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Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON THE MANAGEMENT OF IRON DEFICIENCY ANEMIA DURING PREGNANCY WITH ORAL AND PARENTERAL IRON THERAPY

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ABSTRACT

Purpose: The purpose of the study was to observe the efficacy of oral and parenteral iron therapy in the treatment of iron deficiency anemia during pregnancy. **Method:** The study design was a prospective observational study, the study was carried out at tertiary hospital, Hyderabad. Patients included in the study were classified into two groups based on the therapy prescribed into oral and parenteral groups. The patients were asked to report after four weeks for the estimation of hemoglobin. The patients were followed up to their delivery, and the gestational age at the time of delivery, analysis was carried out to compare non nominal parameter (hemoglobin) between the two groups. **Result:** The results showed between the two groups: In patients who were prescribed with Oral iron therapy 62% of patients out of which 39% patients shows an increase in Hemoglobin levels and 23% patients doesn't show any significant improvement in their hemoglobin levels. In patients who were prescribed with parenteral intravenous iron therapy was 38% out of which 33% patients shows a significant increase in their hemoglobin levels and 5 % patients doesn't show increase in their Hemoglobin levels. **Conclusion:** It was observed that oral iron therapy is particularly effective in management of mild-moderate anemia during pregnancy and as a prophylactic measure, while Parenteral iron therapy is effective in the management of moderate to severe anemia, which shows significant improvement in hemoglobin levels and is better tolerated in anemic pregnant patients.

INTRODUCTION

Anemia is defined as a decrease in hemoglobin concentration in the blood that falls below the lower limit of the normal range for persons of different ages and sexes. Normal hemoglobin in adults is 13.0 g/dL for males and 11.5 g/dL for females. (1)
Hemoglobin is a crucial protein that is present in red blood cells (RBCs). Red blood cells use this protein, which helps store oxygen & to transport oxygen from the lungs to the body. Additionally, it facilitates the transfer of carbon dioxide from your body to your lungs for exhalation. Hemoglobin is a crucial protein that is present in red blood cells (RBCs). Red blood cells use this protein, which helps store oxygen & to transport oxygen from the lungs to the body. Additionally, it facilitates the transfer of carbon dioxide from your body to your lungs for exhalation.The RBCs transport venous blood's CO2 and O2 to and from the lung. The erythrocytic 2,3-diphospho glycerate acid. (2,3-DPG) is necessary for the transportation process. The -chain of Hb has separated when the O2 is unloaded, allowing the entry of the metabolites 2, 3-DPG and lowering the molecule's affinity for O2. O2 saturation is a measure of the percentage of Hb that is oxygenated. When 92% to 100% of the Hb contains oxygen, the tissues are able to give the necessary amount of oxygen, which results in typical O2 dissociation. (2)

Anemia during Pregnancy

Hemodilution of the RBCs occurs in women who are pregnant, when the plasma extends to fulfill the demands of a growing fetus, but the quantity of red platelets does not increase proportionally to the expanding blood volume, resulting in anemia. For pregnant women, mild anemia is defined as Hb 10.0-10.9 g/dL, moderate anemia as Hb 7.0-9.9 g/dL, and severe anemia as Hb 7.0 g/dL, according to the WHO classification system.(3)

IRON DEFICIENCY ANEMIA DURING PREGNANCY

During the prenatal stage, the body creates additional blood to aid in the growth of the fetus. As a result, more iron and

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vitamins are required to make more red platelets. Pregnant ladies require multiple times Pregnant women require three times the amount of iron as the general population, which includes both men and women. As a result, they are more vulnerable to IDA.

This kind of anemia happens when the body doesn't deliver sufficient hemoglobin, preventing the blood from transporting adequate oxygen to all body tissues.

