Section: General Medicine

Original Research Article

A CROSS SECTIONAL STUDY TO KNOW THE EFFICACY AND SAFETY OF IRON SUCROSE TREATMENT IN SECOND AND EARLY THIRD TRIMISTER ANEMIA IN A TERTIARY CARE CENTER KHPIMS, GADAG

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ABSTRACT

Background: Maternal anemia continues to be a formidable public health challenge in developing nations, precipitating severe maternal and perinatal complications. While oral iron supplementation serves as the standard prophylactic approach, it frequently falls short in resolving established moderate anemia during the critical later stages of gestation due to poor gastrointestinal tolerance and delayed absorption. **Objective:** To assess the efficacy of iron sucrose in treating anaemia among pregnant women in the 2nd and early 3rd trimester**.**

Materials and Methods: A comprehensive cross-sectional study was conducted at the Department of Obstetrics and Gynaecology, K.H. Patil Institute of Medical Sciences, Gadag, between March 2024 and February 2026. The study cohort comprised 410 pregnant women formally diagnosed with moderate anemia (baseline hemoglobin between 8.0 and 9.9 g/dl). To ensure precise dosing, the total iron deficit for each patient was individualized utilizing the Ganzoni formula, systematically adding 500 mg to replenish reticuloendothelial stores.

Results: The parenteral intervention facilitated a rapid and highly significant hematological correction across the cohort. The mean maternal hemoglobin rose from a baseline of 9.04± 0.42 g/dl to 10.14 ± 1.12 g/dl at 3 weeks, and reached an optimal 11.52 ± 1.01 g/dl by 4 weeks post-treatment ($p < 0.001$). Red blood cell morphological indices demonstrated robust normalization, with Mean Corpuscular Volume (MCV) rising significantly from 80.12 fl to 87.09 fl. Crucially, the replenished iron stores buffered intrapartum blood loss, allowing mothers to sustain a highly safe mean postpartum hemoglobin of 10.89 ± 0.50 g/dl.

Conclusion: Intravenous iron sucrose, when meticulously calculated via the Ganzoni formula, is a highly safe, rapid, and definitive therapeutic modality for managing moderate gestational anemia in a tertiary care setting.

Keywords: Iron Sucrose Treatment, Second and Early Third Trimister, Anemia.

INTRODUCTION

Pregnancy-related anaemia is a serious public health issue since it is difficult to measure, prevent, and treat in many nations worldwide1. Anaemia is believed to affect 58.1% of pregnant South Asian women, while the incidence of this condition is considered to be around 38% worldwide.2 By 2030, all types of malnutrition, including anaemia, must be eradicated, according to the Sustainable

Development Goals, which emphasize the necessity of closing the gaps in inequality at the international, national, and subnational levels.3 However, there has been limited and inconsistent progress in preventing anaemia in low and middle-income countries (LMICs), which is especially attributed to complicated, poorly characterized context specific aetiologies.4

The second and early third trimesters are critical periods for addressing anaemia, as this timeframe allows for timely intervention to optimize maternal Hb levels before delivery. Oral iron supplementation is the first-line treatment; however, it is often ineffective due to gastrointestinal side effects, poor compliance, and slow response, necessitating alternative

therapies like intravenous (IV) iron preparations.5 Iron sucrose, an IV iron complex, has emerged as a safe and effective option for rapid correction of iron deficiency anaemia in pregnancy, with studies demonstrating its ability to improve Hb levels without significant adverse effects.6 Its use is particularly advantageous in settings where oral iron fails or in cases requiring urgent correction, such as severe anaemia or intolerance to oral supplements.7

Despite its benefits, the efficacy and safety of iron sucrose in the second and early third trimesters, and its potential associations with fetal outcomes like birth weight and postpartum maternal Hb levels, remain under studied in resource-limited tertiary care settings. Cross-sectional studies have shown correlations between maternal anaemia correction and improved fetal growth, but longitudinal data on IV iron sucrose's long-term impact are limited.8 cFurthermore, while iron sucrose is generally well-tolerated, concerns persist regarding rare adverse reactions like hypersensitivity or oxidative stress, warranting evaluation in diverse populations.9

This cross-sectional study aims to assess the efficacy and safety of iron sucrose treatment for anaemia in the second and early third trimesters.

