### IRON DEFICIENCY ANEMIA IN PREGNANCY INTRAVENOUS IRON SUCROSE AN ALTERNATIVE TO ORAL FERROUS SULPHATE THERAPY

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#### **HOW TO CITE THIS ARTICLE:**

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**ABSTRACT: BACKGROUND AND OBJECTIVE:** Iron deficiency anemia in pregnancy is a commonest medical problem throughout the developing world with the burden of disease impacting in both mother and newborn.<sup>46</sup> Anaemia affects nearly half of all the pregnant women in the world, these figures are 52%<sup>1</sup> in the developing and 23%<sup>26</sup> in the developed world. The high prevalence of iron deficiency anaemia among women during pregnancy in developing countries is of concern and a cause of considerable morbidity and mortality.<sup>27</sup> The aim of the study is to know whether intravenous iron sucrose can be an better alternative in terms of safety, efficacy and compliance over oral ferrous sulphate in the treatment of anaemia in pregnancy. **METHOD:** This prospective study is conducted in Obstetrics & Gynaecology Department of Cheluvamba hospital, Mysore Medical College and Research Institute, Mysore. All these women are randomly assigned (100 women each) to receive either calculated dose of intravenous iron sucrose (Group B) or oral ferrous suphate 200mg BD per day (Group A). Hemoglobin, hematocrit and mean corpuscular estimation is done before treatment and after 4wks of correction in both groups to note the improvement in values and monitored for adverse reactions. **OBSERVATIONS AND RESULTS:** The percentage rise in hemoglobin is statistically significant when baseline hemoglobin levels are compared with that at fourth week of treatment. Statistically significant rise in hemoglobin, hematocrit and mean corpuscular levels are found at fourth week in IV group when compared to oral group. None of the patients had any serious side effects. There were no treatment failures and none of them required blood transfusions. **CONCLUSION:** This study concluded that intravenous iron sucrose is safe, highly efficacious with better compliance for the treatment of iron deficiency anemia in pregnancy. Iron sucrose therapy is more effective in achieving the optimum results, an increase in hemoglobin concentration, mean corpuscular volume levels and an increase in hematocrit %. Therefore it is a suitable alternative to oral iron.

**KEYWORDS:** Iron Sucorse, Pregnancy, Hemoglobin.

**METHODOLOGY:** The study titled —Iron deficiency Anemia in Pregnancy: Intravenous iron sucrose an alternative to oral ferrous sulphate therapy|| is conducted in the Department of Obstetrics and Gynaecology, Cheluvamba Hospital, MMCRI, Mysore.

**AIMS AND OBJECTIVES:** To study the efficacy, safety and compliance of intravenous iron sucrose as compared to oral ferrous sulphate in the treatment of iron deficiency anemia in pregnancy.

#### **INCLUSION CRITERIA:**

- 1. Singleton pregnancy.
- 2. 16 to 32 wks of gestation.

- 3. Hb % 7 to 10.9g%.
- 4. Willingness to enrollment to study.

### **EXCLUSION CRITERIA:**

- 1. Non-iron deficient anemia.
- 2. Hb% <7g%.
- 3. Reactions to i.v iron sucrose.
- 4. H/o blood transfusion in present pregnancy.
- 5. H/o intake of iron in any form orally.
- 6. High risk pregnancy.

**METHODOLOGY:** This is a prospective study conducted on pregnant women of 16 to 32wks of gestation according to inclusion criteria in 18months of study period(2011- 2013). The patients are selected after explaining in detail about study design and written consent is taken. The study is conducted in outpatient basis

Group A (n=A) oral ferrous sulphate group.

Group B (n=B) iv iron sucrose group.

**VISIT 1:** Thorough history is elicited and clinical examination is done. Complete hemogram is done to know pre-treatment Hb%, MCV, Hct along with that peripheral smear asked to rule out non-iron deficient anemias and stool examination for occult blood, cyst and ova. Both group are given a dose of Tab. Albendazole 400mg before commencing therapy.

