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ORIGINAL RESEARCH ARTICLE

A comparative Study of use of Preparation Containing Ferrous sulphate versus Ferrous fumarate in Treatment of Iron Deficiency Anemia.

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ABSTRACT

Objective: The present study was undertaken with the aim of determining and comparing the efficacy of ferrous sulphate and ferrous fumarate in increasing haemoglobin level in girls in the age range of 12 to 17 years suffering from iron deficiency anemia.

Study design: A total number of 100 adolescent girls of lower socio economic class studying in Government Secondary School, Anand, who were diagnosed as suffering from anemia were selected and randomly divided into 2 groups. One group was given ferrous sulphate and the other group was given ferrous fumarate for one month.

Changes in body weight, haemoglobin level, RBC count and MCV value were estimated twice-first after 10 days and then at the end of one month.

The data so recorded was than analyzed by chi-square test and Paired sample T- test to compare the efficacy of the two iron preparations in study groups.

Results: Observations revealed that increase in body weight was found to be more with the use of ferrous fumarate than with ferrous sulphate while increase in haemoglobin level, RBC count and MCV value was found to be more with use of ferrous sulphate than with ferrous fumarate.

Conclusion: Ferrous sulphate is found to be more effective in increasing haemoglobin levels and RBC counts as compared to ferrous fumarate in adolescent girls suffering from iron deficiency anemia.

Key Words: Haemoglobin, Red Blood Cells (RBCs), adolescent girls, nutritional deficiency

Introduction-

Anemia is not a disease but a condition that results from a number of different pathologies[1.] It is defined as a qualitative or quantitative deficiency of circulating haemoglobin (Hb), a molecule found inside Red Blood Cells (RBCs)[2,3]. Anemia leads to hypoxia in organs[2].

Normal haemoglobin value is 12 gm/dL. As per WHO criteria the severity of anemia can be categorized into mild: Hb = 10 - 11.99 gm/dL, moderate: Hb = 8- 9.99 gm/dL and severe: < 8 gm/dL[4].

Nutritional Deficiencies (iron, cobalamine [B_{12}], folate) are the most common cause of anemia through out the world[3]. Iron deficiency is rampant in human beings and its victim's number in hundreds to millions[5]. In India 30% adult males, 45% adult females, 80% pregnant females and 60% children suffer from iron deficiency anemia[6].

FAO and WHO in 1993 reported incidence of iron deficiency among Indians to the extent of 65% of adult women, 45% of adult men and 77% of children under five[7].

The percentage of Indian adolescent girls who were anemic was reported as 73.7% by Chaturvedi et al.[8] and in a study carried out on girls belonging to poor community, Sharma et al. reported incidence of anemia to the extent of 61.9% in urban areas and 85.4% in rural areas[9].

Daily iron needs vary according to age and sex[3]. The adult male has a requirement of only 1mg/day, whereas the menstruating female

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requires about 1.4 mg/day[10]. Iron needs increase to 3 to 4mg/day during pregnancy[11].

Adolescent growth and development is closely linked to the diet they receive[12]. Adolescents girls are a particularly vulnerable group as their requirements of iron as well as its losses from the body are high[13]. Iron needs are determined by total losses from the body[3].

In adolescent females i.e. those who have attained menarche (11-13 years), the need of iron is high due to blood loss during menstruation, resulting in loss of 0.3 - 0.5 mg/day of iron. Hence incidence of iron deficiency anemia is high in adolescent girls[11].

Socio-economic and demographic factors have great impact on the nutritional status of adolescent girls. The types of the family, family size, type and quantity of food consumed and income status of the family influence the health status[14].

It is reported that iron deficiency is common in rural areas and in children belonging to poor socio economic class[10].

Treatment of iron deficiency anemia involves two components[6]

- Correction of anemia with oral or parenteral iron
  Commonly used oral iron preparations are ferrous sulphate, ferrous fumarate, ferrous gluconate, ferrous succinate, ferrous lactate and ferrous glutamate, of which ferrous sulphate and ferrous fumarate are more commonly prescribed in clinical practice[5].
- Eradication of the cause of iron deficiency anemia is often neglected either because no attempt has been made to find the cause or the cause has not been found despite efforts or cause cannot be corrected[6].

Hence, the present study was undertaken with the aim of comparing the efficacy of ferrous sulphate and ferrous fumarate in increasing the haemoglobin in girls belonging to low socio-economic group, in the age range of 12 to 17 years suffering from iron deficiency anemia.