MATERIALS AND METHODS

This cross-sectional hospital-based observational study was conducted among the study population comprised second- and third-trimester pregnant women visiting the OPD, labour room, or admitted to the Department of Obstetrics and Gynaecology, K H Patil Institute of Medical Sciences (GIMS), Gadag, who provided written informed consent during the study period. Duration of study was from March 2024 – February 2026.

Sample Size: A total sample size of 410 was calculated using the formula:

$$n = \frac{4pq}{d^2}$$

$$n = \frac{}{(10 \times 52/100)^2} = 360.23$$

Considering rounding and feasibility, a final sample size of **410** was taken.

Sampling Technique: Purposive sampling

Inclusion Criteria

Pregnant women with haemoglobin levels between 7–9.9 g/dL.

Age between 18–45 years**.**

Singleton pregnancy (both primigravida and multigravida). Gestational age 24–34 weeks.

Willingness to give written informed consent.

Exclusion Criteria

History of bleeding disorders.

Blood transfusion within the previous 120 days.

Hemoglobinopathies including thalassemia syndromes and structural variants (HbS, HbE, HbC).

Acute inflammatory conditions or hypersensitivity to IV iron sucrose.

Methodology

This cross-sectional study was conducted at a tertiary care centre in South India after obtaining Institutional Ethics Committee approval. Written informed consent was obtained from all participants in their local language.

Baseline Evaluation

A detailed history was obtained including: Maternal age, Parity, Socioeconomic status, Obstetric history, BMI, Smoking habits, Complications in current pregnancy

Investigations: Complete blood count Blood grouping and typing Liver function tests, Renal function tests

Administration of Intravenous Iron Sucrose

After all basic investigations done as per inclusion criteria and patient who had given consent are enrolled in our study

The total iron requirement was calculated using the standard formula:

$$\text{Total iron dose (mg)} = \text{Body weight (kg)} \times (\text{Target Hb} - \text{Actual Hb}) \times 0.24 + 500$$

Where, Target Hb=11g/dl.

The dose was rounded to the nearest 100 mg.

Iron Sucrose Dose: 200 mg diluted in 100–200 mL of 0.9% normal saline.

Mode of administration: Slow IV infusion over 20–30 minutes.

Infusions were given on alternate days until the total calculated dose was completed

Monitoring During Infusion

Maternal and foetal parameters were monitored: Maternal pulse, blood pressure, Chest auscultation findings Symptoms of anaphylaxis, Foetal heart rate

Monitoring was done before infusion, every 5 minutes during infusion, and for 2 hours post-infusion.

Follow-up

Participants were followedup at3 weeks and 4 weeks post therapy. Assessments included: Haemoglobin, Clinical improvement, 3rd week and 4th week haemoglobin rise seen.

Statistical Analysis

All collected data will be entered into a Microsoft Excel spreadsheet and subsequently analysed using Statistical Package for Social Sciences (SPSS) version 22.0. Continuous variables will be summarized using mean and standard deviation (SD). Categorical variables will be expressed as frequency and percentage. Chi-square test (χ^2) will be used to assess the association between categorical variables. Appropriate statistical tests (e.g., *t*-test or ANOVA) will be applied for comparison of continuous variables, depending on data distribution (optional—include if required). P-value < 0.05 will be considered statistically significant for all analyses.

RESULTS

In our study observed that; majority of 179 (43.7%) and 170 (41.4%) were belonging to the age group of 21—25 years and 26—30 years respectively. Followed by 34 (8.3%) of cases were belonging to the age of 18-20 years, 21 (5.1%) of cases were belonging to the age group of 31—35 years and 6 (4.5%) of cases were belonging to the age of 35-40 years. The least age group was 19 years and the highest age was 36 years. The mean age of cases was 25.48 years.

In our study; majority of subjects 236 (57.6%) parity was observed multiparous. Followed by 149 (36.3%) of subjects were observed to be primigravida and 25 (6.1%) of subjects were seen grand multiparous.

In our study observed that Majority of subjects 220 (53.6%) observed in the Lower Middle Class. 109 (26.6%) of subjects were observed the socio-economic status was Lower Class, 45 (11.0%) of subjects were observed the socio-economic status Middle Class, 36 (8.8%) of subjects were observed the socio-economic status of Upper Middle Class and no subjects were observed in Upper Class.

