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A Comparative Study Of Oral Iron Therapy Versus Intravenous Iron Therapy In Moderately Pregnant Anaemic Women (7-10g/Dl).

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ABSTRACT

Anaemia in pregnancy exists worldwide but it is a very common problem in most of the developing countries. Anaemia is major public health problem in economically disadvantaged segments of population in developing countries. According to ICMR;MILD-10-10.9g%;MODERATE-7-10g%;SEVERE-<7g%;VERY SEVERE-<4 g%.

Keywords: Anaemia, oral iron ,parentral iron .

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MATERIALS AND METHODS

The "study of outcome of the treatment with intravenous iron sucrose in moderately anemic pregnant women" AFTER ATTAINING ETHICAL COMMITTEE CLEARENCE was conducted in Department of Obstetrics & Gynecology, SREE BALAJI MEDICAL COLLEGE AND HOSPITAL. 200antenatal patients with moderate iron deficiency anemia with hemoglobin between 7-10 g/dl were selected and included in this study. This study was conducted to prove that iron sucrose is more effective, safer and well tolerated than various forms of oral iron salts in pregnant women with moderate anemia complicating pregnancy.

INCLUSION CRITERIA

Primi and multi gravida between 28-36 weeks of pregnancy.Pregnant women with hemoglobin between 7-10 g/dl women with established iron deficiency anemia singleton pregnancy are selected.

GROUP A – PARENTRAL IRON THERAPY – IRON SUCROSE
GROUP B1- ORAL IRON THERAPY- FERROUS SULPHATE.
GROUP B2 – ORAL IRON THERAPY – FERROUS GLUCONATE.
GROUP B3 – ORAL IRON THERAPY- FERROUS FUMARATE.

EXCLUSION CRITERIA

Women with history of blood transfusion
Women who are on other parenteral iron therapy
Anemia other than iron deficiency anemia
Women who are allergic to iron.
Women with medical disorders complicating pregnancy

The study was conducted in SREE BALAJI MEDICAL COLLEGE AND HOSPITAL, CHROMPET CHENNAI. The antenatal women attending the antenatal OP are screened for hemoglobin status. Those antenatal women of gestational age 28-36 weeks with hemoglobin between 7-10g/dl are selected. A total of 200 antenatal women are selected out of which 100 antenatal women are given oral iron therapy and 100 antenatal women are given intravenous iron sucrose.
Iron requirement is calculated by the formula,53

[(Target Hb in gms - patient's Hb in gms) x weight in kg x 2.4] + 1000 mg(for iron stores) administered. In the formula, weight represented the patient's weight in kilograms; target hemoglobin was set at 13 g/dl. In each infusion, the maximum total dose administered 200mg iron sucrose in 100 ml of normal saline per day, slow intravenous infused over 30 minutes. Monitoring was done throughout the infusion to observe for any side effects.

ORAL IRON THERAPY

The antenatal pregnant women with moderate anemia in whom eligibility was checked according to the inclusion and exclusion criteria and informed consent was taken from each patient in antenatal op between 28-36 weeks of gestation for whom oral iron therapy is started.Group B1 Ferrous Sulphate Group -33 of the selected group received ferrous sulphate 100mg of elemental iron with folic acid 0.5mg tablet one tablet twice a dayGroup B2Ferrous gluconate Group-34 of the selected group received ferrous gluconate 100 mg elemental iron with folic acid 0.5 mg twice a dayGroup B3 Ferrous fumarate-33 of the selected group received ferrous fumarate 100mg elemental iron with folic acid 0.5mg one tablet twice a day for a period of one month, after which the investigations are done.

