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A Comparative Study Between Ferric Pyrophosphate And Ferrous Ascorbate In Pregnant Women With Anemia In A Tertiary Care Centre.

Kailashnath BS[1], and Chaitanya Indrani[2]*.

[1]House Surgeon, MVJ Medical College & Research Hospital, Bengaluru, Karnataka, India.
[2]Associate Professor, Department of Obstetrics and Gynaecology, MVJ Medical College & Research Hospital, Bengaluru, Karnataka, India.

ABSTRACT

Iron deficiency anemia (IDA) poses a major challenge among women in reproductive age in India. Oral iron therapy is the treatment of choice; however, the utility of oral iron is limited by gastrointestinal complaints and patients non adherence. To know the compliance and clinical response of oral iron preparations ferrous ascorbate (FA) and liposomal ferric pyrophosphate (FP) in pregnant women with IDA. This is a prospective, comparative, randomized study conducted in Department of Obstetrics and Gynaecology at MVJMC&RH, from June 2022 to June 2023. 120 pregnant women who met the inclusion criteria were enrolled and randomly divided into 2 groups. Group 1 was given FA and Group 2 was given FP. Baseline investigations were done on first visit Day 0 and repeated on Day 30. The outcome on day 30 was documented and statistically analysed. 36.7% in group FA and 6.7% in group FP reported side effects. The association was found to be statistically significant between the two groups. The mean rise in haemoglobin (Hb) between the two groups after was not found to be statistically significant. Our study showed FP as a promising oral preparation with better compliance and low adverse events.

Keywords: Liposomal iron, micro encapsulated, micro ionized, iron deficiency anemia, pregnancy, ferrous ascorbate

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Corresponding author

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INTRODUCTION

Anemia has been a global public health problem, among its various causes iron deficiency anemia is the foremost responsible for half of the burden. The World Health Organization (WHO) defines anemia as hemoglobin (Hb) below 13g/dl for adult males, 12g/dl for non-pregnant adult women and 11g/dl for pregnant women. WHO classifies anemia as mild when Hb is between 10-10.9 g/dl; moderate 7-9.9 g/dl and severe when below 7g/dl [1]. As per National Family Health Survey (NHFS-5) by the Ministry of Health and Family welfare, India. Prevalence of anemia is particularly high among rural women and under privileged women and it has slightly increased by 3% points since NFHS-4.

48% of women in Karnataka (India) have anemia, including 22% with mild, 23% with moderate and 3% severe anemia [2]. Indian government has also implemented programmes like Anemia MUKT Bharath programme and National Nutritional Anemia control program (NNACP) implemented through the Primary Health Center (PHC) to decrease the prevalence and incidence of anemia in women of reproductive age. As we know during singleton pregnancy, maternal plasma volume gradually expands by approximately 50% (1000 ml) but the total RBC mass increases by approximately 300mg (25%) hence hemoglobin and hematocrit levels usually fall during gestation representing physiologic anemia, an alteration which occurs to meet up the increase in fetal demand. Approximately 75% of anemia that occurs during pregnancy is secondary to iron deficiency (ID). In developing nations, like India, it is overwhelming problem due to cultural diversity, traditional practices and individual dietary preferences, and presence of inhibitory ligands like phytates, polyphenols and tannins and phosphates in diet. IDA is caused by either inadequate intake (vegetarian cereal diet) or impaired absorption (Inflammatory Bowel Syndrome), further exacerbated by growth spurt in children or physiological iron demand like pregnancy, lactation. IDA has severe consequences on maternal fetal outcome. Supplementing oral iron preparation is used to correct mild and moderate IDA and parenteral also preferred option for those who are intolerant to oral supplements and near-term pregnant women. There are many bivalent(ferrous salts) and trivalent salts(ferric preparation) among which ferrous ascorbate is used as reference molecule, due to physiological form of ferrous used in combination with ascorbic acid which increases utilization of iron without causing iron overload [3]. With development of micro-ionized dispersible ferric pyrophosphate for food fortification [4] and to overcome the poor tolerability and adverse events of ferrous forms like abdominal pain, diarrhea, constipation upto 40% [5] treatment with ferric salts looked promising. This micro ionized dispersible ferric pyrophosphate (MDFP) showed similar bioavailability like ferrous salts due to its highly micro-ionized particle size and micro encapsulation with phospholipid layer creating a liposomal iron [6].

Our study is observational comparative study to know the compliance and response of ferric pyrophosphate and ferrous ascorbate in pregnant woman with IDA in a tertiary rural centre.

