



Safety And Efficacy of Parenteral Iron Sucrose in Treating Anaemic Patients and Role of Clinical Pharmacist In Patient Counselling

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ABSTRACT

Anaemia is the most common medical problem in pregnancy. A WHO technical group documented that parenteral iron therapy has shown a rapid iron correction. The purpose of the study is to assess the safety and efficacy of parenteral iron sucrose in treating anaemic patients and the role of the clinical pharmacist in patient counselling. The method of study is a prospective cohort study. A self-designed and validated questionnaire was used. Collected data was tabulated and interpreted using statistical software. On reviewing the demographic data, it was found that anemia was more prominent in the 21–25 year age group (53.080%) with mean haemoglobin before treatment with IVIS was 8.58 g/dl and after treatment was 9.87 g/dl with a P-value of 0.0001. Among 211 subjects, 11.848% experienced an adverse drug reaction to IVIS. With reference to the WHO ADR assessment scale, all reactions are probable. On Hartwig's severity assessment scale, mild, moderate and severe reactions were 1.41%, .05% and 2.36%. After the treatment with IVIS patient were counselled on iron rich diet and life style modifications. The study concluded that IVIS is safe to administer and efficacious in increasing haemoglobin levels.

Keywords: Adverse reaction, Anaemia, Counselling, Haemoglobin, Hartwig's scale, Iron sucrose, Pharmacist.

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INTRODUCTION

Anaemia is a medical condition where the number of red blood cells (RBC) or their oxygen-carrying capacity is insufficient to satisfy physiological needs²². WHO (World Health Organization) estimates that 40% of Worldwide estimates of 2022 indicated that in Asia, 40% of women suffered from anaemia at their reproductive ages. The average monthly menstrual blood loss is about 45ml, which causes 22mg of iron loss from the body per month. Anaemia affects people at all stages of life, including infants, pre-school children, adolescents, pregnant women of childbearing age, and the elderly, but it is more common in young children and pregnant women [16].

In developing and developed countries, nearly half of all pregnant women are affected by anaemia [29, 32]. About 90% of anaemia is iron deficiency anaemia [24, 14], which is due to inadequate intake of dietary iron. [15, 19]. The nutritional deficiencies which cause iron deficiency anaemia are folate, vitamin B12, and vitamin A [7, 28]. The known risk factors for developing anaemia during pregnancy are grand-multiparity, too early pregnancies, too many and too frequent pregnancies spacing 1 year, low socioeconomic status, illiteracy, and late presentation of pregnant women at antenatal care unit [26].

In India, the second most common cause of maternal death is anaemia, which accounts for 20% of the total ^{4,21,23,27}. Anaemia in pregnancy results in poor outcome in both maternal and foetus [11].

The health and nutrition of mother and child are well related. Hurdles related to the building of iron stores during pregnancy provide a strong rationale for health education concerning the iron status of women before pregnancy [12]. Nutritional knowledge is essential for individuals to have a healthy lifestyle and be free from disease.

The aim of the present study is to assess the safety and efficacy of IVIS (Intravenous Iron Sucrose) in treating anaemic patients with obstetric and gynaecological problems. The primary objective of the present study is to monitor the safety and efficacy of iron sucrose. The secondary objective of the study to assess anaemia knowledge and to counsel and raise awareness about anaemia by a clinical pharmacist.

MATERIAL AND METHODS

Materials: Iron sucrose injection USP-100mg/5ml obtained from Germen Remedies (composition: Ferric hydroxide in complex with sucrose equivalent to elemental iron 100 mg, M.L. No: MB/06/300, Batch no: ZBR0005, Mfg. date: 10/2018, Exp. date: 09/2020).

Study Design: Prospective Cohort Follow up Study

Study Site: Department of Obstetrics & Gynaecology, Government General Hospital, Guntur.

Period of Study: September 2019 to February 2020 (6 months)

Sample Population: Individuals having anaemia and receiving parenteral iron sucrose referred to the gynaecology department.

Inclusion Criteria:

- Patients receiving parenteral iron sucrose.
- Moderate to severe anemic patients of age 18-50 yrs.

Exclusion Criteria:

- Patients who are known hypersensitive to parenteral iron sucrose.
- Patients with hereditary hematological disorders like thalassemia.
- Patients who received a blood transfusion in the past three months.
- First-trimester pregnant women.

Ethical committee approval: The present study got approval from Institutional Ethics Committee of Guntur Medical college and Government General Hospital with IEC No: GMC/IEC/107/2019.