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PARENTRAL INTRAVENOUS IRON THERAPY

Test dose is not required for intravenous iron sucrose administration. Injection epinephrine, hydrocortisone, oxygen should be available in the event of anaphylactic reaction. Intravenous iron sucrose diluted in normal saline given slowly initially. If there is no reaction, it can be given faster. Therapy is given according to the calculated dose Total iron requirement = (normal Hb in gms – patient's Hb in gms) x wt in Kg x 2.24 + 1000.Normal Hb = 13g/dl as per WHO standard

Visit I:

Information regarding patient's name, address, age and history of amenorrhea was obtained and results of general and obstetric examination were noted, maternal weight was noted. Investigation include estimation of hemoglobin value, hematocrit and peripheral smear, MCV, MCHC, S.Ferritin examination to note the type and degree of anemia. For the infusion of iron sucrose, test dose is not needed. The patients were given 100 mg of iron sucrose diluted in 100 ml of 0.9% normal saline and infused over 30 minutes followed by 200 mg of iron sucrose diluted in 100 ml of 0.9% normal saline and infused over 30 minutes every consecutive days until the required dosage is infused. Patients were administered folic acid along with therapy and were advised to avoid oral iron during iron sucrose therapy. One should look for any reaction in the form of chest pain, rigor, chills, fall in blood pressure, dyspnea, hemolysis, and anaphylactic reaction. For any such reaction, infusion should be stopped and antihistamine, corticoids, and epinephrine given. This can also be done as OPD procedure .They were explained about repeating investigations during follow-up visits after a period of 4 weeks. The side effects volunteered by the women were noted.

Visit II:

Patients were evaluated from baseline to 4 week interval adverse effect if any reported were noted, whether the patient could tolerate oral iron is noted, and vital like blood pressure and pulse rate noted. The patient should bring back the empty packs of tablets and there were enquired about the color of the stool. At the end of 4 weeks repeat hemoglobin estimation was done. The results and data was analyzed with statistical test. If the hemoglobin at the end of 4 weeks was 11gm% then ferrous sulphate 100mg of elemental iron i.e., 1 tablet is continued till 3 months after delivery. If the Hemogllobin is less than 13gms ferrous sulphate 100mg of elemental iron one tablet twice a day is given till 13gms is reached.After a period of 4 weeks, the pregnant women were examined clinically and maternal weight was noted. Hemoglobin, hematocrit, MCV, MCHC, S. Ferritin, Peripheral smear were done in both groups to note the improvement in values.

ANALYSIS AND RESULTS

200 antenatal women after confirming iron deficiency anemia were included in this study and the required dosage of iron was infused intravenously in the form of iron sucrose complex in 100 patients and various forms of oral iron salts in 100 patients.

Analysis of data

Table 1: Age Distribution

GROUPS	N	Mean	SD	Oneway ANOVA
Iron sucrose	100	24.63	3.623	F=0.31 p=0.82
Ferrous Sulphate	33	23.97	3.610	
Ferrous Gluconate	34	24.56	3.164	
Ferrous Fumarate	33	24.58	3.172	

Table 2: Socio Economic Status

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Groups	SEC						Chi Square Test
	3		2		1		
	N	%	N	%	N	%	
Iron sucrose	10	10.0%	44	44.0%	46	46.0%	
Ferrous Sulphate	5	15.2%	12	36.4%	16	48.5%	
Ferrous Gluconate	5	14.7%	14	41.2%	15	44.1%	χ=2.28 P=0.89
Ferrous Fumarate	5	15.2%	16	48.5%	12	36.4%	

Table 3: Gestational Age in Weeks

Groups	N	Mean	SD	Oneway ANOVA
Iron sucrose	100	31.18	2.341	
Ferrous Sulphate	33	31.18	2.325	F=0.97 p=0.40
Ferrous Gluconate	34	31.59	3.006	
Ferrous Fumarate	33	31.97	2.531	

Table 4: Parity Status

Groups	Parity						Chi Square Test
	3		2		1		
	N	%	N	%	N	%	
Iron sucrose	45	45.0%	39	39.0%	16	16.0%	
Ferrous Sulphate	12	36.4%	12	36.4%	9	27.3%	χ2=3.96
Ferrous Gluconate	16	47.1%	12	35.3%	6	17.6%	P=0.68
Ferrous Fumarate	18	54.5%	11	33.3%	4	12.1%	

