Assessment of effectiveness of intravenous Iron Sucrose therapy in pregnant women with Iron Deficiency Anemia

Shivali Bhalla [1], Nayana Pathak[2]
[1]Assistant Professor, [2] Professor & Head,
Department of Obstetrics &Gynaecology, Gian Sagar Medical College & Hospital, Punjab, India.
Corresponding Author: Dr Nayana Pathak
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Abstract:
Iron deficiency anemia is a common medical disorder complicating pregnancy. Oral iron therapy during pregnancy is a common treatment modality, but it is time consuming & not useful in severe cases of anemia as well as its utility is limited by gastrointestinal intolerance leading to poor patients' compliance. Blood transfusion although can promptly and reliably treat anemia, entails risk of cross reactions and viral infections. So, Intravenous iron sucrose is a convenient and reliable solution. Materials and methods: Present study was conducted to study the effectiveness of intravenous iron sucrose in pregnant women with Hemoglobin (6-8 gm/dl) between 24-34 wks gestational age. Results: statistically significant difference ($p<0.01$) were observed in various laboratory parameters i.e. Hb %,RBC count, reticulocyte count ,PCV,MCV,MCHC, serum ferritin, serum Iron,TIBC before and after treatment. So, it was concluded from our study that the intravenous ferrous sucrose is very safe and effective modality for correcting and replenish iron stores in antenatal iron deficiency anemic mothers.

Keywords: *Iron deficiency anemia; Iron sucrose; Antenatal; intravenous Iron therapy.*

INTRODUCTION

Nutritional Iron Deficiency is the most common deficiency disorder in the world, affecting more than two billion people worldwide and pregnant women are more at risk(1,2)]. World Health Organization data shows that iron deficiency anemia (IDA) in pregnancy is a significant problem throughout the world with a prevalence ranging from an average of 14% in developed countries to 56% (range 35–75%)in developing countries(2,3). So the developing world is the most vulnerable group, especially low socioeconomic and illiterate populations which are disproportionately affected by iron deficiency, therefore will be benefited more by reducing iron deficiency anemia. It is estimated that 20% to 50% of the world population is suffering from iron deficiency & pregnancy is being one of the most important risk factors for iron-deficient states and iron deficiency anemia.(4)

Maternal iron deficiency and Iron deficiency anemia have detrimental effects on maternal and infant health and have increased risk of intrauterine fetal growth restriction, intrauterine fetal death, infection, preterm delivery, low birth weight and poor APGAR scores neonates. According to WHO, Hemoglobin concentration < 11 gm/dl (7.45 mmol /lit) and hematocrit of less than 0.33(3,,4) is considered as anemia in pregnancy. The CDC recommends that hemoglobin ideally should be maintained at or above 11.0 g/dl, in first and third trimester and should not fall below 10.5g/dl in the second trimester. Women in the reproductive age frequently have anemia and iron deficiency due to menstrual blood loss and most of these women are already anemic by the time they get pregnant. Iron deficiency anemia is more common during pregnancy due to increased demand of iron by growing fetus, placenta and expanded blood volume. The human body does not have a mechanism of getting rid of extra iron from the body so mechanism of iron absorption plays a crucial role in iron homeostasis (5)..

Oral iron supplementation during pregnancy is a very common modality to treat iron deficiency anemia but usually it is time consuming and not suitable for severe cases of anemia as well as its utility is limited by severe gastrointestinal intolerance and noncompliance .On the other hand, blood transfusion which can promptly and reliably treat anemia, entails a lot of danger like cross reactions and viral infections. In order to avoid these side effects parenteral iron therapy can be given. Unlike previous formulations, most notoriously ferrous dextran which was associated with significant risk of anaphylactic reactions, ferrous sucrose is a convenient and reliable solution. Clinical trials and the long history of use of iron sucrose injections worldwide have established the efficacy and safety of this drug in patients with IDA. It is metabolically available very quickly after administration, very safe, convenient, and

most effective than intramuscular iron therapy during pregnancy. The present study was conducted to study the effectiveness of intravenous iron therapy with iron sucrose in pregnant women and evaluate the intravenous Iron-Sucrose therapy as an effective, feasible & safe mode of treatment in early gestation to reduce anemia in later months of pregnancy. Standard evaluation of iron deficiency anemia is made from peripheral blood smear (PBS) and other blood indices i.e. PCV (decreased), MCV (decreased), MCHC (<25pg, most sensitive blood index in pregnancy).