METHODOLOGY

After obtaining the ethical committee approval reference number MVJMC&RH/IEC-05/2022. We have undertaken this study in a rural tertiary care centre at MVJ Medical College and Research Center, which caters to 43 villages in rural Bengaluru. This is a 840 bedded hospital. All pregnant women who attended our outpatient department in the Department of Obstetrics and Gynaecology, who met our inclusion criteria, were informed about the study and enrolled with their consent. This study has been conducted over duration of 12 months from June 2022 to June 2023.

Inclusion criteria: All pregnant women with Mild to Moderate iron deficiency anemia, duration of pregnancy from 12 weeks to 34 weeks of gestation, women consenting for the study.

Exclusion criteria: Duration of pregnancy before 12 weeks, after 34 weeks of gestation, Severe Anaemia, Pregnant women with Co-morbidities, multifetal gestation, Other pharmacological treatment before and during pregnancy were excluded.

The sample size collection was based on a study conducted by Sunitha B H[7]. 120 pregnant women who are between 12-34 weeks of pregnancy and consenting for the study would be divided into 2 groups consisting of 60 women in each group. On the 1st visit, information of the patient was recorded like name, age, demographic characteristics, weight, pulse rate, blood pressure. Her general and obstetrical examination was done. Deworming done to all the participants with 400mg Albendazole, as

anemia is mostly related to parasitic infections (malaria, intestinal worms).[25] Her dietary history was noted in detail and advice regarding iron rich diet was given. All participants were explained about the study, need for repeating investigations on 1st visit(D0) and Day 30(D30). Base line investigations done on Day 0(first antenatal visit) included peripheral smear (with Leishman's stain) to assess the type of anemia, complete blood count (CBC) with indices and reticulocyte count for all participants. After which the intervention was given by nurse in a sequentially numbered sealed envelopes, both principle investigator and participant, analyst were unaware of the intervention given, hence triple blinded prospective study. Group 1 will be given Ferrous ascorbate (FA) which contains 100mg elemental iron. Group 2 will be given Emulsified Ferric pyrophosphate (FP) which contains 30mg elemental iron and the participants were asked to take tablet between meals and not to drink tea or coffee before or after taking tablet.

All patients will be followed up telephonically weekly once for 4weeks to ensure compliance and record any adverse effects, and reminder call given one day prior to repetition of test(D30). On D30 the participants were examined clinically, CBC with indices, reticulocyte count repeated. Those who reported no side effects and compliant with therapy were asked to continue the same intervention and those who experienced nausea, vomiting, abdominal pain, intolerance or any other gastrointestinal side effects like gastritis, diarrhea, constipation, dark stained stools, intervention stopped and switched to the other intervention. Participants were encouraged to come over for regular antenatal visits to note sustained improvements in subsequent visits. Response to the therapy was concluded, when overall outlook of the patient improved like general wellbeing, increased appetite, hematological parameters like increase haemoglobin values and reticulocyte count. The collected data will be analysed statistically to evaluate the response of ferric pyrophosphate and ferrous ascorbate in treatment of iron deficiency anaemia. The primary outcome of the study is compliance to intervention and the secondary being the response.

Intervention given

Group 1- Ferrous Ascorbate (100mg Iron) + 1.5mg Folic Acid
Group 2- Emulsified ferric pyrophosphate (30mg Iron) + 10 mg Glycine+ 250mcg Folic Acid

RESULTS

Group 1: Ferrous Ascorbate (FA),
Group 2: Ferric Pyrophosphate (FP)

Table 1: Age Group

AGE GROUP		GROUP			P VALUE
		1(FA)	2(FP)	Total	
20-25	Count	28	27	55	1.000
	%	46.7%	45.0%	45.8%	
26-30	Count	12	13	25	
	%	20.0%	21.7%	20.8%	
31-35	Count	14	13	27	
	%	23.3%	21.7%	22.5%	
36-40	Count	6	7	13	
	%	10.0%	11.7%	10.8%	
MEAN ± SD		27.72±4.975	27.77±5.469	27.75±5.31	

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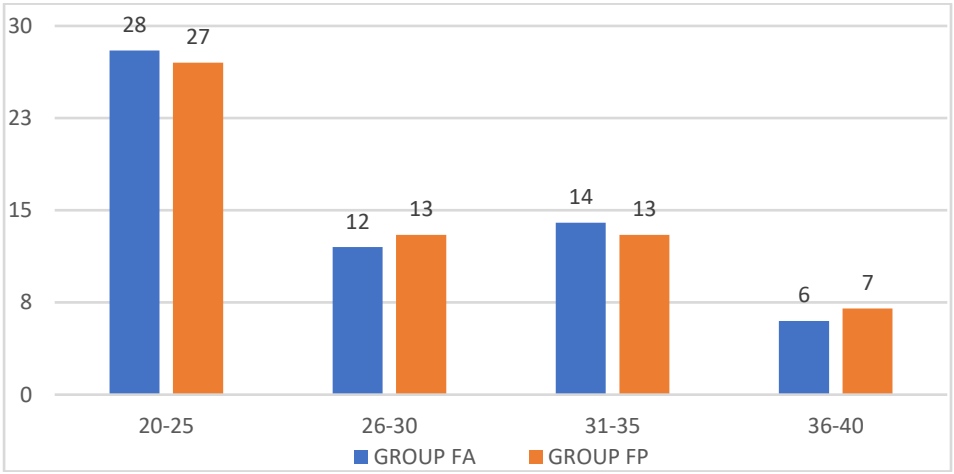
Figure 1: Age Group