**GROUP A:** They received ferrous sulphate orally 200mg containing 60mg of elemental iron BD for 4wks after food.

**GROUP B:** They received iron sucrose intravenously dose depending on the formula 2.4 x Hb deficit in gm% x body weight in kgs<sup>38</sup>. It is given in divided doses, 200mg each time with minimum 48hrs apart. Each ml contained 20mg of elemental iron. Every 5ml of it is dissolved in 100ml of 0.9% of NS. Per day maximum of 200mg infusion is given. No test dose is given<sup>38</sup>. If there are any adverse reactions, then drip is stopped and treated. Injections given on outpatient basis,no admissions required.

**VISIT 2:** The patient are questioned about compliance and examined again for general conditions. The complete hemogram is repeated to know the post treatment response.

### STATISTICAL METHODS APPLIED:

**FREQUENCIES:** The Frequencies procedure provides statistics and graphical displays that are useful for describing many types of variables. The Frequencies procedure is a good place to start looking at your data.

**DESCRIPTIVE:** The Descriptives procedure displays univariate summary statistics for several variables in a single table and calculates standardized values (z scores). Variables can be ordered by

the size of their means (in ascending or descending order), alphabetically, or by the order in which you select the variables (the default).

**CROSSTABS (CONTINGENCY COEFFICIENT TEST):** The Crosstabs procedure forms two-way and multiway tables and provides a variety of tests and measures of association for two-way tables. The structure of the table and whether categories are ordered determine what test or measure to use.

**INDEPENDENT-SAMPLES T TEST:** The Independent-Samples T Test procedure compares means for two groups of cases. Ideally, for this test, the subjects should be randomly assigned to two groups, so that any difference in response is due to the treatment (or lack of treatment) and not to other factors.

**REPEATED MEASURE ANOVA:** Repeated Measures analyzes groups of related dependent variables that represent different measurements of the same attribute. This dialog box lets you define one or more within-subjects factors for use in GLM Repeated Measures. Note that the order in which you specify within-subjects factors is important. Each factor constitutes a level within the previous factor. All the statistical calculations were done through SPSS 16.0 (2007) for windows.

**OBSERVATIONS AND RESULTS:** This randomized trial is conducted in Obstetrics & Gynaecology Department, Cheluvamba hospital, Mysore Medical College and Research Institute, Mysore. The aim of the study is to know the response of intravenous iron sucrose with that of oral ferrous sulphate in terms of safety, efficacy and compliance of intravenous iron sucrose over oral ferrous sulphate in the treatment of iron deficiency anaemia in pregnancy. All these women were randomly assigned (100 women each) to receive either calculated dose of intravenous iron sucrose(Group B) or oral ferrous sulphate 200mg BD per day(Group A).

Los in Verre		GR	GROUP	
Age in Years		Group A	Group B	Total
	Count	30	39	69
16-20	% of GROUP	30.0%	39.0%	34.5%
21-25	Count	49	46	95
	% of GROUP	49.0%	46.0%	47.5%
26.20	Count	18	11	29
26-30	% of GROUP	18.0%	11.0%	14.5%
21.26	Count	3	4	7
31-35	% of GROUP	3.0%	4.0%	3.5%
Total	Count	100	100	200
Total	% of GROUP	100.0%	100.0%	100.0%

#### TABLE 1: AGEWISE DISTRIBUTION OF CASES

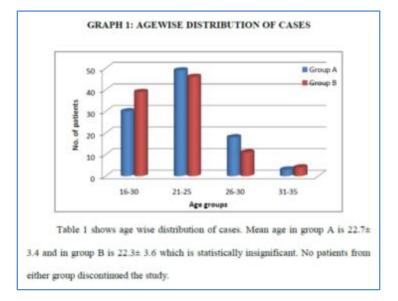
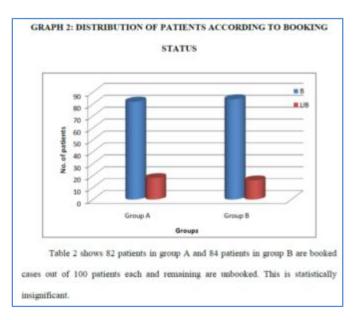


