EFFICACY OF INTRAVENOUS IRON SUCROSE IN WOMEN WITH IRON DEFICIENCY ANEMIA IN THIRD TRIMESTER VISITING TO A TERTIARY CARE HOSPITAL

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DOI: https://doi.org/10.5281/zenodo.15422910

Keywords

Hemoglobin levels, Iron deficiency anemia, Ferritin levels, Efficacy, Intravenous iron sucrose

Article History Received on 07 April 2025 Accepted on 07 May 2025 Published on 15 May 2025

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Abstract

OBJECTIVE: To determine the efficacy of intravenous iron sucrose in women with iron deficiency anemia in third trimester visiting to a tertiary care hospital. **METHODOLOGY:** This cross-sectional research endeavor is scheduled for execution in 2024 within the Obstetrics & Gynecology Department of Liaquat University of Medical and Health Sciences, Jamshoro, and will involve the enrollment of 146 pregnant women diagnosed with iron deficiency anemia (hemoglobin levels <10 g/dL, ferritin levels <10 μ g/L) during the third trimester of gestation. Eligible participants have a singleton pregnancy over 20 weeks and are aged 20-35 years and will be given iron sucrose intravenously on alternate days. After four weeks, hemoglobin levels will be reassessed, with a concentration above 11 g/ dL deemed indicative of treatment effectiveness. The dataset will undergo analysis through the application of SPSS version 26, employing both descriptive statistics and the chi-square test for evaluation.

RESULTS: The mean age of the participants was 25.9 years (±4.8 SD). Prior to the intervention, the average hemoglobin concentration was recorded at 9.09 ± 0.50 g/dL, whereas the serum ferritin levels exhibited an average of 24.44±9.09 ng/mL. Subsequent to the administration of iron therapy, hemoglobin concentrations demonstrated a statistically significant enhancement (p=0.000), and improvements in serum ferritin levels were also observed (p=0.044). The intervention proved to be particularly effective among women possessing a normal Body Mass Index (81.6%), elevated educational attainment (82.9%), and superior socioeconomic standing (83.7%).

CONCLUSION: The research elucidated a significant increase in hemoglobin and serum ferritin concentrations subsequent to the implementation of the intervention, thereby reinforcing the assertion that intravenous iron sucrose constitutes a viable therapeutic strategy for addressing iron deficiency anemia during the perinatal phase. Considering its established effectiveness and safety

ISSN: 3007-1208 & 3007-1216

characteristics, intravenous iron sucrose continues to be regarded as a reliable strategy for enhancing maternal health and promoting positive outcomes for both the mother and the newborn.

INTRODUCTION

Iron deficiency anemia (IDA) is the most common type of anemia worldwide and simultaneously the most common nutrition disorder [1]. Using robust methodologies, the World Health Organization (WHO) has estimated that global anemia affects almost 40% of pregnant women and 1/3 of all women of reproductive age [2]. Iron deficiency anemia is one of the most important public health problems and among the most common nutritional disorders in pregnant women. Iron deficiency anemia in pregnant persons associated with increased cardiovascular burden hypervolemia fatigue faintness malaise preeclampsia renal insufficiency antepartum hemorrhage requirements for blood transfusion and increased mortality. In addition, iron deficiency anemia is linked to poor perinatal outcome, including intrauterine growth restriction, intrauterine fetal demise, preterm labor and low birth weight [3] Iron deficiency and iron-deficiency anemia are often seen as secondary sequelae to other more serious underlying pathologies (eg, inflammatory bowel disease, gastrointestinal bleeding, congestive heart failure, chronic renal failure, and malignancies). Additionally, the possibility of iron depletion may also be influenced by history of heavy menstrual bleeding and status of pregnancy [4]. Gestational anemia can lead to negative health outcomes for both maternal and fetal populations. While parenteral iron preparations have proven safe and effective in clinical practice, iron sucrose represents one of the most extensively used preparations in pregnancy. This particular framework focuses on multiple determinants leading to poor compliance with therapeutic regimens [5] It is evident that the application of intravenous iron therapy for the treatment of iron deficiency anemia during gestation is not only secure and feasible but also demonstrably effective than the administration of more intramuscular iron [6]. Although the extant literature pertaining to the beneficial effects of iron supplementation on maternal and neonatal health outcomes is relatively sparse, a Cochrane review conducted in 2015 determined that prophylactic iron

