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Research article

COMPARATIVE STUDY ON EFFICACY & SAFETY OF INTRAVENOUS IRON SUCROSE VERSUS INTRAMUSCULAR IRON SORBITOL THERAPY IN ANEMIA DURING PREGNANCY

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ABSTRACT

Aims and Objectives: To compare the efficacy, safety, and rate of response of intravenous iron sucrose and intramuscular iron Sorbitol therapy for anemia during pregnancy. **Material and Methods**: 100 antenatal cases of gestational age 16-32 weeks were included in this prospective study. Cases were randomly divided into two groups. Group A, having 50 cases received intravenous iron sucrose, and 50cases in group B received intramuscular iron sorbitol. Response to therapy in both groups was studied and compared. **Results:** The mean pretherapy hemoglobin in group A was 6.49 g/dl and in group B was 6.48 g/dl. The rise in hemoglobin after 4 weeks of starting therapy was 3.52 g/dl in group A and 2.33 g/dl in group B The difference was Statistically significant (P<0.01) The mean time taken to achieve target hemoglobin (≥11 g/dl) was 6.37 weeks in group A and 9.04 weeks in group B. In group A, 8% (four) cases had grade I adverse effects. In group B, 24% (12) cases had grade I adverse effects. The difference was statistically significant (P=0.027). In both the groups no case discontinued the therapy. **Conclusion:** Intravenous iron sucrose is safe, convenient, more effective, and faster acting therapy than intramuscular iron sorbitol therapy for treating moderate to severe anemia during pregnancy.

Keywords: Iron sucrose, Iron sorbitol, Pregnancy, Iron deficiency.

INTRODUCTION

Anemia is associated with higher perinatal mortality and morbidity[1]. Anemia is the most common hematologic abnormality diagnosed during pregnancy. It is most often caused by iron deficiency & occasionally by more complex conditions involving deficient production of or accelerated destruction of erythrocytes.[1] In developing countries nearly two third of the pregnant women suffering from anemia out of which 95% of cases are having iron deficiency anemia.[2]

Over the past years, various routine methods like oral iron therapy, intramuscular iron therapy, and blood transfusion were used to treat anemia during pregnancy[3,4]. These methods are not without deficiencies, and also there are conditions in which these conventional iron therapies are not helpful, like inadequate

gastrointestinal absorption, late pregnancy, and intolerance to required oral iron, requirement of emergency supplement, and severe anemia with contraindications to blood transfusion[5]. So, to treat these conditions, we require a relatively new mode of iron therapy with better efficacy, less side effects, fast action and better compliance. Intravenous iron sucrose therapy seems to be a safe convenient and more effective treatment for anemia during pregnancy

MATERIALS AND METHODS

After the approval of Institutional Ethics committee of Dr VPMC, Nashik, total 100 antenatal women between 16 and 32 weeks of gestation with hemoglobin level of 8 g/dl or less, attending the outpatient department & antenatal ward at Civil Hospital Nashik, were included in the present study.

Inclusion Criteria: 1. Pregnant women aged ≥18, gestational week between 16 to 32, at baseline with normal antenatal screening test results, Pregnant women willing to give conform consent form for the study 2. Iron deficiency anemia defined as Hb concentration ≤ 8g/dl, serum iron less than 60 micro g/dl, and total iron-binding capacity more than 400 micro g/dl

Excusing Criteria: 1. The cases having hemoglobin level >8 g/dl 2. Gestational age <16 or >32 weeks

3. History of allergic reaction to previous iron therapy 4. Anemia due to causes other than iron deficiency.

All the 100 cases enrolled in the study were assigned into two groups. Group A: 50 cases received intravenous iron sucrose, Group B: 50 cases received intramuscular iron sorbitol therapy. Iron was given after proper sensitivity testing in both the groups. All the selected cases were subjected to a thorough history taking, general, systemic and obstetrical examination. The dose of iron required in both the groups was calculated by the formula

Total iron required =Body weight (kg) X Hb deficit X 0.3 + (Body Wt.(kg) X10)

[Hb deficit=target Hb- patient`s Hb (Target Hb=11g/dl)]

In group A iron sucrose was given as 150 mg (3 ampoules, each of 2.5ml) in 100 ml of 0.9% normal saline infusion over 1 hr every third day up to the total calculated dose. In group B, iron sorbitol complex was given as a daily intramuscular injection of 1.5 ml till the total calculated dose, by means of 'Z' technique. All the cases were monitored for adverse effects. Adverse effects were graded as grade I and grade II. Grade I reactions were mild to moderate and settled with an antiallergic drug but not requiring discontinuation of drug. Grade II reaction was severe in nature threatening the life of patients and requiring discontinuation of therapy.

