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Safety, Efficacy, And Compliance of Intravenous Iron Sucrose in Moderate-To-Severe Iron Deficiency Anemia in Pregnancy: A Prospective Study

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ABSTRACT

Background: Iron deficiency anemia (IDA) affects 35-75% of pregnant women in developing countries like India, contributing to significant maternal and fetal morbidity. Intravenous (IV) iron sucrose offers a promising alternative to oral iron and blood transfusions for managing moderate to severe IDA in pregnancy, with potential for improved efficacy and safety.

Objective: To evaluate the safety, efficacy, and compliance of IV iron sucrose in treating moderate to severe IDA (hemoglobin [Hb] 6-9 g/dL) in pregnant women at 20-28 weeks of gestation.

Methods: A prospective observational study was conducted enrolling 112 pregnant women aged 18-38 years with IDA. After excluding 8 for co-existing diseases and 4 for loss to follow-up, 100 women received IV iron sucrose (dose calculated via Ganzoni equation, administered in 3-5 infusions over 1-2 weeks). Hematological parameters (Hb, mean corpuscular volume [MCV], mean corpuscular hemoglobin concentration [MCHC], hematocrit [HCT]) were assessed at baseline and at 3, 6, and 9 weeks. Secondary outcomes included side effects, compliance, and fetal outcomes (birth weight, preterm delivery, mode of delivery, neonatal ICU [N-ICU] admission, blood transfusion need). Statistical analyses included ANOVA and chi-square tests ($p < 0.05$ significant).

Results: Baseline mean Hb (7.70 g/dL) increased to 10.09 g/dL at 3 weeks, 10.86 g/dL at 6 weeks, and 11.29 g/dL at 9 weeks ($p < 0.05$ for gravida differences at 6 and 9 weeks). MCV rose from 65.71 fL to 81.80 fL, MCHC from 30.80 g/dL to 33.99 g/dL, and HCT from 24.99% to 33.25% by 9 weeks, with maximal improvements by week 3. Rural (59%) and non-educated (39%) women had lower baseline values but comparable endpoint improvements. Only 10% experienced minor side effects (6 chills/rigors, 4 thrombophlebitis), with no anaphylaxis. Compliance was high (89.3% retention). Mean birth weight was 2.91 kg; 3 preterm deliveries occurred ($p = 0.034$ for gravida association), 19 cesarean sections ($p = 0.075$), 6 N-ICU admissions ($p = 0.125$), and 4 blood transfusions ($p = 0.000$).

Conclusion: IV iron sucrose is a safe, effective, and well-tolerated treatment for moderate to severe IDA in pregnancy, rapidly improving hematological parameters and reducing adverse maternal and fetal outcomes. Its high compliance makes it suitable for high-risk populations, supporting its integration into clinical practice in resource-limited settings.

Keywords:*Iron deficiency anemia, intravenous iron sucrose, pregnancy, hemoglobin, maternal outcomes, fetal outcomes, safety, efficacy, compliance.*

INTRODUCTION

Iron deficiency anemia (IDA) remains a significant global public health challenge, particularly in developing countries, where it affects 35-75% of pregnant women, with an average prevalence of 56% in India. In contrast, developed nations

report a prevalence of 25-30% [1]. IDA in pregnancy is associated with severe maternal and fetal complications, contributing to approximately 20% of maternal deaths and 9% of perinatal mortality through risks such as preterm delivery, intrauterine growth restriction (IUGR), postpartum hemorrhage (PPH), lactation failure, and increased susceptibility to infections [2]. The total iron requirement during pregnancy is approximately 1000 mg, with 500 mg needed for fetal and placental development and another 500 mg for red blood cell increment [3]. While women with adequate iron stores can meet this demand, those with depleted reserves—common in Indian populations due to nutritional deficiencies—require supplementation to prevent or treat anemia.

Traditional treatments for IDA, such as oral iron and blood transfusions, have significant limitations. Oral iron often causes gastrointestinal side effects, leading to poor compliance, while transfusions carry risks of infections and immune reactions, limiting their use to life-threatening cases [4]. Intravenous (IV) iron, particularly second-generation formulations like iron sucrose, offers a promising alternative by bypassing hepcidin-mediated absorption barriers, enabling direct iron delivery to transferrin and macrophages [5]. Compared to oral iron, IV iron sucrose has shown superior efficacy and tolerability in managing IDA, with fewer adverse effects than older iron dextran formulations [6].

