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Research Article

EFFECTIVENESS OF IRON POLYMALTOSE COMPLEX SALTS AND FERROUS SULPHATE IN THE CONDITION OF REDUCED CONCENTRATION HEMOGLOBIN (HB) RANDOMIZED CONTROLLED TRIAL

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Abstract:

Objective: The purpose of this study is to find out the effectiveness of iron polymaltose complex (IPC) salts and ferrous sulphate (FS) in the condition of reduced concentration haemoglobin (Hb) or we can say reduced number of red blood cells which is known as IDA (Iron deficiency of anaemia) in children.

Material and Methods: We carried out the current Randomized Controlled Trial (RCT) study in the time duration of the ½ year starting from 1st January 2018 to 30th June 2018 at pediatric ward of Services Hospital, Lahore. Children facing iron deficiency anaemia and ageing from ½ year to five years were the participants of this research study. The researcher made two groups A and B of total selected children (150). Each group consist of 75 randomly selected victims. Prescribed FS (ferrous sulphate) to Group A and IPC (iron polymaltose complex) to Group B. Carried out the analysis of the results after three months in the relation between the reference point and rise in Hb in three months. Considered that rise in Hb level as effective which was more than or equal to (02 mg/dl) after treatment of three months. SPSS software was there to analyze the results. Through Chi-square test carried out the comparison of FS and IPC for effectiveness with significant P value as less than or equal to (0.05).

Results: We divided the children as age wise and calculated the frequency of gender. There was 82 (54.7%) male children and female children were 68 (54%). According to the distribution of the age as three years to five years, one year to three years and ½ year to one year there was 39 (26%), 77 (51.3%) and 34 (22.7%) cases correspondingly. Recorded the average starting level of Hb in all participant of the research which was (6.64 ± 1.08) gm/dl and in group B it was (6.69 ± 1.04) gm/dl as well as in group A it was (6.59 ± 1.13) gm/dl. The average Hb level of all children of the current study at the completion of treatment was (9.15 ± 1.21) gm/dl and (9.20 ± 1.17) gm/dl, (9.11 ± 1.25) gm/dl in group A & B respectively. Calculated the mean increase of Hb as (2.52 ± 0.67) gm/dl in all the patients of the present research study. In group B it was (2.42 ± 0.71) gm/dl and in group A it was (2.62 ± 0.61) gm/dl. The calculations and observations on efficacy rate were as (96%) in between all participants and in group A & B it was (97.34%) & (94.66%) accordingly. There was a considerable difference in statistical analysis amongst these two groups.

Conclusion: According to the findings of the current research study found no considerable dissimilarity in the effectiveness of FS and IPC drugs. Iron polymaltose complex (IPC) salts are expensive as compared to ferrous sulphate (FS) and despite compromising side effects these medicines have same alike effectiveness.

Keywords: Hemoglobin (Hb), iron polymaltose complex (IPC), ferrous sulphate (FS) and Iron deficiency anaemia (IDA).

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INTRODUCTION:

The main cause of IDA (Iron deficiency anaemia) is a shortage of iron storage in the human body [6]. Reduced Hb (haemoglobin) level because of a shortage of one or more necessary nutrients is known as nutritional anaemia according to the definition by the World Health Organization (WHO) [5]. Overall populations containing kids and grownups in Pakistan have very high iron deficiency anaemia showing a very high percentage as (65%) of people around the country [7]. Percentage of affected children of Pakistan and all around the world is (29%) and (43%) respectively as calculated by the World Health Organization (WHO) [7]. Due to fast propagation and augmented demand in kids under 24 months of age, particularly at beginning of complementary feeding are at the greater possibility of IDA. Socioeconomics, Biology and diet are the most complex factors in such a situation [8]. Somewhat interrelated in a malicious sequence, malnutrition and Iron deficiency anaemia remain beside to each other. The situation becomes more annoying as further reduction of food eating due to irritability, anorexia and apathy which are penalties of IDA (Iron deficiency anaemia) [7].