In our study; Majority of subjects 127 (31.0%) occurred in the gestational age between 30weeks – 32weeks. 109 (26.6%) of subjects were occurred in the gestational age between 28weeks –30weeks. 77 (18.8%) subjects had gestational age of 32weeks–34weeks,49 and 48 subjects were belong to gestational age of 26weeks-28weeks and 24weeks-26weeks respectively. The mean gestational age was 28.2 weeks.

In our study; out of 410 sample subjects, 265 (64.6%) of cases BMI was 18.5—24.9 (Normal weight), followed by 135 (32.9%) of subjects BMI was in the range of 25.0—

29.9 (Over-weight) and 7 (2.8%) of subjects BMI was observed ≥ 30 (obesity) and 4 (0.7%) of subjects BMI was observed <18.5 (Under-weight). The average BMI was 24.46.

In our study; Majority of subjects 266 (64.9%) mode of delivery was lower segment caesarean delivery, 144 (35.1%) of subjects mode of delivery was vaginal delivery.

Table 1: Distribution of study subjects according to indication of LSCS

Indication of LSCS	Number of subjects	Percentage (%)
Previous LSCS	109	41.0%
Fetal Distress	95	35.7%
Failure of labor to progress	29	10.9%
Severe Pre-eclampsia	22	8.3%
Breech	11	4.1%
Total	266	100.0%

In our study out of 266 LSCS subjects; majority of subjects 109 (41.0%) of subject indication of LSCS was Previous LSCS. Followed by 95 (35.7%) of subject indication of LSCS was Fetal distress, 29 (10.9%) of subject indication of LSCS was Failure of labor to progress, 22 (8.3%) of subject indication of LSCS was Pre-eclampsia and 11 (4.1%) of subject indication of LSCS was Breech presentation.

Table 2: Distribution of study subjects according to pre-treatment hemoglobin level

Pre-treatment hemoglobin Level(g/dl)	Number of subjects	Percentage (%)
7.0--7.9	9	2.2%
8.0—8.9	145	35.4%
9.0—9.9	256	62.4%
Total	410	100.0%
Mean ± SD	9.05 ± 0.42	

In our study observed that; out of 410 subjects 256 (62.4%) of subjects had the hemoglobin level in the range of 9.0—9.9g/dl, 145 (35.4%) of subjects had the hemoglobin level in the range of 8.0—8.9g/dl and 9 (2.2%) of subjects had the hemoglobin level of 7.9g/dl. The minimum hemoglobin level was seen 7.9g/dl and maximum hemoglobin level seen was 9.9g/dl. The mean hemoglobin was 9.04g/dl.

Table 3: Distribution of study subjects according to total dose required

Total dose required (grams)	Number of subjects	Percentage (%)
700	144	35.1%
800	217	52.9%

900	43	10.5%
1000	6	1.5%
Total	410	100.0%
Mean ± SD	778.29 ± 68.37	

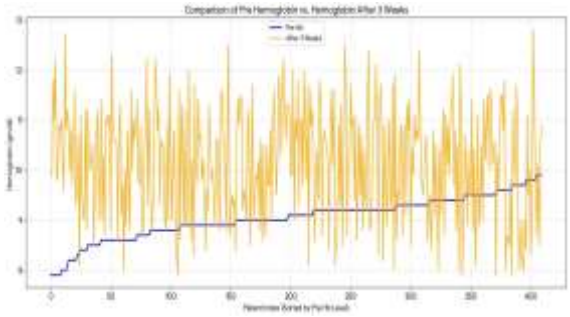
In our study considering the baseline hemoglobin was calculated by using Ganzoni Formula (Total iron deficit= body weight × 2.4 {Target haemoglobin-actual heamoglobin} + 500. Whereas Target haemoglobin=11g/dl.) and required dose was calculated for individual subjects rounding off to nearest multiples of 100 which is summarized in table number. 9. The required dose of each patient was infused on alternate day maximum 200mg/day.

In those 144 (35.1%) subjects received 700mg/subject, 217(52.9%) subjects received 800mg/subject, 43(10.5%) subject received 900mg/subject and 6(1.5%) were received 1000mg. The minimum infusion was 700mg/subject whereas maximum was 1000mg/subject. On an average 217(52.9%) subjects received infusion of 800mg/subject whereas 6(1.5%) subjects received infusion of 1000mg/subject. Mean dose of infusion is 778.29mg/subject.