Study design-

The approval for the conduct of the study was obtained from HREC of Pramukh Swami Medical College, Karamsad. The study was conducted on girls studying at Government Secondary School, Anand. Permission for conduct of the study was obtained from the Principal of the school.

The study enrolled 100 adolescent girls belonging to lower socio economic class, suffering from iron deficiency anemia. Before including any girl in the study her parents / guardian were explained the aspects of the research work and their written consent was taken on Informed Consent Form (ICF).

Inclusion criteria:

- Anemic girls in the age range of 12 to 17 years and who had attained the stage of menarche.

Exclusion criteria:

- Girls with GI disorders.
- Girls who were taking any drug affecting iron absorption like antacids, ascorbic acid, some antibiotics etc.

On visit 1: (Day 0)

A total number of 114 girls were screened by carrying out complete blood count. Maintaining all aseptic conditions and using disposable syringe and needle, 2ml of blood was collected by the trained lab technician of Krunal Laboratory, Anand.

Detailed history of the girls was recorded by questioning them.

Girls having haemoglobin value less than 12 gm/dl were considered as anemic. 100 (87.71%) girls were found to be anemic and remaining were non anemic.

The selected 100 girls were randomly divided into 2 groups of 50 girls each. First group of girls was given ferrous sulphate (generic, 200 mg) and second group was given ferrous fumarate (generic, 210 mg) Iron supplementation was carried out daily after lunch for 1month.

Relevant details were obtained by questioning the girls included in the study in accordance with the attached questionnaire.

On Visit 2: (10 days after visit 1) and on visit 3: (1 month after visit 1)

Complete blood count was repeated and results were appropriately documented.

Statistical analysis:

Results were expressed as percentage and comparison of efficacy of ferrous sulphate and ferrous fumarate in treatment of iron deficiency anemia was carried out using chi-square test and paired sample T-test. P value < 0.05 was considered to be statistically significant.

Results-

A total number of 114 girls were screened of which 100 (87.71%) girls were found to be anemic and 14 (12.29%) were non anemic.

1- Frequency distribution of girls based on severity of anemia:

Based on initial haemoglobin levels, subjects were classified as normal (Hb>12gm/dL), mildly anemic (Hb=10-11.99 gm/dL), moderately anemic (Hb=8-9.99gm/dL) or severely anemic (Hb< 8gm/dL) as per the WHO standards[18].

In our study incidence of mild anemia was found to be highest, followed by moderate anemia and least incidence was of severe anemia (**Fig.1**).Z

2- Frequency distribution of various signs and symptoms of anemia and their correlation with severity of anemia-

Statistically significant correlation was observed between severity of anemia and some signs and symptoms of anemia like fatigue or tiredness, weakness, pale skin, shortness of breath and rapid heartbeats.

However, the correlation between severity of anemia and some signs and symptoms of anemia like dizziness, difficult to concentrate, irregular menstural cycle, numbness or coldness of hands or feet, irritation and depression was not found to be statistically significant (**Table 1**)

Table 1- Frequency distribution of various signs and symptoms of anemia and their correlation with severity of anemia.

Sr. No.	Signs and symptoms of anemia	Severity of anemia						Total	Percentage	*p*- Value
		Mild anemia		Moderate anemia		Severe anemia				
		N	Percentage	N	Percentage	N	Percentage			
1	Fatigue or tiredness	41	46.6	34	38.6	13	14.8%	88	22.3	.001*
2	Weakness	32	42.1	31	40.8	13	17.1%	76	19.3	.002*
3	Pale skin	14	26.4	26	49.1	13	24.5%	53	13.5	.000*
4	Shortness of breath	7	26.9	13	50.0	6	23.1%	26	6.6	.011*
5	Dizziness	19	42.2	16	35.6	10	22.2%	45	11.4	0.063
6	Difficult to concentrate	6	40.0	6	40.0	3	20.0	15	3.8	0.569
7	Rapid heartbeats	3	20.0	6	40.0	6	40.0	15	3.8	.000*
8	Irregular menstrual cycle	18	56.3	12	37.5	2	6.3	32	8.1	0.309
9	Numbness or coldness in hands and feet	16	41.0	14	35.9	9	23.1	39	9.9	0.070
10	Irritation	1	100.0	0	0.0	0	0.0	1	3	0.627
11	Feeling sad or depressed	2	50.0	2	50.0	0	0.0	4	1	0.638
	Total	N=52		N=34		N=14		100		

***Statistically significant**

3- Mean increase in body weight after one month and correlation between body weight and drug type-

Mean increase in body weight on 3rd visit was more with ferrous fumarate as compared to ferrous sulphate. This observation was found to be statistically significant (P = 0.000*) (**Table 2**).

