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Original Research Paper

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A COMPARATIVE STUDY ON ORAL IRON AND INTRAVENOUS FORM OF IRON(FCM) IN TREATMENT OF MODERATE ANEMIA DURING POSTPARTRUM PERIOD.

Dr. Surayya Tahseen*

Assistant Professor, Department of Obstetrics & Gynecology, Deccan College of Medical Sciences, Owaisi Hospital & Research Centre, Hyderabad, Telangana. *Corresponding Author

Dr. Amtul Asra

Post Graduate Student MS, Department Of Obstetrics & Gynecology, Deccan College Of Medical Sciences, Owaisi Hospital & Research Centre, Hyderabad, Telangana.

ABSTRACT

Background: Anemia is a major public health problem worldwide. The global prevalence of anemia during pregnancy is estimated by World Health Organization to be 47.4%. According to recent WHO figures, India is included in the list of countries with high prevalence of anemia in pregnant women (>40%). Prevalence of postpartum Iron Deficiency Anemia is very high in the India, The maternal mortality rates are also significant. Postpartum anemia is observed in up to 27% of women. It is a major contributing factor and indirect cause of maternal death.

Materials And Methods: This comparative study was conducted in the department of Obstetrics and Gynaecology, over a period of 18 months after obtaining clearance from Institutional Review Board. Total 100 postnatal women with microcytic hypochromic anemia attending the department will be included in the study .Cases were randomly distributed into two groups consisting of 50 cases each.

Results: Among the study population, in group with iron supplementation, 24% had hemoglobin levels between 7.1-7.9 gm%, 22% had hemoglobin levels between 8.0-8.9 gm% and 24% had hemoglobin levels between 9.0-9.9 gm%. The improvement was seen in around 30% of the patients with 14% between 10-10.9 gm% and 16% above 11 gm%. Overall improvement was seen in 30% of the patients.

Conclusions: There was significant improvement in the hemoglobin status among both the group. Among the oral iron group, 30% of them improved their status to either mild anemia or normal status. Amog the FCM group, it was 66%.Treatment oral iron or FCM markedly raised the blood hemoglobin levels but FCM was superior to oral iron

KEYWORDS :

INTRODUCTION

Anemia is a major public health problem worldwide. The global prevalence of anemia during pregnancy is estimated by World Health Organization to be 47.4%.[1] According to recent WHO figures, India is included in the list of countries with high prevalence of anemia in pregnant women (>40%).[1]

The prevalence of anemia among all age groups is high in India. Every second woman is anemic (55%).[2] Iron deficiency starts in childhood, worsens in adolescence and gets aggravated in pregnancy. The WHO defines anemia in pregnant women as hemoglobin level below 11 g/dl.

Prevalence of postpartum Iron Deficiency Anemia is very high in the India, The maternal mortality rates are also significant. Postpartum anemia is observed in up to 27% of women. It is a major contributing factor and indirect cause of maternal death. The importance of prevention and treatment of IDA in postpartum period should be given further thrust in the maternal health programs. Untreated IDA during the postpartum period is a cause of maternal morbidities such as tiredness, lethargy, dizziness, headaches, lactation failure, and postpartum depression.[3-6]

Anemia is a major cause of maternal mortality. Anemia accounts for 20% direct and 20% of indirect maternal deaths.[7] Anemia leads to increased risk of blood transfusion during postpartum period. Iron therapy before delivery may reduce the transfusion rate for iron deficient women.

Need for the Study:

The WHO guideline recommends postpartum prophylactic iron supplementation of 60 mg elemental iron + 400 μg folic for 3 months. Universal iron supplementation was demonstrated to be effective in reducing the prevalence of anemia among low-income postpartum women .

The MoHFW guideline recommends daily iron (100mg elemental iron with 500μg folic acid) for all non-anemic women in postpartum period for 6 months, whereas the same tablet is advised to be taken twice daily for mild to moderately anemic postpartum women .Generally anemia in postpartum represents a dire need for iron supplementation, in such anemic patients parenteral iron supplementation was found to be more effective in treating anemia, as compared to oral iron supplementation.

Anemia during the antenatal period is always stressed upon but the same anemia during post natal period is rarely followed up both by the patients and obstetricians. In the present study, the management of post partum anemia was dealt with special emphasis on Ferro carboxy maltose and iron sucrose as modalities of treatment.

AIM & OBJECTIVES

AIM :

To compare oral iron and intravenous form of iron(FCM) in treatment of moderate anemia during postpartrum period.

