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Outcomes & Adverse Effects of Ferrous Fumarate & Unani formulations in Iron deficiency Anemia (*Faqr-ud-dam*) in Pregnancy at Govt. Nizamia Hospital Hyderabad: A Comparative Study.

*** Dr. Amreen Begum [1], Dr. Asma Khan [2], Dr. Mohammad Danish [3], Dr. Asif Ali Ghulam Mohammed Chaudhary [4], Dr. Mohammed Wahid Ansari [5], Dr. Tauseef Ahmad [6]**

[*1] Assistant Professor, Dept. of Amraze Niswan-wa-Qabalat, Govt. Nizamia Tibbi College & Hospital Hyderabad, Telangana, India

[2] Associate Professor, Dept. of Amraze Niswan-wa-Qabalat, Inamdar Unani Medical College & Hospital, Kalaburgi, Karnataka, India.

[3] Assistant Professor, Dept. of Moalajat, University College of Unani, Tonk, Rajasthan, India

[4] Assistant Professor, Dept. of Moalijat, Dr. M.I.J. Tibbia Unani Medical College & Hospital, Mumbai. India

[5] Assistant Professor, Dept. of Ilaj-e-bit-Tadbeer, Ahmad Garib Unani Medical College & Hospital, Akkalkuwa, Maharashtra, India

[6] M.D. Dept. of Ilmul Saidla, National Institute of Unani Medicine, Bengaluru, Karnataka

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Abstract: *The incidence of anemia is advanced in developing countries due to its health and socioeconomic difficulties. It is considered by reduced amounts of RBCs or hemoglobin level below 11 gram/dl. In conventional literature mentioned that Su Mizaj Barid wa Ratab (abnormal temperament of cold and wet) leads to the change of feature of Iron deficiency anemia, which they have defined as Su al qinya (Anemia). Unani Medicine has a rich of single drugs and compound formulations for the treatment of anemia. All the single drugs and compound formulations, those mentioned in Unani classical books for treatment of anemia have various pharmacological actions like Muwallid-I-dam (hemopoietic), Muqaww-i-mi'da (stomachic) and Muqaww-i-kabid (heptatonic). It has been traditionally used for the treatment of anemia (Faqr al dam) since ages. Many compound formulations have been reported for its hematinic effect in recent years. The therapeutic options in faqr al dam in conventional medicine have got their own side effects and complications. Looking at the side effects of conventional therapy and complications of conventional medicine, it is need of the time to shift to an alternative system of medicine that is harmless, cost effective, non-surgical and can easily be affordable by everyone and has long lasting effects. Various classical Unani texts were reviewed. Unani herbal drugs viz. Amla (emblica officinalis), Pamba dana (gossypium), Elachi khurd (Elettaria cardamomum), Rub-e-anar (punica granatum linn), Rub-e-tamatar (lycopersium esculentum), Khand-e-siya (caryota urens, jaggery) used in the management of Anemia. The present study was conducted at Govt. Nizamia General Hospital for the period of 2yrs from 2016-2018 in ANC unit of Govt. Nizamia General Hospital. Present study also proves*

the efficacy of Unani medicine for improvement in Hb level

Keywords: *Anemia, iron deficiency anemia, nutritional anemias, anemia of inflammation*

I. Introduction of Anemia

Anaemia is defined as Haemoglobin concentration less than 12g/dl in non-pregnant women and less than 10g/dl during pregnancy or puerperium. It is the most common type of anaemia in pregnancy. Women with normal Haemoglobin levels but poor iron stores manifest as over "Iron Deficiency Anameia During Pregnancy". The centers for disease control and prevention defined Anaemia as less than 11g/dl in the first and third trimester and less than 10.5g/dl in the second trimester. 25-65% incidence of anaemia in developing countries and 10-20% incidence in developed countries with the age of 20-45 years Females. Bodnar and associates studied a cohort of 59,248 pregnancies and found a prevalence of 27%for postpartum anaemia. Although this was strongly correlated with prenatal anaemia, it was found 21% of women with normal prenatal haemoglobin levels. The tittle "Outcomes & Adverse Effects of Ferrous Fumarate & Unani formulations in Iron deficiency Anemia (Faqr-ud-dam) in Pregnancy at Govt. Nizamia Hospital Hyderabad: A Comparative Study" has selected to compare the efficacy of unani medicine with ferrous fumarate for treatment of anaemia in pregnancy. The present study is first of its kind to scientifically evaluate the efficacy of selected unani drugs for the treatment and improvement of Anaemia in pregnancy. Randomized single blind comparative trials has designed into two groups, group "A" (in this group patients treated by unani medicines) and group "B" (patients treated by ferrous fumarate tablet livogen)) with the sample size of 60 patients, 30 in each group. This study has proved the efficacy of selected unani medicines for the management of Anaemia in pregnancy with good response and improvement in haemoglobin levels as compare to livogen tablet. The modest fall in haemoglobin levels during pregnancy is caused by a relatively greater expansion of plasma volume compared with the increase in red cell volume. The specific cause of anaemia is important when evaluating effects on pregnancy outcome that is iron deficiency anaemia most studies of the effects of anaemia on pregnancy, describe large population. The risk periods when the patient may even die at about 30-32 weeks of pregnancy, during labour, immediately following delivery, anytime in puerperium specially 7-10 days following deliveries due to pulmonary embolism. This likely deal with nutritional anaemia and specifically those due to iron deficiency. In studied nearly 27,000 women and found a slightly increased risk of preterm birth with mid-trimester Anaemia, low birth weight babies with its incidental hazards, intrauterine death due to severe maternal anoxaemia. Lieberman and colleagues (1987) found an association with low hematocrit and preterm birth in black women. According to world health organization, anaemia contributes to 40% of maternal deaths in third world countries. In the present scenario Anaemia is the most common problem among the women during pregnancy as a result in the deficiency of iron and nutrition disorder. According to Unani concepts the functional disturbance of liver following a change in its mizaj (temperament), affects the production of blood as such and alters its normal composition and the quality. The proper functioning of spleen which is necessary to maintain the physiology of blood is also modified. If spleen fails to clean the blood having undesirable barid yabis (cold and dry) substances then mizaj of liver becomes abnormal drifting to barudat (coldness) and yabusat (dryness). According to ismail jurjani khun-e-safra (billous sanguine) is less viscous, strong in odour, frothy, hotter, takes much time to coagulate and is relatively bitter in taste. Khun-e-

