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A COMPARATIVE STUDY OF FERROUS ASCORBATE AND FERROUS FUMARATE IN TREATING IRON DEFICIENCY ANEMIA DURING PREGNANCY: EFFICACY AND SAFETY ANALYSIS

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Abstract:

Background: *Iron deficiency anemia (IDA) is a common condition among pregnant women, adversely affecting maternal and fetal health. Oral iron supplements such as ferrous ascorbate and ferrous fumarate are commonly prescribed, yet comparative studies evaluating their efficacy, safety, and cost-effectiveness are limited.*

Objective: *To compare the efficacy, safety, and cost-effectiveness of ferrous ascorbate and ferrous fumarate in pregnant women diagnosed with iron deficiency anemia.*

Methods: *This prospective observational study included 118 pregnant women recruited from the In-Patient and Out-Patient facilities of the Department of Obstetrics and Gynecology, King George Hospital, Visakhapatnam. Participants were divided into two equal groups: Group A received ferrous ascorbate (n=59) and Group B received ferrous fumarate (n=59). Baseline demographic, clinical, and laboratory parameters were recorded, including hemoglobin (Hb), red blood cell (RBC) count, hematocrit (Hct), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and red cell distribution width (RDW-CV). Follow-up assessments were conducted after 60 days of supplementation. Adverse effects and cost-effectiveness were also evaluated.*

Results: *The majority of participants were aged 21–25 years (44.9%), multigravida (77.9%), and urban residents (56.8%). Most subjects were mildly anemic (69.5%). After 60 days, Group A showed a greater mean increase in Hb (9.74 → 11.49 g/dL) compared to Group B (10.43 → 11.36 g/dL). Similar trends were observed for RBC count, Hct, MCV, MCH, and MCHC. RDW-CV decreased in both groups. Minor gastrointestinal side effects were reported in 11 subjects in Group A and 7 subjects in Group B, with no hypersensitivity reactions observed. The average cost-effectiveness per 1% rise in Hb was Rs. 58.87 for Group A and Rs. 50.72 for Group B.*

Conclusion: *Ferrous ascorbate demonstrated superior improvement in hematological parameters with comparable safety and slightly higher cost-effectiveness compared to ferrous fumarate in pregnant women with iron deficiency anemia. These findings suggest ferrous ascorbate as an effective and safe option for managing IDA during pregnancy.*

Keywords: *Iron deficiency anemia, pregnancy, ferrous ascorbate, ferrous fumarate, efficacy, safety, cost-effectiveness.*

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INTRODUCTION:

Anemia in Pregnancy

Anemia is one of the most frequent medical complications experienced by women during pregnancy. According to the World Health Organization (WHO), pregnant women with hemoglobin (Hb) concentrations below 11 g/dL are considered anemic. This condition reduces the blood's capacity to transport oxygen efficiently to tissues, which is vital for maternal and fetal health. Anemia represents a serious public health concern worldwide, affecting both developed and developing nations. Its consequences extend beyond individual health, impacting socioeconomic development due to decreased productivity and increased healthcare costs. Pregnant women and young children are particularly vulnerable, with global estimates indicating that 41.8% of pregnant women and 30.2% of non-pregnant women are affected. In industrialized countries, anemia prevalence among pregnant women is approximately 14%, whereas underdeveloped nations report rates as high as 51%. In South Asia, and particularly in India, roughly 80% of maternal anemia-related fatalities occur, making it a significant contributor to maternal morbidity and mortality.

Pregnancy is a critical period in a woman's life, marked by physiological changes that support fetal growth but increase maternal susceptibility to anemia. Hemoglobin concentration naturally falls during pregnancy due to blood dilution as plasma volume increases, even in healthy women. Anemia is defined by a deficiency of red blood cells (RBCs), impairing oxygen delivery to tissues. RBCs are produced by the bone marrow and typically have a lifespan of approximately 120 days. The production of RBCs relies on adequate supplies of iron, vitamin B12, and folic acid. A deficiency of one or more of these components, or accelerated RBC loss, leads to anemia.