Iron Studies	Normal	IDA
Serum ferritin (µg/l)	15-300 microgram/L	<50 microgram/L
Serum iron(µg/dl)	50-150 microgram/L	<30 microgram/L
TIBC(µmol/L)	47 -70 microgram/L	Elevated

Iron deficiency can be classified as severe ID when the serum ferritin level is below 20–30 μg/l, mild-moderate ID if the serum ferritin level is<70–100μg/l.
SerumFerritin Level> 100microgram/l- No Iron Deficiency (7).

MATERIALS AND METHODS

This Prospective interventional study of 150 pregnant women was done in the department of Obstetrics & gynecology of a tertiary care hospital, attending antenatal outdoor department or admitted in maternity ward, over a period of one year. Pregnant women of gestational age between 24-34wks, having hemoglobin concentration between 6-8 g/dl, without any other pregnancy or non-pregnancy related complications, were included in this study. All women of study group had serum ferritin level ≤ 20.0 µg/lit and were hemo dynamically stable .Written informed consent from all patients were taken. Detailed history and clinical examination were done and relevant clinical data was collected according to a preset proforma. Patients were subjected to appropriate investigations e.g. Hb%, PCV, MCV,MCHC, RBC count, reticulocyte count, serum ferritin level, serum iron level, TIBC. The blood was withdrawn from antecubital vein with a dry iron free sterile syringe with minimum stasis. About 12.5 cc blood was collected and put into 3 vials. 2.5 cc of blood was put into vial containing anticoagulant EDTA from which Hemoglobin, hematocrit or PCV, RBC count, Reticulocyte count, MCV & MCHC were estimated. 5 cc was collected as clotted blood in a vial containing no anticoagulant & used for the estimation of ferritin. Another 5 cc was collected for determination of Serum Iron & TIBC. After proper clinical examination and laboratory investigations, the patients were administered intravenous iron sucrose.

Total Iron Dose was calculated by using **Ganzoni's Formula.**

Calculated total dose [Ganzoni'sFormula (Medical University of Vienna)]:

2.4 × Body Weight (kg) × D + 500 mg

D= (Target Hemoglobin level in gm/dl (11gm/dl) – current Hemoglobin level in gm/dl)

The required iron dose varied depending upon baseline Hemoglobin level and pre-pregnancy weight).
Calculated iron dose was administered in a dose of 200 mg elemental iron/day, diluted in 200 ml 0.9% NaCl and given over a period of 30 minutes thrice a week, until the total calculated dose had been achieved.
The above laboratory parameters were repeated in all patients on 15th day & 42nd day of conclusion of therapy .The change in above parameters were observed for determining the effectiveness of the therapy in terms of clinical improvement, blood picture improvement & improvement in terms of replenishment of depleted iron stores.

Pregnant women with Hemoglobin>8gm%,,having any pregnancy or non-pregnancy related complications like hepatic, renal or other medical diseases, women with history of asthma, thrombo-embolism, seizures or having signs & symptoms of infections/inflammations, women with hemoglobinopathies, hemolytic anemia ,or had history of currently received myelo suppressive drugs or allergic to parenteral iron , or had history of blood transfusion were excluded from the study.

Statistical analysis – Data had been summarized by descriptive statistics. Numerical variables (maternal age, gestational age, Hemoglobin% , Hematocrit , RBC count, reticulocyte count, MCHC ,MCV,Serum ferritin, Serum iron ,TIBC)were measured at Day 1 prior to iron sucrose therapy (baseline) and at Day 15 and Day 42 post iron sucrose therapy . Changes in these parameters over the study period were analyzed by't' test. All analysis were single tailed .p value < 0.05 were considered statistically significant.

