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Intravenous Iron Sucrose versus Intramuscular Iron Sorbitol in management of iron deficiency anemia during pregnancy

Obstetrics & Gynecology

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ABSTRACT

Background: The greatest prevalent nutrient shortage in pregnant women across the globe is iron deficiency anemia (IDA). Maternal anemia continues to significantly increase neonatal morbidity and death, and there is worry over the elevated incidence of iron and other micronutrient deficiencies among pregnant women in poor nations.

Aim of the work: To examine the effectiveness and safety of intramuscular iron sorbitol citric acid complex and intravenous iron sucrose in the treating of iron deficiency anemia (IDA) in gestation.

Patients and methods: At the Department of Obstetrics and Gynecology, Faculty of Medicine, Al-Azhar University, 100 pregnant women were separated into two groups for this randomized controlled trial. Between July 2021 and December 2021, 50 pregnant women were separated into two groups: group A got intravenous iron sucrose treatment, while group B got intramuscular iron sorbitol medication.

Results: Regarding the negative effects of the therapy, there was a statistically substantial variation between the two trial groups.

Conclusion: We concluded that for treating mild anemia in pregnancy, intravenous iron sucrose treatment was shown to be both substantially more efficient and safer than intramuscular iron sorbitol citrate therapy.

Keywords: *Anemia; Ferritin; Pregnancy; Sorbitol; Sucrose.*

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INTRODUCTION

Reduced hemoglobin levels, red-cell count, or packed-cell volume are characteristics of anemia. According to World Health Organization (WHO) guidelines, 11 g/dL is considered the mean minimum tolerable hemoglobin level during gestation.[1]

Anemia in gestation is defined by the Centers for Disease Control (CDC) as hemoglobin lower than 11 g/dl (Hematocrit: Hct < 33%) in the first and third trimesters and lower than 10.5 g/dl (Hct < 32%) in the 2nd trimester.[2]

The most widespread nutritional issue in the world is iron insufficiency, which is pandemic in many underdeveloped nations. Up to 50% of cases are caused by inadequate iron consumption, making it the most prevalent dietary deficit in the industrialized world. The incidence of IDA rises in gestation because of the increasing need for iron. In the underdeveloped world, this affects up to 52% of pregnant women.[3]

Both the mother's and the fetus's health are significantly impacted by anemia. It hinders the fetus's ability to get oxygen via the placenta and interferes with its normal intrauterine development, which may result in miscarriage and neonatal fatalities. Preterm birth rates (28.2%), preeclampsia (31.2%), and maternal sepsis are all up due to anemia.[4]

40–60% of maternal mortalities from heart failure, bleeding, infection, and pre-eclampsia are directly or indirectly attributable to iron deficiency anemia.[5]

In areas where anemia incidence is more than 40% in women and adolescents, the WHO established a worldwide guideline in 2016 suggesting daily oral iron intake (60mg iron) for 12 weeks. The WHO's position is based on the assumption that women who are iron deficient experience advantages from iron supplements, and that iron deficiency accounts for around 50% of anemia in low-income countries.[6]

Recent national recommendations include the tried-and-true intramuscular iron sorbitol citric acid combination as one of the first-line medications for managing mild IDA during pregnancy. This

medication's main drawbacks are injection site discomfort and swelling, quick clearance necessitating greater dosages, and the necessity for frequent injections, all of which contribute to low compliance and high dropout rates. [7] Therefore, we need an iron treatment that is relatively recent and has superior effectiveness, less side effects, quick action, and better compliance. [8]

Recent alternative strategies, such as parenterally administered iron sucrose, promise to be more effective because it slows the release of elemental iron from the complex, reduces renal excretion, speeds up the replenishment of iron stores, increases the availability of iron for erythropoiesis and, consequently, causes a rapid increase in hemoglobin, and is safe because of its low allergic impact and organ toxicity.[9]

The goal of the research was to assess the effectiveness and safety of intramuscular iron sorbitol citric acid complex and intravenous iron sucrose in treating iron deficiency anemia (IDA) in pregnancy.