Study procedure:

Based on inclusion and exclusion criteria subjects were enrolled. During the 6 months of the study first 3 months' data were collected from the subjects and last 3 months follow up was done. Prior data collection subjects were provided with informed consent form in their local language and got signed. After data collection patients were provided with self-designed and validated diet chart. Counselling on anemia and their complications and asking them to adhere to diet chart. Follow up was done after 3 months of IVIS (Intravenous Iron Sucrose) administration.

Statistical analysis: Data were analysed using SPSS 23.0 version for paired t-test, mean, standard deviation and the data was presented in Microsoft excel 2007.

RESULTS AND DISCUSSION

A total of 211 patients were screened to include the subjects in the study. Results of the present study are tabulated and analysed by using specific statistical tools. Descriptive data were expressed as percentage, mean and standard deviation and for continuous data Student t-test was used. The test used was two-sided and the level of significance was set at $p < 0.05$ with 95% confidence interval.

The results of the present study include demographic distribution of subjects, the role of a clinical pharmacist in lifestyle modification and disease outcome. Statistical analysis was done and proved the influence of clinical pharmacist role on disease outcome and to reduce anaemia risk in OBG (Obstetrics and Gynaecology).

Demographic data of study subjects:

The mean age group of the study population was 23.194 ± 3.83 and anemia was most commonly seen in the age group of 21-25 yrs. Occupation of subject's anemia mostly was seen in house wife (60.1%). The mean BMI (Body Mass Index) of the population was 23.49 ± 4.03 . Tea consumers are commonly affected with anemia rather than coffee consumers and non-consumers of tea and coffee. Among all the subjects 81.99% were taking one tablet of iron supplement. Two tablets of iron supplement were taken by 13.74% subjects and 1.9% subjects were not using any iron supplements. As per gravida anemia was most commonly seen in 2nd gravida with 39.81% when compared to other gravidas. Among the blood groups most commonly seen in B positive 86 (40.75%) and O positive 75 (35.54%) blood groups.

Main content of the study:

In the study population 88.625% subjects are not having any medical co-morbidities like hypothyroidism, hypertension, jaundice, Bell's palsy, asthma, renal calculi etc. The medical complications arise during pregnancy were 16.18% like Gastro Esophageal Reflux Disease (5.21%), hypothyroidism (3.31%), Pre-eclampsia (2.48%), constipation (2.36%), Gall stones (0.47%), seizures (0.47%), Urinary Tract Infections (0.47%), Pregnancy induced Diabetes (0.47%), Bell's palsy (0.47%) and HIV positive (0.47%). Based on

haemoglobin level before iron sucrose administration 46% subjects were with mild anaemia, 45% subjects were with moderate anaemia and 9% of subjects were with severe anaemia. During the day of administration of IVIS patients were counselled not to take oral iron supplementations. The laboratory data before administration of IVIS 100% of subjects were having low MCV value which indicates microcytic anaemia, 28(13.27%) subjects were having abnormal urine components such as pus cells and epithelial cells, 10 (4.73%) subjects were having abnormal blood glucose level, 9 (4.26%) subjects were having abnormal thyroid profile with altered TSH levels and 3 (1.42%) subjects were positive to HIV.

As per literature the IVIS should be administered with dose dilution of 0.5-2.0 mg/ml for 15-30 min. so in order to check which dilution is well tolerated subjects are divided into 4 groups they are shown in **Table:01**. More adverse reactions were observed in dose of 200mg in 100ml NS (2mg/ml) is 31.7% when compared with other groups and very few adverse reactions were observed in 100mg in 200ml(0.5mg/ml) group is 1.85%. There was vitals abnormality after transfusion of IVIS 20 (9.47%) subjects experienced abnormal BP, 3(1.42%) subjects experienced tachycardia (HR:120-140 bpm) and 3 (1.42%) subjects experienced fever around 100-101°F. the observed abnormal vitals were mostly seen in 200mg in 100ml NS group.

The observed adverse reactions to IVIS are shown in **Table: 02**. The most commonly observed adverse reactions were chills and rigours, head ache, low back ache etc. In the observed adverse reactions to IVIS the immediate adverse reactions were 8(31%), early reactions were 7(28%) and late reactions were 10(40%) out of 25 adverse reactions. The observed adverse reactions were assessed by WHO causality assessment scale and severity was assessed by Hartwig's severity assessment scale was shown in **Table:03**.
Assessment of adverse drug reactions to IVIS:

In WHO causality assessment scale all the observed reactions are probable/likely. In Hartwig's severity assessment scale mild reactions were 3, moderate reactions were 17 and severe reactions were 5. The subjects who are experienced with adverse reaction to IVIS were provided with alert cards and asked them to show the alert card to physician whenever reaches him. All the adverse reactions were reported to PVPI centre present in GGH, Guntur and got acknowledgement from PVPI for submitting ADRs on IVIS.

