A COMPARATIVE STUDY OF INTRAVENOUS IRON SUCROSE WITH ORAL IRON FERROUS SULPHATE IN TREATMENT OF ANAEMIA IN ANTENATAL MOTHER

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ABSTRACT

BACKGROUND

Anaemia is the most common medical disorder in pregnancy. Iron Sucrose is a suitable alternative source of iron which is well tolerated with few mild side effects to combat this massive problem of anaemia.

The aim of the study was to compare the efficacy of intravenous iron sucrose with oral iron ferrous sulphate for treatment of anaemia in pregnancy.

MATERIALS AND METHODS

It is an open-label parallel group hospital based randomized controlled trial to evaluate the efficacy and safety of Parenteral iron with oral iron for treatment of anaemia in antenatal mother attending Agartala Govt. Medical College at antenatal clinic. 50 subjects in each group were included. Independent t test and chi square test was applied.

RESULTS

The present study showed statistically significant rise in haemoglobin (Hb%) in IV Iron sucrose compared to oral iron. The rise of Hb% is 3.19 gm% in IV Iron sucrose in comparison to 2.44 gm% in oral iron group within a span of 4 weeks. There was no major side effect in IV group as compared to mild to moderate side effects in about 36% subjects in oral iron group.

CONCLUSION

The study reveals that intravenous iron sucrose therapy was better tolerated with higher increase in mean Hb% and packed cell volume (PCV) when compared with oral iron therapy.

KEYWORDS

Anaemia, Randomized Controlled Trial, Iron Sucrose, Pregnancy, Antenatal Mother.

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BACKGROUND

Anaemia is estimated to affect 20-50% of the world's population and Pregnancy.[1] Anaemia is the most common medical disorder in pregnancy.[2] In India more than 90% of anaemia cases are estimated to be due to iron deficiency, because of largely vegetarian dietary patterns.[3] Anaemia particularly iron deficiency anaemia is the most common among all anaemia and one of the major causes of maternal mortality in India. Gravity of problem in our Institution is serious. Sixty two percent of parturating mothers are anaemic.[4] Oral iron therapy though in practice since long period, the intolerance to iron make oral iron therapy inadequate and these can be benefited from parenteral iron therapy.[5] Iron Sucrose is a suitable alternative source of iron which is well tolerated with few mild side effects.[6]

Therefore, present study was planned to compare the efficacy and acceptability of parenteral iron with that of oral iron for treatment of anaemic pregnant woman in AGMC and GBPH by evaluating the blood indices.

Aim

To compare the efficacy of intravenous iron sucrose with that of oral iron ferrous sulphate for treatment of anaemia in anaemic pregnant women.

MATERIALS AND METHODS

We have conducted a single centered, open level parallel group hospital based randomized controlled trial to evaluate, compare the efficacy and safety of parenteral iron with oral iron treatment for antenatal women attending AGMC and GBPH with anaemia.

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Sample Size

Taking level of significance, alpha= 0.01 and power of study as = 0.90, sample size was calculated as 34 by using appropriate formulae for randomized controlled trail. Finally, 50 participants each in both groups, i.e. a total of 100 participants were included in this study, taking 40 % as drop out or non-response rate.

Study Population

Singleton pregnancy with gestational age of 18 to 28 weeks and haemoglobin concentration between 7 gm% to 10.9 gm% are included in this study.

Patients who were lost during follow-up, seriously ill during study period with any serious complications during pregnancy are excluded from the study.

Allocation of Study Sample

Sample participants were randomly assigned to a treatment and each participant has the same probability of being assigned to any particular treatment. Random allocation would minimize the effect of possible confounders, reducing extraneous systematic bias, leading to a fair comparison between treatments by reducing the possibility of partial confounding and hence helping to rule out other potential competing causal explanations. Block randomization was done to assign patients to either the intravenous iron sucrose (IVIS) or the oral iron group. This method was used to balance in sample size in across groups over time. Blocks were small and balanced with predetermined group assignments, which keeps the number of subjects in each age group similar at all times. Equal proportion of participants from each block was allocated in both groups (oral iron and IVIS).

Study Procedure

The block randomization method was used to randomize study participants into groups of equal size. From each block, half of the patients were given oral iron therapy (group 1) and half were given IV iron sucrose (group 2). Total 50 patients were included from all the blocks in each group by randomization.

In group 1, participants were given 200mg of elemental iron as ferrous sulphate for 100 days twice daily. They were given a simple calendar to tick mark whenever they took daily dose to maintain compliance in group 2, total iron dose was calculated by formula = (weight in kg x target Hb – actual Hb in gm %) x 0.24 + 500mg and rounded to nearest multiple of 100.[7]

The total dose calculated was given in divided doses on alternate days by 100mg of iron sucrose with 100 ml of normal saline per day as per requirement of total dose.

The outcomes of this study were analysed by change in Hb% rise by oral and intravenous (IV) route of iron therapy. Secondary outcome measured by adverse effects graded as mild, moderate and severe and acceptability by like and dislike.