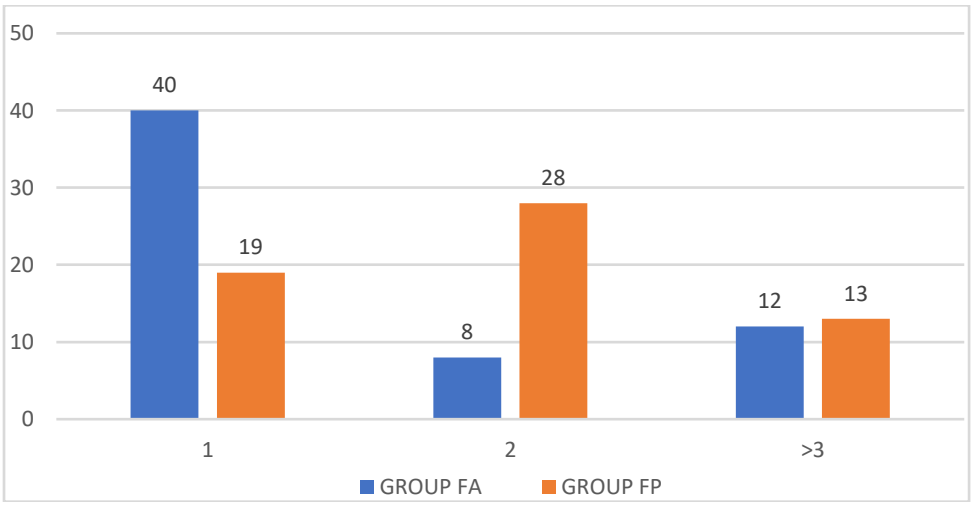


46.7% of the study participants in group FA belonged to the age group FP 0-25 years. 45.0% of the study participants in group FP belonged to the age group FP 0-25 years. The mean age of study participants in group FA and FP were found to be 27.72±4.975 and 27.77±5.469 respectively. The association was not found to be statistically significant between the age and the 2 groups of study participants.

Table 2: GRAVIDA

GRAVIDA		GROUP		Total	P VALUE
		1(FA)	2(FP)		
1	Count	40	19	59	0.387
	%	66.7%	31.7%	49.2%	
2	Count	8	28	36	
	%	13.3%	46.7%	30.0%	
≥3	Count	12	13	25	
	%	20.0%	21.6%	20.9%	

Figure 2: GRAVIDA



66.7% of the study participants in group FA were gravida 1. 46.7% of the study participants in group FP were gravida 2. The association was not found to be statistically significant between gravida and the 2 groups of study participants.

Table 3: Laboratory Parameters Before And After Treatment

LABORATORY PARAMETERS			Mean	Std. Deviation	P VALUE
Hb	BEFORE TREATMENT	1(FA)	9.243	1.3480	0.793
		2(FP)	9.178	1.3611	
	AFTER TREATMENT	1(FA)	10.245	1.4907	0.360
		2(FP)	10.493	1.4713	
PCV	BEFORE TREATMENT	1(FA)	27.72	4.04	0.793
		2(FP)	27.53	4.08	
	AFTER TREATMENT	1(FA)	30.735	4.4721	0.318
		2(FP)	31.540	4.3215	
MCV	BEFORE TREATMENT	1(FA)	79.677	4.4455	0.911
		2(FP)	79.585	4.4768	
	AFTER TREATMENT	1(FA)	82.32	5.177	0.264
		2(FP)	83.43	5.703	
MCH	BEFORE TREATMENT	1(FA)	24.493	3.3939	0.857
		2(FP)	24.382	3.3899	
	AFTER TREATMENT	1(FA)	26.320	3.8574	0.526
		2(FP)	26.763	3.7860	
MCHC	BEFORE TREATMENT	1(FA)	28.033	4.6951	0.896
		2(FP)	27.922	4.6753	
	AFTER TREATMENT	1(FA)	31.327	4.3990	0.899
		2(FP)	31.422	3.7367	
RC	BEFORE TREATMENT	1(FA)	1.3532	0.34779	0.757
		2(FP)	1.3337	0.34124	
	AFTER TREATMENT	1(FA)	1.6393	0.31434	0.952
		2(FP)	1.6362	0.26450	