Table 4: Distribution of study subjects according to hemoglobin level after 3 weeks of iron sucrose supplemention

After 3 weeks hemoglobin Level (g/dl)	Number of subjects	Percentage (%)
7.0--7.9	4	1.05%
8.0—8.9	71	17.3%
9.0—9.9	100	24.4%
10.0—10.9	131	31.9%
11.0--11.9	88	21.4%
12.0--12.9	16	3.8%
13.0—13.9	0	0.0%
Total	410	100.0%
Mean ± SD	**10.14 ± 1.12**	

In our study observed that; after 3 weeks of iron sucrose supplementation hemoglobin level was analyzed, out of 410 subjects 131 (31.9%) of subjects hemoglobin level was in the range of 10.0—10.9g/dl, 100 (24.4%) of subjects the hemoglobin level was in the range of 9.0—9.9g/dl, 88 (21.4%) of subjects the hemoglobin level was in the range of 11.0—11.9g/dl and 71 (17.3%) subjects the hemoglobin level was in the range of 8.0—8.9g/dl. The minimum hemoglobin was seen 7.9g/dl and maximum were 12.8g/dl. The mean haemoglobin.



Graph 1: Comparison of pre treatment hemoglobin and after3weeks of iron sucrose supplementation.

Table 5: Distribution of study subjects according to hemoglobin level after 4 weeks of iron sucrose supplementation

After 4 weeks hemoglobin Level(g/dl)	Number of subjects	Percentage (%)
7.0--7.9	0	0.0%
8.0—8.9	5	1.2%
9.0—9.9	26	6.3%
10.0—10.9	77	18.8%
11.0—11.9	149	36.3%
12.0—12.9	131	32.0%
13.0—13.9	22	5.4%
Total	**410**	**100.0%**
Mean ± SD	**11.52 ± 1.01**	

In our study observed that; after 4 weeks of iron sucrose supplementation hemoglobin level was analyzed, out of 410 study subjects149 (36.3%) of subjects the hemoglobin level was in the range of 11.0—11.9g/dl, 131 (32.0%) of subjects the hemoglobin level was in the range of 12.0—12.9g/dl, 77 (18.8%) of subjects the hemoglobin level was in the range of 10.0—10.9g/dl, 26 (6.3%) of subjects the hemoglobin level was in the range of 9.0—9.9g/dl, 22 (5.4%) of subjects the hemoglobin level was in the range of 13.0—13.9g/dl and 5 (1.2%) of subjects were diagnosed the hemoglobin level was in the range of 8.0—8.9g/dl. The minimum hemoglobin was seen 8.1g/dl and maximum were 13.8g/dl. The mean hemoglobin was 11.52g/dl.

After end of 4 weeks of iron sucrose supplementation about 31 subjects had less hemoglobin in the range of 8.0-9.9g/dl, 5 subjects

undergone blood transfusion,14 subjects received Inj. Ferric Carboxy Maltose (FCM) infusion, remaining 12 subjects received repeat iron sucrose supplementation.

DISCUSSION

In our study subjects age ranged from 18 years to 45 years, the majority (43.7%) of them were age group between 21 to 25 years with a mean age of 25.58 ± 3.64 years. The study conducted by R Nanthini et al. (2015),[10] found higher prevalence of anaemia in age group between 19 to 32 years and mean age of 23.4±1.76.

In our study out of 410 subjects 149(36.3%) were Primigravida ,236(57.6%) were Multigravida and 25(6.1%) were Grand multiparous. The study conducted by R Nanthini et al. (2015),[10] 40% of subjects were found to be primigravida while 60% were multigravida.

Majority of subjects 220 (53.6%) observed in the Lower Middle Class. 109 (26.6%) of subjects were Lower Class, 45 (11.0%) of subjects were Middle Class, 36 (8.8%) of subjects were Upper Middle Class. Rama Jyothi et al.(2023),[11] 70% in both groups belong to middle class and 30% belong to lower class.

In our study observed that most of the subjects were in the gestational age of 28–32 weeks, with mean gestational age of 28.2 weeks. The study Lakshmikantha G and Trupta Gopal Naik (2018) majority of subjects in the range of 30-36 weeks (84%).

The mean BMI observed in our cohort closely aligns with the findings of Prasad A. (2024. In their study, the mean BMI in the iron sucrose group was 23.71 ± 3.1 kg/m²,

In the present study,266 (64.9%) subjects were delivered via Lower Segment Caesarean Section (LSCS), while 144 (35.1%) underwent a normal vaginal delivery.

