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A COMPARATIVE STUDY TO DETERMINE THE SAFETY AND EFFICACY OF INTRAVENOUS IRON SUCROSE AND INTRAMUSCULAR IRON SORBITOL THERAPY FOR IRON DEFICIENCY ANEMIA DURING PREGNANCY

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ABSTRACT

Aims and Objectives: To compare the safety, efficacy and rate of response of intravenous iron sucrose and intramuscular iron sorbitol therapy for anemia during pregnancy. Material and Methods:In this prospective study about 100 antenatal cases of gestational age 14–32 weeks were included. Cases were randomly divided into two groups. Group A, having 50 antenatal cases who received IV iron sucrose, and 50 antenatal cases in Group B who received IM iron sorbitol. Response to therapy in both groups were also studied and compared. Results: The mean hemoglobin (Hb) before therapy in group A was 6.49 g/dL and in group B was 6.47 g/dL. The increase in Hb after 4 weeks of starting therapy was 3.61 g/dL in group A and 2.36 g/dL in group B. The difference was statistically significant ($P<0.01$). The mean time taken to achieve target Hb (11 g/dL) was 6.42 weeks in group A and 9.09 weeks in group B. In group A, 10% (Five) cases had grade I adverse effects. In group B, 20% (10) cases had grade I adverse effects. The difference was statistically significant ($P = 0.025$). No case were discontinued the therapy in both the groups. Conclusion: IV iron sucrose is safe, convenient and also more effective, faster acting therapy than IM iron sorbitol therapy in treating moderate to severe anemia during pregnancy.

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

INTRODUCTION

Anemia is estimated to affect nearly 2/3rd of the pregnant women in developing countries like India and iron deficiency anemia accounts for 95 % those cases. In pregnant women, iron deficiency anemia is one of most common nutritional pathology [1]. Among them, nearly 45 % of pregnant women suffer from moderate to severe anemia. Anemia is linked with high perinatal morbidity and mortality. Over the past years, a range of usual methods like oral iron therapy, intramuscular iron therapy, and blood transfusion were used in the treatment of anemia during pregnancy [2]. There are certain conditions in which these typical 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 [3]. So, to treat these conditions, it is necessitate finding a relatively new mode of iron therapy with better efficacy, least side effects, faster action, and better compliance. Intravenous iron sucrose therapy appears to be a safe, convenient, and

more effective treatment for anemia during pregnancy.

MATERIALS AND METHODS

Total of 100 antenatal women between 14 and 32 weeks of gestation with hemoglobin level of 8 g/dL or less, serum iron less than 60 µg/dL, and total iron-binding capacity more than 400 µg/dL who were attending the outpatient department and antenatal wards were included in the current study.

The cases having hemoglobin level > 8 g/dL, gestational age <14 or >32 weeks, normal serum iron levels, history of allergic reaction to previous iron therapy, and anemia due to causes other than iron deficiency were excluded from the study.

All the 100 cases enrolled in the study were assigned into two groups ie., Group A including 50 cases who received IV iron sucrose and Group B including 50 cases who received IM iron sorbitol therapy. After proper sensitivity testing in both the groups, Iron was given. All the selected cases were subjected to a thorough history, general, systemic, and obstetrical assessment. The dose of iron required in both the groups was calculated using the formula.

Total iron required = Body weight (kg) x Hb deficit x 0.3 + (Body Wt. (kg) x 10)

Hb deficit = Target Hb - Patient's Hb x (Target Hb =11 g/dL)

In group A, iron sucrose was given as 150 mg in 100 ml of 0.9 % normal saline infusion over 1 h every third day up to the total dose calculated, Where as in group B, iron sorbitol complex was given as daily intramuscular injection of 1.5 ml till 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 therapy. Grade II reaction was severe in nature, life threatening and often requires discontinuation of therapy.

RESULTS

Both the groups were equivalent for age, parity, socioeconomic status, and period of gestation (Table 1). The mean pretherapy hemoglobin level in group A was 6.49 g/dL and in group B was 6.47 g/dL (Table 2). In group A, the mean hemoglobin level after 2 weeks of starting therapy was 8.92 g/dL with a rise of 2.43 g/dL. In group B, the mean hemoglobin level after 2 weeks of starting therapy was 7.75 g/dL with a rise of 1.28 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 10.1 g/dl with a rise of 3.61 g/dL and in group B mean hemoglobin was 8.83 gm/dl with a total rise of 2.36 g/dL from the pretherapy level (Table 3). The difference was statistically significant (P<0.01). In group A, 86% (43) cases achieved target hemoglobin level after 8 weeks of starting therapy, while in group B only 30 % (15) cases achieved target hemoglobin levels after 8 weeks of therapy. The difference was statistically highly significant (P<0.001).