4- Mean increase in haemoglobin (gm/dl) after one month and correlation between mean increase in haemoglobin(gm/dl) and drug type-

Mean increase in haemoglobin on 3rd visit was more with ferrous sulphate as compared to ferrous fumarate. This observation was also found to be statistically significant (P =0.000*) (**Fig 2**).

5- Correlation between mean increase in haemoglobin (gm/dl) after one month and severity of anemia

All mildly anemic girls became normal (Hb=12 gm/dL) while all moderately anemic girls reached near normal levels of haemoglobin after one month treatment.

All the severely anemic girls showed maximum increase in haemoglobin level after one month, yet they could not reach normal level. Probably they require a slightly longer period of supplementation to become completely normal (**Fig 3**)

6- Mean increase in RBC (million/cmm) and MCV (fl) and their correlation with drug type:

Mean increase in RBC and MCV on 3rd visit was more with ferrous sulphate as compared to ferrous fumarate. This observation was also found to be statistically significant (P =0.000*) (**Table 3**)

Discussion-

Prevalence of anemia in our study was found to be 87.71% which is similar to 96.5% reported by Gawarika et al.[15], 83% reported by S.Shobha[13] and 73.7% reported by Chaturvedi et al.[8].

Also the study conducted by ICMR (Toteja et al.) in India in the year of 2001, reported that 90.01% girls were found to be anemic, among which 32.1% girls were mildly anemic, 50.9% girls were moderately anemic and 7.1% girls were severely anemic[12].

As per WHO standards[4] anemic girls were categorized as mildly, moderately and severely anemic based on their initial haemoglobin levels.

In our study incidence of mild anemia was found to be highest (52%), followed by 34% moderate anemia and least incidence (15%) of severe anemia.

Our results are consistent with the report of Gawarika et al, who reported an incidence of 42.91% mild anemia, 42.47% moderate anemia and 11% severe anemia[15].

Incidence of anemia based on severity in adolescent Gaddi girls as reported by Rita Rani from Himachal Pradesh is 16.5% mild anemia, 72% moderate anemia and 11.5% severe anemia[16]. Variation of our results as compared to this result may probably be due to regional difference or tribal difference.

Fatigue or tiredness, weakness, pale skin, shortness of breath and rapid heartbeats were observed to be most common signs and symptoms of anemia in the study population. Correlating these signs and symptoms of anemia with severity of anemia, statistically significant results were obtained.

The 100 anemic girls included in the study were divided into two groups, of which one group was given ferrous sulphate and other group was given ferrous fumarate supplementation.

Correlation of use of two ferrous salts with increase in body weight, haemoglobin levels, RBC count and MCV value was studied.

Use of ferrous fumarate produced statistically significant increase in body weight as compared to use of ferrous sulphate.

On the other hand ferrous sulphate was found to be more effective as compared to ferrous fumarate as it increased not only mean haemoglobin level but also mean RBC count and mean MCV value at the end of one month treatment. These results were found to be statistically significant.

Chan Gunn[17] carried out similar study and reported almost equal effectiveness of the two ferrous salts in increasing haemoglobin level.

When the total mean increment in haemoglobin was examined, the severely anemic girls showed the maximum increase. It is observed that lower the initial haemoglobin level, the greater the increase on supplementation. It is a fact that the body dictates the amount of iron to be absorbed depending on its own iron status[18].

Conclusion-

As per the results it was found that 87.71% girls were anemic with highest incidence of mild anemia. Severely anemic girls showed maximum increase in haemoglobin level after one month treatment, followed by moderately anemic girls and mildly anemic girls showed minimum increase in haemoglobin level after one month treatment. Thus, it was observed that fatigue or tiredness, weakness, pale skin, shortness of breath and rapid heartbeats were found to be the most common signs and symptoms of anemia. Increase in body weight (Kg) was found to be more with the use of ferrous fumarate than with ferrous sulphate. Increase in haemoglobin level (gm/dL), RBC count (million/cmm) and MCV value (fl) were found to be more with use of ferrous sulphate than with ferrous fumarate.

Thus, from our study we can conclude that ferrous sulphate is more effective in increasing haemoglobin levels and RBC counts as compared to ferrous fumarate in adolescent girls belonging to lower socioeconomic class suffering from iron deficiency anemia.

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Table 2- Mean increase in body weight and its correlation with drug type.