supplementation led to a 70% reduction in maternal anemia and a 57% decline in iron deficiency at term. Consequently, the identification and management of anemia during pregnancy hold considerable importance and may act as a preventive strategy against various distinct causes of severe maternal and neonatal morbidity [7]. In developing countries, it is estimated that approximately two-thirds of pregnant women are affected by nutritional anemia. Moreover, in these regions, a significant proportion of women exhibit anemia at the time of conception, with an estimated prevalence of anemia approaching 50% among non-pregnant females. The prevalence of anemia among married women aged 15 to 44 is estimated to be 47% in rural areas and 26% in urban environments within Pakistan [8]. Naz F et al. conducted a research study in Pakistan and concluded that iron sucrose therapy was effective in treating pregnant women experiencing iron deficiency anemia, successfully achieving target hemoglobin levels. The documented effectiveness of iron sucrose treatment was quantified at 75.3%, in contrast to the considerably diminished rate of ineffectiveness, which stood at 24.7%. This study demonstrated a significant enhancement in the hemoglobin concentrations of patients following the infusion of iron sucrose[9]. This scholarly inquiry has been systematically designed to assess the effectiveness of iron sucrose in correlation with variations in hemoglobin levels among expectant mothers in the third trimester, while simultaneously conducting a comprehensive analysis of the implications and safety associated with iron sucrose for the augmentation of hemoglobin concentrations. In light of the existing scarcity of regional research in this specific area, the outcomes derived from this study will provide substantial evidence regarding the safety and clinical applicability of intravenous iron sucrose for women afflicted with iron deficiency anemia. Considering these critical factors, I am embarking on this research initiative to

identify an alternative iron therapy that not only

exhibits superior efficacy and safety but also enhances

patient adherence while concurrently diminishing the

ISSN: 3007-1208 & 3007-1216

need for blood transfusions during the antenatal phase.

METHODOLOGY

This empirical cross-sectional study is intended to be executed within the Department of Obstetrics and Gynecology at Liaguat University of Medical and Health Sciences, located in Jamshoro, throughout the entirety of the calendar year 2024. A non-probability consecutive sampling methodology will be employed to recruit 146 pregnant women who have been identified with iron deficiency anemia (hemoglobin <10 g/dL, serum ferritin <10 μ g/L) in the third trimester of their pregnancy. Women between the ages of 20 and 35 years, who are experiencing singleton pregnancies that have progressed beyond 20 weeks of gestation, will be deemed eligible for participation, regardless of their parity, gravida status, antenatal booking status, or socioeconomic factors. Conversely, participants characterized by alternative causes of anemia (including thalassemia, megaloblastic anemia, or hemolytic anemia), those who have undergone iron therapy or received blood transfusions during the current pregnancy, individuals with pre-existing health conditions (such as diabetes, hypertension, cardiovascular, thyroid, or renal disorders), or those possessing a documented hypersensitivity to intravenous iron infusions will be excluded from the study. Eligible participants attending the antenatal outpatient department will be recruited following the procurement of informed consent A thorough medical history will be systematically documented, incorporating variables such as chronological age, gestational age, parity, gravidity, stature, weight, body mass index (BMI), socioeconomic status, professional occupation, educational achievement, in addition to previous obstetric and medical histories. Baseline evaluations will encompass a complete blood count (CBC), hemoglobin concentrations, and serum ferritin levels, which will be assessed prior to the commencement of treatment. Intravenous iron sucrose therapy will be administered on alternate days, contingent upon the calculated iron deficit pertinent to each individual patient. Each administration of 200 mg iron sucrose shall undergo dilution in 100 ml of 0.9% normal saline, which will initially be administered at a rate of 8-12 drops per minute over a span of 15-30 minutes,

