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Parenteral iron sucrose therapy along with blood transfusion in moderate to severe anaemia in pregnancy

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Abstract
Background: Iron deficiency anemia (IDA) is more prevalent in South Asian countries which accounts for more than half of the maternal death. India is the leader in maternal death due to IDA. Iron deficiency anaemia (IDA) is the most common nutritional deficiency in pregnancy. Prophylactic oral iron is recommended during pregnancy to meet the increased requirement. In India, women become pregnant with low baseline haemoglobin levels resulting in high incidence of moderate to severe anaemia in pregnancy, where oral iron therapy cannot meet the requirement. Pregnant women with anaemia are to be treated with parenteral iron therapy. Iron-deficiency anaemia during pregnancy and postpartum occurs frequently and may lead to severe maternal and foetal complications. New treatment regimens include intravenous iron administration in particular clinical situations. The aim of the study was to assess the diagnosis and treatment of iron-deficiency anaemia in pregnancy and postpartum.
Aims and Objectives: To study improvement in haematological parameters after parenteral Iron sucrose therapy with or without blood transfusion in pregnant women with moderate to severe iron deficiency anaemia.
Materials and methods: Thirty patients with iron deficiency anemia who were admitted having hemoglobin <10gm% were studied. Study cohort received 300 to 600 mg of iron sucrose by intravenous route with or without blood transfusion. Hematocrit, mean corpuscular volume and haemoglobin were recorded before and after therapy at the end of one week.
Methods/Design: This is a prospective study performed on pregnant women with moderate to severe anaemia. A sample size of 30 patients was selected for the present study. The study subjects were divided into two groups: Group A: (11) patients who were treated with iron sucrose + blood transfusion and Group B: (19) patients who were treated with iron sucrose only.
Conclusion: The study reported Hb level recorded at 1 week was 9.29 ± 0.68 g/dl in group A and 10.1 ± 0.83 g/dl in group B. Significant improvement in Hb levels of patients in group A was observed as the study reported that at baseline the Hb concentration of all patients was ≤9 g/dL however, after 6 weeks there were only 27.3% with Hb concentration less than ≤9 g/dL. The study concluded that the iron sucrose and blood transfusion (group A) is a better indicator for raising the Hb levels of pregnant women.

Keywords: Anaemia, iron deficiency, haemoglobin, iron sucrose and blood transfusion

Introduction

Study Design: Prospective, observational analytical study.

Background: According to the World Health Organization (WHO), anemia affects approximately 1.5 billion people worldwide. The prevalence is very high in Africa, Asia, India, Latin America, Eastern Europe, and China; however, it is also high in developed countries (WHO, 2012) [3].

Iron deficiency can be classified as severe ID when the serum ferritin level is below 20–30µg/L and mild-moderate ID if the serum ferritin level is below 70–100µg/L. Ferritin level is considered the surrogate marker for ID. However, serum ferritin is an acute phase reactant and may be raised in cases of inflammation or infection, therefore a concurrent test for inflammatory markers is advisable in cases of anaemia with raised ferritin to exclude reactive causes. ID is most likely not present if the ferritin level is above 100µg/L (Goddard, *et al.*, 2000) [1].

Anemia has the highest prevalence in 3 groups: children aged <5 years (47%), pregnant women (42%), and women of reproductive age (30%). Iron deficiency is seen in 50% of cases and is the most common cause of anemia (WHO, 2012) [3]. No national epidemiologic study on the prevalence of anemia has been conducted in Turkey but some regional studies have been

performed (Bestepe, *et al.*, 2002; Api, *et al.*, 2009;) [6, 4]. The WHO placed Turkey on the worldwide anemia map by extrapolating these data. Accordingly, Turkey is in the intermediate group, with a prevalence of anemia between 20% and 39.9% among women of reproductive age, and is in the severe group for pregnant women, with a prevalence of 40% (WHO, 2012 [3]; worldwide prevalence of anaemia, 2008) [2].

Attention has focused on the alternative use of intravenous (IV) iron preparations because oral iron therapy has some disadvantages (Bhandal, *et al.*, 2006) [7]. Many studies on IV iron sucrose and ferric carboxymaltose have been conducted. Data on other IV iron preparations such as iron gluconate, iron sorbitol, iron polymaltose, iron isomaltoside, and low molecular weight iron dextran are very limited, and there are increasing safety concerns about high molecular weight iron dextran, which is no longer available in Europe due to a high rate of serious adverse events.

