

Prospective Study of I/V Iron Sucrose in Anemic Women and Its Effect

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ABSTRACT

Objective: To determine different grades of anaemia, observe the effect of I/V sucrose in anaemic patients at different age groups, and to observe the combined effect of I/V iron sucrose and blood transfusion in anaemic patients to find out the impact of antenatal visits in improvement of anaemia in pregnant women presenting at Department of Obstetrics and Gynecology at Kamla Raja Hospital, Gwalior from 2007-2009.

Methodology: 50 antenatal primipara patients' with anaemia having haemoglobin (Hb) <11 gm/dl in third trimester were included in the study. Distribution of cases according to grading of anaemia and socioeconomic condition (SE) was calculated in to moderate (7 to 10.9 gm/dL), severe (4 to 6.9 gm/dL) and very severe (<4 gm/dL) and SE status from I to V was tabled according to BGP Classification. Impact of antenatal visit was also tabled in to no antenatal, ≤ 2 antenatal visit and ≥ 3 antenatal visit. Blood smear was analysed for most common type of anaemia in study population. Intravenous route was used to administer iron sucrose.

Results: The present study showed that moderate anaemia (76%) was more common among population. It was also found that incidence of anaemia was more common in illiterate (64%) and with SE status class IV (44%) patients. The most common predisposing factors for anaemia as shown by the present study were worm infestation (16%), malaria (14%), puberty menorrhagia (10%) and TB (6%). It was also observed that out of 50 patients, 44 (88%) had ≤ 2 antenatal visits. Present study also showed that microcyte hypochromic anaemia (72%) was most common followed by dimorphic anaemia among population. Present study did not find any sign of allergic reactions with i/v sucrose.

Conclusion: This study has shown that I/V Iron sucrose is the most effective and rapid therapy to correct anaemia especially in third trimester of pregnancy and in preoperative stage of patients in due time interval. It also decreases the requirement for blood transfusion in preoperative patients and in third pregnancy and correct anaemia rapidly.

Key words: Iron sucrose, anaemic pregnant women, iron deficiency anemia

Abbreviations: BG Prasad's Classification; BGP, World Health Organization; WHO, Tuberculosis; TB, Socioeconomic; SE

INTRODUCTION

Pregnancy as well as childbirth, both are universally celebrated events.¹ A mother expresses her motherhood by growing foetus in her womb². Near about 1/3 of the world population is anaemic³. According to World Health Organization (WHO) prevalence of anaemia in women with pregnancy is 18% in developed countries and relatively high 35-75 % 4 (average 56%) in developing countries.² In South East Asian countries prevalence of anaemia is highest. According to WHO among South East Asian countries, highest prevalence is present in India,² prevalence ranges between 58%.^{2,4}

In India anaemia is still a very common cause of mortality and morbidity.² Major reasons being low intake and high demands of iron, maladjusted metabolism, pre pregnant health status and high iron demands as in multiple pregnancies, women with recurring pregnancies, infectious diseases, labor induced blood loss, heavy menstrual cycle, inflammation, hook worm infection are some important factors which can lead to pregnancy induced anaemia.⁵

According to WHO anaemia is defined as "haemoglobin less than 11gm/dl and a haematocrit of less than 0.33".⁶ In pregnancy, demand for iron increases to meet the red cells mass expansion in the mother, for making placental blood and blood loss at delivery time⁷. In pregnancy, anaemia is the most common medical disorder and in developing countries, is indirectly responsible for 40-60% of the maternal death⁸. Would be mother may be anaemic if her haemoglobin (Hb) is <11 g/dL.¹⁰ The degree of anaemia is graded according to Hb levels as moderate (7 - 10.9 g/dL), severe (4 - 6.9 g/dL) and very severe (< 4g/dL) in current study.¹¹

Despite responding well to iron supplementation, anaemia due to iron deficiency is a major health related problem in whole world. For effective management of this condition new approaches are required. Initially, iron dextran and iron sorbitol citrate was the main therapy for the treatment. The main drawback of afore said therapy was that it required test dose before injections due to severe anaphylactic reactions. But Iron sucrose is reported safe and effective during pregnancy in many studies¹². For iron sucrose test dose is not required¹³.

