

Efficacy of intravenous iron sucrose therapy for iron deficiency anaemia in pregnancy

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Abstract

Background: The therapeutic use of iron for the treatment of anaemia dates from ancient times. An iron preparation of ancient 'Hindu' medicine known as *lauha bhasma* was prepared by roasting sheets of iron and then formulating it with other ingredients to be used in the treatment of anaemia. **Objectives:** To see efficacy of intravenous iron sucrose therapy in pregnancy for iron deficiency anemia. **Material and Methods:** This was a prospective observational study carried out at Bharati Vidyapeeth, Medical College and Hospital which is a tertiary care center and in Sangli. 207 pregnant women were selected during a period of 1 year. They were investigated for iron deficiency and treated for the same. They were followed for 1 month. Resulting data was analyzed using SPSS v20. **Results:** In total n=207 cases, the mean gravida was 1.94 ± 0.96 ; mean weight was 53.70 ± 5.57 kg; mean period of gestation at the time of diagnosis was 28.88 ± 5.11 wks. The increase in the mean of Haemoglobin was 1.14g/dl (from baseline Hb of 7.86g/dl to 9.00g/dl) after two weeks and 2.76g/dl (from baseline Hb of 7.86 to 10.62g/dl) after 4 wks. P value is 0.000 and the test is highly significant. Mean of RBC count, PCV(%), MCV (fL), MCH (pg), MCHC (%), Serum ferritin (μg/L), Serum iron (μg/dL), TIBC (μg/L) p values before and after treatment was found to be highly significant $p < 0.000$. **Conclusions:** Intravenous iron sucrose is highly efficacious in improving iron deficiency anemia in pregnant women.

Key Word: Haemoglobin, Iron Deficiency Anaemia, Intravenous Iron Sucrose.

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INTRODUCTION

Anaemia is the commonest medical complication met within pregnancy. India is among the countries with highest prevalence of anaemia in the world. Prevalence of Iron deficiency anaemia among pregnant women is 58% and among non-pregnant non-lactating is 50 % and among adolescent girls it is 56 % according to National Family Health Survey-3.1

It is estimated that about 20 to 40 % of maternal deaths in India are due to anaemia. Anaemia contributes to about 50

% of Global Maternal deaths.2 In WHO ranking, Iron deficiency anaemia is 3rd leading cause of Disability Adjusted Life years Lost for females in age group 15 to 44 years. To combat anaemia in our country government has given one of the goal for 12th five year plan is to reduce anaemia in girls and women by 50 %. Even though supplementation of diet with iron and folic acid has been part of the government program for over 3 decades, National Family Health Survey-3 data shows Iron and Folic Acid intake still remains low. Data's are <20 % women of <20 yrs age took Iron and Folic Acid supplementation and only 22 % pregnant women were reported consuming Iron and Folic Acid for 90 days or more during pregnancy3. To put the matter in nutshell one may say that obstacles in correcting iron deficiency anaemia by oral route and also patient presenting herself for first time in later weeks of pregnancy can be overcome by parenteral administration of iron. In this regards we have conducted this study to see efficacy of intravenous iron sucrose in pregnant women with iron deficiency anaemia.

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MATERIAL AND METHODS

This was a prospective observational study carried out at Bharati Vidyapeeth, Medical College and Hospital which is a tertiary care center and in Sangli. 207 Patients were picked up from outpatient department of obstetrics and gynaecology department of the hospital from March 2017 to August 2018 who fulfilled the iron deficiency criterias. All pregnant patients with iron deficiency anaemia were selected. Informed consent was taken from all women before the start of the study. preformed questionnaire was used for recording history in detail. This study was approved by institutional ethics committee. All the necessary investigation regarding iron deficiency were carried out, along with those stool and urine also examined. Automated Blood Analyser was used to carry out the haematological investigations including haemoglobin, RBCs count and blood indices. Peripheral blood smear done by slides and stain method. Serum iron, Total iron binding capacity and serum ferritin were done by multipurpose automated analyser. Inclusion criteria's: Only those pregnant women during 2nd and 3rd trimester having iron deficiency anaemia with haemoglobin between 6.0g/dl and 10.0g/dl with cases of low serum iron, low ferritin and increased total iron binding capacity were included. Exclusion criteria's: Patients with gastrointestinal disorders like hyperacidity, peptic ulcers

