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RESEARCH ARTICLE

COMPARISON OF FERROUS SULPHATE WITH COLLOIDAL IRON IN THE TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN

Dr. Prajwala B.A¹ and Dr. Premalatha R.²

1. Resident of Department of Paediatrics at MVJMC and RH.
2. HOD and Professor of Department of Paediatrics at MVJMC and RH.

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Abstract

Background: Anemia is a major health problem throughout the world and children under 5 years of age are at highest risk. Nutritional deficiency is the most common cause of anemia in children under 2 years of age due to high rate of growth and increased demand of iron, vitamin B12 and folic acid. According to WHO, 1 out of every 2 pre-school children are suffering from IDA in developing countries. Different oral iron preparations are available to treat IDA. Hence, this study was done to compare the therapeutic efficacy and side effects of ferrous sulphate with colloidal iron in the treatment of IDA in children.

Objectives:

1. To compare the therapeutic efficacy of ferrous sulphate with colloidal iron in the treatment of IDA in children aged 6 months to 18 years.
2. To compare the side effects between the two groups.

Methods: This randomized control study was conducted in MVJ medical college and research hospital, Hoskote, Bangalore. Eligible children were randomized to 2 groups. Group A consisting of 75 children were given ferrous sulphate in a dose of 3mg/kg/day of elemental iron once daily for 4 weeks. Group B consisting of 75 children were given colloidal iron in a dose of 3mg/kg/day of elemental iron once daily for 4 weeks. Reticulocyte count between the two groups was checked at the end of one week and haemoglobin at the end of one month. Side effects and compliance of the two iron formulations were checked on followup.

Results: The mean rise in the reticulocyte count at the end of 1 week is higher in colloidal iron in comparison to ferrous sulphate group. The mean rise in haemoglobin at the end of one month is more in colloidal iron compared to ferrous sulphate group, however the difference is not statistically significant. Compliance with colloidal iron is better than ferrous sulphate group, as nausea is comparatively more with ferrous sulphate group which attributed to decreased compliance which is statistically significant.

Conclusion: Colloidal iron and ferrous sulphate are found to be equally efficacious in the treatment of iron deficiency anemia. However, owing to its good compliance and lesser GI side effects,

Corresponding Author:- Dr. Prajwala B.A

Address:- Resident of Department of Paediatrics at MVJMC and RH.

colloidal iron is found to be preferable over ferrous sulphate. Hence, the study suggests the use of colloidal iron to treat IDA in children between 6 months to 18 years.

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Introduction:-

Anemia is a major health problem throughout the world and children under 5 years of age are at highest risk. Anemia is defined as a haemoglobin level that is two standard deviations below the mean for age and sex. According to WHO, 1 out of every 2 pre school children are suffering from IDA in developing countries. In India in the year 2019, 58.5% of children in the age group of 6-59 months had IDA. Oral iron preparations are available in the form of ferrous and ferric salts.

Ferric forms are poorly soluble in acidic medium. Various ferrous salts available are ferrous Sulphate (hydrated salt 20%, dried salt 32% iron), ferrous ascorbate (14% iron), ferrous gluconate (12% iron), ferrous fumarate (33% iron). Absorption from chelated iron is four times higher than ferrous sulfate. Colloidal iron has more iron content than ferrous salt and better tolerability with lesser side effects but rise of hemoglobin with it is still not assured. It is very much important to treat anemia with the effective drug to prevent series of events occurring due to it. Ferrous sulphate and colloidal iron formulations have been widely used in the treatment of iron deficiency anemia due to its high effectiveness and easy availability.

As there is paucity of studies directly comparing ferrous sulphate and colloidal iron in pediatric age group, this study was undertaken with the aim to compare oral ferrous sulfate and colloidal iron in the treatment of iron deficiency anemia in terms of safety and efficacy.

Aims And Objectives:-

1. To compare the therapeutic efficacy of ferrous sulphate with colloidal iron containing ferric hydroxide in the treatment of iron deficiency anemia in children aged 6 months to 18 years.
2. To compare the side effects between the 2 groups.