RESULTS

Mean maternal age and gestational age in the present study was 24.4 years & 30 weeks respectively .Majority of the women were multigravida (68.67%) and belonged to Below poverty line (BPL)group (62.6 %). Overall mean baseline Hb %(D1) of the patients was 7.05gm/dl (SD: 0.1) which increased to8.21gm/dl (SD: 0.06) & 12.94gm/dl (SD: 0.14) at (D15) & (D42) respectively following intravenous Iron Sucrose therapy with statistically significant p values of <0.01. Majority (55%; N=83) were between 28-32 weeks of gestational age. The mean baseline Hb % in this gestational age group (28-32 weeks) was 7.08gm/dl and rose to

8.24gm/dl & 12.87gm/dl on D15 and D42 respectively after therapy.

The mean RBC count increased significantly from baseline(D1)3.23million/cmm (S.D: 0.06) to 3.48million /cmm (S.D: 0.06) and 4.26 million/cmm (S.D: 0.04) at (D15) and (D42) respectively with p values of <0.01(Table 1).

Mean reticulocyte count of patients prior to the therapy was 0.77% (S.D: 0.04) which increased to 1.53% (S.D: 0.09) & 2.08 % (S.D: 0.06), post therapy at D15 & D42, with p values of <0.01, statistically significant.

Mean PCV values increased significantly from 23.76(S.D: 0.25) to 26.42(S.D:0.197) & 38.37 (SD: 0.478) at D15 & D42 with p values of <0.01(Table 2).
Mean MCV values also increased significantly post therapy. The mean MCV pre-therapy was 73.87 (S.D: 1.33) and increased to 76.20 (S.D:1.48) & 90.08 (S.D: 0.46) at D15 & D42 post therapy with significant p values of <0.01.

Mean MCHC values also increased significantly post iron sucrose therapy. The mean MCHC value of the study population was 29.81 (S.D: 0.3957) D1 and 31.18 (S.D: 0.264) D15 & 33.81 (S.D: 0.394) D42, P <0.01 (Table 3 & Figure 1).

Mean Serum iron increased significantly post therapy with values being 66.16 (S.D: 2.03) pre-therapy and 85.4 (S.D:1.13) & 113.97 (S.D: 1.97) at Day 15 and Day 42 post therapy with p< 0.01 (Figure 2).

Mean Serum TIBC decreased post therapy. The mean Serum TIBC value of the study population was 378 (S.D:1.83) pre –therapy and decreased to 336.46 (S.D: 4.74) & 320.47 (S.D1.61) on D15 and D42 post therapy with p values of <0.01 statistically significant (Table 4).Mean Serum ferritin value of the study population was 16.42 +- 0.92 pre-therapy, which increased to 67.04 +- 1.26 & 116.46 +- 0.95 at D15 and D42 post therapy with p values of <0.01 i.e. statistically significant (Table 5).

Comparison of mean Hb values , RBC Count, Reticulocyte Count, Serum Ferritin and MCHC pre- and post iron sucrose therapy among primigravida (P)and multigravida(M) anemic women of study population showed , the mean Hb value p re-therapy (Day 1) in the primigravida group was 7.45gm/dl while that in multigravida group was 6.91gm/dl.Hence, representing that the multigravida group patients are more anemic than primigravida patients ,as explained by multiple births at shorter intervals .The rise in Hb % at D42 post therapy was 13.02gm/dl in primigravida in contrast to 12.8gm/dl in multigravida.

The mean baseline RBC count of the primigravida group was 3.27/cmm while that of multigravida group was 3.18/cmm. The rise in mean RBC count at D 42 post therapy was 4.27/cmm in primigravida in contrast to 4.25 in multigravida. However, the mean baseline serum ferritin values & MCHC values in multigravida was paradoxically, a little more than that of primigravida group. (Table 6).