PATIENTS AND METHODS

This study is randomized controlled research that was carried out on 100 pregnant ladies. They were recruited from Obstetrics and Gynecology clinics during the period from July 2021 till December 2021. This research was done at Kafr El Sheikh General Hospital and the Department of Obstetrics and Gynecology at Al-Azhar University's Faculty of Medicine.

Ethical and legal consideration: Approval of ethical committee was obtained as well as written consent was signed from all cases before participation in this study.

Sample size: The sample size was determined utilizing Epi Info STATCALC while taking into account the following presumptions: An odds ratio of 1.115 was derived using a- 95 percent two-sided confidence level, an 80 percent power, and a 5 percent error. In developing nations, IDA prevalence ranges from 35 to 75 percent (on average 56 percent).[7]

From the Epi-Info output, 86 was the ultimate maximum sample size. In order to account for potential drop-off cases during follow-up, the sample size was raised to 100 cases.

Inclusion criteria: Age between 21 and 35, Singleton gestation, and IDA diagnosed between 14 and 28 weeks with hemoglobin levels of 7-9 g/dL.

Exclusion criteria: the existence of anemia due to conditions other than iron insufficiency (such as thalassemia, folate insufficiency anemia, vitamin B12 insufficiency, etc.), multiple pregnancies, the existence of clinical or laboratory findings of hepatic, renal, or hematological abnormalities, cardiovascular disorders, renal malfunction, infections like malaria, hook worm infestation, and schistosomiasis, people who are known to be hypersensitive to iron preparations, instances with anti-partum hemorrhage (APH), pregnancy-induced hypertension, hemoglobin values <7 or >9 gm/dl, gestation age <14 or >32 weeks, recent blood transfusion, and G6PD deficiency or anti-partum hemorrhage (APH), pregnancy-induced hypertension(PIH), or a past of any hemorrhage propensity or gestation complications.

Intervention(s)

All cases were subjected to the followings:

Detailed history including personal history and past history, obstertric history history of last menstrual period (LMP), any previous contraceptive method medical and surgical history, Clinical examination: Body Mass Index (BMI) for mothers was computed, Symptoms and signs of anemia including pallor.

Investigations: Complete blood count (CBC): level of hemoglobin, Hematocrit (PCV), Median corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH), Median corpuscular hemoglobin concentration (MCHC).

Vitamine B12 and Folic acid

Serum Ferritin was measured by ELISA kits.

Randomization and allocation: 100 patients who met the requirements were randomly assigned using a computer-generated list of random numbers in such a manner that each patient had an equal chance of being in either of the two groups (1:1). Then, allocation into two equal groups as follows: Group A: contained 50 pregnant women who got intravenous iron sucrose therapy (Sacrofer IV). Group B: contained 50 pregnant women who got intramuscular iron sorbitol therapy (Haempower injection IM).

Interevention: Following thorough sensitivity testing in both groups, iron was administered. The Ganzoni Formula was used to determine the amount of iron needed in both groups, with the target hemoglobin set at 11 gm/dl: Total iron deficit (mg) = Body wt (kg) × {Target Hb - Actual Hb (gm/dl)} ×2.4+500 [10], In group A, up to the predicted dosage, iron sucrose was administered as 150 mg (3 ampules, each of 2.5 ml) in 100 ml of 0.9 percent normal saline infusion over 3 h every third day (Sacrofer IV).

In group B, Using the "Z" approach, daily intramuscular injections of 1.5 ml of iron sorbitol complex up to the estimated dosage were administered (Haempower injection IM). Every instance was watched for negative outcomes:

Follow up: After the course of therapy, the patients were told to make one visit on day 21. Both spontaneous complaints from patients and unfavorable effects that were detected were documented. Blood samples from both groups were taken for analysis in order to determine the efficacy parameters (serum ferritin, TIBC, median corpuscular volume, median corpuscular hemoglobin, median corpuscular hemoglobin concentration, median corpuscular volume, median corpuscular hemoglobin, PCV, and median hemoglobin level).

