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Heme Iron Polypeptide (Proferrin®-ES) Versus Iron Saccharate Complex (Ferrosac) for Treatment of Iron Deficiency Anemia during Pregnancy

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ABSTRACT

Objectives: Anemia is one of the world's leading causes of considerable perinatal morbidity and mortality. This study designed to compare the efficacy and safety of Heme iron polypeptide (Proferrin®-ES) versus iron saccharate complex (Ferrosac) in treatment of iron deficiency anemia during pregnancy. **Methods:** Two hundred and sixty (260) pregnant women with hemoglobin level below 10 gm/dl due to iron deficiency anemia were included in this study and randomized to receive either; intravenous Iron Saccharate (IV group) or oral Proferrin®-ES (PO group) for correction of iron deficiency anemia during pregnancy. Treatment efficacy checked by comparing pre-treatment values of hemoglobin, serum ferritin, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and reticulocytes count by the 3-months' post-treatment values. **Results:** The 3- months' post-treatment hemoglobin level increased compared to the pre-treatment level without any significant difference between the two studied groups (from 8.5 ± 3.5 to 11.3 ± 1.3 gm/dl in PO group and from 8.7 ± 2.5 to 11.7 ± 0.9 gm/dl in IV group). In addition; the 3-months' post-treatment ferritin level, increased compared to the pre-treatment level without any significant difference between the two studied groups (from 19.4 ± 4.9 to 118.8 ± 7.1 ug/l in PO group and from 15.3 ± 5.6 to 122.3 ± 6.4 ug/l in IV group). 1.6% (2/124) of the studied women developed gastrointestinal intolerance and upset with oral Proferrin®-ES (insignificant difference and excluded from the study) and no other side effects recorded with oral Proferrin®-ES. **Conclusion:** HIP (Proferrin®-ES) is an effective, safe, well tolerable oral iron preparation as well as intravenous iron saccharate complex for treatment of iron deficiency during pregnancy; it increases the hemoglobin and replaces the depleted iron store.

Key words: HIP, Proferrin®-ES, Iron Saccharate, Anemia, Pregnancy.

INTRODUCTION

The World Health Organization defined hemoglobin below 11 gm/dl as anemia. Anemia is a public health problem and a direct cause of disability.¹

Fifty-two percent (52%) of pregnant women in developing countries suffering from anemia compared to 23% in developed countries.¹

Causes of anemia include; iron deficiencies, poor nutrition, malabsorption, hook-worm infestation, schistosomiasis, human immune deficiency (HIV) and hemoglobinopathies.^{1,2}

There is a high demand for iron during pregnancy (average 600 mg) and on top of

the demands of pregnancy is the inevitable blood loss during deliveries.^{3,4}

A blood loss of ≥1 Liter occurs in 7% of vaginal deliveries. But 23% of cesarean deliveries are associated with 1000-1500 ml blood loss.^{3,4}

Maternal anemia is an important cause of perinatal morbidity, adverse outcome in obstetrics, blood transfusion and maternal mortality.⁵⁻⁸

Nissenon *et al*, found that 6 months after evaluation of HIP (Proferrin®-ES) in hemodialysis patients who had been on maintenance intravenous iron therapy, the intravenous iron was discontinued, and replaced with oral HIP.⁹

This study was designed to compare the efficacy and safety of oral Heme iron polypeptide (Proferrin[®]-ES) versus intravenous iron saccharate complex (Ferrosac) in treatment of iron deficiency anemia during pregnancy.

MATERIALS AND METHODS

This randomized comparative multicenter study conducted over 9 months from March to November 2016 in three private hospitals in Kuwait (Royal Hayat, Al Seef and Hadi), after approval of the study by the hospitals ethical committee. Two hundred and sixty (260) pregnant women with hemoglobin level below 10 gm/dl due to iron deficiency anemia were included in this study and randomized to receive either; intravenous iron saccharate (IV group) or oral Proferrin[®]-ES (PO group) for correction of iron deficiency anemia during pregnancy after informed consent.

Treatment efficacy checked by comparing pre-treatment values of hemoglobin, serum ferritin, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and reticulocytes count by the 3-months' post-treatment values.

Inclusion criteria includes; pregnant women >18 years, 24-30 weeks' gestation with hemoglobin level between 8-10 gm/dl.

Pregnant women with anemia due to causes other than iron deficiency and pregnant women received blood transfusion during current pregnancy excluded from this study.

