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Study of safety and efficacy of iron-sucrose in the treatment of pregnancy with anaemia

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Abstract :

Background

The causes for anaemia in pregnancy include increased demand during pregnancy, poor diet, repeated pregnancies and pre-existing anaemia that affect 59.9% of our pregnant women. There is a need to correct anaemia with iron preparation which can be administered in short period with no gastro intestinal side effects like Injection iron sucrose preparation This study was therefore done to evaluate the safety and efficacy of intra venous iron sucrose injections in pregnant women.

Materials and methods

This was an interventional prospective study carried out for a period of six months , on pregnant anaemic women at Vanivilas Women and Children hospital.76 pregnant ladies between 18 to 34 weeks with the haemoglobin level of equal to or less than 8 gms%. were admitted after obtaining informed consent admitted as in patients in the hospital. The haematological investigations were done periodically. The required dose of Injection iron sucrose was calculated as per the Standard formula

Result

There was rise in mean serum iron and ferritin level on day 28 when compared to the levels on day 1 which was statistically significant (P value being 0.000) This is the expected response after iron therapy.This indicates improved iron stores and peripheral iron levels on Day-28

Conclusion: Injection iron sucrose is safe and effective in the management of anaemia in pregnancy.

Introduction

Anaemia is estimated to affect 59.9% of our pregnant women.[7, 15] Iron deficiency anaemia is responsiblefor 95% of anaemia in pregnancy. It is the single most important cause of maternal morbidity and mortality contributing directly to 20% of deaths and indirectly to a further 20%. Reducing the number of maternal deaths by 3/4th by 2015 is one of the key goals of the millennium declaration of WHO.

The causes for anaemia in pregnancy include increased demand during pregnancy, poor diet, repeated pregnancies and pre-existing anaemia.. In our country oral Iron & folic Acid supplementation is incorporated in the antenatal care. As per NFHS III survey about 40% of pregnant women consume oral iron. Oral iron & folic acid supplementation has poor patient compliance due to various reasons like nausea; gastritis etc.

Over the past few decades, various oral, intramuscular and intravenous preparations of iron have been used for the management of iron deficiency anaemia.[1,2] However these preparations have lot of side effects resulting in poor patient compliance. Other drawbacks of these preparations are they are unable to increase Hb% in short period.[3] Injection iron sucrose preparation has less side effects and the ability to administer the required dose of iron in short period is its advantage.[1] Injectable Iron sucrose finds a suitable place in the management of these anaemic pregnant women. This study was therefore done to evaluate the safety and efficacy of intra venous iron sucrose injections in pregnant women.

Materials and Methods

This was an interventional prospective study. This study was carried out for a period of six months from June 2010

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to November 2010, on pregnant anaemic women at Vanivilas Women and Children hospital, Department. of obstetrics and gynaecology. Institutional ethics committee approval from Bangalore Medical College and research Institute, was taken 76 patients were recruited from the antenatal OPD and Inpatients of the hospital after obtaining informed consent.Patients of the study group were pregnant women between 18 to 34 weeks with the haemoglobin level of equal to or less than 8 gms%.Pregnant women with other causes of anaemia like, Thalassemia, Haemolytic anaemia, Hypersplenism' Chronic infection, Chronic hepatic/ renal disease. All patients were admitted as in patients in the hospital.

The haematological investigations were done on the study patients on Day 1, day 7 and day 28.

Patients of the study group were pregnant women between 18 to 34 weeks with the haemoglobin level of equal to or less than 8 gms%. A written informed consent was obtained from the participants who were willing to participate in the study.The haematological investigations were done on the study patients on Day 1, day 7 and day 28 were Hb%,Reticulocyte count, peripheral smear.

The required dose of Injection iron sucrose was calculated as per the formula=2.4 X pre-pregnancy weightinKgs X Hb% deficit (11-Actual Hb% of pt.)+500 in milligrams.

Method of administration of the drug: Iron sucrose injection was administered as Intravenous infusion of 200mg of the drug diluted in 100 ml normal saline over a period over 30 minutes; dose was repeated on alternate days up to three times a week (maximum dose at a time is 200mg infused over 30 minutes).Subsequent doses were given as per the requirement on alternate days.

All the participants were given one tablet of albendazole 400 mg (broad spectrum ante helminthic) at the beginning of therapy.

All the participants were also given protein powder as a part of therapy.

Pulse, blood pressure and general examination of the patient were done prior to therapy and at 5, 10 minutes, then half hourly twice and at 4 hours after therapy.

All adverse events after each infusion of iron sucrose were noted. The adverse events looked for were hypotension, pain at the site of injection, urticarial, anaphylactic reactions etc.

