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RESEARCH ARTICLE

A comparative prospective study to assess the efficacy and safety of iron sucrose versus iron sorbitol citric acid in pregnant women with iron deficiency anemia in a tertiary care hospital

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ABSTRACT

Background: The prevalence of iron deficiency anemia (IDA) is 58% among pregnant women in developing countries. According to the recent national guidelines, intramuscular iron sorbitol citric acid (ISCA) complex is one of the first-line drugs for treating moderate IDA in pregnancy. A novel intravenous preparation, iron sucrose promises to be more effective as it causes faster replenishment of iron stores and rapid rise of hemoglobin (Hb). **Aims and Objective:** The aim of this study is to evaluate the efficacy and safety of iron sucrose versus ISCA complex in IDA of pregnant women. **Materials and Methods:** A total of 127 pregnant women whose Hb between 7 and 9 g/dl were recruited in the study. They were randomized into two groups to receive iron sucrose (intravenous) and ISCA (I.M), respectively. Hematological parameters were measured at baseline, 4 weeks and 8 weeks of treatment. **Results:** Mean rise in Hb and serum ferritin from baseline was 3.15 ± 0.08 ($P < 0.0001$) and 14.1 ± 2.6 ($P < 0.0001$) at the end of 8 weeks, respectively, with ISCA. Mean rise in Hb and serum ferritin from baseline was 3.36 ± 0.06 ($P < 0.0001$) and 16.28 ± 3.1 ($P < 0.0001$) at the end of 8 weeks with iron sucrose. 18% and 42% of pregnant women in iron sucrose and ISCA group experienced side effects, respectively. **Conclusion:** The rise in hemoglobin and serum ferritin was significant in iron sucrose group with fewer adverse effects. Hence, iron sucrose can be a safe and effective agent in the treatment of IDA in pregnancy.

KEY WORDS: Iron Deficiency Anemia; Pregnant Women; Iron Sucrose; Iron Sorbitol Citric Acid Complex

INTRODUCTION

Iron deficiency with its resultant anemia is the most widespread micronutrient deficiency in the world leading to an epidemic public health crisis. According to the WHO, while the prevalence of iron deficiency anemia (IDA) is about 18% in the developed countries and is 35-75% in the developing countries.[1] In India, it affects about 33-89% of the population, of which 50-90% were pregnant women according to a study conducted by Indian Council of Medical Research during the 10th 5 year plan.[2,3]

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According to the WHO, IDA in pregnancy is defined as hemoglobin (Hb) <11 g% and serum ferritin <12-15 µg/l.[1,4] It is classified into three categories, *viz*., mild (8-11 g%), moderate (5-8 g%), and severe (<5 g%) anemia.[3]

Anemia in pregnancy results in poor maternal and fetal outcomes. It is associated with preterm labor, preeclampsia, sepsis, postpartum hemorrhage, and increased need for blood

transfusions.[5] Furthermore, maternal anemia adversely affects the fetus and leads to intrauterine growth retardation, premature births, and low birth weight babies. This not only results in higher perinatal morbidity and mortality and a higher infant mortality rate but also causes poor growth in infancy, childhood, and adolescence. Further, maternal Hb <8 g/dl causes a 2-3 fold increase in the perinatal mortality rate and doubles the incidence of low birth weight babies.[4,6]

Treatment of IDA includes oral iron, parenteral iron, recombinant erythropoietin, and blood transfusion. Oral iron therapy inadequately raises the Hb levels and is associated with poor response rates in moderate anemia. While an attempt to increase the dose results in increased side effects and reduced compliance, increased dose also increases the gut motility and thereby reduces iron absorption. Hence, oral iron therapy is not the standard of care in the treatment of moderate anemia.[7,8]

According to recent national guidelines, time-tested intramuscular iron sorbitol citric acid complex (ISCA) is one of the first-line drugs for treating moderate IDA in pregnancy.[9] The major drawbacks of this preparation are pain and swelling at the injection site, requirement of higher doses due to rapid clearance and need for multiple injections leading to poor compliance and high dropout rates.[10] A novel intravenous preparation, iron sucrose promises to be more effective as it releases elemental iron slowly from the complex and has a lower rate of renal excretion, thus leading to high availability of iron for erythropoiesis, a rapid rise in hemoglobin (Hb) and faster replenishment of iron stores. It also has a favorable safety profile due to its low allergic potential and organ toxicity.[11]

The limited body of evidence among Indian population comparing ISCA and iron sucrose in pregnant women with IDA prompted us to evaluate the efficacy and safety of these two parenteral iron preparations.

