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Original Research Article

Efficacy, Safety and Compliance of Intravenous Iron Sucrose and Intramuscular Iron Sorbitol in Iron Deficiency Anaemia of Pregnancy: A Comparative Study

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Abstract

Background: In developing nations, anaemia is thought to affect approximately two-thirds of expectant mothers, with iron deficiency anaemia accounting for 95% of cases. In pregnant women, it is the most prevalent nutritional disorder. Among them, about 45 % of pregnant women suffer from moderate to severe anaemia. High prenatal morbidity and death are linked to anaemia. This study compares intravenous iron sucrose and intramuscular iron Sorbitol treatments for anaemia during pregnancy in terms of their effectiveness, safety, and rate of response.

Methods: In this prospective investigation, 50 prenatal cases with gestational ages ranging from 16 to 32 weeks were examined. The cases were split into two groups at random. A total of 25 patients were treated in group A with intravenous iron sucrose, while a total of 25 cases were treated with intramuscular iron sorbitol. Both groups' responses to therapy were investigated and contrasted.

Results: In group A, the mean pretherapy haemoglobin was 6.49 g/dl, while in group B, it was 6.48 g/dl. Hemoglobin levels increased by 3.52 g/dl in group A and 2.33 g/dl in group B after 4 weeks after starting treatment. Statistically significant ($P<0.01$) difference existed. In group A it took an average of 6.37 weeks, whereas in group B it took an average of 9.04 weeks to reach the target haemoglobin (>11 g/dl). 8% (2) of the cases in group A exhibited grade 1 negative effects. 24% (6) of the patients in group B had grade 1 negative effects. ($P=0.027$) The difference was statistically significant. In neither group did anyone stop their therapy.

Conclusion: For the treatment of moderate to severe anaemia during pregnancy, intravenous iron sucrose is a safe, practical, more efficient, and quicker acting therapy than intramuscular iron sorbitol therapy.

Keywords: Iron Sucrose, Iron Sorbitol, Pregnancy, Iron Deficiency.

Introduction

Higher prenatal mortality and morbidity are linked to anemia1. The most frequent hematologic disorder identified during pregnancy is anaemia. Most frequently, iron shortage is the culprit, although occasionally, more complicated diseases involving inadequate erythrocyte synthesis or fast erythrocyte decomposition are to blame [1]. Almost two thirds of expectant mothers in underdeveloped nations have anaemia, with iron deficiency anaemia accounting for 95% of cases [2].

Blood transfusions and injectable iron therapy are a few common treatments for anaemia during pregnancy that have been employed over the years [3,4]. Inadequate gastrointestinal absorption, late pregnancy, resistance to necessary oral iron, need for an emergency supplement, and severe anaemia with contraindications to blood transfusions are a few instances in which these traditional iron therapies are not beneficial [5].

Hence, a relatively new form of iron therapy that has superior efficacy, fewer side effects, quick action, and improved compliance is needed to treat these disorders. Anemia during pregnancy may be treated more successfully and safely with intravenous iron-sucrose therapy.

Material and Methods

50 antenatal women between the ages of 16 and 32 weeks of gestation with haemoglobin levels of 8 g/dl or less who were attending the outpatient department (Obstetrics and Gynecology) and antenatal ward (MCH) at Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, from the study period of three months were included in the present study after receiving approval from the institutional ethics committee of SKMCH, Muzaffarpur, Bihar.

Pregnant women age ≥18, gestational weeks 16 to 32, baseline results from normal antenatal screening tests, willingness to sign a consent form, and iron deficiency anaemia, defined as Hb concentration ≤8 g/dl, serum iron less than 60 micro g/dl, and total iron-binding capacity greater than 400 micro g/dl, were the inclusion criteria for this study. Cases with haemoglobin levels >8 g/dl, gestational ages <16 or >32 weeks, a history of an adverse reaction to prior iron therapy, and anaemia caused by factors other than iron deficiency were excluded from this investigation.

Each of the 50 study participants' cases was divided into two groups. Iron sucrose was administered intravenously to 25 instances in Group A, and iron sorbitol was administered intramuscularly to 25 cases in Group B. Following thorough sensitivity testing in both groups, iron was administered. A complete history taking, general, systemic, and obstetrical examination were performed on each of the chosen cases.

The dose of iron required in both the groups was calculated by the formula

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

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

In group A, iron sucrose was administered as a 150 mg (3 ampoules, each containing 2.5 ml) infusion over an hour every third day until the prescribed amount was reached. By using the "Z" approach, daily intramuscular injections of 1.5 ml of iron sorbitol complex were administered to group B until the prescribed total dose. We kept an eye out for any negative impacts in every situation. Grade I and II were assigned to negative consequences. Grade I responses were mild to moderate and could be treated with an antiallergic medication without stopping the medication altogether. The severity of the grade II reaction necessitated stopping the

patient's therapy and put their lives in danger. To compare the effects of intravenous iron sucrose and intramuscular iron sorbitol before and after therapy, statistical analysis was done using the paired t test. The "unpaired t" test was used to compare intravenous iron sucrose with intramuscular iron sorbito

