Abstract

Background: Iron deficiency anemia is the most common and important public health problem all over the world in the risk group of antenatal women. Research is going on to improve the iron status of the pregnant women with different forms of iron available. In this regard Carbonyl Iron is showing promising result in improving the red cell mass with better compliance.

Objective: The purpose of present study was to compare the efficacy of Ferrous Sulfate and Carbonyl Iron in the blood film of iron deficiency anemia in pregnant women.

Methodology: An observational prospective study in obstetric and gynec out – patient department of Sir Salimullah Medical College and Mitford Hospital. Women between 16 – 28 weeks of pregnancy with haemoglobin level 7 – 10 gm/dl and with microcytic hypochromic blood film were included in this study. Pregnant women in 1st and 3rd trimester of pregnancy were excluded from the study. Among the study population one group was given tablet Ferrous Sulfate and another group was given capsule Carbonyl Iron.

Results: At the end of study (after 12 weeks) MCV, MCH, MCHC level were more increased incase of Carbonyl Iron group than Ferrous Sulfate group which is statistically significant.

Conclusion: Carbonyl Iron is more effective than Ferrous Sulfate in the treatment of iron deficiency anemia in pregnancy.
during pregnancy, especially in the third trimester. A pregnant woman needs six times more iron than a nonpregnant woman. Increased iron requirements to supply the expanding blood volume of the mother and the rapidly growing fetus and placenta can cause Iron Deficiency Anemia (Pyarelal 2015).

Maternal Iron Deficiency Anemia early in pregnancy can result in low birth weight subsequent to preterm delivery as well as association exists between maternal anemia and lower infant apgar score. Therefore, iron supplementation is mandatory to improve or maintain the iron status of the mother during pregnancy. (Pyarelal 2015).

The increased need of iron during pregnancy makes the iron supplementation mandatory. All most all cases of iron deficiency anemia respond readily to treatment with iron supplementation. The most common iron salt used for oral administration is Ferrous Sulfate. But it is known to produce gastrointestinal side effects like nausea, constipation, black stool, metallic taste, vomiting, diarrhea and abdominal pain etc.

Among the possible alternatives to control iron deficiency Carbonyl Iron is now being prescribed for the patients with iron deficiency anemia Carbonyl iron is highly purified small metallic iron particle. It describes the process of manufacture of the iron particles, not their composition. Heating gaseous iron pentacarbonyl [Fe(CO)5], deposits metallic iron as submicroscopic crystals that forms spheres of less than 5μ in diameter. Solubilization of Carbonyl Iron particles acidity of stomach is a pre requisite for absorption of Carbonyl Iron supplement. The slow rate of solubilization leads to more prolonged absorption for low toxicity.

A mild deficiency should not affect baby while pregnancy. But if mild iron deficiency anemia goes untreated and becomes more severe during pregnancy is linked to an increased risk of a baby being born with a low birth weight. Having severe iron deficiency anemia may even increase the risk of still birth and newborn death. It is responsible directly or indirectly for 40% - 60% of maternal deaths from cardiac failure, hemorrhage, infection and preeclampsia (Singhal et al. 2015).

The present study is performed to find out the efficacy of Ferrous Sulfate and Carbonyl Iron, in the blood film of iron deficiency anemia in pregnant women.

Methodology

Study Design and Place: This observational prospective study was conducted in the department of pharmacology and therapeutics in Sir Salimullah Medical College, Dhaka with the study period from July 2016 – June 2017.

Study Population: All pregnant women with Iron deficiency anemia attending the obstetric and gynaec outpatient department of Sir Salimullah Medical College and Mitford Hospital those were prescribed Ferrous Sulfate and Carbonyl Iron were included in the study population. They were selected on the basis of inclusion and exclusion criteria. Women between 16 – 28 weeks of pregnancy with haemoglobin level of 7 – 10 gm/dl and with microcytic hypochromic blood film were included in the study while pregnant women in 1st and 3rd trimesters of pregnancy were excluded from the study.

Study Procedure: An observational prospective study was conducted in a tertiary care hospital in Bangladesh. New patient according to the selection criteria attending the outpatient department of obstetrics and gynaec in Sir Salimullah Medical College and Mitford Hospital during the study period were considered for analysis. After proper counseling, the aim, objectives, risk and the procedure of the study were explained in details to the subjects. Only positive respondent was recruited as study subjects and were allowed to withdraw themselves from the study even after participation. Informed consent was obtained from all participants. The study subjects were divided in two groups, Group A taking tablet Ferrous Sulfate (150 mg twice or thrice daily) and Group B taking capsule Carbonyl Iron (50 mg twice or thrice daily). MCV, MCH, MCHC were observed on the day of enrollment and at 12th week. Tablet Ferrous Sulfate was given three times daily for the patient whose haemoglobin level was between 7.0 – 8.0 gm/dl and two times daily for the patient whose haemoglobin level was between 8.1 – 10 g/dl. Capsule Carbonyl Iron was given three times daily for the patient whose haemoglobin level was between 7.0 – 8.0 gm/dl and two times daily for the patient whose haemoglobin level was between 8.1 – 10 gm/dl.

