SHORT COMMUNICATION

Comparison of the Efficacy of Intravenous Iron Sucrose and Intramuscular Iron Sorbitol in Iron Deficiency Anemia of Pregnancy: A Prospective Comparative Study

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ABSTRACT

Objective: To compare the effectiveness of parenteral iron sucrose and iron sorbitol in iron deficiency anemia of pregnancy.

Study Design: Prospective comparative study.

Place and Duration of Study: This study was conducted at the Department of Obstetrics and Gynecology, Combined Military Hospital (CMH), Bahawalpur, Pakistan, from 1st September 2023 to 29th February 2024.

Methods: A total of 120 females having iron deficiency anemia of pregnancy, 18 to 40 years of age, were included. Group A was given intravenous iron sucrose daily for 3 weeks, whereas Group B administered intramuscular iron sorbitol in partial doses over 96 hours (i.e., 75 mg 24-hourly) for 21 days. All cases were tracked for 21 days, and effectiveness was documented.

Results: The average age of females in group A was 25.13 ± 4.32 years, and in group B, 24.57 ± 4.93 years. Gestational age ranged from 12 to 28 weeks, with a mean of 23.08 ± 3.66 weeks. Efficacy (in terms of rise in hemoglobin >2.5 g/dl and plasma stored iron ≥15 µg/L at the end of 3 weeks of therapy) was seen in 46 (76.67%) females in group A (intravenous iron) and in 24 (40.0%) females in group B (intramuscular iron) with a *P*-value of 0.0001.

Conclusion: The present research determined that the effectiveness of intravenous iron sucrose is consistently greater than that of intramuscular iron sorbitol in anemia of pregnancy.

Keywords: *Anemia, Gestation, Iron, Parenteral.*

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Introduction

Low hemoglobin progresses once plasma is sufficiently deficient in hemoglobin. Low hemoglobin is the most frequently encountered health condition during gestation. Low hemoglobin is one of the delayed conditions of iron deficiency; therefore, the occurrence of iron deficiency is two and a half times that of low hemoglobin.[1] As per the World Health Organization, the occurrence of low hemoglobin is approximately 18 % in advanced nations and around 56% in developing nations.[2] An important factor of harmless maternity is obliteration of low hemoglobin.[3] Bodily and intellectual debilities might affect the offspring of iron-deficient women with low hemoglobin. Low hemoglobin anemia in gestation might be a consequence of increased requirement, decreased nutrition consumption, prenatal health, rapidly developing pregnancies with brief intervals, young gestation, recurrent fetal losses, and multiple gestations.[4]

The chief reason for low hemoglobin during gestation is due to iron deficiency, approximately 95%.[5], which ultimately results in greater gestational injury and death, and also results in greater newborn deaths.[6] Few studies demonstrated that modern

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intravenous iron formulation, iron sucrose, is harmless and effective for managing low hemoglobin and might be given prior to a trial dosage.[6,7] In a study, no significant difference was found in the effectiveness of intravenous and intramuscular iron treatment.[8] In his research, Gaikwad HS A et al. showed the effectiveness of intravenous iron sucrose treatment as 70% compared to 27% of intramuscular iron sorbitol citric acid.[9] One more study, Subhadra S et al., showed the effectiveness of intravenous iron sucrose treatment as 92% compared to 76% of intramuscular iron sorbitol citric acid, which is statistically significant.[10]

It is seen that in our society, anemia in pregnancy is very common due to unawareness and poverty, which hinders the proper dietary intake during pregnancy. A local study has shown the overall prevalence rate of anemia in pregnancy as 75%.[11] In another study, the frequency of anemia in pregnant women was calculated to be 57%.[12] The study compares the efficacy of two intravenous iron formulations, i.e., iron sucrose complex and iron sorbitol citric acid, in low hemoglobin correction in the local population, so that our population can be provided with better preparation for anemia correction during pregnancy in order to decrease maternal and fetal consequences. At present, both preparations are used in our population, but the best among these two has not been evaluated previously, which is why I have planned this study.

