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Original Research Article

## Study of effectiveness, tolerability and safety of intravenous iron sucrose in iron deficiency anaemia in postnatal women

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### ABSTRACT

**Background:** Iron deficiency anaemia is the most common type of reversible anemia encountered during pregnancy and postpartum period. The present study was done with the objective to find out the efficacy and safety of intravenous iron sucrose in the treatment of iron deficiency anaemia in the postpartum period.

**Methods:** Fifty (50) postnatal patients both after vaginal and caesarean section with iron deficiency anaemia within the first 48 hours with haemoglobin percentage between 6 g/dl and 8g/dl were studied prospectively at the Institute of Obstetrics and Gynaecology, Madras Medical College, Chennai. The patients were given 100 mg of elemental iron diluted in 100 ml of 0.9% normal saline and infused over 15 minutes every alternate day (not more than 3 days in a week) until the required dosage is infused. The blood samples of all the patients were collected and analyzed for haemoglobin (g/dl), hematocrit, mean corpuscular volume (MCV), serum iron, total iron binding capacity (TIBC) and compared before and after therapy.

**Results:** The mean age group of the patients was 24.94 years. Majority of the patients were multipara (68%) and belongs to the class V socio economic status (84%). All the blood parameters were increased significantly ( $p=0.000$ ) when compared from baseline values to end of the treatment. Mean raise in haemoglobin% after 30 days of treatment was 3.60. Average raise in the mean hematocrit was 8.73. The mean difference in the mean corpuscular volume, total iron binding capacity and the percent saturation was 129.77, 13.55, was 22.26 respectively.

**Conclusions:** Our data confirm that the intravenous iron sucrose was very effective, well tolerated and safe than other forms of iron preparations for treating iron deficiency anaemia in postnatal women.

**Keywords:** Intravenous iron-sucrose complex, Iron deficiency anaemia, Post-natal women

### INTRODUCTION

Anaemia is defined by a decrease in haemoglobin concentration with a consequent decrease in the hematocrit. It is the most common medical disorder in pregnancy. The two most common cause of anaemia are iron deficiency and acute blood loss.<sup>1</sup> Anaemia was defined by World Health Organization as a medical condition associated with haemoglobin levels <11 g/dl. It

is one of the most serious global public health problems, affecting 52% of pregnant women in developing and 23% of the developed countries.<sup>2</sup>

The first choice in the management of iron deficiency anaemia (IDA) was oral iron supplementation because of its effectiveness and low cost. But its efficacy was limited in many of the patients due to its side effects related to gastrointestinal toxicity in about 35% to 59% of the

patients.<sup>3,4</sup> The other traditional choice of treatment was blood transfusion, but the process was associated with the risk of infection, immunologic impact and transfusion reactions.<sup>5</sup> Parental iron preparations also available in the past, were associated with serious life threatening anaphylactic reactions that may result to death.<sup>6</sup>

Modern alternative strategies call for parenteral administration of new, well tolerated iron preparation e.g., iron sucrose which has been successfully used in the treatment of postpartum anaemia and increasingly during 2nd and 3rd trimester of pregnancy.<sup>5</sup>

This study was done to find out the efficacy and safety of intravenous iron sucrose in the treatment of iron deficiency anaemia in the postpartum period.

## METHODS

This was a prospective study was conducted in Institute of Obstetrics and Gynaecology, Madras Medical College, Chennai June 2007 to June 2009. Fifty (50) postnatal patients both after vaginal and caesarean section with iron deficiency anaemia within the first 48 hours with haemoglobin percentage between 6 g/dl and 8g/dl were selected and included in this study.

Patients of age >18 years and diagnosed with postpartum anaemia with Hb% equal to or greater than 6 g/dl and less than 8 g/dl were included in the study. Patients with history of allergy to iron containing medications, or with history of allergic conditions or bronchial asthma, thalassemia, history of bleeding tendency, noniron deficient anaemia were excluded from the study.