Anemia during pregnancy is defined by the Indian Council of Medical Research as a hemoglobin (Hb) level less than 10.9 g/dl. Hemoglobin levels less than 11.0 g/dL in the first trimester and 10.5 to 11.0 g/dL in the second and third trimesters is considered as anemic.[4]

Epidemiology

Anemia is a severe public health issue that affects approximately 1.6 billion people globally. Anemia has been linked to a higher risk of maternal and newborn mortality. Anemia is projected to impact 56% of reproductive-age women, 59% of pregnant women, 63% of breastfeeding mothers, and 70% of small children in India. Iron deficiency is the major cause of anemia globally; it is believed that iron deficiency accounts for 50% of anemia[5]

According to WHO, the global estimate for pregnant women is at 41.8%. Anemia affects 14% of pregnant women in industrialized nations and 51% in impoverished countries. It is unpleasant to note that India accounts for around 80% of maternal mortality related to anemia in South Asia.[6]

Iron deficiency anemia (IDA) affects 60% of the urban population and 69% of the rural population in India.
Anemia is a late sign of iron deficiency. Between 2005-06 and 2015-16, over half of the pregnant women in India were anemic, however severe anemia decreased from 2.2% to 1.3%. India has pledged to reduce the frequency of anemia in pregnant women from 50% to 32% by 2022.[7]

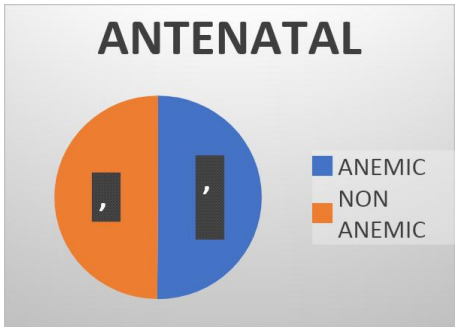

Figure 1 Prevalence of anemia during antenatal period

Pathophysiology

IDA is a form of hypochromic-microcytic anemia in which hemoglobin concentration of red blood cells (RBCs) is abnormally low (hg). IDA occurs when the body requires more iron than it has available. The physiological need for iron rises throughout pregnancy to promote fetal development and maternal pregnancy adaption.

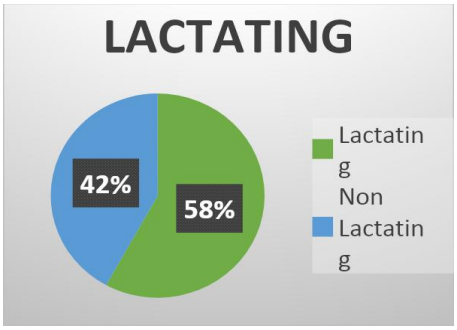

Figure 2 Prevalence of anemia in lactating females

Hepcidin, an iron-regulatory hormone, is a need for the mechanism. In a healthy pregnancy, the second and third trimesters see suppression in the maternal hepcidin concentration, which makes it easier for more iron to enter the bloodstream. Pregnancy appears to sustain hepcidin regulation by the recognized triggers (iron, erythropoietic activity, and inflammation) an inappropriate increase in maternal hepcidin can compromise the iron availability for placental transfer and impair the efficacy of iron supplementation. High levels of hepcidin prevent intestinal absorption of iron and macrophage recycling of iron, resulting in iron-restricted erythropoiesis and anemia.

Inflammatory response: Cytokine production, nitric oxide production, and T-cell proliferation are all regulated by iron in the immune system. Many diseases require iron to survive, therefore acquired IDA may be the body's reaction to one of them.[8]

Iron Metabolism

In pregnancy, the proportion of absorption is raised to 20-30%. The absorption is taken place at the duodenum and proximal jejunum. Absorption is regulated by the mucosal block mechanism-when iron stores are low.

After absorption, the iron circulates in the blood, and transferrin present in the plasma and extravascular serves to transport iron from the site of absorption and storage to its intracellular utilization.

Iron is distributed in the body as under: Hemoglobin: contains most of the body's iron (65%) which is present in the red cells. Myoglobin: about 3.5% of iron is present in the muscles. Haem and Non-Haem enzymes: like cytochrome succinic dehydrogenase, peroxidases, catalase, and flavoproteins constitute about 0.5% a fraction of total body iron. Transferic-Bond Iron circulates in the plasma and constitutes about 0.5% of total body iron.[9] The amount of iron lost per day is 0.5-1 mg which is independent of iron intake.

