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PARENTERAL IRON SUCROSE VERSUS DOUBLING DOSE ORAL FERROUS FUMARATE FOR TREATMENT OF IRON DEFICIENCY ANEMIA IN PREGNANCY

By

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ABSTRACT

Background: Iron deficiency anemia (IDA) is considered one of the leading problems in pregnancy.

Objective: To compare the impact of doubling the standard dose of oral iron ferrous fumarate versus I.V iron sucrose to improve Hb, and S.ferritin levels in pregnancy for those women suffering from IDA between fourteen and thirty four week of gestation.

Patients and Methods: This was a controlled randomized clinical trial done over five hundred women with gestational age between fourteen and thirty four weeks in the department of Obstetrics and Gynecology at Al-Sayd Galal Hospital, from June 2019 to October 2020. All pregnant women included were counselled with an informed consent obtained before beginning of this study. Pregnant women were randomly divided into 2 equal groups: Group A for ferrous fumarate oral iron therapy while Group B for parenteral iron sucrose therapy. Pregnant women precipitating in this study were asked for medical history in details. Also they had undergone clinical examination and laboratory investigations including CBC and S. ferritin pretreatment and post treatment.

Results: The parenteral iron sucrose had more significant results than doubling the dose of ferrous fumarate oral iron treating IDA women during pregnancy. Few side effects were detected, and thus, it considered as a useful and alternative formulation in treatment of IDA. So, i.v iron sucrose infusion was more favorable for doubling the standard dose of ferrous fumarate as anaphylaxis risk was minimal. On the contrary, non-compliance to ferrous fumarate oral iron increased with doubling the dose. Parental iron showed a faster and more significant response than that for oral iron because of increased amount of iron available for Hb synthesis in the bone marrow when treating women using I.V iron therapy.

Conclusion: Parenteral iron sucrose has better results than that when using double the standard dose oral iron ferrous fumarate treating IDA in women during pregnancy as I.V iron improves the concentration of Hb and S.ferritin more significant than oral iron therapy.

Key words: parenteral iron sucrose, doubling dose, oral ferrous fumarate, treatment, iron deficiency anemia, pregnancy.

INTRODUCTION

Pregnancy anemia can cause severe adverse outcomes for the mother, the fetus or for both. Maternal adverse outcomes such as postpartum hemorrhage, sepsis, pre-eclampsia, preterm labor and

increased possibility of blood transfusion, while adverse fetal outcome may include high fetal mortality rate at the 3rd trimester. Also, IDA can affect the motor and mental development of children and adolescents *(Saeed et al., 2018).*

Routine supplementation of iron is strongly advised during pregnancy as most of pregnant women do not have adequate iron stores. WHO states that 38.2% of women in pregnancy suffer from anemia and about half of them suffer from IDA *(WHO, 2015).*

Singleton pregnancy maternal requirements of iron are about 1000 mg during term pregnancy that will be divided as follows: 300 mg for both fetal and placental requirements and 500 mg for maternal RBCs expansion. The rest of iron will be lost through gut, skin and urine extraction (Shinar et al., 2017).

Diagnosis of IDA in pregnancy is strongly advised to be as early as possible as it can help early management. IDA has certain characteristics which include decreased concentrations of Hb, decreased number of RBCs, total S.iron and S. ferritin low levels *(Maria et al., 2018).*

Experts recommend increased intake of O.I from 15 up to 30 mg elemental iron during pregnancy. An amount readily met by most prenatal vitamins formulations used *(Cantor et al., 2015).*

Prophylaxis and treatment of mild form of IDA needs the use of O.I therapy as a 1st choice, while in moderate and severe forms of IDA pregnant women, oral therapy needs a prolonged time. As a result of this, treatment whether by I.V. iron or blood transfusion is related to patient condition (degree of anemia, hemodynamic status, and period of gestation) should be recommended in women suffering from moderate or severe anemia during pregnancy *(Kriplani et al., 2013).*

