PARENTERAL IRON SUCROSE AS AN ALTERNATIVE TO PACKED CELLS/BLOOD TRANSFUSION IN MODERATE-TO-SEVERE ANAEMIA IN PREGNANCY

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ABSTRACT

AIM

This case study focuses on the efficacy of iron sucrose in moderate-to-severe anaemia in pregnancy and to compare the efficacy of iron sucrose with packed cell transfusion and based on the study to establish whether iron sucrose could be an alternative to packed cells transfusion for the management of moderate-to-severe anaemia complicating pregnancy remote from the term gestation.

MATERIALS AND METHODS

It is a case control study for a period of 2 years. Women were randomly selected where for the study group 50 patients intravenous iron sucrose was given and for control group 50 patients packed cells transfusion was given.

RESULTS

The study group and the control group had 50 subjects each. On an average 80% were in the age group of 15-24 yrs. in both groups. In both groups, on an average 85% were with moderate anaemia (6-8 g/dL) and 15% were with severe anaemia (<6 g/dL). Mean requirement of iron sucrose for moderate anaemia was 1100 mg and for severe anaemia it was 1300 mg. Mean requirement of packed cells for moderate anaemia was 3 units and for severe anaemia 4-5 units. In iron sucrose group, mean haemoglobin% at baseline 7.1±0.8 g/dL, after 1 week 7.9±0.6, after 4 weeks 11±0.5 g/dL and at delivery 11.7±0.6 g/dL. In packed cells group, mean haemoglobin% at baseline 7.0±0.7 g/dL, after 1 week 10.2±0.5 g/dL, after 4 weeks 10.3±0.5 g/dL and at delivery 10.4±0.4 g/dL. The mean haematocrit values in iron sucrose group at baseline 20.9±2.5%, after 1 week 25.3±2.2% and after 4 weeks 33.6±2.0%. The mean haematocrit values in packed cells group at baseline 20.8±2.3%, after 1 week 30.0±1.9% and after 4 weeks 30.2±2.0%. Mean rise of haematocrit from baseline to 1 week in iron sucrose and packed cells group were 4.4±1.3% and 9.1±2.0% respectively. Mean rise of haematocrit from baseline to 4 weeks in iron sucrose and packed cell group were 12.7±2.1% and 9.3±2.3 respectively. The mean ferritin values in iron sucrose group at baseline and after 4 weeks are 8.9±1.7 ng/L and 89.8±6.7 ng/L respectively whereas in packed cells group, at baseline 8.7±1.8 ng/L and at 4 weeks 40.1±5.4 ng/L. The mean rise in ferritin values from baseline to 4 weeks in both groups is 80.9±6.7 ng/L and 31.4±4.9 ng/L respectively in iron and packed cells group.

CONCLUSION

There is a need for an alternate line of management for moderate-to-severe anaemia complicating pregnancy other than routine packed cells transfusion. The risks associated with packed cell transfusion like hypersensitivity reactions, risk of transmitting viral diseases like HIV, hepatitis B, febrile reactions preclude the use of transfusion of packed cells. Parenteral iron sucrose is a safe, nontoxic alternative to packed cell transfusion in the management of moderate-to-severe anaemia complicating pregnancy.

KEYWORDS

Severe anaemia, Parenteral Iron Sucrose.

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INTRODUCTION: Anaemia is a condition of low circulating haemoglobin where the haemoglobin concentration has fallen below a threshold, lying at 2 standard deviations below the median of a healthy population of same age, sex and gestational age.[1] The WHO defined anaemia in pregnancy as haemoglobin values <11 g/dL and the Centres for Disease Control (CDC) as a haemoglobin level <11 g/dL during the first and third trimesters and <10.5 g/dL during the second trimester, taking into account the physiological changes of pregnancy.[2] According to the National Academy of Sciences Panel on Nutrition and Pregnancy, iron deficiency in pregnancy has been defined as ferritin levels lower than 12 ng/mL and it is considered the gold standard for the diagnosis of iron deficiency anaemia in pregnancy.[3] According to ICMR, the degree of anaemia is graded

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according to Hb% level as mild:10-10.9; moderate:7-10; severe<7; very severe <4 g/dL. Some authors use Hb% of 9-11 g/dL as mild anaemia. Iron deficiency anaemia (IDA) remains the commonest medical disorder in pregnancy in the developing world, with the burden of disease impacting on both the mother and the newborn (and subsequent child and later adult). And also the dimorphic anaemia due to iron and folic acid deficiency is common in developing countries. The prevalence of iron deficiency anaemia in pregnancy in the developing world is 56% (range 35-75%) vs. 18% in the developed world.[4] The corresponding figures in non-pregnant women are 43 and 12% respectively.[5] Without adequate iron supplementation, ferritin falls to subnormal levels towards the end of pregnancy even in the industrialised nations.