Methods

This prospective comparative study was conducted at the Department of Obstetrics and Gynecology, Combined Military Hospital (CMH), Bahawalpur, Pakistan, from 1st September 2023 to 29th February 2024. Approval from the Ethical Committee of the hospital has been obtained with serial number: 89, dated 18th August 2023. The size of the sample was calculated using the WHO calculator. Informed consent has been obtained in accordance with the hospital's defined protocols. Initially, a total of 60 females, i.e., 30 in each group, were included in this research, with a 95% confidence level, 90% power, and assuming an efficacy of intravenous iron sucrose therapy of 70% compared to 27% for intramuscular iron sorbitol citric acid. But we included 120 patients, with 60 females in each respective group. Non-probability, consecutive sampling techniques were used in this research. Females with low hemoglobin during pregnancy, Singleton pregnancy (assessed on ultrasonography), Gestational age 12-28 weeks (evaluated by Last Menstrual Period), females from 18-40 years, and Para 0-5 were included in this research. While females having unembellished low hemoglobin (Hb <5 g/dl), Several gestations (assessed on ultrasonography), Women with chronic kidney disease (evaluated by previous documentations and serum creatinine >1.5 mg/dl), Women with continuing hepatic disorder (evaluated by previous records and serum bilirubin >2.0 mg/dl), Patients with intolerance to iron derivatives and Patients who had missing track report remained omitted in this research.

Overall, 120 gravid women were reported at the Department of Obstetrics and Gynecology of the Combined Military Hospital (CMH), Bahawalpur, who met the inclusion criteria. Group A was given intravenous iron sucrose as a rapid intravenous preparation completed in thirty minutes daily for 3 weeks, whereas Group B was administered intramuscular iron sorbitol in separate dosages over 96 hours (i.e., 75 mg in 24 hours) for 21 days. All cases were tracked for 21 days, and effectiveness was documented. Patients whose misplaced track reports were omitted from this research.

Numerical analysis was conducted using SPSS version 20.0. The mean and SD were calculated for age, gestational age, and pre- and post-therapy hemoglobin levels. Occurrence and fraction were considered as per residence (rural/urban), parity, monthly income (<20000/200001-40000/>40000), education level (illiterate/primary/middle/matric/graduate), and effectiveness (yes/no). Chi-Square remained appropriate for comparing effectiveness between the two groups. *P*-value ≤0.05 will be measured as substantial.

Result transformers like age, gestational age, number of children, place of living (rural/urban), monthly income (<20000/200001-40000/>40000), education level (illiterate/primary/middle/matric/graduate), and pre-therapy hemoglobin levels were measured by stratifications, and post-stratification chi-square remained pragmatic for comparability the effectiveness, and *P*-value ≤0.05 remained substantial.

Table 1: Categorization by age and gestational age (N=120)

Variable	Category	Group A (N=60)		Group B (N=60)		Total (N=120)	
		No of Females	% age	No of Females	% age	No of Females	% age
Age (years)	18-30	52	86.67	52	86.67	104	86.67
	31-40	08	13.33	08	13.33	16	13.33
	Mean ± SD	25.13 ± 4.32		24.57 ± 4.93		24.77 ± 4.74	
Gestational age (weeks)	12-22	24	40.00	26	43.33	50	42.67
	23-28	36	60.00	34	56.67	70	58.33
	Mean ± SD	23.30 ± 3.48		22.87 ± 3.82		23.08 ± 3.66	

Table 2: Distribution of patients according to parity and pre-therapy hemoglobin levels

Variable	Category	Group A (N=60)		Group B (N=60)		Total (N=120)	
		Frequency	%	Frequency	%	Frequency	%
Parity	1	22	36.67	24	40.00	46	38.33
	2	38	63.33	36	60.00	74	61.67
	Mean ± SD	3.00 ± 1.25		2.97 ± 1.18		2.98 ± 1.21	
Hb level	< 7 g/dL	16	26.67	20	33.33	36	30.00
	≥ 7 to < 10 g/dL	44	73.33	40	66.67	84	70.00
	Mean ± SD (g/dL)	7.85 ± 1.28		7.61 ± 1.03		7.73 ± 1.17	

Table 3: Stratification of effectiveness in relation to gestational age -- Stratification of effectiveness in relation to age and parity

Variable	Category	Group A (N=60)		Group B (N=60)	
		Effective	Not Effective	Effective	Not Effective
Age (years)	18–30	30	22	20	32
	31–40	6	2	4	4
Gestational age (weeks)	12–22	20	4	10	16
	23–28	26	10	14	20
Parity	0–2	18	4	10	14
	3–5	28	10	14	22

Results

Patient ages ranged from 18 to 40 years, with an average of 24.77 ± 4.74 years. The average age of females in group A was 25.13 ± 4.32 years, and in group B, 24.57 ± 4.93 years. Overall, 104 (86.67%) patients were from 18 to 30 years.

Gestational age ranged from 12 to 28 weeks, with a mean of 23.08 ± 3.66 weeks. The average gestational age in group A was 23.30 ± 3.48 weeks, and in group B was 22.87 ± 3.82 weeks, as shown in Table 1.

