Original Research Article

# Efficacy and safety of intravenous iron sucrose therapy in a pregnant women with iron deficiency anaemia in pregnancy

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Abstract

**Background:** There have been many attempts to find a satisfactory iron preparation, suitable for parenteral administration. Blood transfusion has risk of transferring injections so intravenous iron preparations hold keys in anemia. **Objectives:** To see efficacy and safety of intravenous iron sucrose therapy in a pregnant women with iron deficiency anaemia in pregnancy. **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 one year. They were investigated for iron deficiency and treated for the same using intravenous iron sucrose as per dose calculated. They were followed for one month. Resulting data was analyzed using SPSS 20. **Results:** The change in haemoglobin improvement in all the three groups was found to be significant. Also there were no any major side effects seen with iron sucrose in this study. Most common side effects found were headache 8.21%. **Conclusions:** This study shows satisfactory clinical safety and efficacy of intravenous iron sucrose injection used in pregnant patients with iron deficiency anaemia during 2<sup>nd</sup> and 3<sup>rd</sup> trimester.

Keywords: Iron sucrose, Anemia, Haemoglobin

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Received Date: 09/02/2019 Revised Date: 21/03/2019 Accepted Date: 04/05/2019 DOI: https://doi.org/10.26611/101210213

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	Accessed Date: 16 May 2019	

## **INTRODUCTION**

Anaemia of pregnancy is generally defined as haemoglobin <11.0 g/dL or <11.5 g/dl, in some clinical practice guidelines with a slight variation according to the trimester of pregnancy  $^{1,2}$  The complications of anaemia in women are many as it adversely affects both their productive and reproductive capabilities. Among pregnant women due to extreme iron demands of growing fetus, which is approximately 4 to 6 times demands in non pregnancy state, the prevalence is higher. Anaemia in pregnancy can impair oxygen delivery to fetus and interfere with normal intrauterine growth resulting in

intrauterine growth retardation, stillbirth, low birth weight babies and neonatal deaths along with obstetric complications like uterine inertia, post-partum hemorrhagic, cardiac failure and shock.<sup>3</sup>

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Intolerance of oral iron in form of indigestion and diarrhoea is a known side effect. Also poor absorption of oral iron acts as a huge hurdle (along with A its prohibitive long duration of treatment). Oral iron is a less than ideal treatment, however, with gastrointestinal toxicity occurring in > 35% to 59% of patients, and a long course needed to resolve anaemia and replenish stores<sup>(5,6)</sup>. Time factor is important for correction of anaemia particularly when patient presents with anaemia during end of 2nd or

How to cite this article: Bhagwan Mahadev Patil, Vishwanath Iraba Dange. Efficacy and safety of intravenous iron sucrose therapy in a pregnant women with iron deficiency anaemia in pregnancy. *MedPulse International Journal of Gynaecology*. May 2019; 10(2): 79-81. http://medpulse.in/Gynaecology/index.php 3rd trimester. Fastest way to correct anaemia is blood transfusion but not recommended in all cases unless we have too short time or patient is landing in severe complications of anaemia.<sup>5</sup>

We studied the efficacy and safety of Injection Iron Sucrose in pregnant women in this study.

# MATERIAL AND METHODS

This was a prospective experimental study administered at Bharati Vidyapeeth, Medical faculty and Hospital that may be a tertiary care center and in Sangli. 207 Patients were picked up from OBGY department of the hospital from March 2017 to August 2018. World Health Organization consummated the iron deficiency criterias. All pregnant patients with iron deficiency anaemia were selected. Consent was taken from all ladies before the beginning of the study. preformed form was used for recording history. This study was approved by institutional ethics committee. All the mandatory investigation concerning iron deficiency were administered, at side the of the stool blood additionally examined. Automated analyser was used to perform the medical specialty investigations together with hemoglobin, RBCs count and blood indices. Peripheral blood smear done by slides and stain technique. Serum iron, total iron binding capability and body

fluid protein were done by useful automatic instrument. Cases were selected as per determined inclusion and exclusion criterias. Total Dose = (2.21 \*weight of patient)target Hb (10.5g%)-actual I-Ib)+ 500mg. 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 100m1 or 200m1 of normal saline respectively, over a period of 15 to 20 minutes, thrice a week till the total calculated dose is administered. 1st dose was given in ward wherever equipment's for resuscitation was obtainable. The subsequent doses got on patient basis. Patients were ascertained for the facet effects or hypersensitivity reaction reactions. Any minor or major facet effects were documented. All the patients were additionally given vitamin В complex pill 5 mg once on daily basis. Anthelmintic a а 100 mg doubly daily for 3 days to all or any the patients. No patient is permissible to use any other iron preparation, oral or parental, throughout the study duration. All the cases were followed for a month. Paired 't' check for every parameters of study was administered and tested for significance. price of < zero.05 was taken р as vital. additionally the teams were divided into three teams on basis of severity of anaemia and rise in hemoglobin for every cluster was additionally studied and tested for significance.