According to World Health Organization (WHO) data presented at the Fédération Internationale de Gynécologie Obstétrique (FIGO) meeting in 2003 in Chile, around 500,000 maternal death cases per year and 20,000,000 morbidity cases per year are related to iron deficiency and anaemia.[6] WHO had classified different regions of the world into zones depending on the prevalence of anaemia[7]: High Prevalence >40%, Medium Prevalence 15-39%, Low Prevalence 5-14.9%, Not a problem <5%. High prevalence is seen particularly in areas of Sub-Saharan Africa and South East Asia. Nearly half of the global total number anaemic women live in the Indian subcontinent, and in India alone the prevalence of anaemia during pregnancy may be as high as 88% according to ICMR.[8] In India, The National Nutritional Anaemia Control Programme (NNACP) was initiated in 1970 to provide free iron-folic acid (IFA) supplementation to all pregnant women commencing from the second trimester until 3 months of lactation. Following nearly 20 years of the iron-folic acid, a program The National Family Health Survey (NFHS) reported that the prevalence of IDA had dropped from the previous estimated 80-90% to 49.7%.

Hence this case study focuses on the efficacy of iron sucrose in moderate-to-severe anaemia in pregnancy and to compare the efficacy of iron sucrose with packed cell transfusion and based on the study to establish whether iron sucrose could be an alternative to packed cells transfusion for the management of moderate-to-severe anaemia complicating pregnancy remote from the term gestation

MATERIALS AND METHODS: This study entitled was done at Govt. Maternity Hospital, Hanamkonda in the Department of Obstetrics and Gynaecology, Kakatiya Medical College, Warangal between August 2013 to August 2015. The type of study was case control study.

Inclusion Criteria: All antenatal women presenting with moderate-to-severe anaemia i.e., Hb%<8 g/dL, haematocrit <25 and serum ferritin<12 ng/mL between gestational age of 16-34 weeks are included in the study.

Exclusion Criteria: All antenatal women below 16 weeks and more than 34 weeks of gestational age, women with very severe anaemia who are hemodynamically unstable, known allergy to parenteral iron and women with haemoglobinopathies are excluded from the study.

METHODOLOGY: All antenatal women presenting to Outpatient Department with moderate-to-severe anaemia fulfilling the inclusion criteria were enrolled for the study. These women were randomly selected to Study and Control groups where for the Study group intravenous iron sucrose given and for Control group, packed cells transfusion given. A detailed history, clinical examination, obstetric examination and investigations were done for this antenatal women and an informed consent was taken. In the study group i.e., the iron sucrose group, haemoglobin deficit was calculated. The total dose of iron sucrose was administered at a dose of 200 mg in 200 mL of 0.9% normal saline over a period of 40-50 minutes on alternate days. No test dose was required. Facilities for cardiopulmonary resuscitation made available nearby. Monitoring during infusion was done at every 10 minutes and at the end of infusion. Any signs and symptoms of adverse reactions were looked for. In the same way in the Control group, the subjects were given packed cells transfusion on alternate days depending on the Hb deficit (calculated on the basis of improvement of Hb% by 1.3-1.5 g/dL with every transfusion of packed cells). Monitoring was done same as for iron sucrose infusion. The haemogram was done at 1st week, 4th week after the transfusion and at the time of delivery to look for improvement in Hb% and haematocrit. Serum ferritin levels were measured 4 weeks after the transfusion.

RESULTS: Total number of subjects in iron sucrose group (Study group) were 50. Total number of subjects in packed cells group (Control group) were 50.

Age (years)	Iron Sucrose		Packed Cells	
	Age			
	No. of patients	%	No. of patients	%
15-24	40	80	41	82
More than 25	10	20	9	8
Gravida	**Parity**			
Primi	27	54	30	60
Multi	23	46	20	40
Gestational Age (Weeks)	**Gestational Age**			
16-27	22	44	16	32
28-34	28	56	34	68
Severity (Hb%)	**Severity of Anaemia**			
Moderate (6-8 g/dL)	43	86	42	84
Severe (<6 g/dL)	7	14	8	16

Table 1: Distribution according to age, parity, gestational age and severity of anaemia

Mean Requirement of Iron sucrose (mg)	Moderate (6-8 g/dL)	Severe (6g/dL)
	1100	1300
Mean Requirement of packed cells (units)	3	4.5