Both iron sucrose and ferric gluconate are second-generation i.v. iron formulations, is really a improvement over i.v. iron dextran.⁹

Required iron dose depends upon documented Hb level and weight before pregnancy. Below formula⁴ is used for the calculation of iron sucrose dose:

$$\text{Required iron dose (mg)} = (2.4 \times (\text{target Hb} - \text{actual Hb}) \times \text{pre-pregnancy weight (kg)}) + 1000 \text{ mg for replenishment of stores}$$

Some characteristics of the different intravenous iron formulation are shown in table 1. We therefore evaluated the efficacy and safety of intravenous iron sucrose in primipara patients' with proven iron deficiency with Hb <11 gm/dl in third trimester.

Table 1: Some characteristics of the different intravenous iron formulation

	Iron Gluconate	Iron Sucrose	Low molecular weight iron dextran	Ferric carboxy-maltose
Carbo-hydrate shell	Gluconate (mono)	Sucrose (dia)	Dextran (branched poly)	Carboxy-maltose (branched poly)
Molecular weight (KD)	289-440	30-60	165	150
Initial distribution volume (L)	6	3.4	3.5	3.5
Plasma half-life (h)	1	6	20	16
Direct Iron donation to transferrin (% injected dose)	5-6	4-5	1-2	1-2
Test dose required	No	No	Yes	No
Iron content (mg/mL)	12.5	20	50	50
Maximal Single dose (mg)	125	200-300	20 mg/kg	15mg/kg

AIMs and Objectives

1. To determine the grade of anaemia
2. Effect of I/V iron sucrose in anaemic patients at different age groups
3. Combines effect of I/V iron sucrose and blood transfusion in anaemic patients
4. Impact of antenatal visits in improvement of anaemia

MATERIALS AND METHODS

Approval of institutional ethics committee was taken before starting the study. Informed written consent was taken from all the patients before starting the study. A prospective, open-label, single

center study was performed in 50 primipara patients' with proven iron deficiency with Hb <11 gm/dl in third trimester at Department of Obstetrics and Gynecology at Kamla Raja Hospital, Gwalior from 2007-2009. Women in third trimester of gestation with Hb<11 gm/dl, were included in the study and who have given written consent in this study. Women having iron deficiency anaemia due to other causes, multiple pregnancies, high risk for preterm labor and recent blood transfusions, thalassaemia and other medical disorders were not included in the study.

Baseline investigations like liver and kidney function tests, urine test by routine microscopy and culture sensitivity, stool examination for ova and cyst were done in the current study. Distribution of cases according to grading of anaemia and socioeconomic condition (SE) was calculated in to moderate (7 to 10.9 gm/dL), severe (4 to 6.9 gm/dL) and very severe (<4 gm/dL) and SE status from I to V was tabled according to BG Prasad's (BGP) Classification²¹. Impact of antenatal visit was also tabled in to, no antenatal, ≤ 2 antenatal visit and ≤ 3 antenatal visit. Blood smear was analysed for most common type of anaemia in study population. Iron sucrose was administered by intravenous infusion.

Statistical analysis: The statistical analysis was done using SPSS version 15 (SPSS Inc., USA). All the values are expressed in percentage (%) and Mean± SD. P<0.5 was taken as significant.

RESULTS

The mean age of patients were 27.8 ± 3.9 (range 21-34) years and mean parity was 1.3; mean period of gestation (PDG) at the time of diagnosis was 25.69 ± 4.82 (14-32) wk. At the beginning, mean Hb was 7.63 ± 0.61 g%. 76% of patients had moderate (7-10.9 g/dL), 14% had severe (4-6.9 g/dL) and 10% had very severe (<4 g/dL) anaemia (Table 2).

Table 2: Distribution of cases according to grading of anaemia

Types of anaemia	No of cases	Percentage (%)
Moderate (7-10.9 g/dL)	38	76
Severe (4-6.9 g/dL)	7	14
Very Severe (<4 g/dL)		

There was total 1.2 g% increase in Hb level in 68% patients of moderate anaemia within one week after one complete dose of I/V iron sucrose injection (4 amp.). In 22% cases where iron sucrose was given along with blood transfusion, Hb level was increased to > 2.2 g% within one week.

According to BGP classification various grades of anaemia as per socioeconomic condition (SE status I to V) of patients were analysed and study found that 44 % of patients fall in class IV of BGP classification (Rs 773-1546 income). In class I, II, III

and V percentage of patients were 4, 10, 24 and 18 respectively (Table 3).