OBJECTIVES:

- To identify the postnatal patients with microcytic hypochromic anemia.
- To divide the patients into two groups.
- To compare oral iron and intravenous form of iron(FCM) in treatment of moderate anemia during postpartrum period

MATERIALS AND METHODS

This comparative study was conducted in the department of Obstetrics and Gynaecology, Deccan Medical College, Hyderabad over a period of 18 months after obtaining clearance from Institutional Review Board.

Total 100 postnatal women with microcytic hypochromic anemia attending the department will be included in the study .Cases were randomly distributed into two groups consisting of 50 cases each.

Microcytic hypochromic anemia is diagnosed on basis of peripheral blood film, complete blood count.

Inclusion Criteria

- Postnatal women with Hb between 7.1-9.9 g/dl and with microcytic hypochromic anemia
- Willing for enrolment in study
- Likely to come for follow up
- Age greater than 20 years.

Exclusion Criteria

- Postnatal women with Hb <7g/dl > 10g/dl
- Patient with obstetrical complications and postpartum complications
- Patient with acute and chronic infections
- Patients with thalassemia

In group A 50 women received carbonyl iron 100mg twice daily for 6 weeks. Patients were instructed to take the tablets with empty stomach and not to take coffee or tea after taking tablet. Adverse Drug Reactions of Carbonyl Iron Upto 10% of women may have side effects with oral iron in the form of gastrointestinal symptoms such as nausea, vomiting, constipation, abdominal cramping and diarrhoea which are dose related. Side effects can be minimized by advising to take the tablet with food.

Woman in Group B(patients who don't tolerate oral iron are included) received intravenous ferric carboxymltose (FCM). It is available in formulations of 80mg, 100 mg, 250 mg,500 mg and1000mg.The total iron required was be calculated and administered as single dose in 250ml of 0.9% normal saline over 15 minute. In case if any patients requires more than 1000 mg, the next dose was administered after 1week.

The total dose required will be calculated Based on the formula given below:

Total iron dose required (mg)=2.4 x Bodyweight (in Kg) x (Target Hb- Actual Hb in gm/dl) + 500mg.

The factor 2.4 is derived from the blood volume which is 7% of body weight and iron content of Hb, which is 0.34% (0.07x0.0034x100=2.4mg) (Conversion from gm/dl to mg).

Advantages of FCM over other intravenous forms of Iron:

It does not contain dextran and chances of anaphylaxis are very low. Test dose is not required.

Hemoglobin levels was checked after 6 weeks in both the groups. Rise of Hb will be compared among the groups.

Data Entry and Analysis:

Data will be entered in excel and will be analyzed using EpiInfo 7.1.2.0 version.

Descriptive analysis like frequencies, mean and standard deviation will be performed. The statistical test used for comparing the hemoglobin levels between the two groups will be student t test or Z test.

Variations of P<0.05 were considered to be statistically significant.

OBSERVATIONS AND RESULTS

Total 100 postnatal women with microcytic hypochromic anemia attending the department will be included in the study .Cases were randomly distributed into two groups consisting of 50 cases each.

Table 1 : Age wise distribution of study subjects:

Age (In years)	Number	Percent
<20	7	7
20-30	85	85
>30	7	7.
Total	100	100

Mean age (in years) = 25.1972, Standard deviation (SD) ± 3.976

Out of the total 100 respondents, majority 85% of them belonged to the age group of 20-30 years. The mean age was 25.1972 years with standard deviation (SD) ± 3.976 years.

Table 2: Parity of the study subjects:

Parity	Number	Percent
Primi	43	46
Multi	54	54
Total	100	100

With regards to status of parity of the respondents, majority 54% were multiparous, followed by 46% were primi.

Table 3 showing the hemoglobin status of study population at baseline:

Hemoglobin values	With oral Iron (n=50)	Percentage	With FCM (n=50)	Percentage
7.1-7.9	18	36	17	34
8.0-8.9	16	32	18	36
9.0-9.9	16	32	15	30
Total	50	100	50	100

Among the study population, in group with iron supplementation, 36% had hemoglobin levels between 7.1-7.9 gm%, 32% had hemoglobin levels between 8.0-8.9 gm% and 9.0-9.9 gm%.

In FCM group, 34% had hemoglobin levels between 7.1-7.9 gm%, 36% had hemoglobin levels between 8.0-8.9 gm% and 30% had hemoglobin between 9.0-9.9 gm%.