Six (6) women in the oral group (travelling (3), intolerance to oral iron (2) and incomplete ante-natal follow up (1)) and four (4) women in the intravenous group (travelling (2) and preterm labor (2)) excluded from this study and the study completed with two hundred fifty (250) women; 124 women in Oral group (PO group) and 126 in Intravenous group (IV group).

Diagnosis of iron deficiency anemia confirmed by hemoglobin concentration (gm/dl), serum ferritin (ug/l), mean Corpuscular Volume (MCV) and mean corpuscular hemoglobin (MCH).⁶⁻⁸

Heme Iron Polypeptide (Proferrin[®]-ES), (Nexgen Pharma Inc, Coloeado, USA) derived from bovine hemoglobin and it has unique carrier intestinal receptors Heme Carrier Protein-1 (HCP-1). HIP peptides and amino acids content of the Proferrin[®]-ES tablets cleaved during processing to increase the concentration of the bioavailable form and to enhance the solubility of HIP at wide range of PH (<3 to >6).

According to the manufacturer instructions, the HIP (Proferrin[®]-ES) tablets given to the studied women twice daily (1 tablet morning and 1 tablet evening) not related to meals till hemoglobin level of 11-12 gms/dl, then the studied women asked to continue one tablet of Proferrin[®]-ES daily as maintenance therapy.⁹

After oral intake, Proferrin[®]-ES tablets, the iron content of the tablets absorbed by the HCP-1 receptors of the small intestine and the serum peak of iron reached within 2-4 hours. Each tablet of Proferrin[®]-ES contains 11 mg of HIP and it increases the serum iron level by 3.15 mg.⁹

The intravenous iron dose calculated according to the formula; total iron needed in mg = 2.4 × pre-pregnancy weight in kg × (target hemoglobin concentration - actual hemoglobin concentration) gm/dl + 500 mg. Twelve (12) gm/dl was the target hemoglobin concentration and 2.4 is a correction factor, while the 500 is the amount of stored iron in adult pregnant women.^{4,5}

The calculated total intravenous iron dose was given over 6-8 sessions, in each session 200 mg of Iron Saccharate Complex (Spimaco, Al-Qassim Pharma, Saudi Arabia) diluted in normal saline, given by an intravenous infusion over one hour every other day and the patients were monitored during the first 15 minutes for signs of intolerance, hypotension, tachycardia or anaphylaxis.⁶

Iron sucrose (Iron Saccharate Complex) is stable, cleared from serum within 5-6 hours and used immediately for erythropoiesis.¹⁰

The two studied groups asked during each ante-natal care visit for any side effects related to given iron preparations as; hypotension, tachycardia, arthralgia, abdominal or chest pain, headache, vertigo and skin eruptions with intravenous iron and gastrointestinal upset, metallic taste, constipation and/or intolerance with oral iron preparation.

Oral folic acid given to the studied women to avoid folic deficiency and treatment efficacy checked by comparing pre-treatment values of hemoglobin, serum ferritin, MCV, MCH and reticulocytes count by the 3-months' post-treatment values.^{10,11}

Sample Size And Statistical Analysis

G* Power software used for calculation of the studied sample size, statistical analysis done using statistical package for social sciences (SPSS) version 20 (Chicago, IL, USA) and the Student's t-test used for quantitative data analysis. The significance level set as $p < 0.05$.

RESULTS

Two hundred and sixty (260) pregnant women with hemoglobin level below 10 gm/dl due to iron deficiency anemia were included in this multicenter study and randomized to receive either; intravenous iron saccharate (IV group) or oral Proferrin[®]-ES (PO group) for correction of iron deficiency anemia during pregnancy after informed consent. Six (6) women in the oral group and four (4) women in the intravenous group excluded from this study and the study completed with two hundred fifty (250) women; 124 women in

the oral group (PO group) and 126 in the intravenous group (IV group). Figure 1

The two studied groups were matched with no significant difference regarding; the mean age (25.3 ± 4.5 in PO group versus 24.8 ± 4.3 years in the IV group), mean parity (3.2 ± 3.1 in PO group versus 3.8 ± 2.1 in IV group) and the mean weight (70.8 ± 6.9 in PO group versus 72.1 ± 7.8 Kg in IV group). In addition; there was no significant difference between the two studied groups regarding; the mean gestational age (25.2 ± 3.4 in PO groups versus 24.6 ± 2.7 weeks' gestation in IV group) and the mean pre-treatment hemoglobin (8.5 ± 3.5 in PO group versus 8.7 ± 2.5 gm/dl in IV group). Table 1

The 3-month' post-treatment hemoglobin level increased compared to the pre-treatment level without any significant difference between the two studied groups (from 8.5 ± 3.5 to 11.3 ± 1.3 gm/dl in PO group and from 8.7 ± 2.5 to 11.7 ± 0.9 gm/dl in IV group), ($p > 0.05$).