Statistical Analysis: All the findings were recorded, compiled, tabulated and analyzed. The data was expressed as mean ± SD for windows version 21. Unpaired ‘t’ tests, paired ‘t’ tests, Chi-Square tests were done as the test of significance and p value <0.05 was significantly considered as significant. Statistical analysis was done by using Statistical Package of Social Service (SPSS). The summarized data were presented in the form of tables.

Results:

The research work was conducted in the Department of Pharmacology and Therapeutics, Sir Salimullah Medical College using a prospective observational study design.
A total of 160 study subjects were enrolled from Sir Salimullah Medical College and Mitford Hospital and followed up at 12th week of therapy. Group A comprised of 80 patients who received Ferrous Sulfate and Group B comprised of 80 patients who received Carbonyl Iron. MCV, MCH and MCHC level were calculate before therapy and after the completion of 12th weeks therapy. At the end of the study, after 12th week the MCV value with Carbonyl Iron was 72.28 ± 2.28 while the MCV value with Ferrous Sulfate was 71.06 ± 2.62, the MCH value with Carbonyl Iron group was 25.13 ± 2.68 and MCH value with Ferrous Sulfate group was 23.69 ± 2.84, MCHC value with Carbonyl Iron group was 30.89 ± 2.86 while the MCHC value with Ferrous Sulfate group was 29.36 ± 3.38.

Table-I

| MCV, MCH and MCHC level of the study subjects at baseline and after treatment at different follow ups in both groups (n = 160) |
|---|---|---|
| Group | Day 0 | Week 12 | p-value |
|      | Mean ± SD | Mean ± SD |      |
| MCV  | FS 69.66 ± 2.77 | 71.06 ± 2.62 | 0.001** |
|      | Cl 69.41 ± 2.92 | 72.28 ± 2.28 | <0.001*** |
| MCH  | FS 22.63 ± 2.87 | 23.69 ± 2.84 | 0.001** |
|      | Cl 22.06 ± 2.88 | 25.13 ± 2.68 | <0.001*** |
| MCHC | FS 27.91 ± 3.74 | 29.36 ± 3.38 | 0.001** |
|      | Cl 27.44 ± 3.60 | 30.89 ± 2.86 | <0.001*** |

Paired t test was done to measure the level of significance. P value < 0.05 was accepted as level of significance. ns = non-significant; ** = significant

Table I showed that at the end of the study (after 12 weeks) MCV, MCH, MCHC level were more significantly increased in case of Carbonyl Iron group than Ferrous Sulfate Group.

Discussion

As we know iron deficiency anemia is very common worldwide. A recent estimate based on WHO criteria indicated that around 600 – 700 million people world wide have marked Iron deficiency anemia (IDA) and the bulk of these people live in developing countries like Bangladesh. Pregnancy with anemia has a significant impact on the health of fetus as well as that of the mother. The treatment of Iron deficiency anemia (IDA) is given to replenish Hb and restore iron stores by supplying sufficient iron.

Routine iron supplementation with iron salts shows low efficacy for the control of Iron deficiency anemia (IDA) due to poor compliance with the treatment, because of its disagreeable flavor and adverse effects. Among the possible alternatives to control iron deficiency Carbonyl iron is formulated in such a way that it has remarkably low toxicity when compared with ionized form of iron such as Ferrous Sulfate.

The present study compared the therapeutic efficacy and tolerability of Ferrous Sulfate and Carbonyl iron. 160 patients were enrolled for the study and followed up at 2nd, 4th, 8th, and 12th week of therapy. Group A comprised of 80 patients, who received Ferrous Sulfate and Group B comprised of 80 patients, who received Carbonyl iron.

MCV, MCH, MCHC were observed on the day of enrollment and after 12th weeks of therapy. At the end of the study MCV, MCH, MCHC level were more significantly increased in case of Carbonyl Iron group than Ferrous Sulfate group. Similar result was reported by Gordeuk VR et al.

Conclusion

The study shows that individual efficacy of both compounds was good and they were effective in the treatment of iron deficiency anemia in pregnancy. Efficacy of Carbonyl Iron was higher than Ferrous Sulfate. The result of the present study suggest that Carbonyl Iron can be considered as a useful alternative formulation for the treatment of iron deficiency anemia in patients due to its better efficacy.

References