Statistical analysis: Using the SPSS software (Statistical Package for Social Science), version 26, the acquired data were processed and statistically

evaluated. The Shapiro Walk test was performed to check the data for normal distribution. For both parametric and non-parametric variables, the student t test was employed to determine the variance between quantitative variables in two groups.

RESULTS

Variable	Group A	Group B	P value
Age			
Mean± SD	26.8± 5.2	27.3± 5.3	0.662
BMI			
Mean± SD	25.1± 2.4	25.4± 2.3	0.537

Student t test; *p is significant at <0.05

Table 1: Basic characteristics of the two investigated groups

Group A had an average age of 26.8 ±5.2 and group B 27.3± 5.3. Between the two study groups, there was no statistically substantial variation. The average BMI for group A was 25.1± 2.4 while for group B it was 25.4 ±2.3. Between the two study groups, there was no statistically substantial variation in BMI. (Table 1).

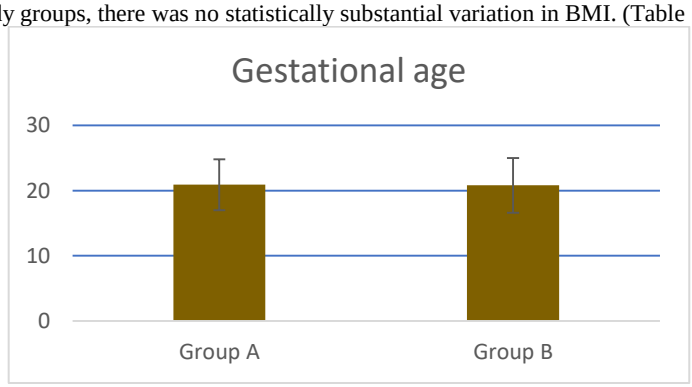

Fig. 1: Gestational age among the two studied groups

The median gestation ages for groups A and B were 20.9± 3.9 and 20.8± 4.2, respectively. Between the two study groups, there was no statistically substantial variation.

Variable	Group A n (%)	Group B n (%)	P value
Abortion			
Yes	8 (16)	10 (20)	0.830
No	42 (84)	40 (80)	
Previous surgery			
Yes	22 (44)	20 (40)	0.840
No	28 (56)	30 (60)	

Chi square test; *p is significant at <0.05

Table 2: Abortion and previous surgery among the two studied groups

There were 84% and 80% had no history of abortion and 16% and 20% had previous history of abortion among group A and group B respectively. Regarding prior abortions, there was no statistical substantial variation between the two study groups. according prior surgery, there was no statistically substantial variation between the two study groups (Table 2).

Variable	Group A Mean ± SD	Group B Mean ± SD	P value
Serum ferritin	22.7 ± 4.6	23.4 ± 4.3	0.448
TIBC	352.8 ± 48.3	349.2 ± 47.6	0.448

Student t test; *p is substantial at <0.05

Table 3: Serum ferritin pretreatment among the two studied groups

according serum ferritin and TIBC pretreatment, there was no statistically substantial variation between the two study groups. (Table 3).

Variable	Group A Mean± SD	Group B Mean± SD	P value
Hb	11.3 ± 1.4	9.2 ± 1.2	<0.001*
MCV	81.7 ± 8.8	71.7 ± 8.1	<0.001*
HCT	30.3 ± 4.1	23.1 ± 2.1	<0.001*
MCH	31.0 ± 1.3	28.5 ± 1.1	<0.001*
MCHC	26.2 ± 3.5	24.5 ± 3.7	0.020*

Student t test; *p is substantial at <0.05

Table 4: Comparison between the two groups according Hb, MCV, HCT, MCH, MCHC post treatment

Group A was statistically substantially greater than group B regarding Hb, MCV, HCT, MCH and MCHC post treatment (Table 4).