Obvious side effects like arthralgia, uneasiness, and headache were seen in 46% women in our study, which were seen when the rate of infusion was fast and subsided by slowing down the infusion rate. Potentially fatal hypersensitivity reactions (characterized by anaphylactic shock, loss of consciousness, collapse, hypotension, dyspnea or convulsion) were not reported in our study .However, 9% patients had mild flushing and 22% complained of mild respiratory discomfort which subsided soon after slowing down the infusion rate. This absence of side effects is partly due to the low allergenic effect of the sucrose complex caused by very slow release of elementary iron from the complex and the accumulation of iron sucrose in organic parenchyma is much lower compared to iron dextrans& iron gluconate.Iron sucrose injection is contraindicated in patients with known hypersensitivity to iron sucrose or any of its inactive components, & anemia other than iron deficiency e.g. sickle cell anemia (Figure 3).

DISCUSSION

Present study shows that intravenous iron sucrose is a highly and rapidly effective therapy without major side effects. Other modalities for the treatment of IDA like oral iron, other parenteral iron preparations(iron dextran, iron gluconate) & blood transfusion have some or the other drawbacks. Oral iron has poor absorption, frequent gastrointestinal side effects, and poor compliance. Both iron dextran and iron gluconate cause unpredictable anaphylactic reactions and require a test dose before administration. However, iron sucrose is safe and can be administered without a test dose(8).Blood transfusion is also an attractive treatment modality in IDA but the numerous hazards of blood transfusion, including transfusion of wrong blood, infection, anaphylaxis & lung injury make intravenous iron sucrose therapy a better treatment modality. Present study observed rise in mean Hb % from pre therapy values of 7.05 +- 0.1gm/dl to 8.21+- 0.06gm/dl & 12.94 +- 0.14 gm/dl at Day 15 and Day 42 post therapy. This rise in mean Hb% was in concordance to a study by **Dewan bhupesh et al,** rise in Hemoglobin level from baseline of 6.90-9.33 gm % after 30 days, depicting a mean rise of 2.43%).

The rise in mean Hb values, RBC Count, Reticulocyte Count, Serum Ferritin and MCHC post therapy observed in the present study was in concordance to various other studies. In a study by **Shrivastva Deepti et al**(9) ,mean values of Hemoglobin on day 1 was 6.9+_0.9g%,Hematocrit was 29.2%+-1.3,MCV was 81.8Fl+_3.1.Mean rise in Hb % were 1.1+-0.2,2.3+-0.8,and 3.0+-0.4 after 1 ,2 ,3 weeks of therapy) .In another study by **Dr Alka Kriplani et al (10)** ,mean hemoglobin raisedfrom 7.63 ± 0.61 to 11.20 ± 0.73 g% (*P*<0.001) after eight wks of therapy. There was significant rise in serum ferritin levels (from 11.2 ± 4.7 to 69 ± 23.1 µg/l) (*P*<0.001). Reticulocyte count increased significantly after two wk of starting therapy from 1.5 ± 0.6 to 4.6±0.8%), findings, were in concordance to our study. Yet another study consistent to present study was by **Perewunsnyk*et al* (11).** However unlike above studies, we had not measured transferring saturation because of cost considerations .Present study observed a significant reduction in rates of blood transfusion .Many anemic women, were managed well with intravenous iron sucrose therapy, hence avoiding blood transfusions and its associated complications .Hence therapy with iron sucrose gives a good opportunity to avoid the risk of hemotransfusional infections, incompatible hemo-transfusions, and immune-compromising effects of hemo-transfusion. Also economically intravenous iron sucrose therapy is more effective. The WHO has stated that transfusion should be considered only for conditions for which there is no other treatment. Blood transfusion gives a temporary elevation in Hb concentration, and thus acts as a symptomatic management of anemia. It cannot address the fundamental issue and restore balance ,it doesn't rebalance the production and destruction of RBCs ,and is simply a transient and often ineffective in Hb "fix" ;hence ,it is not a part of rational approach to the IDA and should be reserved for acute emergency cases of anemia.