This prospective observational study, conducted at the Department of Obstetrics and Gynecology, R.N.T. Medical College and Associated Group of Hospitals, Udaipur, India, aimed to evaluate the safety, efficacy, and compliance of IV iron sucrose in treating moderate to severe IDA (hemoglobin 6-9 g/dL) in pregnant women at 20-28 weeks of gestation. By assessing hematological parameters (hemoglobin, mean corpuscular volume, mean corpuscular hemoglobin concentration, and hematocrit), side effects, and fetal outcomes (birth weight, preterm delivery, neonatal ICU admission), the study sought to provide evidence for IV iron sucrose as a viable intervention to improve maternal and perinatal outcomes in a high-risk population. Given the high burden of IDA in India, particularly among rural and less-educated women, this study addresses a critical need for effective and safe anemia management strategies in pregnancy.

METHODS

Study Design: This was a prospective hospital-based observational study designed to evaluate the safety, efficacy, and compliance of intravenous iron sucrose supplementation in treating moderate to severe iron deficiency anemia (IDA) in pregnancy. Key elements include enrollment of eligible pregnant women, administration of calculated doses of intravenous iron sucrose, and follow-up assessments of hematological parameters and outcomes at 3-week intervals up to 9 weeks, with continued monitoring until delivery.

Study Setting: The study was conducted in the Department of Obstetrics and Gynecology at R.N.T. Medical College and Associated Group of Hospitals, Udaipur, India. Participants were recruited from the antenatal clinic during routine visits. The study duration encompassed enrollment from an unspecified start date until completion with 100 participants (initially 112 enrolled, with exclusions). Periods of recruitment, treatment, follow-up, and data collection spanned gestational ages of 20-28 weeks at enrollment, with follow-up extending to delivery. Data collection included baseline assessments, serial hematological tests at 0, 3, 6, and 9 weeks post-treatment initiation, and perinatal outcomes.

Participants: Eligibility criteria included pregnant women aged 18-38 years with documented IDA (hemoglobin [Hb] concentration between 6-9 g/dL) and gestational age of 20-28 weeks. Participants were sourced from those reporting to the Obstetrics and Gynecology department's antenatal clinic who met inclusion criteria and provided informed written consent.Exclusion criteria comprised: history of chronic illnesses (e.g., liver or kidney disease, malabsorption syndromes) potentially causing anemia; multiple pregnancy; decompensated anemia; anemia types other than IDA; high risk for preterm labor; and history of recent blood transfusion.A total of 112 pregnant women were initially enrolled. Eight were excluded due to co-existing diseases, and four were lost to follow-up. The final analysis included 100 participants who received the full calculated dose of intravenous iron sucrose and completed follow-up.

Variables:
Primary outcomes (efficacy measures): Improvements in hematological parameters, including hemoglobin (Hb) level (g/dL), mean corpuscular volume (MCV; fL), mean corpuscular hemoglobin concentration (MCHC; g/dL), and hematocrit (HCT; %).

Secondary outcomes: Safety (side effects of therapy, such as chills, rigors, thrombophlebitis, or anaphylaxis); compliance (completion of treatment and follow-up); fetal outcomes (birth weight [kg], preterm/term delivery, mode of delivery [normal vaginal or cesarean], need for blood transfusion, and neonatal ICU [N-ICU] admission).

Exposures: Administration of intravenous iron sucrose.
Predictors and potential confounders: Age group (<25 years, 25-35 years, >35 years); gestational age at recruitment (20-22 weeks, 23-25 weeks, 26-28 weeks); anemia severity (moderate [Hb 7-9 g/dL] or severe [Hb 6-6.9 g/dL]); residential area (rural/urban); gravida (1st, 2nd, 3rd, 4th, ≥5th); education level (educated [able to read and write name] or non-educated); presenting complaints (breathlessness, edema, generalized weakness, loss of appetite).

Diagnostic criteria for IDA: Hb 6-9 g/dL with microcytic hypochromic features on peripheral smear (implied by low MCV and MCHC), after ruling out other causes via baseline investigations.

Effect modifiers: Not explicitly predefined, but analyses explored associations by age, gravida, education, and residence.
Data Sources/Measurement: Data sources included patient medical records, antenatal clinic visits, and laboratory reports from the hospital.

Hematological parameters (Hb, MCV, MCHC, HCT) were measured via automated blood analyzers (specific model not stated) at baseline (0 weeks) and at 3, 6, and 9 weeks post-treatment initiation. RBC indices were derived from complete blood counts.

Baseline investigations: Liver and kidney function tests, urine microscopy and culture, stool examination for ova and cysts.

All participants received anti-helminthic therapy (albendazole 400 mg single dose) and folic acid supplementation, with encouragement for a protein-rich diet.

Iron dose calculation: Using the Ganzoni equation—Total Iron Deficit = Weight (kg) × (Target Hb – Actual Hb) (g/L) × 2.4 + Iron stores (mg)—where pre-pregnancy weight was used, target Hb was 110 g/L (11 g/dL), and iron stores were 500 mg for weight >35 kg or 15 mg/kg for weight <35 kg.

