

Original Articles

Study of Minor and Major adverse drug reaction of intravenous Iron Sucrose in the treatment of severe iron deficiency anemia.

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KEY WORDS : Iron deficiency anaemia, intravenous iron sucrose, Antenatal and Postnatal patient.

ABSTRACT

Anaemia is a major health problem worldwide. Intravenous iron sucrose appears to be treatment of choice with no serious side effects, indicated in the rapid correction of anaemia in pregnancy or restoring maternal iron stores.

AIMS: To evaluate the effects of injectable iron sucrose therapy in terms of minor and major adverse drug reactions in antenatal and postnatal patients. **MATERIALS AND METHODOLOGY:** The present study was conducted on antenatal and postnatal patients within the age group of 19-40 years clinically diagnosed as anaemic. Routine haematological investigations including peripheral blood smear examination, complete blood count and injectable iron sucrose therapy was given and minor and major adverse reaction was studied. **RESULT:** 10 % of antenatal patient and 16% of postnatal patients developed adverse reactions to intravenous iron sucrose. Out of 12 minor side effects 4 were developed in antenatal patients and 8 in postnatal patients. Only 1 major reaction developed in antenatal and no major reaction developed in postnatal patient.

CONCLUSION: Intravenous iron sucrose transfusion is an effective treatment strategy for antenatal and postnatal patients with negligible side effect and leads to rapid rise in Hb level.

INTRODUCTION

In India, prevalence of anaemia has been reported to be in the range of 33-89% and characteristically 50% in the women of reproductive age group. Anaemia in pregnancy is not only associated with adverse maternal outcomes like puerperal sepsis, Antepartum Haemorrhage, Postpartum Haemorrhage, increased risk of maternal morbidity and mortality but also adverse fetal outcome like premature birth, low birth weight babies and high perinatal mortality. In India anaemia is very prevalent because most of the women are from low socioeconomic class, illiterate, having false dietary habits, blood loss due to heavy menstrual cycle, younger age of marriage, early pregnancy, less spacing between pregnancies, social negligence, health problems neglected by females. Intravenous iron sucrose appears to be a treatment of choice with no serious side effect, indicated in the rapid correction of anaemia in pregnancy or restoring maternal iron stores, specially because the total stores can be administered over a short period.

AIMS AND OBJECTIVES

- 1) To evaluate the effects of injectable iron sucrose therapy in terms of minor and major adverse drug reaction in antenatal and postnatal patients.
- 2) To evaluate the efficacy of injectable iron sucrose in terms of rise in Hb.

MATERIALS AND METHODS

This is a prospective study conducted in the maternity wards of Shalin Hospital for 1 year. A total of 100 Antepartum singleton pregnancy and postpartum patients with haemoglobin levels less than 7gm% and MCV <100fl and a ferritin level <50microgm/L were included. Patients with medical disorders, multiple pregnancy, women with other comorbidities like DVT, Thrombocytopenia, Renal or Hepatic disorder, COPD, Asthma, Cardiovascular disorder, Hb level > 7 gm%, and with anemia other than iron deficiency anemia were excluded.

DEFICIT OF IRON WAS CALCULATED BY THE FOLLOWING FORMULA:

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TOTAL IRON DOSE (mg) = WEIGHT (kg) *(TARGET HB-PRESENT HB IN gm/dl) *2.4 +500 mg FOR REPLENISHMENT OF IRON STORES.

Calculated dose of iron sucrose is given in divided doses thrice weekly or on alternate day. 200 mg is mixed in 100 ml normal saline solution and given intravenously, the first 10 ml infused over a period of 15 min, if there are no adverse reactions, the remaining portion of the infusion is given over 60 min. ADR monitoring done. Hb levels were repeated after 3 weeks of administration of injectable iron sucrose.

OBSERVATIONS AND ANALYSIS

Table 1: Distribution Of Antenatal Patients According To Weeks Of Gestation

Antenatal patients with Gestational age	No. of patients	Percentage
13-20 weeks	12	24%
20-28 weeks	15	30%
28-36 weeks	23	46%
TOTAL	50	100%

Table 2: Distribution Of Postnatal Patients

POSTNATAL PATIENTS	No. of patients	Percentage
CS	20	40%
NORMAL DELIVERIES	30	60%
TOTAL	50	100%

Table 3: Iron Sucrose Requirement

DOSE REQUIRED	NO. OF PATIENTS
800-999	32
1000-1199	56
1200-1400	12

Table 4: Reactions In Antenatal And Postnatal Patients

REACTIONS	ANTENATAL PATIENTS	POSTNATAL PATIENTS
MINOR REACTION	4(33.33%)	8(66.66%)
MAJOR REACTION	1(100%)	0(0%)

Table 5: Type Of Minor Reactionsn

TYPE OF REACTION	NO. OF ANTENATAL PATIENT	NO. OF POSTNATAL PATIENTS	TOTAL
INJECTION SITE PAIN	1	2	3
PHLEBITIS	0	1	1
HEADACHE	1	1	2
FEVER WITH CHILL	1	2	3
PRURITIS	1	1	2
ARTHRALGIA	0	1	1
TOTAL	4	8	12

Table 6: Major Reactions

TYPE OF REACTION	NO. OF ANTENATAL PATIENT	NO. OF POSTNATAL PATIENTS	TOTAL
ANAPHYLACTIC	1	0	1
TOTAL	1	1	1

Table 7 : Rise In Hb Levels

HEMOGLOBIN IN gm%	NO OF PATIENT
1-1.9	13
2-2.9	52
3-4	31
>4	3

RESULT

- 1) A total of 13 patients developed adverse reactions to iron sucrose. Among them 5 (38.46%) antenatal and 8(61.53%) were postnatal patients.
- 2) 12 patients developed minor reaction and 1 patient developed major reaction. Out of these 12 patients, 4 patients developed intravenous route related side effect (3 of them developed pain at injection site and 1 patient developed phlebitis) and 8 patients developed generalized type of side effect
- 3) Only 1 patient developed major reaction.
- 4) Increase in haemoglobin was significantly high, around 2-3 gm% increase.

CONCLUSION

- 1) Anaemia is a serious health problem in India where the pregnant women and her child are in danger.
- 2) Intravenous iron sucrose transfusion is an effective treatment strategy for pregnant patients with severe anaemia during late pregnancy.
- 3) Intravenous iron sucrose is associated with negligible side effects and is safe in antenatal and postnatal period.
- 4) Intravenous iron sucrose causes rapid rise in Hb level and replacement of stores was faster.

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