Simply put, Anaemia is one of the most common problems in obstetrics. It is well known that, depending on its severity, anaemia constitutes an important risk factor in both maternal and foetal morbidity. If the mother suffers from iron deficiency anaemia, the risks to the foetus include a higher rate of premature birth, intrauterine growth retardation, unfavourable impact on placental development, and reduced neonatal iron stores. Maternal risks include depleted blood reserves during delivery and thus an increased risk of an allogeneic blood transfusion in case of significant blood loss, cardiovascular stress, anaemia symptoms (fatigue, reduced physical and mental capacities, headaches, ortho-static dizziness, exhaustion, prolonged hospitalizations, decreased milk production in the puerperium, depleted maternal iron stores postpartum and subsequently. For these reasons, the efficient treatment of anaemia following its diagnosis has a positive impact on maternal as well as foetal outcomes.

There are previous studies available that have reviewed the diagnosis and treatment of iron-deficiency anaemia during pregnancy and postpartum. Khalafallah, *et al.*, (2012) [9] in their study stated that intravenous iron can be used safely for a rapid repletion of iron stores and correction of anaemia during and after pregnancy. Iron deficiency occurs frequently in pregnancy and can be diagnosed by serum ferritin-level measurement (threshold value <30μg/L). Screening for iron-deficiency anemia is recommended in every pregnant women, and should be done by serum ferritin-level screening in the first trimester and regular hemoglobin checks at least once per trimester. In the case of iron deficiency with or without anaemia in pregnancy, oral iron therapy should be given as first-line treatment. In the case of severe iron-deficiency anemia, intolerance of oral iron, lack of response to oral iron, or in the case of a clinical need for rapid and efficient treatment of anaemia (e.g., advanced pregnancy), intravenous iron therapy should be administered. In the postpartum period, oral iron therapy should be administered for mild iron-deficiency anemia (haemorrhagic anemia), and intravenous iron therapy for moderately severe-to-severe anemia (Hb <95g/L). If there is an indication for intravenous iron therapy in pregnancy or postpartum, iron-containing drugs which have been studied in well-controlled clinical trials in pregnancy and postpartum such as ferric carboxymaltose must be preferred for safety reasons (Breymann, *et al.*, 2017), [8].

Primary objectives

To study improvement in haematological parameters after parenteral Iron sucrose therapy with or without blood transfusion in pregnant women with moderate to severe iron deficiency anaemia.

Materials and methods

This section deals with the description of methods that will be applied in carrying out the research. It covers research design, plan of research work and talks about how the research was performed. A observational study was performed in a tertiary hospital involving 30 subjects who were admitted for moderate to severe form of anemia for 180 months. Pre-tested questionnaire containing demographic data, diagnosis, preliminary investigations showing complete blood count (CBC), blood grouping and was filled and data was recorded in excel sheet. All patients received 300 mg to 600 mg of Iron sucrose intravenous in 500 ml normal saline in divided dose. Hematocrit, mean corpuscular volume and haemoglobin percentage were studied before and after therapy at the end of one week. All the data were analyzed. Frequency distribution and cross tabulation was used to generate tables. Analysis was performed using chi-square test and independent sample student t test. P values <0.05 was considered to be significant.

The formula used for calculation of iron sucrose dose was as follows: Required iron dose (mg) = (2.4 × (target Hb-actual Hb) × pre-pregnancy weight (kg)) + 500 mg for replenishment of stores.

The prescribed doses of IV Iron Sucrose for Iron Deficiency Anaemia patients were as follows: 10 ml Ampule: 200 mg of iron diluted in sterile 0.9% NaCl solution and administered by slow intravenous injection over minimum 30 minutes time.

Max dose is 200 mg not more than 3 times for week; dose must be 24hrs apart

Setting of the study: The study was performed at Department of obstetrics and Gynecology, Grant Government Medical College, Mumbai.

Study population

Pregnant women with moderate to severe anaemia was included in this study.

Study Design

This is a prospective study performed to assess the intravenous iron sucrose along with blood transfusion in pregnant women with moderate to severe anaemia.

Sample Size

A sample size of 30 patients was selected for the present study.

The study subjects were divided into two groups:

The study subjects were divided into two groups:

- **Group A:** (11) patients who were treated with iron sucrose + blood transfusion.
- **Group B:** (19) patients who were treated with iron sucrose only.