CONCLUSION

The present study observed statistically significant difference (p<0.01) in various laboratory parameters (Hb %,RBC count, Reticulocyte count ,PCV,MCV,MCHC, serum ferritin, serum Iron,TIBC) before and after treatment . So, it can be concluded from our observations that the intravenous ferrous sucrose is very safe and able to correct Iron Deficiency Anemia efficiently and replenish iron stores in antenatal anemic mothers. Parenterally administered iron sucrose elevates Hb and restores iron stores earlier and also leads to reduction in blood transfusion rates. By single hospitalization and total dose infusion of iron sucrose, it is possible to reduce the commonest medical disorder of pregnancy, thereby dramatically reducing maternal morbidity and mortality. At the same time it was also seen that intravenous iron sucrose was very safe. Limitations of the present study were lack of control group and small size of study population in a single geographical area. Also, follow up period was short. The study population was not followed for the change in parameters after the delivery or during lactation period. So, larger prospective multicentric studies with prolonged follow up period are required to reach more precise inferences. Future fields of research are the evaluation of patients' satisfaction and quality of life, impact on costs and hospital stay, impact on blood transfusion frequency and mortality rate.

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TABLES

Table 1: Comparison of mean Hb% and RBC count values pre and post iron sucrose therapy among the study population (as per gestational age).

S .No	Gestational Age	No. of Women	Hb% (g/dl)			RBC (/cumm)		
			Baseline Value	Day 15	Day 42	Baseline Value	Day 15	Day 42
1	24-26	9	6.98	8.18	12.80	3.33	3.57	4.21
2	26-28	12	6.95	8.14	13.20	3.19	3.47	4.30
3	28-30	41	7.08	8.20	12.88	3.22	3.45	4.26
4	30-32	42	7.09	8.28	12.86	3.16	3.40	4.22
5	32-34	31	7.21	8.28	12.98	3.23	3.49	4.27
6	34	15	6.98	8.18	12.90	3.24	3.50	4.31
Mean			**7.05**	**8.21**	**12.94**	**3.23**	**3.48**	**4.26**
SD			**0.10**	**0.06**	**0.14**	**0.06**	**0.06**	**0.04**
p value	**Day 1 vs. Day 15** **Day 15 vs. Day 42** **Day 1 vs. Day 42**		**<0.001** **<0.001** **<0.001**			**<0.001** **<0.001** **<0.001**		

Table 2: Comparison of Reticulocyte count and PCV values pre and post iron sucrose therapy among the study population (as per gestational age).

S. No	Gestational Age	No. of Women	PCV			Reticulocyte count (%)		
			Baseline Value	Day 15	Day 42	Baseline Value	Day 15	Day 42
1	24-26	9	23.83	26.32	37.60	0.72	1.58	2.03
2	26-28	12	23.89	26.56	38.61	0.74	1.68	2.20
3	28-30	41	23.77	26.48	38.34	0.79	1.48	2.07
4	30-32	42	23.52	26.34	38.04	0.79	1.46	2.04
5	32-34	31	24.12	26.69	38.77	0.82	1.50	2.10
6	34	15	23.44	26.13	38.85	0.77	1.45	2.07
Mean			**23.76**	**26.42**	**38.37**	**0.77**	**1.53**	**2.08**
SD			**0.24**	**0.19**	**0.47**	**0.04**	**0.09**	**0.06**
p-value	**Day 1 vs. Day 15** **Day 15 vs. Day 42** **Day 1 vs. Day 42**		**<0.001** **<0.001** **<0.001**			**<0.001** **<0.001** **<0.001**		

Table 3: Comparison of MCV &MCHC values pre and post iron sucrose therapy among the study population (as per gestational age).

S.No.	Gestational Age	No. of Women	MCV			MCHC		
			Baseline Value	Day 15	Day 42	Baseline Value	Day 15	Day 42
1	24-26	9	71.96	73.97	89.32	29.44	31.14	34.10
2	26-28	12	75.20	76.88	90.02	29.23	30.78	34.33
3	28-30	41	74.00	76.97	90.05	29.88	31.07	33.67
4	30-32	42	74.58	77.78	90.14	30.26	31.54	33.97
5	32-34	31	74.96	76.79	90.74	30.08	31.16	33.51
6	34	15	72.53	74.78	90.24	30.00	31.40	33.27
Mean			**73.87**	**76.20**	**90.08**	**29.81**	**31.18**	**33.81**
SD			**1.33**	**1.48**	**0.46**	**0.39**	**0.26**	**0.39**
p – value	**Day 1 vs. Day 15** **Day 15 vs. Day 42** **Day 1 vs. Day 42**		**<0.001** **<0.001** **<0.001**			**<0.001** **<0.001** **<0.001**		

Table 4: Comparison of Serum Iron & Serum TIBC values pre and post iron sucrose therapy among the study population (as per gestational age).

