



## SAFETY AND EFFECTIVENESS OF INTRAVENOUS IRON SUCROSE VERSUS ORAL IRON: A STUDY AMONG PREOPERATIVE ANEMIC WOMEN WITH MENORRHAGIA

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### ABSTRACT

**Objective:** To compare the safety and efficacy of iron sucrose over oral iron for the correction of preoperative anemia in women with menorrhagia.

**Methods:** Women with menorrhagia having Hemoglobin (Hb) <10 gm/dl and features of iron deficiency allocated to group A (IV iron sucrose) or group B (oral iron). IV iron sucrose was administered as 100 mg (2 ampoules) in 100 ml normal saline by slow IV infusion. The women in the group B received ferrous sulphate as oral iron in the dose of one tablet (200 mg salt) three times a day. Repeat laboratory estimations were done after four weeks.

**Results:** Before treatment, mean Hemoglobin level (mean  $\pm$  SD) was similar in both groups ( $7.18 \pm 1.18$  gm/dl in group A and  $7.18 \pm 1.02$  gm/dl in group B). After treatment, rise of Hb level was more in group A ( $10.70 \pm 0.73$  gm/dl) than group B ( $9.64 \pm 0.70$  gm/dl). After treatment, the desired Hb level of 10 gm/dl or more were achieved in 96% of women in group A while only in 56% of women in group B.

**Conclusion:** Preoperative intravenous iron sucrose administration is more effective than oral iron and is as safe as oral iron therapy in the correction of preoperative anemia due to menorrhagia.

**Key words:** Preoperative anemia, oral iron, parenteral iron, iron sucrose

### INTRODUCTION

There is a high incidence of perioperative anemia among women undergoing major surgery (20-70%)<sup>1</sup>. Preoperative anemia has been linked to an increased postoperative morbidity and mortality, as well as a decreased quality of life after surgery<sup>2</sup>. Because of the low incidence of side effects and the rapid increase of hemoglobin levels, intravenous iron sucrose emerges as a safe and effective drug for treating preoperative anemia in these women<sup>3,4,5,6,7</sup>.

The aim of this prospective, randomized, comparative study is to compare the safety and efficacy of iron sucrose over oral iron for the correction of preoperative anemia in women with menorrhagia.

### MATERIALS AND METHODS

Study was conducted in department of Obstetrics and Gynecology, Surat Municipal Institute of Medical Education and Research (SMIMER)

from April 2011 to March 2013. Approval from Institutional Ethics Committee was obtained prior to conducting the study. Women suffering from menorrhagia and having Hemoglobin (Hb) less than 10 gm/dl and features of iron deficiency were included in the study. Total 110 women were included in the study. Heavy menstrual bleeding during the preoperative period was controlled with haemostatic drugs and/or progestin according to the case. Informed consent was taken.

**Inclusion criteria includes** Hb less than 10 gm/dl; features of iron deficiency were evidenced by: hypochromic microcytic anemia, low MCV, MCH and MCHC values, increased RDW, low serum iron and serum ferritin levels; and women having their surgical procedure at least three to four weeks after preoperative assessment.

**Exclusion criteria were** anemia other than iron deficiency; those women requiring early surgery i.e. women with malignancy; and those unwilling to participate in the study.

Women matching the above criteria, allocated to group A (IV iron sucrose) or group B (oral iron) by sequentially numbered opaque envelope prepared by the person not involved in the study.

The women in group A received IV iron sucrose. The dose of iron sucrose was calculated as follows:  $2.4 \times \text{Body weight (in kg)} \times (\text{target Hb} - \text{actual Hb})$ . Target Hb was 10 gm/dl. The drug was administered as 100 mg (2 ampoules) in 100 ml normal saline by slow IV infusion. No any specific brand of iron sucrose was selected during the study. The dose was repeated on alternate day basis. No test dose was given. The women in the group B received ferrous sulphate as oral iron in the dose of one tablet (200 mg salt) three times a day.

All women were followed regularly and assessed for side effects, compliance, clinical and laboratory response. Repeat laboratory estimations were done after four weeks. Results were analyzed by paired t test using SPSS 15 and Microsoft excel.

**RESULTS**

As shown in table 1, majority of women were in the age group of 40-49 years (59% and 57% in group A and B respectively). Etiological causes of menorrhagia is shown in table 2. 40% of women in both groups had dysfunctional uterine bleeding (DUB). Leiomyoma of uterus were present in

35% women in group A and 31% in group B, Adenomyosis (20% vs 25% in groups A and B respectively). Benign ovarian cysts were present in 5% and 4% of cases in group A and B respectively.