Treatment administration: Total dose divided into 3-5 infusions on alternate days over 1-2 weeks. First dose in ward with monitoring (BP, pulse, temperature before, at 15 minutes, and end of infusion); subsequent doses outpatient. Infusion rate: Initial 15-20 drops/min for 5 minutes, then full dose over ~30 minutes if no reaction. No oral iron allowed post-treatment.

Side effects: Documented via direct observation and patient reporting during/after infusions.
Fetal outcomes: Recorded at delivery from hospital records (birth weight, gestational age at delivery for preterm/term classification, mode of delivery, blood transfusion need, N-ICU admission).

Bias: Potential selection bias was addressed by consecutive enrollment of eligible women from the antenatal clinic. Information bias minimized through standardized laboratory measurements and prospective data collection. Confounding addressed in analyses by stratifying results by age, gravida, education, and residence. Loss to follow-up (4/112) was minimal; excluded participants with co-existing diseases to reduce confounding from other anemia causes. No blinding, as observational; efforts to rule out other anemia etiologies via baseline tests.

Study Size: The sample size was set at 100 pregnant women, based on previous similar studies reporting sample sizes of 50-100. No formal power calculation was described; the size was pragmatic, including all eligible participants reporting within the study duration until reaching 100 analyzable cases (from 112 enrolled).

Quantitative variables (e.g., Hb, MCV, MCHC, HCT, birth weight) were handled as continuous measures, reported as means with standard deviations. Groupings were applied for categorical analyses: age (<25, 25-35, >35 years); gestational age (20-22, 23-25, 26-28 weeks); anemia severity (mild [not included], moderate, severe); gravida (1st, 2nd, 3rd, 4th, ≥5th); education (educated/non-educated); residence (rural/urban). These groupings were chosen based on clinical relevance (e.g., age and gravida for risk stratification, education/residence for socioeconomic factors influencing anemia).

Statistical Methods
Descriptive statistics: Frequencies, means, and standard deviations for baseline characteristics and outcomes.
Inferential statistics: Analysis of variance (ANOVA) to assess differences in hematological parameters across groups (e.g., by age, gravida, education, residence) at each time point (0, 3, 6, 9 weeks), with post-hoc tests for significant differences (e.g., means with different letters indicating significance). Chi-square tests for associations (e.g., between preterm/term delivery and age/gravida; mode of delivery and gravida; N-ICU admission and gravida; blood transfusion and gravida). P-values <0.05 considered significant.Confounding control: Stratified analyses by potential confounders (age, gravida, etc.).

Subgroups and interactions: Examined via ANOVA across subgroups; no specific interaction terms mentioned.

RESULTS
Efficacy of Intravenous Iron Sucrose Supplementation:
The results demonstrate strong efficacy in treating moderate to severe iron deficiency anemia (IDA) in pregnancy, as evidenced by significant improvements in key hematological parameters over the 9-week treatment period. The study

involved 100 pregnant women with baseline hemoglobin (Hb) levels between 6-9 g/dL, receiving calculated doses of IV iron sucrose based on the Ganzoni equation. Efficacy is primarily measured by rises in Hb, mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC), and hematocrit (HCT), with maximum improvements observed within the first 3 weeks, indicating rapid response to therapy.

Hemoglobin (Hb): Baseline mean Hb was 7.70 g/dL. It increased to 10.09 g/dL at 3 weeks (rise of 2.39 g/dL), 10.86 g/dL at 6 weeks, and 11.29 g/dL at 9 weeks (total rise of 3.59 g/dL). This aligns with the objective of correcting anemia, as the therapy stimulated erythropoiesis in iron-deficient states. No significant differences were noted across age groups ($p > 0.05$ at all stages), but significant variations occurred by gravida at 6 and 9 weeks (e.g., highest Hb in primigravida at 9 weeks: 11.44 g/dL; $p < 0.05$ for differences between 1st/5th, 2nd/5th, and 3rd/5th gravida). Additionally, baseline Hb was lower in non-educated (7.43 g/dL) vs. educated women (7.87 g/dL; $p < 0.05$), but treatment equalized improvements regardless

Table 1: Frequency, mean and standard deviation of Hb based on age groups
The mean difference is significant at the 0.05 level.