TABLE 2: DISTRIBUTION OF PATIENTS ACCORDING TO BOOKING STATUS

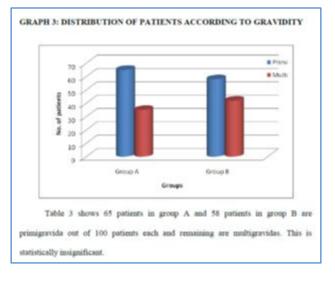
Pooling Status		GROUP		
Booking Status		Group A	Group B	Total
	Count	82	84	166
в	% of GROUP	82.0%	84.0%	83.0%
T.P.	Count	18	16	34
UB	% of GROUP	18.0%	16.0%	17.0%
	Count	100	100	200
Total	% of GROUP	100.0%	100.0%	100.0%



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GRAVIDA		GR	Total	
		Group A	Group B	
primi	Count	65	58	123
	% of GROUP	65.0%	58.0%	61.5%
multi	Count	35	42	77
	% of GROUP	35.0%	42.0%	38.5%
Total	Count	100	100	200
	% of GROUP	100.0%	100.0%	100.0%

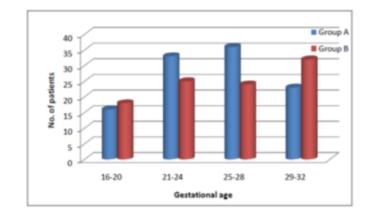
#### TABLE 3: DISTRIBUTION OF PATIENTS ACCORDING TO GRAVIDITY

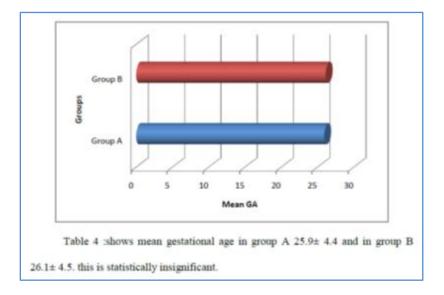


#### TABLE 4: GESTATIONAL AGE WISE DISTRIBUTION OF CASES

GA		GROUP		Teres
GA		Group A	Group B	Total
	Count	16	18	34
16-20	% of GROUP	16.3%	18.0%	17.2%
21-24	Count	33	26	59
	% of GROUP	33.7%	26.0%	29.8%
	Count	26	24	50
25-28	% of GROUP	26.5%	24.0%	25.3%
	Count	23	32	55
29-32	% of GROUP	23,5%	32.0%	27.8%
2022	Count	98	100	198
Total	% of GROUP	100.0%	100.0%	100.0%

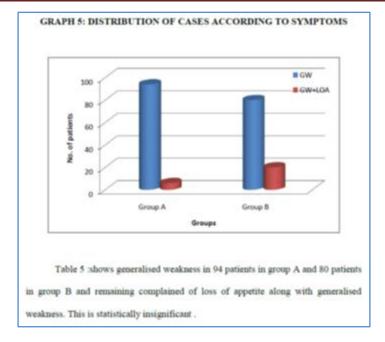
#### GRAPH4: GESTATIONAL AGE WISE DISTRIBUTION OF CASES





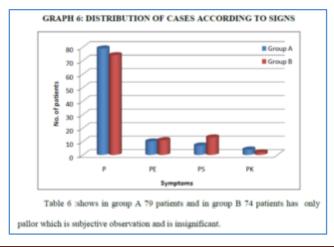
#### TABLE 5: DISTRIBUTION OF CASES ACCORDING TO SYMPTOMS

SYMPTOM		GROUP		Total	
SIMPIOM		Group A	Group B	Total	
GW	Count	94	80	174	
GW	% of GROUP	94.0%	80.0%	87.0%	
GW+LOA	Count	6	20	26	
GW+LOA	% of GROUP	6.0%	20.0%	13.0%	
Tetal	Count	100	100	200	
Total	% of GROUP	100.0%	100.0%	100.0%	



and the second		GR	GROUP	
SIGN		Group A	Group B	Total
	Count	79	74	153
Р	% of GROUP	79.0%	74.0%	76.5%
PE	Count	10	11	21
	% of GROUP	10.0%	11.0%	10.5%
53-53-	Count	7	13	20
PS	% of GROUP	7.0%	13.0%	10.0%
РК	Count	4	2	6
	% of GROUP	4.0%	2.0%	3.0%
200	Count	100	100	200
Total	% of GROUP	100.0%	100.0%	100.0%
		-	-	

