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Comparative Study of Oral Ferrous Sulphate and Intravenous Iron Sucrose for Iron Deficiency Anaemia in Pregnancy

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Abstract: ***Background: Iron deficiency anaemia (IDA) in Pregnancy can cause placental problems, fetal death, infections, and low iron stores in newborns. It takes weeks for oral iron to raise haemoglobin and months to replenish the iron stores in the body. Therefore many women fail to comply with such prolonged therapy. Alternative treatment methods for anemia include intravenous (IV) iron therapy or blood transfusion. In present study we have used iron sucrose for parenteral iron therapy. This study was undertaken to evaluate the efficacy, safety and acceptability of intravenous iron sucrose complex in comparison to oral ferrous sulfate in mild to moderate iron deficiency anemia during pregnancy. Material and methods: Type of study; Comparative Prospective, Interventional study. Current study was conducted in department of Obstetrics and Gynaecology, Govt. Medical College Kota from February 2021 to December 2022. A total 200 pregnant woman attending Antenatal clinic between 16 to 32 weeks were randomly assigned either to intravenous or to oral iron group. Results: Statistically significant Hb and serum ferritin increase in both the groups from pre - treatment to post 4 week. Our study revealed that at 4 week and 6 week Hb was significantly more increase in group IV compare to group Oral iron and out of the 100 participants in IV group, maximum 97 had no side effect, Out of the 100 participants in group Oral, maximum 88 had no side effect and this difference was statistically insignificant. Conclusion: For women with mild to moderate anemia, intravenous iron therapy under supervision is a superior option then oral iron. intravenous iron sucrose is safe & highly effective, for the treatment of iron deficiency anemia. Because of rapid absorption, iron sucrose treatment is more successful in attaining the better results than oral iron.***

Keywords: Iron Deficiency Anaemia, pregnancy, oral ferrous sulfate, Serum ferritin, Haemoglobin

1. Introduction

Anemia is a worldwide health issue that affects roughly one - third of the world's population. Anemia affects approximately 2 billion people worldwide. According to the latest World Health Organization (WHO) report of 2016, the global prevalence of anaemia during pregnancy is 40.1%[1]. The situation is grave in Southeast Asian Countries where about half of all global maternal deaths are due to anaemia India alone contributes to about 80% of the maternal deaths due to anaemia in South Asia.[2]

At the national level, the findings of the NFHS - 5 reveal that there has been an increase in the prevalence of anaemia among women and children compared to the previous NFHS - 4 survey [3] The increase in anaemia among pregnant women is by 1.8 percentage points.[4]

Iron deficiency anaemia (IDA) in Pregnancy can cause placental problems, fetal death, infections, and low iron stores in newborns. Iron is essential as a cofactor of enzymes and proteins involved in the development of the central nervous system. As a result, iron deficiency may be associated with serious consequences. Early iron deficiency, in fact, alters the morphology and metabolism of brain cells, has a negative impact on oligodendrocytes, altering myelination, and impairs neurotransmission. Iron deficiency increases the risk of poor cognitive, motor, and social - emotional performance, as well as interfering with neurophysiologic development, for all of these reasons.[5 - 7]

It takes weeks for oral iron to raise haemoglobin and months to replenish the iron stores in the body. Therefore many women fail to comply with such prolonged therapy. Alternative treatment methods for anemia include intravenous (IV) iron therapy or blood transfusion.

Intravenous iron sucrose can be administered as an infusion in small doses (about 200mg) over a 30 minute time period. In present study we have used iron sucrose for parenteral iron therapy. This study was undertaken to evaluate the safety and efficacy of intravenous iron sucrose complex in comparison to oral ferrous sulfate in mild to moderate iron deficiency anemia during pregnancy.

2. Material and Methods

Type of study; - Comparative prospective, Interventational study

Current study was conducted in in department of Obstetrics and Gynaecology, Govt. Medical College Kota from February 2021 to December 2022. This study aimed to evaluate the safety and efficacy of IV iron sucrose complex in comparison to oral iron therapy in mild to moderate iron deficiency anemia. A total 200 pregnant woman attending Antenatal clinic between 16 to 32 weeks were randomly assigned either to intravenous or to oral iron group.