MATERIALS AND METHODS

It was a prospective, randomized, open label, parallel group, comparative study conducted at the Department of Obstetrics and Gynaecology, Vani Vilas hospital attached to BMC&RI. 127 pregnant women were recruited by simple random sampling and included in the study as per selection criteria. Inclusion criteria were women aged 18-45 years, singleton pregnancy between 12 and 32 weeks with Hb level between 7 and 9 g/dl, on folic acid therapy and patient who gave written informed consent. Exclusion criteria were anemia due to other causes, known hypersensitivity to parenteral iron preparation, recent blood transfusion, associated cardiovascular, renal, hepatic dysfunction, infections including malaria, hook worm infestation, schistosomiasis, hereditary defects such as sickle cell anemia, thalassemia, G6PD deficiency and previous history of any bleeding tendency. Ethics committee clearance was taken. Study subjects were then randomly assigned into two groups. One group of 62 pregnant women received intravenous iron sucrose and another group of 65 pregnant women received intramuscular ISCA complex. The target Hb to be achieved was 11 g/dl. Total iron requirement was calculated as per the formula.[12]

Total iron deficit (mg) = [body wt (kg) ×{target Hb-actual Hb (g/dl)} × 0.24]+1000

Group A: Iron sucrose, one ampoule of 5 ml (100 mg elemental Iron) was added to 100 ml of sterile normal saline and the first 25 ml was infused over a period of 15 min which act as a test dose. Patients were closely monitored for adverse reactions during this period, after which the remaining portion of the infusion was administered over next 15 min. Total calculated dose is given on alternate day regimen.

Group B: ISCA, daily limiting dose of 100 mg (2 ml) was administered by deep intramuscular route in gluteal region till the total calculated iron requirement is reached. At every visit of daily therapy, a test dose of 0.5 ml of was given by deep intramuscular and observed for 1 hr and if no adverse reactions were seen during this period, remaining portion is injected by '*Z*' track technique.

At the end of 4 and 8 weeks, blood sample was drawn for evaluation from both groups for the measurement of efficacy parameters.

Demographic data, history, clinical examination, and details of drug prescription by the treating obstetrician were recorded in the study pro forma. Efficacy was assessed in terms of primary and secondary outcomes. Primary outcome was to assess the efficacy of iron sucrose and ISCA in pregnant women with moderate anemia. Secondary outcomes were taken as to assess the safety and tolerability of therapy in pregnant women with moderate anemia. Tolerability was assessed by Likert's scale. Data in the two groups were analyzed using percentages, mean, standard deviation, student *t*-test. Level of significance was taken as 5%. Power of the study was taken as 80% and confidence interval 95%.

RESULTS

During the study period (December 2013 - December 2014), the total number of patients selected according to the inclusion and exclusion criteria were 127. They were randomly assigned into two groups, i.e., Group A received iron sucrose (n = 62) and Group B received ISCA (n = 65). Seven women were lost to follow-up. At the end of 8 weeks, 60 pregnant women from both the group were included in the analysis.

The baseline demographic characteristics with respect to age, weight, gestational weeks, and hematological parameters were comparable in both the groups (Table 1).

About 50% of the study population belonged to lower middle socioeconomic class in both the groups according to modified Kuppuswamy classification. The regional distribution of the study population from rural and urban area was 54% and 46%, respectively. Primigravida was 44% and multigravida was 56% in the study group.

Efficacy Measures

After completion of therapy, there was a significant increase in Hb concentration, MCV, MCH, MCHC, serum ferritin, serum reticulocyte count in both the treatment groups compared to baseline.

In the iron sucrose group (Table 2), the Hb concentration at the end of 4 weeks and 8 weeks increased by 1.46 ± 0.14 g/dl and 3.36 ± 0.06 g/dl, respectively. Serum ferritin level at the end of 8 weeks increased by 16.28 ± 3.1 µg/L. The rise in hematological parameters was significant when compared to pretreatment ($P < 0.0001$).

In the ISCA group (Table 3), the Hb concentration at the end of 4 weeks and 8 weeks increased by 1.18 ± 0.09 g/dl and 3.15 ± 0.08 g/dl, respectively. Serum ferritin level at the end of 8 weeks increased by 14.1 ± 2.6 µg/L. The rise in hematological parameters was significant when compared to pretreatment ($P < 0.0001$).

As seen in Figure 1, the mean Hb was increased by 1.46 g/dl and 1.18 g/dl in iron sucrose group and ISCA group, respectively, at the end of 4 weeks as compared to baseline.

As seen in Figure 2, the mean Hb was increased by 3.36 g/dl and 3.15 g/dl in iron sucrose group and ISCA group, respectively, at the end of 8 weeks as compared to baseline.