S. No.	Gestational Age	No. of Women	Serum Iron			Serum TIBC		
			Baseline Value	Day 15	Day 42	Baseline Value	Day 15	Day 42
1	24-26	9	64.61	85.20	112.42	380.39	332.69	321.74
2	26-28	12	66.10	83.40	112.08	378.43	328.68	318.19
3	28-30	41	64.25	85.50	115.82	378.39	339.67	320.84
4	30-32	42	65.61	86.09	112.46	375.91	339.49	322.42
5	32-34	31	69.93	86.76	116.74	375.75	337.70	320.61
6	34	15	66.45	85.43	114.32	379.13	340.55	319.00
Mean			**66.16**	**85.40**	**113.97**	**378.00**	**336.46**	**320.47**
SD			**2.03**	**1.13**	**1.97**	**1.83**	**4.74**	**1.61**
p - value	**Day 1 vs. Day 15** **Day 15 vs. Day 42** **Day 1 vs. Day 42**		**<0.001** **<0.001** **<0.001**			**<0.001** **<0.001** **<0.001**		

Table 5: Comparison of Serum ferritin values pre and post iron sucrose therapy among the study population (as per their gestational age).

S.No	Gestational Age	No. of Women	Baseline Value	Day 15	Day 42
1	24-26	9	17.90	68.37	117.17
2	26-28	12	16.04	68.63	117.76
3	28-30	41	16.76	65.86	115.49
4	30-32	42	16.32	65.88	115.44
5	32-34	31	16.43	67.39	116.87
6	34	15	15.07	66.14	116.01
Mean			**16.42**	**67.04**	**116.46**
SD			**0.92**	**1.26**	**0.95**
p - value	**Day 1 vs. Day 15** **Day 15 vs. Day 42** **Day 1 vs Day 42**		**<0.001** **<0.001** **<0.001**		

Table 6: Comparison of mean Hb values, RBC count, Reticulocyte count, Serum Ferritin and MCHC pre- and post iron sucrose therapy among primigravida (P) and multigravida (M) anemic women of study population.

Parity	Baseline Hb%	Day 15 Hb%	Day 42 Hb%
M	6.9	8.0	12.8
P	7.4	8.6	13.0
Parity	Baseline RBC Count(/cumm)	Day 15 RBC Count (/cumm)	Day 42 RBC Count (/cumm)
M	3.18	3.43	4.25
P	3.27	3.50	4.27
Parity	Baseline Reticulo.count%	Day 15 Reticulo.count%	Day 42 Reticulo.count%
M	0.7	1.4	2.0
P	0.8	1.5	2.1
Parity	Baseline Serum Ferritin(ug/l)	Day 15 Serum Ferritin(ug/l)	Day42 Serum Ferritin(ug/l)
M	16.52	65.82	115.18
P	16.15	68.23	118.09
Parity	Baseline MCHC(g/dl)	Day 15 MCHC(g/dl)	Day 42 MCHC(g/dl)
M	29.99	31.21	33.76
P	29.87	31.26	33.75

FIGURES

Figure 1: Comparison of MCHC values pre and post iron sucrose therapy among the study population (as per gestational age).