Treatment

The treatment include iron therapy the primary function of additional iron is the prevention and treatment of iron deficient anemia the routes of iron administration include oral and parenteral ones. Parenteral iron therapy is indicated in pregnancy from the second trimester onwards. The most appropriate parenteral route is the intravenous.[10]

Table 1 Oral Iron Therapy: Recommendation.

Prophylaxis during pregnancy	Treatment during pregnancy	Postpartum

Elemental Iron:60mg daily+Folic acid 500 mcg daily (min 180 days)	Mild to Moderate anemia to Iron in Folic acid Tablets Per day. Severe anemia: Parenteral Iron Very Severe Anemia: Blood Transfusion	Elemental Iron 60 Mg daily+Folic acid 500 mcg for 6 months

Table 2 Common Oral Iron Preparation

Preparation	Total Iron (Mg/Tablet)	Elemental Iron (Mg/Tablets)	% Elemental Iron
Ferrous Sulphate	200	65	32%
Ferrous fumarate	300/150	100,50	33%
Ferrous Gluconate	300	36,15 mg/5ml	12%
Ferrous Ascorbate	730	100	14%
Carbonyl Iron	100	98	98%
Ferric Ammonium Citrate	160	30	18.5%

Parentral Iron Therapy

Intravenous (IV) iron

Oral iron therapy can be switched to IV therapy in some clinical conditions such as a weak or absent response to oral iron, low absorption due to intestinal disease, intolerance of oral iron, lack of compliance, or the need for rapid and adequate treatment (bleeding due to placenta previa, advanced gestational age, etc.) The maximum single dose is 125 mg.[(11)]
Iron sensitivity test for allergy:Intravenous iron preparations can cause severe hypersensitivity reactions, which can be fatal. A test dose is given before the initiation of intravenous iron therapy.

Common Parenteral Iron Preparation

Table 3 Common Parenteral Intravenous Iron Preparations

FORMULATIONS	DOSE	PER ML ELEMENTAL IRON
Ferric carboxy maltose	750 mg	50 mg
Ferric gluconate	125 m	12.5 mg
Ferumoxytol	510 mg	30 mg
Iron sucrose	200-300 mg	20 mg
LMW iron dextrane	1000 mg	50 mg
Iron isomaltoside	1000 mg	100 mg

Additional Supplements

Folic Acid

Pregnant ladies are urged to take folic acid supplementation during their antenatal period, as well as expanding their admission of folate-containing food sources. A portion of 5mg is usually endorsed during pregnancy. Ladies of conceptive age ought to likewise take 400 micrograms (mcg) of folic corrosive.

Vitamin B12

When combination of both the supplements (Vitamin B12 & folic acid) are thought to help prevent anemia, spina bifida, and other birth defects of the spinal cord and central nervous system in unborn children. Vitamin B12 is necessary for sustaining the integrity of the nervous system; the recommended daily amount is 2.6 micrograms (mcg).

Calcium & Vitamin D

Pre-eclampsia, premature delivery, neonatal mortality (NNM), maternal bone mineral content, breast milk concentration, and neonatal bone development can all be decreased or prevented if adequate calcium is consumed throughout pregnancy and lactation.Swallowable tablets providing 500 mg of natural calcium and 250 IU of Vitamin D two times a day.

Non-Pharmacological Treatment

Blood Transfusion: Indications for Blood Transfusion:

- Severe anemia after 36 weeks of pregnancy.
- Anemia is caused by a sudden loss of blood.
- Infections that are associated.
- Patients who are not responding to oral or parenteral medication.
- Pregnant women who are very anemic and symptomatic (Dyspnea, Chances of heart failure).
- Patients in labor with severe anemia (Hb less than 7 gm/dL)[(12)]
- Diet counseling: All mothers should be encouraged to eat iron-rich meals and to avoid processed foods. Meals high in iron and avoiding coffee and tea[(13)]

Treatment of choice for immediate improvement in Hb status in third trimester severe anemia.

Table 4 Indication for Blood Transfusion

Period of gestation	Hemoglobin (gm/dL)	Condition
<36weeks	<5	5-7 with 1 or more co-existing condition.
>36 weeks	<6	6-8 with 1 or more co-existing condition.