After getting approval from institutional ethics committee, informed consent was taken from all the patients. Detailed history of the patient was taken in a predesigned proforma.

The dosage of iron required for each individual patient is calculated using the formula:

$(\text{Target Hb\%} - \text{patient Hb \%}) \text{ in gm\%} \times 2.4 \times \text{weight in kg}$

The patients were given 100 mg of elemental iron diluted in 100 ml of 0.9% normal saline and infused over 15 minutes every alternate day (not more than 3 days in a week) until the required dosage is infused.

Before therapy, blood investigations were sent for the patients who looked clinically anaemic within the first 48 hours of either vaginal or caesarean delivery, which includes Hb%, PCV, MCV and tests to confirm iron deficiency anaemia by peripheral smear, serum iron and total iron binding capacity. During therapy patients were observed for their vitals (temperature, pulse rate and BP), adverse effects like nausea, vomiting, abdominal pain, chills, etc. and anaphylactic reactions.

Patients were discharged after infusing the required dose of iron and asked to attend the postnatal clinic after four weeks of therapy and the following parameters haemoglobin in g/dl, hematocrit, MCV, serum iron, TIBC were assessed. Hb%, PCV, MCV were analyzed by automatic cell counter and serum iron and total iron binding capacity were calculated using semi auto analyzer ERBA CHEM 5 PLUS V2.

## Statistical analysis

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions.

## RESULTS

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

**Table 1: Socio-demographic characteristics of study participants (n=50).**

Characteristics	N	Percentage
<b>Age in years</b>		
≤20	4	8
21-25	26	52
26-30	16	32
>30	4	8
<b>Socio-economic status</b>		
Class IV	8	16
Class V	42	84
<b>Booking status</b>		
Booked	36	72
Unbooked	14	28
<b>Parity</b>		
Para I	16	32
Para II	28	56
Para III	06	12
<b>Mode of delivery</b>		
Labour natural	11	22
Labour natural with episiotomy	16	32
Labour natural with LP	1	2
Emergency LSCS	10	20
Emergency repeat LSCS	3	6
Emergency repeat LSCS with St.	9	18

Table 1 presents the socio-demographic status of the patients. Among the fifty (50) women studied, 8% (4/50) were less than or equal to 20 years, 52% (26/50) of the patients belong to the age group between 21-25 years, 32% (16/50) of the patients belong to the age group between 26-30 years and 8% (4/50) belong to age group above 30 years. The mean age group in our study was 24.94 years. 84% (42/50) belonged to the class V socio economic status who were more prone for nutritional

deprivation and 16% (8/50) belonged to the class IV socio economic status and none belonged to the class I, II and class III. Among 50 patients, 72% (36/50) were booked and 28% (14/50) were unbooked. 32% (16/50) were primipara and 68% (34/50) were multipara. Among them 56% (28/50) were para two and 12% (6/50) were para three. 56% (28/50) delivered vaginally and 44% (22/50) were delivered by caesarean section.

The mean Hb% was raised significantly by the end of the treatment ( $10.90 \pm 0.90$  g/dl) compared to baseline ( $7.30 \pm 0.63$  g/dl) ( $p=0.000$ ). As shown in Table 2, highly significant mean difference with a p value of 0.000 was observed for all the other parameters before and after completion of the treatment (hematocrit- $8.73 \pm 2.66$ ; MCVs- $13.55 \pm 5.40$ ; serum iron- $38.81 \pm 7.32$ ; TIBC- $129.77 \pm 38.8$ ; percentage saturation- $22.26 \pm 6.12$ ).