Drug type	1st visit	3rd visit	P-Value	Mean increase in body weight ± S.E.M
Ferrous Sulphate	35.9400 ±0.81637	36.8600 ±0.81354	0.000*	-0.92000 ±0.09934
Ferrous Fumarate	36.2700 ±0.73335	37.5600 ±0.6741	0.000*	-1.29000 ±0.24163

*Statistically significant

Table 3- Mean increase in RBC count (million/cmm) and MCV (fl) and their correlation with drug type.

Drug	Ferrous sulphate				Ferrous fumarate			
	Mean count ± S.E.M. 1st visit	3rd visit	Mean increase ± S.E.M	P-Value	Mean count ± S.E.M. 1st visit	3rd visit	Mean increase ± S.E.M	P-Value
RBC (milli/cmm)	4.2600 ±0.06958	5.4618 ±0.05933	-1.2018 ±.02792	0.000*	4.3126 ±0.07763	5.2162 ±0.0696	-.90360 ±.01767	0.000*
MCV (fl)	72.3800 ±1.10735	84.8360 ±1.1016	-12.4560 ±.16638	0.000*	72.9780 ±1.04762	82.9580 ±1.033	-9.9800 ±.11521	0.000*

*Statistically significant

Fig. 1- Frequency distribution of girls based on severity of anemia

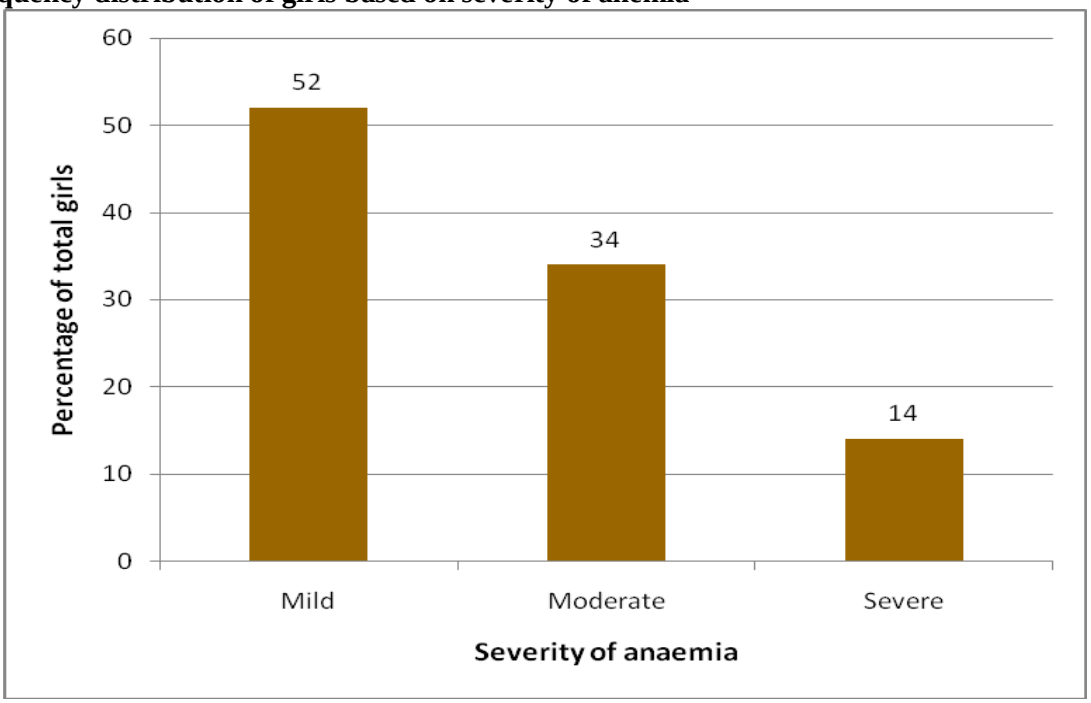


Fig. 2- Mean haemoglobin value (gm/dl) at I and III visit and comparison of mean increase in haemoglobin one month after treatment with the two drugs