balgami (phlegmatic sanguine) when exposed outsidethe body it is soggy but very soon it becomes viscous, coagulates in a very short time and has mild odour, bit if infected it causes to emit bad odour and when kept for an hour it releases fluid. Whereas khun-e-sawdavi (melancholic sanguine) is black, viscous and has bad odour. It does not take much time to coagulate. If a little water is added to it and shaken, it scatters and takes the shape of fibers and liberates bluish watery fluid.

II. Causes According to Unani Concept:

- *Amraaz-e-kabid (Liver Disorders)*
- *Amraaz-e-Meda wa Amaa (Gastrointestinal disorder)*
- *Amraz-e-kuliya (Renal Disorders) eg: haematuria*
- *Amraz-e-sadar (cardio-pulmonary diseases) eg:haemoptysis*
- *Mutafarreqat (Miscellaneous) eg: nuqs-e-taghzia (malnutrition)*
- *Gareebi wa faqa (poverty & starvation)*
- *Ghair mamooli mehnat wa riyazat (extreme exertion and exercise)*
- *Shadeed jiryan-ud-dam (severe haemorrhage)*
- *Sue hazam (dyspepsia)*

III. Classification of Anaemia

The anaemia may be classified in various ways

1. Physiological Anaemia in Pregnancy:

*There is disproportionate increase in plasma volume, RBC volume and haemoglobin mass during pregnancy. In /*addition, marked demand for extra iron in second half of pregnancy even an adequate diet cannot meet extra demand of iron. Fall in haematacrit value, low serum iron, increased iron binding capacity and increased rate of iron absorption.*

2. Pathalogical Classification:

1. Based on positive factors (aetiological) anemias are classified into three types

(A) Anaemia due to decreased production of erythrocytes

a) Nutritional deficiency anaemia

i. Iron deficiency

ii. Folic acid deficiency

iii. Vitamin B12 deficiency

iv. Protein deficiency

(B) Hemorrhagic

a) Anaemia due to excess loss of blood

i. Acute – following bleeding in early months or APH

ii. Chronic – Hookworm infestation, bleeding piles etc.

(C) Hereditary

a) Anaemia due to increased destruction of RBC

i. Thalassemias

ii. Sickle cell haemoglobinopathies

iii. Hereditary hemolytic anaemia

(D) Bone marrow insufficiency–Hypoplasia and aplasia due to radiation and drugs.

(E) Anaemia of infection (malaria and tuberculosis)

(F) Chronic disease (renal) or neoplasm

2. According to WHO based on the level of Hb anaemia are graded into

A) Mild: Hb level between 8-10 gm %

B) Moderate: Hb level less than 8-7 gm %

C) Severe: Hb level less than 7 gm %

3. Morphological Classification of Anaemia

(A) Microcytic hypochromic: (MCV < 78 µ3)

(B) Normocytic normochromic

(C) Macrocytic (MCV > 100 µ3)

IV. Aetiology / Causes of Iron Deficiency Anaemia:

- *Nutritional causes (50%)*

a) Poor intake of dietary iron

b) Poor absorption/bioavailability of iron

c) Increased demand during pregnancy

- *Paracytic infestation (25-30%)*
- *Chronic blood loss/continuous loss of blood (5-7%)*
- *Haemoglobinopathies (1-2%)*
- *Others like leukemia and hemolytic anaemia.*