Inclusion criteria

- The patients of age group 18-50 years.
- Patients consisted of women who sustain a primary post-partum haemorrhage in excess of 1000 mL with a resultant Hb drop of ≥3 g/dL and Hb of 5.5-8.0g/dL.
- Asymptomatic women, as well as patients with mild signs and/or symptoms of anaemia including dizziness, increased respiratory rate to >/ = 25 on minimal exertion, HR 100-130 or a postural blood pressure drop of >10 mmHg are eligible.

Exclusion criteria

- Exclusion criteria were causes other than iron deficiency anaemia, multiple pregnancy, high risk for preterm labour and recent blood transfusions, thalassemia and other medical disorders.

Procedure

About 8-10 ml blood was taken from each patient. High performance liquid chromatography (HPLC) of blood was performed, and red cell indices, peripheral blood smear and detailed serum iron studies were also conducted.

The group a patients were provided with both iron sucrose and blood transfusion and group B patients were treated with iron sucrose alone. The required details were collected from the study subjects as per the study Performa at admission. The study subjects were intervened and were observed for the impact after 1 week to assess the impact on the anaemia among the study subjects of both study groups.

Ethical clearance for the study protocol was taken from the Ethics Committee of the institute. Informed written consent was taken from all the patients before starting the treatment. Baseline and 1 week follow-up investigations were done.

Statistical methodology

All required data was collected in a computerized database and analysed using SPSS software. A p-value < 0.05 was considered statistically significant. For univariate statistical analysis, Pearson's x^2 test was used for qualitative variables and Student's t-test was used for quantitative variables. Categorical variables were presented in number and percentage (%) and continuous variables will be presented as mean ± SD and median.

Results

The study was conducted on 30 patients consisted of asymptomatic women, as well as patients with mild signs and/or symptoms of anaemia including dizziness, increased respiratory rate to >/ = 25 on minimal exertion, HR 100-130 or a postural blood pressure drop of >10 mmHg are eligible. The patients who are accepted for the study were in age group 18-50 years.

Table 1: Age Distribution

Age (Years)	Iron Sucrose	Iron Sucrose + Blood Transfusion	Total
18-25	12(63.15%)	05(45.45%)	17(56.7%)
26-30	04(21.05%)	03(27.27%)	07(23.3%)
31-35	03(15.79%)	03(27.27%)	06(20%)
Total	19(100%)	11(100%)	30(100%)

In the above table we found that, most of the patients were in the age group between 18-25 years.

Table 2: Haematocrit Level

Hematocrit level	Iron Sucrose + Blood Transfusion	Iron Sucrose	Total
<36%	11(100%)	19(100%)	30(100%)
≥36%	0	0	0
Total	11(100%)	19(100%)	30(100%)

As the normal levels of Haematocrit for women ranging from 36% to 48% but in this study, we found that all the patients' haematocrit level were below than 36%. This result indicate that all the patients were iron deficiency anaemia. The effect in the patients were statistically significant.

Table 3: Baseline Hemoglobin Level

Hb level	Iron Sucrose + Blood Transfusion	Iron Sucrose	Total
≥11g/dL	0	0	0
<11g/dL	0	08(42.10%)	8(26.7%)
≤9g/dL	11(100%)	11(57.90%)	22(73.3%)
Total	11(100%)	19(100%)	30(100%)

Regarding to haemoglobin levels, the result suggested that majority of the patients were Hb concentration ≤9 g/dL which is considered severe anaemia, followed by the patients having Hb concentration <11 g/dL indicates clinically significant anaemia. After that, all the patients were given 3 doses of inj. of iron sucrose and after 1 week again checked up and the result were recorded.

Table 4: Mean Score (Baseline)

Variables	Iron Sucrose + Blood Transfusion	Iron Sucrose	Total	Inference
Hb Level	7.02±0.92	8.85±0.75	8.18±1.20	
MCV (FL)	72.90±5.02	78.52±2.93	76.46±4.65	NS

Regarding mean score (baseline) the Hb level was 7.02 ± 0.92 in group A and 8.85 ± 0.75 in group B. Regarding mean MCV (FL) the study observed mean MCV (FL) was 72.90 ± 5.02 in group A and 78.52 ± 2.93 in group B.

Table 5: Haematocrit Level (1 Week)

Haematocrit level	Sucrose + Blood Transfusion	Iron Sucrose	Total
<36%	10(90.9%)	17(89.47%)	27(90%)
≥36%	1(9.1%)	2(10.53%)	3(10%)
Total	11(100%)	19(100%)	30(100%)

The result indicated that three patients were found statically not-significant while majority of patient were found statically significant in Haematocrit levels.

