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Research Article

A RANDOMIZED TRIAL TO REPORT THE EFFECTIVENESS OF FERROUS SULFATE (FS) ALONG WITH IRON POLYMALTOSE COMPLEX (IPC) FOR ANEMIA MANAGEMENT

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Abstract

Objective: The purpose of the research was to find out the effectiveness of FS (Ferrous Sulfate) with IPC (Iron Polymaltose Complex) in managing anemia of iron deficiency in nonage.

Material and Methods: The design of the research was a randomized trial research which was held at Services Hospital, Lahore from February to November 2017. The numbers of iron deficiency anaemia children included in the research are seventy having to age between six months to six years. Researcher irregularly distributed them into two categories and give iron polymaltose complex along with ferrous sulfate category, IPC and FS for the time period of two months respectively. The dosage of iron arrangement given was 6mg/kg/day of preliminary iron in three separate doses. The researcher followed up the research participator's after two-month duration and recorded the effectiveness of FS and IPC in term of regulation of haemoglobin along with serum ferritin.

Results: Among seventy enrolled children, the number of male and female children were thirty-nine (55.7%) and thirty-one (44.3%) respectively. the average age of enrolled children is 2.46 years \pm 1.36 standard deviation. Sixty percent of the children having age less than two years. The average weight of selected children was (10.7 kilogram). The number of children having a weight less than twelve kilograms was forty-six (65.7%), twenty-four (34.3%) were twelve kilograms or more than this. Average Hb and ferritin prior to the start of treatment in selected research children were 7.85 g/dl \pm 0.82 standard deviation and 8.22 ng/ml \pm 2.42 standard deviation respectively. Average post-treatment Hb and ferritin in selected research children were 10.9 g/dl \pm 0.90 g/dl \pm 0.82 standard deviations and 42.8 ng/ml \pm 21 SD respectively. Docility was better in (94.3%) children of iron polymaltose complex category and (85.7%) children in the ferrous sulfate category. Researcher during comparison of both the categories noticed effectiveness in thirty-two (91.4%) children of iron polymaltose complex category and thirty (85.8%) children in ferrous sulfate category that was unimportant statistically with P value = 0.45. The effectiveness of iron polymaltose complex with respect to ferrous sulfate was statistically unimportant in entire age categories i.e. age category of six months to less than two years (P-value = 0.71), age category of children of two to six years (P-value = 0.45) and in males and females (P value = 0.13) & (P-value = 0.50) respectively. Researcher did not notice any statistical expressive variation in the effectiveness between iron polymaltose complex as well as ferrous sulfate category in children weighing less than twelve kilograms (P-value = 0.48), children greater than or equal to twelve kilograms (P-value = 0.8), children with better docility (P value =0.42) and children with poor docility (P value =0.61).

Conclusion: Finding of the research declared that there was statistically unimportant variation in the effectiveness rate of IPC and FS when utilized as informal iron substitute management in IDA children. FS and IPC could be utilized as substitute drugs as both have balanced effectiveness.

Keywords: Iron deficiency anaemia (IDA), ferrous sulfate (FS), iron polymaltose complex (IPC)

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INTRODUCTION:

Iran inadequacy is the extreme prevailing and general nutritional complication in the globe. Almost thirty percent of the world population experienced from IDA and many of them living in progressing states [1]. World health organization estimated that one out of two preschool children in progressing states is suffering from IDA as well as the dominance of anaemia is too much in preschool-age children (forty-seven percent). In 2004 IDA (iron deficiency anaemia) consequences in 0.273 million casualties, forty-five percent among these were from Southeast Asia [2]. IDA can develop fatigue, may influence working capability and exercise progressiveness, decrease neurotransmitter capacity, attenuate immunological as well as inflammatory protection [3]. The most severe consequence of iron inadequacy in young as well as neonate children is paralyzed cerebral as well as motor function. The main factors of iron inadequateness are, less iron intake, declined intestinal immersion/absorption of nutritional iron, huge iron demand, (while fast growth duration) or persistent blood loss [4]. Prolong duration informal iron is commonly utilized as a first-line treatment, anyhow iron salt such as FS is regularly connected with huge occurrences of gastrointestinal drawbacks like vomiting, nausea, diarrhoea as well as constipation and might be the factor of discontinuation of management. Polynuclear arrangements founded in ferric iron just like IPC have progressed to advance sufferableness [5]. The two additional randomized controlled studies (trials) just like ours, conducted in conceived females who verified that iron polymaltose complex has uniform effectiveness but improved sufferableness [6 – 8]. The information in children on iron polymaltose complex effectiveness is deficient. The two randomized research conducted at world level, initial conducted on sixty children having six to eighteen months of age with IDA and 2nd on one hundred and three children having age less than six months presented that iron polymaltose complex has uniform effectiveness along with improved sufferableness to FS, moreover two additional regional research presented disputed results [9 – 12]. one research performed in India in the year 2009 presented the effectiveness of ferrous sulfate was (98.1%) and iron polymaltose complex presented the effectiveness of (71.7%) with statistically expressive variation in both categories, another study presented the effectiveness of ferrous sulfate as (97.3%) and effectiveness of iron polymaltose complex was (94.6%) with nil statistical important variation [11, 12].

The problem of effectiveness between two treatments constantly not solved till now. This research was

design to solve this problem and to verify whether there is an important variation in the effectiveness of ferrous sulfate and iron polymaltose complex or there is nil important variation in both.

MATERIALS AND METHODS:

The design of the research was a randomized trial research which was held at Services Hospital, Lahore from February to November 2017. Researcher included entire patient of both genders having age between six months to six years, children with IDA as well as Hb prior to start of treatment is less than 10.5 and Serum Ferritin is less than or equal to 15ng/ml and expelled all those patients except anaemia cases, serious periodic sickness (kidney, hepatic and cardiovascular), haemorrhage complications proposed by record of bruises, familiar the hypersensitivity to ferric as well as ferric arrangement/preparation, gastrointestinal haemorrhage proposed by blood vomiting record, the Lena and bloody stools.

If haemoglobin is less than 10.5g/dL and Serum ferritin is less than or equal to 15ng/mL, called iron deficiency anaemia. Define efficacy as, if haemoglobin is greater than 10.5g/dL and Serum ferritin is greater than 15ng/mL, the aluated after daily usage of suggested drugs in sufficient dosage (6 mg/kg/day of preliminary iron in three separate doses) for the duration of the two months.

The numbers of iron deficiency anaemia children hospitalized via the department of emergency care, as an outdoor patient, accomplishing required criteria were divided into two categories through lottery technique. The researcher takes written approval from patients' guardians and given 1st category (ferrous sulfate category) to FS and the 2nd category (iron polymaltose complex category) to IPC for the duration of two months. The dosage of iron arrangement given was 6mg/kg/day of preliminary iron in three separate doses, as well as obtained demographic information along with a thorough record and conducted the assessment. They were again called for a subsequent visit after two-month duration along with utilized bottles as well as a cover of the prescribed tablets. The researcher took Hb and ferritin level on initial as well as after two months, if haemoglobin is greater than 10.5g/dL and Serum ferritin is greater than 15ng/mL, than it is effective and entered all the information on Performa prepared for the said purpose. Researcher performed an analysis of information on SPSS software and calculated SD and average for age, initial Hb and ferritin, after management ferritin and Hb. The researcher also calculated periodicity and percentage for effectiveness and gender, applied Chi-square test

for comparison of effectiveness, managed effect developers by categorization and post categorization Chi-square test and applied for comparison of various strata as well as an assumed P value less than or equal to (0.05) as expressive.