Iron deficiency anaemia is very common in pregnancy. The materials essential for erythropoiesis, the deficiencies of which are mainly responsible for anaemia in pregnancy are iron, folic acid and vitamin-B12. The two most common causes of anaemia during pregnancy and puerperium are iron deficiency and acute blood loss by epistaxis gastric, uterine and accidental hemorrhages. With the rapid expansion of blood volume during the second trimester, iron deficiency is often manifested by an appreciable dropping haemoglobin concentration. In the third trimester, additional iron is needed to augment maternal haemoglobin and for transport to the fetus. In a typical gestation with a single fetus, the maternal need for iron induced by pregnancy changes may be around 1000 mg. The fetus and the placenta require around 300 mg and 500 mg for maternal Hb mass expansion, iron deficiency anaemia develops.

V. Clinical Features of Iron Deficiency Anaemia during Pregnancy:

In the mild forms, there may be few symptoms and the anaemia is detected in routine antenatal screening. Severe forms give rise to symptoms. The clinical features depend more on the degree of anaemia than anything else.

- *Parity: Iron deficiency anaemia is more common in mutigravidas or when the interval between pregnancies is less.*

- *Multiple Pregnancy: In multiple pregnancy the demand for iron is more and hence there is increased likelihood of developing iron deficiency anaemia.*
- *History Of Chronic Illness:*

Repeated urinary tract infection and history of menorrhagia prior to pregnancy may be elicited.

Lathery, palpitation and breathlessness on exertion may be the complaints in severe forms of anaemia. These include pallor, presence of oedema of feet and face. In very severe forms patients may have features of cardiac failure. Signs and symptoms are depended on the severity of anaemia Patient appears slightly pale (on palpebral conjunctiva, tongue) slight glossitis and stomatitis. In severe cases signs are marked pallor, on palpebral conjunctiva, tongue, skin, slight oedema feet or anasarca, glossitis, cardiac dilatation, haemic murmur at heart, heart failure. Commonly asymptomatic. Fatigue, asthenia, feeling of exhaustion, weakness, lassitude, anorexia, giddiness, exertion dyspnea sometimes appears. In severe cases symptoms are loss of appetite, diarrhea, breathlessness, palpitation on exertion, swelling of face and feet

VI. Differential Diagnosis:

The iron deficiency anaemia can be differentiated from the following diseases

- *Pernicious anaemia: The average diameter of RBC's is greater than normal in pernicious anaemia while it is smaller than normal in iron deficiency anaemia. There is no evidence of hemolysis which is characteristic feature of pernicious anaemia. In iron deficiency anaemia tongue becomes smooth flabby and pale but in pernicious anaemia soreness and pain are not so common.*
- *Thalassaemia syndrome: Thalassaemia is also marked by reduced red cell volume. It is congenital disease. A constantly high reticulocytosis, enlarged liver and spline help distinguish thalassaemia from iron deficiency anaemia.*
- *Sideroblastic anaemia: Iron deficiency anaemia is distinguished from pyridoxine sensitive anaemia sideroblastic anaemia by a low content of Iron in blood serum and a reduced content of sideroblastic in blood and bone marrow. Iron preparations are content indicated in sideroblastic anaemia and leukemia develops in many of them over a longer or shorter period of time.*

VII. Aims And Objectives of the Study:

- *To show the Efficacy of Unani medicine with compare of T. Livogen.*
- *To avoid significant maternal and pre-natal mortality and morbidity.*
- *To avoid complication of growing fetus.*
- *To find out the response of selected drugs in treating iron Deficiency Anaemia in pregnancy.*
- *To correct cold in temperament and weakness of liver and stomach.*
- *To increase bio-viability and to enhance better absorption of iron, medicine rich in vitamin-c were used.*
- *To check whether the iron that is present in used drugs can be utilizes to treat anaemia or not.*

VIII. Method Of Preparation of Drugs and Administration:

The drugs for clinical and therapeutical trial were selected on the basis of Unani medicine and allopathic medicine. All the Unani drugs were cleaned with all its impurities and grinded to fine powder and make a rubb and qiwam. The drug and dosage

Group A:

1) Group A will be treated for Iron Deficiency Anemia in pregnancy by Unani formulation in the form of Majoon. Given Orally

NUSQAE MAJOON (1 kg):

1) Amla (emblica officinalis)-100gms

2) Pamba dana(gossypium)-100gms

3) Elachi khurd (ele hariacardamomum)-50gms

4) Rub-e-anar (punica granatum linn)-50gms

5) Rub-e-tamatar (lycopersium esculentum)-50gms

6) Khand-e-siya (caryota urens, jaggery)-double of all ingredients

Method: Fine powder of all 1,2,3 and make the qiwam from KHAND-E-SIYA and add the powder and RUBS in the qiwam and mix them well.

