Efficacy and safety of intravenous iron sucrose versus oral iron in pregnant women with mild to moderate iron deficiency anaemia

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Abstract

Background: Efficient treatment of iron deficiency anaemia in pregnant women would lead to a considerable reduction in the risk factors, affecting maternal and fetal outcome.

Patients and Methods: This prospective study was carried out in 84 women between 20 to 34 weeks of pregnancy with established iron deficiency anaemia and haemoglobin 6-10g/dL. They were randomised to receive either oral or intravenous iron in required dose. Haemoglobin and ferritin levels were measured at recruitment and after 4 weeks of therapy. Adverse drug reactions were also noted in both the groups. Results were analysed by student's t-test.

Results: The mean increase in haemoglobin values with IV sucrose group was 1.26 ±0.58g % as compared to 0.78 ±0.37 gm% in oral iron group after 4 weeks of oral iron therapy ($p<0.03$). Similarly, The mean increase in ferritin values with IV sucrose group was 12.00 ± 11.77ng/ml as compared to 6.50 ± 9.53ng/ml in oral iron group ($p<0.02$).

Conclusion: This study indicates iron sucrose not only treats but also corrects iron stores which are not seen with oral iron.

Keywords: Iron deficiency anaemia, Iron sucrose, Oral iron therapy

Introduction

Iron deficiency with its resultant anaemia is the most widespread micronutrient deficiency in the world. During 10th Five Year Plan (2002-2007), a study conducted by ICMR[1] showed that the prevalence of anaemia was highest among pregnant women (50-90%) and that of moderate (<8 gm%) and severe anaemia (<5 gm%) was persistently high.

WHO defines anaemia as hemoglobin (Hb) <11 g %1. In India, the ICMR classification of iron deficiency anaemia is: 8-11 g% as mild, 5-8 g % as moderate and <5 g% as severe anaemia. In absence of interfering factors, serum ferritin <12-15 µg /l is considered as iron deficiency.[(1)]

The standard approach to treatment in the majority of institutions is oral iron supplementation, with blood transfusion reserved for more severe or symptomatic cases.

There is irrefutable evidence that compared to oral iron, intravenous iron sucrose results in a much more rapid resolution of IDA, has minimal side-effects, and because it is administered intravenously, it circumvents the problems of compliance.[(2,3)] Iron sucrose has been reported to be safe and effective during pregnancy. A recent Cochrane review[(4)] on treatments for iron deficiency in anemia highlighted the need for good quality randomized controlled trials in particular to assess clinical outcomes and adverse events.

This prospective randomized controlled trial is aimed to evaluate the effect of intravenous iron-sucrose complex versus oral iron therapy to improve the haemoglobin level and record adverse events among antenatal women with iron deficiency anaemia attending a tertiary care hospital in North India.

Material and Methods

The present prospective study was conducted in the Department of Obstetrics and Gynecology, Santosh Medical College and Hospital, Ghaziabad, during the period January 2015 to June 2016. 84 anaemic pregnant women between 20 to 36 weeks of gestation, having singleton live pregnancy and with diagnosis of iron deficiency anaemia with hemoglobin of 6-10 g/dl, who demonstrated willingness to comply to research protocol were included in the study.

Women with Hemoglobin <6 or > 10g/ dl, severe anemia requiring blood transfusion, anemia other than iron deficiency or having history of hematological disease, bronchial asthma, suspected acute infection, chronic blood loss, placenta previa, renal or hepatic dysfunction were excluded from the study.

The study was approved by the ethics institutional board of Santosh University and informed consent was obtained from the participants.

All eligible women were randomised to receive either oral ferrous sulphate containing elemental iron 100 mg thrice daily or required dose of intravenous iron sucrose 200 mg in 200 ml NS on alternate days.

Results were compared at baseline and on day 30 after treatment. The rate of improvement was measured in terms of hemoglobin, serum ferritin and general improvement of the patient.

Statistical Analysis: For statistical analysis of difference between groups, independent sample-t test, Chi square test or analysis of covariance was applied when appropriate. Statistical significance accepted was at $P < 0.05$.

Results

The mean age of women was 25.76± 4.50 (range 18-36) years. Mean period of gestation (POG) at the time of diagnosis was 30.4± 2.30(26-34) weeks. Table 1 shows the demographic profile in 84 cases.

Table 1: Demographic profile (n=84)

Parameters	Treatment Groups		
	IV Sucrose Group	Oral Iron Group	Total
n (Number of cases)	46	38	84
Age (mean±SD) in Years and Range	26 ± 4.69 (range 18-36)	25.47± 4.31 (range 18-34)	25.76± 4.50 (range 18-36)
BMI (mean±SD)	24.28±2.90	20.9±3.14	22.76±3.93
Nulliparan(%)	5(10.9)	18(47.4)	23 (27.4)
Multipara n(%)	41 (81.1)	20(52.6)	61 (72.6)
Class			
Upper n(%)	2 (4.3)	2 (5.3)	4(4.8)
Upper Middle n(%)	7 (15.2)	9 (23.7)	16 (19)
Upper Lower n(%)	16 (34.8)	8(21.0)	24 (28.6)
Lower Middle n(%)	11 (24.0)	9 (23.7)	20 (23.8)
Lower	10 (21.7)	10 (26.3)	20 (23.8)