Parameters	Age groups	No. of women	Mean in gm%	Std. Deviation	P value
Hb at starting	<25 yrs	50	7.790	.7049	0.468
	25 – 35 yrs	35	7.637	.7807	
	>35 yrs	15	7.567	.6683	
	Total	100	7.703	.7256	
Hb at 3rd week	<25 yrs	50	10.108	.6321	0.962
	25 – 35 yrs	35	10.071	.7702	
	>35 yrs	15	10.120	.6538	
	Total	100	10.097	.6799	
Hb at 6th week	<25 yrs	50	10.944	.4409	0.234
	25 – 35 yrs	35	10.817	.5261	
	>35 yrs	15	10.720	.5570	
	Total	100	10.866	.4922	
Hb at 9thweek	<25 yrs	50	11.296	.4764	0.468
	25 – 35 yrs	35	11.354	.4307	
	>35 yrs	15	11.173	.5612	
	Total	100	11.298	.4733	

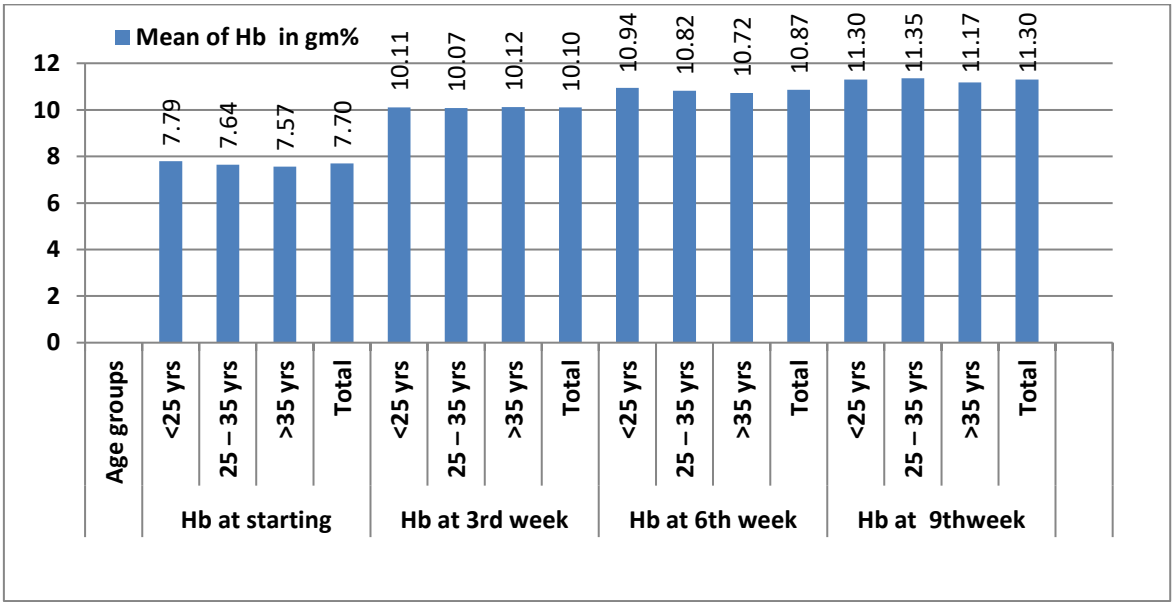

Fig. 1 Showing frequency, mean and standard deviation of Hb based on age groups

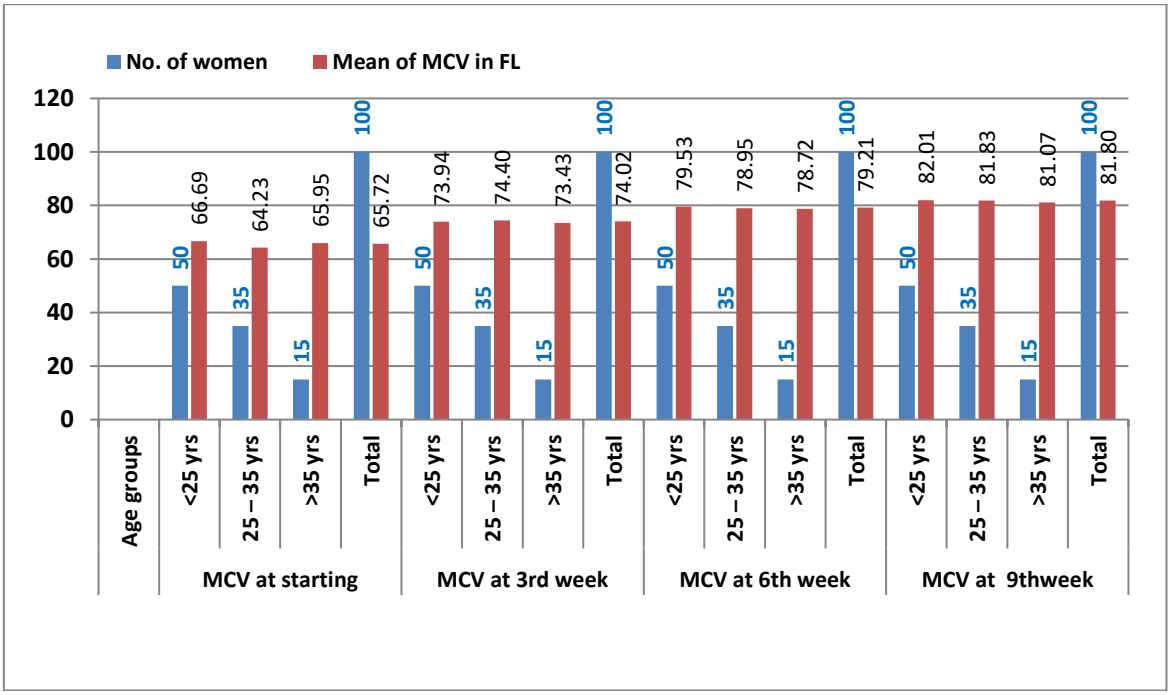

Fig. 2 Showing frequency, mean and standard deviation of MCV (FL) based on age groups

Mean Corpuscular Volume (MCV): Baseline mean MCV was 65.71 fL (indicative of microcytic anemia). It rose to 74.02 fL at 3 weeks (rise of 8.31 fL), 79.20 fL at 6 weeks, and 81.80 fL at 9 weeks (total rise of 16.09 fL). As with Hb, maximum improvement was in the first 3 weeks. No significant age-related differences ($p > 0.05$), but gravida-based significance at 6 and 9 weeks (e.g., highest at 9 weeks in primigravida: 82.24 fL; $p < 0.05$ for 1st vs. 5th at 6 weeks). Baseline MCV was lower in non-educated (62.96 fL) vs. educated women (67.47 fL; $p < 0.05$).

Table 2:Frequency, mean and standard deviation of MCV(FL) based on age groups

Parameters	Age groups	No. of women	Mean in femtoliters	Std. Deviation	P value
MCV at starting	<25 yrs	50	66.690	7.7344	0.362
	25 – 35 yrs	35	64.226	8.0735	
	>35 yrs	15	65.947	7.5402	