Variable	Group A Mean ± SD	Group B Mean ± SD	P value

Serum ferritin	38.6± 4.7	30.3± 3.9	<0.001*
TIBC	326.3 ± 42.1	332.5 ± 44.7	0.477

Student t test; *p is substantial at <0.05

Table 5: Comparison the two studied groups regarding serum ferritin post treatment.

Group A was statistically substantial higher regarding serum ferritin. Moreover, regarding post-treatment TIBC, there was no statistically substantial variation between the two study groups. (Table 5).

Variable	Group A (pre) Mean± SD	Group A (post) Mean± SD	P value
Hb	8.3± 0.6	11.3± 1.4	<0.001*
MCV	71.2± 5.9	81.7± 8.8	<0.001*
HCT	19.3± 1.7	30.3± 4.1	<0.001*
MCH	23.3± 2.0	31.0± 1.3	<0.001*
MCHC	21.2± 5.3	26.2± 3.5	<0.001*
Serum ferritin	22.7± 4.6	38.6± 4.7	<0.001*
TIBC	352.8 ± 48.3	326.3 ± 42.1	0.004

Student t test; *p is substantial at <0.05

Table 6: Comparison between lab results of the pre and post treatment among group A

Group A post treatment was statistically substantially higher than group A pre-treatment regarding Hb, MCV, HCT, MCH, MCHC and serum ferritin, however TIBC was statistically significantly lower in post-treatment compared to pre-treatment (Table 6).

Variable	Group B (pre) Mean± SD	Group B (post) Mean± SD	P value
Hb	8.2 ± 0.6	9.2 ± 1.2	<0.001*
MCV	70.6 ± 6.6	71.7 ± 8.1	0.425
HCT	19.2 ± 1.8	23.1 ± 2.1	<0.001*
MCH	23.3 ± 2.4	28.5 ± 1.1	<0.001*
MCHC	20.9 ± 5.0	24.5 ± 3.7	<0.001*
Serum ferritin	23.4 ± 4.3	30.3 ± 3.9	<0.001*
TIBC	349.2 ± 47.6	332.5 ± 44.7	0.074

Student t test; *p is substantial at <0.05

Table 7: Comparison between lab results of the pre and post treatment among group

Group B post treatment was statistically substantially higher than group B pre-treatment regarding Hb, HCT, MCH, MCHC and serum ferritin, however MCV was increased and TIBC was decreased post-treatment but without statistically significant difference (Table 7).

Adverse effects	Group A n (%)	Group B n (%)	P value
Anaphylactic reaction	12 (24)	5 (10)	0.062
Brown pigmentation at site of injection	0 (0)	7 (14)	0.006
Constipation	5 (10)	3 (6)	0.461
Diarrhea	4 (8)	3 (6)	0.695
Fatigue	1 (2)	3 (6)	0.309
Local thrombophlebitis	3 (6)	0	0.079
Myalgia	6 (12)	5 (10)	0.749
Nausea	6 (12)	7 (14)	0.766
Pain	4 (8)	3 (6)	0.695
Tachycardia and dyspnea	7 (14)	3 (6)	0.183
Upper GIT troubles	4 (8)	6 (12)	0.505

Fisher Exact test; *p is substantial at <0.05

Table 8: Adverse effect among the two studied groups

Anaphylactic reaction, constipation, diarrhea, local thrombophlebitis, myalgia, pain, and tachycardia & dyspnea were more prevalent in group A compared to group B but without statistically substantial difference. Moreover, fatigue, nausea, and upper GIT troubles were more prevalent in group B compared to group A but without statistically substantial difference. However, Brown pigmentation at site of injection was substantially more often in group B compared to group A (Table 8).