The 3-months' post-treatment ferritin level also, increased compared to the pre-treatment level without any significant difference between the two studied groups (from 19.4 ± 4.9 to 118.8 ± 7.1 ug/l in PO group and from 15.3 ± 5.6 to 122.3 ± 6.4 ug/l in IV group), ($p > 0.05$).

The 3-months' post-treatment MCV increased compared to the pre-treatment MCV without any significant difference between the two studied groups (from 71.9 ± 7.6 to 91.5 ± 7.2 FL in PO group and from 73.8 ± 8.2 to 92.0 ± 6.6 FL in IV group), ($p > 0.05$). In addition; the 3-months' post-treatment MCH increased compared to the pre-treatment MCH without any significant difference between the two studied groups (from 24.2 ± 4.2 to 25.6 ± 3.3 pg in PO group and from 23.9 ± 3.7 to 25.8 ± 2.6 pg in IV group), ($p > 0.05$).

While, the 3-months' post-treatment reticulocytes count decreased compared to the pre-treatment count without any significant difference between the two studied groups (from 3.7 ± 5.3 to 0.9 ± 1.3 $10^6/\text{mm}^3$ in PO group and from 3.9 ± 4.8 to 1.2 ± 0.9 $10^6/\text{mm}^3$ in IV group), ($p > 0.05$). Table 1

The adverse reaction reported by women received IV iron was an unpleasant metallic taste during injection, no other serious or major side effects were recorded with intravenous iron. 1.6% (2/124) of the studied women developed gastrointestinal intolerance and upset with oral Proferrin[®]-ES (insignificant difference and excluded from the study) and no other side effects recorded with oral Proferrin[®]-ES.

DISCUSSION

The inevitable blood loss during deliveries aggravates maternal anemia and increases the risk of blood transfusion.^{3,4,7,8}

Two hundred and sixty (260) pregnant women with hemoglobin level below 10 gm/dl due to iron deficiency anemia were included in this multicenter study and randomized to receive either; intravenous iron saccharate (IV group) or oral

Proferrin[®]-ES (PO group) for correction of iron deficiency anemia during pregnancy.

Six (6) women in the oral group and four (4) women in the intravenous group excluded from this study and the study completed with two hundred fifty (250) women; 124 women in PO group and 126 in IV group.

In this study; the 3-month' post-treatment hemoglobin and ferritin levels increased compared to the pre-treatment level without any significant difference between the two studied groups.

Al Momen et al, found that the intravenous iron sucrose complex group achieved significantly higher hemoglobin levels 12.85 ± 6.6 versus 11.14 ± 12.4 gm/dl in the oral iron group and they concluded that iron sucrose was a safe and effective alternative in treatment of iron deficiency anemia during pregnancy.¹²

In this study; the adverse reaction reported by women received IV iron was an unpleasant metallic taste during injection, no other serious or major side effects were recorded with intravenous iron. 1.6% (2/124) of the studied women developed gastrointestinal intolerance and upset with oral Proferrin[®]-ES (insignificant difference and excluded from the study) and no other side effects recorded with oral Proferrin[®]-ES.

Abhilashini et al, found that gastrointestinal side effects were not seen in women on intravenous iron therapy and 44% of patients in oral iron group had gastrointestinal side effects.¹³

In addition; *Shafi et al*, concluded that the hemoglobin level elevated and iron stores restored rapidly when women with iron deficiency anemia during pregnancy treated parenterally with iron sucrose compared to oral ferrous ascorbate.¹⁴

Al RA et al, found that the change in hemoglobin from baseline was significantly higher in intravenous group than oral group on day 14th and 28th after treatment and the serum ferritin levels were significantly higher in intravenous group compared to oral group at the fourth week of treatment and at birth.¹⁵