MATERIALS AND METHODS

The study design was a prospective observational study, the study was carried out at teritary hospital, Hyderabad. In the department of obstetrics and gynecology for the period of six months .One hundred pregnant women with iron deficiency anemia confirmed by a hemoglobin of 7-10.9g/dl were included in the study age more than 21 years and less than 40 were taken into consideration. Patients included in the study were classified into two groups based on the therapy prescribed into oral and parenteral groups. The patients were asked to report after 4 and weeks for the estimation of hemoglobin and to inquire about the effect. The patients were followed up to their delivery, and the gestational age at the time of delivery. Analysis was carried out to compare non nominal parameters (hemoglobin) between the two groups.

Study Procedure

In order to gain a better knowledge of the disease, eligible patients who were diagnosed with iron deficiency anemia during pregnancy were enrolled in this observational study with their agreement.

We prepared information data collection form to gather information about the disease condition. This form mostly includes the patient's personal information, comorbid conditions, and a list of their current medications.
We used pamphlet to explain the patients about the disease, patient counseling was provided and there was ongoing follow-up.

After the oral and parenteral iron therapy prescribed,patients' hemoglobin was noted during each trimester.All information pertinent to the study was gathered from the time of admission to the date of review follow-up. The data was examined after being entered into a Microsoft Excel sheet, and frequency tables was created using appropriate methods for analysis.

RESULTS

Classification of pregnant females as per their age and their anemic condition

Patients were divided into four groups based on their age and anemia level. These groups are further sub-categorized according to the disease condition into mild, moderate and severe.

- Mild: Hb:10-10.9 mg/dL
- Moderate: Hb:7-9.9 mg/dL
- Severe: Hb:4-6.9 mg/dL

Table 5 Classification of Pregnant Females According To Their Age and Their Anemic Condition

Classification of Pregnant Females According to Their Age And Their Anemic Condition				
Disease severity	Patients Age Group			
	21-25 YEAR	26-30 YEAR	31-35 YEAR	35-40 YEAR
Mild	11	36	21	4
Moderate	7	5	7	4
Severe	3	1	1	2

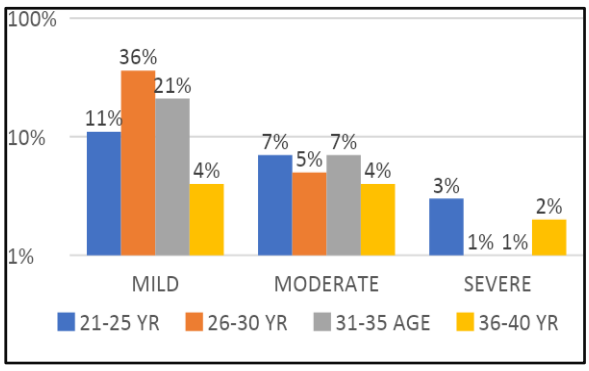

Figure 3 classification of Pregnant Females According To Their Age and Their Anemic Condition

TRIMESTER WISE DISTRIBUTION

The patients were classified according to prevalence of anemia during each trimester and it was noted that patients during the second trimester are more anemic compare to other trimesters.

Table 6 Trimester Wise Dissemination

Trimester Wise Dissemination	
Trimester	**No. of anemic patients**
Trimester-I	81
Trimester-Ii	86
Trimester-Iii	42

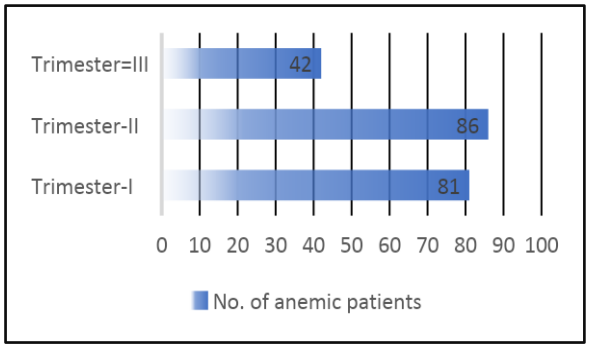

Figure 4 Trimester Wise Dissemination

Comorbidities: Distribution of Patients As Per Their Comorbid Conditions.

