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Original Research Article

A comparative study on efficacy and safety of intravenous iron sucrose and oral iron among anaemic pregnant females

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ABSTRACT

Background: Iron deficiency anaemia (IDA) is the most common medical problem in pregnancy. Both parenteral and oral iron therapies are modalities used for management of anaemia in pregnant females. The present study aimed to compare the efficacy of oral and intravenous iron therapy in improving iron deficiency anaemia in pregnancy and restoring iron stores, compare the pregnancy outcome in the two groups and evaluate their safety.
Methods: This prospective randomized clinical trial conducted among pregnant women between 14 and 36 weeks with established IDA who were treated with IVIS (Intravenous Iron Sucrose) or OI (ferrous sulphate). All patients were monitored for laboratory response and adverse effects. Independent sample-t test, Chi square test and ANOVA were used for statistical analysis. P <0.05 was considered significant.
Results: From first follow up till the end of the study the mean hemoglobin level of IV Group was found to be significantly higher as compared to that of oral Group. The MCV (mean corpuscular volume) values increased to a significant level in the intravenous group as compare to oral. After therapy increase transferrin saturation in the intravenous group were significantly higher at all-time interval than the oral group. The mean neonatal hemoglobin at birth was significantly higher in IV group 16.88±1.96 gm/dl than oral group 16.88±1.96 (p= p<0.0001).
Conclusions: Intravenous iron sucrose is comparatively more efficient in improving haemoglobin than oral iron and has better pregnancy outcomes.

Keywords: Anaemia, Intravenous iron sucrose, Oral Ferrous Sulphate

INTRODUCTION

In India about 52%of the women of reproductive age group and 74% of children are anemic.[1] Iron Deficiency anemia (IDA) is the most common form of nutritional deficiency in the world and approximately 80% of all anaemia in pregnancy occur due to Iron deficiency.

IDA is the eighth leading cause of disease disability and death in girls and women in the developing world.[2] A rough estimate indicates that an additional 1000 mg of iron is required in pregnancy.[3] Prevalence of IDA is increased 2-fold or more for those women who are minorities, below the poverty line or with less than 12 years of education.[4] Risk is also increased with parity, nearly threefold higher for women with 2-3 children and 4-fold greater for women with 4 or more children.[5]

During pregnancy there is significant increase in the amount of iron required to allow for growth of fetal-placental unit and blood loss during pregnancy.[6] During pregnancy anemia increases four fold from 1st trimester to

the 3rd trimester in the low income group women monitored by the nutritional surveillance by the CDC.[7] IDA is associated with poor pregnancy outcome in the form of preterm birth, fetal wastage during pregnancy and increased perinatal mortality and morbidity.[8] In the mother due to increased incidence of infection, inability to tolerate hemorrhage during labor, cardiac failure and deterioration in the quality of life.[4] In these situations, laboratory testing takes on an even greater significance in the assessment of maternal iron deficiency anemia.[9] Anaemia leads to increased risk of blood transfusion during the peri-partum and postpartum period.[9]

Adequate supplementation of iron either orally or parentally is an important intervention for the management and prophylaxis of iron deficiency states in pregnant women.[10] However, long experience with oral iron has shown only limited success as a public health strategy. To combat the above problems for particular patient alternative strategies in the form of parental iron therapy has been studied in various parts of worlds and many studies have shown that parental iron is able to replenish iron store more efficiently, completely and faster than oral iron therapy.[11] Nowadays iron sucrose is being used most commonly in place of iron dextran for intravenous infusion purposes for the correction and prophylaxis of iron deficiency anemia.[10,12]

Various studies here concluded that in IDA effective treatment option is replacement of iron either orally or intravenous. It is now used as second options; if oral iron fails to increase hemoglobin within three weeks; and as first option in profound iron deficiency anemia (<9gm%) in any trimester beyond >14 weeks of gestation. Till date there is no good randomized control trial, comparing the efficacy and safety of intravenous versus oral iron therapy for the treatment of IDA in pregnant women in India. We therefore propose to compare the safety and efficacy of intravenous versus oral iron for the treatment of IDA in pregnant women.

METHODS

It was a double blind randomized control trial. The study was conducted in department of Obstetrics and Gynecology, Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, Uttar Pradesh.

Sample size

We proposed to study of a continuous response variable from independent control and experimental subjects with one control per experimental subject.

