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Original Research Article

A Cross-Sectional Observational Study Assessing Efficacy of Intravenous Iron Sucrose for the Treatment of Iron Deficiency Anemia in Pregnancy

Naaz Ahmed[1], Vinita Sahay[2]

[1]Assistant Professor, Department of Obstetrics and Gynaecology, Netaji Subhas Medical College, Bihta, Patna, India

[2]Professor and HOD, Department of Obstetrics and Gynaecology, Netaji Subhas Medical College, Bihta, Patna, India

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Corresponding Author: Dr. Naaz Ahmed
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Abstract

Aim: The aim of the present study was to evaluate the efficacy of intravenous iron sucrose for the treatment of iron deficiency anemia in pregnancy.

Methods: The present study carried out in the Department of Obstetrics and Gynaecology Netaji Subhas Medical College, Bihta, Patna, India. The duration of the study was about 9 months. 50 pregnant women were enrolled for this study.

Results: The study results showed that the mean age of the pregnant women was 23.57±4.08 years, their mean weight was 59.61±12.28 kg, their mean gestational week was 28.72±4.08, 8 (16%) of them had gestational diabetes, 5 (10%) of them had hypertension, 4 (8%) of them had hyperthyroidism, 6% had asthma and 6% genitourinary infection whereas 4 (4%) of them had chronic kidney disease. The study results further showed that both the hemoglobin ($p<0.001$) and ferritin levels ($p<0.001$) of females were significantly increased at term after receiving intravenous iron sucrose as compared to the baseline. Furthermore, significant difference was observed in PCV ($p<0.001$) and MCV as well ($p<0.001$).

Conclusion: This study concluded that the administration of iron sucrose intravenously (Axifer) is a secure and effective choice in the management of iron deficiency anemia in pregnant women particularly for those who had inadequate response to oral iron supplementation. Intravenous iron sucrose is well accepted along with controllable safety profile clinically and enhanced Hemoglobin and ferritin level both and thus decrease complications during pregnancy due to iron deficiency anemia.

Keywords: Iron deficiency anemia, intravenous iron sucrose, Efficacy, Safety

Introduction

The World Health Organization [1] refers to this condition as anemia when hemoglobin is less than 11 grams/dl and hematocrit is less than 33. It is also known as the most common medical disorder in pregnancy. Anaemia is indirectly responsible for 40 percent to 50 percent of maternal deaths, especially in developing countries. [2] In well-developed countries, about 18 percent of females are affected by anemia. Moreover, in developing countries, about 35% to 75% of females are affected by anaemia. [3] All around the world, the most common cause of anaemia in pregnancy is the deficiency of iron. [4] It is reported by the World Health Organisation that women of fertile age are mostly affected by iron deficiency anaemia, representing a 50% proportion. [5] Multiple factors are involved in anemia in pregnant women in the developing countries that vary by topographical areas.[6] Globally, deficiency of iron is the major cause of anemia throughout pregnancy, while the secondary cause is the constant insufficient intake and menstruation, increased requirement of the fetus and increase volume of maternal blood in pregnancy, physiologically. [6,7]

Anemia during pregnancy is associated with complications such as post-partum hemorrhage, low birth weight, premature births, stillbirths, and maternal deaths. [8] The World Health Organization (WHO) estimates that nearly 40% of pregnant women and one-third of all women of reproductive age worldwide are anemic. [9] In India, the National Family Health Survey, 2019-2021 (NFHS-5) reported that 52.2% of pregnant women in India were anemic, the prevalence being higher in rural areas (54.3%) than in urban areas (45.7%). Iron deficiency is the most common cause of anemia and is estimated to contribute to approximately 50% of all cases of anemia among non-pregnant and

pregnant women worldwide. [10] Oral iron supplementation (iron-folic acid tablets) is the therapy of choice for prophylaxis and treatment of mild and moderate iron deficiency anemia in pregnancy. [11] However, oral iron therapy requires a prolonged duration of treatment, which is often beset with poor compliance. [12] Therefore, parenteral iron therapy is an alternative treatment modality for pregnant women with moderate anemia. [13]

The determinants of birth weight and intrauterine growth are maternal weight and parental height. In 80% of the patients, the target is to achieve a haemoglobin of 11 g/dl, which can be achieved by giving intravenous iron sucrose. [14] For iron-defined patients, erythropoiesis is used to incorporate intravenous iron into haemoglobin within three to four weeks. [15] Intravenous iron is effective as it has no serious adverse effects and restores iron more effectively and faster. [16] It is a very safe, effective, and convenient therapy to treat iron deficiency anaemia in pregnancy. [17]

The aim of the present study was to evaluate the efficacy of intravenous iron sucrose for the treatment of iron deficiency anemia in pregnancy.

Materials and Methods

The present study carried out in the Department of Obstetrics and Gynaecology Netaji Subhas Medical College, Bihta, Patna, India . The duration of the study was about 9 months. 50 pregnant women were enrolled for this study.

Pregnant women with Hb level equivalent to or <10 g/dl, Serum ferritin level equivalent to or <15 ng/l, with the age ranging from 18-40 years, gestational age of 16 weeks till at term were included in the study while identified allergic reaction to any active component, anemia not caused by lack of iron (such as hemolytic anemia), chronic or acute bacterial infection, pregnant women with gestational age <16 weeks, excess of iron or interruption in consumption of iron (such as haemosiderosis, haemochromatosis), liver cirrhosis and hepatitis, treated with iron products intravenously or transfusion of blood in 4 weeks were excluded from the study.