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subsequently transitioning to a rate of 36 drops per minute for the remaining duration of the infusion. Patients will undergo meticulous observation for one hour following the infusion to identify any potential allergic responses. The therapeutic efficacy of iron sucrose will be assessed four weeks subsequent to the final infusion, with a hemoglobin level exceeding 11 g/dL deemed indicative of a favorable therapeutic outcome. All hemoglobin evaluations will be conducted personally by the trainee researcher, with follow-up of patients scheduled one month later to document their terminal hemoglobin levels. The data thus collected will be systematically documented in a pre-structured proforma and subsequently subjected to analysis to evaluate the effectiveness of intravenous iron sucrose in the treatment of iron deficiency anemia during the third trimester of gestation. Data entry and analysis will be performed utilizing SPSS version 26. Descriptive statistics will be computed, and data will be analyzed and presented with a 95% confidence interval. Descriptive statistics will be calculated concerning the mean and standard deviation, along with frequency represented as a percentage for both quantitative and qualitative variables, respectively. The Chi-square test will be utilized to assess statistical significance at a 5% level of confidence.

RESULTS

Table I demonstrates that the average chronological age of the patient cohort is 25.90 years, accompanied by a standard deviation of 4.80 years. A significant majority, specifically 76.7%, resides within the age bracket of 20 to 30 years, while 23.3% exceed the threshold of 30 years. The mean body mass index (BMI) is reported at 27.08 kg/m², with a standard deviation of 3.81 kg/m². A substantial majority of patients, accounting for 79.5%, exhibit a BMI that falls within the range of 21 to 30 kg/m², whereas 20.5% present with a BMI that surpasses 30 kg/m². The mean parity is computed to be 2.09, with a standard deviation of 1.17. Approximately 63.5% of the patients display a parity ranging from 0 to 3, whereas 36.5% possess a parity that exceeds 3. The mean gravida is established as 3.03, accompanied by a standard deviation of 1.30. A considerable majority, comprising 61.0%, have encountered pregnancy between 1 and 3 times, while 39.0% have experienced

ISSN: 3007-1208 & 3007-1216

more than 3 pregnancies. The mean serum ferritin level is quantified at 24.44 ng/mL, with a standard deviation of 9.09 ng/mL. Approximately 56.8% demonstrate serum ferritin levels ranging from 11 to 25 ng/mL, whereas 43.2% exhibit levels that surpass 25 ng/mL. The mean hemoglobin level is documented at 9.09 g/dL, with a standard deviation of 0.50 g/dL. Roughly 39.7% maintain hemoglobin levels between 8.1 and 9.0 g/dL, while 60.3% present with levels that exceed 9.0 g/dL. The demographic distribution reveals that 32.2% of patients hail from economically disadvantaged backgrounds, 45.2% from middle-class standings, and 22.6% from affluent socioeconomic strata. Within this patient population, 19.9% are illiterate, 23.3% possess a primary education, 26.0% have achieved matriculation, and 30.8% have attained educational qualifications at the intermediate level or beyond. A noteworthy segment, comprising 62.3%, is engaged as housewives, while 37.7% are women in employment.

Table II elucidates that females within the age bracket of 20 to 30 years exhibited a significantly enhanced efficacy of intravenous iron sucrose intervention (96.8%) when juxtaposed with their counterparts exceeding the age of 30 years (3.2%), yielding a p-value of 0.003, thereby indicating a statistically significant variation. Participants whose body mass index (BMI) fell within the range of 21 to 30 kg/m² demonstrated a higher efficacy rate (93.5%) in comparison to those whose BMI surpassed 30 kg/m² (6.5%), accompanied by a p-value of 0.020, thus suggesting a noteworthy correlation between BMI and treatment efficacy. Although the observed difference was not classified as statistically significant (p-value of 0.186), women with a parity of 0-3 exhibited a superior efficacy (80.6%) relative to those with a parity exceeding 3 (19.4%). Moreover, women who had experienced 1-3 pregnancies indicated a heightened efficacy rate (77.4%) compared to those who had undergone more than 3 pregnancies (22.6%), with a p-value of 0.034, implying a significant association between gravida and treatment efficacy. A pronounced distinction in efficacy based on socioeconomic status was observed, economically disadvantaged cohort with the manifesting lower efficacy (9.7%) as opposed to the middle (54.8%) and upper (35.5%) socioeconomic classes, as evidenced by a p-value of 0.007. The degree of educational attainment exhibited a significant