In a previous study the response within each subject group was normally distributed with standard deviation in the range of 2 mg/dl. If the true difference in the experimental and control means is around 1 mg/dl, we will need to study 80 experimental subjects and 80 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. The sample size calculated for the study is therefore at least 80 for each group.

Study participants

A total 220 pregnant females between 16-34 weeks of gestation were primarily enrolled in the present study, out of which 36 patients refused to give consent and 24 were excluded as per criteria. Therefore, the randomization was finally done for 160 patients using block randomization and finally 80 patients were put on oral iron therapy (Group A) as well as intravenous iron sucrose therapy (Group B)

Inclusion criteria

Includes those patients with serum ferritin less than 20ng/ml, serum iron less than 60µgm/dl, Total Iron Binding Capacity (TIBC) range 250-435 µg/dl, Transferrin saturation less than 20%, GBP – Microcytic hypochromic and MCV less than 78fl, MCH less than 28 pg/ml.

Exclusion criteria

Excludes those patients with multiple pregnancy, heart disorder with pregnancy, patient with history of antepartum hemorrhage, severe anemia (less than 5 gm /dl) with pregnancy, history of allergy to iron or iron containing medications or any other allergic condition, history of blood transfusion within the prior 120 days and any chronic systemic disorder (inflammatory bowel disease- ulcerative colitis, Crohn's disease, liver and renal disease, hyper-splenism, infection)

Study protocol

Participants of the study were informed about the nature of the study and then informed consent was taken. Detailed history including age, parity, social economics status, education level, obstetrical history, history regarding any chronic illness like diabetes, tuberculosis, hypertension, thyroid disease, renal and heart disease etc. other causes of anemia i.e. thalassemia etc. were excluded.

Baseline anthropometric data like weight, height, BMI were measured and all data were recorded in a predesigned proforma. Thereafter every subject underwent complete general examination, systemic examination, per-abdomen and per-vaginal examination (if indicated).

Baseline investigation of each subjects were done in the department of pathology of the hospital. Baseline iron profile of each subject was done on registration. 10 ml of venous blood was withdrawn from each subject and was

dispatched within half an hour to one hour to the department of pathology for estimation of complete blood counts, serum ferritin, serum iron, serum TIBC etc.

Intervention methods

Initially each subject was dewormified with tablet albendazole (400 mg)

Group A (Oral)

Received oral treatment of Iron Sulphate (Ferrous sulphate) 300 mg /day (Ferrsolate) one hour before meal. This treatment is also supplemented with 500 µg of folic acid per day.

Group B (Intravenous)

Received Intra Venous Iron Sucrose complex (ISC). ISC was administered as 200 mg of the elemental iron in 100 ml of 0.9% of normal saline over one hour every alternate day up to the total calculated dose after a test dose of 1 ml of ISC was given and followed by a 15 minutes window period. Formula used to calculate the iron requirement of the patient to fulfill the deficient as well as to replenish the Iron Stores were calculated as follows –[TDI (Total dose infusion) = Wt. (kg.)×(120g/L – Actual Haemoglobin g/L)×0.24+500mg]. Blood sample where taken before the start of the therapy and at 4 weeks interval to evaluate the level of Hb, MCV, serum ferritin, serum iron and TIBC values.

Follow-up

Oral group

Subjects were asked to bring the empty strips on every visit. Patients were asked on every visit about any side effect related to iron tablets intake, like heartburn, nausea, vomiting, gastric upset, diarrhea and constipation etc. and were recorded in the questionnaire along with complete antenatal checkup which was done routinely on regular intervals.

Intravenous group

Iron sucrose complex infusion was given. Side effect or allergy was asked after every cycle of infusion along with side effect related to iron therapy; were recorded in the questionnaire form. The cases were followed till delivery and the outcome was noted.

Statistical analysis

After accumulation of the data the statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0. The values were represented in number (%) and Mean±SD. Independent sample-t test and, Chi square test were used for statistical analysis. P <0.05 was considered significant.

RESULTS

A total of 160 subjects were enrolled in the study. Majority of subjects (n=106; 66.3%) were in age group 21-30 years followed by 31-40 years (n=42; 26.3%) and then <20 years (n=12; 7.5%).

An equal number of subjects were Para 0 and Para 1 (37.5%) followed by Para 2 (18.8%) and Para 3 (6.3%). Out of total number of patients registered, 77 (48.1%) subjects were from rural and 83 (51.9%) subjects were from urban area.

