



STUDY TO EVALUATE THE EFFECTIVENESS OF FERROUS SULPHATE VS FERROUS ASCORBATE IN THE MANAGEMENT OF ANAEMIA IN PREGNANCY AT SELECTED DISTRICTS OF MADHYA PRADESH

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ABSTRACT

Introduction High priority districts (the bottom 25% of the districts) were identified based on composite health index to bring about sharper improvements in health outcomes. Ferrous ascorbate supplementation is being carried out in Raisen district, a HPD, when compared to the nearby district Bhopal where Ferrous sulphate is still the preferred modality for prophylaxis and management of anaemia in pregnancy. Studies showing the efficacy of Ferrous ascorbate over ferrous sulphate in pharmacological settings are available in plenty, but the data regarding real time effectiveness is not sufficiently available in this part of the country. **Objectives** To study the sociodemographic factors associated with anaemia in pregnant women. To study the effectiveness of Ferrous sulphate vs Ferrous ascorbate in the management of anaemia in pregnancy. **Methods** It was a prospective observational study, including 50 pregnant females in each treatment group with gestational week of 12-14 getting themselves registered at the anganwadis (Selected by random selection without replacement method) of urban and rural field practice area of GMC Bhopal. They were followed up after 1 and 3 months of the initial visit to evaluate their compliance and changes in haemoglobin level. **Results** The mean change in haemoglobin level among FS group after three visits was found to be 0.30 ± 0.23 gm/dl, while it was 0.54 ± 0.32 gm/dl among FA group. The mean change in haemoglobin level was more in compliant when compared to non-compliant. And the mean change in haemoglobin level in compliant females of FA treatment group was 0.52 ± 0.30 gm/dl, and was higher than that of FS group, i.e. 0.37 ± 0.22 gm/dl. The difference observed was statistically significant. **Conclusion** Ferrous ascorbate was found better and effective in improving haemoglobin status, with better compliance and less adverse drug reactions.

KEYWORDS : Ferrous Sulphate, Ferrous Ascorbate, Haemoglobin, Compliance.

INTRODUCTION

An estimate by WHO attributes about 591,000 perinatal deaths and 1, 15,000 maternal deaths globally to IDA, directly or indirectly^[1]. To ensure equitable health care and to bring about sharper improvements in health outcomes, the bottom 25% of the districts in every state according to the ranking of districts based on composite health index have been identified as High Priority Districts (HPDs). All Left Wing Affected districts and districts with majority tribal population, whose composite health index is below 50%, are also categorized as HPDs. 17 districts were categorized as HPD in the state of Madhya Pradesh. Raisen district is one among those HPD, and by virtue of this, Ferrous ascorbate tablet supplementation is being carried out in this district, when compared to the other districts like Bhopal where Ferrous sulphate is still the preferred modality for the prophylaxis and management of anaemia in pregnancy.^[2]

Studies showing the efficacy of ferrous ascorbate over ferrous sulphate in pharmacological settings are available in plenty, but the data regarding real time effectiveness of both drugs in management of anaemia is not sufficiently available and no such studies were carried out in this part of the country. Hence to bridge this gap in knowledge, this study was carried out in two selected districts of Madhya Pradesh – Bhopal and Raisen (Urban and Rural field practice areas in both districts under Department of Community Medicine, Gandhi Medical College Bhopal).

OBJECTIVES

1. To study the sociodemographic factors associated with anemia in pregnant women
2. To study the effectiveness of Ferrous sulphate vs Ferrous ascorbate in the management of anemia in pregnancy

MATERIAL & METHODS

Study Design:

Community based prospective Observational study

Study Area:

Urban and Rural field practice area of Department of Community Medicine, Gandhi Medical College Bhopal, coming under Phanda block of Bhopal district and Obedullaganj block of Raisen district respectively.

Study Population:

Pregnant women registering in the study period in the anganwadis of Bhopal and Raisen district i.e., at less than 14 weeks of gestation

Study Duration:

1 year

Inclusion Criteria:

- Pregnant women (< 14 weeks gestation) registering during the initial months of study period

Exclusion Criteria:

- Pregnant females with Moderate/severe anaemia with Haemoglobin <9 gm/dl requiring either IV Iron Sucrose/Blood transfusion as per the initial Hb levels
- History/diagnosis of any other forms of anaemia, chronic GI illnesses
- Grand multipara, Patients on IV Iron or with a history of recent blood transfusion

Sample Size:

50 females from each district who registered themselves before 14 weeks of gestation and full fills the criteria at the anganwadis were included in the present study.