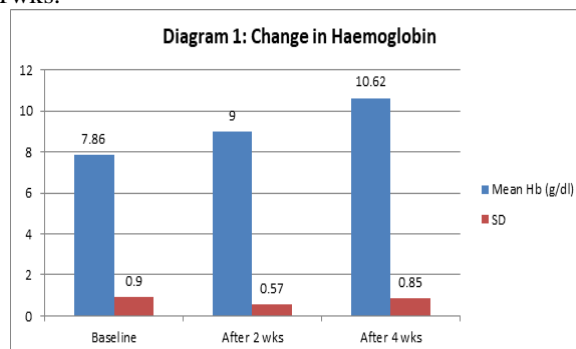
etc., patients already on haematinics in preceding 2 wks, patient with hepatic and renal diseases, thyroid diseases, patients with any kind of sepsis, or allergy to injectable iron sucrose were excluded from the study. Total Dose = $(2.21 \times \text{weight of patient target Hb (10.5g\%)} - \text{actual I-Ib}) + 500\text{mg}$. Average dose requirement in our study was 811 mg. Injectable iron sucrose (Injection Orofer S, Emcure Pharmaceuticals Limited, India) was given in a dose 100mg or 200mg, diluted in 100ml or 200ml of normal saline respectively, over a period of 15 to 20 minutes, thrice a week till the total calculated dose is administered. First dose was given in ward where equipments for cardiopulmonary resuscitation was available. The following doses were given on outpatient basis. Patients were observed for the side effects or anaphylactic reactions. Any minor or major side effects were documented. All the patients were also given folic acid tablet 5 mg once a day. Mebendazole 100 mg twice daily for three days to all the patients. No patient is permitted to take any other iron preparation, oral or parental, during the study period. All the cases were followed for a month. Statistical analysis: Applying paired 't' test for each parameters of study was carried out and tested for significance. Value of $p < 0.05$ was taken as significant. Also the groups were divided into 3 groups on basis of severity of anaemia and rise in haemoglobin for each group was also studied and tested for significance.

RESULTS

Table 1: Distribution as per demographic profile

Parameter	Value
Total number of patients	207
Weight (mean \pm SD)	53.70 \pm 5.75kg
Gravida	1.94 \pm 0.96
Age of gestation at the time of diagnosis	28.88 \pm 5.11wks

In total n=207 cases, the mean gravida was 1.94 ± 0.96 ; mean weight was 53.70 ± 5.57 kg; mean period of gestation at the time of diagnosis was 28.88 ± 5.11 wks.



The increase in the mean of Haemoglobin was 1.14g/dl (from baseline Hb of 7.86g/dl to 9.00g/dl) after two weeks and 2.76g/dl (from baseline Hb of 7.86 to 10.62g/dl) after 4 wks. P value is 0.000 and the test is highly significant.

Table 2: Effect of iron sucrose on various parameters

Parameter	Baseline	After 4 wks	Standard error mean		t value	p value
			Baseline	After 4 wks		
RBC(million/mm ³)	3.66 ± 0.2	4.28 ± 0.3	0.02	.02	-20.3	0.000
PCV(%)	29.36 ± 2.2	36.75 ± 2.8	.16	.20	-29.1	0.000
MCV (fL)	69.12 ± 8.2	79.59 ± 7.3	.58	.51	-14.6	0.000
MCH (pg)	29.39 ± 5.7	30.56 ± 2.0	.40	.14	-2.7	0.000
MCHC (%)	30.34 ± 2.6	37.98 ± 6.6	.18	.46	-15.4	0.007
Serum ferritin (µg/L)	23.65 ± 4.6	29.43 ± 2.6	.29	.18	-16.6	0.000
Serum iron (µg/dL)	34.94 ± 2.8	37.94 ± 2.8	.20	.20	-11.3	0.000
TIBC (µg/L)	498.92 ± 57.0	324.17 ± 14.4	3.97	1.01	42.9	0.000