Dosage:5gms bd (after meals)

Group B:

- *Tab. LIVOGEN (Ferrous fumarate 152mg+Folic acid 1500 mcg)*
- *2 Tablets bice (bd) daily*

Source of Data:

- *OP & IP units of Government Nizamia Tibbi College & General Hospital, Charminar, Hyderabad, Telangana.*

Place of study:

- *Department of Qabalath-o-Amraaz-e-Niswan, OP & IP units of Government Nizamia Tibbi College & General Hospital, Charminar, Hyderabad, Telangana.*

Duration Of the Study: 18 months

- *3 cycles with each an interval of a month in Group A patients*
- *The period of treatment will be 10 days in each cycle*

Medicine Prescribed for Clinical Trials Drugs Given for Both 'A' and 'B' Group Patients: Drugs given for group 'A' patients

1) Amla (emblica officinalis)

2) Pamba dana(gossypium)

3) Elachi khurd (ele hariacardamomum)

4) Rub-e-anar (punica granatum linn)

5) Rub-e-tamatar (lycopersium esculentum)

6) Khand-e-siya (caryota urens, jaggery)

Drugs given for group 'B' patients Tab. LIVOGEN (Ferrous fumarate)

Name of Pharmacognosy Drugs	Chemical constituents	Therapeutic action and uses
Aamla [Fruit] **Botanical Name:** Emblica officinalis Family: Euphorbiaceae	calories, vit C, iron, tannin, galic acid, glucose etc.	Qabiz, habis, musakin-e-hararath, mufareh, mushtahi, muqawwi-e-Aaza-e-Raisa, muqawwi-e-meda, muqawwi-e-chasham, muqawwi-e-shaar, mana-e-tabqeer, mudir-e-baul, muqawwi-e-aasab
Anar (fruit) Punica Granatum Linn Family [punicaceae]	**Chemical constituents: Glucose, Sugar, Calcium, Phosphorous, Iron etc**	Rind of fruit: Astringent Fruit: Laxative, used in inflammation of stomach and heart. Seeds: Stomachic
Jaggery (Khand-e-siyah) **Botanical Name:** Caryota urens	50 % Sucrose, 20 % Invert sugar, 20 % moisture, Iron and some insoluable matter such as wood ash, protein, bagasse fibers	Appetizer, anti-inflammatory, drug purifier, laxative, digestive, and used in preparation of majoon & jawarish.
Ilaychi-e-khurd Elettaria Cardamomum linn **Family:** Tamaraceae	Glycosides, steroids, tannin, flavonoids, sodium, potassium	Headache, bad humours of the liver, bitter, Fruit-agent, perfumery, carminative, aromatic, stimulant & diuretic
Pambadana Botanical name: Gossypium herbaceum linn Family: Malvaceae	Organic: Glycosides, steroids, resins, saponius, carbohydrates, proteins & phenolic compounds /tannins. Inorganic: Sodium, Potassium, Iron & Calcium	It is used for sual [cough], zeequnnafas [asthama] & Zof-e-bah [sexual weakness]
Tomato Botanical name: Solanum Lcopersicum Family: Solanaceae	**Water – 95 %, Carbohydrates – 4 %, Fat & protein 1 %, Iron 27mg /100 gms (4%), Vit A - 42µg, B1 Thiamine 0.037 mg (3%) B3 Niacin - 0.594**	**Appetizer, Relaxant, Correct Anemia**

	Mg (4 %) B6 - 0.08 mg (6%) Vit C - 14 mg (	

IX. Pharmacognosy of Drugs

Ferrous Fumarate:

It is a type of iron also known as iron fumarate. It is the iron salt of fumaric acid occurring as a reddish orange powder. Other name: Feostat, iron fumarate Colour: Reddish orange Odour: Odourless

Indication: Correction of anaemia Side effects: Allergic reaction like swelling on face, lips, tongue and throat Difficulty in breathing, chest pain, constipation, diarrhea, nausea, vomiting, heart burn, loss of appetite, black and dard colored stool.

Dosage: 600 mg/day (200 mg/day elemental iron) divided by 1 – 3 times per day.