Table 5: Hemoglobin Level

Groups	Hb in Baseline		Hb in 4th Week		Paired t-Test
	Mean	SD	Mean	SD	
Iron sucrose	8.35	.71	9.49	.70	t=38.20 p=0.001*** significant
Ferrous Sulphate	8.12	.51	8.65	.50	t=32.12 p=0.001*** significant
Ferrous Gluconate	8.11	.73	8.63	.73	t=32.90 p=0.001*** significant
Ferrous Fumarate	8.24	.68	8.76	.68	t=33.53p=0.001*** significant

Table 6: Hematocrit Level

Groups	PCV in Baseline		PCV in 4th Week		Paired t-Test
	Mean	SD	Mean	SD	
Iron sucrose	28.36	.85	29.38	.85	t=71.48 p=0.001*** significant
Ferrous Sulphate	27.78	.70	27.92	.67	t=2.44 p=0.02* significant
Ferrous Gluconate	28.00	.89	28.15	.89	t=2.39 p=0.02* significant
Ferrous Fumarate	28.21	.96	28.24	.97	t=1.00 p=0.32 not significant

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Table 7: MCV Level

Groups	MCV in Baseline		MCV in 4th Week		Paired t-Test
	Mean	SD	Mean	SD	
Iron sucrose	81.08	.77	82.10	.78	t=72.49 p=0.001*** significant
Ferrous Sulphate	80.88	.70	81.00	.66	t=2.10 p=0.04* significant
Ferrous Gluconate	81.00	.74	81.00	.74	t=1.71p=0.09 not significant
Ferrous Fumarate	80.94	.70	80.94	.70	t=1.68 p=0.10 not significant

Table 8: MCHC Level

Groups	MCHC in Baseline		MCHC in 4th Week		Paired t-Test
	Mean	SD	Mean	SD	
Iron sucrose	27.96	.89	28.97	.87	t=16.16 p=0.001*** significant
Ferrous Sulphate	28.42	.83	28.73	.91	t=3.73 p=0.01** significant
Ferrous Gluconate	28.47	1.02	28.56	1.05	t=1.79p=0.08 not significant
Ferrous Fumarate	28.48	1.09	28.55	1.12	t=1.43 p=0.16 not significant

Table 9: Serum Ferritin Level

Groups	SF in Baseline		SF in 4th Week		Paired t-Test
	Mean	SD	Mean	SD	
Iron sucrose	16.11	1.67	23.45	1.64	t=25.54 p=0.001*** significant
Ferrous Sulphate	17.02	1.35	18.03	1.33	t=17.03 p=0.001*** significant
Ferrous Gluconate	16.65	1.52	17.56	1.54	t=16.47p=0.001*** significant
Ferrous Fumarate	16.85	1.44	18.15	2.28	t=4.30 p=0.001*** significant

Table 10a: Side Effects

Groups	Side Effects									
	C&R		EP		H		NO		V	
	N	%	N	%	N	%	N	%	N	%
Iron sucrose	1	1.0%					98	98.0%	1	1.0%
Ferrous Sulphate			5	15.2%	2	6.1%	21	63.63%	5	15.2%
Ferrous Gluconate			3	8.8%	2	5.9%	25	73.5%	4	11.8%
Ferrous Fumarate			1	3.0%			29	87.88%	3	9.09%

Table 10b: Side Effects

Groups	Side Effects				Chi Square Test
	Yes		No		
	N	%	N	%	
Iron sucrose	2	2.0%	98	98.0%	$\chi 2$=23.26 P=0.001*** significant
Ferrous sulphate	12	36.36%	21	63.63%	
Ferrous Glucomate	9	26.5%	25	73.5%	
Ferrous fumarate	4	12.12%	29	87.88%	