In this study; the increase in the 3-month' post-treatment hemoglobin and ferritin levels were statistically insignificant between the PO group and IV group. In addition; *Bayoumeu et al*, found that the hemoglobin increased from 9.6 ± 0.79 to 11.11 ± 1.3 gm/dl in intravenous group and from 9.7 ± 0.5 to 11 ± 1.25 gm/dl in oral group 30 days after treatment without any significant difference between the two studied groups.¹⁶

In addition; *Mishra et al*, concluded that parenteral iron therapy in iron deficiency anemia is only recommended in patients where oral iron therapy is ineffective due to mal-absorption states and noncompliance.¹⁷

Although, *Barraclough et al*, concluded that HIP (Proferrin[®]-ES) showed no clear safety or efficacy in peritoneal dialysis patients compared with conventional oral iron supplements.^{18, 19}

Table 1: Demographic data of the two studied groups, pre-treatment and 3-months' post-treatment values

Variables	PO group (n = 124)	IV group (n = 126)	P value, Significance (95% CI)
Age (years)	25.3 ± 4.5	24.8 ± 4.3	0.6* (-1.5, -0.5, 0.6)
Weight (Kg)	70.8 ± 6.9	72.1 ± 7.8	0.08* (-0.5, 1.3, 3.1)
Parity	3.2 ± 3.1	3.8 ± 2.1	0.9* (-0.05, 0.6, 1.3)
Gestational age (weeks)	25.2 ± 3.4	24.6 ± 2.7	0.9* (-1.36, -0.6, 0.2)
Pre-treatment hemoglobin (gm/dl)	8.5 ± 3.5	8.7 ± 2.5	0.9* (-0.5, 0.2, 0.9)
3-months' post-treatment hemoglobin (gm/dl)	11.3 ± 1.3	11.7 ± 0.9	0.9* (0.12, 0.4, 0.7)
Pre-treatment reticulocytes (10 ⁶ /mm ³)	3.7 ± 5.3	3.9 ± 4.8	0.8* (-1.05, 0.2, 1.5)
3 -months' post treatment reticulocytes (10 ⁶ /mm ³)	0.9 ± 1.3	1.2 ± 0.9	0.9* (0.02, 0.3, 0.6)
Pre-treatment ferritin (ug/l)	19.4 ± 4.9	15.3 ± 5.6	0.06* (-5.4, -4.1, -2.8)
3-months' post treatment ferritin (ug/l)	118.8 ± 7.1	122.3 ± 6.4	0.8* (1.8, 3.5, 5.2)
Pre-treatment MCV (FL)	71.9 ± 7.6	73.8 ± 8.2	0.1* (-0.05, 1.9, 3.9)
3-months' post treatment MCV (FL)	91.5 ± 7.2	92.0 ± 6.6	0.8* (-1.2, 0.5, 2.2)
Pre-treatment MCH (pg)	24.2 ± 4.2	23.9 ± 3.7	0.9* (-1.3, 0.3, 0.7)
3-months' post treatment MCH (pg)	25.6 ± 3.3	25.8 ± 2.6	0.9* (-0.13, 0.6, 1.3)

*= non-significant difference. CI = Confidence interval. Data presented as mean and ±SD. MCH = Mean corpuscular hemoglobin. MCV = Mean corpuscular volume. RBCS = Red blood cells. Student's t-test used for statistical analysis.