Complete systemic and obstetric examination was carried out. Period of gestation calculated from last menstrual period (LMP) or first trimester obstetric scan, if patient not sure of her dates. Investigations were done in Central Laboratory of New Medical College & associated Hospital Kota with the help of automated analyzer (XN - 1000) (integrated system) and automated cell counter (SYSMEX XS - 800i).

Study Group A: Oral iron (Ferrous sulphate) - The participants of oral iron group was given oral tablets of 100 mg elemental Iron (Ferrous Sulphate) & 500 mcg of Folic acid (FOLIFER - Ministry of health) thrice daily.

Study group B: IV Iron Group - Total dosage of Injection Iron sucrose was calculated by the following formula:

Total Iron deficit (mg) = Body wt. X 0.24 X (desired Hb% - Patient's Hb %) + 500 (rounded up to the nearest multiple of 100 mg).

Method of administration: Iron dosage calculated and administer as 200 mg parental iron in 100 ml of 0.9%. Normal Saline. Intravenously slowly over 20 – 30 min on alternate day in day care up to total dose. It was supplemented with 500 mcg folic acid daily for 4 week to prevent and eventual folic acid deficiency and eliminate the influence of such a deficiency on results additional and administration of iron was excluded during the 4 week of study. Adrenaline, Hydroctisone, Pheneramine maleate and Oxygen kept ready to combat any serious allergic reaction.

Safety analysis: - safety was assessed on the basis of patients complaints with respect to gastrointestinal symptoms like nausea, vomiting, diarrhea, pain abdomen or allergic reactions if any.

Efficacy **analysis**: - changes in haematologicl (Hb, MCV and S. ferritin) parameters were measured.

Follow - up: - follow up was scheduled at 4 week and 6 week from the date of starting of treatment and haematological parameters compared Pretreatment and Post treatment.

Unpaired t - test test were used to compare the continuous variable and chi - square test were used for categorical variables. Data are presented as mean (standard deviation) or number or proportions. A p - value <0.05 was considered as statistically significant.

3. Results

Table 1: Sociodemographic profile of study participants

	IV iron sucrose (n=100)		Oral ferrous sulfate (n=100)		p - value
	n	%	n	%	
Age (Mean±SD)	23.76±3.76 years		22.99±3.14 years		0.122
Age					
<20 years	22	22.0%	28	28.0%	0.409
21 - 25 years	48	48.0%	46	46.0%	
26 - 30 years	26	26.0%	26	26.0%	
>30 years	4	4.0%	0	0.0%	
Residence					
Urban	30	30.0%	34	34.0%	0.544
Rural	70	70.0%	66	66.0%	
Gravida					
G1	30	30.0%	23	23.0%	0.356
G2	52	52.0%	52	52.0%	
Multi	18	18.0%	25	25.0%	
Gestational age					
16 - 24 weeks	32	32.0%	25	25.0%	0.421
25 - 28 weeks	50	50.0%	50	50.0%	
29 - 32 weeks	18	18.0%	25	25.0%	

Table 2: Clinical profile of study participants

	IV iron sucrose (n=100)		Oral ferrous sulfate (n=100)		p – value
	n	%	n	%	
Hb (gm%)					
10 - 11 (Mild)	18	18.0%	12	12.0%	0.433
7 - 10 (Moderate)	82	82.0%	88	88.0%	
Sign and symptoms					
Loss of appetite	30	30.0%	23	23.0%	0.356
Weakness	52	52.0%	52	52.0%	
Lack of concentration	18	18.0%	25	25.0%	
Side effect:					
No Side effect	97	97.0	88	88.0	0.143
Local pain	1	1.0%	0	0%	0.998
GI side effect	1	1.0%	12	12%	0.001
Allergic reaction	1	1.0%	0	0%	0.998
Nausea vomiting	0	0%	7	7%	0.01

Table 3: Comparison of Hb (g/dL) between both group at different time interval:

Group		Pre treatment	4 Weeks	6 Weeks	p - value (Anova test)
IV	Mean	8.5360	10.5780	11.3680	0.0001
	SD	.47216	.44599	.61182	
Oral	Mean	8.5714	10.2264	10.9304	0.0001
	SD	.39132	.54301	.59364	
p - value		0.564	0.0001	0.0001	
MCV (femtoliter):					
IV	Mean	78.94	86.28	88.18	0.0001
	SD	4.44	2.08	1.40	
Oral	Mean	80.12	84.22	85.47	0.0001
	SD	3.07	2.32	2.16	
p - value		0.130	0.0001	0.0001	
Serum ferritin (mcg/l)					
IV	Mean	35.21	261.03	130.86	0.0001
	SD	13.85	69.91	22.28	
Oral	Mean	36.89	113.67	199.04	0.0001
	SD	9.34	21.35	50.23	
p - value		0.313	0.0001	0.0001	

In this study, mean age of participants in group IV and Oral was 23.8±3.8 years and 22.9±3.1 years, maximum were in

age of 21 - 25 years, rural residence, gravida 2 and 25 - 28 weeks of pregnancy among both the groups. All the sociodemographic profile were comparable between both groups. (Table 1)

Out of the 100 participants in IV group, maximum 82 had Hb between 7 - 10 gm% and 18 had Hb 10 - 11 gm%, maximum 52 had weakness followed by 30 had loss of appetite and maximum 97 had no side effect. while in rest Giddiness local pain at injection site and mild allergic reaction reported only in 1 participants separately. While in group Oral, maximum 88 had Hb 7 - 10 gm% and 12 had Hb 10 - 11 gm%, maximum52 had weakness followed by 25 had lack of concentration and maximum 88 had no side effect. While in rest gastritis in 7 participates, constipation in 4 participates and diarrhoea was reported 1 participant. (Table 2)

Pretreatment mean Hb Concentration in IV group was 8.53 which was rise to 10.5 in 4wktreatment and 11.3 at 6wk of treatment. While in ORAL group pretreatment Hb Concentration was 8.57which was rises to 10.22 at 4wkand 10.93 at 6wk of treatment. Pretreatment MCV Concentration was in IV group 78.94 which was rises to 86.28 at 4wk of treatment and 88.18 at 6wk of treatment. While inORAL group pretreatment MCV concentration was 80.12 which was rises to 84.22 at 4wk of treatment and 85.47 at 6wk of treatment. and a statistically significant serum ferritin increase in both the group from pre - treatment to post 4 week. Our study also revealed that at 4 week and 6 week serum ferritin level was significantly more increase in group IV compare to group Oral patients. (Table 3)

4. Discussion

Anaemia in pregnancy is associated with adverse consequences both for the mother and the fetus. Studies have shown that the adverse consequences of maternal anemia may affect not only the neonate and infant but also increase the risk of non - communicable diseases when the child grows into an adult and the risk of low birth weight in the next generation. So current study was conducted to evaluate the safety and efficacy of IV iron sucrose complex in comparison to oral iron therapy in mild to moderate iron deficiency anemia.

In our study, a statistically significant Hb increase in both the group from pre - treatment to post 4 week. Our study also revealed that at 4 week and 6 week Hb was significantly more increase in group IV compare to group Oral iron.