Demographic data and co-morbidities were recorded at the time of registration. A two times-weekly dose of 200 mg of iron sucrose (Axifer) intravenously were infused to pregnant women, until the aim of Hb level of patient accomplished. The total collective dose of iron sucrose, equal to the total iron deficit (mg) can find out by the hemoglobin level (Hb) and body weight (BW). The dose of iron sucrose was individually calculated for each patient according to the total iron deficit with this formula.

Data Analysis

SPSS version 22 was applied to analyze the data. Frequency and percentages were calculated for categorical variables such as gender, co-morbidities and adverse effects etc. Mean±Standard deviation was calculated for numerical variables such as age, Hb and Ferritin level. Wilcoxon rank- test was used to compare mean Hb and ferritin level at, baseline and at term. P<0.05 were taken as statistically significant level.

Results

Table 1: Baseline profile of pregnant females

Variables	N (%)/Mean±SD
Age (years)	23.57±4.08
Maternal weight (kg)	59.61±12.28
Gestational week	28.72±4.08
Gestational diabetes	8 (16)
Hypertension	5 (10)
Hyperthyroidism	4 (8)
Asthma	3 (6)
Chronic kidney disease	2 (4)
Genitourinary infection	3 (6)

The study results showed that the mean age of the pregnant women was 23.57±4.08 years, their mean weight was 59.61±12.28 kg, their mean gestational week was 28.72±4.08, 8 (16%) of them had gestational diabetes, 5 (10%) of them had hypertension, 4 (8%) of them had hyperthyroidism, 6% had asthma and 6% genitourinary infection whereas 4 (4%) of them had chronic kidney disease.

Table 2: Comparison of baseline and term of hematological values

Variables	Day-zero	at Term	P
	Mean±SD	Mean±SD	value
Hb (mg/dl)	8.06±0.74	13.87±12.08	<0.001
Ferritin (ng/ml)	9.90±12.58	52.78±56.44	<0.001
Mean corpuscular volume (fl)	76.44±13.27	77.43±13.07	<0.001
Pack cell volume (%)	28.92±5.15	38.22±40.06	<0.001

The study results further showed that both the hemoglobin ($p<0.001$) and ferritin levels ($p<0.001$) of females were significantly increased at term after receiving intravenous iron sucrose as compared to the baseline. Furthermore, significant difference was observed in PCV ($p<0.001$) and MCV as well ($p<0.001$).

Discussion

Globally, one of the most frequent nutritional deficiency is anemia. Even though, both the genders and all the ages are affected by nutritional anemia, the dilemma is more wide spread in women that lead to maternal morbidity and death, in addition to low weight of their babies at birth. [18] In developing countries, it has been predicted that about two-third of pregnant women are affected by the nutritional anemia. Though, in developing countries mostly women were anemic at the time of conception by a projected occurrence of anemia approximately 50% amongst non-pregnant women. Multiple factors are involved in anemia in pregnant women in the developing countries that vary by topographical areas. [19] Globally, deficiency of iron is the major cause of anemia throughout pregnancy, while the secondary cause is the constant insufficient intake and menstruation, increased requirement of the fetus and increase volume of maternal blood in pregnancy, physiologically. [19,20]

Generally, this iron is activated from iron stores. Moreover, women with already deprived stores of iron, develop deficiency of iron during pregnancy. One of the study has revealed that Hb levels less than 8 g% (moderate to severe anemia) in pregnancy are related to higher maternal morbidity whereas Hb <5 g% is linked with cardiac de- compensation and edema of lungs. Loss of even 200 ml of blood in third phase of labor leads to abrupt shock and fatality in these women. [21] The study results showed that the mean age of the pregnant women was 23.57±4.08 years, their mean weight was 59.61±12.28 kg, their mean gestational week was 28.72±4.08, 8 (16%) of them had gestational diabetes, 5 (10%) of them had hypertension, 4 (8%) of them had hyperthyroidism, 6% had asthma and 6% genitourinary infection whereas 4 (4%) of them had chronic kidney disease. Multiple studies have proposed that IV iron sucrose is harmless and effective substitute to oral iron in the management of Iron deficiency anemia. [22-24]

The study results further showed that both the hemoglobin ($p<0.001$) and ferritin levels ($p<0.001$) of females were significantly increased at term after receiving intravenous iron sucrose as compared to the baseline. Furthermore, significant difference was observed in PCV ($p<0.001$) and MCV as well ($p<0.001$). A randomized control assessment reported by Neeru et al [25], utilized iron sucrose intravenously in contrast with oral iron for management of iron deficiency anemia and observed that efficacy of iron sucrose was more in raising hemoglobin level significantly (23.62% vs 14.11% in oral iron) ($p<0.05$). In another randomized study by Dubey et al [26] after administration of iron sucrose intravenously or oral iron in 200 pregnant women, it was observed that iron sucrose augmented hemoglobin level and iron stores more rapidly as compared to oral iron significantly ($p<0.001$). The high acceptance of the drug has been partially accredited to sluggish discharge of iron from the iron sucrose complex and also because of low tendency to cause allergic reaction of sucrose. [27] The finding of the above study was contradictory to present study, where no major side effect was reported.

Conclusion

This study concluded that the administration of iron sucrose intravenously (Axifer) is a secure and effective choice in the management of iron deficiency anemia in pregnant women particularly for those who had inadequate response to oral iron supplementation. Intravenous iron sucrose is well accepted along with controllable safety profile clinically and enhanced Hemoglobin and ferritin level both and thus decrease complications during pregnancy due to iron deficiency anemia.

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