There is a huge impact of IDA (Iron deficiency anaemia) on the health of infants. It disturbs learning abilities, working capacity and neurologic development of a kid [9]. Psychiatric illness in later life might be due to the iron deficiency in childhood [10]. Through childhood and risk in future lifespan for the happening of febrile fits and breath holding periods, IDA is one of the main reasons [11]. Regardless of normal IQ, deficiency of iron results in low grades in school which is not only annoying for the kids but also effects the guardians by involving them to economic burden in the form of extra tuitions, anguish and disquiet. Handling of iron deficiency anaemia during childhood is very easy. Recommendations for the curing are the use of Iron polymaltose complex (IPC) and ferrous sulphate (FS) (aqueous solution of ferrous salts) as guided by world public health authorities [12]. Although a time-tested drug therapy is FS due to its side effects like free radical-mediated mucosal destruction, little and inconstant gut immersion and chelation with nutrients particles, its usage is inadequate. To overcome these problems introduced the iron polymaltose complex [13].

In many types of research carried out a comparison of FS (ferrous sulphate) and IPC (Iron polymaltose complex) in terms of efficacy and bio-availability. The evaluation of both medicines in some researches recommend Iron polymaltose complex being more

effective or even higher to ferrous sulphates salts [14, 15]. Although, found no backing for these findings in other local researches [7, 12]. On the condition of one gm per dl rise in Hb from starting point, in a research study on children affected by iron deficiency anaemia conducted in 2009 findings exposed the expected percentage of effectiveness of FC and IPC in comparison as (98.1%) & (71.7%) accordingly.

With truncated socioeconomic conditions and huge populace, there are limited resources in Pakistan. Hence, Expensive medical treatment and medication for curing of iron deficiency anaemia, people of this country may not accept and adopt it on a large scale. There are unsettled results till now on the effectiveness of both drugs. Therefore, if these results are comparable then health care workers should advise cheap drugs, especially at the community level for the infants of iron deficiency anaemia. Along with compliance, price and inconvenient properties, exploring the case of the efficacy of FC and IPC in curing the infants of iron deficiency anaemia is the main aim of the current research study.

MATERIALS AND METHODS:

Completed the present research study in the time duration of six months starting from 1st January 2018 to 30th June 2018 at paediatric unit of Services Hospital, Lahore. A total number of 150 Kids suffering from iron deficiency anaemia (IDA) with Serum ferritin less than (12 mcg/l) or Hb level less than (8 g/dl) suffering from microcytic hypochromic anaemia on peripheral blood smear selected as participants of the study. Age of the chosen children was from half year to five years. Used non-probability purposive sampling technique for the selection. Obtained notified written consent from guardians of the selected children.

Divided the selected infants into two groups A and B. Each group consist of 75 randomly selected patients. Prescribed FS (ferrous sulphate) to Group A and IPC (iron polymaltose complex) to Group B. Calculated expected percentage of efficacy, (5%) level of significance and 80% power in both groups. Ferrous sulphate group A was (98.1%) as compared to (71.7%) in iron polymaltose complex group B. Excluded all those kids who received any kind of iron deficiency curing ever before, those with hemoglobinopathies, systemic disorders like liver diseases or renal failure, severe anemia requiring emergency blood transfusion, hypersegmented neutrophils, dysmaturity of RBC's, megaloblastic anemia MCV more than (95 fl) and having anemia of prematurity (assessed from gestational age).

Prescribed the oral dose of ferrous sulphate salt as (6 milligrams per kilogram) daily for the time duration of three months to the children of group A and oral dose of Iron polymaltose complex salt as (3 milligrams per kilogram) daily for the time duration of three months to the children of group B. Carried out the analysis of the results after three months in relation between reference point and rise in Hb in three months. Considered that rise in Hb level as effective which was more than or equal to (02 mg/dl) after treatment of three months. Labelled as dropouts and excluded from data analysis to those patients who did not complete the course of therapy and with irregular follow up.

The researcher analyzed the results through SPSS software and presented qualitative variables like