In Group A, majority of subjects (55%) was from rural area while in Group B majority of subjects (58.8%) were from urban area. Almost half the subjects (48.8%) were graduate or above. Only 8.1% subjects were illiterate. Almost half the subjects (49.4%) had a monthly family income between Rs 5001-10000.

Majority of subjects in both the groups were enrolled at gestational age 16-20 weeks. In oral group, 9 (11.25%) subjects were enrolled at gestational age 26-30 weeks while in I.V. group 10 (12.5%) subjects were enrolled at this gestational age. Only 12.5% subjects reported to be performing heavy physical activity while 21.9% were performing mild physical activity.

None of the subjects was having a sedentary lifestyle. Non-vegetarians comprised less than a quarter of subjects in both the groups. In group A maximum number of subjects had a BMI between 18-25 while in Group B maximum number of subjects had a BMI between 25-30 kg/m^2. Thus, demographically and anthropometrically, both the groups were matched.

At baseline, majority of subjects in both the groups had hemoglobin levels between 9.1-10 gm% followed by those with hemoglobin levels between 8.1-9 gm%. There were 6.25% subjects in Group I and 11.25% subjects in Group II with hemoglobin levels below 8 gm% at baseline. On comparing the data statistically, no significant difference was seen between two groups (Table 1).

At baseline, no statistically significant difference in mean MCV of two groups was seen (p=0.281).

However, from follow up at 24 weeks and thereafter till the term the mean MCV of Group II was significantly higher as compared to that of Group I (p<0.05). But at postpartum observation no significant difference between two groups was seen. At baseline the mean S.

Table 1: Comparison of baseline characteristics of the study population in two groups.

Variable	Oral (n=80)		I.V. (n=80)		Total	
	No.	%	No.	%	No.	%
Age-group						
≤20 Years	6	7.5	6	7.5	12	7.5
21-30 Years	54	67.5	52	67.5	106	66.3
31-40 Years	20	25	22	25.0	42	26.3
χ^2=0.133 (df=2); p=0.936						
Parity						
0	31	38.8	29	36.3	60	37.5
1	30	37.5	30	37.5	60	37.5
2	15	18.8	15	18.8	30	18.8
3	4	5.0	6	7.5	10	6.3
χ^2=0.467 (df=3); p=0.926						
Residence						
Rural	44	55.0	33	41.3	77	48.1
Urban	36	45.0	47	58.8	83	51.9
χ^2=3.029 (df=1); p=0.082						
Educational Status						
Illiterate	2	2.5	11	13.75	13	8.1
Just literate	8	10.0	9	11.25	17	10.6
High School/Intermediate	24	30.0	28	35.0	52	32.5
Graduate	33	41.25	25	31.25	58	36.3
Postgraduate and above	13	16.25	7	8.75	20	12.5
χ^2=9.501 (df=4); p=0.050						
Occupation						
Housewife	67	83.75	66	82.5	133	83.1
Working	13	16.25	14	17.5	27	16.9
χ^2=0.045 (df=1); p=0.833						
Monthly family income						
≤Rs 2000	1	1.25	2	2.5	3	1.9
2001-5000	28	35.0	29	36.25	57	35.6
5001-10000	41	51.25	38	47.5	79	49.4
10001-20000	10	12.5	11	13.75	21	13.1
χ^2=0.512 (df=3); p=0.916						
Gestational age (weeks)						
16-20 weeks	49	61.25	41	51.25	90	56.3
21-25 weeks	22	27.5	29	36.25	51	31.9
26-30 weeks	9	11.25	10	12.5	19	11.9
χ^2=1.725 (df=2); p=0.422						
Physical activity						
Mild	23	28.75	12	15.0	35	21.9
Moderate	49	61.25	56	70.0	105	65.6
Heavy	8	10.0	12	15.0	20	12.5
χ^2=4.724 (df=2); p=0.094						
Dietary habits						
Non-Vegetarian	18	22.5	17	21.3	35	21.9
Vegetarian	62	77.5	63	78.8	125	78.1
χ^2=0.037 (df=1); p=0.848						
BMI category (kg/m^2)						
<18	1	1.25	2	2.5	3	1.9
18-25	33	41.25	28	35	61	38.1
25-30	30	37.50	38	47.5	68	42.5
>30	16	20	12	15.0	28	17.5
χ^2=2.256 (df=3); p=0.521						
Complications						
No H/o previous complications	65	81.25	64	80.0	129	80.6
Low birth weight	9	11.25	12	15	21	13.12
Previous LSCS	6	7.5	4	5.0	10	6.3
H/o previous abortions	16	20	19	23.75	35	21.87
χ^2=1.048 (df=3); p=0.790						
Hemoglobin level category						
≤8	5	6.25	9	11.25	14	8.8
8.1-9	22	27.5	18	22.5	40	25.0
9.1-10	53	66.25	53	66.25	106	66.3
χ^2=1.543 (df=2); p=0.462						

Table 2: Comparison of MCV, serum ferritin and transferrin saturation values at baseline and follow up in two groups.