Dietary habits changes alone are not adequate to help IDA correction so iron supplementions are necessary. Ferrous iron salt preparations of choice include ferrous fumarate O.I, ferrous sulphate O.I and ferrous gluconate O.I. Elemental iron amounts which comes out of this iron salts are different. O.I recommended dose in patients suffering from IDA should be 100mg up to200 mg. Using combination of O.I ferrous fumarate with folic acid preparations should be adviced *(Pavord et al., 2012).*

Several adverse effects can result from using ferrous fumarate O.I therapy in treatment of IDA including gastric irritation, diarrhea, constipation, vomiting and abdominal pain, which can be treated by intake of O.I tablets after meals, but iron absorption of O.I therapy will decrease leading to decreased effectiveness of treatment *(Di Renzo et al., 2015).*

I.V. iron sucrose is one of preparations which is associated with higher availability for erythropoiesis than that of other I.V. preparations like iron dextran *(Cançado and Muñoz, 2011).* However, its use is limited by the total dose that can be administered in one infusion. The newer preparations, iron III carboxymaltose or iron III isomaltoside, aims to solve this problem, with single dose administration in an hour or less *(Gozzard, 2011).*

This study aimed to compare the impact of doubling O.I ferrous fumarate dose versus parenteral iron sucrose

infusion in improving Hb and S.ferritin outcome in women suffering from IDA in pregnancy at gestational age of fourteen up to thirty four weeks.

PATIENTS AND METHODS

This controlled randomized clinical trial was conducted at The Department of Obstetrics and Gynecology, Al-Sayd Galal hospital from June 2019 to October 2020. Five hundred pregnant women with gestational age between fourteen up to thirty four weeks were involved in the study with an informed consent asked for all women precipitating.

All involved pregnant women undergone both general and abdominal examination. BMI calculation was done by dividing patient weight in kg by her height in square meters. Also, serial obstetric ultrasound examination was done for every woman.

The study inclusion criteria for precipitating women was Hb concentration 70 up to 105g/L, S.ferritin less than 15ng/ml, ages from twenty to fourty years old, singleton pregnancy and BMI 18 – 25.

On the other hand multifetal gestations, active vaginal bleeding, women suffering from hyperemesis gravidarium in the past twenty weeks of pregnancy, malabsorption diseases (inflammatory bowel diseases such as crohns disease and ulcerative colitis), and pregnant women suffering from chronic diseases causing anemia, hemoglobinpathies, and chronic renal diseases were excluded from the study.

Patients were randomly divided into 2 equal groups: Group A for oral iron (O.I) therapy and **Group B** for parenteral (I.V) iron therapy.

The following measurements were recorded: HB %, CBC, and S.ferritin. Four weeks later, Hb and S.ferritin were repeated for both groups.

In the oral (O.I) iron therapy group, patients received double recommended dose of O.I ferrous fumarate (two capsules) each capsule contained 305 mg iron salt which subsequently gave 100 mg elemental iron daily for four weeks. This treatment was associated with 500 ug of folic acid supplementations daily. All participant patients were asked to take two capsules 12 hours apart at least two hours after eating dairy products or one hour before meals with vitamin C source such as orange Juice to increase iron absorption. Women were asked to give back empty iron and folic acid packs during follow up visits. Treatment compliance was noted carefully. Adverse effect symptoms like vomiting, diarrhea, or constipation was recorded. No other medications affecting iron absorption was taken at the same time.

In the parenteral (I.V) iron group, total iron sucrose dose needed was calculated by using this formula:

Total dose needed =weight in kg x (target Hb in g/L – Actual Hb in g/L) x 0.24+ 500mg. rounded up to nearest multiple of 100 mg .

Parenteral iron sucrose was given as 200 mg of iron sucrose in 100 ml 0.9% sodium chloride solution infusion over 30 minutes in three separated doses day after day with maximum dose of 600 mg in the week. Folic acid supplementation in 500 ug per dose was given once daily for four

weeks (study time) to eliminate folic acid deficiency effect on the results. Additional oral iron tablets for the parenteral iron group were prevented during the study time.