	Total	100	65.716	7.8298	
MCV at 3rd week	<25 yrs	50	73.936	3.8017	0.697
	25 – 35 yrs	35	74.397	4.1611	
	>35 yrs	15	73.433	2.7696	
	Total	100	74.022	3.7803	
MCV at 6th week	<25 yrs	50	79.534	2.6700	0.425
	25 – 35 yrs	35	78.951	2.3755	
	>35 yrs	15	78.720	2.4975	
	Total	100	79.208	2.5420	
MCV at 9thweek	<25 yrs	50	82.006	2.7476	0.427
	25 – 35 yrs	35	81.829	2.0083	
	>35 yrs	15	81.073	2.1073	
	Total	100	81.804	2.4190	

The mean difference is significant at the 0.05 level

Mean Corpuscular Hemoglobin Concentration (MCHC): Baseline mean MCHC was 30.80 g/dL, increasing to 32.27 g/dL at 3 weeks (rise of 1.47 g/dL), 33.19 g/dL at 6 weeks, and 33.99 g/dL at 9 weeks (total rise of 3.19 g/dL). Improvements were consistent, with no significant differences by age, gravida, or residence ($p > 0.05$ at all stages). Baseline values were lower in non-educated (30.14 g/dL) vs. educated women (31.23 g/dL; $p < 0.05$), and also at 3 weeks (31.69 g/dL vs. 32.65 g/dL; $p < 0.05$).

Table 3: Frequency, mean and standard deviation of MCHC based on age groups

Parameters	Age groups	No. of women	Mean in gm/dl	Std. Deviation	P value
MCHC at starting	<25 yrs	50	31.022	2.3213	0.692
	25 – 35 yrs	35	30.563	2.6380	
	>35 yrs	15	30.667	2.8540	
	Total	100	30.808	2.5012	
MCHC at 3rd week	<25 yrs	50	32.418	1.8646	0.474
	25 – 35 yrs	35	31.934	2.4049	
	>35 yrs	15	32.620	2.3211	
	Total	100	32.279	2.1303	
MCHC at 6th week	<25 yrs	50	33.290	1.4837	0.484
	25 – 35 yrs	35	32.929	1.8309	
	>35 yrs	15	33.467	1.8137	
	Total	100	33.190	1.6573	
MCHC at 9thweek	<25 yrs	50	34.038	1.1816	0.612
	25 – 35 yrs	35	33.840	1.3998	
	>35 yrs	15	34.213	1.3887	
	Total	100	33.995	1.2858	