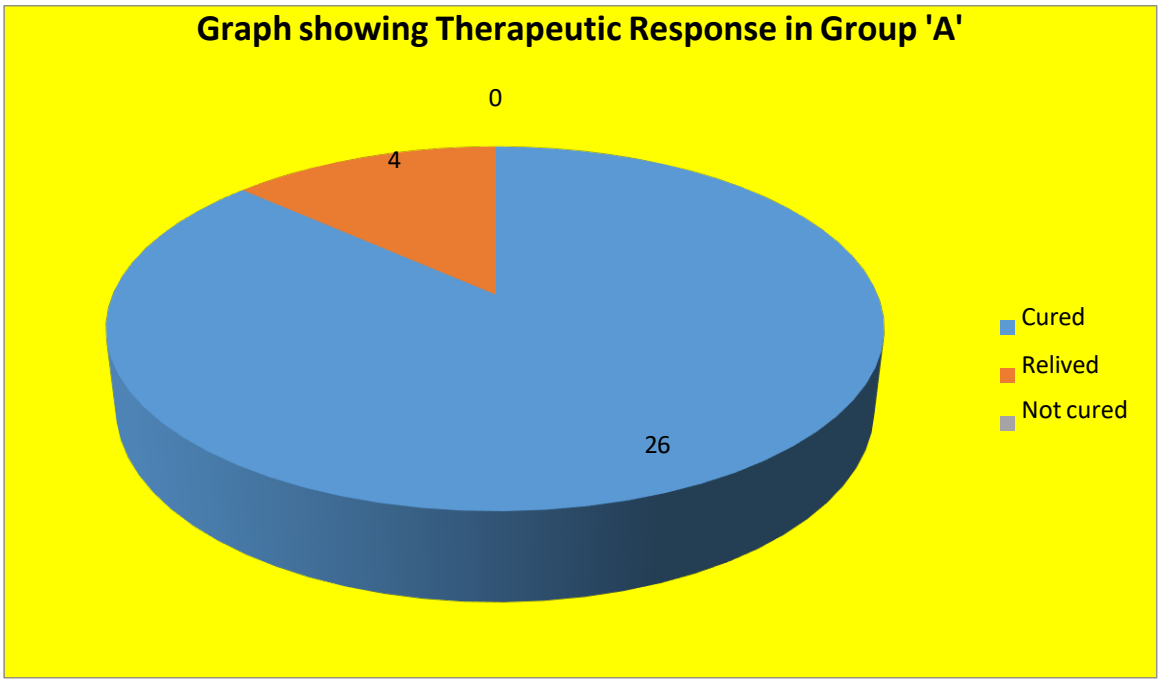
X. Observation and Results:

1. Table showing Therapeutic response in Group-A Patients

No:	Response	No. of cases	Percentage (%)
1	Cured	26	86.67
2	Relived	4	13.33
3	Not cured	----	----
	Total	30	100

This table shows:

- *The therapeutic response of group 'A' patients, the results of study group 'A' with Unani medicines were very encouraging.*
- *Among the 30 patients, 26 (86.67%) patients had shown 100% cured rate and 4 (13.33%) patients had relieved in clinical features improvement of haemoglobin.*
- *Therefore, the Unani drugs are best for anaemia cost effective and free from side effects.*

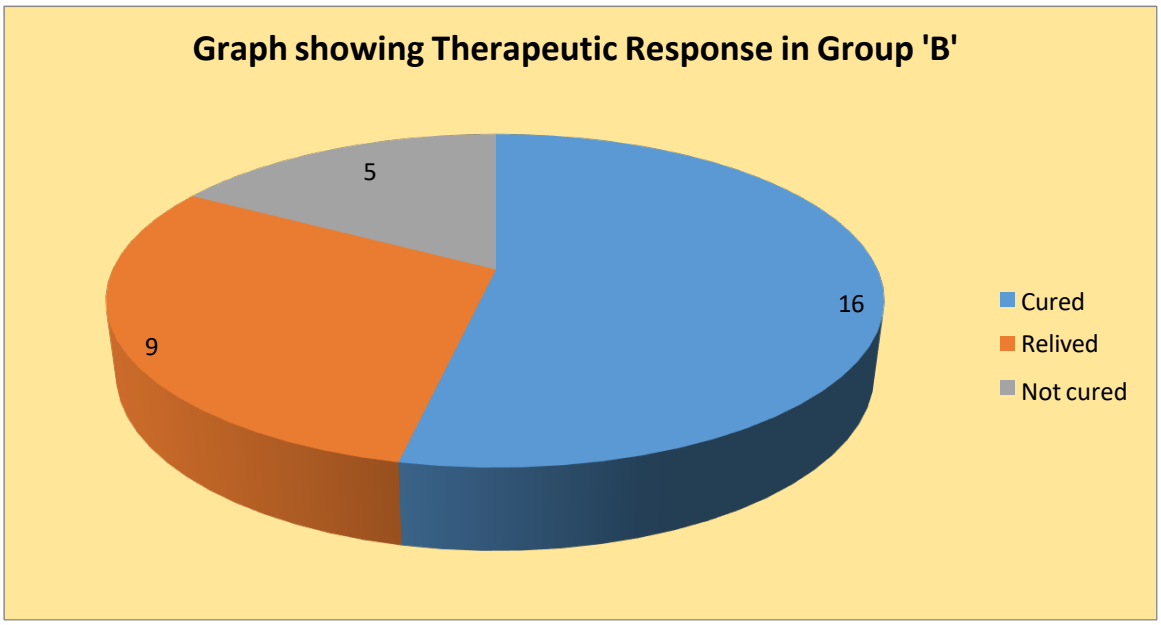


2. Table showing Therapeutic response in Group-B Patients

No:	Response	No. of cases	Percentage (%)
1	Cured	16	53.33
2	Relived	9	30.0
3	Not cured	5	16.67
	Total	30	100