Weeks of gestation	Oral (n=80)		I.V. (n=80)		Statistical Significance	
	Mean	SD	Mean	SD	t	p
MCV values						
Baseline	70.91	3.46	70.33	3.38	1.083	0.281
24 wk	72.14	3.14	73.19	3.02	2.141	0.034
28 wk	73.55	2.90	76.79	2.87	7.088	0.001*
32 wk	76.55	2.63	79.40	2.43	7.132	0.001*
At term (36 wk)	79.54	1.47	81.67	2.24	7.123	0.001*
PP	78.89	0.81	80.29	9.21	1.358	0.176
S. Ferritin						
Baseline	17.66	5.81	15.82	5.39	2.070	0.040
First FU	59.68*	18.02	111.18*	57.00	7.702	<0.001*
Second FU	55.29*	16.56	66.69*	16.43	4.028	<0.001*
At term	45.37*	13.93	54.89*	16.42	3.956	<0.001*
Transferrin saturation						
Baseline	9.79	1.59	9.85	1.45	0.227	0.821
Follow-up	10.33*	1.85	19.37	3.26*	21.568	<0.001*
At term	18.60*	3.77	26.89	4.58*	12.516	<0.001*

*p value significant

Ferritin levels in Group II were significantly lower as compared to Group I (p=0.040) but from first follow up onwards the mean S. ferritin levels of Group II subjects were significantly higher as compared to that of Group I subjects (p<0.001). At all the time intervals the difference from baseline in both the groups was significant statistically (p<0.001) (Table 2).

There was significant rise in haemoglobin levels in both the groups, but rise in IV treated group, was significantly higher than the orally treated group (p<0.001). It means that haemoglobin values at all times points after 4 weeks of therapy were higher in the intravenous treated group (Table 3).

Table 3: Comparison of rise in haemoglobin value in both groups from baseline till term.

Haemoglobin level (gm%)	Oral (n=80)					I.V. (n=80)				
	Before	At term				Before	At term			
		7-8.9	9-9.9	10-11.9	>12		7-8.9	9-9.9	10-11.9	>12
7-8.9	20	1	6	13	0	19	0	3	16	0
9-9.9	50	0	0	50	0	52	0	0	41	11
10 and above	10	0	0	10	0	9	0	0	3	6
Statistical significance of change in each group	Z=7.751; p<0.001*					Z=7.938; p<0.001*				
Group I vs Group II, Before treatment = Z=0.020; p=0.984 (NS), After treatment = Z=4.097; p<0.001*										

*p value significant

Table 4: Iron nutrition indicators at baseline and at term of gestation.

Time interval	Oral				I.V.			
	S. Ferritin		TS%		S. Ferritin		TS%	
Baseline	17.66	5.81	9.79	1.59	15.82	5.39	9.85	1.45
Term	45.37	13.93	18.60	3.77	54.89	16.42	26.89	4.58
Difference	27.71	13.07	8.80	2.62	39.07	12.26	17.05	3.47
Significance of difference (baseline versus term)	t=18.968; p<0.001		t=30.089; p<0.001		t=28.50; p<0.001		t=43.891; p<0.001	

*p value significant

At baseline the transferrin saturation was matched between two groups but at both the intervals thereafter the mean TS% in Group B was significantly higher as compared to that of Group A. In both the groups a significant increment in both the indicators i.e. serum ferritin and TS% was seen (p<0.001) (Table 4).

Table 5: Comparison of side effects profile in both the groups.