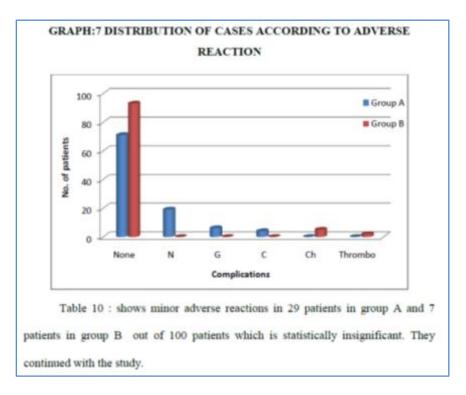
TABLE 6: DISTRIBUTION OF CASES ACCORDING TO SIGNS



#### TABLE:7 DISTRIBUTION OF CASES ACCORDING TO ADVERSE

REACTION

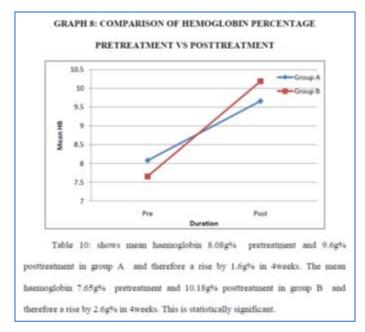
ADVERSE		GR	OUP	Total
EFFECTS		Group A	Group B	
None	Count	71	93	164
	% of GROUP	71.0%	93.0%	82.0%
NAUSEA	Count	19	0	19
	% of GROUP	19.0%	.0%b	9.5%
GASTRITIS	Count	6	0	6
	% of GROUP	6.0%	.0%6	3.0%
CONSTIPATION	Count	4	0	4
	% of GROUP	4.0%6	.0%6	2.0%
CHILLS	Count	0	5	5
	% of GROUP	e90,	5.0%	2.5%
THROMBOPHLE	Count	0	2	2
BITIS	% of GROUP	.0%	2.0%	1.0%
Total	Count	100	100	200
	% of GROUP	100.0%	100.0%	100.09



#### TABLE 8: COMPARISON OF HEMOGLOBIN PERCENTAGE

	GROUP	Mean	Std. Deviation	N
	Group A	8.0800	.53504	100
HBPRE	Group B	7.6570	.50598	100
	Total	7.8685	.56101	200
HBPOST	Group A	9,6620	.85183	100
	Group B	10.1873	1.43527	100
	Total	9.9247	1.20629	200

#### PRETREATMENT AND POSTTREATMENT

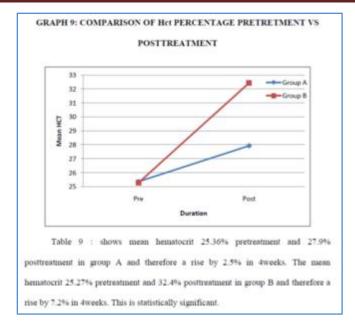


#### TABLE 9: COMPARISON OF Het PERCENTAGE PRETREATMENT VS

#### POSTTREATMENT

	GROUP	Mean	Std. Deviation	N
	Group A	25.3600	1.15049	100
HCTPRE	Group B	25.2710	2.71421	100
	Total	25.3155	2.07977	200
HCTPOST	Group A	27.9300	1.89766	100
	Group B	32.4400	1.95050	100
	Total	30.1850	2.96559	200

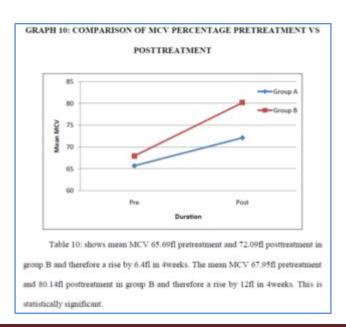
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	GROUP	Mean	Std. Deviation	N
MCVPRE	Group A	65.6900	1.68592	100
	Group B	67.9500	6.12888	100
	Total	66.8200	4.62434	200
MCVPOST	Group A	72.0900	1.71208	100
	Group B	80.1400	4.75675	100
	Total	76.1150	5.38486	200