This table shows:

- *The therapeutic response of group B' patients, the results of study group 'B' with tablet livogen.*
- *Among the 30 patients, 16 (53.33%) patients had shown 100% cured rate, 9 (13.33%) patients had relieved in clinical features improvement of Hb% and 5 (16.67%) patients had not cured, not showing any response in the sign symptoms and management of anaemia in pregnancy.*



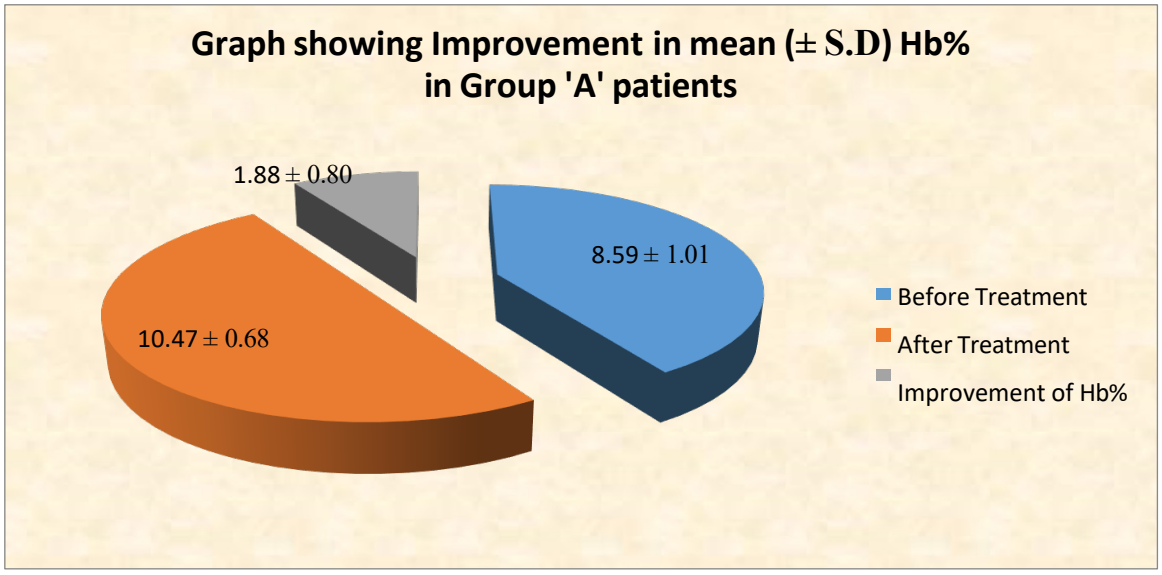
3. *Table showing improvement in mean (± S.D) Hb% in Group-A*

n = 30

No:	Group-A		Improvement of Hb%
	Before Treatment	After Treatment	
1	8.59 ± 1.01	10.47 ± 0.68	1.94 ± 0.80

This table shows:

Table shows the mean ± S.D with improvement in haemoglobin percentage among group A patients from 8.59 ± 1.01% before treatment to 10.47 ± 0.68 gram% after treatment. There is a significant change of 1.94 ± 0.80 gm% (vide graph).