Research Methodology:-

Patients between the age group of 6 months to 18 years who visited MVJMC and RH on OPD basis or who were admitted at MVJMC and RH, diagnosed with iron deficiency anemia based on clinical presentation and laboratory findings (complete blood count) were taken up for the study. A total of 150 cases were taken up for the study. A detailed history including the birth history and feeding history was noted. Eligible children were randomized to 2 groups using computer generated table of random number. Group A was given ferrous sulphate at a dose of 3mg/kg/day of elemental iron once daily for 4 weeks orally in syrup form.

Group B was given colloidal iron containing ferric hydroxide at a dose of 3mg/kg/day of elemental iron once daily for 4 weeks orally in syrup form. Both groups were also given diet advice and B-complex supplements. The patients were asked to return for follow-up after 1 week for reticulocyte count. Compliance and side effects were checked by verbal enquiry. Verification was done by checking the used bottles. A repeat hemoglobin was done at the end of 1 month. Rise in hemoglobin, compliance and side effects were compared between the groups.

Statistical Methods:-

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. **Chi-square test or Fischer's exact test** (for 2x2 tables only) was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. **Independent t test or Mann Whitney U test** was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively.

Inclusion Criteria:

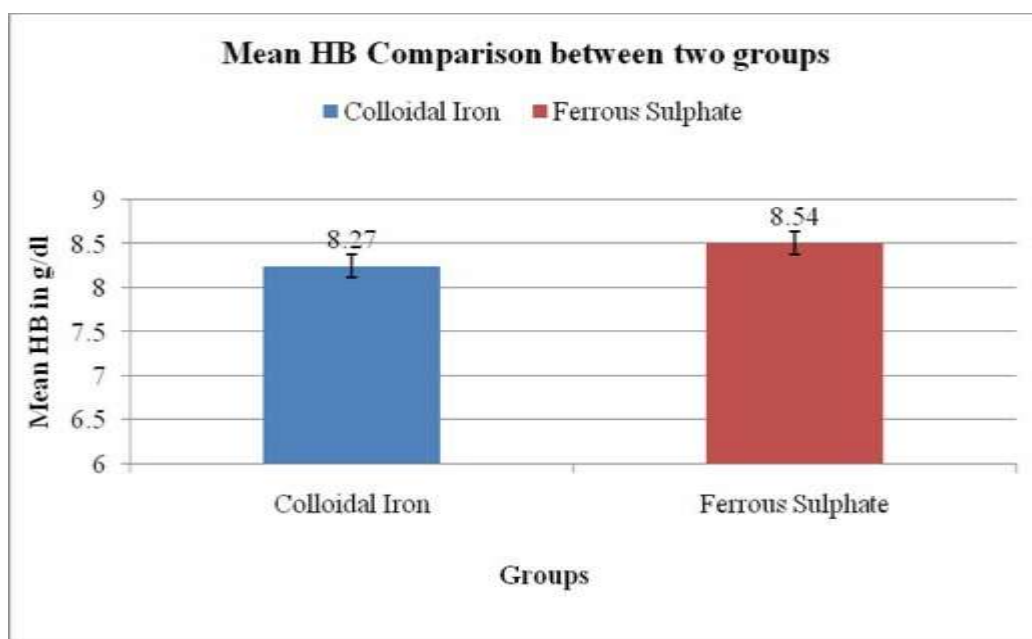
All OPD and admission cases at MVJ hospital aged between 6 months to 18years who are diagnosed as Iron deficiency anemia based on clinical and laboratory parameters (Complete blood count)

Exclusion Criteria:

1. Severe concurrent illness (cardiovascular, renal, hepatic)
2. Ongoing blood loss (epistaxis, GI blood loss)
3. Co-morbidities affecting the absorption (malabsorption, celiac disease)