**Table 2: Laboratory parameters before and after treatment (n=50).**

Parameters	Before treatment	After treatment	Mean change	P value
Hemoglobin (%)	$7.30 \pm 0.63$	$10.90 \pm 0.90$	$3.60 \pm 0.63$	0.000
Hematocrit	$24.35 \pm 3.06$	$33.09 \pm 2.17$	$8.73 \pm 2.66$	0.000
Mean corpuscular volume (MCV)	$73.26 \pm 5.63$	$86.82 \pm 3.12$	$13.55 \pm 5.40$	0.000
Serum iron	$57.95 \pm 5.11$	$96.77 \pm 7.56$	$38.81 \pm 7.32$	0.000
Total iron binding capacity (TIBC)	$399.03 \pm 21.9$	$269.26 \pm 36.98$	$129.77 \pm 38.87$	0.000
Percent saturation	$14.47 \pm 1.63$	$36.74 \pm 6.62$	$22.26 \pm 6.12$	0.000

Among the fifty (n=50) postnatal patients, minimal side effects were noted in 6 patients (12%). They were headache in 2% (1/50) patients, chills and rigors in 6% (3/50) and thrombophlebitis in 4% (2/50) patients. There were no deaths during the study, no moderate or serious adverse events were recorded. There were no anaphylactic reactions noted in the study group (Table 3).

**Table 3: Side effects of the treatment (n=50).**

Adverse reaction	N	Percentage
Head ache	1	2
Nausea/vomiting	-	-
Abdominal pain	-	-
Chills and rigors	3	6
Joint pain	-	-
Thrombophlebitis	2	4
Pain at injection site	-	-
Anaphylactic reactions	-	-
No side effects	44	88

## DISCUSSION

Anaemia in young women arises usually due to severe menstrual blood loss, pregnancy and the delivery. About 30% of them have iron deficiency anaemia with hemoglobin levels below 10 g/dl and for 10% women, the Hb% levels were below 8 gm/dl.<sup>7</sup> In about 5% of all deliveries postpartum hemorrhage was very high (i.e 1000 ml).<sup>8</sup> The only available excellent method to treat anaemia in the past was blood transfusion. But the procedure was found to be associated with high risk for transmission of viral infections and serious transfusion cross reactions.<sup>1</sup> Administration of oral iron supplements are not sufficient enough to correct the anaemia promptly due to limited absorption or due to poor compliance for

longer treatment period. Recent evidence suggest that intravenous iron treatment had shown very effective results to treat anaemia in patients with poor compliance of oral supplementations, in cases with poor iron absorption (GI symptoms), in severe renal impairment cases and in post-partum hemorrhage.<sup>5,9</sup>

In present study fifty postnatal patients with iron deficiency anaemia were selected according to the inclusion and the 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 the present study, very highly significant rise in hemoglobin percentage, hematocrit, serum iron levels, MCV, TIBC, and percent saturation values when compared from baseline values i.e. from before to after treatment period. These findings were consistent with the observation of Dede et al and Raja et al.<sup>10,11</sup>

Many studies reveal that IV iron sucrose complex is well tolerated with a safety profile than other forms of iron supplementations. Iron sucrose complex is very effective because of the rapid removal from the plasma and the availability of iron for erythropoiesis.<sup>12</sup> Previous studies demonstrated that iron sucrose is well accepted with no serious adverse effects and with minimal side effects. The underlying mechanism may be due to the lower allergenic effect of the sucrose complex and due to the slow release of iron from the complex.<sup>13,14</sup>

In present study the side effects were very minimal and seen in only 12%. They were head ache in 2% patients, chills and rigors in 6% and thrombophlebitis in 4% patients.

There were no anaphylactic reactions and serious adverse effects were noted in the study. Similar observation was done by Bhandal et al.<sup>8</sup> In his study, five women (23%) complained of metallic taste during the infusion of the drug which was 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 Raja et al, which included fifty pregnant women with iron deficiency anaemia (Hb <8 g/dl), only two patients, had mild reactions.<sup>11</sup> One had pain in the epigastrium and the other had restlessness. No patient had reactions of severe nature, threatening the patient's life and requiring discontinuation of infusion.

## CONCLUSION

The study findings conclude that intravenous iron sucrose complex is safe, convenient and more effective mode of treatment of iron deficiency anaemia in postnatal women. It could be used to reduce the number of blood transfusions in the postnatal period in asymptomatic women with Hb% between 6 and 8 g/dl.

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