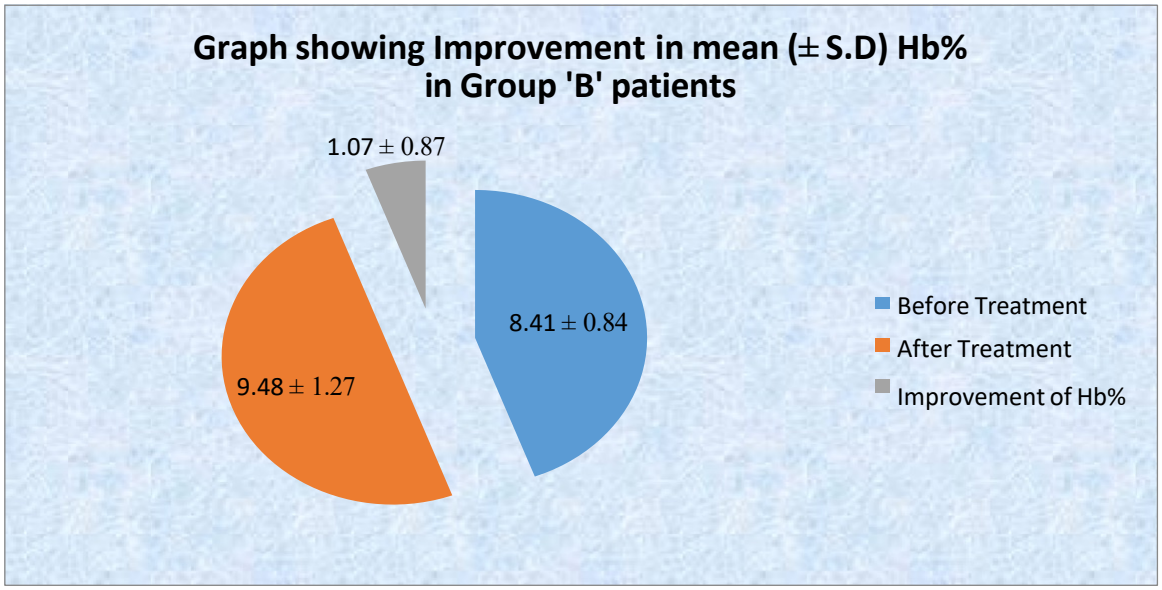


4. *Table showing improvement in mean (±S.D.) Hb % in Group-B n = 30*

No:	Group-B		Improvement of Hb%
	Before Treatment	After Treatment	
1	8.41 ± 0.84	9.48 ± 1.27	1.26 ± 0.87

This table shows:

Table shows improvement in haemoglobin level among group B patients, before treatment, the mean



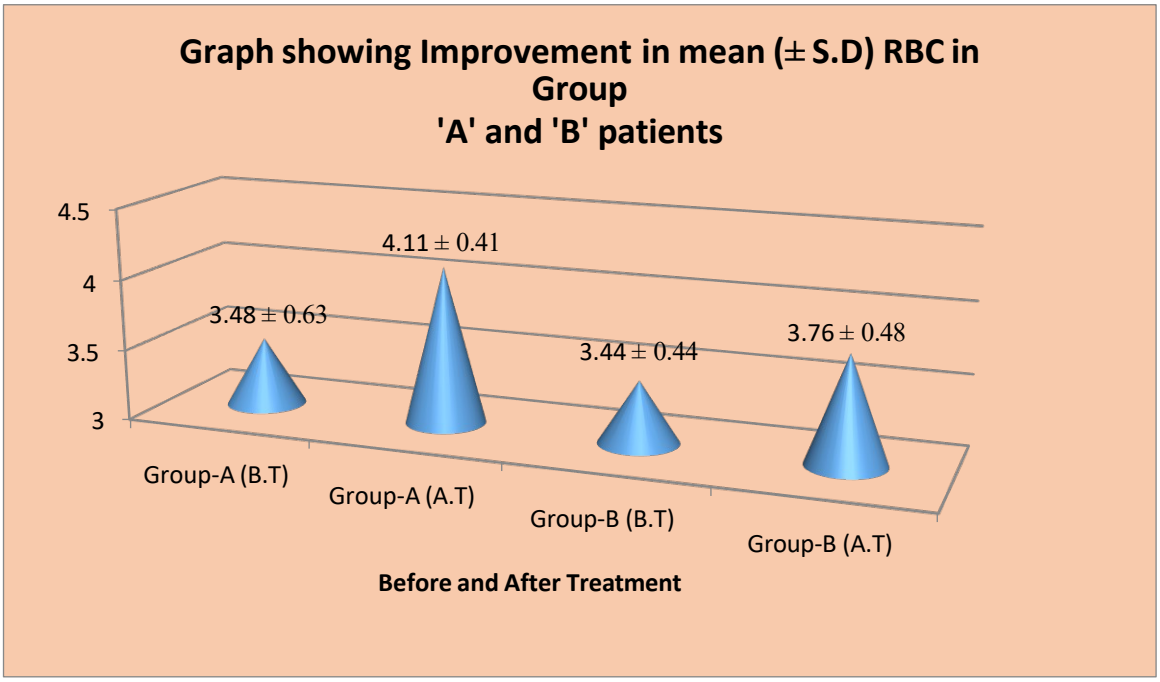
± S.D value was 8.41 ± 0.84 and after treatment it progress to 9.48 ± 1.27 gram %. There is a significant rise of 1.26 ± 0.87 gram% (vide graph).

Table showing improvement in mean (± S.D) RBC in Group- A and B n = 30

No:	Group-A		Group-B	
	Before Treatment	After Treatment	Before Treatment	After Treatment
1	3.48 ± 0.63	4.11 ± 0.41	3.44 ± 0.44	3.76 ± 0.48

This table shows:

Table shows improvement in red blood cells among group A and group B patients mean ± S.D before treatment of group A was 3.48 ± 0.63 million/cu.mm and after treatment there is a improvement of 4.11 ± 0.41 million/cu.mm and group B was 3.44 ± 0.44 million/cu.mm after treatment there is a improvement of 3.76 ± 0.48 million/cu.mm (vide graph).