Results:-**Comparing baseline haemoglobin between two groups :**

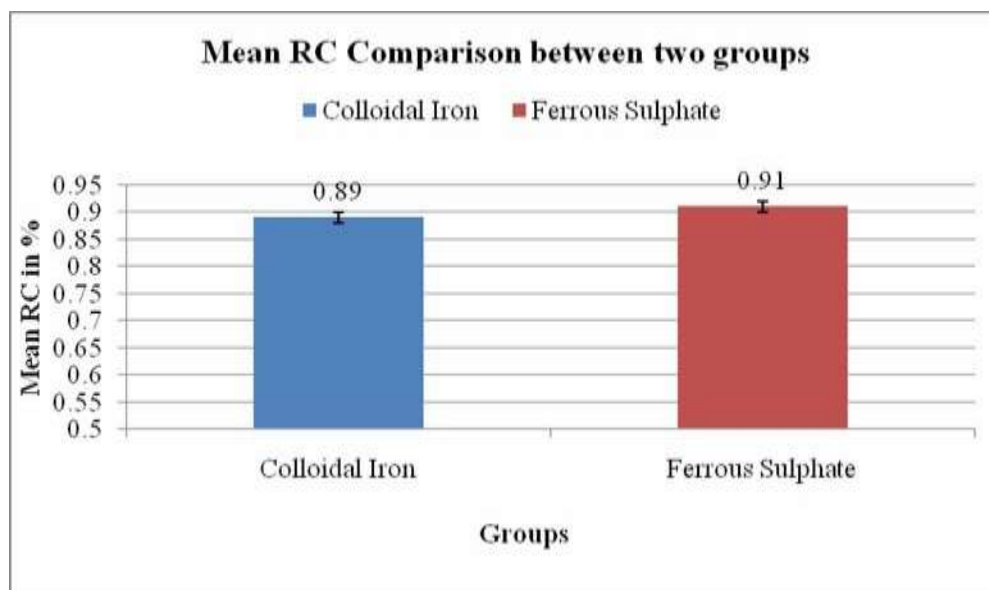
	Group				pvalue
	ColloidalIron		FerrousSulphate		
	MeanHBing/dl	SD	MeanHBing/dl	SD	
HB	8.27	1.98	8.54	1.86	0.497
TOTAL	75		75		

**Bar diagram showing Mean HB Comparison between two groups**

Mean baseline haemoglobin in colloidal iron group was 8.27 ± 1.98 and in ferrous sulphate group was 8.54 ± 1.86 . Hence, the baseline hemoglobin was not statistically significant before the start of the treatment.

Mean baseline reticulocyte count comparison between two groups:

1)	Colloidal Iron		Ferrous Sulphate		
	Mean RC in %	SD	Mean RC in %	SD	
RC	0.89	0.44	0.91	0.7	0.848
TOTAL	75		75		