A study by Khan et al. (2018): had an LSCS rate of 57.5%, and a study by Gupta et al,[12] the cesarean section rate was reported at 44%, while 56% delivered vaginally.

In the present study, the pre-treatment hemoglobin (Hb) analysis of the 410 pregnant women revealed a mean baseline Hb of 9.04 ± 0.42 g/dl. The majority of the study subjects (62.4%) presented with hemoglobin levels in the upper-moderate range of 9.0–9.9 g/dl, while 35.4% fell into the 8.0–8.9 g/dl range, and only a minimal fraction (2.2%) presented below 8.0 g/dl. In a study by Deepthisri et al. (2023) the baseline mean hemoglobin was reported as 8.76 ± 0.54 g/dl.and a Saha et al. (2024),[13] reported a mean baseline Hb for the intravenous group was recorded at 8.2 g/dl. In a large international study by Breymann C. et al., 2017 the participants had a baseline mean hemoglobin of 9.82 ±0.79 g/dl Our distribution profile revealed, 217 subjects (52.9%) required 800 mg, and 144 subjects (35.1%) required 700 mg, 43 subjects (10.5%) needing 900 mg and just 6 subjects (1.5%) requiring 1000 mg.

Consequently, the mean total dose required in our study was 778.29 ± 68.37 mg.

Whereas Samsudin et al. (2020): reported a mean total dose requirement of 835 ± 150 mg and Morgan & Lin (Canadian Cohort, 2024),[14] reported a mean infused dose of 679 ± 246 mg.

In the present study, the hematological evaluation conducted 3 weeks post-intravenous iron sucrose infusion demonstrated a mean hemoglobin increase to 10.14 ± 1.12 g/dl, reflecting a mean rise of +1.10 g/dl. Analysis of the distribution reveals that a majority of the study population (57.1%) successfully crossed the 10.0 g/dl threshold within this short timeframe. Specifically, 31.9% of subjects clustered in the 10.0–10.9 g/dl range, 21.4% achieved 11.0–11.9 g/dl, and 3.8% reached 12.0–12.9 g/dl. Conversely, 42.7% of the cohort remained below 10.0 g/dl, with the largest portion (24.4%) in the 9.0–9.9 g/dl range and 17.3% in the 8.0–8.9 g/dl range.

Whereas in a study by Kolkata Hospital (2022),[14] researchers reported a 3-week post-treatment mean hemoglobin of 9.39 ± 0.72 g/dl. Crucially, their recorded mean change at exactly 3 weeks was +1.16 ± 0.43 g/dl. and Gupta A. et al. (2014): In their evaluation of iron sucrose in advanced pregnancy, the mean hemoglobin rose from a baseline of 7.81 g/dl to 9.25 ± 1.66 g/dl on Day 21 (3 weeks) and a mean rise of +1.44 g/dl at 3 weeks .in contrast to our study Lakshmikantha G. & Trupta Gopal Naik (2018),[15] reported a absolute rise in hemoglobin by +2.46 g/dl in their subjects.

In our study, the mean hemoglobin rose from a baseline of 9.04 g/dl to an optimal 11.52 ± 1.01 g/dl:. Specifically, the largest clusters were found in the 11.0–11.9 g/dl range (149 subjects, 36.3%) and the 12.0–12.9 g/dl range (131 subjects, 32.0%), with an additional 5.4% achieving 13.0–13.9 g/dl. While a study by Deepthisri et al. (2023): reported a mean hemoglobin increased from a baseline of 8.76 g/dl to 11.47 ±0.85 g/dl at 4 weeks and Haldar P. et al. (2022) reported a 4-week post-infusion,[16] mean hemoglobin of 10.3 ± 1.24 g/dl (rising from a baseline of 8.5 g/dl.

CONCLUSION

This study demonstrates that intravenous iron sucrose is a highly effective and safe therapeutic option for the management of moderate anaemia in pregnancy. A significant and progressive rise in haemoglobin levels was observed from baseline to 3 weeks, 4 weeks indicating rapid correction of anaemia. The improvement in red cell indices such as MCV, MCH, and MCHC further confirms effective replenishment of iron stores and correction of iron deficiency.

The safety profile of intravenous iron sucrose in this tertiary care setting was excellent. Consequently,

intravenous iron sucrose should be strongly advocated as the standard of care for pregnant women presenting with moderate anemia in the late trimesters.

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