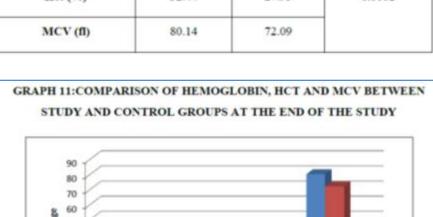
POSTTREATMENT

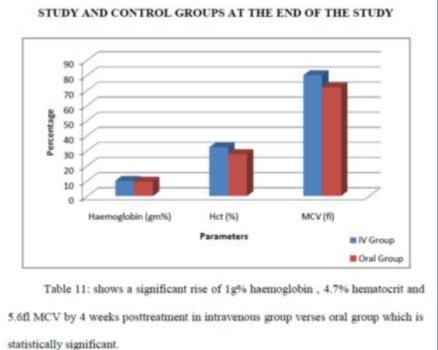


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#### TABLE .11:COMPARISON OF HEMOGLOBIN, HCT AND MCV BETWEEN STUDY AND CONTROL GROUPS AT THE END OF THE STUDY

Р Parameters IV Group **Oral Group** Haemoglobin (gm%) 10.18 9.66 0.0001 Hct (%) 32.44 27.93 72.09 MCV (fl) 80.14





**DISCUSSION:** Anemia due to iron deficiency is the commonest malnutrition disorder seen throughout the world and in India, affecting 35-75%<sup>26</sup> (average 56%) of pregnant women in developing countries and 18%<sup>27</sup> of women from industrialized countries are anemic. Currently there are many oral iron and intravenous preparations available. The traditional treatments, i.e., oral iron therapy and blood transfusion, involve significant drawbacks. High doses of oral iron frequently cause side effects, and noncompliance is common.

Administration of oral iron supplementations is not sufficient enough in order to reverse anemia promptly, due to the limited absorption, the gastrointestinal symptoms and the poor compliance for long treatment of the patients.<sup>28</sup> As far as blood transfusions are concerned, because of the risk of infection (bacterial, viral, prions) and immunomodulation associated with allergenic blood products, especially in this young and otherwise healthy population, transfusions are used only in the most severe cases and particularly in life threatening situations.<sup>46</sup>

Therefore, intravenous iron has been considered as an alternative in the management of iron deficiency anemia. This randomized trial is conducted in Obstetrics & Gynaecology Department of Cheluvamba Hospital of Mysore Medical College and Research Institute, Mysore. The aim of the study was to show that intravenous iron sucrose can be an alternative to oral ferrous sulphate in terms of safety, efficacy and compliance in treating anaemia in pregnancy. All these women were randomly assigned (100women each) to receive either calculated dose of intravenous iron sucrose(Group B) or oral ferrous sulphate 200mg, BD per day (Group A).

The characteristics of patients in group A and in group B were statistically comparable in relation to age. In the study majority of women were in the age group of 21 - 25 years. Mean age of the patients in other studies were approximately similar to present study. In all the studies maximum number of patients were primigravidas. This is explained by high prevalence of iron deficiency anemia in adult non-pregnant women (In our study group 61.5% were primigravidas).

When these anemic women become pregnant their anemia will be aggravated by increased need of iron during pregnancy, and it is important to screen iron deficiency anemia in all non-pregnant child bearing age group women as recommended by Centre of Disease Control and Prevention (CDC). In the present study the mean of gestational age at the time of inclusion in both the groups is comparable (in group A 25.92 ± 4.40 weeks and in group B 26.12 ± 4.5weeks).

The mean of gestational age in the Aggarwal Rohina et al is 28.8wks and 28.2wks and Al Momen et al is 21.9wks and 21.7wks in oral and IV group respectively. Among 200 patients studied 79% and 74% showing presence of pallor on general physical examination in either groups respectively, most of other studies not commented as the parameter is more subjective. In our study, the mean baseline hemoglobin was 8.08 and 7.65g/dl in oral and IV group respectively, which is found to be statistically insignificant between the groups.

Post treatment hemoglobin after 4 weeks showed a mean value of 9.6 gm/dl and 10.18gm/dl in oral and IV group respectively (p value <0.0001), which is statistically significant. The average rise of hemoglobin is 1.6gm/dl and 2.6 gm/dl in oral and IV group respectively (p value 0.0001), which is statistically significant. In the Aggarwal Rohina et al study, baseline hemoglobin levels is 5.94 and 6.27 g/dl and in the Al Momen et al, baseline haemoglobin is 7.6 and 7.5 g/dl are studied. In the Aggarwal et al study, average rise of hemoglobin is 4.32gm/dl and 5.03gm/dl and in the Al Momen et al, average rise of haemoglobin is 3.54g/dl and 5.3g/dl in oral and IV group respectively.