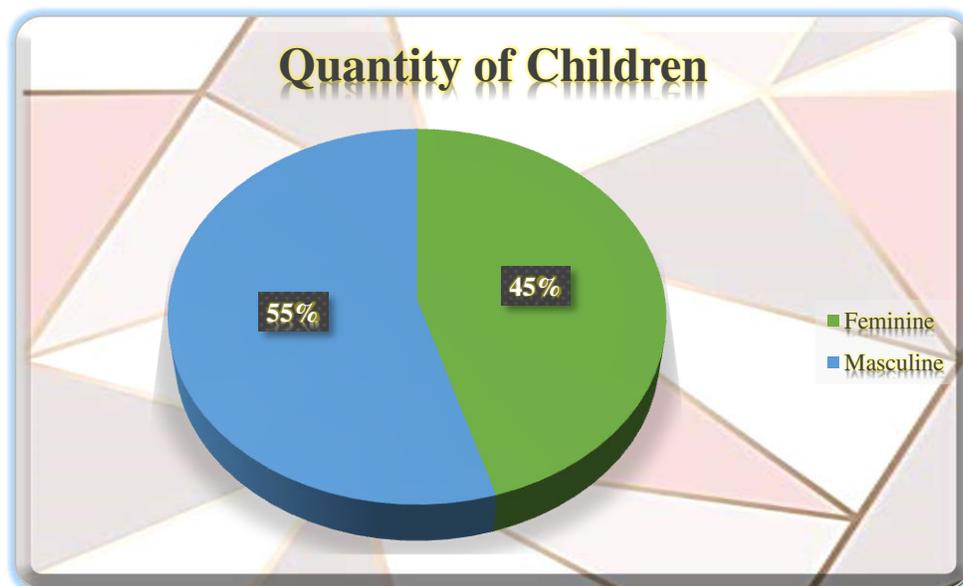
efficacy in form of percentages and frequency. He also presented quantitative variables like age in the form of average \pm S.D. Through Chi-Square test researcher completed the comparison of FS and IPC for effectiveness and accepted a P-value of less than (0.05).

RESULTS:

Researcher enrolled 150 patients of iron deficiency anaemia as controls and randomized them into two equally divided groups. There was 82 (54.7%) male children and female children were 68 (45.3%) with a male to female ratio (1.2:1). According to the distribution of the age as 3 years to 5 years, 1 year to 3 years and ½ year to 1 year there was 39 (26%), 77 (51.3%) and 34 (22.7%) cases respectively. The table below shows the description.

Table – I: Sex of the Children

<i>Statistics</i>	Feminine	Masculine	Sum
<i>Quantity of Children</i>	68	82	150
<i>Ratio</i>	45.3 %	54.7 %	100 %