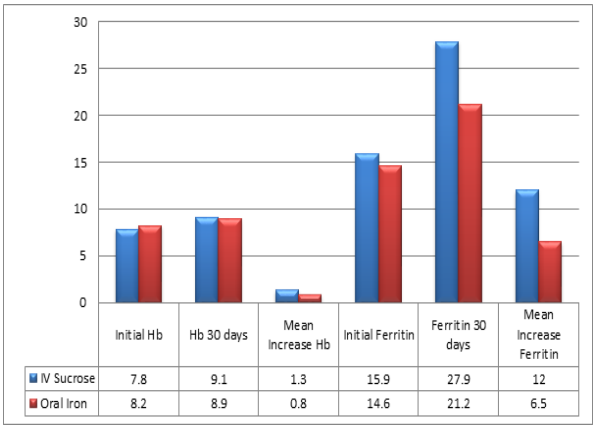
The mean increase in haemoglobin values with IV sucrose group was 1.26±0.58g % as compared to 0.78 ±0.37 g% in oral iron group at the end of 4 weeks of therapy (p<0.03).

The mean increase in ferritin values with IV sucrose group was 12.00±11.77ng/ml as compared to 6.50±9.53ng/ml in oral iron group at the end of 4 weeks of therapy (p<0.02). (Table 2 and Histogram1)

Table 2: Haemoglobin and ferritin concentrations before and after iron therapy by intravenous and oral routes

Parameter	Intravenous Iron (n=46)	Oral Iron (n=38)	P value
Haemoglobin			**<0.03**
Initial (gm%)	7.82 ± 0.99	8.17 ± 0.77	
Follow up (gm%)	9.08 ± 0.99	8.93 ± 0.75	
Mean Increase (gm%)	1.26±0.58	0.78 ± 0.37	
Ferritin			**< 0.02**
Initial (ng/ml)	15.93 ± 20.86	14.62 ± 16.96	
Follow up (ng/ml)	27.93 ± 22.94	21.12 ± 20.29	
Mean Increase (ng/ml)	12.00 ± 11.77	6.50 ± 9.53	

Histogram 1: Hb and Ferritin concentrations before and after IV Sucrose and Oral Iron

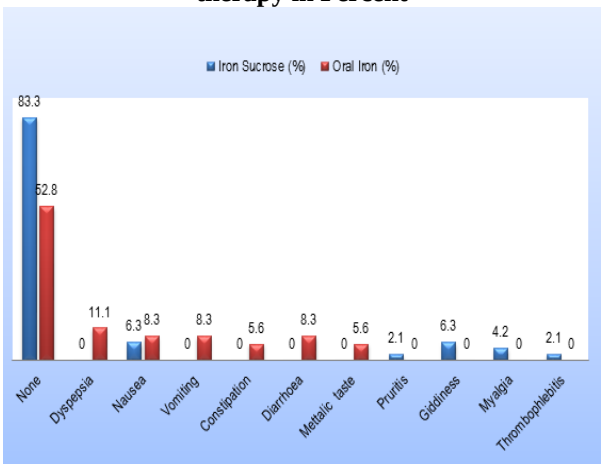


There were no side effects in 83.3% patients who received IV Sucrose, as compared to 52.8% patients who received oral iron (Table 3 Histogram 2).

Table 3: Side effects during iron therapy by intravenous and oral routes

Side effects	Iron sucrose (n=46) (%)	Oral iron (n=38)(%)
None	40 (83.3)	19 (52.8)
Dyspepsia	0	4 (11.1)
Nausea	1 (6.3)	3 (8.3)
Vomiting	0	3 (8.3)
Constipation	0	2 (5.6)
Diarrhoea	0	3 (8.3)
Metallic taste	0	2 (5.6)
Pruritis	1 (2.1)	0
Giddiness	3 (6.3)	0
Myalgia	2 (4.2)	0
Thrombophlebitis	1 (2.1)	0

Histogram 2: Side Effects Oral Iron vs IV sucrose therapy in Percent



In the present study, I.V. sucrose tolerance seems to be excellent without adverse effects, in accordance with literature.

Discussion

Once oral iron is started, it takes about 3 weeks for haemoglobin to start rising and about 6-8 weeks if stores are exhausted and need to be replenished. Replenishment of the iron stores begins only after the haemoglobin returns to normal. This is a very slow process and takes about 3-4 months with oral iron therapy.[5] However there is rapid replenishment of stores with intravenous iron sucrose therapy as shown in our study. This is comparable to other studies where hemoglobin was significantly increased and continued to rise even after the conclusion of treatment.[6,7] Iron stores were regenerated as well.[2,8] In all patients, anaemia symptoms and signs subsided very quickly upon initiation of therapy. The patients felt stronger and reported a better ability to perform their daily tasks.[3]

The only limitation of iron sucrose is that it is costlier than oral iron and requires a hospital setting for administration.

Conclusion

Iron sucrose is safe, effective and highly reliable form of treatment for iron deficiency anaemia. It is considered in patients with intolerance, unresponsiveness or non-compliance to oral iron or in patients near term with moderate-severe anaemia.

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