Statistical analysis:

Recorded data were analyzed using the statistical package for the social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done: Independent-samples t-test of significance was used when comparing between two means. Paired sample t-test of significance was used when comparing between related samples. Mann Whitney U test: for two-group comparisons in non-parametric data. Comparison between two related samples for non-parametric data using Wilcoxon Rank Sum test. Chi-square (□2) test of significance was used in order to compare proportions between qualitative parameters. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, P-value <0.05 was considered significant.

RESULTS

No statistically significant differences were found between both groups according to their demographic data regarding age, parity, BMI and GA **(Table 1)**.

Table (1): Comparison between Group A: Oral Iron (O.I) therapy and Group B: Parenteral Iron therapy according to demographic data

Group / Demographic data	Group A: Oral Iron (n= 234)	Group B: Parenteral Iron (n=237)	p-value
Age (years)			
Range	20-40	20-40	0.339
Mean±SD	29.15±3.51	28.83±3.74	
Parity‡			
Range	0-3	0-3	0.654
Median (IQR)	2 (1)	2 (1)	
P0¥	41 (17.5%)	55 (23.5%)	0.232
P1	55 (23.5%)	47 (20.1%)	
P2	76 (32.5%)	64 (27.4%)	
P3	62 (26.5%)	71 (30.3%)	
BMI [wt/(ht)^2]			
Range	18-25	18-25	0.074
Mean±SD	21.76±2.43	22.07±1.30	
GA (wks).			
Range	14-34	14-34	0.260
Mean±SD	27.19±2.01	26.97±2.22	

Using: t-Independent Sample t-test; ‡z-Mann-Whitney test; ¥ Chi-square test,
p-value>0.05 NS

There was no significant difference statistically between both groups according to their pre MCV, MCT and MCHC, while significant statistically mean increase in Parenteral Iron therapy compared to (O.I) Oral Iron therapy is noticed according to their laboratory data regarding post Hb, MCV and HCT, MCHC, while s.Ferritin significant higher in Group B **(Table 2)**.

Table (2): Comparison between Group A: Oral Iron (O.I) therapy and Group B: Parenteral Iron therapy according to pre and post laboratory data

Group / Laboratory data	Group A: Oral Iron (n= 234)	Group B: Parenteral Iron (n=237)	p-value
Pre Laboratory			
Hb. (mg/dl)			
Range	7.14-10.71	7.14-10.2	0.443
Mean±SD	8.70±1.17	8.78±1.09	
MCV			
Range	62-81	61-83	0.056
Mean±SD	70.48±5.25	71.53±6.56	
HCT			
Range	17.34-22.24	17.44-22.13	0.134
Mean±SD	20.30±1.50	20.52±1.68	
MCHC			
Range	13-30	13-29	0.136
Mean±SD	21.82±4.96	22.52±5.20	
Serum Ferritin‡			
Range	7-14	8-14	0.174
Median (IQR)	12 (3)	12 (2)	
Post Laboratory			
Hemoglobin	9.80±1.23	10.97±1.88	0.025
MCV	74.05±8.44	80.50±5.96	0.008
HCT	25.49±1.74	28.47±1.62	0.009
MCHC	23.99±5.57	26.33±4.98	0.029
s.Ferritin‡	Median 39 (IQR: 15)	Median 83 (IQR: 32)	<0.001

Using: t-Independent Sample t-test; ‡ Mann-Whitney test

There was a statistically significant mean increase in post-treatment and pre-treatment according to their laboratory data regarding Hb, MCV, HCT, MCHC and Ferritin **(Table 3)**.

Table (3): Comparison between pre-treatment and post-treatment according to laboratory data in Group A: oral (O.I) iron therapy

O.I Group / Laboratory data	Pre-Treatment	Post-Treatment	Mean Diff.	Change%	p-value
Hemoglobin	8.70±1.17	9.80±1.23	1.10±0.37	12.64±4.30	**0.006**
MCV	70.48±5.25	74.05±8.44	3.57±1.21	5.07±1.72	**0.041**
HCT	20.30±1.50	25.49±1.74	5.19±1.76	25.57±8.69	**0.012**
MCHC	21.82±4.96	23.99±5.57	2.17±0.74	9.95±3.38	**0.042**
Ferritin€	Median 12 (IQR: 2)	Median 39 (IQR: 15)	Median 27 (IQR: 9)	Median 229 (IQR 78)	**<0.001**

Using: Paired Sample t-test; €Wilcoxon test
*p-value <0.05 S; **p-value <0.001 HS

There was a highly statistically significant mean increase in post-treatment and pre-treatment according to their laboratory data regarding Hb, MCV, HCT, MCHC and Ferritin **(Table 4)**.