DISCUSSION

The usage of intravenous iron was limited by severe systemic side effects related to iron dextran and iron gluconate. A relatively new medication called iron sucrose complex (ISC) is administered intravenously to treat IDA. An important focus has been placed on the extensively used and secure iron sucrose complex in an effort to avoid iron deficiency anemia.[11]

This randomized controlled study that was carried out on 100 pregnant ladies. They were recruited from Obstetrics and Gynecology clinics during the period from July 2021 till December 2021. The patients were separated into two groups. In group A, iron sucrose will be administered as 150 mg (3 ampules, each containing 2.5 ml) in 100 ml of 0.9 percent normal saline over the course of an hour, every third day, until the prescribed dosage has been reached. By using the "Z" approach, daily intramuscular

injections of 1.5 ml of iron sorbitol complex will be administered to group B patients until the prescribed total dosage.

Regarding the basic characteristics of the two study groups, our results revealed that the median age of group A was 26.8± 5.2 and group B was 27.3± 5.3. Between the two study groups, there was no statistically substantial variation. The mean BMI was 25.1± 2.4 among group A and 25.4± 2.3 among Group B. Between the two study groups, there was no statistically substantial variation in BMI.

Our study was supported by the research by Gaikwad et al.[7] noted that in pregnant anemic patients, contrast the effectiveness and safety of iron sucrose against iron sorbitol treatment. Study participants Two groups of 200 pregnant women were randomly allocated to have intramuscular and intravenous iron treatment. There was no statistically substantial variation in the average age of women in the intravenous and intramuscular groups, which were 24.8 and 25.6 years, respectively.

Also, the comparative prospective study by Nanthini et al.[10] In IDA of pregnant women, compare the effectiveness and safety of iron sucrose vs ISCA complex. The research enrolled a total of 127 pregnant women; they were randomized into two groups to receive iron sucrose (intravenous) and ISCA (I.M), respectively. The median ages were 23.4±1.76 and 23.7±1.74 years and the mean Weight was 55.7±6.3 and for 55.8±5.7 of the two groups respectively with no statistically significant change as regard age and weight.

As well, the study by Singh et al.[12] In order to treat anemia during pregnancy, assess the effectiveness, safety, and rate of response of IV iron sucrose and IM iron sorbitol treatment. 100 participants in the research the cases were split into two groups at random. Group A got IV iron sucrose in 50 instances, whereas Group B got IM iron sorbitol in 50 cases. There was no discernible difference in the mean ages of groups A and B, which were 26.46 and 26.62 years, respectively.

According the Obstetric data among the two studied groups, we found that the median gestation age was 20.9 ±3.9 and 20.8 ± 4.2 in group A and group B respectively. The median gravidity was 3.5 ± 1.6 and 3.6 ± 1.8 in group A and group B respectively. The median parity was 1.8 ± 1.5 and 1.9 ± 1.5 among group A and group B respectively. There was 72% and 78% had used IUD, 22% and 18% had used hormonal contraceptive method and 6% and 4% had used barrier method among group A and group B respectively. Regarding gestational age, gravidity, parity, and methods of contraception, there was no statistically substantial variation between the two study groups.

In accordance with our study by Nanthini et al.[10] demonstrated that the Iron sucrose and Iron sorbitol citric acid groups' gestational weeks 23.2±6.06 and 23.3±5.72, respectively, showed no discernible change.

As well the study by Singh et al.[12] demonstrated that the median period of gestation (weeks) 24.48 and 23.94 and the mean Parity C2 (% of cases) 68 and 56 for groups A and B respectively with no substantial variation.

Also, Dhanani et al.[3] reported that the Gestational weeks 23.86 ± 5.63 and 23.10 ± 6.62 of Iron sucrose and Iron sorbitol citric acid groups respectively with no substantial variation.