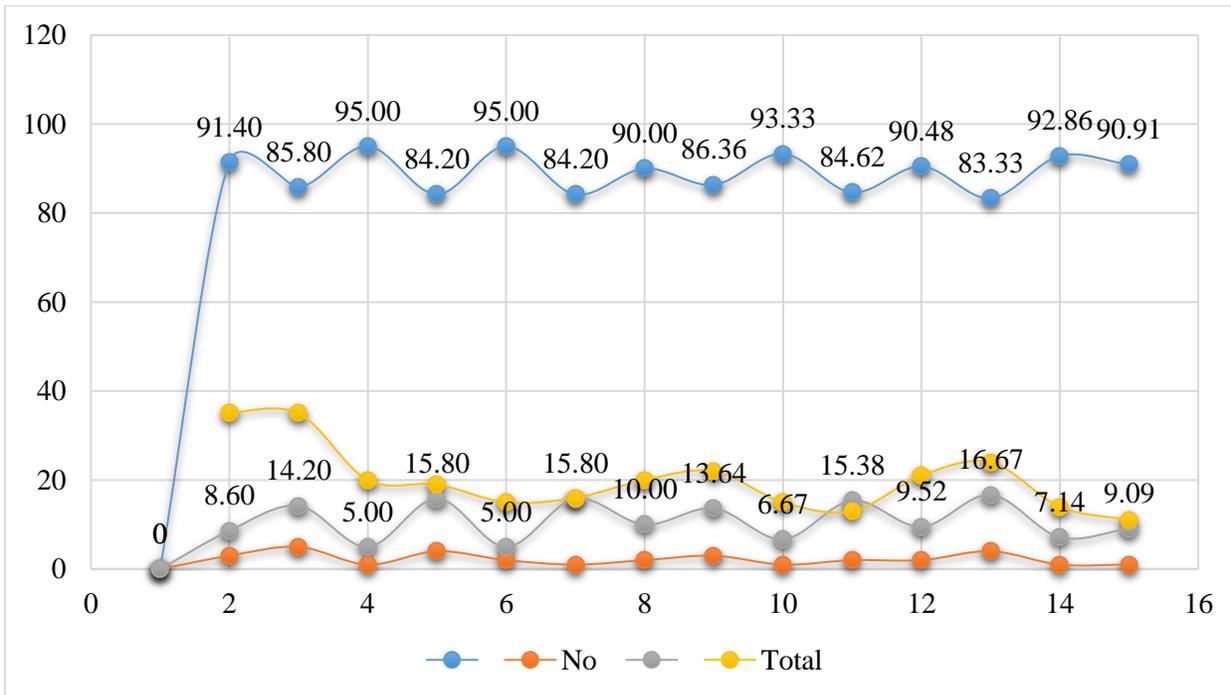