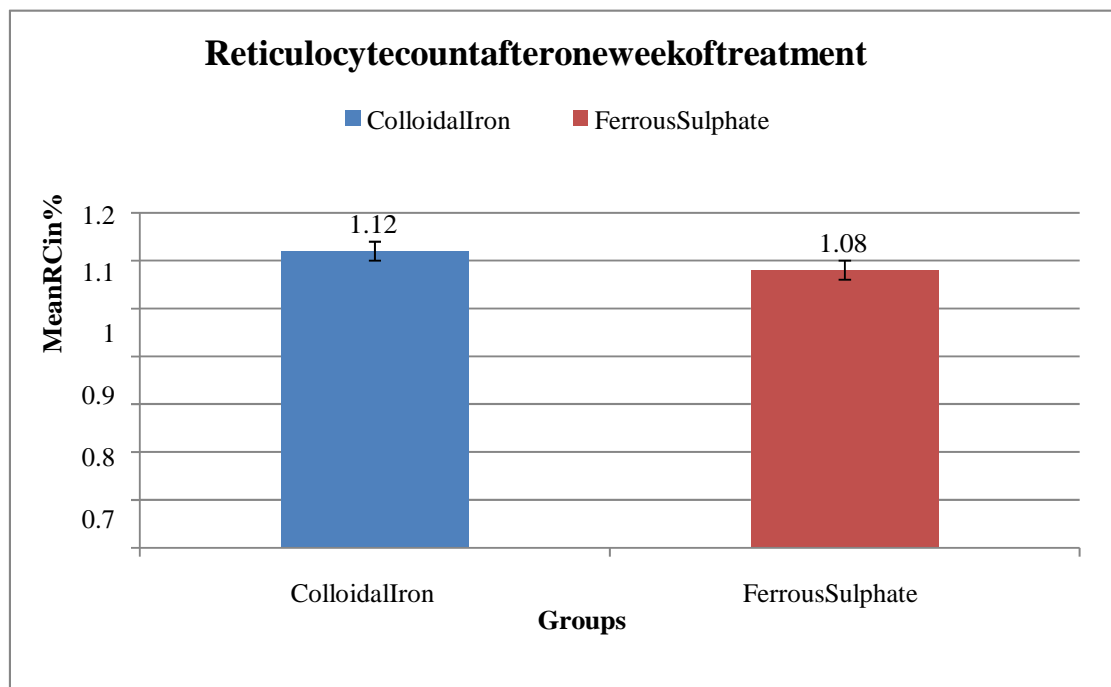


Bar diagram showing Mean RC Comparison between two groups

Mean baseline reticulocyte count in colloidal iron group was 0.89 ± 0.44 and in ferrous sulphate group was 0.91 ± 0.7 . Hence mean baseline reticulocyte count was not statistically significant.

Mean reticulocyte count after 1 week of treatment :

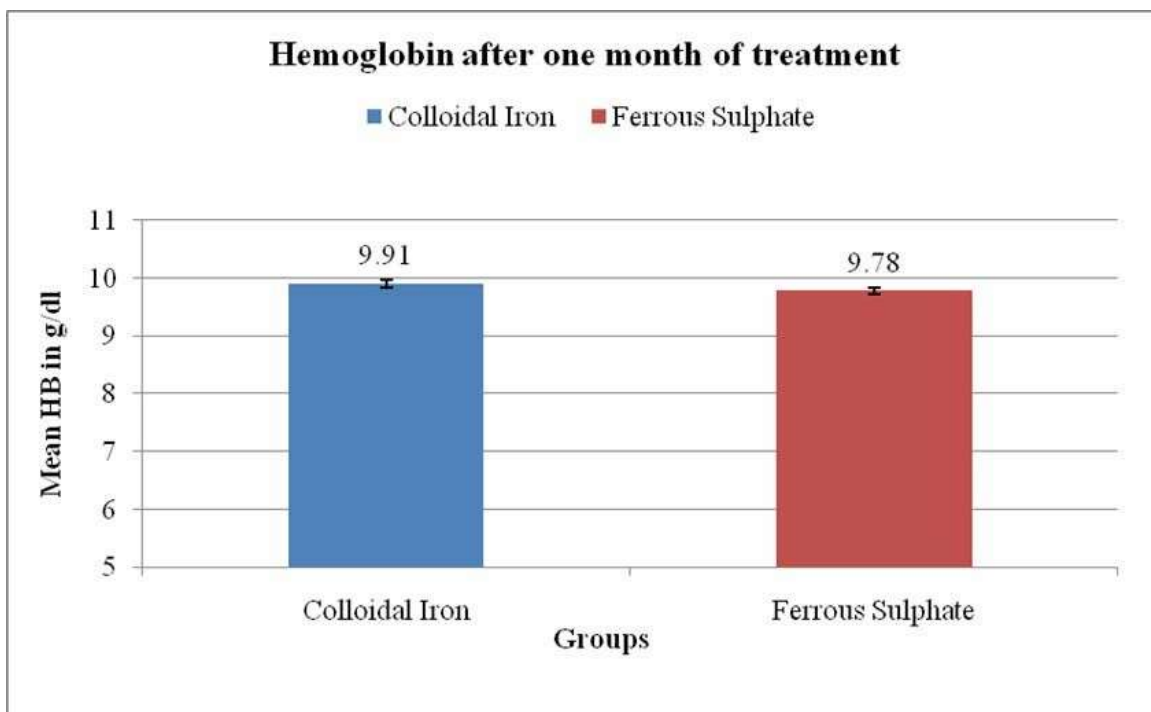
	Group				pvalue
	ColloidalIron		FerrousSulphate		
	MeanRCin%	SD	MeanRCin%	SD	
F/URC	1.12	0.49	1.08	0.59	0.748
TOTAL	75		75		