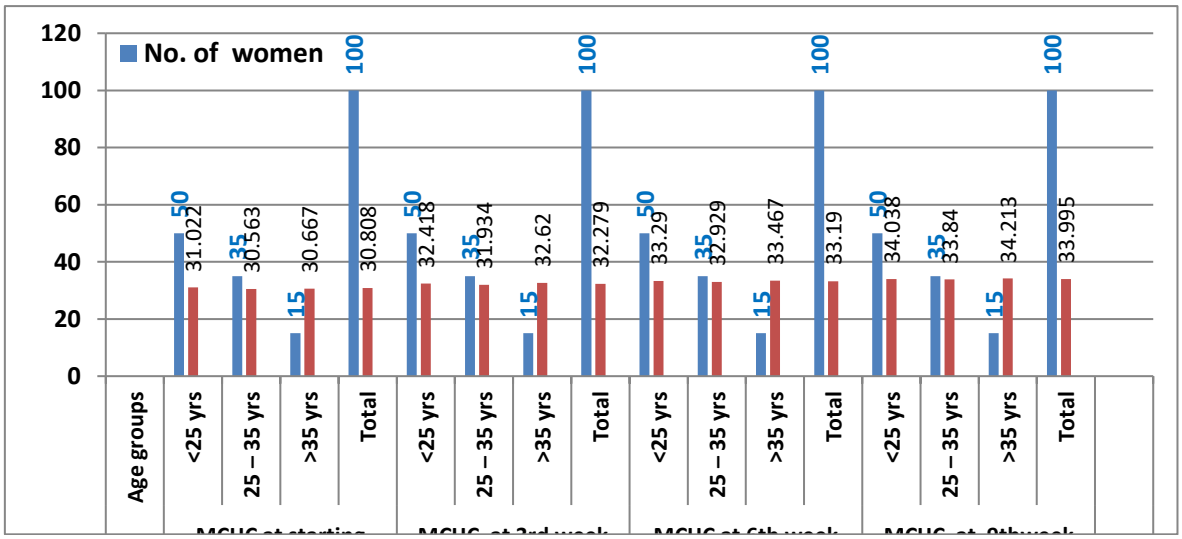

Fig. 3 Showing frequency, mean and standard deviation of MCHC (gm/dl) based on age groups

Hematocrit (HCT): Baseline mean HCT was 24.99%, rising to 31.30% at 3 weeks (rise of 6.31%), 32.77% at 6 weeks, and 33.25% at 9 weeks (total rise of 8.26%). No age-related significance ($p > 0.05$), but gravida-based differences at 0 and 3 weeks ($p < 0.05$; e.g., highest baseline in primigravida: 25.47%). Baseline HCT was lower in non-educated (24.66%) vs. educated women (25.21%; $p < 0.05$).

Fetal outcomes further support efficacy, as anemia correction reduced associated risks:

- Mean birth weight was 2.91 kg overall, with no significant gravida differences ($p > 0.05$). Highest in primigravida (2.96 kg).
- Only 3 preterm deliveries (mostly in <25 years age group and primigravida/2nd gravida; $p = 0.034$ for gravida association), with 97 term deliveries. No age association ($p = 0.378$).
- NICU admissions: 6 newborns (mostly preterm/low birth weight; no gravida dependence, $p = 0.125$).
- Blood transfusions: Only 4 cases (2 primigravida, 2 multigravida; $p = 0.000$ for gravida association, linked to multigravida as a risk factor).
- Mode of delivery: 19 cesarean sections (more in primigravida and rural areas; $p = 0.075$, no significant gravida dependence).

These improvements confirm IV iron sucrose's efficacy in rapidly restoring iron stores, bypassing hepcidin-related absorption issues common in oral therapy, and improving maternal and fetal outcomes in moderate (84 cases) to severe (16 cases) IDA.

Safety of Intravenous Iron Sucrose Supplementation

The therapy exhibited a favorable safety profile, with minimal and minor side effects reported, aligning with the objective of safe treatment for pregnant women. No severe adverse events occurred, supporting its use as an alternative to blood transfusions or high-dose oral iron, which often cause gastrointestinal issues.

- Side effects: Only 10 patients experienced any (6 with chills/rigors, 4 with thrombophlebitis). No cases of anaphylaxis, gastritis, nausea, vomiting, or other serious reactions.
- No maternal or fetal deaths, infections, or hypersensitivity events.
- The low incidence (10%) is consistent with second-generation IV iron formulations, avoiding risks associated with older dextrans.

This safety data reinforces IV iron sucrose as well-tolerated in pregnancy, particularly in hospital settings where monitoring is feasible.