Follow-up of study subjects:

The subjects were counselled to have an iron rich diet by providing diet chart in local language, follow up was done regularly and the haemoglobin levels were determined. During follow up through phone call few questionnaires were asked and also regarding symptoms. Haemoglobin levels before IVIS administration and after IVIS administration was shown in table. The mean rise of Hb after follow up is 1.21g/dl as shown in **Fig.01**.

Statistical analysis of data:

Before administration of IVIS the minimum Hb is 5.2g/dl, maximum Hb is 10.6g/dl, the mean Hb is 8.66g/dl and Standard Deviation (SD) is 1.072. The Hb value after administration of IVIS is 7.5g/dl (Minimum value) and 11.9g/dl (maximum value), the mean value is 9.8g/dl and SD is 0.869. The Paired t-test showed 44.7288 and P-value is <0.0001 which is statistically significant done by SPSS version 23.0 was shown in **Table:04**

The symptoms of the subjects before IVIS administration and after IVIS administration was shown in **Table: 05**. Most of the symptoms were resolved to most of the subjects but hair fall reduction was not reduced.

DISCUSSION

Anemia is one of the most common hematological problems observed in pregnancy. Anemia is associated with maternal complications like preterm labour, preeclampsia, postpartum hemorrhage, sepsis and shock. Anemia is the leading cause of maternal morbidity and mortality.

In the present study, we observed that intravenous administration of iron sucrose elevated Hb concentration and also restores iron stores effectively. Low availability, poor absorption of iron, and repeated and closely spaced pregnancies places a constant strain on iron stores of pregnant women resulting in IDA.

In a study conducted by Ashutosh D Jorgia et al in 406 pregnant women, the mean age group is 24.3 ± 3.81 years and the majority (50%) were in the age group of 20-25 yrs [3]. Kriplani et al in her study the observed mean age group was 27.8±3.9 years among 97 women [1]. Gopal Krishna et al in his study observed the mean age group was 23.28±3.38 years among 76 subjects[8]. A study conducted by Gourab Ranjan et al in 104 subjects the mean age group was 25.4 ± 3.26 years [13]. Nimbalkar B Pankaj Kumar B et al in a study with 150 subjects the most of the subjects are in the 20-24 yrs age group [18]. In our study with 211 subjects, we observed that the mean age group were 23.194 ± 3.83 yrs.

In the occupation distribution of subjects with anaemia, most of the subjects were housewives (60.1%). In BMI distribution of subjects, most of them were with normal BMI (18.5-25 kg/m²) i.e 129 subjects with

mean BMI is 23.49 ± 4.03 kg/m². In literacy wise distribution of subjects, low literacy level (53.5%) and illiterate (25.1%) subjects were observed with more anaemia and tea consumers (52.132%) were with high anaemia incidence rather than coffee consumers. Subjects of 81.990% were prescribed previously with one tablet oral iron even though they are adhering to medication it doesn't reduce the risk of anemia. Urmila G et al in her study out of 300 subjects 84 (28%) subjects were with primigravida and 216 (72%) subjects were with multigravida⁷. In the present study out of 211 subjects, 74 (37.07%) subjects were having primigravida and 137 (64.92%) subjects were having multigravida. Suchhitha et al in her study out of 110 subjects observed that 89(90.73%) subjects were asymptomatic and 21(9.27%) subjects exhibited symptoms like weakness, fatigue, pedal edema and fever [20]. In the present study out of 211 subjects 126 (59.71%) subjects were asymptomatic and 85 (40.28%) subjects with symptoms like headache, fatigue, tingling, hair fall edema, S.O.B and pallor.

In a study conducted by Akhileshwar S et al in 109 subjects were with medical co-morbidities and medication use is a risk factor for anemia [25]. In the present study reference to past medical and medication history, 24 (11.37%) subjects were having a medical history like hypothyroidism, hypertension, UTI, GERD, hypotension, Bell's palsy, jaundice, RVD, asthma, Renal calculi and Hypertension with jaundice and healthy subjects were 187 (88.62%). During pregnancy, the medical condition a raised was 35 (16.58%) subject's like HIV, hypothyroidism, hyperglycemia,, abnormal urine level and 176 (83.89%) were healthy.

