

# Comparison of Iron Bisglycinate to Iron Polymaltose for the Treatment of Iron Deficiency Anemia in Children

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## ABSTRACT

**Objective:** To compare the efficacy of Iron Bisglycinate with Iron Polymaltose in treating iron deficiency anemia in children.

**Methodology:** A parallel group randomized double blind study was carried out at Benazir Bhutto hospital from 1st July 2022 to 31st December 2022. A total of 132 children were enrolled. Participants were allocated 1:1 to either Group A or Group B. Group A was given iron bisglycinate and Group B received iron polymaltose. Patients were assessed at baseline and were followed up at one month and three months. At all these intervals hemoglobin levels, MCV, MCH, Serum ferritin and adverse effects were noted and outcomes were assessed.

**Results:** The mean age of the patients in Group A versus B was  $7\pm 2.31$  versus  $6\pm 2.33$ . The mean hemoglobin levels at baseline in Group A versus B was  $9\pm 0.48$  versus  $8.9\pm 0.49$  g/dl and at 3 months in Group A versus B was  $10\pm 0.43$  versus  $9.4\pm 0.48$  g/dl, respectively with p value of 0.000. The mean serum ferritin levels at baseline in Group A versus B was  $9.1\pm 1.31$  versus  $8.8\pm 1.19$  ng/ml and at 3 months was  $29\pm 5.65$  ng/ml and in Group B was  $23\pm 1.87$  ng/ml, respectively with p value of 0.000.

**Conclusion:** In children with iron deficiency anemia, iron bisglycinate significantly increased hemoglobin, MCV, MCH and serum ferritin levels compared to iron polymaltose.

**Keywords:** Anemia, Ferritin, Hemoglobin, Iron Bisglycinate, Iron Polymaltose, Iron Deficiency.

### Authors' Contribution:

<sup>1,2</sup>Conception; Literature research; manuscript design and drafting; <sup>3,4</sup>Critical analysis and manuscript review; <sup>5</sup>Data analysis; Manuscript Editing.

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## Introduction

Iron deficiency anemia is the most common type of nutritional anemia globally, comprising about 50% of all anemia cases.<sup>1</sup> According to an estimate by the World Health Organization in 2019 prevalence of iron deficiency anemia in children from age 6 to 59 months of age was 39.8%.<sup>2</sup> In Pakistan the prevalence of iron deficiency is reported in about 43.2% in children less than 5 years of age.<sup>3,4</sup> Iron deficiency anemia is the 3rd leading cause of long-term disability worldwide. It is associated with poor

physical and mental growth, cognitive impairment and high mortality rate among infants in developing countries. For the treatment of iron deficiency anemia different iron formulations have been used. Ferrous Sulphate is the most commonly used oral iron formulation. However, this compound has been associated with adverse gastrointestinal effects resulting in poor compliance by the patients leading to poor replenishment of iron stores in the body.<sup>5</sup> Iron Bisglycinate and Iron Polymaltose are also used as oral supplements in children for the

treatment of iron deficiency anemia. Iron Bisglycinate is composed of two glycine molecules chelated to ferrous ions while Iron Polymaltose is a stable complex of ferric ion and dextrin (partially hydrolyzed polymaltose). The structural difference between these molecules results in a different response in iron deficiency anemia. They exhibit greater tolerability and low gastrointestinal adverse effects in comparison to Ferrous Sulphate.<sup>6,7</sup>

Different studies have separately compared the efficiency of Ferrous Sulphate with Iron Polymaltose or Iron Bisglycinate. In study carried by Mahmood T et al on comparison of iron polymaltose and ferrous sulphate and results showed the advantage of Ferrous Sulphate over Iron Polymaltose.<sup>8</sup> A similar study was done conducted by Khalid et al Faisalabad to compare these two entities but that resulted in equal efficacy in the treatment of iron deficiency anemia.<sup>9</sup> A comparative study done in Brazil showed greater efficacy of Iron Bisglycinate over Iron Polymaltose in children.<sup>10</sup>

In developing countries like Pakistan iron deficiency anemia is still the most prevalent type of anemia among children of growing age. Different iron formulations are prescribed to correct iron deficiency anemia. Various studies have been conducted in Pakistan to compare efficacy of different iron formulations but there is a lack of data which can directly compare iron Bisglycinate with Iron Polymaltose in treating iron deficiency anemia in Pakistan. Aim of study was to compare the efficacy of these two entities in the treatment of iron deficiency anemia in children. Rationale of this study will be that both iron compounds are being used in paediatric population for iron deficiency anemia. Iron bisglycinate has different structural composition than polymaltose, therefore eliciting different response to treatment. Both compounds result in increased levels of both hemoglobin and Ferritin but due to better absorption and tolerability, bisglycinate will be more effective in treating iron

deficiency. Different researchers separately compared both iron preparations but there is still scarcity of studies that directly compare both compounds.

This study was designed to compare the efficacy of Iron Bisglycinate with Iron Polymaltose in treating iron deficiency anemia in children.