Table 6: Hemoglobin Level (1 Week)

Hb level	Iron Sucrose + Blood Transfusion	Iron Sucrose	Total
≥11/dL	0	4(21.05%)	4(13.3%)
<11g/dL	8(72.7%)	13(68.42%)	21(70%)
≤9g/dL	3(27.3%)	2(10.52%)	5(16.7%)
Total	11 (100%)	19(100%)	30(100%)

Regarding to haemoglobin levels, the patients were again tested after 1 week, the result indicated that majority of patient were found statically significant anaemia and 5 patients were found severe anaemia while 4 patients were found insignificant.

Regarding mean score (1 week) of Hb level and MCV level recorded at 1 week, the study found non-significant difference between both groups.

Discussion

More than half of the pregnant women (58%) in India suffer

from anemia, defined as hemoglobin (Hb) level <11 g/dL, at any time during pregnancy (NFHS, 2007 [10]). The global reported range of prevalence of anemia in pregnancy is 35%–75% in developing countries (Allen, *et al.*, 2000 [11]). The primary cause of anemia in pregnancy is iron deficiency. Anemia in pregnancy could result in adverse health consequences both for mother and child (Allen, *et al.*, 2000 [11]). There has been no perceptible decline in the prevalence of anemia in India, among pregnant women in the last few decades using standard supplementations with oral iron therapy formulations (NFHS, 2007 [10]). Iron sucrose, one of the parenteral iron preparations, has been reported to be safe and effective during pregnancy (Silverstein, *et al.*, 2004 [12]). It is well established in literature that iron sucrose and blood transfusion may help to overcome many of the factors linked to poor adherence (Silverstein, *et al.*, 2004; Charytan, *et al.*, 2001) [12, 13].

The study was conducted on 30 patients consisted of women who sustain a primary post-partum haemorrhage in excess of 1000 mL with a resultant Hb drop of ≥3g/dL and Hb of 5.5-8.0g dL. The study was aimed to assess the diagnosis and treatment of iron deficiency anaemia in pregnancy and postpartum period.

In our study we found that, majority of the patients (56.7%) were in the age group between 18-25 years. As the normal levels of Haematocrit for women ranging from 36% to 48% but in this study, we found that all the patients' haematocrit level were below than 36%. This result indicate that all the patients were iron deficiency anaemia. The effect in the patients were statistically significant ($p<0.05$). In our study, it was found that majority of the patients (73.3%) Hb concentration was ≤9 g/dL which is considered severe anaemia, followed by the 26.7% patients having Hb concentration <11g/dL indicates clinically significant anaemia.

The total requirement of iron during pregnancy is approximately 1000 mg (500 mg for developing foetus and placenta and similar amount for red cell increment) (Rome, *et al.*, 1988 [14]). Usually, this iron is mobilized from iron stores. However, women with poor iron stores become iron deficient during pregnancy. Studies have shown that Hb levels <8g% (moderate to severe anaemia) in pregnancy are associated with higher maternal morbidity (Prema, *et al.*, 1981; Toteja, *et al.*, 2006; Kriplani, *et al.*, 2013) [15-17]. Hb less than 5 g% is associated with cardiac DE compensation and pulmonary oedema. Blood loss of even 200 ml in third stage of labour can cause sudden shock and death in these women (Toteja, *et al.*, 2006; Kriplani, *et al.*, 2013) [16, 17].

In the present study after recording the clinical findings of the study subjects at admission, all the patients of group A were given 3 doses of inj. of iron sucrose and blood transfusion while group B patients were given only 3 doses of inj. of iron sucrose. The study subjects were again checked up after 1 week and the result were recorded. In a reference study by Kriplani, *et al.*, (2013) [17], 5-9g% Hb was taken as cut-off. Intravenous iron is superior to oral iron with respect to faster increase in Hb and faster replenishment of body iron stores (Bashiri, *et al.* 2003) [18].

In our study at baseline the mean Hb level was 7.02 ± 0.92 g/dl in group A and 8.85 ± 0.75 g/dl in group B. It was also observed that mean MCV (FL) recorded at baseline was 72.90 ± 5.02fl in group A and 78.52 ± 2.93fl in group B. The study found non-significant difference between both groups ($p>0.05$).

In our study haematocrit level recorded at 1 week signified improvement in 9.1% patients of group A (iron sucrose + blood transfusion) and 10.53% patients of group B. The result indicated that three patients were found statically not- significant while majority of patient were found statically significant in Haematocrit levels.

