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Original Research Article

Safety and effectiveness of intravenous iron sucrose versus standard oral iron therapy in pregnant women with moderate anaemia in India

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ABSTRACT

Background: Aim of the study was to diagnose and treat pregnant females with iron deficiency anaemia, to reduce the complications associated with anaemia in pregnancy and to compare the efficacy, safety and side effects of iron sucrose with ferrous sulphate in the treatment of iron deficiency anaemia in pregnancy.
Methods: The subjects for study were enrolled on fulfilling the inclusion and exclusion criteria. After detailed history, examination and investigations of patient the dose of intravenous iron sucrose was calculated by using the following formula: dose of iron: 2.4 x Hb deficit (11-patient's actual Hb) x body weight in kg + 500. The following investigations were done on day 1: (a) complete blood count (CBC)- Hb, MCV, MCH, MCHC and PCV; (b) urine examination. Patients was randomly allocated into two groups. Group-A: oral group- containing 150 pregnant females. Group-B: intravenous group- containing 150 pregnant females.
Results: Majority of women (48%) were from lower middle class and lower class (30%). Only 5.3% were from higher socioeconomic class (p value 0.0001). Maximum women (60%) were primigravida and 40% were multigravida. which indicates that most ladies enter pregnancy with poor iron reserves. Improvement in the mean haemoglobin levels after 4 weeks of treatment was statistically significant in both the groups (p value 0.0001). Similarly rise in the mean PCV levels after 4 weeks of the treatment was significantly associated in both the groups (p value 0.0001). There was slight rise in the mean MCV and MCH after 4 weeks. Peripheral blood film had changed from microcytic hypochromic to normocytic normochromic after 4 weeks of the treatment in both the group (p value 0.004). Presence of side effects with the oral and parenteral treatment were 81.3% and 12% respectively (p value 0.0001).
Conclusions: From our study, it can be concluded that intravenous iron sucrose has lesser side effects along with better absorption.

Keywords: Hemoglobin, Iron deficiency anaemia, Microcytic-hypochromic, Peripheral blood film

INTRODUCTION

Iron deficiency anaemia (IDA) is one of the commonest medical disorders encountered in pregnancy. There is not only a physiological drop of haemoglobin due to haemodilution, but also most women enter pregnancy with depleted iron stores.[1] It affects nearly half of all pregnant women in the world, contributes to major maternal and fetal morbidity and mortality.[2] According to the WHO report, about 32.4 million pregnant women suffer from anaemia world wide of which 0.8 million women are severely anaemic. Moreover 50% cases of anaemia are attributed to iron deficiency anaemia.[3] WHO estimated prevalence of anaemia in pregnant women to be 14% and 51% respectively for developed and developing countries and for India about 65-75%.[4] In India, this prevalence has been reported to be in range of 33.0-89.0% and 16% of maternal mortality attributed to anaemia.[5] According to the nutrition Impact model study's 2011, the worldwide prevalence of anaemia in pregnant women was found to be 38%, which translates to 32 million pregnant women.[6] In India, there is marginal decrease in prevalence of anaemia

in pregnant women from 58% in NFHS-3 (National Family Health Scheme 2005-2006) to 50% in NFHS-4 survey (2015-2016).[7]

World health organization defines anaemia as HB less than 11 gm/dl or haematocrit of less than 0.33 at any time during pregnancy.[8] According to WHO, severity of anaemia is graded as: mild (10-10.9 gm%), moderate (7-9.9 gm%), severe (less than 7 gm%).[9] The Indian council of medical research (ICMR) expert group had added one more category in the above classification as very severe, which is haemoglobin less than 4 gm%.[10]

Aims

To diagnose and treat pregnant females with Iron deficiency anaemia. To reduce the complications associated with anaemia in pregnancy.

Objectives

To compare the efficacy, safety and side effects of iron sucrose with ferrous sulphate in treatment of iron deficiency anaemia in pregnancy.

METHODS

Study design

It was a hospital based interventional comparative study.

Study period

Study was carried out over a period of 18 months from November 2020 to April 2022.

Study place

The present study was conducted at department of obstetrics and gynecology at Mata Kaushalya Government Hospital, Patiala, Punjab.

Study population

300 antenatal females with any parity with haemoglobin level between 7-10 gm/dl, coming to obstetrics and gynecology department in Government Mata Kaushalya Government hospital, Patiala, Punjab were taken up for the study.