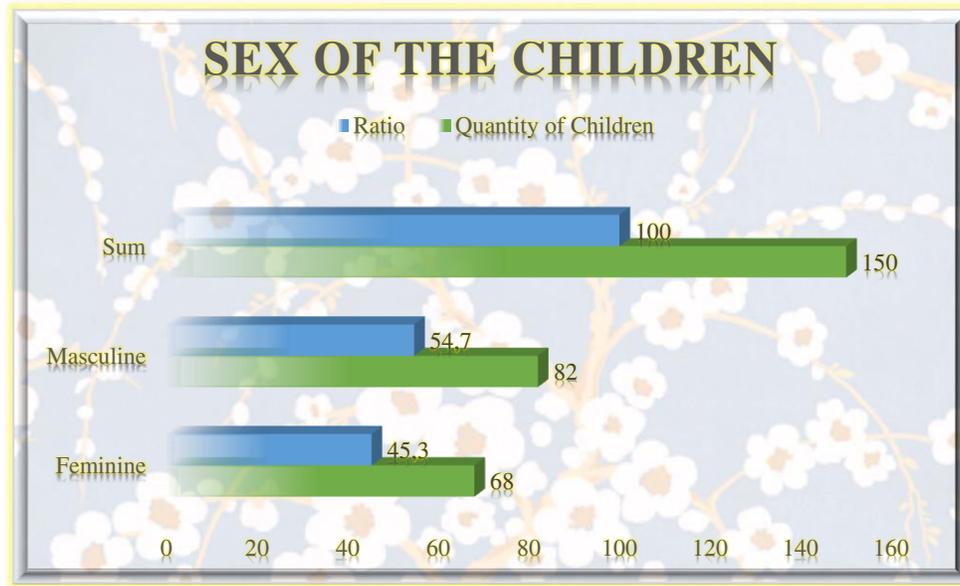


Table – II: Age Description of the Children

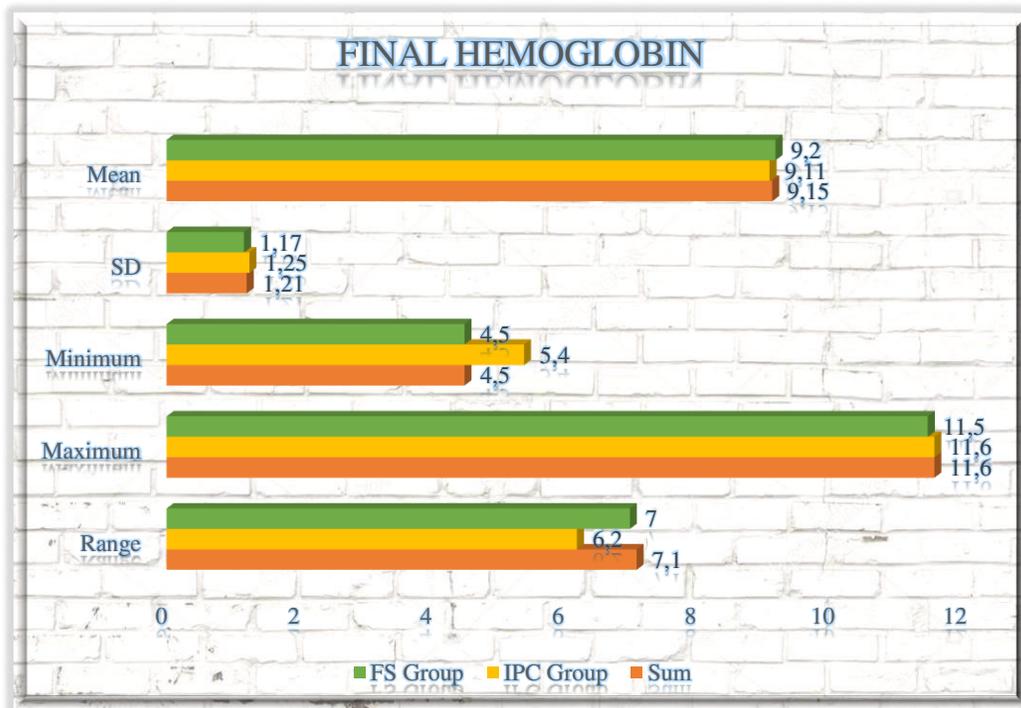
Range of Age	Ratio	Quantity
3-5 years	26.0 %	39
6-12 months	22.7 %	34
1-3 years	51.3 %	77



The average Hb status of all kids of the present research study at the accomplishment of treatment was (9.15 ± 1.21) gm/dl and (9.11 ± 1.25) gm/dl, (9.20 ± 1.17) gm/dl in group B & A correspondingly. The prefix calculated range is from (4.5 to 11.6) gm/dl. Dissimilarity amongst two groups was insufficient with the P value as equal to (0.618). The table below shows the description.

Table – III: Comparison Between FS and IPC of Final Hemoglobin

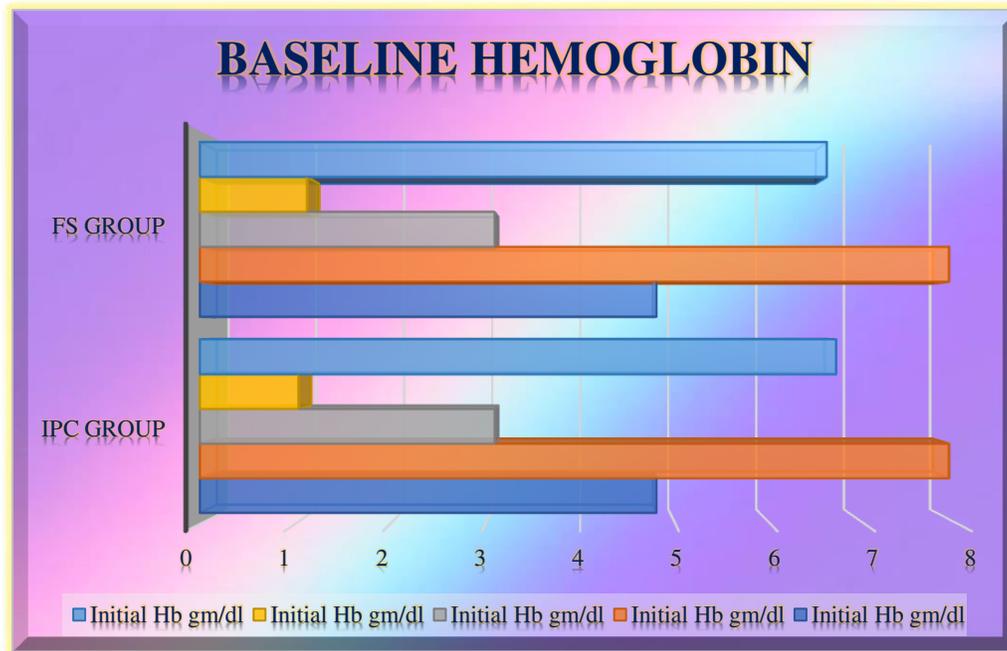
Statistics	Sum	IPC Group	FS Group	
Final gm/dl	Range	7.10	6.20	7.00
	Maximum	11.6	11.6	11.5
	Minimum	4.50	5.40	4.50
	SD	1.21	1.25	1.17
Hb	Mean	9.15	9.11	9.20