Compliance with Intravenous Iron Sucrose Supplementation

Compliance was high, as the IV administration ensured direct delivery and overcame common noncompliance issues with oral iron (e.g., side effects leading to discontinuation). Of 112 enrolled patients, 100 completed the study (89.3% retention):

- 8 excluded due to co-existing diseases.

Four lost to follow-up (likely unrelated to therapy). The supervised IV infusions (typically in outpatient or hospital settings) promoted adherence, with all 100 patients receiving the full calculated dose over the study period. This addresses the objective by highlighting IV therapy's advantage in populations with poor oral compliance, such as rural (59 patients) or non-educated (39 patients) women, where anemia prevalence is higher due to nutritional and awareness gaps.

DISCUSSION

This prospective observational study conducted at the Department of Obstetrics and Gynecology, R.N.T. Medical College and Associated Group of Hospitals, Udaipur, India, evaluated the safety, efficacy, and compliance of intravenous (IV) iron sucrose supplementation for treating moderate to severe iron deficiency anemia (IDA) in 100 pregnant women with hemoglobin (Hb) levels between 6-9 g/dL and gestational ages of 20-28 weeks. The results align well with the objective, demonstrating that IV iron sucrose is a safe, effective, and well-tolerated treatment option, particularly in a high-risk population where IDA is prevalent due to nutritional deficiencies and socioeconomic factors.

Efficacy of IV Iron Sucrose

The study's primary outcome—improvement in hematological parameters—demonstrated significant efficacy [7].. Baseline mean Hb (7.70 g/dL) increased by 3.59 g/dL to 11.29 g/dL by 9 weeks, with the most rapid rise occurring within the first 3 weeks (2.39 g/dL to 10.09 g/dL). Similarly, mean corpuscular volume (MCV) rose from 65.71 fL to 81.80 fL, mean corpuscular hemoglobin concentration (MCHC) from 30.80 g/dL to 33.99 g/dL, and hematocrit (HCT) from 24.99% to 33.25% over 9 weeks, with maximum improvements by week 3. These findings indicate that IV iron sucrose effectively corrects microcytic hypochromic anemia, characteristic of IDA, by stimulating erythropoiesis and restoring iron stores. The rapid response within 3 weeks aligns with the mechanism of IV iron bypassing hepcidin-mediated absorption blocks, unlike oral iron, which often faces compliance issues due to gastrointestinal side effects.

Subgroup analyses revealed nuanced patterns. While no significant differences were observed across age groups ($p > 0.05$), significant variations by gravida emerged at 6 and 9 weeks for Hb and MCV ($p < 0.05$), with primigravida showing the highest values (e.g., Hb 11.44 g/dL at 9 weeks). This suggests that anemia severity may increase with higher parity, possibly due to cumulative iron depletion, but treatment efficacy remains consistent across gravidity. Education level influenced baseline hematological parameters, with non-educated women starting with lower Hb (7.43 g/dL vs. 7.87 g/dL), MCV (62.96 fL vs. 67.47 fL), MCHC (30.14 g/dL vs. 31.23 g/dL), and HCT (24.66% vs. 25.21%) compared to educated women ($p < 0.05$). However, post-treatment improvements were comparable, indicating that IV iron sucrose effectively addresses anemia regardless of socioeconomic factors. Rural women (59% of the cohort) had lower baseline values than urban women, reflecting greater nutritional deficiencies and limited healthcare access, yet achieved similar endpoint improvements (e.g., Hb 11.29 g/dL rural vs. 11.30 g/dL urban).

Fetal outcomes further underscore efficacy. The mean birth weight was 2.91 kg, with no significant gravida differences ($p > 0.05$), suggesting that anemia correction mitigated risks of intrauterine growth restriction (IUGR) and low birth

weight, common in untreated IDA. Only 3 preterm deliveries occurred, primarily in primigravida and second gravida ($p = 0.034$ for gravida association), with no age-related dependence ($p = 0.378$). The low incidence of adverse perinatal outcomes (e.g., 6 N-ICU admissions, mostly preterm/low birth weight; $p = 0.125$ for gravida) and minimal need for blood transfusions (4 cases; $p = 0.000$, linked to multigravida risk) highlight the protective effect of timely anemia correction on maternal and fetal health.

These results are consistent with prior studies.[8] reported significant Hb and ferritin increases with parenteral iron in moderate anemia, while [9]noted faster and more effective correction with IV iron sucrose compared to oral iron. similarlyone study [11]found IV iron sucrose reduced perinatal complications and transfusion needs, supporting its role in improving maternal and fetal outcomes in developing countries where IDA contributes to 20% of maternal deaths and 9% of perinatal mortality.