Sampling:

The list of anganwadis under the field practice area of Department of Community Medicine was initially obtained. Later Anganwadis were selected from each district from the above list by simple random sampling. All pregnant females meeting the criteria were included in the study from an anganwadi and the process continued with other AWCs of both districts till the required sample size of 50 pregnant females per treatment group were met.

METHODOLOGY

After obtaining clearance from the IEC, the selection of anganwadis was carried out. Later the investigator visited the respective anganwadis on fixed days of the week and approached the eligible participants for the present study. After obtaining informed consent, from those females who got themselves registered before 14 weeks of gestation, were then later interviewed using a Pretested Pre designed Semi structured questionnaire.

The questionnaire included socio-demographic variables such as age, education, Religion, Caste, occupation, type of family etc. Personal/Obstetric history included Age at menarche, Age at marriage, Age at first and Present pregnancy, gap between pregnancies, gravidity, parity and history of abortions. Details of antenatal visits and IFA supplementation during last pregnancy were then obtained during the first visit.

Details regarding TT doses, folic acid consumption, dietary practices and anthropometrical parameters were obtained during the first visit. Haemoglobin level was also obtained using a digital hemoglobinometer. Two follow up visits were done first at a gap of 4-6 weeks and second follow up visit after a gap of 8-10 weeks after the second visit, to elicit the changes in haemoglobin level by measuring Hb level, compliance to oral iron therapy, factors causing noncompliance, dietary practices and anthropometrical measures.

Statistical Analysis:

Data was entered MS excel 2007, analysis was done with the help of Epi-Info 7 software. Frequency and percentage were calculated & statistical test (Chi Square) was applied wherever applicable; P<0.05 was taken as statically significant. Independent t test was used to compare the mean haemoglobin level of both groups wherever applicable and paired t test, to find out the changes in the same group at various visits.

OBSERVATIONS AND RESULTS

Section A - Socio-demographic profile of study participants
Table 1 – Distribution of participants according to socio demographic profile

S No.	Variable	Ferrous Sulphate treatment group N (%)	Ferrous Ascorbate treatment group N (%)	Total N (%)
Age at present pregnancy (In Years)				
1	<21	12(24.0)	17(34.0)	29(29.0)
2	22-25	19(38.0)	16(32.0)	35(35.0)
3	26-29	8(16.0)	12(24.0)	20(20.0)
4	30-33	7(14.0)	3(6.0)	10(10.0)
5	>33	4(8.0)	2(4.0)	6(6.0)
Educational qualification of the participants				
1	Illiterate	1(2.0)	5(10.0)	6(6.0)
2	Primary	1(2.0)	3(6.0)	4(4.0)
3	Middle School	9(18.0)	15(30.0)	24(24.0)
4	High School	14(28.0)	5(10.0)	19(19.0)
5	Intermediate	10(20.0)	8(16.0)	18(18.0)
6	Graduate	14(28.0)	14(28.0)	28(28.0)
7	Professional	1(2.0)	0(0.0)	1(1.0)
Religion				
1	Hindu	23(46.0)	43(86.0)	66 (66.0)
2	Muslim	27(54.0)	7(14.0)	34 (34.0)
Type of family				
1	Nuclear	24 (48.0)	5 (10.0)	29 (29.0)
2	Joint	26 (52.0)	45 (90.0)	71 (71.0)

Table - 2 Mean hemoglobin level of both treatment groups at three visits

Treatment group	Mean Hemoglobin level (In gm/dl)					
	First Visit		Second Visit		Third Visit	
	Mean (In gm/dl)	95%C I	Mean (In gm/dl)	95%C I	Mean (In gm/dl)	95%C I
Ferrous Sulphate treatment group	9.59	9.44-9.74	9.73	9.57-9.88	9.89	9.73-10.06
Ferrous Ascorbate treatment group	9.54	9.39-9.68	9.75	9.57-9.92	10.08	9.91-10.25

Table - 3 Comparison of mean change in hemoglobin level of both treatment groups at different visits
A) Ferrous Sulphate treatment group

Haemoglobin level at visit (I)	Haemoglobin level at visit (J)	Mean difference (In gm/dl) (I-J)	Standard Error	P-Value	95% confidence interval for the difference	
					Lower bound	Upper bound
First Visit	Second Visit	-0.136	0.020	<0.001	-0.176	-0.096
	Third Visit	-0.304	0.033	<0.001	-0.370	-0.238
Second Visit	First Visit	0.136	0.020	<0.001	0.096	0.176
	Third Visit	-0.168	0.024	<0.001	-0.217	-0.119
Third Visit	First Visit	0.304	0.033	<0.001	0.238	0.370
	Second Visit	0.168	0.024	<0.001	0.119	0.217