Types of Anemia Based on Severity

Anemia in pregnancy is classified based on hemoglobin levels as follows:

- **Mild anemia**: Hb 10.0–10.9 g/dL
- **Moderate anemia**: Hb 7.0–9.9 g/dL
- **Severe anemia**: Hb 4.0–6.9 g/dL
- **Very severe anemia**: Hb <4.0 g/dL

Mild anemia generally results in reduced work capacity but does not usually affect pregnancy outcomes significantly. Women with mild anemia can often maintain normal daily activities and undergo pregnancy and labor without adverse effects.

Moderate anemia leads to a greater reduction in physical capacity, affecting household responsibilities and childcare. Pregnant women with Hb below 8 g/dL have higher maternal morbidity and are more likely to experience preterm birth and deliver low-birthweight infants. These women may struggle to tolerate blood loss during labor and may fatigue more easily. Moderate anemia is associated with increased maternal mortality due to complications such as pregnancy-induced hypertension, sepsis, and antepartum or postpartum hemorrhage.

Severe anemia can be subdivided into compensated, decompensated, and anemia associated with circulatory failure. Cardiac decompensation typically occurs when Hb drops below 5 g/dL, resulting in increased cardiac output, stroke volume, and heart rate, even at rest. Symptoms such as palpitations and dyspnea appear as the compensatory mechanisms fail. Severe anemia can lead to lactic acidosis due to inadequate oxygen delivery and ultimately circulatory collapse, increasing the risk of maternal mortality, especially during labor. In India, maternal deaths sharply rise when Hb levels fall below 5 g/dL. Anemia is responsible for approximately 20% of maternal deaths directly and an additional 20% indirectly.

Common Types of Anemia in Pregnancy

Several forms of anemia are frequently observed during pregnancy, including:

- **Vitamin B12 deficiency anemia**: Also called cobalamin deficiency, this anemia occurs when the body cannot produce sufficient healthy RBCs due to a lack of vitamin B12. Sources of B12 include animal products such as dairy, meat, fish, and eggs, as well as fortified cereals and nutritional yeast. Impaired absorption, as seen in pernicious anemia or gastrointestinal disorders, can also lead to deficiency.
- **Folate deficiency anemia**: Folate, a water-soluble B vitamin, is essential for fetal growth and cell division. Deficiency can result in poor birth outcomes, including neural tube defects. Foods rich in folate include spinach, romaine lettuce, Brussels sprouts, asparagus, avocados, and beans. The CDC recommends a daily intake of 400 µg of folic acid for women of reproductive age.
- **Iron deficiency anemia (IDA)**: IDA is the most prevalent form during pregnancy. Iron requirements increase significantly due to expanded red cell mass, fetal growth, and placental development. Iron is critical for oxygen transport, electron transfer, and enzymatic activities. Insufficient iron leads to inadequate

hemoglobin and myoglobin synthesis, affecting oxygen delivery and energy metabolism. Iron absorption occurs primarily in the duodenum and upper jejunum, and the bioavailability of iron is influenced by dietary composition. Heme iron from animal sources is absorbed more efficiently than non-heme iron from plant-based diets. Non-heme iron absorption is enhanced by ascorbic acid and inhibited by polyphenols, phytates, and calcium.

Recommended Daily Intake of Iron

For an average woman weighing 55 kg, the total iron requirement during pregnancy is approximately 1000–1200 mg, divided among fetal and placental development (350 mg), increased maternal red cell mass (500 mg), and blood loss at delivery (250 mg). First-trimester iron requirements are relatively low (0.8 mg/day), increasing significantly in the third trimester (3.0–7.5 mg/day). Around 40% of women begin pregnancy with minimal iron stores, and up to 90% have reserves under 500 mg, insufficient to meet the growing demands, even in developed nations.