Mean of RBC count baseline was 3.66 ± 0.29 million/mm³ and it increased to 4.28 ± 0.34 million/mm³ with difference in mean of 0.62 millions/mm³ and p value 0.000 which is highly significant. Mean of packed cell volume baseline was $29.36 \pm 2.29\%$ and it increased to $36.75 \pm 2.89\%$ with difference of 7.39% and p value 0.000 which is highly significant. Mean of Mean Corpuscular Volume baseline was 69.12 ± 8.28 fL and it increased to 79.59 ± 7.31 fL with difference of 10.47 fL and p value 0.000 which is highly significant. Mean and standard deviations of Mean corpuscular haemoglobin baseline was 29.39 ± 5.71 pg and it increased to 30.56 ± 2.04 pg with difference of 1.17pg and p value 0.007 which is highly significant. Mean of mean corpuscular haemoglobin concentration baseline was 30.34 ± 2.64 g/dl and it increased to 37.98 ± 6.61 g/dl with difference of 7.64g/dl and p value of 0.000 which is highly significant. Mean of serum ferritin baseline was 23.65 ± 4.61 µg/L and it increased to 29.43 ± 2.66 µg/L with difference of 5.78 µg/L and p value of 0.000 which is highly significant. Mean of serum iron baseline was 34.94 ± 2.84 µg/dl which increased to 37.94 ± 2.83 µg/dl with difference of 3.0µg/dl and p value of 0.000 which is highly significant. Mean of total iron binding capacity was 498.92 ± 57.06 µg/dL which decreased to 324.17 ± 14.47 µg/dL with difference of 174.75 µg/dl and p value of 0.000 which is highly significant.

DISCUSSION

Usually, this iron is mobilized from iron stores. However, women with poor iron stores become iron deficient during pregnancy. Studies have shown that Haemoglobin levels < 8g %, (moderate to severe anaemia) in pregnancy are associated with higher maternal morbidity.⁴ Haemoglobin less than 5g % is associated with cardiac decompensation and pulmonary oedema. Blood loss of even 200 ml in third stage of labour can cause sudden shock and death in these women. As compared to western women whose iron stores are sufficient and they need 30-40 mg elemental iron per day for anaemia prophylaxis in pregnancy,^{5,6} the stores in Indian women are deficient and they need 100 mg

elemental iron per day for prophylaxis. For treatment of anaemia, dose recommended is 200 mg elemental iron per day.⁷ In the present study, 6-10 g% Haemoglobin was taken as cut-off. Intravenous iron is superior to oral iron with respect to faster increase in Haemoglobin and faster replenishment of body iron stores. Also, it reduces the need of blood transfusions, and it can be given an outpatient basis. Perewusnyk G *et al*⁸ studied 400 women who received a total of 2000 ampoules of iron sucrose. Minor general adverse effects including a metallic taste, flushing of the face and burning at the injection site occurred in 0.5 per cent cases. The high tolerance of the drug has been partly attributed to slow release of iron from the complex and also due to the low allergenicity of sucrose. Breymann C *et al*⁹ treated more than 500 antenatal women diagnosed with iron deficiency anaemia. Intravenous iron sucrose was given according to the calculated dose as either IV push over 5-10 min or iv infusion over 20-30 min. All injections were given on outpatient basis without any test dose. This study emphasizes on the safety of iron sucrose injection. In the present study, the first dose was given in ward where facilities for emergency care were available. All subsequent doses were given on Outpatient basis. None of the patients required any emergency care. In other studies,^{4,7} target haemoglobin for calculation of required dose has been taken 11 g/dl and for replenishment of stores 500 mg has been added. In our study target haemoglobin was taken as 10.5g/dl and 500 mg added for replenishment of stores. As compared to previous studies,^{4,7} ferritin levels in our study women showed a lesser increase. The reason can be due to severely depleted iron stores in Indian women or faster erythropoiesis. Hookworm is one of the well established causes of anaemia in developing countries. Routine antihelminthic therapy in pregnancy is recommended.⁴ In our study all the patients were given antihelminthic therapy.

CONCLUSION

Through this study, it has been proved that parenterally administered iron sucrose elevates haemoglobin and

restores iron stores faster and also intravenous iron sucrose administration is highly safe and effective.

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