Sampling technique

Simple random sampling technique was employed.

Data analysis

Data collection was entered into MS-Excel 2013 Spread sheet. The collected data was analysed using IBM statical package for social sciences (IBM SPSS) version 22 software (trial version).

Inclusion criteria

Haemoglobin between 7-10 gm/dl. Singleton and uncomplicated pregnancy with period of gestation 24-34 weeks. Anaemic pregnant women of any parity.

Exclusion criteria

Haemoglobin level <7 gm/dl and >10 gm\dl. Allergic to iron therapy. Patients with obstetrical complications (pre-eclampsia, antepartum-haemorrhage and gestational diabetes. Known case of haemoglobinopathies. The subjects for study were enrolled on fulfilling the inclusion and exclusion criteria.

After detailed history, examination and investigations of patient the dose of intravenous iron sucrose was calculated by using the following formula.

Dose of iron: 2.4 x Hb deficit (11 − patient's actual Hb) x body weight in Kg + 500. The following investigations were done on day 1: (a) complete blood count (CBC)- Hb, MCV, MCH, MCHC and PCV; (b) urine examination.

Procedure of study

Patients was randomly allocated into two groups. Group-A: oral group- containing 150 pregnant females. Group-B: intravenous group- containing 150 pregnant females.

Group-A: oral group

Pregnant females received Ferrous sulphate 100 mg containing 60 mg of elemental iron and 0.5 mg of folic acid BD orally and instructed to take the tablet with empty stomach and not to take coffee or tea after taking the tablet.

Group-B: intravenous group

Intravenous iron sucrose was given to pregnant females (total calculated doses of iron sucrose in divided doses of 200 mg each in 100 ml of normal saline as slow intravenous infusion over 45 minutes).

The follow up was done by repetition of following investigations at 4th week: (a) complete blood count (CBC)- Hb, MCV, MCH, MCHC and PCV; (b) urine examination.

RESULTS

Out of 300 women, 16 women belonged to upper class and received oral therapy, 11 women belonged to upper middle class and received oral therapy, 39 women belonged to middle class in which 20 received parenteral and 19 received oral, 144 belonged to lower middle class in which 97 received parenteral and 47 received oral therapy, 90

women belonged to lower class in which 33 received parenteral and 57 received oral therapy (socioeconomic status were made on the basis of Prasad's scale). In our study socioeconomic status was significantly associated with route of iron.

Table 1: Distribution of socioeconomic status.

Socio-economic status	Group						Chi-square	P value
	Oral		Parental		Total			
Upper class	16	10.7%	0	0.0%	16	5.3%	50.787	0.0001**
Upper middle	11	7.3%	0	0.0%	11	3.7%		
Middle class	19	12.7%	20	13.3%	39	13.0%		
Lower middle	47	31.3%	97	64.7%	144	48.0%		
Lower class	57	38.0%	33	22.0%	90	30.0%		
Total	150	100.0%	150	100.0%	300	100.0%		

Table 2: Distribution between gravidity versus route of iron administration.

Obstetric score	Group						Chi-square	P value
	Oral		Parental		Total			
Primigravida	93	62.0%	87	58.0%	180	60.0%	0.500	0.480
Multigravida	57	38.0%	63	42.0%	120	40.0%		
Total	150	100%	150	100%	300	100%		

Table 3: Distribution of haemoglobin level pre and post treatment.

Group		N	Mean	SD	t-value	P value
Parenteral	HB-Pre	150	7.93	0.51	20.146	0.0001**
	HB-4 week	150	9.37	0.95		
Oral	HB-Pre	150	7.98	0.49	12.973	0.0001**
	HB-4 week	150	8.92	0.99		

Table 4: Distribution of PCV pre and post treatment.

Group		N	Mean	SD	t-value	P value
Parenteral	PCV-Pre	150	25.64	2.37	17.033	0.0001**
	PCV-4 week	150	29.95	2.76		
Oral	PCV-Pre	150	26.07	2.15	10.989	0.0001**
	PCV-4 week	150	28.71	2.79		

Out of 300 women 180 women were primigravida in which 87 received parenteral and 93 received oral therapy, 120 women were multigravida in which 63 received parenteral and 57 received oral therapy. In our study there was no significant association between gravidity and route of iron administration with p value of 0.48. Majority of women were primigravida means most women enter pregnancy with poor iron reserves. So proper dietary counselling and health education in the community is important to tackle the issue (Table 2).