#### **RESULTS**

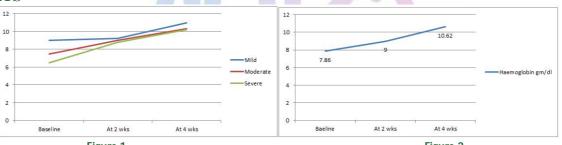




Figure 2

**Diagram 1:** Haemoglobin improvement improvment after iron sucrose treatment in anemia groups; **Diagram 2:** Average haemoglobin improvent after iron sucrose treatment

The haemoglobin improvement was found to be significant.

Table 1: Adverse effects of iron sucrose			
Type of Reaction	No. of patients	Percentage	
Headache/uneasiness	17	8.21%	
Giddiness	11	5.31%	
Diarrhoea	8	3.86%	
Arthralgias and Other pains	7	3.38%	
Flushing	7	3.38%	
Muscle cramps	4	1.93%	
Fever	3	1.45%	
Breathlessness and chest pain	2	0.97%	
Hypotension	2	0.97%	
Venous thrombosis	Nil	-	
Anaphylaxis	Nil	-	

Most common side effects found were headache 8.21%, uneasiness 8.21%, giddiness 5.31% and diarrhea 3.86%. No severe anaphylactic reactions were found in this study. All other women well tolerated the injections. There were no other major side effects

#### DISCUSSION

The consequences of iron deficiency anemia are serious and include reduced exercise tolerance, stomatitis, gastritis, structural and chemical changes to hair, nails and skin and impairment of thermogenesis, thyroid metabolism and catecholamines turnover. When such patients become pregnant the condition worsens and the effects of anaemia on pregnancy are well documented like low birth weight baby, increase preterm births and perinatal mortality. Iron deficiency in fetus can lead to sometimes irreversible damage to the central nervous system, with impairment of psychomotor development.<sup>6</sup> Increased iron requirement in pregnancy and the puerperium carries with it an increased susceptibility to iron deficiency and iron deficiency anaemia. The total requirement of iron during pregnancy is approximately 1000mg.

For treatment of anaemia, dose recommended is 200 mg elemental iron per day.<sup>7</sup> 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.

Breymann C *et al*<sup>8</sup> treated more than 500 antenatal women diagnosed with iron deficiency anaemia. 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.

There are also other modalities for the treatment of Iron deficiency Anaemia like oral iron and iron dextran both of them have some or other drawbacks. Oral iron has poor absorption, frequent gastrointestinal side effects, and poor compliance. Iron dextran can cause unpredictable anaphylactic reactions and require a test dose before the first administration. However, iron sucrose is safe and can be administered without a test dose. It is convenient and cost effective (as compared to blood transfusion) in pregnant iron-deficient women who are unable to obtain an adequate amount of iron rapidly by oral route. The only contraindication to the use of iron sucrose is hypersensitivity to iron sucrose, or any of its inactive components. Iron sucrose complex infusion overcomes the problem of compliance and absorption, and has excellent safety record. By treatment with iron sucrose, it is possible to eradicate the commonest medical disorder of pregnancy, thereby dramatically reducing maternal mortality and morbidity. Iron sucrose is safe as it is a dextran-free complex. The risk of allergic reactions is extremely low, it is also cost effective as it is an alternative to blood transfusion except for acute hemorrhagic emergencies, and it enables to shorten hospitalization time, as there is faster clinical recovery than with oral iron

therapy in iron deficiency anaemia. Recent evidence suggests that iron sucrose can be detected in high levels in the liver circulation and marrow within 5 min after intravenous administration.<sup>7,9</sup>

Therapy with iron sucrose gives a good opportunity to avoid the risk of hemotransfusional infections, incompatible hemotransfusions, and immunocompromising effect of hemotransfusion.

#### CONCLUSION

There was rapid and significant improvement in haemoglobin, with maximum increase in severely anaemic patients. Adverse event profile shows minimal side effects indicating it is very safe drug. Hence we conclude that intravenous iron sucrose therapy in pregnancy is the best method to treat iron deficiency anaemia.

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Source of Support: None Declared Conflict of Interest: None Declared