Tigga MP et al[8] found similar results and pretreatment mean Hb level in the oral group was 9.6 ± 0.74 g/dL, whereas it was 8.84 ± 0.66 g/dL in the IVIS group. The mean differences of rise of Hb level (g/dL) in the oral group after 4 and 8 weeks of therapy were 1.6 g/dL and 2.91 g/dL, respectively. However, in the IVIS group, after 4 weeks, Hb rise was 2.12 g/dL and after 8 weeks it was 4.03 g/dL. A statistically significant difference was observed between the two groups after 4 (P = 0.01) and 8 weeks (P = 0.00). Al Momenet al[9], in their study compared 52 women treated with intravenous iron sucrose and 59 women treated with 300 mg oral iron sulfate. Intravenous iron sucrose complex achieved significantly higher hemoglobin levels 128.5 ± 6.6 versus 111.4±12.4 g/l in the oral iron group (p<0.01) in a shorter period 6.9 ± 1.8 versus 14.9 ± 3.1 weeks in control group (p - 0.001). DeebaS et al[10], in their study concluded that difference in Hb from baseline in IV group was 1.72±0.484 at 2 weeks, 2.18±0.865 at 4 weeks, 2.89±0.5989 at 6 weeks compared to oral iron, which was 0.5550±0.456 at 2 weeks, 1.39±0.4402 at 4 weeks, and 1.9±0.3020 at 6 weeks. P value was 0.000 which was clinically significant and showed that Hb levels were increased more in intravenous group. These results are similar to our study. Dubey S et al[11] compare the efficacy and safety of intravenous iron sucrose to oral iron in the treatment of iron deficiency anemia in pregnancy. In this study, the significant rise in hemoglobin from 8.0 ± 0.79gm/dl to10.80± 0.61gm/dl in intravenous group as compared to oral iron group from 8.19 ± 0.60gm/dl to 9.86± 0.61 gm/dl was seen at 4th week of treatment (P = 0.000). After 2 week of treatment rise in serum ferritin values were higher in intravenous group from 6.25 ± 1.05 ng/ml; to 155.33 ± 57.4 ng/ml and in oral group from 5.71 ± 1.71ng/ml to 20.8 ± 9.5 ng/ml (p=.000). Parmar M et al[12] found that In patients having moderate anaemia (Hb 7 - 9 gm%), the rise in Hb found to be 2.17 ± 0.45 gm% from pre - treatment Hb of 7.88 ± 0.58 gm% to 9.9 ± 0.53 gm%. In patients with severe anaemia (Hb < 7 gm%), the rise in Hb was observed up to 2.73 ± 0.51 (SD) gm% after 1 month of iron sucrose treatment. Tariq N et al[13] also find similar results and in the group - A (iron sucrose group), mean pre - infusion Hb levels was 9.09 ± 0.83 gm/dl. Mean increase in Hemoglobin (Hb) was 10.75 ± 1.097 gm/dl after 4 weeks of infusion and 11.06 ± 0.866 gm/dl at delivery (p < 0.001). In group - B (iron dextran group) pre - infusion haemoglobin was 8.735 ± 0.956 gm/dl and the mean increase in hemoglobin was 10.613 ± 1.22 gm/dl at 4 - week while mean increase of 10.859 ± 1.11 gm/dl at the time of delivery (p < 0.001).

In our study, a statistically significant serum ferritin increase in both the group from pre - treatment to post 4 week. Our study also revealed that at 4 week and 6 week serum ferritin level was significantly more increase in group IV compare to group Oral iron.

Gupta A et al[14] found that Serum ferritin value was significantly higher in the IV group, 37.45 ± 5.73 ng/mL as compared to 13.96 ± 1.88 ng/mL in the oral group at 4th week (p <0.001). Radhika AG et al[15] did a Meta - analysis of randomized controlled trials and estimated mean ferritin level from first week to six weeks was 63.1 µg/l and 28.6 µg/l, respectively, in intravenous and oral iron groups. Bhavi S B et al[16]and revealed that 48% of patients in I. V group showed increase in ferritin level between 51 to 100 ng/ml in comparison to only 3.5% in oral group.

In our study, out of the 100 participants in IV group, maximum 97 had no side effect. Out of the 100 participants in group Oral, maximum 88 had no side effect. This difference was not found to be statically significant.

Tigga MP et al[8] found similar results and revealed that in the iron sucrose group, no adverse effects were observed, suggesting its safety, and the acceptability and newborn birth weight were noted to be higher. Neogi SB et al[17] did a study

and 2018 women were enrolled, and 999 were randomly assigned to the intravenous iron sucrose group and 1019 to the standard therapy group. The primary maternal composite outcome was reported in 89 (9%) of 958 patients in the intravenous iron sucrose group and in 95 (10%) of 976 patients in the standard therapy group.16 (2%) of 958 women in the intravenous iron sucrose group and 13 (1%) of 976 women in the standard therapy group had serious maternal adverse events.

5. Conclusion

For women with mild to moderate anemia, intravenous iron therapy under supervision is a superior option then oral iron. intravenous iron sucrose is safe & highly effective, for the treatment of iron deficiency anemia. Because of rapid absorption, iron sucrose treatment is more successful in attaining the better results then oral iron.

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