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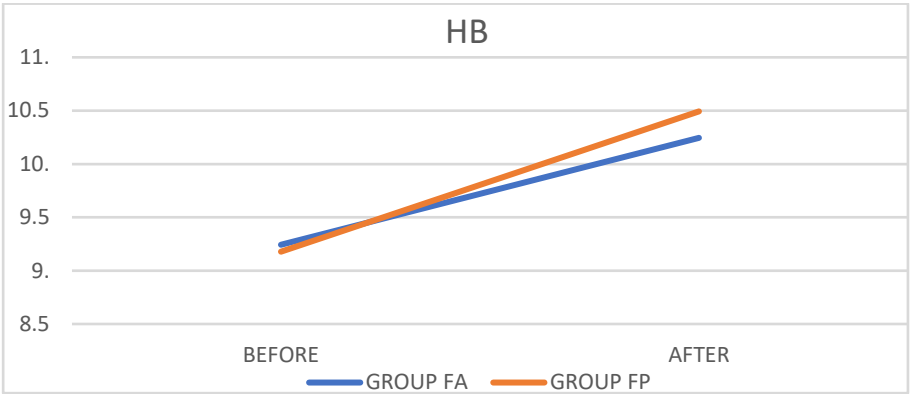
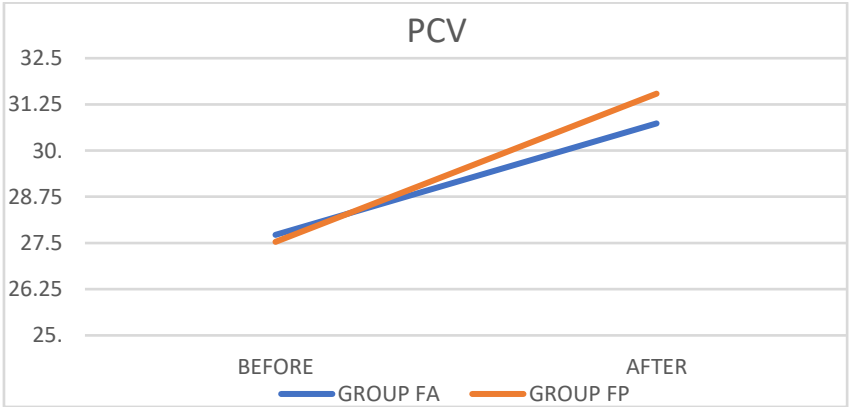
Figure 3A: Haemoglobin (Hb)



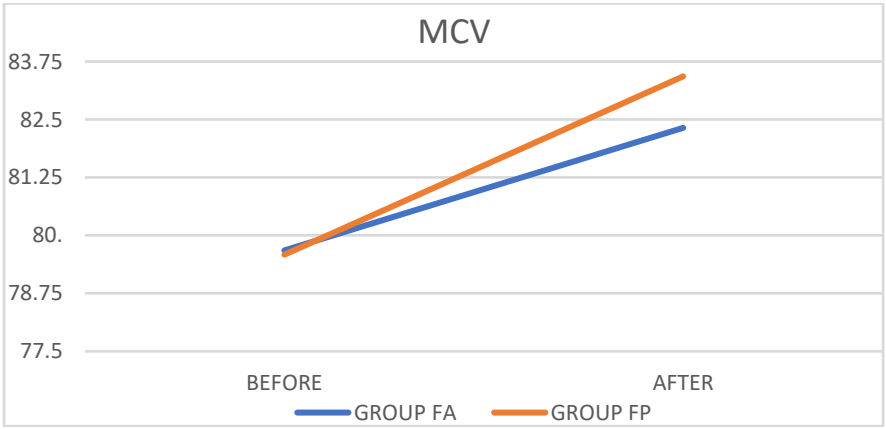
The mean Hb of study participants before treatment in group FA and FP were found to be 9.243±1.3480 and 9.178±1.3611 respectively. The mean Hb of study participants after treatment in group FA and FP were found to be 10.245±1.4907 and 10.493±1.4713 respectively. The association was not found to be statistically significant between Hb before and after treatment and the 2 groups of study participants.

Figure 3b: Packed Cell Volume(PCV)



The mean PCV of study participants before treatment in group FA and FP were found to be 27.72±4.04 and 27.53±4.08 respectively. The mean PCV of study participants after treatment in group FA and FP were found to be 30.735±4.4721 and 31.540±4.3215 respectively. The association was not found to be statistically significant between PCV before and after treatment and the 2 groups of study participants.