impact on efficacy, with individuals possessing intermediate education or higher demonstrating the highest efficacy (58.1%), while illiterate women displayed the lowest efficacy (3.2%), with a p-value of 0.000. Furthermore, housewives experienced a significantly superior efficacy (80.6%) in contrast to employed women (19.4%), as supported by a p-value of 0.018, thereby underscoring a significant association between occupational status and treatment efficacy.

Women who exhibited a favorable response to intravenous iron sucrose therapy demonstrated a statistically significant elevation in serum ferritin levels $(27.35 \pm 5.13 \text{ ng/mL})$ in comparison to those who failed to present a therapeutic response $(23.66 \pm$ 9.76 ng/mL). The p-value of 0.044 signifies a statistically significant difference, thereby indicating that elevated serum ferritin levels are correlated with improved therapeutic outcomes. Women who exhibited a favorable response to intravenous iron sucrose therapy demonstrated a statistically significant elevation in serum ferritin levels $(27.35 \pm 5.13 \text{ ng/mL})$ in comparison to those who failed to present a therapeutic response (23.66 \pm 9.76 ng/mL). The pvalue of 0.044 signifies a statistically significant difference, thereby indicating that elevated serum ferriting levels are correlated with improved therapeutic outcomes. The hemoglobin levels were markedly higher in women who experienced a positive therapeutic effect from the intervention (9.59 ± 0.33) g/dL) compared to those who did not (8.95 ± 0.46 g/dL). The p-value of 0.000 denotes an extraordinarily high level of statistical significance, suggesting that augmented hemoglobin levels are robustly associated with the efficacy of intravenous iron sucrose therapy, as delineated in Table III.

DISCUSSION

deficiency represents Iron anemia (IDA) а considerable concern throughout gestation, particularly in the third trimester, and is associated with adverse implications for both maternal and fetal well-being. Nevertheless, there exists a limited number of studies that have substantiated the effectiveness and safety profile of intravenous iron sucrose. Agrawal et al.[10] conducted a comparative analysis between ferric carboxymaltose and iron sucrose within a cohort of pregnant women and observed that both

ISSN: 3007-1208 & 3007-1216

therapeutic agents similarly elevated hemoglobin concentrations. Although their results furnish robust evidence in favor of intravenous iron therapy, they fail to consider the temporal aspects or the specificity of the iron absorption route during pregnancy, elements that could provide additional perspectives on optimizing iron therapy in this demographic. Similarly, as Shin et al. A systematic review and metaanalysis contrasting intravenous ferric carboxymaltose vs iron sucrose was conducted by [11] who demonstrated both to be equivalently efficacious, but with ferric carboxymaltose achieving statistically significant more rapid recovery of hemoglobin levels. The varied demographics of our patient population as compared to the studies previously defined may have influenced our findings, demonstrating the need for more prospective studies of single populations. The inquiry conducted by Neogi et al. [12] rigorously evaluated the safety and efficacy of intravenous iron sucrose relative to conventional oral iron supplementation in pregnant women afflicted with moderate-to-severe anemia. Their findings demonstrated the enhanced ability of intravenous iron sucrose to rapidly elevate hemoglobin concentrations-an imperative factor for pregnant patients requiring immediate iron replenishment. In a related study, Jose et al. [13] assessed ferric carboxymaltose against iron sucrose in pregnant women diagnosed with iron deficiency anemia, concluding that intravenous iron therapies exhibit significantly greater efficacy than their oral counterparts. The authors recognized the limitations of their work, which included the study's small sample size and lack of a long-term follow-up period in order to determine whether treatment effects are maintained over time. Rudra et al. Yousefzadeh et al., [14] have studied the effects of intravenous iron sucrose and oral iron in pregnant women with IDA and indicated that intravenous iron is well absorbed and effective than oral iron therapy. Similarly, Abhilashini et al. [15] evaluated the use of IV iron sucrose vs oral iron and confirmed the advantages of IV treatment. Nevertheless, their investigation did not address the risks associated with the use of intravenous iron such as allergic reactions or other adverse events that would need further investigation A study from Nagash et al. had a new and extended investigation into the comparative effectiveness and