Data Analysis and Statistical Procedure

Statistical package for social science (SPSS-15) was used for statistical compilation and analysis. For statistical analysis of difference between groups, independent sample –t test, Chi square test was applied when appropriate. Statistical significance was accepted at p value <0.05.

RESULTS

Parity	Route of Administration		P value
	Oral	**IV**	
Primi	33(66%)	32(64%)	
2nd Gravida	13(26%)	11(22%)	
3rd Gravida and above	4(8%)	7(14%)	0.69
Total	**50**	**50**	

Table 1. Showing Parity Wise Distribution of Study Subjects (n=100)

Variables	Group A (Oral)	Group B (IV)
Gestational age on inclusion (weeks)	25.90 ± 3.73	27.88 ± 1.30
Maternal weight (kg)	51.25 ± 0.85	52.93 ± 1.06
Haemoglobin level (g/dL)	9.6 ± 0.74	8.84 ± 0.66
PCV	29.56 ± 1.36	29.73 ± 1.36

Table 2. Showing Mean and Standard Deviation of Different Variables among Study Participants (n=100)

Variables	Haemoglobin Level (g/dL)		P Value
	Pre - treatment	At 4 weeks	
Oral	9.6 ± 0.74	11.20 ± 0.51	0.00
IV	8.84 ± 0.66	10.96 ± 0.46	0.00
	Haemoglobin Level (g/dL)		
	At 4 weeks	At 8 weeks	
Oral	11.20 ± 0.51	12.51 ± 0.47	0.00
IV	10.96 ± 0.46	12.87 ± 0.41	0.00

Table 3. Showing Haemoglobin Level (g/dL) of Participants at Pre-Treatment, at 4 Weeks and at 8 Weeks (n=100)

Parameter	Time Interval	Group A (Oral)	Group B (IV)	P Value
Haemoglobin level (g/dL)	Pre – treatment	9.6 ± 0.74	8.84 ± 0.66	
	At 4 weeks	11.20 ± 0.51	10.96 ± 0.74	0.01
	At 8 weeks	12.51 ± 0.47	12.87 ± 0.41	0.00
Packed Cell Volume (PCV)	Pre – treatment	29.56 ± 1.36	29.73 ± 1.36	0.00
	At 4 weeks	34.67 ± 1.6	35.89 ± 1.05	

Table 4. Showing Mean Values of Haemoglobin and PCV Result Before and After Iron Treatment

Target Reached	Route of Administration	Oral	Intravenous
At 4 weeks	Yes	41	48
	No	2	9
Total		**50**	**50**
At 8 weeks		2	9
Total		**2**	**9**

Table 5. Showing Mean Values of Blood Hb Results Before and After Oral and Intravenous Iron Treatment (n=100)

Side Effects	Route of Administration	
	Oral	Intravenous
Nausea	8 (16%)	0
Vomiting	4 (8%)	0
Dyspepsia	8 (16%)	0
Constipation	3 (6%)	0
Diarrhoea	3 (6%)	0
Metallic taste	8 (16%)	0
Myalgia	1 (2%)	0
Pruritus	1 (2%)	0
No side effect	14 (28%)	50
Total	**50**	**50**

Table 6. Showing Side Effect Profile Among Both Groups (n=100)

No Side Effects	Oral Iron	Intravenous Iron
No side effect	14	50
Mild	26	00
Moderate	7	00
Severe	3	00
Total	50	50

Table 7. Showing Grading of Adverse Reaction Among Study Participants in Both Groups (n=100)

Acceptability	Oral	IV	Chi Square Test	p-Value
Like	39	43	1.084	0.298
Dislike	11	7		
Total	**50**	**50**		

Table 8. Acceptability of Oral vs. IV Iron Therapy Among Study Participants

In the present study there was no significant statistical difference (P value 0.69) in Parity wise distribution of study subjects at inclusion. Oral iron ferrous sulphate group had 33(66%) subjects as Primigravida, 13(26%) subjects as 2nd gravida and 4(8%) subjects as 3rd gravid while Intravenous Iron Sucrose group had 32(64%) subjects as Primigravida, 11(22%) subjects as 2nd gravida and 7(14%) subjects as 3rd gravid, depicted in Table 1.

There was no statistically significant difference in respect of Gestational age, Maternal weight, Haemoglobin level and PCV between the two groups as depicted in Table 2.

In the present study the mean difference of HB% level in oral group after 4 weeks was observed 1-6 g/dl and after 8 weeks 2-91 g/dl and mean difference Haemoglobin level in IV group after 4 weeks was observed 2.12 g/dl and after 8 weeks 4.03 g/dl, which was statistically significant, depicted in Table 3 & 4.

The percentage of patients who reached target Hb level at 4 weeks was 41% with Oral group and 48% with IV group. After 8 weeks, 9% reached target Hb levels in Oral group and 2% in IV group, depicted in Table 5.