Statistical analysis:

Statistical analysis was carried out by using paired't' test for comparing effects of intravenous iron sucrose & intramuscular iron sorbitol before and after therapy. For comparisons between intravenous iron sucrose & intramuscular iron sorbitol 'unpaired t' test was applied.

RESULTS

Table 1: Demographic distribution of cases

	Group A (n=50)	**Group B (n=50)**
Mean age (years)	26.46	26.62
Mean period of gestation	24.48	23.94
Parity ≥2 (% of cases)	68	56
Socioeconomic status class IV or lower (%of cases)	76	80

Table 2: Hemoglobin level before starting therapy

Hemoglobin level (g/dl)	Group A		Group B	
	No.	%	No.	%
≤4	6	12	3	6
4.1-6	8	16	12	24
6.1-8	36	72	35	70
Mean	6.49		6.48	
P value	>0.05			

Table 3: Hemoglobin level 2 and 4 weeks after starting therapy

Hemoglobin level (g/dl)	After 2 weeks of therapy				After 4 weeks of therapy			
	Group A		Group B		Group A		Group B	
	No.	%	No.	%	No.	%	No.	%
5-7	7	14	12	24	-	-	5	10
7.1-9	16	32	33	66	9	18	21	42
9.1-11	27	52	5	10	39	78	24	48
>11	-	-	-	-	2	4	-	-
Mean	8.79		7.74		10.01		8.81	
P value	< 0.01				<0.01			

Table 4: Time period taken to achieve target hemoglobin level (≥11g/dl)

Time period (weeks)	Group A		Group B	
	No.	%	No.	%
2-4	3	6	-	-
>4-8	42	84	17	34
>8-12	5	10	28	56
>12	-	-	5	10
Mean	6.37		9.4	
P value	<0.01			

Table 5: Adverse effects in both the groups

Adverse effects (all grade I)	Group A		Group B	
	No.	%	No.	%
Local phlebitis	2	4	-	-
Shivering and weakness	1	2	-	-
Moderate abdominal pain	1	2	-	-
Local pain	-	-	6	12
Skin staining	-	-	6	12
Headache	-	-	1	2
Total	4	8	12	24

The mean pre therapy hemoglobin level in group A was 6.49 g/dl and in group B was 6.48 g/dl (Table 2). In group A, the mean hemoglobin level after 2 weeks of staring therapy was 8.79 g/dl with a rise of 2.33 g/dl. In group B, the mean hemoglobin level after 2 weeks of starting therapy was 7.74 g/dl with a rise of 1.26 g/dl(Table 3) the difference was statistically significant (P<0.01).

After 4 weeks of starting therapy, the mean hemoglobin level in group A was 10.01 g/dl with a rise of 3.52 g/dl and I group B mean hemoglobin was 8.81 g/dl with a total rise of 2.23g/dl from the pre therapy level (Table 3). The difference was statistically significant (P<0.01). In group A, 90% (45) cases achieved target hemoglobin level after 8 weeks of starting therapy, while in group B only 34% (17) cases achieved target hemoglobin levels after 8 weeks of therapy. The difference was statistically highly significant (P< 0.001).

The mean time period taken to achieve target hemoglobin level was 6.37 g/dl in group A and 9.04 weeks in group B (Table4). The difference was found to be statistically significant (P<0.01).

In group A, 8% (four) cases had grade I adverse effects: while in group B, 24% (12) cases had grade I adverse effects (Table5). The adverse effects were minimal and managed symptomatically. On statistically analyzing the results, the difference was found significant (P= 0.027).

In group A, 60% (30) cases were completely relieved of their clinical symptoms at 4 weeks after therapy: while in group B, only 20% (10) cases were completely relieved of their symptoms. The difference was statistically highly significant.

DISCUSSION

The current study was undertaken to evaluate the efficacy and safety of intravenous iron sucrose therapy for treating anemia during pregnancy and compare it with intramuscular iron sorbitol therapy. The rise in hemoglobin level in cases, which were given intravenous iron sucrose therapy, was 2.3 g/dl after 2 weeks and 3.52 g/dl after 4 weeks (table 3). It was significantly higher when compared to rise after intramuscular iron sorbitol therapy. The rise in hemoglobin level was 2.6 g/dl in intravenous group and 1.2 g/dl in intramuscular group after 3 weeks of therapy in the study by Hashmi et al.[5] In the study conducted by wali et al.[6] the rise in hemoglobin level was 2.8 g/dl after 3 weeks of intravenous iron sucrose therapy.