The patients were categorized based on existing co-morbidity conditions along with anemia.
The most common morbidities were folic acid deficiency and Vitamin D deficiency

Table 7 Comorbidities: Distribution Of Patients As Per Their Comorbid Conditions

Comorbid conditions	No. Of patients
Hypothyroid	43
Vitamin D Deficiency	58
Vitamin B_{12}	46
Folic Acid Deficiency	65
Uti- Urinary Tract Infection	52
Hypertension	15
Pcos-Polycystic Ovarian Syndrome	28
Dm- Diabetes Mellitus	36

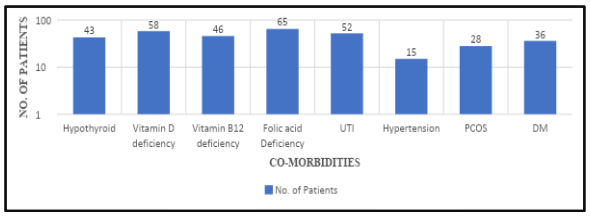

Figure 5 Comorbidities: Distribution of Patients Based on Their Comorbid Conditions

Classification of Pregnant Females Based on the Therapy Prescribed

The pregnant females were categorized based on therapy prescribed, the most commonly prescribed therapy include oral iron therapy (62%) and parenteral therapy (38%)

Table 8 Classification of pregnant females based on the therapy prescribed

Therapy prescribed	No of patient prescribed
Oral Iron Therapy	62
Parenteral Iron Therapy	38

Effect of oral iron therapy on hemoglobin levels in anemia

In our observational study, 62 patients were given oral therapy, and their effectiveness was measured in terms of Hb levels, with the results recorded.

The Hb levels of 39 patients increased significantly. While 23 patients show no increase in Hb levels.

Table 9 Effect of oral iron therapy on hemoglobin levels in anemia

Number Of Patients Prescribed With Oral Therapy	Haemoglobin Level Improvement	
	Improvement	No Improvement
62	39	23

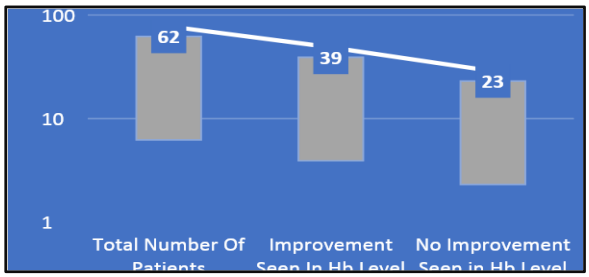

Figure 6 Classification of pregnant females based on the therapy prescribed

Effect of Parenteral Iron Therapy on Hemoglobin Levels in Anemia

In our observational study, a total of 38 patients were given parenteral therapy, and their effectiveness was measured in terms of Hb levels, with the results being recorded.Hb levels in 33 patients increased significantly,while 05 patient' Hb levels did not increase.

Figure 8 & Table 10 Effect of Parenteral Iron Therapy and Its On Hemoglobin Levels in Anemia

Number of Patients Prescribed With Parenteral	Hemoglobin Level Improvement	
	Improvement	No Improvement
38	33	5

Combined effect of oral and parenteral iron therapy on hemoglobin levels in anemia

In our study, anemic pregnant women were given oral and parenteral therapy, and their hemoglobin levels were measured. Oral therapy was prescribed for 62 patients, while parenteral therapy was prescribed for 38.

When compared to oral therapy It was observed that parenteral therapy results in a significant increase in Hb levels, and the oral therapy results in little improvement.