In our study haemoglobin levels recorded at 1 week indicated that there were 21.05% patients in group B with Hb concentration ≥11 g/dL however there were no patients reported in group A. However, the findings of study signified significant improvement in Hb levels of patients in group A as the study reported that at baseline the Hb concentration of all patients was ≤9 g/dL however, after 1 weeks there were only 27.3% with Hb concentration less than ≤9 g/dL. In a study to compare the clinical efficacy and safety of intravenous iron sucrose with intramuscular iron sorbitol citrate, it was found that rise of Hb was more in intravenous group (Wali, *et al.* 2002 [19]). This study emphasized the superiority of IV iron therapy to intramuscular therapy in terms of rise of Hb and also safety profile.

In the present study it was found that the mean Hb level recorded at 1 week was 9.29 ± 0.68 g/dl in group A and 10.1 ± 0.83g/dl in group B. The study also reported mean MCV at 1 week was 86.90 ± 1.13fl in group A and 86.52 ± 1.12fl in group B patients. Both groups have shown improvement in the Hb levels and MCV levels as compared to the initial clinical findings of the study subjects. However, the findings were found not statistically significant ($p>0.05$).

In a reference study Breymann, *et al.*, (2006) [20] 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 inpatient basis with prior test dose. This study also emphasizes on the safety of iron sucrose injection. Hookworm is one of the well-established causes of anaemia in developing countries. Routine anthelminthic therapy in pregnancy is not recommended. But due to high prevalence in developing countries including India, it is advisable to give anthelminthic therapy to pregnant women presenting with anaemia (Brooker, *et al.*, 2008) [21]. In another study Bencaiova, *et al.*, (2009) [22] tried to assess and compare the efficacy of two and three doses of intravenous iron sucrose with oral iron therapy, there was higher frequency of responders (Hb> 11g%) in intravenous group (75 vs. 80%). There was a significant difference of depleted iron stores before delivery (ferritin> 50mg/l) in the group with three intravenous iron doses in comparison to the oral iron group (49 vs. 14%; $P<0.001$).

The first choice for prophylaxis and treatment of mild iron deficiency anaemia in pregnancy is oral iron therapy. But in patients with moderate and severe anaemia, oral therapy takes long time and compliance is a big issue in our country. Thus, pregnant women with moderate anaemia should be better treated with parenteral iron therapy and/or blood transfusion depending upon individual basis (degree of anaemia, haemodynamic status, period of gestation, etc.) (Kriplani, *et al.*, 2013) [17]. Kochhar in their study reported that there was a statistically significant difference in increase of hemoglobin levels (3.1g/dL in group a vs 5.1g/dL in group B:$P = 0.002$) and ferritin levels between the two groups on day 30 ($P = 0.005$). The findings of our study were consistent with the findings of previous studies reported that intravenous administration of iron sucrose is a safe treatment for correction of anemia in pregnancy.

In a reference study assessed the effect of intravenous iron sucrose on hemoglobin (Hb) levels among the pregnant anaemic women and reported that the mean increase in Hb-level was 1.76 mg/dL. Severely anaemic pregnant women had larger increase in Hb-level when compared with pregnant women with moderate anemia. There were a number of studies that have explored and discussed the effectiveness of iron sucrose and blood transfusion in treating anaemia in pregnancy (Knight, *et al.*, 2009) [23]. The present study is a novel study that has explored the effectiveness

of intravenous iron sucrose along with blood transfusion in pregnant women with moderate to severe anaemia. The study has compared two groups intravenous iron sucrose along with blood transfusion v/s intravenous iron sucrose. The findings of the present study suggest that iron sucrose + blood transfusion (group A) is much better indicator for raising the Hb levels.

Conclusion

The findings of the present study reported that the mean Hb level recorded at 1 week was 9.29±0.68g/dl in group A and 10.1±0.83g/dl in group B. The findings of the study signified that both groups have shown improvement in the Hb levels and MCV levels as compared to the initial clinical findings of the study subjects. The study reported that haemoglobin levels recorded at 1 week indicated that there were 21.05% patients in group B with Hb concentration ≥11g/dL however there were no patients reported in group A. However, the findings of study signified significant improvement in Hb levels of patients in group A as the study reported that at baseline the Hb concentration of all patients was ≤9g/dL however, after 1 week there were only 27.3% with Hb concentration less than ≤9g/dL.

The study concluded that iron sucrose and blood transfusion (group A) is a better indicator for raising the Hb levels of pregnant women. However, the study recommends that intravenous iron sucrose along with blood transfusion should be included as second choice for severely anomic pregnant women who are unable/unwilling to undergo blood transfusion.

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