Recorded the average starting level of Hb in all members of the research study which was (6.64 ± 1.08) gm/dl and in group B it was (6.69 ± 1.04) gm/dl as well as in group A it was (6.59 ± 1.13) gm/dl. The prefix calculated range is from (3.1 to 7.9) gm/dl. For starting Hb level difference amongst the two groups was insufficient with the P value as equal to (0.553). The table below shows the description.

Table – IV: Comparison Between FS and IPC of Baseline Hemoglobin

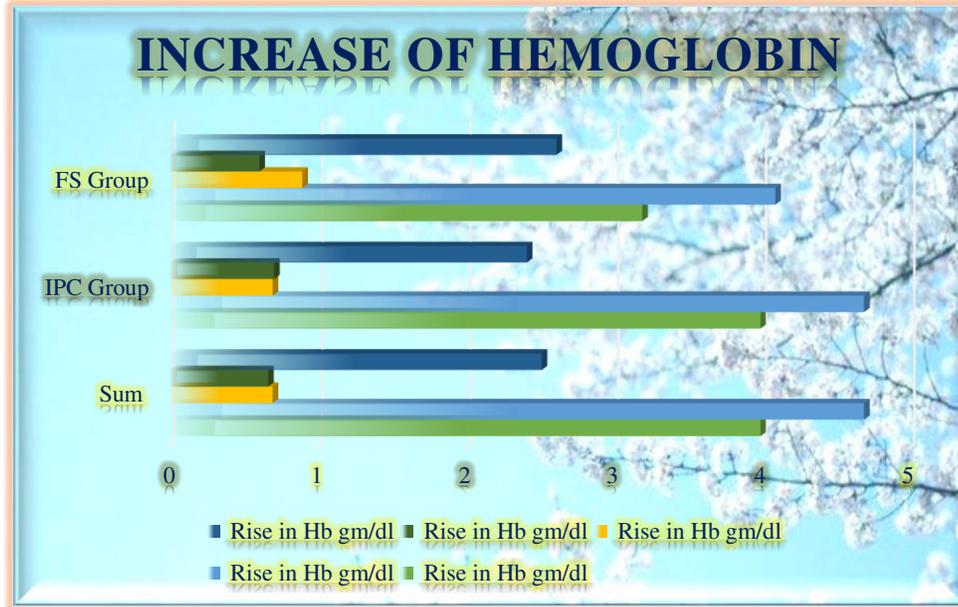
Statistics	IPC Group	FS Group	
Initial Hb gm/dl	Range	4.80	4.80
	Maximum	7.90	7.90
	Minimum	3.10	3.10
	SD	1.04	1.13
	Mean	6.69	6.59
	N	75	75



Calculated the mean increase of Hb with the prefix calculated range from (0.67 to 0.70) gm/dl was as (2.52 ± 0.67) gm/dl in all the patients of the present research study. In group B with the prefix calculated range from (0.70 to 4.70) gm/dl it was (2.42 ± 0.71) gm/dl and in group A with the prefix calculated range from (0.70 to 4.70) gm/dl it was (2.62 ± 0.61) gm/dl. Distinction amongst two groups was insufficient with the P value as equal to (0.618). The table below shows the description.