**Table1. Age of women**

Age (Years)	Group A (n=55) (%) (IV ISC)	Group B (n=55) (%) (Oral iron)
<30	4 (7%)	6 (11%)
30-39	13 (23%)	13 (23%)
40-49	32 (59%)	31 (57%)
>50	6 (11%)	5(9%)

**Table2. Etiology of menorrhagia**

Pathology	Group A (n=55)(%) (IV ISC)	Group B (n=55) (%) (Oral iron)
Dysfunctional uterine bleeding (DUB)	22 (40%)	22 (40%)
Leiomyoma	19 (35%)	17 (31%)
Adenomyosis	11 (20%)	14 (25%)
Ovarian cyst	3 (5%)	2 (4%)

**Table3. Hemoglobin level after treatment**

After 4 weeks	Group A (n=55)(%) (IV ISC)	Group B (n=55) (%) (Oral iron)	P value
Hb (gm/dl) (Mean± SD)	10.70 ± 0.73	9.64 ± 0.70	<0.05*
Women with Hb >10 gm/dl	53 (96%)	31 (56%)	<0.001*

\*Paired t test- Significant

**Table4. Adverse reactions**

Side effects	Group A (n=55)(%) (IV ISC)	Group B (n=55) (%) (Oral iron)
Nausea/ Vomiting	0	10 (18)
Constipation/ Diarrhea	0	12 (22)
Metallic taste	3 (5)	0
Pain at injection site	10 (18)	0
Phlebitis	6 (11)	0
Fever	3 (5)	0

Before treatment, mean Hemoglobin level (mean ± SD) was similar in both groups ( $7.18 \pm 1.18$  gm/dl in group A and  $7.18 \pm 1.02$  gm/dl in group B). After treatment, rise of Hb level was more in group A ( $10.70 \pm 0.73$  gm/dl) than group B ( $9.64 \pm 0.70$  gm/dl). The difference was statistically significant (P <0.05) (Table 3). After treatment, the desired Hb level of 10 gm/dl or more were achieved in 96% of women in group A

while only in 56% of women in group B. This difference was also significant.

Gastrointestinal side effects were observed in 40% of women in oral iron group. In intravenous iron sucrose group, no any serious side effects were observed. Metallic taste was observed in 5% of women at the time of infusion, phlebitis in 11% of women, pain at injection site in 18% of women and low grade fever in 5% of women in iron sucrose group. But none of women had refused to complete the treatment due to side effects (table 4).

## DISCUSSION

Hysterectomy is the one of the common surgical procedure among the premenopausal women. The common indications are fibroid, adenomyosis, dysfunctional uterine bleeding (DUB) etc<sup>2, 4</sup>. Due to excessive and/or irregular menstrual bleeding, which is a common symptom of women undergoing hysterectomy, they suffer from anemia. Serum ferritin levels are inversely proportional to the duration and intensity of menstrual bleeding indicating iron deficiency anemia in these women<sup>2</sup>. Moreover, hysterectomy may result in significant blood loss. Average blood loss is 500- 800 ml in abdominal hysterectomy and 200-460 ml in vaginal hysterectomy<sup>2</sup>. Minimum hemoglobin level should be 10 gm/dl in women undergoing gynecological surgery. It can be corrected by either blood transfusion or iron therapy (oral or injectable iron)<sup>2, 4</sup>. Although blood transfusion corrects anemia promptly, it has large number of disadvantages, including transfusion of wrong blood, infection, anaphylaxis and lung injury, any of which would be devastating<sup>8</sup>. It may not be necessary to take these risks in an elective surgical procedure that should otherwise be uneventful for all concerned<sup>2</sup>. These hazards, together with national shortage of blood products, mean that transfusion should be viewed as less appropriate option. Oral iron is an effective but require longer time to correct anemia and the compliance is poor due to gastrointestinal side effects<sup>4, 5</sup>.

Due to low molecular weight, adverse reactions with iron sucrose are much less, also more often self limited<sup>1, 5, 9</sup>. The best recommended way to administer iron sucrose is 100 mg IV three times weekly. No test dose is required<sup>10</sup>. It can not be given by IM route and as total dose infusion. It can be given as slow IV injection undiluted over a period of two to five minutes or IV infusion (

100 mg to be diluted in 100 ml of normal saline immediately prior to infusion and is to be infused over a period of at least 15 minutes). It is taken up mainly by reticuloendothelial system and it is unlikely that it would be taken up by the parenchymal cells of liver, kidney, adrenal or other organs, hence, organic toxicity such as pancreatic, myocardial or hepatic hemosiderosis is less likely even with iron sucrose over load. Iron sucrose leads to rapid rise of haemoglobin level than oral route<sup>11, 12</sup>. In a study by KimYH et al target haemoglobin level was achieved in 76.7% women in iron sucrose group and only 11.5% women in oral iron group. In our study, target haemoglobin level was achieved in 96% women in iron sucrose group and 56% in oral iron group after four weeks. This difference may be due to lower target Hb level in our study. By using iron sucrose, the rate of blood transfusion can be reduced to a great extent.

## CONCLUSION

Preoperative intravenous iron sucrose administration is more effective than oral iron and is as safe as oral iron therapy in the correction of preoperative anemia due to menorrhagia.

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