The mean serum ferritin (Figure 3) at the end of 8 weeks increased by 16.28 ± 3.1 µg/L and 14.1 ± 2.6 µg/L in the iron sucrose group and ISCA group, respectively. The rise in serum ferritin was significant with iron sucrose ($P < 0.005$).

All the adverse effects observed were mild to moderate in nature and none of the patients required any medical intervention (Tables 4 and 5).

Table 1: Baseline characteristics in the two groups

Characteristics	*n*=60		*P*
	Iron sucrose	Iron sorbitol citric acid	
Age (year)	23.4±1.76	23.7±1.74	0.98
Weight (kg)	55.7±6.3	55.8±5.7	0.76
Gestational weeks	23.2±6.06	23.3±5.72	0.56
Hb (g/dl)	8.02±0.56	8.0±0.5	0.92
MCV (fL)	79.6±6.03	79.4±6.02	0.85
MCH (pg)	27±3.67	26.9±3.71	0.79
MCHC (g/dl)	36±3.51	35.9±3.4	0.87
Serum ferritin (µg/L)	15.1±1.80	14.8±1.53	0.90
Serum reticulocyte count (%)	1.3±0.59	1.37±0.5	0.68

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

Parameters	Baseline	4 weeks	8 weeks	*P**
Hb (g/dl)	8.02±0.56	9.48±0.7	11.38±0.5	0.0001
MCV (fL)	79.67±6.03	84.1±5.9	89.6±5.7	0.0001
MCH (pg)	27.09±3.67	30.1±3.9	35.3±4.2	0.0001
MCHC (g/dl)	36.07±3.5	39.5±3.7	42.7±4.2	0.0001
Serum ferritin (µg/l)	15.12±1.80	-	31.4±4.9	0.0001
Serum reticulocyte count (%)	1.3±0.5	3.8±0.3	5.1±0.37	0.0001

*$P<0.05$

DISCUSSION

Maternal iron deficiency anemia is very common in India and is responsible for 95% of anemia during pregnancy.[13] Total

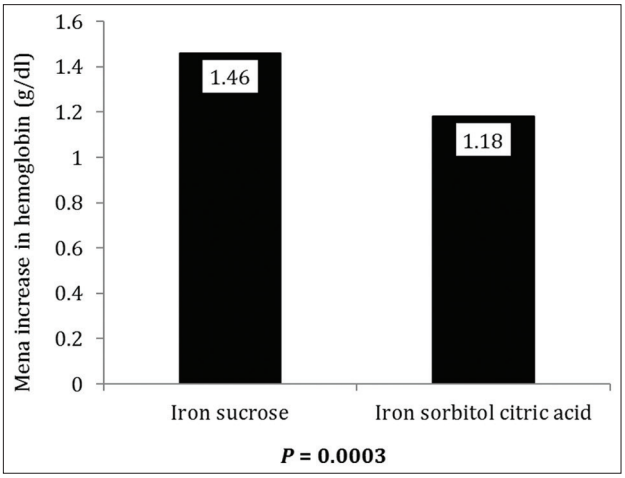

Figure 1: Mean increase in hemoglobin at 4 weeks

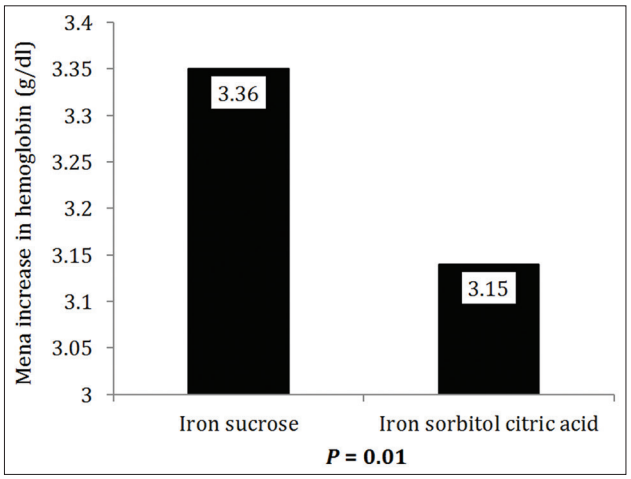

Figure 2: Mean increase in hemoglobin at 8 weeks

amount of extra iron requirement during pregnancy ranges from 700 to 1400 mg with an average of 1000 mg. The fetal iron requirement during pregnancy is 20 mg at 20 weeks, 200 mg at 32 weeks, and 300 mg at 36 weeks of gestation.[14] This is implausible to be provided by dietary iron, thus warrants the use of iron supplementation. It is the state of iron stores that largely determine whether pregnant women become anemic or not. Thus, lesser the iron stores, earlier the anemia occurs.[15,16]