Table 2: Mean requirement of iron sucrose (mg) and the mean requirement of packed cells(units)

Mean values of Hb% in moderate anaemia (6-8 g/dL)				
Hb%	**Baseline Hb (g/dL)**	**After 1 week (g/dL)**	**After 4 weeks (g/dL)**	**At delivery (g/dL)**
Iron Sucrose	7.4	8.1	11	11.8
Packed Cells	7.3	10.2	10.4	10.2
Mean Values of Hb% in severe anaemia (<6 g/dL)				
Iron Sucrose	5.5	6.7	10.1	10.9
Packed Cells	5.6	10.6	10	9.9

Table 3: Shows the mean values of Hb% in moderate anaemia and in severe anaemia

Mean Values of Haematocrit % in Iron sucrose group				
Iron sucrose group	**Mean Haematocrit %**	**Standard deviation**	**Confidence interval (95%)**	**P Value**
Baseline Hct%	20.9	2.5	20.1-21.6	
After 4 weeks	33.6	2.0	32.9-34.2	0.001
Mean values of haematocrit % in packed cells group				
Baseline Hct%	20.8	2.3	20.1-21.5	
After 4 weeks	30.2	2.0	29.5-30.7	0.001
Mean values of ferritin % in iron sucrose group				
Iron sucrose group				
Baseline	8.9	1.7	8.4-9.4	
After 4 weeks	89.3	6.7	87.9-91.7	<0.001
Mean values of ferritin % in packed cells group				
Baseline	8.7	1,8	8.3-9.3	
After 4 weeks	40.1	5.4	38.6-41.7	0.001

Table 4: Mean values of haematocrit% and ferritin% in both groups

	Mean Baby weight (Kg)	Standard deviation	Confidence interval (95%)
Iron Sucrose	3.1	0.4	2.9-3.1
Packed Cells	2.6	0.2	2.5-2.7

Table 5: Mean baby weight at delivery

NICU admissions at delivery were 2 out of 50 in iron sucrose group and 9 out of 50 in packed cell group.

Reaction	No. of subjects in iron sucrose group	No. of subjects in packed cell group
Pain at cannula site	3	Nil
Arthralgia	1	Nil
Vomiting	2	2
Hypotension	1	5
Abdominal Cramps	1	Nil
Febrile Reaction	Nil	6
Dyspnoea	Nil	2
Urticaria	Nil	4
Jaundice	Nil	1

Table 6: Adverse reactions in present study

DISCUSSION: We had a total number of 50 subjects in each group. The groups were the iron sucrose group and the control group was packed cells group. More number of subjects were in the age group of 15-24 years in both the groups. Primi and multigravidae were in the average of 54% and 60% in iron sucrose and packed cells groups respectively. In the iron sucrose group and packed cells group, the average percentage of subjects in the gestational age of 28-34 weeks were 56% and 68% respectively. In our study on an average of 82% of subjects in both groups with moderate anaemia i.e., 6-8 g/dL and on average 15% of both the groups percentage haemoglobin less than 6 g/dL i.e., severe anaemia. The causes for anaemia in both groups were nutritional anaemia due to deficiency of iron and folic acid followed by malaria and hook worm infestations. Sickle cell anaemia and thalassaemia in 1-2% of subjects which have been excluded from our study. The mean requirement of iron sucrose in mg in moderate anaemia is 1100 and in severe anaemia is 1300 i.e. rounded up to nearest multiples of 100. The mean requirement of packed cells in units is 3 and 4.5. In our study, the mean base line value of haemoglobin% in the iron sucrose group in moderate anaemia was 7.4 g/dL which increased to 8.1 g/dL after 1 week, 11 g/dL after 4 weeks and 11.8 g/dL at delivery. In the severe anaemia group i.e., with Hb% less than 6 g/dL, the mean base line values of Hb% was 5.5 g/dL which increased to 6.7 g/dL after 1 week, 10.1 g/dL after 4 weeks and 10.9 g/dL at delivery. From these figures, it is very obvious that iron sucrose gives a steady increase in the Hb% which is more perceptible after 4 weeks and up to the delivery. Also this is an objective measurement which can be quantified to measure the efficacy of the drug.