Absorption and Bioavailability of Iron

Iron exists in the diet as heme (animal sources) and non-heme (plant sources). Heme iron is absorbed more efficiently and less affected by dietary inhibitors. Non-heme iron absorption can be enhanced by ascorbic acid, which reduces ferric iron (Fe^{3+}) to ferrous iron (Fe^{2+}) and forms soluble chelates in the small intestine. Animal tissue consumption also improves absorption of non-heme iron, while phytates, polyphenols, and calcium inhibit absorption. Thus, dietary choices and meal composition play crucial roles in maintaining adequate iron status.

Complications of Iron Deficiency Anemia

IDA during pregnancy is associated with increased maternal morbidity and mortality, as well as adverse fetal outcomes. Symptoms in pregnant women include pallor, fatigue, dyspnea, palpitations, irritability, and reduced thermoregulation. IDA can contribute to postpartum iron depletion, reduced breastfeeding, and higher rates of postpartum depression. Severe anemia increases risks of hemorrhagic shock, pre-eclampsia, cardiovascular insufficiency, infections, and the need for peripartum transfusions. Fetal complications include preterm birth and low birthweight, with risk rising alongside anemia severity.

Diagnosis of Iron Deficiency Anemia

IDA diagnosis is based on hemoglobin and hematocrit thresholds adjusted for pregnancy stage:

- First trimester: Hb <11 g/dL, Hct <33%
- Second trimester: Hb <10.5 g/dL, Hct <32%
- Third trimester: Hb <11 g/dL, Hct <33%

Additional tests include serum ferritin (<30 µg/L), complete blood counts, blood smears (microcytic, hypochromic cells), and differentiation from other causes such as vitamin B12 deficiency, folate deficiency, hemoglobinopathies, or chronic diseases.

Iron Supplementation

Oral iron supplementation is first-line therapy for IDA in pregnancy, with recommended doses of 30–120 mg of elemental iron daily. Common preparations include ferrous sulfate, ferrous gluconate, ferrous ascorbate, and ferrous fumarate. Gastrointestinal side effects, including nausea, constipation, and epigastric pain, limit compliance. Parenteral iron therapy (iron sucrose, iron dextran, ferric carboxymaltose) is reserved for severe anemia or intolerance to oral iron. Iron tablets should ideally be taken with vitamin C or fruit juice and separated from calcium-rich supplements, tea, and coffee to optimize absorption.

Dietary Considerations

Dietary strategies include promoting heme iron sources such as red meat, chicken, and fish, while limiting phytate-rich foods like legumes and unfortified cereals at the same time as iron consumption. Processing methods such as soaking, germination, and fermentation can reduce phytate content, enhancing iron bioavailability. Including vitamin C-rich foods in meals significantly improves non-heme iron absorption.

METHODOLOGY:

1. Study Design

This study was designed as a prospective observational study to evaluate and compare the efficacy and safety of ferrous ascorbate and ferrous fumarate in treating iron deficiency anemia during pregnancy.

2. Study Site

The study was conducted at the In-Patient (IP) and Out-Patient (OP) facilities of the Department of Obstetrics and Gynecology, King George Hospital (KGH), Down Road, Opposite KGH OP Gate, Maharani Peta, Visakhapatnam, Andhra Pradesh – 530002.

3. Study Period

The study was carried out over a period of six months.

4. Sample Size

A total of 100 patients were enrolled in this study based on the inclusion and exclusion criteria.

5. Study Procedure

Eligible patients were enrolled after explaining the purpose of the study and obtaining written informed consent. Patient details, including

demographic data, medical history, and relevant clinical information, were collected from patient profiles, treatment charts, and direct communication. Baseline laboratory investigations were performed, and follow-up assessments were conducted after 60 days. All collected data were recorded in an Excel spreadsheet, and appropriate statistical analyses were applied to evaluate study outcomes.