In blood group distribution of subject's B+ve (40.75%) and O+ve (35.54%) were with a high incidence of anemia was observed. Gourab R T et al in his study observed that out of 104 subject's mild anemia were 46 (44.2%) subjects, moderate anemia was 20 (19.2%) and severe anemia were 38(36.6%) subjects [9]. Anitha et al in her study observed that out of 90 subjects 62 (68.88%) subjects were with moderate anemia and 28 (31.11%) subjects with severe anemia were recorded and no severe anemia was found³⁰. Fathima P et al in her study observed that mild anemia were 29%, moderate anemia was 64% and severe anemia were 3%⁶. In the present study, it was found that out of 211 subjects 98 (46.44%) were with mild anemia, 95 (45.02%) were with moderate anemia and 18 (8.53%) were with severe anemia.

In dose dilution and administration of iron sucrose 50 (23.69%) subjects received 100mg in 100ml NS, 51(24.17%) subjects received 200mg in 100ml NS, 54(25.59%) subjects received 100mg in 200ml NS and 56(26.54%) subjects with received 200mg in 200ml NS.

Urmila et al in his study observed that of 18 (6%) experienced adverse effects like nausea and vomiting, rash, myalgia, and thrombocytopenia among 300 subjects [7]. Gupta A et al in his study observed that only one reaction that is shivering after half an hour administration of IVIS and resolved without treatment¹⁰. Devasenapathy N et al in his study observed that 20 episodes of non-fatal reactions like hypotension, nausea, vomiting, rashes, feeling of chest compression were observed [5]. Tariq N et al in his study the observed reactions were palpitations, shivering, heat intolerance, low blood pressure and small joint pains [127]. Shrivastava D et al in his study observed muscle cramps, arthralgia, uneasiness, headache and tightness of the chest [24]. Venkataramana et al in his study observed 14% of adverse effects in the study group³². In the present study, adverse reactions were chills and rigors, headache, low backache, vomiting, S.O.B, body pain, fever, body itching, chest pain, sweating, whole-body numbness, tingling sensation, cough and runny nose were observed.

The present study was compared with other study for Hb level before and after administration and P-values was shown in Table:06.

CONCLUSION

Present study is a Prospective cohort follow up study, based on findings, concluded that administration of IVIS (Intravenous Iron Sucrose) to an iron deficiency anaemia is very good option in patients with oral iron therapy has either failed or not suitable. IVIS along with patient counselling by the clinical pharmacists on lifestyle modifications and diet has significantly increased haemoglobin levels in the study population. Reference to literature of tertiary sources after parenteral therapy the expected increase in Hb is 0.7-1.0g/100ml/week. In present study along with patient counselling on anaemia, the mean rise of Hb is 1.21g/dl. Therefore, non-pharmacological therapy like diet, exercise along with pharmacological therapy increases the Hb levels than expected. To minimize the repeated adverse reactions to IVIS, alert cards are provided. Proper protocol or guidelines were used in the calculation of iron dose and monitored the subjects for 24 hours to reduce adverse reactions and to increase the safety and efficacy of the parenteral iron sucrose.

Table 01: Iron sucrose dose dilution and administration

Dose and dilution	No. of subjects (n=211)	Concentration of elemental iron /ml	Rate & duration of infusion	Reactions observed (n=25)	Percentage (%)
100 mg in 100ml	50	1mg/ml	68-70 drops/min for 15 min	2	4%
200 mg in 100ml	51	2mg/ml	68- 70 drops/min for 15 min	16	31.37%
100 mg in 200ml	54	0.5mg/ml	68-70 drops/min for 30 min	1	1.85%
200 mg in 200ml	56	1mg/ml	68-70 drops/min for 30 min	6	10.71%

Table 02: Adverse drug reactions to IVIS administration

S.no	ADR	No of subjects	Total Percentage	ADR Percentage
01.	Chills & rigors	9	4.265 %	36 %
02.	Headache	8	3.791 %	32 %
03.	Low Backache	5	2.369 %	20 %
04.	Vomiting	4	1.895 %	16 %
05.	Shortness of breath	4	1.895 %	16 %
06.	Body pains	4	1.895 %	16 %
07.	Fever	3	1.421	12 %
08.	Body itching	3	1.421 %	12 %
09.	Chest pain	2	0.947 %	8 %
10.	Sweating	2	0.947 %	8 %
11.	Whole-body numbness	2	0.947 %	8 %
12.	Injection site blisters formation	1	0.473 %	4 %
13.	Tingling	1	0.473 %	4 %
14.	Cough & Runny nose	1	0.473 %	4 %
15.	Nil	186	88.151 %	0 %