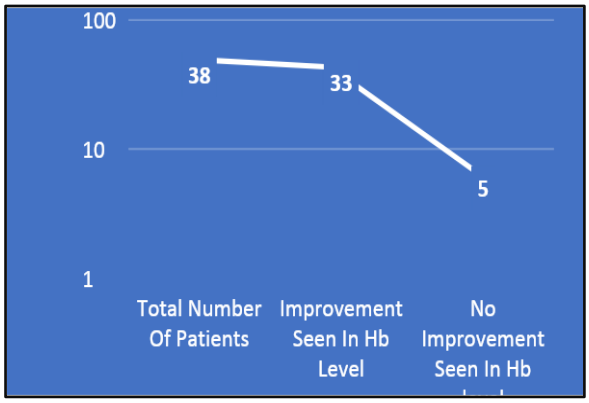

Figure 8 Effect of parenteral iron therapy and its on hemoglobin levels in anemia

Table 11 The combined effect of oral and parenteral intravenous iron therapyand their impact on hb levels in anemia

Total Number Of Patients	Oral Therapy		Parenteral Therapy	
100	62		38	
Results	Improvement Seen In Hb Levels	No Improvement Seen In Hb Levels	Improvement Seen In Hb Levels	No Improvement Seen In Hb Levels
	39	23	33	5

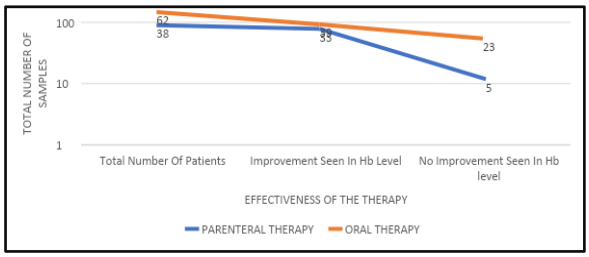

Figure 9: Combined Effect of Oral and Parenteral Intravenous Iron Therapy and Their Impact on Hb Levels in Anemia

DISCUSSION

A prospective observational study on "The Management of iron deficient anemia during pregnancy with oral and parenteral therapy was conducted for over a six-month period.

In our study, we observed that both oral and parenteral therapies were commonly used to treat anemic pregnant women. The patients in our study ranged in age from 21 to 40 years.

Oral iron clinical treatment was the most commonly prescribed regimen during pregnancy as a prophylactic measure and for treating mild to moderate anemia

Intravenous clinical iron treatment was the desired regimen for treating patients with moderate to extreme anemic conditions during pregnancy.

Our study include a small sample size which includes patients with mild-moderate and severe anemic conditions. Hemoglobin values were utilized to evaluate the viability of oral and parenteral therapy in improving the anemic conditions in pregnant women.

There were 61% of mildly anemic patients, 32% of moderately anemic patients, and 7% of severely anemic patients among the cases collected.

The female pregnant women were distributed trimesters wise and it was observed and evaluated that more no. of patients was anemic during the II trimesters (86%), I trimesters (81%) and III trimesters (42%) respectively.

Among the gathered information, it was noted that most patients have comorbidity conditions vitamin D deficiency (58%), vitamin B12 deficiency (46%), folic acid deficiency (65%), UTI (52%), hypothyroid (43%), HTN (15%), PCOS (28%) and DM (36%).

The therapy prescribed in our study includes oral iron therapy - 62% and parenteral iron therapy -38% & their effects were seen on hemoglobin levels in anemic patients

In patients who were given the prescribed regimen with Oral iron therapy was 62% patients out of which 39% patients shows an increase in Hemoglobin levels and 23% patients doesn't show any significant improvement in their hemoglobin levels.

In patients who were given the prescribed regimen with parenteral intravenous iron therapy was 38% out of which 33% patients shows a significant increase in their hemoglobin levels and 5 % patients doesn't increase in their Hemoglobin levels.
Oral iron treatment was given as prescribed regimen for mild to moderate anemia which showed slow improvement in patients' Hb levels

Parenteral intravenous therapy shows to be effective for significant improvement in patients' Hb levels and for reducing the symptoms efficiently.

CONCLUSION

To conclude that oral iron therapy is particularly effective in management of mild – moderate anemia during pregnancy and as a prophylactic measure.

Parenteral iron therapy is effective in the management of moderate to severe anemia, which shows significant improvement in hemoglobin levels and is better tolerated in anemic pregnant patients.

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