The study done at Zurich Obstetrics Clinic in the year 2005 demonstrated a significant rise of Hb% from the mean base line haemoglobin of 9.1 g/dL to 11 g/dL by the end of day 25 with a mean total dose of 1000 mg (400-1600 mg) iron sucrose corresponding 3 5 dose of 200 mg. With p value <0.01,[9] thus this study demonstrated high efficacy and safety of parenteral iron in subjects <9 g/dL which is in conformity with our study. Also Al-Momen et al, in the study demonstrated an average rise of Hb% from mean baseline

Hb of 7.5 g/dL to 12.8 g/dL in an average period of 6.9 weeks.[10] And other study done by Gravier el al showed a Hb rise of 3.8 g/dL after 14 days, thus showing a significant improvement of Hb% with iron sucrose in 2 weeks.[2] In comparison to packed cells group i.e., control group, the rise in Hb% is observed immediately after one week i.e., 3.2 g/dL, but beyond that there is no demonstrative increase in Hb% rise at 4 weeks and at delivery, after giving packed cells transfusion. The Hb% levels show a plateau after 1 week. This is in contrast to iron sucrose which shows a steady rise up to 4 weeks and till delivery. In our study, when we analysed the study and control groups with respect to mean rise of Hb% after 1 week, we found that in control group (Packed cell) it was 3.3±0.6 g/dL., Iron sucrose group 0.8±0.2 g/dL. By Kolmogorov-Smirnov test, p-value is 0.0001 which is statistically significant in favour of packed cell transfusion. The mean rise of Hb% from 1 week to 4 weeks in Iron sucrose group is 3±0.5 g/dL whereas in Packed cells group it is 0.3±0.3. By Equal Variance T Test, p value is <0.0001 which is statistically significant in favour of Iron sucrose. Furthermore, at delivery, the mean Hb rise was 4.6±0.6 g/dL in Iron sucrose group as compared to 3.21±0.7 g/dL in Packed cells group from mean baseline value of Hb. By Equal Variance T Test, p value< 0.001, which is statistically significant.

We can conclude from these figures that iron sucrose gives a steady Hb rise which is maintained up to delivery in contrast to packed cells which shows immediate improvement but shows a plateau after that. This is clinically and statistically significant. The haematocrit values were also taken into consideration in our study. Haematocrit reflects the actual number of circulating RBC in the body. Therefore, it is more accurate than Hb%. The mean haematocrit values in Iron sucrose group were at baseline 20.9±2.5%, after 1 week 25.3±2.2% and after 4 weeks 33.6±2.0%. By paired T test (two tailed), the p values were significant with respect to baseline haematocrit values. The mean haematocrit values in packed cells group at baseline 20.8±2.3%, after 1 week 30.0±1.9% and after 4 weeks 30.2±2.0%. Mean rise of haematocrit from baseline to 1 week in iron sucrose and packed cells group were 4.4±1.3% and 9.1±2.0% respectively. By Mann-Whitney U test, p value = 0.0001. It is statistically significant in favour of packed cell transfusion. Mean rise of haematocrit from baseline to 4 weeks in iron sucrose and packed cells group were 12.7±2.1% and 9.3±2.3% respectively. By equal variance T test P value = 0.001 which is statistically significant. These values show that the haematocrit values increased by 1 week but further showed a plateau up to delivery in packed cells group. In our study, these values prove that the efficacy of iron sucrose in having a sustained rise of haematocrit which is maintained up to delivery. These figures are again an objective evidence of the superiority of iron sucrose in comparison to packed cells. Most of the studies quoted in our review of literature support these statistics. These figures are clinically and statistically significant. From the literature survey, the primary outcome measure was haemoglobin levels and secondary outcomes were haematocrit and ferritin levels. Our study confirms the improvement of both primary outcome measure and secondary outcome measures. S. ferritin levels were used because they represent the iron stores in the reticuloendothelial system and also rules out haemoglobinopathy like thalassaemia. Improvement of iron stores which is reflected in normal serum ferritin levels is an object to secondary outcome measure.

In our study, the mean baseline serum ferritin in the study group was 8.9±1.7 ng/mL which improved to 89.8±6.7 ng/mL which is clinically and statistically significant (p value <0.0001). In the Packed cell group the mean baseline ferritin was 8.7±1.8 ng/mL and at the end of 4 weeks it was 40.2 ng/mL. This shows that serum ferritin levels almost doubled with iron sucrose treatment in contrast to packed cell transfusion. The mean rise in ferritin values from baseline to 4 weeks in Iron and Packed cells groups are 80.9±6.7 ng/mL and 31.4±4.9 ng/mL respectively. By Mann-Whitney U test, P value was <0.0001 which is statistically significant.

