $\pm$  2.5 ng/mL in study group and 5  $\pm$  2.2 ng/mL in control group.

In the present study, the mean  $\pm$  SD haemoglobin levels after 14 days of treatment were 9.37  $\pm$  0.37 gm/dL and 9.67  $\pm$  0.47 gm/dL in the study and control groups, respectively. The apparently higher level of haemoglobin in control group at this stage maybe explained by higher pretreatment haemoglobin level in control group. There was significant increase in mean haemoglobin level after 14 days of treatment in the study group compared to control group with the value of  $1.04 \pm 0.15$  gm/dL and  $0.52 \pm 0.12$  gm/dL, respectively (p-value <0.001), which is similar to the findings reported by Al-Ragip A et al<sup>8</sup> where the rise in haemoglobin was significantly higher in the study group than the control group after 14 days of treatment with p-value of 0.004.

In this study, the mean  $\pm$  SD haemoglobin level after 28 days of treatment in the study group was  $10.99 \pm 0.26$  gm/dL with increase in haemoglobin level of  $2.66 \pm 0.34$  gm/dL from the baseline. The findings of this study are similar to the findings reported by many current studies. Naj F et al<sup>4</sup> recorded an increase in haemoglobin level from 8.7  $\pm$  1.2 to  $11.1 \pm 1.97$  gm/dL with mean  $\pm$  SD increase of 2.4  $\pm$  0.7 gm/dL. Wali A et al<sup>6</sup> found that the haemoglobin level rose from  $8.0 \pm 1.1$  to  $10.6 \pm 0.81$  gm/dL with mean  $\pm$  SD increase of  $2.7 \pm 1.1$  gm/dL. Raja KS et al<sup>9</sup> observed that haemoglobin level increase of 3.5 gm/dL in 4 weeks. Bayoumeu F et al<sup>11</sup> recorded an increase in haemoglobin from  $9.7 \pm 0.5$  gm/dL to  $11.0 \pm 1.125$  gm/dL on the day 30, which was not significant when compared with oral iron group. This maybe

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because of the reason that in their study, intravenous ironsucrose was administered over 21 days (on day 0, 1, 4, 8, 12, 15 and 21), which is relatively long period of time, whereas in this study, iron-sucrose was administered over a period of  $3.96 \pm 0.96$  days only.

In this study, the mean  $\pm$  SD haemoglobin level after 28 days of treatment in control group was 10.72  $\pm$  0.44 gm/dL with mean  $\pm$  SD increase of 1.55  $\pm$  0.23 gm/dL, which is similar to the findings of Bayuomeu F et al<sup>11</sup> who recorded increase in haemoglobin from 9.6  $\pm$  0.8 gm/dL to 11.11  $\pm$  1.3 gm/dL.

Thus, this study found that there was remarkable rise in the haemoglobin level after 28 days of treatment in both oral iron and intravenous iron-sucrose group, but the gamut of raise was prominently more in cases of women treated with intravenous iron-sucrose, which was statistically significant.

In the present, the mean  $\pm$  SD serum ferritin level in the study group was 27.65  $\pm$  1.80 ng/mL with mean increase of 17.92  $\pm$  3.34 ng/mL after 28 days of treatment. Al-Ragip A et al<sup>8</sup> recorded increase in serum ferritin from 4.1  $\pm$  to 28  $\pm$  26 ng/mL. Sharma JB et al7 recorded increase in serum ferritin level from 7.0  $\pm$  1.67 to 23.1  $\pm$  2.27 ng/mL.

In the control group, mean  $\pm$  SD serum ferritin level after 28 days of treatment was 16.89  $\pm$  0.76 ng/mL with mean increase of 5.33  $\pm$  1.59 ng/mL, which is similar to findings reported by Al-Ragip A et al<sup>8</sup> who recorded an increase from 5  $\pm$  2.2 to 11  $\pm$  11 ng/mL. Sharma JB et al<sup>7</sup> in their study found it to be 7.5  $\pm$  1.84 ng/mL.

Thus, this study found that after 28 days of treatment, the difference in serum ferritin levels between the two groups were highly significant with much higher increase in intravenous iron-sucrose group.

One of the drawbacks of intravenous iron-sucrose is its high cost of treatment in comparison to the conventional oral iron. The average cost of treatment, in this study, was Rs.  $1505.90 \pm 221.87$  in the study group, which was five times higher than the cost incurred by the control group where the cost of treatment was Rs.  $293.60 \pm 59.47$ . Asma S et al<sup>14</sup> and Tan AE et al<sup>15</sup> in their study reported the treatment with iron-sucrose to be more expensive than oral iron.

Major inconvenience of intravenous iron-sucrose treatment is the need for short hospitalisation or least an outpatient setting for close monitoring. The average days of hospital stay in the study group was  $3.96 \pm 0.96$  days, whereas the control group did not need to stay in the hospital. Al-Ragip A et al<sup>8</sup> found the hospitalisation time for the intravenous iron-sucrose group to be 1 to 6 days.

There were no serious drug reactions, anaphylaxis, hypotensive attack, withdrawals or drug discontinuation. Adverse events possibly related to iron-sucrose administration were experienced by 4 patients (8%), which included hot flush (4%), metallic taste (2%) and nausea (2%). In control group, 12 patients (24%) experienced minor side effects, mostly upper gastrointestinal symptoms. Naz F et al<sup>4</sup> in their study did not find any major adverse reaction in iron-sucrose group. Raja KS et al recorded 4% mild reactions with iron-sucrose. Various other studies also

showed less adverse reactions with iron-sucrose compared to oral iron.

### CONCLUSION

Despite several interventions and efforts to combat anaemia during pregnancy, it is still widespread in the underdeveloped and developing countries including India.

The present study shows that parenterally administered iron-sucrose elevates the haemoglobin level and restores iron stores better and faster than oral iron, which is of paramount importance, especially if the patient is in late stage of pregnancy. The mean haemoglobin and serum ferritin levels throughout the treatment were significantly higher in the intravenous iron-sucrose group than in the orally administered iron group and significantly higher number of patients achieved the target haemoglobin of 11.0 gm/dL after 28 days of treatment. It may reduce the blood transfusion rates in pregnant women who have severe anaemia near term.

Intravenous iron-sucrose was well tolerated with minimal mild side effects and no serious side effects. Hence, the compliance in the study group was very good.

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