Table (4): Comparison between pre-treatment and post-treatment according to CBC in Group B: Parenteral Iron therapy

Parenteral iron group / Laboratory data	Pre-Treatment	Post-Treatment	Mean Diff.	Change%	p-value
Hemoglobin	8.78±1.09	10.97±1.88	2.19±0.74	24.94±8.48	**<0.001**
MCV	71.53±6.56	80.50±5.96	8.97±3.05	12.54±4.26	**<0.001**
HCT	20.52±1.68	28.47±1.62	7.95±2.70	38.74±13.17	**<0.001**
MCHC	22.52±5.20	26.33±4.98	3.81±1.30	16.92±5.75	**<0.001**
Ferritin€	Median 12 (IQR: 2)	Median 83 (IQR: 32)	Median 76 (IQR: 26)	Median 622 (IQR: 211)	**<0.001**

Using: Paired Sample t-test; €Wilcoxon test
**p-value <0.001 HS

There was a statistically significant higher mean change in Parenteral Iron therapy compared to Oral Iron (O.I) therapy according to their laboratory data regarding Hemoglobin, MCV and HCT, MCHC, while S.Ferritin significant higher in Group B **(Table 5)**.

Table (5): Comparison between Group A: Oral Iron (O.I) therapy and Group B: Parenteral Iron therapy according to change between pre and post-treatment at laboratory data

Groups / Laboratory data	Group A: Oral Iron (n= 234)	Group B: Parenteral Iron (n=237)	p-value
Hemoglobin			
Diff. Median (IQR)	1 (0)	2 (1)	**0.002**
Change% Median (IQR)	13 (4)	25 (8)	
MCV			
Diff. Median (IQR)	4 (1)	9 (3)	**0.002**
Change% Median (IQR)	5 (2)	13 (4)	
HCT			
Diff. Median (IQR)	5 (2)	8 (3)	**0.021**
Change% Median (IQR)	26 (9)	39 (13)	
MCHC			
Diff. Median (IQR)	2 (1)	4 (1)	**0.005**
Change% Median (IQR)	10 (3)	17 (6)	
Ferritin			
Diff. Median (IQR)	27 (9)	76 (26)	**<0.001**
Change% Median (IQR)	229 (78)	622 (211)	

Using: Mann-Whitney test

There was a statistically significant higher nausea, vomiting and gastritis in oral iron therapy group compared to parenteral iron therapy group. Also, a statistically significant higher anaphylactic reaction and local thrombophlebitis in parenteral iron was present compared to oral iron according to side effects **(Table 6)**.

Table (6): Comparison between Group A: Oral Iron (O.I) therapy and Group B: Parenteral Iron therapy according to their side effects

Groups / Side effects	Group A: Oral Iron (n= 234)	Group B: Parenteral Iron (n=237)	p-value
Nausea & vomiting	17 (7.3%)	5 (2.1%)	**0.015**
Gastritis	37 (15.8%)	7 (3.0%)	**<0.001**
Anaphylacticreaction symptoms	2 (0.9%)	12 (5.1%)	**0.016**
Local thrombophlebitis	0 (0.0%)	17 (7.3%)	**<0.001**

Using: Chi-square test

DISCUSSION

Pregnancy is accompanied with physiological hemodilution which peaks in gestational age 20–24 weeks which leads to Hb level differences through trimesters *(Di Renzo et al., 2015).*

Serum ferritin level can be used as a diagnostic investigation of IDA and to reflect iron stores condition as bone

marrow sampling isn't practical to measure iron stores status in the body *(Daru et al., 2017).*

This study proved that the I.V. iron sucrose therapy was much more effective than the doubling O.I dose of ferrous fumarate therapy in management of severe IDA.