Figure 3C: Mean Corpuscular Volume(MCV)



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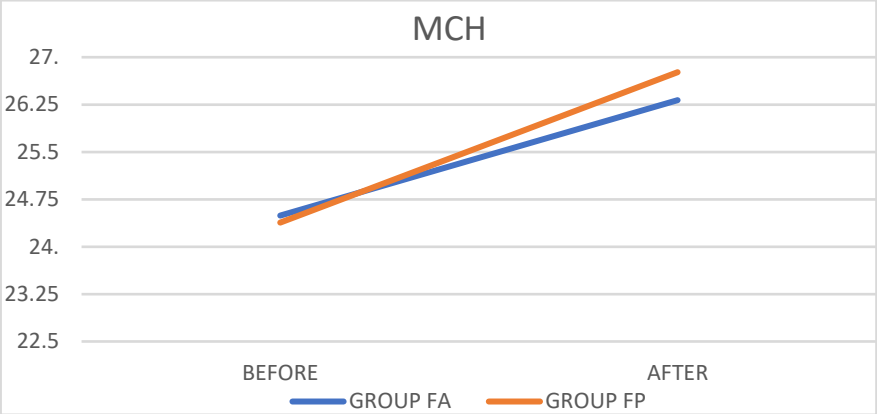
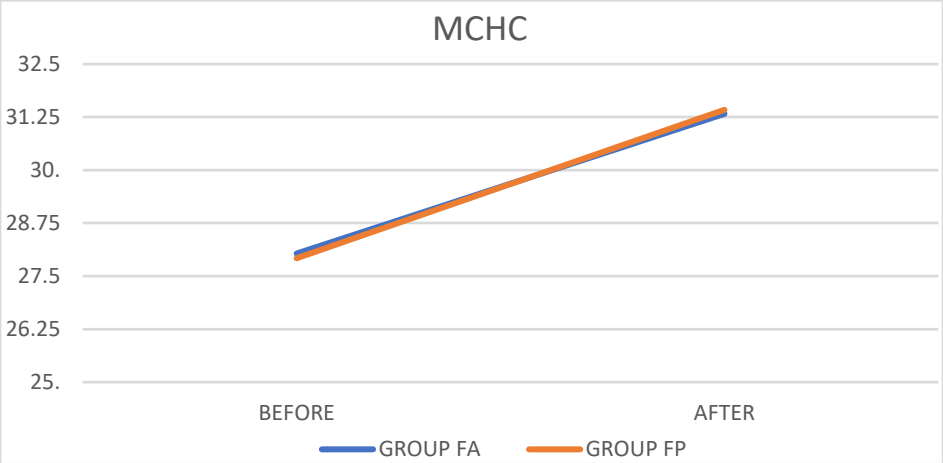
The mean MCV of study participants before treatment in group FA and FP were found to be 79.677±4.4455 and 79.585±4.4768 respectively. The mean MCV of study participants after treatment in group FA and FP were found to be 82.32±5.177 and 83.43±5.703 respectively. The association was not found to be statistically significant between MCV before and after treatment and the 2 groups of study participants.

Figure 3D: Mean Corpuscular Haemoglobin (MCH)



The mean MCH of study participants before treatment in group FA and FP were found to be 24.493±3.3939 and 24.382±3.3899 respectively. The mean MCH of study participants after treatment in group FA and FP were found to be 26.320±3.8574 and 26.763±3.7860 respectively. The association was not found to be statistically significant between MCH before and after treatment and the 2 groups of study participants.

Figure 3E: Mean Corpuscular Haemoglobin Concentration (MCHC)



The mean MCHC of study participants before treatment in group FA and FP were found to be 28.033±4.6951 and 27.922±4.6753 respectively. The mean MCHC of study participants after treatment in group FA and FP were found to be 31.327±4.3990 and 31.422±3.7367 respectively. The association was not found to be statistically significant between MCHC before and after treatment and the 2 groups of study participants.

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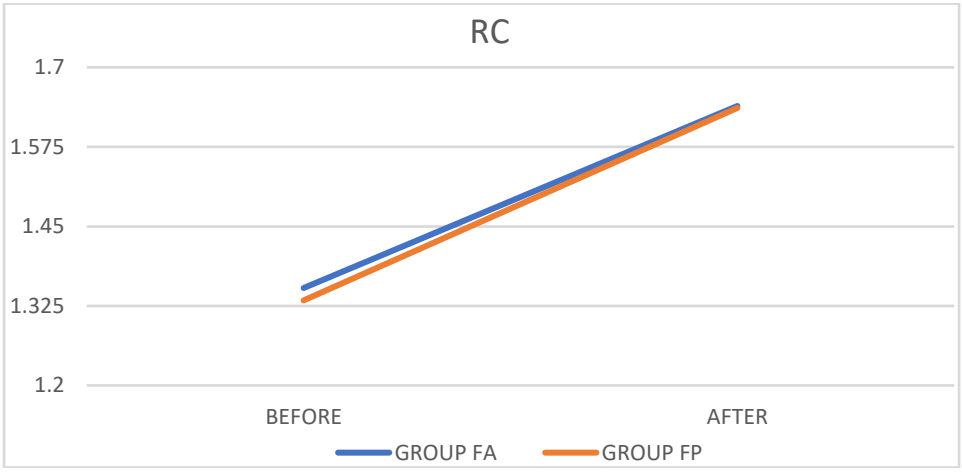
Figure 3F: Reticulocyte Count (RC)