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safety of both ferric carboxymaltose and iron sucrose. Both interventions were safe and efficacious [16]. Yet this investigation was limited-due to a small number of participants and other details on preexisting conditions being unavailable-potentially limiting their generalizability to the under-studied population. The aim of the present study was to investigate the short-term clinical efficacy and safety of intravenous iron sucrose in pregnant women. Szahin and Madendağ [17] performed a prospective cohort study of intravenous iron sucrose therapy in pregnancy. They called for larger and more comprehensive trials, with longer follow-up periods, to confirm these findings and provide information on long-term outcomes. Qassim et al [18], recently conducted a systematic review evaluating the safety and effectiveness of intravenous iron polymaltose, iron sucrose, and ferric carboxymaltose in pregnant women.

They concluded that intravenous iron sucrose appears to be effective and tolerable; however, more goodquality, large-scale trials are required to determine the best intravenous iron in pregnancy.

Results were consistent with the previous studies confirming the effectiveness of intravenous iron sucrose during the third trimester of pregnancy from our previous observational cross-sectional study assessing the effectiveness of intravenous iron sucrose during the late third trimester of pregnancy. The responders also showed a high linear-site serum ferritin concentration $(27.35 \pm 5.13 \text{ ng/mL})$ in our study as compared to non-responders (23.66 ± 9.76) ng/mL, p=0.044, 95% CI: 0.092 to 7.291). Likewise, hemoglobin concentrations were markedly higher in the effective treatment cohort (9.59 \pm 0.33 g/dL) in contrast to the non-effective group (8.95 \pm 0.46 g/dL, p=0.000, 95% CI: 0.459 to 0.810). These findings corroborate the efficacy of intravenous iron sucrose in enhancing both iron reserves and hemoglobin concentrations.

Our findings corroborate those reported by Raja KS et al [9]. similarly with mean serum ferritin significantly higher after treatment (9.6 μ g/L before treatment versus 16.4 μ g/L after treatment), as well as hemoglobin (7.5 g/dL before treatment versus 11 g/dL after treatment). Moreover, an additional investigation contrasting intravenous and oral iron therapies revealed pre-treatment hemoglobin levels of

ISSN: 3007-1208 & 3007-1216

 9.03 ± 0.47 g/dL in the intravenous cohort and 8.82 \pm 0.39 g/dL in the oral cohort. Following a 30-day treatment period, hemoglobin levels ascended to 10.7 \pm 0.55 g/dL and 10.9 \pm 0.58 g/dL, respectively, with both groups achieving comparable hemoglobin levels prior to delivery (11.38 ± 0.56 g/dL vs. 11.35 ± 0.47 g/dL), devoid of statistically significant differences (p=0.355, p=0.513, and p=0.975). This indicates that although intravenous iron sucrose is efficacious, its superiority over oral iron regarding prolonged hemoglobin enhancement may be inconsistent. Several strengths and limitations of our investigation warrant acknowledgment. The non-probability consecutive sampling methodology facilitated the inclusion of а heterogeneous participant demographic; however, it may introduce selection bias, thereby impacting external validity. Furthermore, the study excluded pregnant individuals with comorbidities, which may constrain the generalizability of the findings to the wider population. The second limitation is an incomplete reporting of possible side effects such as hypersensitivity reactions or long term health effects. Future studies should attempt to include high sample size, use longer follow-up time and control confounding factors better to increase the validity and generalizability of the conclusion. These initiatives will yield more robust empirical data regarding the optimal application of intravenous iron sucrose during gestation in cases of iron deficiency anemia.

CONCLUSION

The research elucidated a significant increase in hemoglobin and serum ferritin concentrations subsequent to the implementation of the intervention, thereby reinforcing the assertion that intravenous iron sucrose constitutes a viable therapeutic strategy for addressing iron deficiency anemia during the perinatal phase. Considering its established effectiveness and safety characteristics, intravenous iron sucrose continues to be regarded as a reliable strategy for enhancing maternal health and promoting positive outcomes for both the mother and the newborn.