The primary outcome measure was rise in Hb% and secondary outcome measures were observed in reticulocyte count, peripheral smear,and in values of Serum iron, Serum transferrin, unbound iron and total iron binding capacity.

All laboratory tests were done on day 1, day 7 and day 28. Hb% was done by automatic-Coulter III part-Sysmax- Transasia-KX21 machine, Japan make.Peripheral smear was done manually by using leishman's stain and reticulocyte counts were done manually by using supra vital retic stain.Serum iron, serum ferritin, serum transferrin, iron binding capacity were done using System Cobas Integra 400 plus of Roche company, Switzerland. Hb%.

Data was analysed using statistical software SPSS 16.

Results

Among the total number of 76 patients studied, mean age of the study group was 23.28±3.38 years. Teenage pregnancies with anaemia formed 9.2% of the study group. Most cases, i.e., 86.8% were between 20 to 29 years. Elderly gravidas comprised of only 3.9%. Mean Hb% of study group on day I was 7.37 gm%. Mean Hb% on day 7 and 28 were 8.88 % and 10.43% respectively. Thus the mean rise of Hb on day 7 and day 28 were 1.51 gm and 3.06 gm respectively. The rise of Hb% was significant statistically, p value being 0.000. (Figure –1) Graph showing that there was increase in the normocytic normochromic patients after 7 days of treatment and even more after 28 days of treatment(Figure -2)

There was rise in mean serum iron and ferritin level on day 28 when compared to the levels on day 1 which was statistically significant (P value being 0.000) This is the expected response after iron therapy.This indicates improved iron stores and peripheral iron levels on Day-28.(Figure-3). There was a decrease in the values of mean serum transferrin and total Iron binding capacity on day 28 when compared with the values on day-1which were statistically significant (P value beining 0.000). These findings are consistent with the expected values after iron therapy.

Statistical test applied in the above table was **paired "t" test**. It shows that after supplementing with iron, there was statistically significant improvement in the Haemoglobin%, serum iron and serum ferritin. But there was statistically significant decrease in the serum transferrin, UIBC, and TIBC when compared with day one and day 28. Decrease in these values is normally expected after iron therapy.(table-4). There were no significant adverse effects of the drug noted. There were only few minor side effects like pain at injection site in 3 patients and chills and rigors in one case.

Discussion

Our study showed that injection Iron sucrose therapy in pregnant anaemic women significantly raised haemoglobin percentage and improved iron storage. There was a significant rise in haemoglobin, serum iron and serum ferritin when compared day 1 values with those on day 28 of therapy. A significant number of study participants reached the target haemoglobin on day 28. The mean rise of haemoglobin from Day 1 to Day 7 was 1.51 and Day 28 was 3.06.

In our study examination of peripheral smear on Day 1 Day 7 & Day 28 revealed that there was increase in the normocytic normochromic patients after 7 days of treatment and even more after 28 days of treatment.

In our study there was rise in mean serum iron and ferritin level on day 28 when compared to the levels on day 1 which was statistically significant (P value beining 0.000). This indicates the improved iron levels including store iron in the body following administration of intravenous iron sucrose injection.

There was a decrease in the values of mean serum transferrin and total iron binding capacity on Day 28 when compared with the values on Day 1 which were statistically significant. (P value being 0.000).

It is generally accepted that injection iron sucrose therapy gives a rapid erythropoietic response in short duration, which is confirmed by our study. The rate of iron delivery to bone marrow is a major factor in the regulation of erythropoiesis. Iron sucrose has an intermediate stability and strength. It is quickly cleared from serum with a terminal half-life of 5 to 6 hours. Thus it is readily available for erythropoiesis.

Iron sucrose as per various studies has shown to be better than other parental iron preparations like iron dextran and iron sorbitol. Iron sucrose is approved for treatment of iron deficiency anaemia in pregnancy.

Seven of our patients delivered during the period of study. In spite of the blood loss at delivery their haemoglobin rise was significant.

In our study the adverse effects reported were minimal, with two patients complaining pain at the site of injection and one patient had rigors. Thus iron sucrose is well tolerated with no serious side effects unlike other parenteral preparations.

Pregnancy as such is a risky situation for a woman to loose blood during delivery, and woman who are anaemic prenatally are at a higher risk of life and complications due to blood loss during delivery. Many of our pregnant women who are anaemic do not tolerate oral iron or have adverse effects with other parenteral iron preparations. Blood transfusion for management of anaemia in pregnancy has many problems like availability; spread of infection, cost, blood transfusion reactions etc.[6], In this context, iron sucrose has a very important role because of its efficacy and safety. The cost of iron sucrose compared other modalities of treatment is affordable.