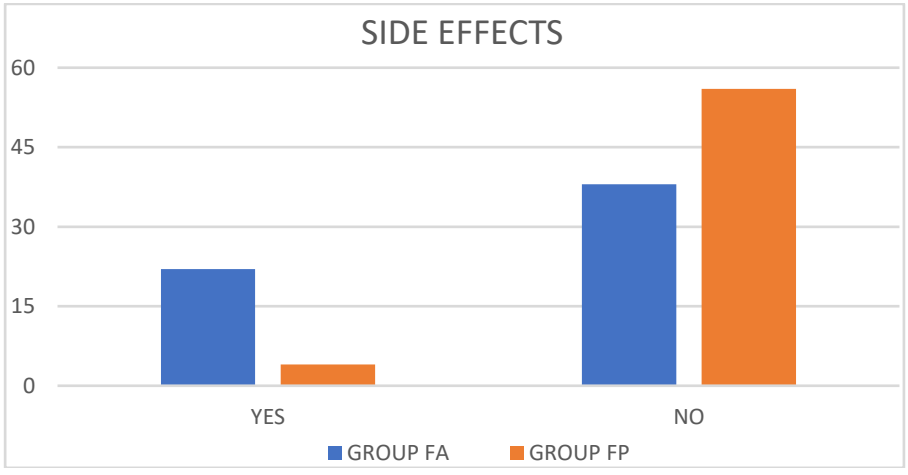
The mean RC of study participants before treatment in group FA and FP were found to be 1.3532±0.34779 and 1.3337±0.34124 respectively. The mean RC of study participants after treatment in group FA and FP were found to be 1.6393±0.31434 and 1.6362±0.26450 respectively. The association was not found to be statistically significant between RC before and after treatment and the 2 groups of study participants.

Table 4: Side Effects

SIDE EFFECTS		GROUP		Total	P VALUE
		1(FA)	2(FP)		
YES	Count	22	4	26	0.000
	%	36.7%	6.7%	21.7%	
NO	Count	38	56	94	
	%	63.3%	93.3%	78.3%	

36.7% of the study participants in group FA were having side effects. 6.7% of the study participants in group FP were having side effects. The association was found to be statistically significant between side effects in the two study groups.

Figure 4: Side Effects



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The notable side effects in group FA were found to be black coloured stools, constipation, diarrhea, vomiting.

The notable side effects in group FP were found to be mild gastric irritation perceived as mild epigastric pain.

The intervention was not stopped and no crossover was done.

Table 4A: Specific Side Effects Observed

SIDE EFFECTS		GROUP		Total	P VALUE
		1	2		
ACIDITY	Count	3	0	3	0.000
	%	5.0%	0.0%	2.5%	
BLACK COLOURED STOOLS	Count	4	0	4	
	%	6.7%	0.0%	3.3%	
CONSTIPATION	Count	4	0	4	
	%	6.7%	0.0%	3.3%	
DIARRHOEA	Count	4	0	4	
	%	6.7%	0.0%	3.3%	
MILD GASTRIC IRRITATION	Count	0	4	4	
	%	0.0%	6.7%	3.3%	
NAUSEA	Count	3	0	3	
	%	5.0%	0.0%	2.5%	
VOMITTING	Count	4	0	4	
	%	6.7%	0.0%	3.3%	

DISCUSSION

The goal of therapy for IDA is to normalize hemoglobin levels and replenish iron stores while also correcting pathways that cause iron loss or malabsorption. Iron deficiency treatment should start with dietary recommendations (eating iron-rich foods), however, iron supplement therapy should be initiated when dietary changes alone are insufficient to replenish iron stores and normalize hemoglobin levels, or in cases of severe anemia.

The first-line treatment for iron deficiency should be oral iron. Oral iron therapy is known for causing constipation, heartburn, diarrhea, nausea, and epigastric pain in approximately 20% of patients, which may limit compliance with oral iron intake. Unfortunately, taking iron orally with meals to reduce gastrointestinal upset reduces iron absorption by up to 50.[8] Intravenous iron therapy has been recommended in cases of intolerance to or contraindications to oral iron, severe anemia, particularly if accompanied by significant ongoing bleeding (when iron loss exceeds that which can be met by oral therapy), inflammatory diseases, and patients with IDA scheduled for elective surgery [9, 10]. In view of this, the present study was undertaken.