The results of the present study were in agreement with those done by *Bhavi and Jaju (2017)* as they conducted a study comparing aspects of efficacy, safety and compliance of patients for O.I ferrous fumarate therapy (group A), and I.V iron sucrose therapy (group B) in treatment of IDA for anemic women during pregnancy.

Serum ferritin levels showed a significant difference in the same study after four weeks of treatment in both the groups. In a study done by *Neeru et al. (2012)* comparing the efficacy, safety and compliance of O.I therapy (ferrous fumarate) with that of I.V iron sucrose therapy and their effect on Hb and S. ferritin levels.

Definitive and comparable increase in Hb and all the blood values (hematocrit, MCH, MCHC, MCV, Serum iron and TIBC) were observed. S.ferritin showed statistically significant increase after parenteral iron treatment in comparison to O.I treatment.

A study done by *Radhika et al. (2019),* showed that O.I was accompanied with significant G.I.T side effects and non-compliance to O.I treatment which led to failure treatment strategies.

On the contarary, *Bhavi and Jaju (2017)* had a study as they used ferrous fumarate O.I for treatment of IDA in pregnant women at dose 200 mg daily. They reported good compliance of pregnant patients receiving oral treatment. However he, they thought that gastrointestinal symptoms are dose related as these symptoms are common by increasing the doses and also affected by the formulation of O.I.

Our study showed that during pregnancy in the parentral group who were treated with I.V iron sucrose, reported local thrombophlebitis. Some pregnant women developed irrelevant complains like nausea and vomiting for one time others suffered from gastritis they were treated and I.V iron sucrose doses were completed.

I.V iron therapy is considered a safe alternative since it decreases blood transfusion for treatment of IDA. In addition, side effects related to supplementation of iron through this route, such as anaphylactic shock, febrile and hemolytic reactions, infections (hepatitis B, C, HIV, protozoan and bacterial) alloimmunization and graft versus host disease are very rare.

Our study was in agreement with study done by *Neogi et al. (2019)* in a study done on women during pregnancy aged above 18 years old, with gestational age of twenty up to twenty eight weeks with a Hb concentration of five to eight mg/dL, or at twenty nine up to thirty two weeks of gestation with a Hb concentration of five to nine mg/dL. Patients showed no serious adverse effects related to the trial procedures or the interventions as assessment was done by the trial investigators, ethics committees, and regulatory body; which ensures the safety of i.v. iron sucrose therapy.

Another study was in agreement with our study done by *Kriplani et al. (2013)* in which pregnant woman was recruited for I.V iron sucrose complex at doses of 200 mg twice weekly. There were no major side effects and no allergic or anaphylactic reaction.

CONCLUSION

The use of I.V. iron sucrose for treatment of IDA in pregnancy was better than the use of double dose oral ferrous fumarate as I.v iron increase the concentration of Hb and S. ferritin more significant than oral iron.

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حقن سكروز الحديد في الوريد مقابل مضاعفة جرعة فومارات الحديدوز عن طريق الفم لعلاج فقر الدم الناتج عن نقص الحديد فى الحمل

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خلفيـة البحـث: يُعتبـر فقـر الـدم بسـبب نقـص الحديـد مـن المشـاكل الرئيسـية أثنـاء الحمـل حيـث أن معظـم السـيدات فـي سـن الإنجـاب مصـابات بفقـر الـدم وتـزداد حدتـه خـلال تلك الفترة.

الهـدف مـن البحـث: مقارنـة تـأثير مضـاعفة الجرعـة المعياريـة مـن فومـارات الحديـدوز عـن طريـق الفـم مقابـل حقـن سـكروز الحديـد عبـر الوريـد لتحسـين مسـتويات الهيموجلـوبين والفيـريتين فـى مصـل الـدم أثنـاء الحمـل للسـيدات اللاتـى تعـانين مـن فقـر الدم بسبب نقص الحديد بين أربعة عشر وأربعة وثلاثين أسبوعًا من الحمل.