In this study the side effects observed were Nausea 8(16%), Vomiting 4(8%), Dyspepsia 8 (16%), Constipation 3(6%), Diarrhoea 3(6%), Metallic taste 8 (16%), Myalgia 1 (2%), Pruritus 1(2%), - only in oral group. 14(28%) patients of Oral group and all patients of Intravenous (IV) group had no side effects, depicted in Table 6.

In the present study, 36 patients have experienced adverse effects in oral groups of which 26 patients had mild, 7 had moderate and 3 pts had severe adverse effects. But no adverse effect was observed in IV group, depicted in Table 7.

In the present study it was observed that acceptability for IV group is larger than oral group. However, there was no statistical significance between the two groups on acceptability of the drug based on like and dislike. (Table 8)

DISCUSSION

In this study, the efficacy, acceptability and adverse effects of Intravenous iron sucrose in treating pregnancy iron deficiency anaemia was compared with oral iron therapy. It corrects anaemia at short duration and replenishes iron stores better than oral iron.[8]

In the present study the mean difference of HB% level in oral group after 4 weeks was observed 1-6 g/dl and after 8 weeks 2-91 g/dl and mean difference Haemoglobin level in IV group after 4 weeks was observed 2.12 g/dl and after 8 weeks 4.03 g/dl, which was statistically significant.[9,10]

In this study, the percentage of patients who reached target Hb levels at 4 weeks were 41% with Oral group and 48% with IV group. After 8 weeks, 9% reached target Hb levels in Oral group and 2% in IV group.

In this study the side effects observed were noted only in oral group like Diarrhoea, metallic taste, myalgia, pruritus, nausea, vomiting, dyspepsia and constipations. Out of which maximum cases reported nausea, vomiting and metallic taste.[11,12.]

In the present study, 36 pts have experienced adverse effects in oral groups of which 26 patients had mild, 7 had moderate and 3 patients had severe adverse effects. In this study no adverse effects were observed in IV group suggesting safety profile of the drug.

In the present study, it was observed that acceptability for IV group is more than oral group which indicate tolerability of the drug.

CONCLUSION

The present study revealed that Intravenous iron sucrose therapy was better tolerated with higher increase in mean haemoglobin and PCV when compared with oral iron therapy. There were no serious side effects with intravenous iron sucrose therapy. Intravenous iron sucrose is a good substitute to oral iron therapy in treatment of anaemia in antenatal mother.

REFERENCES

[1] Arias F, Daftary SN, Bhide AG. Haematological disorder in pregnancy. In: Arias F, Daftary SN, Bhide AG, eds. Practical guide to high-risk pregnancy and delivery. 3rd edn. Haryana: Elsevier India Pvt Ltd. 2010:465-488.

[2] Diejomaoh FME, Abdulaziz A, Adekile AD. Anaemia in pregnancy. Int J Obstet Gynaecol 1999;65(3):299-301.

[3] Sharma JB. Effect of dietary habits on prevalence of anaemia in pregnant women of Delhi. J Obstet Gynaecol Res 2003;29(2):73-78.

[4] National Family Health Survey. 1998-1999 NFHS – II. Mumbai, India: International Population Studies 2000;98:250-260.

[5] Johnson CS. Intravenous iron dextran in the treatment of iron deficient anaemia. J Nat Med Assoc 1979;71(11):1101-1105.

[6] Gupta A, Manaktala U, Rathore AM. A randomised controlled trial to compare intravenous iron sucrose and oral iron in treatment of iron deficiency anaemia in pregnancy. Indian J Hematol Blood Transfus 2014;30(2):120-125.

[7] Abhilashini GD, Sagili H, Rani R. A trial comparing two different modalities of treatment of iron deficiency anaemia in pregnancy. J Clin Diagn Res 2014;8(5):OC04-OC07.

[8] Ashrof Raja A, Sankaran PK, Sivanandan R, et al. Comparative study of intravenous iron-sucrose and oral iron therapy in iron deficiency anaemia during pregnancy. The Health Agenda 2014;2(4):130-134.

[9] Kumar A, Jain S, Singh NP, et al. Oral versus high dose parenteral iron supplementation in pregnancy. Int J Gynaecol Obstet 2005;89(1):7-13.

[10] Bashiri A, Burstein E, Sheiner E, et al. Anaemia during pregnancy and treatment with intravenous ion: review of the literature. Eur J Obstet Gynecol Reprod Biol 2003;110(1):2-7.

[11] Charytan C, Levin N, AI-Saloum M, et al. Efficacy and safety of iron sucrose for iron deficiency in patients with dialysis-associated anaemia: North American clinical trial. Am J Kidney Dis 2001;37(2):300-307.

[12] Shafi D, Purandare SV, Sathe AV. Iron deficiency anaemia in pregnancy: intravenous versus oral route. J Obstet Gynaecol India 2012;62(3):317-321.

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