The study done by Khamaiseh et al., which compared the efficacy and safety of IV iron sucrose with blood transfusion in postpartum anaemia concluded that IV iron sucrose is safe and effective treatment option for postpartum anaemia, which reduces the need for blood transfusion. At one week post treatment the mean rise in haemoglobin was 2.35 g/dL in Packed cells group vs 2.15 g/dL for Iron sucrose group and haematocrit rise (7% vs 6.3%). In this study, both treatments increased hb% and haematocrit after 1 week of intervention but more in favour of blood which was due to immediate restoration of RBCs but the increase in S. ferritin levels were statistically significant in favour of iron group (220% rise) as compared to blood (150%).[11]

In the study done by Ragip et al., the serum ferritin values were higher in patients receiving IV iron sucrose throughout the pregnancy.[12] In a study done by Al-Momen K et al showed that the serum ferritin levels had increased to 95.5±38.1 ng/mL from a baseline value of 11.9±5 ng/mL in a period of 7 weeks with p value <0.001 which is statistically significant.[10]

Our study incorporated the foetal outcome viz., baby birth weight and NICU admissions. In the study group, the mean birth weight was 3.1±0.4 compared to control group i.e., packed cells group which was 2.6±0.2 which was statistically significant. By Kolmogorov-Smirnov test, P value=0.0001. There were 2 NICU admissions in Iron sucrose group and 9 in Packed cells group. By Fisher's exact test, P value (two-tailed) =0.05 which is statistically significant. This shows that there was an improved neonatal outcome due to replenishment of maternal iron stores which indirectly improved the nutrition of the foetus. It has been proved in recent studies that cognitive ability and other neurological functions are affected in iron and folic acid deficiency anaemia especially in the first trimester of the pregnancy. The reasons for increased NICU admissions in the control group is related to neurological deficit caused by lack of storage iron.

In our study, the subjects in Iron sucrose group did not have any serious anaphylactic reactions. The adverse reactions noted in this group were-2 subjects with hypotension, 3 with pain at cannula site, 1 with vomiting, 1 with arthralgia and 1 with abdominal cramps. None of the subjects discontinued from the study.

In Packed cells group there were 3 subjects who discontinued the transfusion of that particular unit of packed cells due to dyspnoea, urticaria and vomiting but were able to recover and participated in the study. Adverse reactions noted were 6 with febrile reactions, 2 with dyspnoea, 4 with urticaria, 2 with vomiting, 1 with jaundice and 5 with hypotension. Jaundice was noted due to haemolytic reactions with repeated transfusions. No subject had severe anaphylactic reactions. Therefore, 40% of the subjects had adverse effects with packed cells.

Cost wise, the economic burden on the subject is equal in modalities of management but iron sucrose has a less toxic profile compared to packed cells and the measurable maternal and neonatal outcomes are much superior in terms of objective measurements viz., clinically and statistically significant. Parenteral iron sucrose stands out as a safe and effective alternative to packed cells in the management of moderate-to-severe anaemia complicating pregnancy who are remote from term gestation.

CONCLUSION: There is a need for an alternate line of management for moderate-to-severe anaemia complicating pregnancy, other than routine packed cells transfusion. The risks associated with packed cell transfusion like hypersensitivity reactions, risk of transmitting viral diseases like HIV, hepatitis B, febrile reactions preclude the use of transfusion of packed cells. Parenteral iron sucrose is a safe, nontoxic alternative to packed cell transfusion in the management of moderate-to-severe anaemia complicating pregnancy. It is not associated with any major side effects. Parenteral iron sucrose therapy has a sustained rise of haemoglobin and haematocrit which persists even after the time of delivery as compared to packed cell transfusion which only has an immediate rise but not sustained till delivery. Parenteral iron sucrose also improves the storage iron which is depicted by improvement of serum ferritin levels over a period of 4 weeks that in turn improves the foetal and maternal outcome as compared to packed cell transfusion. The end point of our study i.e., the directly measurable outcomes, which were maternal-Hb %, haematocrit and serum ferritin levels, Foetal-NICU admissions and baby birth weight, were satisfactorily met in our study. The Hb% and haematocrit levels increased steadily from 1 week to 4 weeks in Iron sucrose group that improved the maternal and foetal outcomes as compared to packed cell transfusion where the improvement in Hb % and haematocrit levels were rapid within 1 week but plateaued thereafter resulting in no clinical and statistical improvement in the outcome. Most of the studies in the literature which were reviewed confirmed the findings of our study. Parenteral iron sucrose therapy should form an integral part of' management for the patients of moderate-to-severe anaemia remote from term gestation in all hospitals (primary or referral). Depending on the objectively measured outcomes, we can conclude that parenteral iron sucrose is a safe and superior alternative to packed cells transfusion.

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