In our country more than 59.9% of pregnant women are anaemic. The major cause for maternal mortality and morbidity is due to anaemia directly or indirectly. Iron sucrose therapy in treatment of anaemia in pregnancy reduces maternal mortality and morbidity to a significant level.

Iron sucrose is definitely the first line of treatment of severe anaemia in pregnancy in view of its easy accessibility, safety and finally good efficacy compared to other parenteral iron and blood transfusion.[9] But the oral iron supplementation in pregnancy is time tested and tried drug, still to be continued for prevention of anaemia in pregnancy as incorporated in our National health programme.

Conclusions

Injection iron sucrose is safe and effective in the management of anaemia in pregnancy. It has minimal side effects, It restores storage iron faster. It raises haemoglobin at a faster rate.

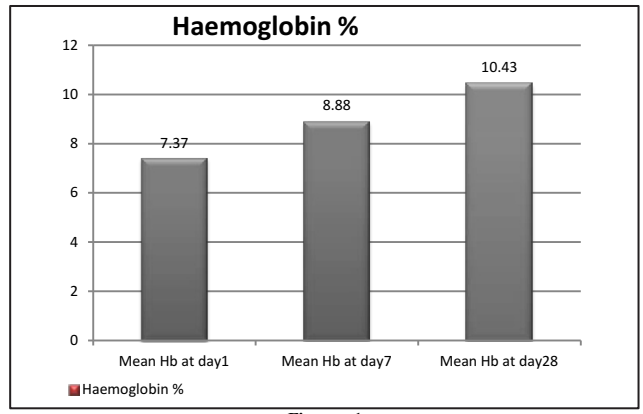

Figure - 1

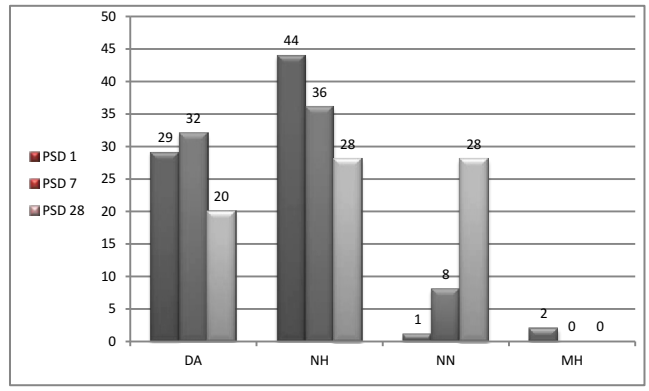

Figure - 2

Figure - 3

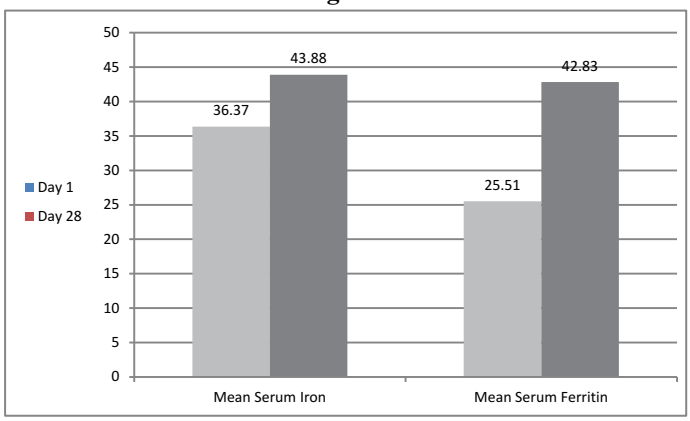

Table-1 showing the mean standard deviation of the different blood values

Variable	Mean	Standard deviation	"t" value	'P' value
Haemoglobin% on day 1 Haemoglobin% on day 7	7.37 8.88	0.73 0.98	13.26	0.000
Haemoglobin% on day 1 Haemoglobin% on day 28	7.37 10.49	0.73 0.70	29.10	0.000
Haemoglobin% on day 7 Haemoglobin% on day 28	8.88 10.49	0.98 0.70	16.49	0.000
Serum iron on day 1 Serum iron on day 28	36.37 43.88	25.87 26.24	13.37	0.000
Serum ferritin on day 1 Serum ferritin on day 28	25.51 42.83	29.32 35.08	11.33	0.000
Serum transferrin on day 1 Serum transferrin on day 28	451.53 408.97	80.55 70.99	13.15	0.000
UIBC on day 1 UIBC on day 28	499.54 443.10	117.33 95.89	12.68	0.000
TIBC on day 1 TIBC on day 28	515.13 456.988	120.05 100.60	13.56	0.000

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