6. Study Criteria

6a. Inclusion Criteria

- Pregnant women attending IP and OP facilities of the Department of Obstetrics and Gynecology diagnosed with iron deficiency anemia.
- Patients with no other co-morbidities.
- Age range between 18–40 years.

6b. Exclusion Criteria

- Pregnant women with complications such as hemoglobinopathies, acute malaria, severe gastrointestinal disorders, or history of oral iron intolerance.
- Patients unwilling to participate in the study.

7 .Materials

The comparative study was conducted at the IP and OP facilities of the Department of Obstetrics and Gynecology, KGH, Visakhapatnam, after obtaining approval from the Institutional Human Ethics Committee (IHEC). A total of 100 patients were recruited under the guidance of a physician, based on predefined inclusion and exclusion criteria. The study utilized the following materials:

- **Patient Consent Form**
- **Data Collection Form**
- **Patient Information Leaflet**

7a. Patient Consent Form

The patient consent form was used to obtain voluntary participation. Once consent was provided, patients signed the form and were enrolled in the study. The form was prepared in four languages—English, Telugu, Hindi, and Urdu—to ensure patient understanding.

7b. Data Collection Form

A structured data collection form was used under physician supervision to record the following information:

- **Demographic details:** Name, age, sex, lifestyle, address, and socioeconomic status.
- **Clinical details:** Chief complaints, diagnosis, past medical history, and medication history.
- **Laboratory investigations:** Complete blood count (CBC), including hemoglobin, RBC, WBC, neutrophils, basophils, eosinophils, monocytes, lymphocytes, hematocrit, MCV, MCH, MCHC, RDW, and peripheral smear analysis.

7c. Patient Information Leaflet

Patient information leaflets were provided during counseling sessions, offering guidance on diet, lifestyle modifications, and iron supplementation to enhance treatment efficacy.

RESULTS:

Out of 150 subjects initially recruited for the study, 6 were excluded due to hypothyroidism, 2 were known cases of diabetes mellitus, and 24 were lost to follow-up. Therefore, the study was completed with 118 subjects.

1. Distribution of Study Population Based on Age

The majority of subjects (44.9%) were aged 21–25 years. The least represented age group was >35 years (3.5%). Other age distributions were <20 years (18.6%), 26–30 years (20.3%), and 31–35 years (12.7%).

Age (years)	Number of Subjects	Percentage
<20	22	18.6%
21–25	53	44.9%
26–30	24	20.3%
31–35	15	12.7%
>35	4	3.5%
Total	118	100%

2 .Distribution Based on Education

Half of the subjects (50%) had completed school/intermediate education, 29.6% were graduates, 10.2% were postgraduates, and 10.2% were illiterate.

Education	Number of Subjects	Percentage
School/Intermediate	59	50.0%
Graduate	35	29.6%
Postgraduate	12	10.2%
Illiterate	12	10.2%
Total	118	100%

3. Distribution Based on Occupation

Among the participants, 66.1% were housewives and 33.9% were employed.

Occupation	Number of Subjects	Percentage
Housewife	78	66.1%
Employee	40	33.9%
Total	118	100%

4. Distribution Based on Residence

Majority of subjects (56.8%) were from urban areas, while 43.2% were from rural areas.

Residence	Number of Subjects	Percentage
Rural	51	43.2%
Urban	67	56.8%
Total	118	100%

5. Distribution Based on Diet

Most subjects (77.1%) were non-vegetarians, while 22.9% were vegetarians.

Diet	Number of Subjects	Percentage
Vegetarian	27	22.9%
Non-vegetarian	91	77.1%
Total	118	100%

6. Distribution Based on Gravida

The majority (77.9%) were multigravida, and 22.1% were primigravida.

Gravida	Number of Subjects	Percentage
Primigravida	26	22.1%
Multigravida	92	77.9%
Total	118	100%

7. Distribution Based on Severity of Anemia

Among the study population, 69.5% had mild anemia, 30.5% had moderate anemia, and none had severe anemia.