The average parity in group A was 3.0 ± 1.25, and in group B was 2.97 ± 1.18, as shown in Table 2. The mean pre-therapy hemoglobin levels in group A were 7.85 ± 1.28 g/dl, and in group B were 7.61 ± 1.03 g/dl, as shown in Table 2. The average post-therapy hemoglobin levels in group A were 10.42 ± 1.29 g/dl, and in group B were 9.56 ± 1.18 g/dl.

Efficacy (in terms of rise in hemoglobin >2.5 g/dl and plasma stored iron ≥15 µg/L at the end of 3 weeks of therapy) was seen in 46 (76.67%) females in group A (intravenous iron) and in 24 (40.0%) females in group B (intramuscular iron), with a *P*-value of 0.0001. Stratification of efficacy by age and gestational age is presented in Table 3.

Discussion

Treatment of iron-deficiency low hemoglobin comprises tablet iron, intravenous iron, and recombinant erythropoietin. Tablet iron treatment inadequately raises the Hb levels and is associated with poor response rates in moderate anemia. While an attempt to increase the dose results in more side effects and reduced compliance, it also increases gut motility, thereby reducing iron absorption. Hence, oral iron treatment is not an authentic option for

management of moderate-to-low hemoglobin conditions.[13,14]

Latest research recommended intramuscular iron sorbitol citric acid complex (ISCA) as the primary drug in managing iron-deficient anemia during gestation. The main drawbacks are redness and edema at the injection site, the need for incremental doses due to rapid clearance, and the necessity for frequent repeat therapies.[15,16] The modern parenteral formulation, iron sucrose, is very efficient owing to its effect in releasing elemental iron slowly from the complex and has a lower rate of renal excretion. It also has a favorable safety profile as it causes fewer anaphylactic reactions and tissue injury.[17]

In this study, the mean age was 24.77 ± 4.74 years, with the majority of cases (86.67%) being from 18 to 30 years of age. It is very similar to research conducted by Wali A et al. and Dhanani JV et al., which reported average ages of 25 and 23 years, respectively.[18,19] Neeru S et al. reported an average age of 29 years in their study, compared with our study.[20] On the other hand, Christoph P et al. and Vijayasree M reported much larger mean ages of 29 and 32 years, respectively.[21,22]

The mean gestational age in the parenteral iron group was 23.30 ± 3.48 weeks, and in the intramuscular iron group, it was 22.87 ± 3.82 weeks in our study, which was similar to the findings of Dhanani JV et al., who reported an average gestational age of 23 weeks in both groups. Similarly, Neeru S et al.showed a mean age of 23 weeks in their study. Besides that, Wali A et al. and Christoph P et al. have reported mean gestational ages larger than in our study, i.e., 27 and 30 weeks, respectively.[23] In our study, the majority of patients presented were multigravida. All these data have similarities with the research of Dhanani JV et al., who reported an increased occurrence of iron-deficient low hemoglobin in multigravida females, but contrary to these findings, Neeru S et al. have shown that the majority of primigravida women.[24]

The efficacy (in terms of rise in hemoglobin >2.5 g/dl and plasma stored iron ≥15 µg/L at the end of 3 weeks of therapy) was seen in 46 (76.67%) females in group A (intravenous iron) and in 24 (40.0%) females in group B (intramuscular iron) with a p-value of 0.0001. According to another study, no significant difference was found between parenteral and intramuscular treatments. In his research, Gaikwad HS A et al. have shown the effectiveness of parenteral iron sucrose treatment as 70% compared to 27% of intramuscular iron sorbitol citric acid.[25] During research, Subhadra S et al. showed the effectiveness of parenteral iron sucrose treatment as 92% compared to 76% of intramuscular iron sorbitol citric acid, which is statistically significant.

The selection of patients as per the inclusion and exclusion criteria is the major limitation of this study. In the future, this study can be extended to include additional variables to better understand the topic.

Conclusion

The present research shows that intravenous iron sucrose is more effective than intramuscular iron sorbitol in the low-hemoglobin condition of pregnancy. We recommend intravenous iron sucrose as first-line therapy in our routine practice for treating iron-deficiency anemia during pregnancy.

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Conflict of Interest: The authors declare no conflict of interest

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ZN: Writing the original draft, proofreading, and approval for final submission
F: Conception and design of the work, and approval for final submission
NN: Manuscript writing for methodology design, investigation, and approval for final submission
KA: Validation of data, interpretation, write-up of results, and approval for final submission
RG: Revising, editing, supervising for intellectual content, and approval for final submission
ZN is the nominated guarantor and takes full responsibility for the overall content and integrity of the work