Table 4 showing the mean values in both the groups at base line:

Parameter	With oral Iron (n=50)	With FCM (n=50)	T test	P value
Age in years	24.45 ±7.5	23.46 ±6.85	0.68	0.16
Mean hemoglobin values gm%	7.8 ± 0.8	7.9 ±0.9	-0.58	0.5

Among the study population, the mean ages and mean hemoglobin levels in both the groups was comparable at the baseline without any statistical significance.

Table 5 showing the hemoglobin status of study population after intervention:

Hemoglobin values	With oral Iron (n=50)	Percentage	With FCM (n=50)	Percentage
7.1-7.9	12	24	0	0
8.0-8.9	11	22	0	0
9.0-9.9	12	24	17	34
10-10.9	7	14	18	36
>11	8	16	15	30
Total	50	100	50	100

Among the study population, in group with iron supp lementation, 24% had hemoglobin levels between 7.1-7.9 gm%, 22% had hemoglobin levels between 8.0-8.9 gm% and 24% had hemoglobin levels between 9.0-9.9 gm%. The improvement was seen in around 30% of the patients with 14% between 10-10.9 gm% and 16% above 11 gm%. Overall improvement was seen in 30% of the patients.

In FCM group, 34% had hemoglobin between 9.0-9.9 gm%. The improvement was seen in around 66% of the patients with 36% between 10-10.9 gm% and 30% above 11 gm%. Overall improvement was seen in 66% of the patients.

Table 6 showing the mean values in both the groups after intervention:

Parameter	With oral Iron (n=50)	With FCM (n=50)	T test value	P value

Mean hemoglobin values gm% before intervention	7.8 ± 0.8	7.9 ±0.9	-0.58	0.5
Mean hemoglobin values gm% after intervention	9.2 ± 1.86	10.9 ±2.4	-3.9	0.0001
Paired T test value	4.88	8.27	--	--
P values	0.000006	<0.0000001	--	--

Among the study population, the difference between the individual means within the group, before and after the intervention was statistically significant. The same phenomena was observed in both the groups. Treatment oral iron or FCM markedly raised the blood hemoglobin levels but FCM was superior to oral iron.

Table 7 showing the comparison of means before and after the intervention:

Parameter	With oral Iron (n=50)	With FCM (n=50)	T test	P value
After intervention	9.2 ± 1.86	10.9 ±2.4	-3.9	0.0001

Among the study population , the mean hemoglobin after intervention with oral iron was 9.2 ± 1.86gm%, with FCM was 10.9 ±2.4 gm%. The difference between the two means was statistically significant with P value of 0.0001.

CONCLUSION

- With an aim of the study to compare oral iron and intravenous form of iron(FCM) in treatment of moderate anemia during postpartum period.
- Complications due to anemia in postpartum women are increased incidence of puerperal infection, sub involution of uterus, lactation failure, poor wound healing, etc. Postpartum women with iron deficiency anemia are also at risk of adverse effects requiring medical interventions such as red blood transfusion, cardiovascular problems, reduced physical and cognitive performance, reduced immune function, tiredness and increased depressive episodes.
- Parenteral iron therapy promises a better response in these patients and can obviate the need for blood transfusions in the antenatal and postpartum period & also helpful in patients with intolerance of or non-adherence to oral iron and malabsorption states. Parenteral iron therapy is more compliant, efficacious, have better tolerance & causes rapid replenishment of iron stores.
- FCM is a safe intravenous agent in pregnancy with multiple advantages, such as large dose administration per sitting, early rise in hemoglobin level, lesser total number of required doses (convenient dosing), hence lesser number of hospital visits and total cost involved in transportation, equipment required for infusion and the discomfort caused to the patient due to multiple needle pricks.
- The rapid delivery option of a large single dose of ferric carboxymaltose is a promising treatment modality for peripartum women who needs correction of iron deficiency and anaemia. Other IV iron formulations that have low dosage limits, such as iron sucrose (200 mg). The disadvantage with ferric carboxymaltose is its high cost in comparison to other parenteral iron preparations, which is well compensated with lesser number of hospital visits and shorter duration of hospital stay.
- There was significant improvement in the hemoglobin status among both the group. Among the oral iron group, 30% of them improved their status to either mild anemia or normal status. Among the FCM group, it was 66%.
- Treatment oral iron or FCM markedly raised the blood hemoglobin levels but FCM was superior to oral iron.

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