Table 3: Distribution of various grade of anaemia according to socioeconomic condition (BGP classification)

SE Status	No of cases			Total	
	Moderate (7-10.9 g/dL)	Severe (4-6.9 g/dL)	Very Severe (<4 g/dL)	No of cases	Percentage (%)
I	2	-	-	2	4
II	4	1	-	5	10
III	10	1	1	12	24
IV	16	3	3	22	44
V	6	2	1	9	18

As per the education of all the patients enrolled, all the cases were divided in to illiterate, primary, Middle, High School, Inter and graduate and it was found that 64% of patients were illiterate and 20%, 8%, 6% and 2% patients were from primary, Middle, High School, Inter and graduate respectively. (Table 4)

Table 4: Distribution of cases according to education profile of patients

Education	No of cases	Percentage (%)
Illiterate	32	64
Primary	10	20
Middle	4	8
High School	3	6
Inter	-	-
Graduate	1	2

Percentage of patients was analysed according to predisposing factor for anaemia in past history and it was found that most common predisposing factor are worm infestation (16%), malaria (14%), puberty menorrhagia (10%) and Tuberculosis (TB) (6%). (Table 5)

Table 5: Distribution of cases according to the predisposing factor for anaemia in past history

Predisposing factor	No of cases	Percentage (%)
Malaria	7	14
Worm Infestation	8	16
UTI	2	4
Puberty menorrhagia	5	10
Piles	2	4
Bleeding disorder	-	-
Dysentery	2	4
Dry causing BM suspension	-	-
Other chronic disease like TB	3	6
Gastritis/Gastric ulcer	2	4

all patients are shown which shows that out of 50 patients with anaemia 44 (i.e. 88%) have, no or two or less than two antenatal visit. Most common type of anaemia was microcytehypochromic (72%). Percentages of other blood smear palliative have been shown in table 6 with dimorphic, megaloblastic, normocytic hypochromic and microcyte hypochromia with reticulocytosis anaemia (Table 6).

Table 6: Distribution of cases according to peripheral blood smear picture

Blood smear palliative	No of cases	Percentage (%)
Microcytic hypochromic	36	72
Dimorphic	8	16
Megaloblastic	2	4
Normocytic hypochromic	3	6
Microcyte hypochromia with reticulocytosis	1	2

DISCUSSION

In current study we can conclude that I/V Iron sucrose therapy is the most effective and rapid therapy to correct anaemia especially in third trimester of pregnancy and in preoperative stage of patients in due time interval. It also decreases the requirement for blood transfusion in preoperative patients in third trimester and correct anaemia rapidly.

According to studies higher maternal morbidity in pregnancy is seen at Hb level < 8 g% 14, 15, 16. Hb < 5 g% is associated with cardiac decompensation and pulmonary oedema. During labor even 200 ml of blood loss can cause sudden shock and death in this type of women.⁴

Iron sucrose is very safe and effective with minor adverse effects like metallic taste, flushing of the face and burning at the injection site (0.5 % of cases).¹⁷ This high tolerance of iron sucrose is due to slow release of iron from the complex. Another reason is due to the low allergenicity of sucrose. Till date, studies have shown only one death due to intravenous iron sucrose injection.¹⁸ it was due to very slow infusion (1-2 h) or free radicals released from the iron sucrose. This case is not mentioned in the any study but in clinical trial registry site it is mentioned.¹⁸

In developing countries hookworm infection is one of the causes of anaemia.²⁰ Our study also showed that Worm infestation is one of the major and common predisposing factor for anaemia. It is evident that routine anthelmintic therapy is not recommended in pregnancy. But due to high prevalence in India, it is advisable to give such therapy to pregnant women with anaemia.²⁰

In Table 6 impact of antenatal visit among

Drawbacks of our study were lack of control

group and non-randomized trial. We still require large randomized controlled trials to compare the efficacy and safety of intravenous iron sucrose complex. In conclusion, our results showed that intravenous iron sucrose therapy was effective to treat moderate anaemia in pregnant women. Intramuscular preparations are known to be associated with local side-effects. Iron sucrose complex iv therapy was with negligible side effects. It caused rapid rise in haemoglobin level and the replacement of stores was faster. Long term comparative studies are required to assess if it can be used at peripheral level.

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