A hospital-based cohort study done in West Bengal showed that the teenage mothers between 15 and 19 years have high prevalence of anemia than in women between 20 and 24 years (62.96% vs. 43.59%). In this study, the pregnant women were between 19 and 30 years and the youngest being 19 years. The study done by Banerjee et al. observed that teenage mothers are prone for anemia, preterm delivery, and low birth weight.[17] The median age of women at first conception is low in developing countries as compared to developed countries (19.9 years vs. 28.7 years).[18] The average age of conception in this study was 24 years which is similar to the study done at APCH, USA by Morales, the average age was 27 years.[19] The lower incidence of teenage pregnancy and higher age at first conception in our study could be attributed to increased literacy rate.

Anemia in pregnant women is a major contributing factor to maternal morbidity and mortality in developing countries. This is attributed to inadequate antenatal care and poor socioeconomic conditions. In this study, 48% of the pregnant women were in lower socioeconomic group.

In this study, 54% of the pregnant women were from rural and 46% from urban and is at par with the study done in Maharashtra by Shafi et al.[20] Both these studies are consistent with National Family Health Survey-2 done between 1998 and 1999 and IDA being the most common.[21]

A study was done in Malaysia by Rosmawati et al.,[22] the proportion of anemia was high in multigravidas than primigravidas (33% vs. 14%). In this study, 56% of anemic women were multigravida, while 44% were primigravida. The reasons being poor socioeconomic status inadequate spacing between child births delayed antenatal booking giving insufficient time for correction of anemia. This is inconsistent with the study done in Nigeria and Ethiopia that showed higher prevalence of anemia in primigravida (69.7%).[23]

For prophylaxis of anemia daily requirement of elemental iron is 30-40 mg in western women as they have sufficient iron stores. In Indian women, the requirement is 100 mg/day.[24] The high requirement is because of inadequate antenatal care, lack of knowledge of dietary needs of pregnant women leading to insufficient iron stores and anemia. For treatment of anemia, dose recommended is 200 mg elemental iron per day in Indian women.[25]

Treatment of IDA includes oral iron, parenteral iron, recombinant erythropoietin, and blood transfusion. Studies

Table 3: Effect of iron sorbitol citric acid therapy

Parameters	Baseline	4 weeks	8 weeks	*P**
Hb (g/dl)	8.01±0.56	9.19±0.65	11.16±0.48	0.0001
MCV (fL)	79.4±6.02	83.2±6.07	88.3±6.02	0.0001
MCH (pg)	26.91±3.71	30.02±3.91	34.31±4.18	0.0001
MCHC (g/dl)	35.97±3.45	38.67±3.58	41.76±4.13	0.0001
Serum ferritin (µg/l)	14.8±1.53	-	28.9±4.13	0.0001
Serum reticulocyte count (%)	1.37±0.57	3.50±0.37	4.98±0.40	0.0001

*$P<0.05$

Table 4: Adverse effects

Side effects	*n* (%)	
	Iron sucrose	Iron sorbitol citric acid
Injection site pain	5 (8)	23 (38)
Injection site burning	6 (10)	-
Swelling	-	15 (25)
Staining	-	13 (22)
Itching at injection site	3 (5)	-
Nausea/vomiting	2 (3)	8 (13)
Headache	3 (5)	6 (10)
Fever	2 (3)	4 (7)
Regional lymphadenopathy	-	5 (8)
Tachycardia	-	3 (5)

Table 5: Overall tolerability

Tolerability	*n* (%)	
	Iron sucrose	Iron sorbitol citric acid
Excellent	42 (70)	17 (28)
Good	16 (27)	15 (25)
Poor	2 (3)	28 (47)

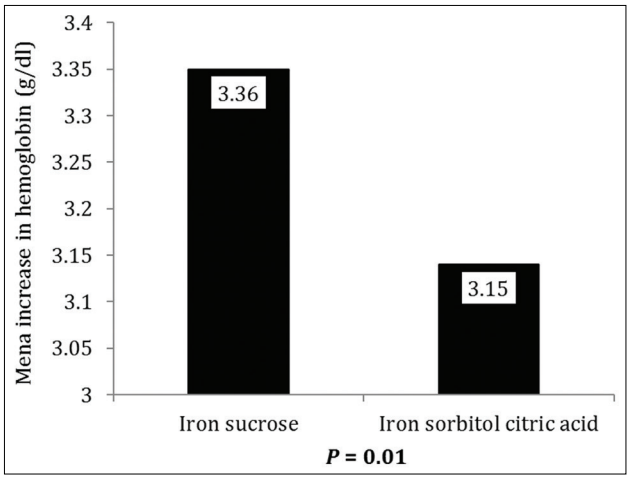

Figure 3: Mean rise in serum ferritin at 8 weeks

have shown that Hb levels <8 g% (moderate to severe anemia) in pregnancy are associated with higher maternal morbidity.[26-28] As per the WHO guidelines, the treatment of moderate anemia requires parenteral iron therapy.