The mean baseline Hct is 25.36% and 25.27% in oral and IV groups respectively. Post treatment Hct after 4 weeks showed, an average rise of Hct is 2.5% and 7.2% in oral and IV group respectively (p value 0.0001), which is statistically significant. The mean baseline MCV is 65.66fl and 67.95fl in oral and IV group respectively. Post treatment MCV after 4 weeks showed an average rise of 6.4fl and 12fl in oral and IV group respectively (p value 0.0001), which is statistically significant.

There are no serious adverse effects in the study, however 7% in IV group and 29% in oral group has minimal side effects, but continued with the study. Same observations reported in other studies like Al-Momen<sup>24</sup> et al, Bayoumeu<sup>29</sup> et al and Aggarwal Rohina et al, without serious adverse effects. There are no serious adverse effects in the study, however 7% in IV group and 29% in oral group has minimal side effects, but continued with the study. Same observations reported in other studies like Al-Momen et al, Bayoumeu et al and Aggarwal Rohina et<sup>16</sup> al, without serious adverse effects. Compliance in the study is, for the most part, fairly high. There are no drop outs from the study and in the clinical setting it may be difficult to get the same rate of compliance for oral iron therapy.

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Our study is comparable with other two studies. In a study done by Aggarwal Rohina S et al in 2010, showed baseline Hb 6.27 and 5.95g%, Hct 18.8 and 17.8%, MCV 71.28 and 70.1fl in IV and oral group respectively. After 4wks, Hb% increased to 11.3 and 10.26g%, Hct increased to 33.9 and 30.77% and MCV increased to 93 and 85.8fl in IV and oral group respectively. In another study done by Al Momen et al in 1996, showed baseline Hb 7.58 & 7.66g% and MCV 68.6 &70.8fl in IV and oral group respectively. After 4wks Hb% increased to 12.8 & 11.1g% and MCV increased to 82.6 & 74.9fl in IV and oral group respectively. In both studies no major side effects is seen.

**SUMMARY:** This study is undertaken as a randomized control trial to compare the efficacy, safety and compliance of injectable iron sucrose with oral ferrous sulphate in the treatment of anaemia in pregnancy on an out-patient basis. Two hundred pregnant women with established diagnosis of iron deficiency anemia are included in the study. All these women are randomly assigned (100 women each) to receive either calculated dose of intravenous iron sucrose (Group B) or oral ferrous sulphate 200mg, BD per day(Group A).

### THE FOLLOWING OBSERVATIONS WERE MADE IN THE STUDY:

- 1. The age distribution of the women in the both groups is statistically comparable. The majority of women were in the age group of 21 to 25 years.
- 2. Among the cases studied majority of them are booked cases as the OPD patients are taken for study.
- 3. Primigravidas comprised the maximum number of patients in both the groups.
- 4. Most of the women presented with symptom of generalised weakness.
- 5. The mean gestational age at the time of inclusion in both the groups is comparable (in group A 25.92±4.4weeks and in group B 26.12±4.50 weeks).
- 6. Among the groups, all patients showed presence of pallor on general physical examination in both oral and IV group.
- 7. The mean baseline hemoglobin is 8.08 and 7.6g/dl in oral group and IV group respectively, which is found to be statistically insignificant.
- 8. The percentage rise in hemoglobin at fourth weeks of treatment is statistically significant when compared to the baseline.
- 9. Statistically significant rise in hemoglobin, MCV and Hct levels are found at fourth week in IV group when compared to oral group.
- 10. None of the patients in the IV group had any of the dreaded side effects which are known to occur with intravenous preparations.
- 11. None of the patients from either group had failure of treatment.
- 12. None of the patients are excluded from the study.

**CONCLUSION:** This study concluded that intravenous iron sucrose is safe, highly efficacious with better compliance for the treatment of iron deficiency anemia in pregnancy. Iron sucrose therapy is more effective in achieving the optimum results, an increase in Hb concentrate, MCV levels and an increase in Hct %. Therefore it is a suitable alternative to oral iron. There were no treatment failures and none of them required blood transfusions.

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