The mean time taken to achieve target Hb (11 g/dL) was 6.42 weeks in group A and 9.09 weeks in group B (Table 4). The difference was statistically significant (P <0.01). In group A, 10% (Five) cases had grade I adverse effects. In group B, 20% (10) cases had grade I adverse effects (Table 5). The adverse effects were nominal and managed symptomatically. On statistically analyzing the results, the difference was statistically significant (P = 0.025). In group A, 76 % (38) cases were completely relieved of their clinical symptoms at 4 weeks after therapy; while in group B, only 24 % (12) cases were completely relieved of their symptoms. The difference was statistically highly significant. No case were discontinued the therapy in both the groups.

Table 1. Demographic Distribution of Cases

Groups	Group A (n=50)	Group B (n=50)
Mean age (years)	26.64	26.58
Mean period of gestation (weeks)	24.28	23.98
Parity ≥2 (% of cases)	66	54
Socioeconomic status class IV or lower (% of cases)	72	78

Table 2. Hemoglobin level before starting therapy

Hemoglobin level (gm/dl)	Group A (n=50)		Group B (n=50)	
	No.	%	No.	%
≤4	7	14	3	6
4.1 – 6	9	18	13	26
6.1 – 8	34	68	34	68
Mean	6.49 g/dL		6.47 g/dL	
P Value	> 0.05			

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

Hemoglobin level (gm/dl)	After 2 weeks of therapy				After 4 weeks of therapy			
	Group A (n=50)		Group B (n=50)		Group A (n=50)		Group B (n=50)	
	No.	%	No.	%	No.	%	No.	%
5-7	8	16	13	26	-	-	6	12
7.1– 9	15	30	34	68	10	20	20	40
9.1 – 11	27	54	3	6	38	76	24	48
> 11	-	-	-	-	2	4	-	-
Mean	8.92 g/dL		7.75 g/dL		10.1 g/dL		8.83 g/dL	
P Value	< 0.01				< 0.01			

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

Time period (weeks)	Group A (n=50)		Group B (n=50)	
	No.	%	No.	%
2-4	3	6	-	-
> 4 – 8	41	82	16	32
> 8 – 12	6	12	29	58
> 12	-	-	5	10
Mean	6.42		9.09	
P Value	< 0.01			

Table 5 Adverse effects in both the groups

Adverse effects (all grade I)	Group A (n=50)		Group B (n=50)	
	No.	%	No.	%
Local phlebitis	3	6	-	-
Shivering and weakness	1	2	-	-
Moderate abdominal pain	1	2	-	-
Local pain	-	-	7	14
Skin staining	-	-	2	4
Headache	-	-	1	2
Total	5	10	10	20

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 who were given intravenous iron sucrose therapy was significantly higher when compared to rise after intramuscular iron sorbitol therapy. Similar result is also obtained after 3 weeks of therapy in the study by Hashmi *et al.*, [4]. In the study conducted by Wali *et al.*, [5], the rise in hemoglobin level was 2.8 g/dL after 3 weeks of intravenous iron sucrose therapy. In the study by Raja *et al.*, [6], the mean time period to achieve target hemoglobin level was 5 weeks in the intravenous iron sucrose group. In our study, the mean time period taken to achieve the target hemoglobin level was 6.42 weeks in intravenous iron sucrose group and 9.09 weeks in intramuscular iron sorbitol group (Table 4). This difference was statistically significant (P<0.01) [7].

In group A, 86% cases achieved target hemoglobin level after 8 weeks of starting therapy, while in group B only 30 % (15) cases achieved target hemoglobin levels after 8 weeks of therapy. The difference was statistically significant (P<0.001). In the study by Hashmi *et al.*,[8], 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 [9]. The results of our study show that the mean hemoglobin level achieved in IV iron sucrose group was significantly higher and the rate of increase in hemoglobin level was also higher in IV group. The number of cases achieving target hemoglobin was significantly higher in IV group and also the target hemoglobin was achieved in a shorter time period in IV group. The incidence of adverse effects was also significantly lower in IV group [10-29].

CONCLUSION

Intravenous iron sucrose therapy is comparatively safe, convenient, more effective, and faster acting with that of Intramuscular iron sorbitol therapy in the treatment of moderate to severe anemia during pregnancy.

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