Table 03: Hartwig severity scale assessment for IVIS

S.no	Levels	No of subjects (n= 25)	Percentage
01.	Level- I	1	4 %
02.	Level- II	2	8 %
03.	Level- III	12	48 %
04.	Level- IV	5	20 %
05.	Level- V	5	20 %
06.	Level- VI	0	0 %
07.	Level- VII	0	0 %

Table04: Improvement in Hemoglobin in statistically by SPSS (23.0 version)

S. no	Iron sucrose	Minimum Hb	Maximum Hb	Mean	SD	Paried t-test	P-value
01.	Before	5.2	10.6	8.66	1.072	44.7288	<0.0001
02.	After	7.5	11.9	9.87	0.869		

Table 05: Chief complaints on admission and after follow up with mean Hemoglobin levels

S.no	Chief complaints	Percentage of symptoms (%)	Mean Hb gm/dl Before treatment	Percentage of Symptoms(%)	Mean Hb gm/dl After treatment
1.	Nil (126)	59.71%	8.821 gm/dl	79.14%	10.031mg/dl
2.	Head ache (60)	28.43 %	8.467 gm/dl	11.33%	9.677 /dl
3.	Fatigue(49)	23.22 %	8.446 gm/dl	12.32%	9.656 /dl
4.	Tingling (44)	20.85 %	8.482 gm/dl	9.00%	9.692 /dl
5.	Hair fall(20)	9.47 %	8.009 gm/dl	8.05%	9.102 mg/dl
6.	Edema (16)	7.58 %	8.216 gm/dl	4.26%	9.321 mg/dl
7.	Shortness of breath(15)	7.10 %	8.156 gm/dl	2.84%	9.361 mg/dl
8.	Pallor(3)	1.42%	6.241 gm/dl	0.47%	7.621 mg/dl

Table 06: Comparison of Hemoglobin rise with other studies

S.no	Study	Year	Before IVIS treatment (Mean Hb %)	After IVIS treatment (Mean Hb %)	Hb rise (gm %)	p- value
01.	Akhileshwar S et al ⁽²⁵⁾	2019	9.689	10.981	1.292	<0.001
02	Pankajkumar B. N et al ⁽¹⁸⁾	2017	7.9 ±0.83	10.3±0.83	2.4±0.9	<0.001
03.	Vijayasree et al ⁽³¹⁾	2013	8.5±1.2	11.2±1.8	2.7	<0.001
04.	Vandana et al ⁽³⁰⁾	2014	6.159	8.625	2.46	0.00
05.	Present study	2020	8.58	9.87	1.21	<0.0001

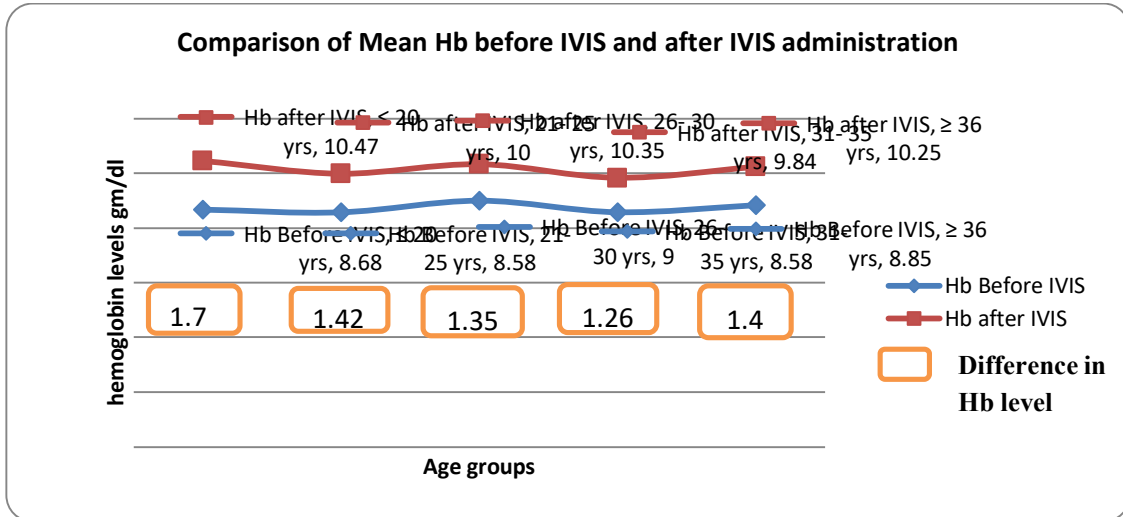


Figure 01: Comparison of mean Hb before and after IVIS infusion

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CONFLIC OF INTEREST:

There is no conflict of interest related to this research study.

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