IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 11 Ver. VII (Nov. 2017), PP 27-29
www.iosrjournals.org

Therapeutic efficacy of Iron polymaltose complex versus Ferrous sulphate in treatment of Iron deficiency anemia in children

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Abstract:
Background: *Iron deficiency anemia is the most prevalent nutritional deficiency of the world, especially in developing countries. It is estimated that 1.3 billion people suffer from anemia, of which most is due to iron deficiency. Children between 6 to 35 months are particularly high risk group for development of iron deficiency due to low content of bioavailable iron in the weaning foods of developing countries. Obviously for supplementing such young children medicinal iron can be used only in liquid form as drops and syrup formulations. However, there is considerable confusion in deciding on a suitable liquid iron preparation in terms of (a) bioavailability (b) side effect (c) cost effectiveness.*
Methods*: A total of 60 patient were screened, and 50 were enrolled (10 patient did not fulfill the inclusion criteria). 26 patients were assigned to the FS group, and 24 patients were assigned to the IPC group. Inclusion criteria were: age 1-14 years; Haemoglobulin (Hb) < 9g/dL and Serum ferritin < 12 mcg /L. . In one group iron polymaltose was given for 8 weeks in therapeutic dose. The other group received ferrous sulphate for 8 weeks. The primary efficacy parameter was the proportion of patients achieving normal Hb level (>11 g/dL) in the treatment groups within 8 weeks of treatment. Other efficacy parameters were packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular haemoglobulin (MCH), and mean corpuscular haemoglobulin concentration (MCHC), serum iron, and serum ferritin.*
Results*: The increase in Hb and PCV value was statistically significant when baseline vs. 8-week values were compared in both groups. There was significant (p< .001) increase in MCV level in both groups at the end of 8 weeks. At the end of 8 weeks of either study treatment, there was a statistically significant increase in both MCH and MCHC value from baseline in both treatment groups, but there was no difference between the two treatment groups. The adverse effects were more common in the FS group than the IPC group [20 (77%) in the FS group vs. 7 (29) in the IPC group, P < .001] .The compliance rate was higher than 80 % in both groups. It was significantly higher (P < .05) in the IPC group (91%) than in the FS group (87%).*
Conclusions*: Thus IPC is effective in the treatment of iron deficiency anemia in children. A superior tolerability profile to that of the conventional iron preparation (FS) and an equivalent efficacy profile strongly suggest that it can be considered as a useful, relatively novel, and alternative formulation for the treatment of IDA during childhood.*
Keywords*: Therapeutic efficacy, Iron polymaltose complex ,Ferrous sulphate ,Iron deficiency anaemia.*

Date of Submission: 10 -11-2017 Date of acceptance: 21-11-2017

I. Introduction

Iron deficiency anemia is the most prevalent nutritional deficiency of the world, especially in developing countries. It is estimated that 1.3 billion people suffer from anemia, of which most is due to iron deficiency. Children between 6 to 35 months are particularly high risk group for development of iron deficiency due to low content of bioavailable iron in the weaning foods of developing countries.1 Obviously for supplementing such young children medicinal iron can be used only in liquid form as drops and syrup formulations. However, there is considerable confusion in deciding on a suitable liquid iron preparation in terms of (a) bioavailability (b) side effect (c) cost effectiveness.

Thus the present study was done to compare the efficacy, tolerability, compliance and cost effectiveness of iron polymaltose complex (IPC) with ferrous sulphate (FS) in iron deficiency anemia (IDA).

II. Materials And Method

The study was conducted in the Department of Paediatrics at Rajendra Institute of Medical Sciences (RIMS), Ranchi, from October 2015 to October 2016. A total of 60 patient were screened, and 50 were enrolled (10 patient did not fulfill the inclusion criteria). 26 patients were assigned to the FS group, and 24 patients were assigned to the IPC group. Inclusion criteria were: age 1-14 years; Haemoglobulin (Hb) < 9g/dL and Serum ferritin < 12 mcg /L. Patients with history of anemia due to any other causes such as chronic blood loss, hemolytic anemia, and thalassemia (including thalassemic trait) were excluded from the study. Patients with Hb < 7 g/dL (severe anemia) were also excluded. In one group iron polymaltose was given for 8 weeks in therapeutic dose. The other group received ferrous sulphate for 8 weeks. The primary efficacy parameter was the proportion of patients achieving normal Hb level (>11 g/dL) in the treatment groups within 8 weeks of treatment. Other efficacy parameters were packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular haemoglobulin (MCH), and mean corpuscular haemoglobulin concentration (MCHC), serum iron, and serum ferritin. At week 0 and week 8, Hb, PCV, MCV, MCH, MCHC, serum iron, serum ferritin were measured. Hb and ADR were also measured at 2, 4, and 6 weeks.

III. Result And Analysis

The baseline hematological parameters including Hb, PCV, MCV, MCH, MCHC, serum ferritin, and serum iron were comparable between the two groups (TABLE 1). In the FS group, 65.38% (17 patients out of 26) achieved Hb > 11g/dL, whereas in the IPC group, 66.67% (16 of 24 patients) achieved Hb >11 g/dL, which was the primary end point. Both groups showed a significant increase in Hb level (mean ± SD change from baseline was 3.85 ± 0.43 g/dL in FS group and 3.52 ± 0.42 g/dL in the IPC group). After treatment with iron preparations for 8 weeks , PCV values in both the treatment groups showed a rise from 25% (baseline) to 34% (at the end of 8 weeks of treatment) in the FS group and from 26% (baseline) to 34% (at the end of 8 weeks of treatment) in the IPC group. The increase in Hb and PCV value was statistically significant when baseline vs. 8-week values were compared in both groups. There was significant (p< .001) increase in MCV level in both groups at the end of 8 weeks.