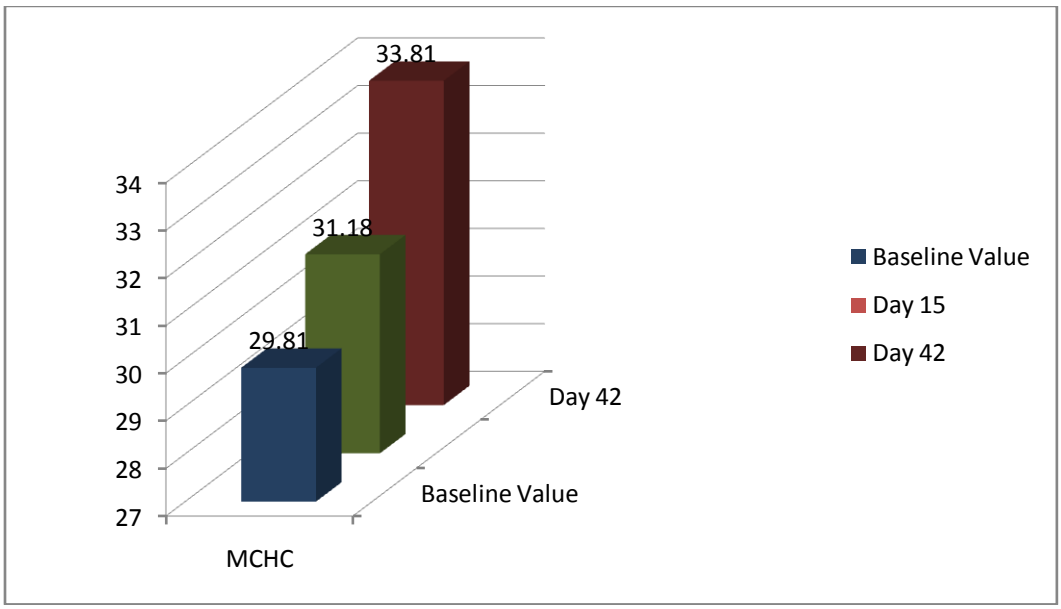

Figure 2: Comparison of Serum Iron values pre and post iron sucrose therapy among the study population (as per gestational age).

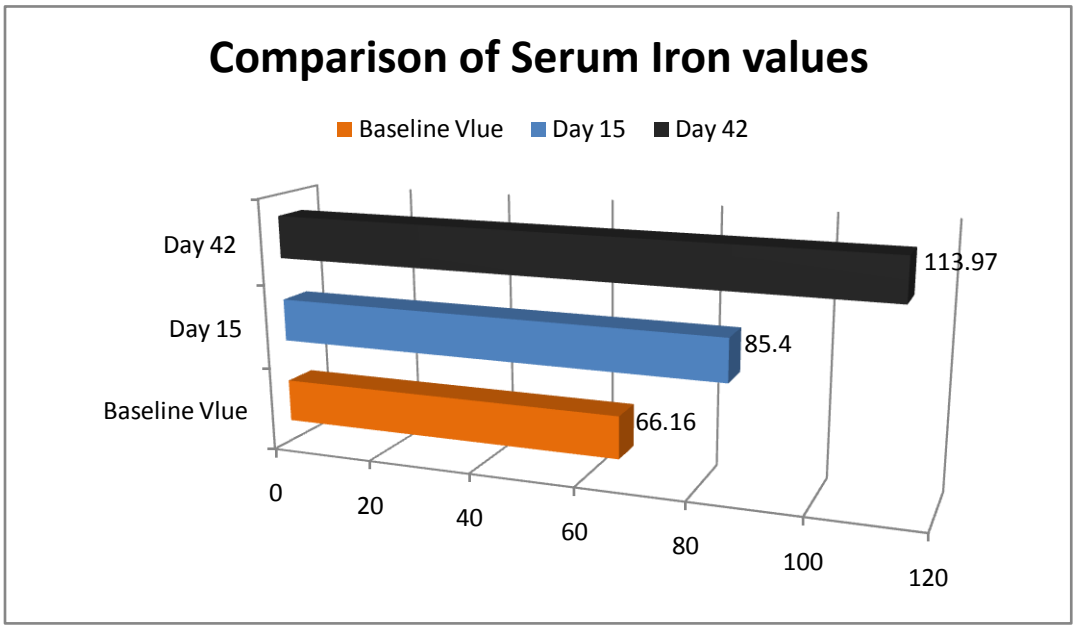

Figure 3: Adverse effects of intravenous iron sucrose therapy.