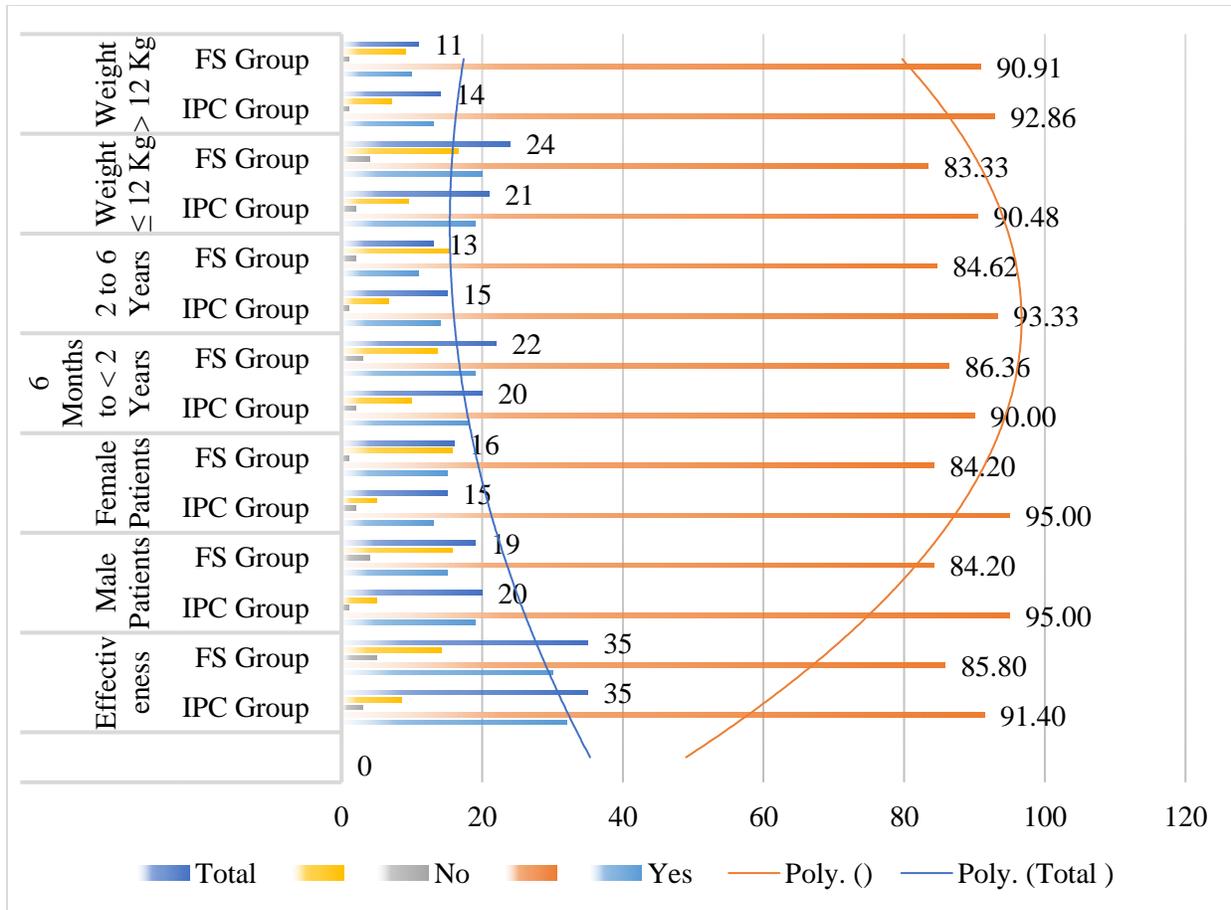
RESULTS:

The numbers of iron deficiency anaemia children included in the research are seventy (thirty-five years in a single category). The average age of the enrolled child is 2.46 years \pm 1.36 standard deviation. In iron polymaltose, complex category average age was 2.47 \pm 1.46 years and the ferrous sulfate category average age of children was 2.46 \pm 1.28 years. Researcher during comparison of both the categories noticed effectiveness in thirty-two (91.4%) children of iron polymaltose complex category and thirty (85.8%) children in ferrous sulfate category that was unimportant statistically with P value = 0.45. Among twenty male patients of the iron polymaltose complex category, the researcher recorded effectiveness in nineteen (ninety-five percent) patients and among nineteen patients of ferrous sulfate category, the researcher recorded effectiveness in fifteen (84.2%) patients. However, the variation of the effective rate in both categories was statistically not important with (P-value = 0.13). Among fifteen female patients of the iron polymaltose complex category, the researcher recorded effectiveness in thirteen (ninety-five percent) patients and among sixteen females' patients of ferrous sulfate category, the researcher

recorded effectiveness in fifteen (84.2%) patients. However, the variation of the effective rate in both categories was statistically not important with (P-value = 0.50). Researcher divides the patients of both the categories into two age categories. I.e. age category of six months to less than two years and age category of children of two to six years. In iron polymaltose complex and ferrous sulfate category, twenty and twenty-two patients belong to age category of six months to less than two years and effectiveness percentage was eighteen (ninety percent) and nineteen (86.36%) respectively. In children age category of two to six years. In iron polymaltose complex and ferrous sulfate category, fifteen and thirteen patients belong to iron polymaltose complex and ferrous sulfate category respectively as well as effectiveness percentage was fourteen (93.33%) in IPC and eleven (84.62%) in FS category with (P-value = 0.71 & 0.45) respectively. patients were distributed into 2 weight groups, less than or equal to twelve kilograms and greater than twelve kilograms. In weight category of less than or equal to twelve-kilogram effectiveness, rates were nineteen (90.48%) and twenty (83.33%) in iron polymaltose complex and ferrous sulfate category respectively. the statistical variation was not expressive (P=0.48). In weight category greater than twelve-kilogram effectiveness rate was thirteen (92.86%) and ten (90.91%) in iron polymaltose complex and ferrous sulfate category respectively. the statistical variation was not expressive (P=0.85).

Table: Group-Wise Variables Analysis

Group		Yes		No		Total	P-Value
		Number	Percentage	Number	Percentage		
Effectiveness	IPC Group	32	91.40	3	8.60	35	0.45
	FS Group	30	85.80	5	14.20	35	
Male Patients	IPC Group	19	95.00	1	5.00	20	0.13
	FS Group	15	84.20	4	15.80	19	
Female Patients	IPC Group	13	95.00	2	5.00	15	0.5
	FS Group	15	84.20	1	15.80	16	
6 Months to < 2 Years	IPC Group	18	90.00	2	10.00	20	0.71
	FS Group	19	86.36	3	13.64	22	
2 to 6 Years	IPC Group	14	93.33	1	6.67	15	0.45
	FS Group	11	84.62	2	15.38	13	
Weight \leq 12 Kg	IPC Group	19	90.48	2	9.52	21	0.48
	FS Group	20	83.33	4	16.67	24	
Weight > 12 Kg	IPC Group	13	92.86	1	7.14	14	0.85
	FS Group	10	90.91	1	9.09	11	



DISCUSSION:

Iron deficiency anaemia is the extreme prevailing and general nutritional complication in the globe. It has expressive effects on country development on the basis of its complicated health results and in billions of financial loss every year in progressing states [7]. The most common sector in Pakistan influenced with Iron deficiency anaemia was reproductive age females and children having age less than five years. The dominance of IDA in children having age less than two years in Pakistan was presented as sixty-nine [8]. In our research sixty percent of the children having age less than two years along with forty percent between two to six years [9]. Uniformly in one additional local research seventy-four percent of the children were less than three years of age and twenty-six percent were between three to five years of age. Huge dominance of Iron deficiency anaemia in this age category is because of greater iron demand for fast development [10]. Hazardous elements related with a huge expansion of Iron deficiency anaemia included huge cow milk intake, less weight at the birth time, short intake of iron-containing diets and lower economic position [11].

The researcher noticed effectiveness in thirty-two (91.4%) children of iron polymaltose complex category and thirty (85.8%) children in ferrous sulfate category that was unimportant statistically with P value = 0.45. the finding is correlated able with other research which has presented uniform findings [12 – 14]. In one more regional research effectiveness was ninety-seven percent in ferrous sulfate and ninety-four percent in an iron polymaltose complex category with no important variation. In our research average post management haemoglobin were 11.0 ± 0.77 g/dl in iron polymaltose complex category and 10.9 ± 1.02 g/dl in ferrous sulfate category. These findings are correlated able to another research in which average post management haemoglobin values were 12.1 ± 1.19 g/dl iron polymaltose complex category and 11.9 ± 1.84 g/dl in ferrous sulfate category.

CONCLUSION:

The finding of the research declared that there was statistically unimportant variation in the effectiveness rate of IPC and FS when utilized as informal iron substitute management in IDA children. FS and IPC could be utilized as substitute drugs as both have balanced effectiveness.

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