Safety of IV Iron Sucrose

The safety profile of IV iron sucrose was favorable, with only 10% of patients experiencing minor side effects (6 chills/rigors, 4 thrombophlebitis), managed by slowing infusion rates or administering antihistamines. Notably, no cases of anaphylaxis, gastritis, nausea, or vomiting were reported, contrasting with oral iron's frequent gastrointestinal side effects. This aligns with the advantages of second-generation IV iron formulations (e.g., iron sucrose, ferric gluconate) over older iron dextrans, which carried higher allergic risks. The absence of severe adverse events, maternal deaths, or infections supports the safety of IV iron sucrose in pregnancy, particularly when administered in a controlled hospital setting with cardiopulmonary resuscitation facilities for the first dose. Studies by Khalfallah et al. (2010), Abhilashini et al. (2014), and Kriplani et al. (2012) corroborate these findings, noting minimal side effects and no anaphylaxis with IV iron sucrose.

Compliance with IV Iron Sucrose

Compliance was high, with 100 of 112 enrolled patients completing the study (89.3% retention). The 4 losses to follow-up and 8 exclusions due to co-existing diseases were minimal and unlikely related to therapy tolerability. The IV administration, delivered in 3-5 doses over 1-2 weeks under medical supervision, ensured adherence, overcoming noncompliance issues common with oral iron due to side effects or forgetfulness. This is particularly significant in the study population, where 59% were rural and 39% non-educated, groups often facing barriers to consistent oral supplementation due to low health literacy or access. The outpatient administration of subsequent doses further enhanced feasibility without compromising safety or efficacy.

Clinical and Public Health Implications

The study's findings advocate for IV iron sucrose as a first-line treatment for moderate to severe IDA in pregnancy, especially in resource-limited settings like India, where IDA affects 35-75% of pregnant women. The rapid hematological improvement, minimal side effects, and high compliance make it a practical alternative to oral iron (limited by side effects and absorption issues) and blood transfusions (reserved for life-threatening cases due to infection risks). The reduction in preterm deliveries, low birth weight, and transfusion needs underscores its potential to lower maternal mortality (e.g., from postpartum hemorrhage) and perinatal complications, addressing a critical public health challenge in developing countries.

The higher baseline anemia severity in rural and non-educated women highlights the need for targeted interventions in these groups. The study's success in equalizing hematological outcomes across socioeconomic strata suggests that IV iron sucrose can bridge disparities when accessible. However, its requirement for hospital-based administration may limit scalability in rural areas without adequate healthcare infrastructure, necessitating policy efforts to expand access.

Limitations

The study has several limitations. The lack of a control or placebo group, due to ethical constraints in pregnant populations, precludes direct comparison with other treatments (e.g., oral iron). The absence of data on total iron-binding capacity (TIBC) and reticulocyte counts, due to economic constraints, limits the assessment of iron metabolism dynamics. The sample size (n=100), while adequate based on prior studies, could be expanded for greater statistical power. The observational design and single-center setting may limit generalizability, particularly to non-tribal or urban populations with different nutritional profiles. Finally, the study did not explore long-term maternal or neonatal outcomes beyond delivery.

Comparison with Existing Literature

The results align closely with existing evidence. DelfiniCançado et al. (2011) confirmed IV iron sucrose's safety and efficacy in IDA patients intolerant to oral iron. Kumar et al. (2017) emphasized its role in reducing peripartum transfusion risks, while Ramana et al. (2017) highlighted its superior tolerability and efficacy compared to oral therapy. The current study extends these findings by demonstrating efficacy across diverse subgroups (e.g., by gravida, education, residence) and reinforcing the low side-effect profile in a high-risk pregnant cohort.

Recommendations for Future Research

Future studies should include larger, multicenter cohorts to enhance generalizability. Comparative trials with oral iron or other IV formulations (e.g., ferric carboxymaltose) could clarify relative efficacy and cost-effectiveness. Including additional biomarkers (e.g., ferritin, TIBC, reticulocyte count) would provide deeper insights into iron kinetics. Long-term follow-up studies assessing maternal and neonatal outcomes post-delivery (e.g., lactation success, infant development) are warranted. Exploring strategies for implementing IV iron sucrose in rural settings, such as mobile clinics, could address access barriers.

CONCLUSION

IV iron sucrose is a safe, effective, and compliant treatment for moderate to severe IDA in pregnancy, rapidly improving hematological parameters and reducing adverse maternal and fetal outcomes. Its benefits are particularly pronounced in high-risk groups like rural and non-educated women, where anemia prevalence is elevated. These findings support its integration into clinical guidelines for managing IDA in pregnancy, especially in developing countries, to enhance maternal and perinatal health outcomes. Further research and policy efforts are needed to optimize its accessibility and confirm long-term benefits.

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