Before starting the therapy mean pre. haemoglobin was 7.93 in the parenteral group, which was raised upto 9.37 after the 4wks of parenteral iron therapy. In the same way mean pre haemoglobin was 7.98 in the oral therapy group which was raised upto 8.92 after the oral iron administration (Table 3).

Improvement in the haemoglobin levels after 4 weeks of the therapy was statistically significant in both the groups (p value.0001).

Before starting the therapy, the mean PCV in parenteral group was 25.64 which improved upto 29.95 after administration of parenteral therapy in the same way mean PCV was 26.07 in the oral group, which improved upto 28.71 after administration of oral therapy. Improvement after the therapy was significantly associated with the treatment (Table 4).

Out of 300 women before administration of iron therapy most of women had microcytic hypochromic anaemia. After administration of parenteral iron therapy in one group of 150 patients 134 were turned into normocytic normochromic anaemia and 16 women still had microcytic hypochromic anemia. In oral iron therapy group out of 150

women, 65 were turned into normocytic normochromic and 85 women still had microcytic hypochromic anaemia. There was significant association between route of iron therapy and peripheral blood film (p value- 0.0001).

Table 5: Peripheral blood film pre and post treatment.

Peripheral blood film		Group						Chi-square	P value
		Oral		Parenteral		Total			
PBF-Pre	MC/HC	150	100.0%	150	100.0%	300	100.0%		
	Total	150	100.0%	150	100.0%	300	100.0%		
PBF-4 weeks	MC/HC	85	56.7%	16	10.7%	101	33.7%	71.06	0.0001
	NC/NC	65	43.3%	134	89.3%	199	66.3%		
	Total	150	100.0	150	100.0	300	100.0		

Table 6: Distribution of various side effects in both the groups.

Side effects	Group						z-proportion	P value
	Oral		Parenteral		Total			
No	28	18.7%	132	88.0%	160	53.3%		
Nausea	19	12.7%	0	0.0%	19	6.3%		
Headache	29	19.3%	1	0.7%	30	10.0%		
Diarrhoea	31	20.7%	7	4.7%	38	12.7%		
Constipation	20	13.3%	0	0.0%	20	6.7%		
Anaphylaxis	0	0.0%	0	0.0%	0	0.0%		
Gastritis	20	13.3%	0	0.0%	20	6.7%		
Fever	0	0.0%	4	2.7%	4	1.3%		
Joint pain	0	0.0%	6	4.0%	6	2.0%		
Altered taste	3	2%	0	0.0%	3	1%		
Thrombophlebitis	0	0.0%	0	0.0%	0	0.0%		
Total	150	100.0%	150	100.0%	300	100.0%		

In the oral group 19 (12.7%) women had nausea, in comparison with this no complaint of nausea was seen in the parenteral group. Headache was seen in 29 (19.3%) and 1 (0.7%) woman in the oral and parenteral group respectively. Diarrhoea was seen in 7(4.7%) and 31 (20.7%) in the parenteral and oral group respectively. In oral group 20 (13.3%) women had constipation in comparison to this in parenteral group no constipation was seen. Similarly, no complaints of gastritis, and fever were seen in the parenteral group but in oral group 20 (13.3%) women had gastritis, 4 (2.7%) women had fever. Contrary to this, 6 (4.0%) women had joint pain in the parenteral group and no such complaints in the oral group. Altered taste was seen in 3 (2.0%) women in the oral group, no such complaints in parenteral group. In both the groups no major side effects like anaphylaxis reaction and thrombophlebitis were seen (Table 6).

DISCUSSION

Socioeconomic status

In our study socioeconomic status has significant association with route of iron administration with significant p value 0.001. comparable to our study Rudra et al had the 72% women in the parenteral group who belonged to low socioeconomic group and 76% women in oral group who belonged to low socioeconomic status.[11]

Gravidity

Out 300 women 180 (60%) women were primigravida in which 87 received parenteral and 93 received oral therapy, 120 (40%) women were multigravida in which 63 received parenteral and 57 received oral therapy. In our study there is no significant association between gravidity and route of iron administration with p value 0.48. This is explained by high prevalence of iron deficiency anaemia in adult non pregnant women, when these anaemic women become pregnant their anaemia will be aggravated by increased need of iron during pregnancy. Thus, it is extremely important to screen for iron deficiency anaemia in all non-pregnant women belonging to reproductive age group. Similar study conducted by Tate et al, Pitale et al, Maiti et al, Neeru et al.[2,5,8,12]

Haemoglobin before and after the treatment

Mean haemoglobin in our study was 7.93±0.51 and 7.98±0.49 in the parenteral and oral group respectively before the therapy and it was improved upto 9.37±0.95 and 8.92±0.99 in parenteral and oral group after the therapy.