While in disagreement with our findings the research by Gaikwad et al.[7] demonstrated that 47% of instances in In-group A were primigravida, which is the highest possible parity. There were 21% primigravida in group B, and the highest parity was 5. This is a considerable variation.

No one has reported in the related studies the history of abortion and previous surgery of the studied women.

Comparison between the two groups regarding Hb, MCV, HCT, MCH, MCHC post treatment revealed that Group A (iron sucrose) was statistically significantly higher than group B (Iron sorbito) regarding Hb, MCV, HCT, MCH and MCHC post treatment.

Our research was consistent with those of Nanthini et al.[10] who reported that the iron sucrose group was statistically considerably higher than Iron sorbito group regarding Hb, MCV, MCH and MCHC post treatment.

As well Gaikwad et al.[7] who showed that compared to group A, group B's intramuscular mean increase in hemoglobin level was reduced (intravenous). Additionally, they stated that both groups' MCH and MCHC values had significantly increased. However, the intravenous group experienced it more ($p<0.05$).

Our results revealed also that Group A was statistically significant higher regarding serum ferritin.

Our research was consistent with those of Nanthini et al.[10] who reported that the iron sucrose group was statistically substantially higher than Iron sorbito group regarding serum ferritin post treatment.

The present study revealed that Group A post treatment was statistically substantially higher than group A pre-treatment regarding Hb, MCV, HCT, MCH, MCHC and serum ferritin. As well Group B post treatment was statistically substantially higher than group B pre-treatment regarding Hb, MCV, HCT, MCH, MCHC and serum ferritin.

In accordance with our findings Nanthini et al.[10] showed that regarding the effect of iron sucrose therapy there was significant improvement in the hematological parameters including Hb, MCV, MCH, MCHC, Serum reticulocyte and serum ferritin. The same result was for iron sorbitol citric acid therapy.

Gaikwad et al. [7] who reported that there was substantial rise in Hb, MCH, MCHC and serum ferritin value in both the groups.

Singh et al.[12] noted that there was substantial improvement in the post-therapy Hb level in both of the study groups.

Dhanani et al.[3] noted that there was statistically substantial improvement in the hematological indices like Hb, Hematocrit, MCV, MCH, Serum

reticulocyte and serum ferritin in both of the studied groups.

The ISCA's adverse effects are its biggest flaw. Iron sorbitol cannot be administered as an intravenous bolus or infusion due to its very low molecular weight and high transferrin saturation capacity. Consequently, it is only used intramuscularly. However, Pain at the injection site, especially with IM injection of Iron sorbitol citric acid (ISCA), was the most prevalent complaint in the trial Nanthini et al.[10]. Other adverse effects including swelling and skin darkening were also recorded in the ISCA group. Because of the high dropout rate (8%) in this trial, all these ISCA adverse effects may be the primary cause of lower compliance. This is comparable to study done by Dhanani et al.[3].

Gaikwad et al.[7] reported that the most frequent negative effects seen in the intramuscular treatment group were localized discomfort and skin discoloration (10-14 percent). Other mild adverse effects that were seen in 2–5% of instances in the intramuscular group were fever, arthralgia, epigastric discomfort, and headache. In the intravenous group, 3-5% of individuals had shivering and phlebitis, although these symptoms did not need treatment to be stopped. Only 1% to 2% of people had other mild side effects, such as nausea and a metallic taste.

Singh et al.[12] reported that regarding the negative effects of the therapy, there was a statistically substantial variation between the two study groups.

Furthermore, Dhanani et al.[3] showed that only two of the total 33 adverse events occurred in the iron sucrose group, where a pregnant lady complained of heat and swelling at the infusion site. However, the iron sucrose group did not experience any additional negative effects.

CONCLUSION

We concluded that for treating mild anemia in pregnancy, intravenous iron sucrose treatment was shown to be both substantially more efficient and safer than intramuscular iron sorbitol citrate therapy.

Conflict of interest : none

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