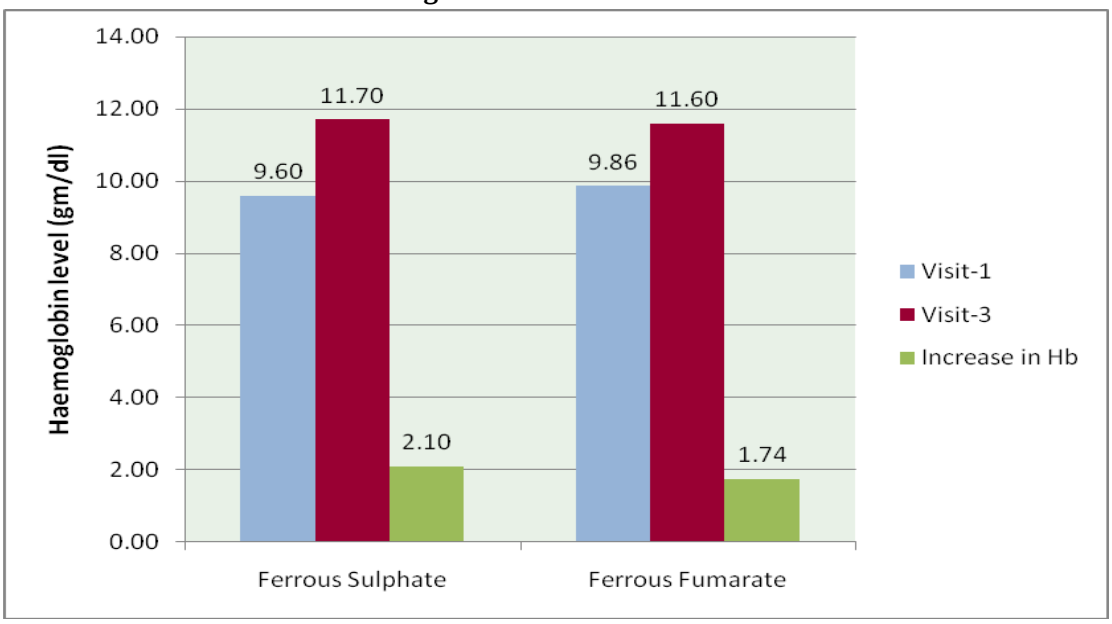
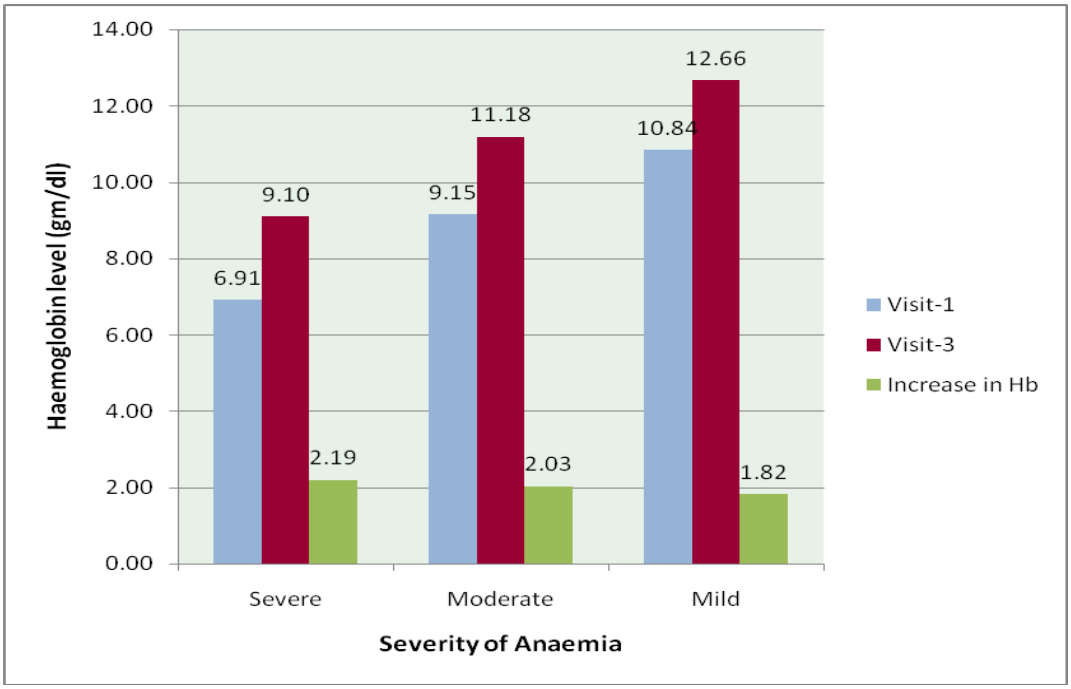


Fig. 3- Correlation of mean haemoglobin value (gm/dl) and mean increase in haemoglobin value(gm/dl) with severity of anemia one month after treatment with the two drugs



IJPBA, Sept - Oct, 2010, Vol. 1, Issue, 5

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