B) Ferrous Ascorbate treatment group

Haemoglobin level at visit (I)	Haemoglobin level at visit (J)	Mean difference (In gm/dl) (I-J)	Standard Error	P-Value	95% confidence interval for the difference	
					Lower bound	Upper bound
First Visit	Second Visit	-0.210	0.038	<0.001	-0.305	-0.115
	Third Visit	-0.542	0.045	<0.001	-0.654	-0.430
Second Visit	First Visit	0.210	0.038	<0.001	0.115	0.305
	Third Visit	-0.332	0.052	<0.001	-0.461	-0.203
Third Visit	First Visit	0.542	0.045	<0.001	0.430	0.654
	Second Visit	0.332	0.052	<0.001	0.203	0.461

Analysis of mean change in the level of hemoglobin at the three visits in both treatment groups shows that the mean change in hemoglobin level between first and third visits was 0.304 gm/dl in ferrous sulphate treatment group, while it was 0.542 gm/dl in the ferrous ascorbate treatment group. The mean change in hemoglobin between second and third visits was found to be 0.332 gm/dl in the ferrous ascorbate treatment group, while it was 0.168 gm/dl among the ferrous sulphate treatment group. When comparing the mean change in haemoglobin level between first and second visits, it was noted that the change in hemoglobin level in the ferrous sulphate treatment group is to 0.136 gm/dl, while it was 0.210 gm/dl in the participants of ferrous ascorbate treatment group.

Table - 4 Comparison of mean change in haemoglobin between first and third visit of both treatment groups

The mean change in haemoglobin level between third and first visits was more i.e. 0.5420 gm/dl, in ferrous ascorbate group when compared to 0.3040 gm/dl in the ferrous sulphate treatment group. The mean changes between groups were analysed using unpaired t test and found to be extremely statistically significant, with p value <0.001

DISCUSSION

The mean age of study participants in present study was 24.56 ± 4.480 years. Mean age among ferrous sulphate treatment group was 25.20 ± 4.682 years, while it was 23.92 ± 4.218 years in the ferrous ascorbate treatment group. Majority of the participants in both groups (i.e. 38.0% and 32.0%) were between 22-25 years. In a study conducted by **Pushpa Omprakash Lokare et.al**^[3] (2006-2008), majority of the subjects were between ages 20 to 29 years with an average age of 22.7 years, similar to the findings of the present study. Another study conducted by **R.G. Viveki et.al**^[4] (2010), noted that the majority of the subjects were between ages 20 to 29 years with an average age of 22.7 years.

Majority of participants in present study were Hindus (66%) and rest 34% were Muslims. In the ferrous sulphate treatment group, 54.0% were Muslims compared to the 86.0% Hindu participants in the ferrous ascorbate treatment group. Similar findings were reported by **Priyanka Sharma et.al**^[5] (2011-2012) and **Dr. Moushumi Biswas et.al**^[6] (2012-2013).

In this study, majority of participants from both groups i.e. 52.0% and 90.0% each were from joint families. Similar findings were reported by **Judith A Noronha et. al**^[7] (2005-2006) and **Priyanka Sharma et.al**^[8] (2011-2012) Findings different from our study was reported by **R.G. Viveki et.al**^[4] (2010), and **Abiselvi A et.al**^[9] (2015).

Nausea and vomiting were the predominant side effects reported in both groups i.e. 56.0% and 34.0% each in both treatment groups. Similar findings were noted by **Deepa Masand et.al**^[9] (2012) and **Satyanarayana V et al**^[10] (2013-2014)

The mean change in hemoglobin level among ferrous sulphate group after three visits was found to be 0.3040 ± 0.23120 gm/dl, while it was 0.5420 ± 0.32013 among ferrous ascorbate group. **Vijaya Manohar Revankar et.al**^[11] (2008-2009) reported the mean Hb rise compared between Ferrous sulphate and Ferrous Ferredetate groups after 1 month of treatment showed statistically very high significant difference and similarly, Hb rise after 2 months of treatment also showed high significant difference. **Savita Rani Singhal et.al**^[12] (2015) also reported that Ferrous ascorbate and ferrous bisglycinate showed significantly ($p < 0.05$) more rise as compared to ferrous sulphate.

SUMMARY & CONCLUSION

Ferrous ascorbate is found better and effective in improving haemoglobin status in pregnant females, with better compliance and less adverse drug reactions than ferrous sulphate. Implementation at large scale may be considered after studying the financial aspect / cost effectiveness and other relevant issues.

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