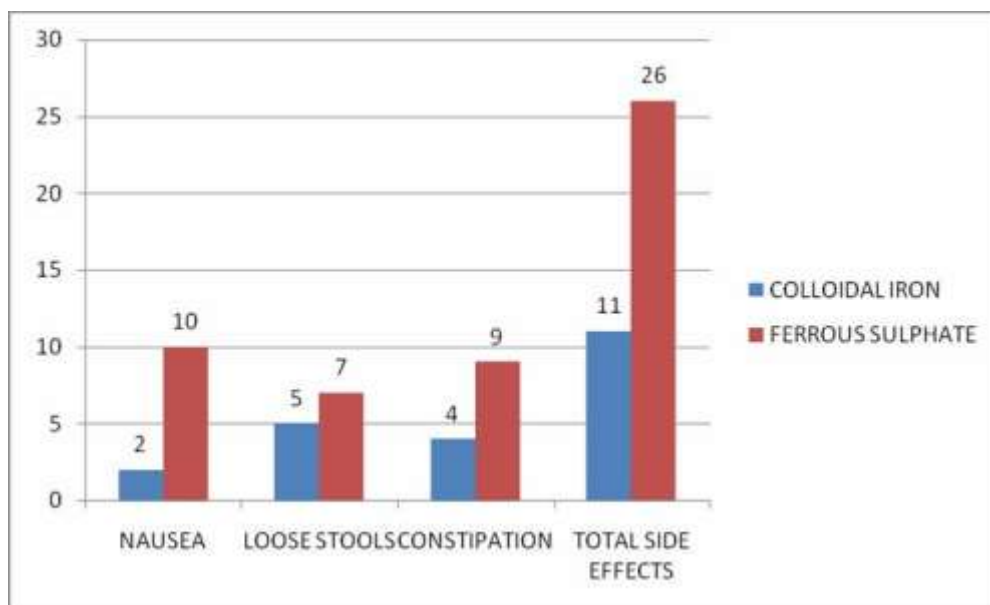
Bar diagram showing Mean F/URC Comparison between two groups

Mean follow-up HB after 1 month of treatment:

	Group				pvalue
	ColloidalIron		FerrousSulphate		
	MeanHBIng/dl	SD	MeanHBIng/dl	SD	
F/UHB1m	9.91	1.75	9.78	1.73	0.689
TOTAL	75		75		

**Bar diagram showing Mean F/U HB 1 month comparison between two groups****Comparison of side effects between two groups:**

		Group				p value
		ColloidalIron		FerrousSulphate		
		Count	ColumnN%	Count	ColumnN%	
Sideeffect	Nausea	2	2.60%	10	13.00%	0.025*
	Loosestools	5	6.600%	7	9.3.00%	0.543
	Constipation	4	5.30%	9	12.00%	1.000
Totalsideeffects		11	14.5%	26	34.3%	0.151