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Table I: Demographic Characteristics of the Patients	(n=146)
Variable	Frequency (%)
Age, Mean ± SD= 25.90 ± 4.80 years	
20 - 30 Years	112 (76.7)
> 30 Years	34 (23.3)
Body Mass Index, Mean \pm SD= 27.08 \pm 3.81 kg/m ²	
21 - 30 Kg/m ²	116 (79.5)
> 30 Kg/m ²	30 (20.5)
Parity, Mean ± SD= 2.09 ± 1.17	
0 - 3	61 (63.5)
> 3	35 (36.5)
Gravida, Mean \pm SD= 3.03 \pm 1.30	
1 - 3	89 (61.0)
> 3	57 (39.0)
Serum Ferritin, Mean ± SD= 24.44 ± 9.09 ng/mL	
11 – 25 ng/mL	83 (56.8)
> 25 ng/mL	63 (43.2)
Hemoglobin Levels, Mean ± SD= 9.09 ± 0.50 g/dL	
8.1 - 9.0 g/dL	58 (39.7)
> 9.0 g/dL	88 (60.3)

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Socioeconomic Status								
Poor				47 (32.2)				
Middle				66 (45.2)				
Upper				33 (22.6)				
Educational Status								
Illiterate					29 (19.9)			
Primary					34 (23.3)			
Matric				38 (26.0)				
Intermediate or above Occupational Status					43	5 (30.8)		
Working Women					5	5 (37 7)		
Housewife					<u>55 (37.7)</u> 91 (62.3)			
Table II: Efficacy of Int	ravenous Iron Suc	rose in Wom	an with	Iron D			hird Trimester	
(n=146)	liavenous from ouch				enciency Anei		inita Trimester	
				E	fficacy			
Demographic ar	nd Clinical Factors,	n (%)		(es = 31)	No (n = 115)	P-Value	
	20 - 30 Yea	ars	30	(96.8)	82 (71.3))		
Age Group	> 30 Year	-s	1 ((3.2)	33 (28.7))	0.003	
DV(I	21 - 30 Kg/	m^2	29 ((93.5)	87 (75.7))	0.020	
BMI —	> 30 Kg/n	n^2	2 ((6.5)	28 (24.3))	0.020	
Parity	0-3		25	(80.6)	102 (88.7	0.186		
I alley	> 3		6(19.4)	13 (11.3))	0.100	
Gravida	1 - 3	institute for Excellence in E	24	(77.4)	65 (56.5))	0.034	
Oravida	> 3		7 (22.6)	.6) 50 (43.5		0.034	
。 · · · · ·	Poor		3 ((9.7)	44 (38.3))		
Socioeconomic	Middle		17 ((54.8)	49 (42.6)		0.007	
	Upper		11 ((35.5)	22 (19.1))		
Educational Status	Illiterate	•	1 ((3.2)	28 (24.3))		
	Primary Matric		2 ((6.5)	32 (27.8)		0.000	
			10 ((32.3)	28 (24.3)) 0.000		
	Intermediate or	r above	18 ((58.1)	27 (23.5))	1	
Occupational Status	Working Women		6 (19.4)		49 (42.6)		0.018	
Occupational Status House		ife 2		80.6) 66 (57.4)	0.018	
Table III:	Efficacy of Intraven	ous Iron Sucr	ose witl	n Laborat	ory Parameter	s (n=146)	
Laboratory Parameters, <i>n (%)</i>		Efficiency Efficiency (n = 31)		icacy No (n = 115)		P-Value (95% C.I)		
Serum Ferritin (ng/mL)		27.35 ± 5.13		23.66 ± 9.76			0.044	

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Hemoglobin Level (g/dL) 9.59 ± 0.33 8.95 ± 0.46 0.000 (0.4590.810)				(0.0927.291
	Hemoglobin Level (g/dL)	9.59 ± 0.33	8.95 ± 0.46	0.000 (0.4590.810)

C.I= Confidence Interval