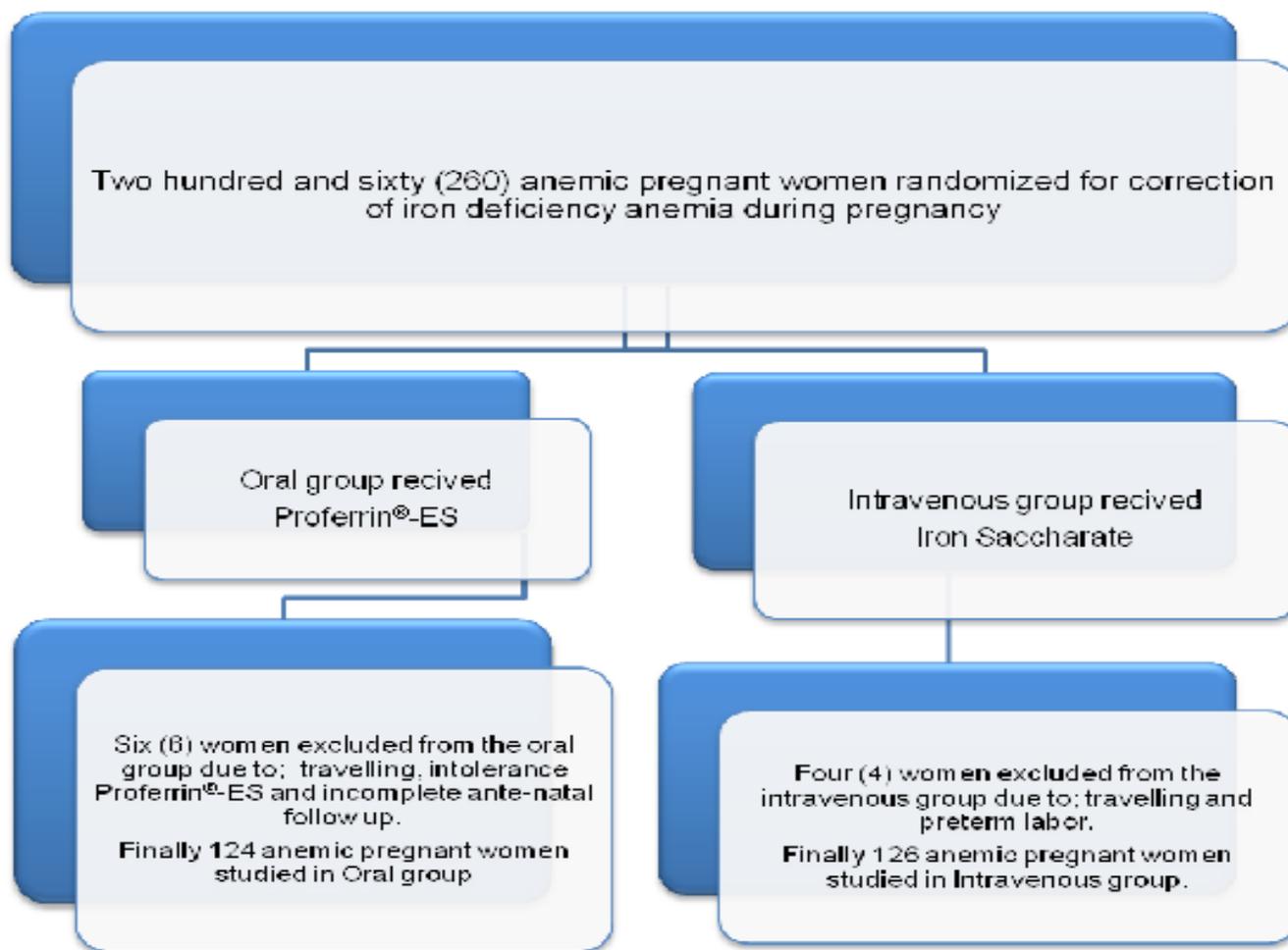


Figure 1: The study design and the number of the studied women in each group.

Nissenson *et al.*, found that 6 months after evaluation of HIP (Proferrin[®]-ES) in hemodialysis patients who had been on maintenance intravenous iron therapy, the intravenous iron was discontinued, and replaced with oral HIP.⁹

Gastrointestinal side effects are very common problem with oral iron preparations. Al Momen *et al.*, in their study compared 52 women treated with intravenous iron sucrose and 59 women treated with 300 mg oral iron sulfate, found that 18 (30 %) of the oral iron group complained of disturbing gastrointestinal symptoms and 18 (30 %) had poor compliance.¹²

While, in this study; 1.6% (2/124) of the studied women developed gastrointestinal intolerance and upset with oral Proferrin[®]-ES (insignificant difference and excluded from the study) and no other side effects recorded with oral Proferrin[®]-ES.

To the best our Knowledge, the current study was the first study designed and conducted to evaluate the efficacy and tolerability of heme iron polypeptide (HIP) compared to iron saccharate complex in treatment of iron deficiency anemia during pregnancy.

The limited data and studies about HIP (Proferrin[®]-ES) was the only limitation faced during conduction of this study. More comparative studies needed to compare the efficacy of HIP (Proferrin[®]-ES) in treatment of iron deficiency anemia during pregnancy with the available oral or intravenous iron preparations.

CONCLUSION

HIP (Proferrin[®]-ES) is an effective, safe, well tolerable oral iron preparation as well as intravenous iron saccharate complex for treatment of iron deficiency during pregnancy; it increases the hemoglobin, and replaces the depleted iron store.

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CONFLICT OF INTEREST

Authors declare no conflict of interest related to this study.

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