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SUMMARY

In our study 200 antenatal mothers with moderate iron deficiency anemia were selected according to the inclusion and exclusion criteria stated in the methodology. The iron requirement is calculated and given orally and intravenously .The results of the study are tabulated, analyzed and summarized as follows:

1. The age distribution of the women in the 4 groups was statistically comparable. Majority of the patients around belong to the age groupbetween18 –34years.
2. Majority of the patients belong to class I and II socio economic status of the Modified Kuppuswamy Classification in all the 4 groups.
3. Majority of the patients were primigravida in all the 4 groups.
4. All of the patients at the time of inclusion in all the 4 groups were in the gestational age between 28-36 weeks.
5. Majority of the patients were showing microcytic hypochromic blood picture.
6. Mean rise in hemoglobin in the intravenous group after 30 days of treatment was 1.14 g/dl with a P value 0.0001 which is statistically significant.
7. Mean rise in hematocrit in the intravenous group after 30 days of treatment was 1.02% with a P value 0.0001 which is statistically significant.
8. Mean rise in the MCV in the intravenous group is 1.02 cu microns after 30 days of treatment with a with a P value 0.0001 which is statistically significant.
9. Mean rise in the MCHC in the intravenous group is 1.01% after 30 days of treatment with a with a P value 0.0001 which is statistically significant.
10. Mean rise in the S.Ferritin in the intravenous group is 7.34mcg/l after 30 days of treatment with a p value 0.0001 which is statistically significant.
11. Statistically significant rise in hemoglobin, hematocrit, MCV, MCHC, S.Ferritin levels were found in the intravenous group when compared to the oral groups.
12. The side effects were very minimal in intravenous group 2% (2/100). The side effect profile was also very mild which included nausea in 1patient, chills & rigors in 1 patient. No anaphylactic reactions occurred. No dreaded side effects were seen.
13. None of the patients from all the groups had failure of treatment.
14. None of the patients from all the groups had any blood transfusion.
15. None of the patients were excluded from the study.

CONCLUSION

In India, Iron deficiency anemia is one of the major causes of maternal deaths. Over the past years, various oral and intra muscular & intravenous preparations of iron have been used for correction of iron deficiency anemia in the pregnant women10-12. However, oral and intra muscular are associated with significant side effects; Intramuscular (Iron dextran) was used as an alternative to oral iron therapy for those who were not compliant to oral therapy. Iron dextran has a lot of side effects such as fever, arthralgia, even anaphylactic reactions extending to pulmonary edema and even death. Further it is not possible to achieve the target rise in Hemoglobin level in a limited time period, when the patient is approaching term. Whereas Intravenous (Iron sucrose complex) is a relatively new drug which is a BOON to medical therapy and is the BEST OPTION of iron therapy when used as an alternative to oral therapy as it restores iron stores more promptly and is able to RAISE THE HEMOGLOBIN TO SATISFACTORY LEVEL when used IN MODERATELY ANEMIC IRON DEFICIENT PREGNANT WOMEN13-14.

1. Intravenous iron sucrose complex is SAFE and HIGHLY EFFICACIOUS in improving and in achieving optimum results in increasing hemoglobin, hematocrit, MCV, MCHC, S.Ferritin concentration in the treatment of moderate iron deficiency anemia in antenatal women than all the 3 forms of oral iron salts.
2. Iron sucrose complex infusion was WELL TOLERATED AND SAFE BOTH TO THE MOTHER AND THE FETUS and there were NO MAJOR ADVERSE REACTIONS.
3. Iron sucrose RESTORES IRON STORES MORE PROMPTLY and is a suitable alternative to all the 3 forms of oral iron salts WITH MINIMAL SIDE EFFECTS in those patients who cannot tolerate oral iron therapy.
4. Iron sucrose can be used TO REDUCE THE NUMBER OF BLOOD TRANSFUSION in the antenatal period in moderately anemic women without failure.

5. COST FACTOR Intravenous (iron sucrose) cost is also well appreciated when compared to all the 3 forms of oral iron salts.

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