Side effects	Oral (n=80)		I.V. (n=80)		Statistical significance	
	No.	%	No.	%	χ^2	p
Nausea/vomiting	21	26.25	3	3.75	15.882	<0.001*
Diarrhoea	12	15.0	3	3.75	5.959	0.015*
Anaphylaxis	0	0	2	2.5	2.025	0.155
Hypotension	0	0	4	5.00	4.103	0.043
Headache	7	8.75	7	8.75	0	1
Metallic taste	7	8.75	14	17.75	2.791	0.095
Arthralgia	3	3.75	12	15.0	5.959	0.015*
Itching	2	2.5	17	21.3	13.438	<0.001*
Rashes	2	2.5	8	10.0	3.840	0.050
Fever	2	2.5	8	10.0	3.840	0.050
Thrombophlebitis	2	2.5	26	32.5	24.935	<0.001*
Dyspepsia	15	18.75	3	3.75	9.014	0.003*
Abdominal cramps	9	11.25	2	2.5	4.783	0.029*
Constipation	21	26.25	2	2.5	18.331	<0.001*

*p value significant

Table 6: Comparison of neonatal outcome in both the groups.

Variable	Oral (n=80)		I.V. (n=80)		Statistical significance	
	No.	%	No.	%	χ^2	P
Baby weight						
<2.5 kg	20	25.00	9	11.3		
2.5-3.0 kg	43	53.75	55	68.8	5.672	0.059
>3 kg	17	21.25	16	20.0		
Preterm	12	66.7	5	6.25	3.225	0.073
IUGR	8	10.0	4	5.0	1.441	0.230
Mean neonatal Haemoglobin at birth	16.88±1.96		18.09±0.96		p<0.0001*	

Incidence of nausea/vomiting, diarrhoea, dyspepsia, abdominal cramps and constipation was significantly higher in oral Group while incidence of hypotension, arthralgia, itching, rashes, fever and thrombophlebitis was significantly higher in IV group (Table 5).

No statistically significant difference between two groups was seen for any of the neonatal outcomes except mean neonatal haemoglobin at birth which was found to be significantly higher in IV group as compared to oral group (p<0.001) (Table 6).

DISCUSSION

Present study is a prospective randomized controlled trial, in which we aimed to compare the efficacy and side effects of iron therapy. In present study both the groups were comparable in terms of parity, socio-demographic as well as anthropometric data. The rise in hemoglobin level was significantly faster in IV Group as compare to oral group (<0.001) throughout pregnancy.

In agreement to present study, studies done by Al-Momen et al, Ragip A et al, Singh K et al, Giannoulis C et al, Bandal et al and Dede A et al had also reported faster and better hemoglobin response of IV Iron, although study done by Bencaiova G et al, did not find better response in IV group in comparison to oral group.[13-20]

Faster and better hemoglobin response of IV iron might be due to high amount of iron or better availability of iron for hemopoietic cells. From first follow up onwards the mean serum ferritin levels of IV group was significantly higher as compared to oral group (p<0.001).

At all the time intervals, the difference from baseline in both the groups was significant statistically (p<0.001).

This was similar with studies done by Al- Momen et al, Bayoumeu et al, Ragip et al, Bencaiova G et al and Singh K et al and Bhandal et al had also reported similar results.[13-15,17,19,20] In follow up and at term the mean transferring saturation of IV group was significantly higher as compared to oral group ($p<0.001$). At all the time intervals, the difference from baseline in both the groups was statistically significant ($p<0.001$).

Study by Singh K et al had also reported similar results.[15] Follow up at 24 weeks and thereafter till the term the mean MCV of IV group was significantly higher as compared to that of oral group ($p<0.05$). This was comparable with the study of Momen A et al had also reported similar finding in their study.[13]

The side effects were comparable to the studies by other author as shown in the previous studies done by Al Momen et al, Bayaumen F et al, Ragip A et al, Bencaiova G et al and they had also reported very high incidence of constipation, nausea, vomiting, dyspepsia and other GI symptoms and non-compliance due to GI upset in the oral group as compared to the intravenous group.[13,14,19,20]

In the study by Oskiet al in new born with iron deficiency anemia is associated with poor performance in the Baylee Mental development Index.[21] In another study done by Idjradinata P et al children born to mother with iron deficiency anemia shows poor mental and motor performance but it improve with Iron therapy in iron deficit infants at 12-18 months of age.[22] Similar findings are also enlightened from the present study.

CONCLUSION

The improvement in serum ferritin and haemoglobin levels was satisfactory in both intervention groups. Intravenous iron sucrose was quite efficient and faster acting than oral for treatment of moderate iron supplement to severe anaemia. But, to keep the risk of adverse effects within limits, parenteral iron injections must be administered in healthcare settings.

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