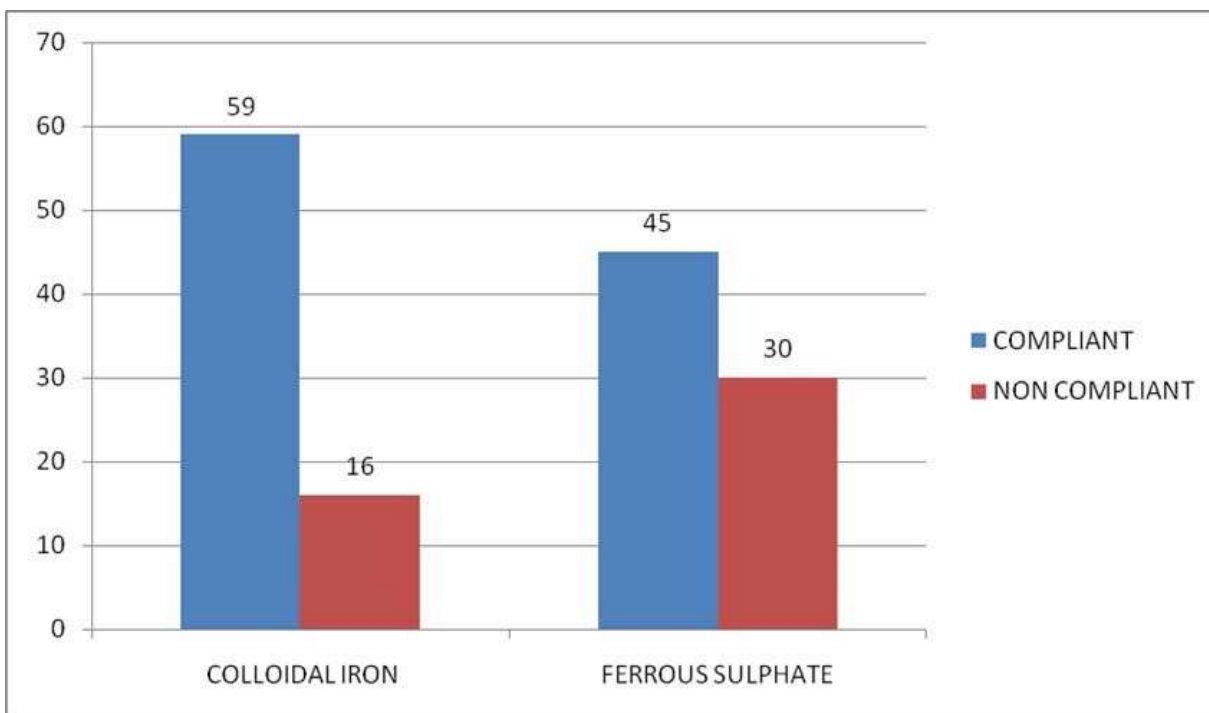


Bar Diagram Showing Side Effects Distribution between two groups .

On comparing the side effects, it was found that total percentage of side effects in colloidal iron group was 14.5% and in ferrous sulphate group was 34.3% but the difference was not statistically significant except nausea, where more participants in ferrous sulphate group developed nausea which was statistically significant.

Compliance between two groups :

		Colloidal Iron		Ferrous Sulphate		
		Count	Column N%	Count	Column N%	
Compliance	Compliant	59	78.00%	45	60.00%	
	Noncompliant	16	21.00%	30	44.00%	0.013



Bar Diagram Showing Compliance Distribution between two groups.

Out of 75 colloidal iron cases, 59 cases (78%) had good compliance. Out of 75 ferrous sulphate cases, 45 cases (60%) had good compliance. Hence, compliance was better with colloidal iron which was statistically significant.

Conclusion:-

The study was done to compare the therapeutic efficacy and side effects of ferrous sulphate with colloidal iron in the treatment of iron deficiency anemia in children aged 6 months to 18 years. It was noted that the mean reticulocyte count by the end of one week of treatment increased by 20% in colloidal iron group and by 15% in ferrous sulphate group. Mean haemoglobin increased by 16% in colloidal iron group and by 13% in ferrous sulphate group. However, the increase in reticulocyte count and haemoglobin was not statistically significant. On comparing the side effects between the two groups, 34.3% cases had GI side effects in ferrous sulphate group compared to 14.5% in colloidal iron group. Hence colloidal iron had 78% good compliance compared to 60% with ferrous sulphate which is statistically significant. Hence colloidal iron and ferrous sulphate are found to be equally efficacious to treat iron deficiency anemia in children between 6 months to 18 years. However, side effects and compliance profile was significantly better in colloidal iron compared to ferrous sulphate.

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