In our study, 46.7% of the study participants in group FA and 45% in group FP belonged to the age group 20-25 years. The mean age of study participants in group FA and FP were found to be 27.72$\pm$4.975 and 27.77$\pm$5.469 respectively. Sunitha BH et al in their study found that the characteristics

of patients in IV group and oral group were statistically comparable in relation to age with majority of women in the age group of 21-25 years [7]. Bhavi SB et al in their study found that 52% of patients were between 21-25 years [11] and Shafi D et al in their study found that the mean age of study participants in IV and Oral group were 24.30 ± 3.98 years and 24.09 ± 3.84 years [12]. These findings correlate with the findings of the present study. An estimate by the World Health Organization (WHO) that over half a billion women (29.9%) or in reproductive age 15–49 years suffered from anemia in 2019 mostly attributed to ID [13, 14]. Reproductive and adolescent women are more prone to anemia due to insufficient dietary intake and iron loss during menstruation and pregnancy [15].

In our study, 66.7% of the study participants in group FA were gravida 1 and 46.7% of the study participants in group FP were gravida 2. Sunitha BH et al in their study found that in IV group 46% were Gravida 1 and in the oral group 38% were Gravida 1 [7]. The incidence of anemia in pregnancy was seen to increase as the parity level of the women increased in a study done by Ramesh BH [16].

Different hematological parameters like hemoglobin, anemic indices (MCV, MCH and MCHC) and biochemical parameter like serum ferritin was also used to diagnose the anemia, determine its severity and low iron store. In our study, the mean Hb of study participants before treatment in group FA and FP were found to be 9.243$\pm$1.3480 and 9.178$\pm$1.3611 respectively. The mean Hb of study participants after treatment in group FA and FP were found to be 10.245$\pm$1.4907 and 10.493$\pm$1.4713 respectively. The association was not found to be statistically significant between Hb before and after treatment in both the groups. FP group showed higher rise in hemoglobin levels during the follow-up. Sunitha BH et al in their study found that the mean baseline hemoglobin was 8.52 and 8.73g/dl in IV group and oral group respectively and the post treatment hemoglobin was 11.45 and 10.8 g/dl in IV group and oral group respectively [7]. Bhavi SB et al in their study found that Hemoglobin increase was observed in group A (oral iron) rising from 9.14 ± 0.11 to 10.65 ± 1.03 as well as in group B (Intravenous iron) rising from 8.9 ± 10.7 to 10.64 ± 13 g/L after 4 weeks. The change in Hb % in I.V group was significantly higher in comparison with Oral group [11]. Hemoglobin levels were increased more in the intravenous group than the oral group in a study done by Shafi D et al [12].

In our study, the mean PCV of study participants before treatment in group FA and FP were found to be 27.72$\pm$4.04 and 27.53$\pm$4.08 respectively and the mean PCV post treatment in group FA and FP were found to be 30.735$\pm$4.4721 and 31.540$\pm$4.3215. The association was not found to be statistically significant. Sunitha BH et al in their study found that the mean baseline PCV was 26.64% and 26.81% in IV group and oral group respectively and the post treatment PCV after 4 weeks showed a mean value of 29.75% and 29.7% IV group and oral group respectively.[7]A parallel improvement in haematological parameters among the 2 groups were noted in our study.

In our study, 36.7% in group FA and 6.7% in group FP reported side effects. The association was found to be statistically significant between the 2 study groups. 27 women in the oral group reported gastrointestinal symptoms in a study done by Shafi D et al [12]. Antonio Pisani et al in their study of "Effect of liposomal iron versus intravenous iron for treatment of IDA in chronic kidney disease patients", reported 3.1% of adverse events in subjects taking oral liposomal iron($p<0.001$) [17]. The treatment with oral and parenteral iron preparations improves availability of elemental iron for erythropoiesis and that improves signs and symptoms of anemia [18]. Cançado RD et al in his study demonstrated that IV iron sucrose administration is well tolerated with a safety profile and effective in increasing Hb levels and restoring body iron in adult patients with IDA [19]. Pregnant women with IDA treated with IV iron restored iron stores faster and more effectively than oral iron, with no serious adverse reactions [20]. But several studies have also shown conflicting results regarding the impact of iron on renal function, in fact have suggested that IV iron therapy may adversely affect renal tubular function and increase proteinuria. Iron produces oxidative stress that is associated with transient proteinuria and tubular damage [17, 21, 22].