Severity of Anemia	Number of Subjects	Percentage
Mild (Hb 10–10.9 g/dl)	82	69.5%
Moderate (Hb 7–9 g/dl)	36	30.5%
Severe (Hb <7 g/dl)	0	0%
Total	118	100%

8. Distribution Based on Gestational Age

The majority (47.4%) of subjects were in the gestational age group 25–30 weeks, followed by 15–20 weeks (26.2%), 20–25 weeks (25.6%), and 30–35 weeks (0.8%).

Gestational Age (weeks)	Number of Subjects	Percentage
15–20	31	26.2%
20–25	30	25.6%
25–30	56	47.4%
30–35	1	0.8%
Total	118	100%

9 .Comparison of Mean Rise in Hemoglobin

Group A (Ferrous ascorbate) showed an increase from 9.74 to 11.49 g/dL (mean difference 1.75), while Group B (Ferrous fumarate) increased from 10.43 to 11.36 g/dL (mean difference 0.93).

Groups	Mean Hb Before Treatment (g/dL)	Mean Hb After Treatment (g/dL)	Mean Difference
Group A (Ferrous ascorbate)	9.74	11.49	1.75
Group B (Ferrous fumarate)	10.43	11.36	0.93

10 .Comparison of Mean Rise in RBC Count

RBC levels increased slightly from 4.23 to 4.37 ×10^6/mm³ in Group A and from 4.07 to 4.23 ×10^6/mm³ in Group B.

Groups	Mean RBC Before (cells/mm³)	Mean RBC After (cells/mm³)	Mean Difference
Group A	4.23	4.37	0.14
Group B	4.07	4.23	0.16

11–15 .Comparison of Other Hematological Parameters

- **Hematocrit (Hct):** Group A increased by 4.13%, Group B by 3.1%.
- **MCV:** Group A increased by 4.52 fL, Group B by 3.07 fL.
- **MCH:** Group A increased by 2.72 pg, Group B by 2.14 pg.
- **MCHC:** Group A increased by 0.99 g/dL, Group B by 0.61 g/dL.
- **RDW-CV:** Group A decreased from 18.66% to 15.18%, Group B from 15.26% to 14.45%.

16. Comparison of Side Effects

Most subjects in Group A (48/59) and Group B (52/59) reported no side effects. Minor gastrointestinal side effects occurred in 11 subjects in Group A and 7 in Group B. No hypersensitivity reactions were observed.

Groups	None	Gastrointestinal Side Effects	Hypersensitivity	Total
Group A	48	11	0	59
Group B	52	7	0	59
Total	100	18	0	118

17. Comparison of Cost-Effectiveness

The total cost for 60 days of treatment was 735.9 for Group A and 334.8 for Group B. The mean improvement in Hb was 12.5% and 6.6%, respectively, resulting in an average cost-effectiveness ratio of 58.87 per 1% rise in Hb for Group A and 50.72 for Group B.

Groups	Total Cost (INR)	Mean Hb Increase (g/dL)	Improvement (%)	Cost-Effectiveness (INR/1% Hb rise)
Group A	735.9	1.75	12.5	58.87
Group B	334.8	0.93	6.6	50.72

DISCUSSION:

The present study aimed to compare the efficacy and safety of **Ferrous Ascorbate** and **Ferrous Fumarate** in pregnant women diagnosed with iron deficiency anemia. A total of 118 patients were enrolled from both inpatient and outpatient departments, and divided into two equal groups of 59 patients each: Group A received Ferrous Ascorbate, and Group B received Ferrous Fumarate.

Distribution of Study Population

Age: The majority of subjects (44.9%) were aged 21–25 years, consistent with the study by Manju Toppo et al., which reported 57.3% of patients in the same age group.

Education: Half of the study population (50%) had completed school/intermediate education. This aligns with findings by Manju Toppo et al., where 90% of participants were educated up to middle school and 17.4% were illiterate.

Occupation: In our study, 66.1% were housewives and 33.9% were employed, comparable to previous research by Manju Toppo et al.