In this study, the efficacy and safety of iron sucrose and ISCA complex was evaluated in pregnant women with IDA.

There was gradual rise in Hb% from baseline in both groups iron sucrose and ISCA throughout the study period. The normal rise in Hb level usually starts after 3 days of starting of iron therapy and the rate of rise of the Hb level in pregnant women is 0.8 g/dl per week as compared to nonpregnant women.[29] The mean rise of Hb in iron sucrose and ISCA group was 3.36 g/dl and 3.15 g/dl, respectively, at the end of 8 weeks. The rise was greater with iron sucrose as compared to ISCA at the end of 8 weeks ($P = 0.01$), which could be due to rapid incorporation of iron sucrose into bone marrow for erythropoiesis.[30]

Nearly 33-35% of ISCA is excreted and also its release from the reticuloendothelial system is slow as compared to iron sucrose release from liver parenchymal cells.[31,32] Hence, the rise in the Hb concentration in the ISCA group was not comparable to that of iron sucrose group at the end of 8 weeks of parenteral therapy.

In this study, iron sucrose was found to be a more effective in raising Hb than ISCA, which is comparable to a study done in Pakistan by Wali 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.[33] In a study conducted by Breymann et al.,[30] 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 in iron sucrose group was 31.4 ± 4.9 µg/l and in ISCA group were 28.9 ± 4.13 µg/l at end of 8 weeks. Although the difference is small, the rise is statistically significant in iron sucrose group ($P = 0.005$). 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.[34] 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 this study, ferritin level showed a lesser increase which could be explained by severely depleted iron stores in Indian women.

The mean increase in MCV from baseline was 89.6 ± 5.71 fL in iron sucrose group and 88.3 ± 6.02 fL in ISCA group at the end of therapy. The mean rise of MCV in iron sucrose group was 9.97 fL at 8 weeks as compared to baseline, which was similar to study by al-Momen et al.[35] and Halimi et al.,[36] which showed that the mean rise was 10 fL. The rise in MCV was higher in this study unlike the study done by Khurshid Shabir in Pakistan which showed minimal rise.[37]

The mean increase in serum reticulocyte count in iron sucrose group was 3.83% at 8 weeks as compared to baseline, which is akin to the study done by Prasanna et al.[38] which showed that the rise in serum Reticulocyte count was 3.27%.

Safety and Tolerability

About 18% of pregnant women in iron sucrose group and 42% of pregnant women in ISCA group experienced side effects.

The main problem with the ISCA is its side effects. Because iron sorbitol has much low molecular weight and high transferrin saturation capacity, it cannot be given as intravenous bolus or infusion.[39,40] Therefore, it is used only intramuscularly. However, the most common complaint in this study was pain at the site of injection, specifically with intramuscular injection of ISCA, which was found to be similar to the study by Wali et al.[33] The other side effects such as swelling and blackening of skin were also reported in the ISCA group. Therefore, all these side effects of the ISCA might be the main reason for less compliance attributing to a high dropout rate (8%) in our study. This is comparable to study done by Dhanani et al.[11]

Shaik et al.[33] showed among the patients who received iron sucrose, 53% reported excellent tolerability while 20% had good tolerability which in comparison to this study, 70% and 27% of the patients reported excellent and good tolerability, respectively. High tolerability to iron sucrose therapy as compared to ISCA could be partly attributed to slow release of iron from complex and also due to low allergenicity.

This study shows that iron sucrose is well tolerated in pregnant women and has fewer side effects which is consistent to the studies done by Perewusnyk et al.[30] and Breymann.[41]

In this study, all laboratory parameters increased significantly after both iron sucrose and ISCA therapy. The rise in all parameters was found to be significantly more in iron sucrose group compared to ISCA group. However, in this study, almost all adverse events such as pain, swelling, and blackening at the site of injection were seen and because of ADRs the dropout rate was much more in ISCA group.

CONCLUSION

Parenteral iron therapy was effective in increasing Hb, serum ferritin and other hematological parameters in pregnant women with moderate anemia. Iron sucrose can be used in hospital settings where it can replace intramuscular therapy due to injection-related side effects.

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