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Original Research Article

A HOSPITAL BASED PROSPECTIVE STUDY TO ASSESS THE USE OF INTRAVENOUS (IV) IRON SUCROSE FOR TREATMENT OF IRON DEFICIENCY ANAEMIA IN PREGNANCY AND ITS MATERNAL OUTCOME AT NEWLY ESTABLISHED TERTIARY CARE CENTER

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ABSTRACT

Background: Iron deficiency anemia (IDA) is the most widespread micronutrient deficiency in the world leading to an epidemic public health crisis. The aim of this study to evaluate the efficacy and safety of intravenous iron sucrose therapy in pregnant women with moderate IDA.

Materials & Methods: This is a hospital based prospective study done on 50 pregnant women aged 18-45 years at the Department of Obstetrics and Gynaecology in government medical college, Dungarpur, Rajasthan, India during study period. Evaluation of efficacy parameters, such as Hb, mean corpuscular volume (MCV), mean corpuscular Hb (MCH), MCH concentration, serum ferritin, and serum reticulocyte count, were recorded at baseline, at the end of 4 weeks, and at the end of 8 weeks.

Results: The mean age of pregnant women was 28.6±5.42 (range 19-35) years. 40% of the pregnant women were found to be primigravida while 60% were multigravida. At the baseline, the mean Hb was 6.28±0.49 g%. After completion of therapy, mean Hb increased to 12.32±0.53 g%. The mean increase in serum ferritin was 43.5±4.7 µg/l at the end of 8 weeks ($p<0.0001$).

Conclusion: Hence, iron sucrose can be an effective agent for the treatment of IDA in pregnancy. Intravenous iron therapy is safe, convenient and more effective than oral iron therapy in the treatment of iron deficiency anemia during pregnancy.

Keywords: Iron deficiency anemia, Hb., MCV, Serum Ferritin, MCH.

INTRODUCTION

Anemia is the most common medical disorder in pregnancy, being more rampant in the developing countries with varied incidence, etiology, and severity.[1] In India, more than 90% of anemia cases are estimated to be due to iron deficiency, because of vegetarian dietary patterns.[2] The high frequency of iron-deficiency anemia during pregnancy in the developing world has substantial health and economic costs and is of concern and a cause of considerable morbidity and mortality.[3]

Prevalence was high in all States of the country with considerable variations in moderate to severe anemia. Other factors responsible for high incidence of anemia in our country include early marriage, teenage pregnancy, multiple pregnancies, less birth spacing, phytate-rich Indian diet, low iron, and folic acid intake and high incidence of worm infections in Indian population.[4] WHO defines anemia as hemoglobin (Hb) <11 g % In India, the ICMR classification of iron deficiency anemia is: 8-11 g% as mild, 5-8 g % as moderate and <5 g% as severe anemia.1 In absence of interfering factors, serum ferritin <12-15 µg/l is considered as iron deficiency.[5]

Iron deficiency anemia (IDA) is the most widespread micronutrient deficiency in the world leading to an epidemic public health crisis. The treatment of anemia depends on its severity and added maternal

risk factors or co-morbidities. The first choice for prophylaxis and treatment of mild IDA in pregnancy is oral iron therapy. In the majority of cases, oral iron is not adequate to treat moderate to severe anemia, since the endogenous iron stores are usually depleted, and less iron is provided for erythropoiesis.

Therefore, as per WHO guidelines, moderate to severe anemia requires parenteral iron therapy.[6] Conventional parenteral iron preparations such as iron dextran and iron sorbitol citrate require test dose, as these are reported to cause anaphylactic reactions. Iron sucrose, a novel, safe intravenous iron preparation, is widely used to prevent functional IDA.[7,8] The aim of this study to evaluate the efficacy and safety of intravenous iron sucrose therapy in pregnant women with moderate IDA.

MATERIALS AND METHODS

This is a hospital based prospective study done on 50 pregnant women aged 18-45 years at the Department of Obstetrics and Gynaecology in a Government medical college, Dungarpur, Rajasthan, India during study period.

Inclusion criteria: women aged 18-45 years, singleton pregnancy between 12 and 32 weeks on folic acid, Hb level between 7 and 9 g/dl, and patients willing to give written informed consent. Exclusion criteria: anemia due to other causes, known hypersensitivity to parenteral iron preparation, recent blood transfusion, associated cardiovascular, renal, hepatic dysfunction, and infections including malaria, hookworm infestation, schistosomiasis, hereditary defects such as sickle cell anemia, thalassemia, G6PD deficiency, and previous history of any bleeding tendency.

All the enrolled subjects were given intravenous iron sucrose therapy. Demographic data, history, clinical examination, hematological parameters, and details of drug prescription were recorded. The target Hb to be achieved was 11gm/dl. Total iron requirement was calculated as per the formula.[9]

At the initiation of therapy, one ampoule of 5 ml iron sucrose (100 mg elemental iron) inj. is added to 100 ml of sterile normal saline and first 25 ml will be infused over a period of 15-min. This worked as a test dose. Subjects were monitored for any adverse reactions during this period. The remaining portion of the infusion is administered over next 15 mins. The total calculated dose of iron is given in divided doses on alternate days until the target Hb level was achieved.

Evaluation of efficacy parameters, such as Hb, mean corpuscular volume (MCV), mean corpuscular Hb (MCH), MCH concentration, serum ferritin, and serum reticulocyte counts, were recorded at baseline, at the end of 4 weeks, and at the end of 8 weeks. Safety and tolerability were assessed by recording the adverse events and by Likert's scale during the study period.[10] Once the target Hb was achieved, all the pregnant women continued to receive oral iron therapy until delivery.