Similarly, study done by Maiti et al haemoglobin was 7.19±0.25 and 9.04±0.20 in the parenteral and oral group respectively, which was improved upto 11.34±0.25 and 11.44±0.20 after the therapy in the parenteral and oral group respectively.[5] Similar study also conducted by Tandon et al, Saloni et al Rudra et al and Apurva et al.[13-16]

PCV (packed cell volume) before and after the treatment

Mean PCV in our study was 25.64±2.37 and 26.07±2.15 in the parenteral and oral group respectively before the therapy which was improved upto 29.95±2.76 and 28.71±2.79 in parenteral and oral group respectively after the therapy. Comparable with our study Neeru et al had the same results where PCV was 28.21±2.41 and 29.38±2.46 in the parenteral and oral group respectively before the therapy which was improved upto 33.87±2.28 and 33.07±1.86 after the therapy.[12] Similar study also done by Archana et al, Saloni et al and Shivika et al.[13,17,18]

Peripheral blood film before and after the treatment

There was significant association between route of iron therapy and peripheral blood film. Comparable to our study Quaram et al had 70% women with microcytic hypochromic blood film, which has been converted to 30% normocytic normochromic blood film after the parenteral therapy.[19] Similar study also conducted by Archana et al.[20]

Side effects with the treatment

Among 300 women taken in our study, who had side effects are total 140 (46.7%) in which 18/140 (12%) belonged to parenteral treatment and 122/140 (81.3%) belonged to oral treatment. Out of 300 women 160 women had no side effects, in which 132/160 (88%) belonged to parenteral treatment and 28/160 (18.7%) belonged to oral treatment. P value was 0.0001 which was significant means side effects with the oral treatment were significantly associated with the study. Similarly, study done by Apurva et al had 16.66% side effects with the parenteral and 46.66% with the oral iron treatment. Agalya et al Archana et al, Saloni et al, Vidhya et al, Shivika et al, Maiti et al also conducted similar study.[4,5,20-22]

In the oral group 19 (12.7%) women had nausea, in comparison with this no complaint of nausea was seen in the parenteral group. Headache was seen in 29 (19.3%) and 1 (0.7%) woman in the oral and parenteral group respectively. Diarrhoea was seen in 7 (4.7%) and 31 (20.7%) in the parenteral and oral group respectively. In oral group 20 (13.3%) women had constipation in comparison to this in parenteral group no constipation was seen. Similarly, no complaints of gastritis, and fever were seen in the parenteral group but in oral group 20 (13.3%) women had gastritis, 4 (2.7%) women had fever. Contrary to this, 6 (4.0%) women had joint pain in the parenteral group and no such complaints in the oral group. Altered taste was seen in 3 (2.0%) women in the oral group, no such complaints in parenteral group. In both the groups no major side effects like anaphylaxis reaction and thrombophlebitis were seen.

Limited financial resources, time constraints, risk of attrition were the limitations of this study.

CONCLUSION

It may not be possible to set up the blood blanks in every remote corner of the country but it is certainly possible to make blood bank in woman's body by building up her haemoglobin. Majority of women (48%) were from lower middle class and lower class (30%). Only 5.3% were from higher socioeconomic class (p value 0.0001). Maximum women (60%) were primigravida and 40% were multigravida. which indicates that most ladies enter pregnancy with poor iron reserves.

Improvement in the mean haemoglobin levels after 4 weeks of treatment was statistically significant in both the groups (p value 0.0001). Similarly rise in the mean PCV levels after 4 weeks of the treatment was significantly associated in both the groups (p value 0.0001).

Peripheral blood film had changed from microcytic hypochromic to normocytic normochromic after 4 weeks of the treatment in both the groups (p value 0.0001). Side effects with the oral and parenteral treatment were 81.3% and 12% respectively (p value 0.0001). From our study, it can be concluded that intravenous iron has lesser side effects along with better absorption.

Hence intravenous iron is not only safer but also more efficacious alternative to oral iron in achieving optimum results in pregnant females with iron deficiency anaemia.

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