Table – V: Comparison Between FS and IPC Increase of Hemoglobin

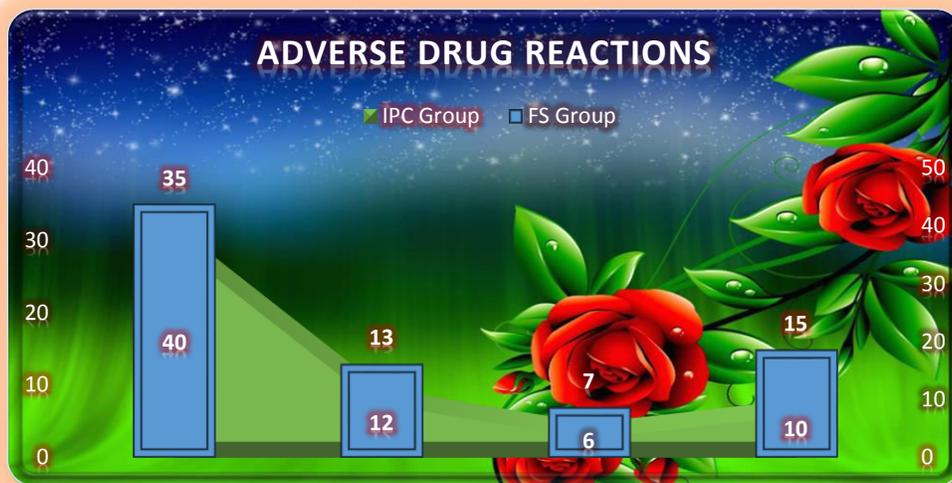
Statistics		Sum	IPC Group	FS Group
Rise in Hb gm/dl	Range	4.00	4.00	3.20
	Maximum	4.70	4.70	4.10
	Minimum	0.70	0.70	0.90
	SD	0.67	0.71	0.61
	Mean	2.52	2.42	2.62



The calculations and observations on efficacy rate were as (96%) in between all participants and in group A & B it was (97.34%) and (94.66%) accordingly. Calculated the efficacy as an increase in haemoglobin concentration by equal to or more than one gm/ dl from the initial point and evaluated at the accomplishment of treatment. Dissimilarity amongst two groups was insufficient with the P value as equal to (0.405). The table below shows the description.

Table – VI: Adverse drug reactions (ADR)

Side Effects	IPC Group	FS Group
Teeth Staining	40	35
Diarrhoea	12	13
Abdominal pain	06	07
Nausea & vomiting	10	15



DISCUSSION:

Infants of poor third world countries normally face iron deficiency anaemia under age of one year to three years with a rate as (4% to 8%) [16, 18]. Selected 150 kids of iron deficiency anaemia (IDA) and distributed them into two equally separated groups of FS and IPC. Female children were 54% (68) and there was 54.7% (82) male children with Male to the Female ratio as (1.2:1) in Afzal et al study signifying masculine predilection compared to feminine kids [7].

Found comparable results between the increase of Hb and efficacy in two groups as observed in the tables mentioned above. Both arrangements produced an analogous increase of haemoglobin and serum iron levels according to a study by Sozmen et al [2]. Some researchers determined that there was no difference in usage of both drugs, equivalent quantity of iron is existing from ferrous sulphate or iron polymaltose complex in adjusting haemoglobin levels over a three months observational time duration [1, 2, 15]. Arvas, Langstaff and Bopche et al found same alike results in their researches that FS group had a significant rise in Hemoglobin level from the initial point to last follow-up [3, 4, 12].

Considered that rise in Hb level as effective which was more than or equal to (02 mg/dl) after the consistent routine of given medication in the suitable dose for treatment of twelve weeks. Concerning efficacy, the distinction between two groups was inconsequential. Bopche et al., exposed that the efficacy of IPC was (71.7%) and efficacy of FS was (98.1%) with significant differentiation among two groups [12]. However, some studies showed conflicting results [14, 15]. With no significant difference, the category and rate of recurrence of side effects of medication are comparable in two groups. The overall inconvenient outcomes were more communal in the FS group (78%) than in IPC group (31%), consulting to a study. Results of IPC usage is more convenient as compared to the FS with a better risk and benefit ratio [10]. Although, IPC medication is costly than the tested over the time FS treatment with FS drugs may cost double with the complete course of therapy. Conclusion for the final approach is still required for the benefits of children and adults.

CONCLUSION:

Doctors should prescribe the ferrous salts confidently in place of the iron polymaltose complex because Iron polymaltose complex (IPC) salts are costly as compared to ferrous sulphate (FS) and regardless of compromising on side effects these drugs have

similar effectiveness. Discussing the observations of the present research study found no considerable dissimilarity in the effectiveness of FS and IPC drugs.

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