Results

Table 1: Demographic distribution of cases

	Group A (n=25)	Group B (n=25)
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	3	12%	2	8%
4.1-6	4	16%	6	24%
6.1-8	18	72%	17	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	4	16%	6	24%	-	-	3	12%
7.1-9	8	32%	16	64%	5	20%	10	40%
9.1-11	13	52%	3	12%	19	76%	12	48%
>11	-	-	-	-	1	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	2	8%	-	-
>4-8	21	84%	9	36%
>8-12	2	8%	14	56%
>12	-	-	2	8%
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	1	4%	-	-
Shivering and weakness	1	4%	-	-
Moderate abdominal pain	0	0	-	-
Local pain	-	-	3	12%
Skin staining	-	-	3	12%
Headache	-	-	-	-
Total	2	8%	6	24%

The mean pre-treatment haemoglobin levels in groups A and B were 6.49 g/dl and 6.48 g/dl, respectively (Table 2). After two weeks after starting medication, the mean haemoglobin level in group A was 8.79 g/dl, an increase of 2.33 g/dl. After two weeks of beginning treatment, the mean haemoglobin level in group B was 7.74 g/dl, up 1.26 g/dl (Table 3). This difference was statistically significant (P <0.01). After beginning treatment, group A's mean haemoglobin level increased by 3.52 g/dl to 10.01 g/dlwhile group B mean haemoglobin increased by 2.23 g/dl to 8.81 g/dl from its pre-therapy level (Table 3).

A statistically significant difference existed (P<0.01). After 8 weeks of medication, 92% (23) of the cases in group A had reached their goal haemoglobin levels, but only 36% (9) of the cases in group B had done so. In terms of statistics, the difference was quite significant (P <0.001).

In group A, it took an average of 6.37 g/dl time to reach the desired haemoglobin level, while in group B, it took an average of 9.04 weeks (Table4). It was determined that the difference was statistically significant (P <0.01). Grade I adverse effects occurred in 8% (2) of the cases in group A, while they occurred in 24% (6) of the cases in group B. (Table5). The negative effects were minor and symptomatically controlled. After the data were statistically analysed, the difference was shown to be significant (P=0.027).

At 4 weeks after therapy, 60% (15) of the individuals in group A had fully recovered from their clinical symptoms, compared to 20% (5) of the cases in group B. Statistics showed that the difference was very significant.

Discussion

The goal of the current study was to compare intramuscular iron sorbitol therapy with intravenous iron sucrose therapy to see which was more effective and safer for treating anaemia during pregnancy. After two weeks and four weeks, subjects receiving intravenous iron sucrose treatment saw an increase in haemoglobin of 2.3 g/dl and 3.52 g/dl, respectively (table 3).

When compared to the rise with intramuscular iron sorbitol treatment, it was noticeably higher. In the study by Hashmi *et al*., the increase in haemoglobin level was 2.6 g/dl in the intravenous group and 1.2 g/dl in the intramuscular group after 3 weeks of therapy [6] After 3 weeks of intravenous iron sucrose therapy, the haemoglobin level increased by 2.8 g/dl in the study by Wali *et al* [7]. After 8 weeks of intravenous iron sucrose therapy, 92% (23) of the cases reached the desired haemoglobin level of >11 g/dl while only 36% (9) of the cases did the same after 8 weeks of intramuscular iron

sorbitol therapy. Statistics showed that the difference was substantial (p <0.001).

In the trial by Hashmi *et al* [6]. after 6 weeks of therapy, 80% of cases in the intravenous iron group and only 20% of cases in the intramuscular iron group reached the goal haemoglobin level. The average amount of time needed in our study to reach the desired haemoglobin level was 6.37 weeks for intravenous iron sucrose and 9.04 weeks for intramuscular iron sorbitol (Table 4); this difference was statistically significant (P <0.01). In the Raja *et al* [8] trial, the intravenous iron sucrose group required an average of 5 weeks to reach their target haemoglobin level.

Just 8% (2) of individuals receiving intravenous iron sucrose therapy experienced grade I side effects, compared to 24% (6) 9-12 cases receiving intramuscular iron sorbitol therapy (Table 5). (P=0.027) The difference was statistically significant. In neither of the groups, there were any grade II negative effects. In the study by Wali *et al* [7] grade I adverse effects occurred in 12% of individuals treated with intravenous iron sucrose therapy and 50% of cases treated with intramuscular iron sorbitol therapy. Only 20% (5) of the cases in group B had fully recovered from their symptoms, compared to 60% (15) of the cases in group A. Statistics showed that the difference was substantial (P <0.001).

According to the findings of our study, the mean haemoglobin level attained by the intravenous iron sucrose group was significantly greater, and the rate at which it increased was also higher. In the intravenous group, both the number of instances obtaining the goal haemoglobin and the time it took to reach the target haemoglobin were both noticeably higher. Additionally, the intravenous group experienced much less negative effects.

Conclusion

For the treatment of moderate to severe anaemia during pregnancy, intravenous iron sucrose therapy is safer, more practical, more successful, and quicker acting than intramuscular iron sorbitol therapy.

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