At the end of 8 weeks of either study treatment, there was a statistically significant increase in both MCH and MCHC value from baseline in both treatment groups, but there was no difference between the two treatment groups.

Statistically significant increase in the serum iron and serum ferritin levels was observed in both treatment groups. The baseline serum iron was 68.66 ± 11.30 mcg /dL in FS group and 72.53 ± 11.64 mcg /dL in the IPC group. In both groups, the serum iron level was increased statistically to 107.77 ± 19.30 mcg /dL in FS group (P <.001) and to 109.41 ± 18.71 mcg /dL in the IPC group (P < .001).Serum ferritin level was also significantly increased from 11.44 ± 3.86 mcg /dL to 26.7 ± 8.16 mcg /dL (P < .001) in the FS group and from 11.35 ± 4.05 to 26.72 ± 8.12 mcg/dL (P < .001) in IPC group..

The adverse effects were more common in the FS group than the IPC group [20 (77%) in the FS group vs. 7 (29) in the IPC group, P < .001] (TABLE 2). The adverse effects experienced were GI intolerance (acidity, gastritis, and heartburn), constipation, metallic taste, diarrhea, and rash.

The compliance rate was higher than 80 % in both groups. It was significantly higher (P < .05) in the IPC group (91%) than in the FS group (87%).

Table1: Effects of ferrous sulphate (FS) and iron polymaltose complex on hematological parameters. All values are expressed as mean ± SD.

PARAMETERS	BASELINE(0 WKS)		AFTER TREATMENT(8 WKS)	
	IPC	FS	IPC	FS
Hb (g/L)	7.82±0.61	7.53±0.67	11.35±0.79	11.39±0.90
PCV (%)	23.58±1.90	22.03±1.77	33.79±2.22	33.69±2.42
MCV(fl)	75.63±4.22	73.91±4.20	91.26±3.84	92.62±4.81
MCH(Pg)	22.80±1.53	21.52±1.69	30.48±0.93	29.37±1.63
MCHC(g/L)	299.05±5.96	296.51±6.74	323.90±5.67	322.8±9.15
Serum iron (mcg/dL)	72.53±11.64	68.66±11.30	108.41±18.71	107.8±19.3
Serum ferritin (ng/mL)	11.35±4.05	11.44±3.86	26.72±8.12	26.70±8.16

Table 2: Comparison of adverse events in ferrous sulphate (FS) and iron polymaltose (IPC) groups.

EVENTS	FS (N =26)	IPC (N=24)	P Value*
	No of patients (%)	No of patients (%)	
GI intolerance	17 (65.4%)	7 (29.17%)	0.97
Constipation	13 (50%)	6 (25%)	0.36
Metallic taste	4 (15.4%)	0	<.001
Diarrhea	1 (3.8%)	0	<.001
Rashes	1(3.8%)	0	<.001
Total	20(77%)	7(29%)	<.001

P* value refers to difference between groups with regard to incidence of adverse effect.

IV. Discussion

Anemia is worldwide public health problem. A WHO report estimates the anemia prevalence among children to be 55.9% globally.2 IDA is the most common form of anemia in children, and it affects approximately 15% of the world's population. When it occurs during childhood, anemia has a significant impact on the growth, motor and mental development of the child.3

The treatment of IDA is directed at replenishing hemoglobin and compensating for the deficit in stored iron by supplying iron.4 The iron polymaltose complex has been formulated in such a way that the elemental form is in non-ionic state. This ensures that there is no gastric irritation with IPC. In addition, the high elemental iron content of IPC eliminates the need for frequent dosing and therefore improves compliance.5

The improvement seen in all hematological parameters were the same in both groups. Other studies have shown comparable efficacy, but they had limitation.6,7 In summary, none of other these studies compared compliance and cost of iron preparation and most of the studies were uncontrolled and open trial and were conducted in adult patient. To best of my knowledge this is the first study that has compared FS and IPC in terms of efficacy, tolerability, compliance, and cost-effectiveness in paediatric age group.

Overall, adverse effect were more common in the FS group than in the IPC group (77% vs. 29%, P <.001) in the present study. Similar observation was seen in the Indian population studied by other author also.8

In the present study, the adverse effects were not severe enough to warrant discontinuation of iron therapy. Increased incidence of adverse effect with FS may be due to release of free radicals which leads to cell damage and cell death. IPC does not release free radicals, which may account for the observed difference. Reduced incidence of adverse effect will improve compliance and ensure regular treatment. In the present study the compliance rate was higher in the IPC group (91%) than in the FS group (87%), and the improvements seen in all hematological parameters were the same in both groups.

Thus IPC is effective in the treatment of iron deficiency anemia in children. A superior tolerability profile to that of the conventional iron preparation (FS) and an equivalent efficacy profile strongly suggest that it can be considered as a useful, relatively novel, and alternative formulation for the treatment of IDA during childhood. However further studies with large patient population are required to strengthen the evidence of the present study. FS is discontinued by most patient because of its adverse effects where as IPC is discontinued because of higher cost. So the Government should make such policies, by which IPC could be distributed free of cost in National Health Programmes for iron deficiency anemia

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Dr Partha Kumar Chaudhuri. "Therapeutic efficacy of Iron polymaltose complex versus Ferrous sulphate in treatment of Iron deficiency anemia in children." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) 16.11 (2017): 27-29