90% (45) cases achieved the target hemoglobin level of $\geq$11g/dl after 8 weeks of intravenous iron sucrose therapy, while only 34% (17) cases achieved target hemoglobin level after 8 weeks of intramuscular iron sorbitol therapy. The difference was statistically significant (p< 0.001). In the study by Hashmi et al.[6], 80% cases achieved target hemoglobin in intravenous iron group and only 20% cases achieved target hemoglobin level in intramuscular iron group after 6 weeks of therapy.

In our study, the mean time period taken to achieve the target hemoglobin level was 6.37 weeks in intravenous iron sucrose group and 9.04 weeks in intramuscular iron sorbitol group (Table 4) this difference was statistically significant (P<0.01). In the study by Raja et al.[8] the mean time period to achieve target hemoglobin level was 5 weeks in the intravenous iron sucrose group.

Only 8 % (four) cases had adverse effects which were of grade I type with intravenous iron sucrose therapy, while 24% (12)[9-12] cases had grade I adverse effect with intramuscular iron sorbitol therapy (Table 5). The difference was statistically significant (P= 0.027). There were no grade II adverse effects in either of the groups. In the study conducted by Wali et al.[7], 12% cases had grade I adverse effects, with intravenous iron sucrose therapy, while 50% cases had grade I adverse effects with intramuscular iron sorbitol therapy. In group A, 60% (30) cases were completely relieved of their symptoms: while in group B, only 20% (10) cases were completely

relieved of their symptoms. The difference was statistically significant (P<0.001). The results of our study shown that the mean hemoglobin level achieved in intravenous iron sucrose group was significantly higher and the rate of increase in hemoglobin level was also higher in intravenous group. The number of cases achieving target hemoglobin was significantly higher in intravenous group and also the target hemoglobin was achieved in a shorter time period in intravenous group. The incidence of adverse effects was also significantly lower in intravenous group.

CONCLUSION

Intravenous iron sucrose therapy is safe, convenient, more effective, and faster acting than intramuscular iron sorbitol therapy for the treatment of moderate to severe anemia during pregnancy.

REFERENCES

1. Fernando Arias, Shirish ND. Anemia in pregnancy. Text book of Obstetrics. 2010, 466-469
2. Allen LH. Pregnancy and iron deficiency: Unresolved Issues. Nutr Rev. 1997; 55; 91-101.
3. Bayoumeu F, Subiran-Buisset C, Baka NE. Iron therapy in iron deficiency anemia in pregnancy: intravenous route versus oral route. Am J Obstet Gyneco. 2002; 186; 518-22.
4. Kanani SJ, Poojara RH. Supplementation with iron & folic acid enhances growth. Jr Nutrition 2000; 130:452S-455S
5. Perewusny KG, Huck R, Huck A. Parenteral iron-sucrose complex. Br. J Nutr. 2002;88;3-10
6. Hashimi Z, Bashir G, Azzem P. Effectiveness of intra-venous iron sucrose complex versus intra-muscular iron sorbitol in iron deficiency anemia. Ann Pak Inst Med Sci. 2006;2;188-91.
7. Waili A, Mushtaq A. Comparative Study-efficacy. Safety and compliance of intravenous iron sucrose and intramuscular iron sorbitol in iron deficiency anemia of pregnancy. J Pak Med Assoc. 2002; 52; 392-95.
8. Raja KS, Janjua NB, Khokhar N. Intravenous iron Sucrose complex therapy in iron deficiency anemia in the pregnant women. Rawal Med J. 2003; 28; 40-3.
9. Sharma JB, Vibha Fatedar. Iron deficiency anemia in pregnancy. Obs & Gynae Today. 2006;9(3);147-148.
10. Pollitt E, Soemangri AG, Yunis F, cognitive effects of Iron deficiency anemia. Lancet 1985; 1:158.
11. Lazoff B, Jimenez E, Walf AW long term developmental out come of infants with iron deficiency. New Eng I J Med 1991; 325(10):687-95.
12. Abel R, Raja ratnamJ, Sapatkumar V. Anemia in pregnancy impact of iron, IEC, RUSHA Depatt Tamilnadu: CMC Vellore 1999.