المريضـات وطـرق البحـث: تـم إجـراء هـذه الدراسـة العشـوائية الضـابطة علـى خمسـمائة سـيدة فـي سـن الحمـل بـين أربعـة عشـر وأربعـة وثلاثـين أسـبوعًا فـي قسـم أمـراض السـيدات والتوليـد، مستشـفى سـيد جـلال، جامعـة الأزهـر مـن يونيـو 2019 إلـى أكتـوبر 2020. وتـم تقـديم المشـورة للنسـاء المتضـمنات بموافقـة مسـتنيرة تـم الحصـول عليهـا قبـل بـدء هـذه الدراسـة. وتـم تقسـيم السـيدات الحوامـل بشـكل عشـوائي إلـى مجمـوعتين متسـاويتين: المجموعـة (أ) تـم إعطاؤهـا فومـارات الحديـدوز عـن طريـق الفـم؛ بينمـا خضـعت المجموعـة (ب) لحقـن سـكروز الحديـد. وقـد طُلـب مـن السـيدات الحوامـل اللاتـي يخضـعن للعـلاج فـي هـذه الدراسـة الحصـول علـى التـاريخ الطبـي بالتفصـيل. كمـا خضـعوا للفحـص السـريري والاختبـارات المعمليـة بمـا فـي ذلـك صورة دم كاملة؛ وتم لاحقاً إعطاء العلاج.

نتـــائج البحـــث: كـــان لســـكروز الحديـــد بـــالحقن نتـــائج أكثـــر أهميـــة مـــن مضـــاعفة جرعـــة كبريتـــات الحديـــدوز (حديـــد الفوماريـــت) عـــن طريـــق الفـــم فـــي عـــلاج الســـيدات مـــن فقـــر الـــدم بســـبب نقـــص الحديـــد أثنـــاء الحمـــل. وقـــد تـــم الكشـــف عـــن آثـــار جانبيـــة قليلـــة، وبالتـــالي يمكـــن اعتبـــاره تركيبـــة مفيـــدة وبديلـــة فـــي عـــلاج فقـــر الـــدم بســـبب نقـــص الحديـــد. لـــذلك، يعتبـــر ســـكروز الحديـــد بـــالتنقيط الوريـــدى أكثـــر ملاءمـــة لمضـــاعفة الجرعـــة القياســـية مـــن فومـــارات الحديـــدوز لأن خطـــر الحساســـية المفرطـــة ضـــئيل. علـــى العكـــس مـــن ذلـــك، فقـــد أظهـــر المرضـــى زيـــادة فـــى عـــدم تفضـــيل فومـــارات الحديـــدوز عـــن طريـــق الفـــم بمضـــاعفة الجرعـــة. أظهـــر الحديـــد اســـتجابة أســـرع وأكثـــر أهميـــة مـــن تلـــك الخاصـــة بفومـــارات الحديـــدوز عـــن طريـــق الفـــم بســـبب زيـــادة كميـــة الحديـــد المتاحـــة لتخليـــق الهيموجلوبين في نخاع العظام عند علاج السيدات باستخدام العلاج بالحديدوز.

الاســـتنتاج: أظهـــرت نتـــائج ســـكروز الحديـــد بـــالحقن تحســـناً أفضـــل مـــن تلـــك التـــى تـــم الحصـــول عليهـــا عنـــد اســـتخدام جرعـــة مضـــاعفة مـــن فومـــارات الحديـــدوز عـــن طريـــق الفـــم التـــي تعـــالج فقـــر الـــدم بســـبب نقـــص الحديـــد عنـــد الســـيدات أثنـــاء الحمـــل؛ حيـــث ظهـــر جليـــاً أن الحديـــد عـــن طريـــق الوريـــد يحســـن تركيـــز الهيموجلـــوبين فـــى مصـــل الـــدم الفيريتين بصورة أكبر من العلاج بفومارات الحديدوز عن طريق الفم.

الكلمـــات الدالـــة: ســـكروز الحديـــد بالوريـــد، مضـــاعفة الجرعـــة، فومـــارات الحديـــدوز بالفم، علاج أنيميا نقص الحديد، الحمل.