Ferrous ascorbate being a synthetic iron molecule with ascorbate, a reducing agent, reduces iron in highly soluble ferrous form and enhances its absorption from gastrointestinal tract [3, 23]. Oral iron though found effective, safe, low cost, but it may fail in efficacy due to noncompliance, achlorhydria, inflammatory bowel diseases, or unrecognized bleeding. Savita et al compared five different oral iron salts in pregnant women with IDA. Maximum side effects was observed with ferrous fumarate followed by ferrous sulphate, bisgylcinate, ascorbate, sodium feredetate. Ferrous ascorbate and bisglycinate were more effective than ferrous sulphate in treatment of IDA [24].

Tolkien et al in his systematic review and meta analysis, involving 20 trials(n=3168) had a placebo arm and 23 trials(n=3663) had an active comparator arm of intravenous iron. Ferrous sulfate supplementation significantly increased risk of GI side effects versus placebo with an odd's ratio (OR) of 2.32[95%CI 1.74–3.08, p<0.0001, I2 = 53.6%] and versus IV iron with an OR of 3.05 [95% CI 2.07-4.48, p<0.0001, I2 = 41.6%]. The most commonly reported symptoms were constipation, nausea and diarrhea. 27 studies that reported constipation, the pooled estimate of incidence in the FeSO4 arm was 12% [95% CI 10%-15%]. Similarly, for the 30 studies that reported nausea the pooled estimate of incidence in the FeSO4 arm was 11% [95% CI 8%-14%] and for the 25 studies that reported diarrhea the pooled estimate of incidence was 8% [95%CI 6%-11%] [25]. Micro ionized dispersible ferric pyrophosphate has been developed for food fortification (Sunactive Fe ™; Taiyo Kagaku (Yokkaichi, Japan) [26]. Oral liposomal iron is not inferior to IV iron preparation to correct anemia. It avoids patient admission to hospital, need for dedicated personnel to administer IV preparation, loss of working hours, travel expenses, which is more expensive option than oral iron administration. Besides it was well tolerated and the compliance was very good if compared with other oral iron salts [17]. Liposomal encapsulation technology (LET) is the newest delivery technique used by medical investigators. Micro ionization and micro encapsulation increase the surface area, solubility provide resistance to degradation of iron from enzymes in mouth and stomach, interaction with alkaline juices, bile salts, intestinal flora and protection from free radicals by liposomes, assisting in targeted delivery [27]. In vitro study by Brille, stated direct absorption of FP via microfilm cells (M cells) in payers patches bypassing conventional routes of absorption. Hence, high bioavailability [28]. Biniwale et al in his study extensively described sophisticated technological details of liposomal iron and vouched for the safety profile of FP which is USFDA approved for food additive. Current clinical evidence suggests no major untoward effects in pregnant and non-pregnant women by FP [29].

In another Romanian study 30 post-menopausal females were supplemented with Turbofer twice daily for 8 weeks, did not cause stomach upset and constipation. Liposomal iron led to higher bioavailability and was well tolerated. The most frequent side effects recorded was stool colouring, evaluated as mild in a 5-points Likert scale. It had no impact on bowel function or treatment efficacy [30].

Parisi et al in his study, evaluated different doses of liposomal iron in comparison to ferrous sulphate. The study concluded changes in hematological parameters seen with 30mg of ferrous sulphate were equivalent to that seen with 14mg of liposomal iron. Hence, low dose of liposomal iron has high bioavailability [31]. Uzma Hussain et al in her study of 12 weeks duration supplemented a sachet of (Ferfer) FP twice daily and assessed the efficacy in non-pregnant women with IDA, the mean taste tolerability also improved throughout the study period from 3.93±5.93 to 4.05±0.88 [32]. Right selection of iron preparation is very critical to get the maximum benefits in the patients.[3]

CONCLUSION

Pregnant women with IDA showed increased adherence to intervention and compliance to micro encapsulated liposomal iron ferric pyrophosphate when compared to ferrous ascorbate which can be supplemented to rural population.

Limitation

Our study has small sample size and short duration of intervention, and serum ferritin levels could not be assessed which represent body iron stores.

Scope of future Research

Further large trial are required comparing FP with other iron salts and with parenteral iron which might prove to be a safe alternative option in pregnant patients with IDA.

Abbreviations

FA- FERROUS ASCORBATE,
FP- FERRIC PYROPHOSPHATE,
IDA- IRON DEFICIENCY ANEMIA,
ID- IRON DEFICIENCY,
USFDA- UNITED STATES FOOD AND DRUG ADMINISTRATION

IV- INTRAVENOUS

Ethical approval

The study was approved the Institutional Ethics Committee MVJ Medical College and Research Hospital. Reference number MVJMC&RH/IEC-05/2022.

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