Residence: Most subjects were from urban areas (56.8%), while 43.2% were from rural areas, similar to prior research.

Diet:A majority (77.1%) were non-vegetarians, and 22.9% were vegetarians.

Gravida: Primigravidae constituted 22.1% and multigravidae 77.9% of the study population. Previous studies reported slightly different distributions (89% primigravidae, 61% multigravidae).

Severity of Anemia: Mild anemia was observed in 69.5% of subjects and moderate anemia in 30.5%; no cases of severe anemia were noted. This is in line with the study by Manju Toppo et al., which reported 50% mild anemia, 10% moderate anemia, and 74.13% with normal hemoglobin (>11 g/dL).

Gestational Age: Most participants (47.4%) were between 25–30 weeks of gestation. This is comparable to Sakthibalan Murugesan et al. (2022), where antenatal women >14 weeks were included.

Comparative Efficacy

Hemoglobin (Hb): Group A (Ferrous Ascorbate) showed a significant rise in mean Hb from 9.74 to 11.49 g/dL, while Group B (Ferrous Fumarate) increased from 10.43 to 11.36 g/dL. These results are comparable to prior studies but show a slightly higher improvement with Ferrous Ascorbate.

Red Blood Cell Count (RBC):A slight increase was observed in Group A from 4.23 to 4.37 ×10^6/mm³ and in Group B from 4.07 to 4.23 ×10^6/mm³. Group A showed a higher rise, indicating better efficacy in improving RBC count.

Hematocrit (Hct): Hct levels increased from 30.21 to 34.34% in Group A and 31.49 to 34.59% in Group B, consistent with trends reported in previous studies.

MCV, MCH, and MCHC:

- MCV: increased by 4.52 fL (Group A) and 3.07 fL (Group B).
- MCH: increased by 2.72 pg (Group A) and 2.14 pg (Group B).
- MCHC: increased by 0.99 g/dL (Group A) and 0.61 g/dL (Group B).

Red Cell Distribution Width (RDW-CV):RDW-CV decreased from 18.66% to 15.18% in Group A and from 15.26% to 14.45% in Group B, reflecting improved red blood cell uniformity.

Safety and Side Effects:

The majority of subjects in both groups did not experience any adverse effects (Group A: 48/59, Group B: 52/59). Minor gastrointestinal side effects were reported in 11 subjects (Group A) and 7 subjects (Group B). No hypersensitivity reactions or serious adverse events were documented, which is consistent with previous studies.

Cost-Effectiveness

The total cost for 60 days of treatment was ₹735.9 for Ferrous Ascorbate and ₹334.8 for Ferrous Fumarate. The corresponding improvement in Hb was 12.5% and 6.6%, resulting in a cost-effectiveness ratio of ₹58.87 per 1% rise in Hb for Group A and ₹50.72 for Group B. These findings indicate that while Ferrous Ascorbate has a slightly higher cost, it provides a greater clinical benefit in Hb improvement. Previous studies reported higher absolute costs but similar trends in effectiveness.

CONCLUSION:

This comparative study demonstrates that **Ferrous Ascorbate** is more effective in improving key hematological parameters—including Hb, RBC count, MCV, MCH, MCHC, and RDW-CV—than **Ferrous Fumarate** in pregnant women with iron deficiency anemia. Both treatments were well-tolerated, with minimal gastrointestinal side effects and no hypersensitivity reactions. Cost-effectiveness analysis suggests that Ferrous Ascorbate provides better value in terms of clinical improvement relative to cost.

Overall, Ferrous Ascorbate can be considered a preferred treatment option for managing iron deficiency anemia during pregnancy due to its superior efficacy, safety, and cost-effectiveness.

LIMITATIONS

- A longer study period (>6 months) could provide more substantial and robust results.
- Follow-up was limited to 60 days, and cost-effectiveness was evaluated only based on direct drug costs, without including indirect or overall healthcare costs.

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