Data were analyzed using percentage, mean, standard deviation, ANOVA test. The level of significance was taken as 5%. The power of the study was taken as 80% and confidence interval 95%.

RESULTS

The mean age of pregnant women was 28.6±5.42 (range 19-35) years. 54% and 46% of the pregnant women were in middle and lower class according to modified Kuppuswamy scale. The regional distribution of the study population from the rural and urban area was 54% and 46%, respectively. 40% of the pregnant women were found to be primigravida while 60% were multigravida (table 1).

At the baseline, the mean Hb was 6.28±0.49 g%. After completion of therapy, mean Hb increased to 12.32±0.53 g%. Table 2 shows the baseline hematological parameters and effect of iron sucrose therapy on all the parameters. The mean increase in serum ferritin was 43.5±4.7 µg/l at the end of 8 weeks ($p<0.0001$).

Table 1: Basic demographic profile of pregnant mothers (n=50)

Parameters	Mean ± SD
Mean Age (Years)	28.6±5.42
Mean Weight (Kg)	54.9±3.43
Parity (Primi/ Multi)	20 /30 (40% /60%)
Mean gestational age (weeks)	28.5±2.25

Table 2: Baseline hematological parameters and effect of iron sucrose therapy

Parameters	Baseline	4 weeks	8 weeks	P-value
Hb (g/dl)	6.28±0.49	10.24±0.76	12.32±0.53	0.0001
MCV (fl)	57.8±6.03	79.3±5.8	89.6±5.6	0.0001
MCH (pg)	23.03±3.58	30.5±3.74	35.9±4.16	0.0001
MCHC (g/dl)	32.05±3.43	39.8±3.62	43.6±4.24	0.0001
Serum ferritin (µg/l)	9.13±1.62	31.5±4.74	43.5±4.7	0.0001
Serum reticulocyte count (%)	1.3±0.4	3.7±0.2	5.3±0.38	0.0001

DISCUSSION

Anemia is a common medical disorder that contributes significantly to maternal morbidity and mortality, intrauterine growth retardation, pre-term delivery, and perinatal morbidity and mortality.[11] In India > 90% of anemia cases are estimated to be due to iron deficiency because high iron requirements

during pregnancy are not easily fulfilled by dietary intake, especially when iron bio-availability is poor because of religious reasons, poverty, or both, the Indian population observes dietary patterns that are largely vegetarian.

The total amount of extra iron requirement during pregnancy ranges from 700 to 1400 mg with an average of 1000 mg. This is implausible to be provided by dietary iron, thus warrants the use of iron supplementation.[12] In the present study, the pregnant women were between 19 and 35 years and the youngest being 19 years which is similar to a hospital based cohort study done in West Bengal[13] that showed that the teenage mothers between 15 and 19 years who were prone for anemia, preterm delivery, and low birth weight.

A study done in Malaysia by Rosmawati et al.,[14] the proportion of anemia was high in multigravidas than primigravidas (33% vs. 14%). In the present study, 60% of anemic women were multigravida, while 40% were primigravida. The reasons being frequent births inadequate spacing between childbirth and delayed antenatal booking giving insufficient time for correction of anemia. Additional causes include poor socioeconomic status, worm infestation. This is inconsistent with the study done in Nigeria and Ethiopia that showed the higher prevalence of anemia in primigravida (69.7%).[15]

Treatment of moderate IDA (Hb levels < 8 g%) in pregnancy is associated with higher maternal and perinatal morbidity and mortality. Therefore, as per WHO guidelines, the treatment of moderate anemia requires parenteral iron therapy.

In the present study, there was a gradual rise in Hb% from baseline throughout the study period. The mean rise of Hb was 3.96 g/dl at the end of 4 weeks and 6.04 g/dl at the end of 8 weeks. The study done by Perewsnyk et al. found that accumulation of iron sucrose complex in parenchyma of organs is low while incorporation into bone marrow for erythropoiesis is rapid.[16]

This is also comparable to a study done in Pakistan by Walli et al. showing a mean increase of 2.6 g/dl Hb level at the end of 3.6 weeks of iron sucrose therapy emphasizing the superiority of intravenous iron therapy.[17] In a study conducted by Breymann et al.,[18] the mean rise in the Hb level was 1.7 g/dl after 3 weeks of iron sucrose therapy.

The mean increase in serum ferritin was 43.5±4.7 µg/l at the end of 8 weeks ($p<0.0001$). This could be explained by the immediate availability of iron sucrose for erythropoiesis and faster replenishment of iron stores. The study done at AIIMS, New Delhi by Kriplani et al.[19] showed the rise in serum ferritin at the end of 8 weeks to be 69±23.1 µg/l, from a baseline of 11.2±4.7 µg/l. In the present study, ferritin level showed a lesser increase which could be explained by severely depleted iron stores in Indian women.

Parenteral administration by intramuscular injection is a painful alternative with a variable degree of efficacy. Parenteral exposure to iron dextran imposed a series of serious risks to the health of the recipient.[20] Many studies have stressed that intramuscular therapy should be discouraged because of its adverse effects which include pain, irregular absorption, staining, and malignancy. Intramuscular iron sucrose complex is particularly contraindicated because of poor absorption.[21]

CONCLUSION

Our results showed that intravenous iron sucrose therapy was effective in raising the hematological parameters, as it caused a rapid rise in Hb level and faster replenishment of iron stores with negligible side effects. Hence, iron sucrose can be an effective agent for the treatment of IDA in pregnancy. Intravenous iron therapy is safe, convenient and more effective than oral iron therapy in the treatment of iron deficiency anemia during pregnancy.

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