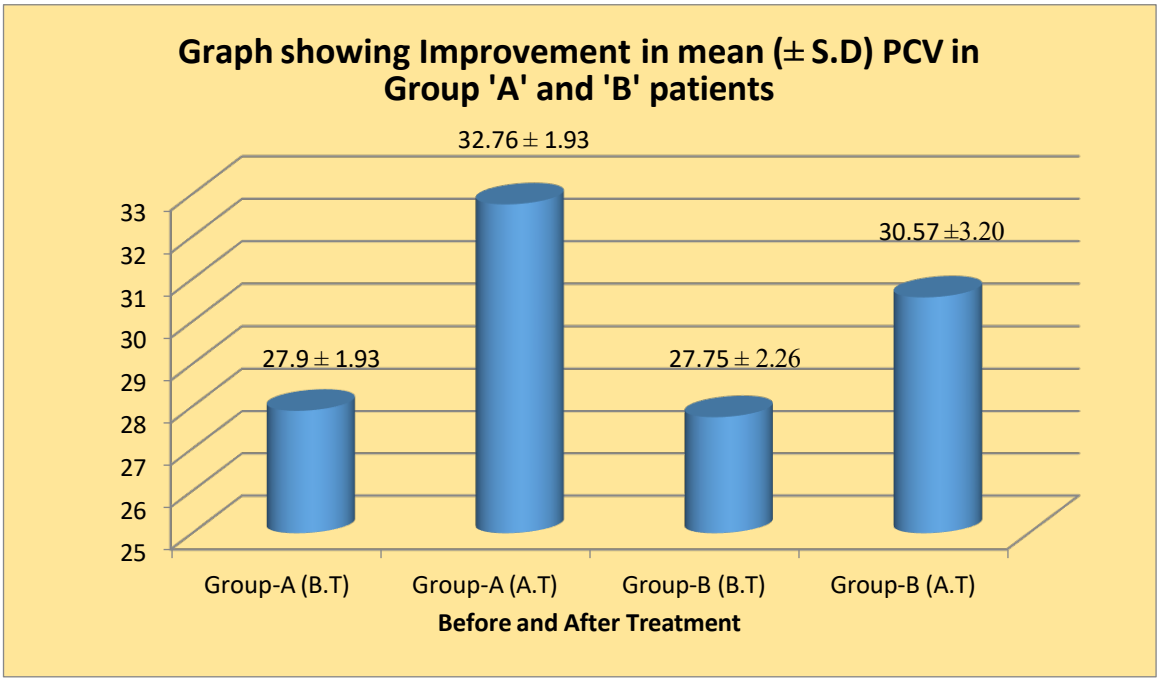
5. Table showing improvement in mean (± S.D) PCV in Group-A and B

n = 30

No:	Group-A		Group-B	
	Before Treatment	After Treatment	Before Treatment	After Treatment
1	27.9 ± 1.93	32.76 ± 1.93	27.75 ± 2.26	30.57 ± 3.20

This table shows:

Table shows improvement in packed cell volume mean ± S.D in group A, there is a significant progress from 27.9 ± 1.93 volume to 32.76 ± 1.93 and in group B 27.75 ± 2.26 volume to 30.57± 3.20 volume improvement. The group A (study group) patients who received Unani treatment were more anaemic whose Hb% was as low as 7 gm% and PCV 21 volume shown a significant improvement.



Conclusion

The present study, titled "Outcomes & Adverse Effects of Ferrous Fumarate & Unani formulations in Iron deficiency Anemia (Faqr-ud-dam) in Pregnancy at Govt. Nizamia Hospital Hyderabad: A Comparative Study" demonstrates that Unani medicine is an effective and safe treatment option for iron deficiency anaemia in pregnancy. Conducted at Govt. Nizamia General Hospital over a period of two years, the study confirms that Unani formulations significantly improve haemoglobin levels, red blood cell count, and packed cell volume in pregnant women affected by anaemia. The study involved 60 women between the ages of 18 to 40 years, predominantly from low and middle socio-economic groups, with a high incidence of anaemia in the second and third trimesters of pregnancy. The results clearly indicate that the Unani treatment group (Group A) showed a higher cure rate of 86.67% compared to 53.33% in the group treated with ferrous fumarate tablets (Group B). Improvement in haemoglobin concentration, RBC count, and PCV was consistently greater in Group A. Unani medicines proved to be not only effective but also cost-efficient, free from significant side effects, and safe for long-term use. They contributed to improving the digestive system, enhancing iron absorption, and strengthening the liver and stomach, thereby supporting better blood formation. These medicines also offered hepatoprotective and hematinic benefits, supplemented by nutrients like vitamin C, calcium, and B-complex vitamins.

In conclusion, the study validates that Unani medicine is a viable, affordable, and safer alternative to conventional iron supplements in treating iron deficiency anaemia during pregnancy, particularly for women from underprivileged backgrounds. The encouraging results recommend wider use of Unani formulations in clinical practice to improve maternal health outcomes and reduce maternal morbidity and mortality associated with anaemia in pregnancy.

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