## Methodology

A randomized double blind parallel group study was conducted at the Pediatrics Department, Benazir Bhutto Hospital, Rawalpindi from 1<sup>st</sup> July, 2022 till 31<sup>st</sup> December, 2022. Study participants were selected by consecutive non probability sampling followed by random allocation between groups. Participants were allocated 1:1 to either Group A or Group B. Group A was given iron bisglycinate and Group B received iron polymaltose. Sample size was calculated by using the WHO formula for sample size for two population mean with following values: Level of significance = 5%. Power of test = 80%. Mean difference in Hb in P1 =  $2.5 \pm 1.3111$  g/dl. Mean difference in Hb in P2 =  $2.67 \pm 0.536$  g/dl. Pooled SD = 0.92. A total of 132 children were included in study and divided into two groups, Group A & B with each group containing 66 children. Children 6 months to 12 years of age of both genders with iron deficiency anemia, weighing up to 40 Kgs and fulfilling the age-appropriate criteria of iron deficiency anemia were included in the study. Children with megaloblastic anemia, thalassemia, hemolytic anemia, severe anemia with hemoglobin less than 6 mg/dl, history of recurrent blood transfusions, malabsorption syndromes, pancytopenia, signs of any infection on the day of sample collection and having diarrheal illnesses were excluded from study. Approval of study was taken from the institutional ethical review committee with reference No232/IREF/RMU. Patients with signs and symptoms of anemia were initially screened for anemia through lab investigations. The diagnosis of iron deficiency

anemia was made as per criteria. Other causes of anemia were excluded by medical records, lab investigations, history and examination. Iron deficiency anemia patients were screened. Written informed consent was taken from parents and patients were randomized either into the group A or group B. The group B was the reference group. Group A was given iron bisglycinate and Group B was given iron polymaltose. An equal number of patients were randomized into two groups. Randomization was done through a computer-generated list of random numbers. Both groups received similar elemental iron concentration i.e. 10 mg Fe/ml. Group A received a daily single oral dose (4 to 6 mg/kg per day) of iron Bisglycinate for 3 months while iron polymaltose was administered to Group B in same dose for a period of three months. The dose of iron formulations was kept variable because there was a difference in the age and weight of the children enrolled. Children were given medicines in syrup formulation for 3 months. Iron supplements were continued for a minimum of 3 months after anemia had been corrected to replenish stores. Medicine was provided to patients free of cost. Parents were instructed to consult immediately for any side effects, any ailment during the study period and discontinuation of the medicine. Patients were recalled for follow-up at 1 and 3 months. Patients during follow up were examined for change in medicine according to weight or discontinuation of medicine in case of any side effect or any other medical condition like acute infection requiring discontinuation of the medicine. Blood complete picture and serum Ferritin was done on the first month of follow up and then after the end of the treatment for final assessment. The clinical information required for the study was collected on the Proforma which contained demographic and clinical variables.

Data was analyzed using SPSS version 23.0. Descriptive statistics were used for qualitative and

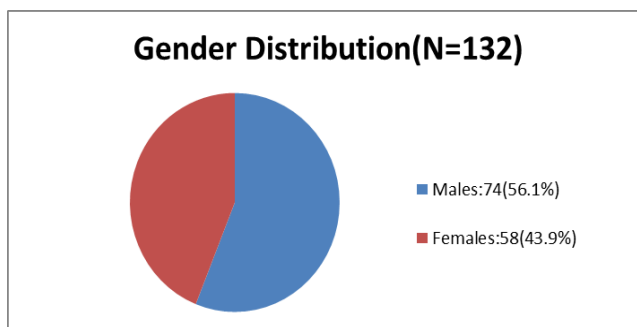
quantitative variables. Mean and standard deviation was calculated for quantitative variables like age, hemoglobin level and serum ferritin levels. Qualitative variables like gender were presented as frequency and percentages. Both study groups were compared for age, gender baseline hemoglobin levels, MCV, MCH and serum Ferritin levels. Chi square test was used for qualitative variables and independent t-test for quantitative variables. The two groups were compared for the post treatment hemoglobin levels by independent t test. Post treatment MCV, MCH and serum ferritin levels were compared between two groups using independent t-test. Subgroup analysis or stratification was done on age and gender of the patients. Post stratification independent t-test was used. At 95% confidence level, p value  $\leq 0.05$  was considered statistically significant for all the statistical tests in the study.

## Results

A total of 132 patients were included in study. Male to females' frequency was 74 (56.1%) and 58 (43.9%) respectively. The mean age of the patients in Group A and Group B was  $7 \pm 2.31$  and  $6 \pm 2.33$  respectively. Shown in Figure I. Comparison of Mean Hemoglobin at Baseline, 1 Month and 3 Months of Age is shown in Table I. Comparison of Both Groups in Terms of Mean MCV (fl) Baseline, 1 Month, 3 Months of Age shown in Table II. Comparison of Both Groups in Term of Mean MCH (Pg) at Baseline, 1 Month, 3 Months of Age shown in Table III. Comparison of Both Groups in Term of Serum Ferritin levels (ng/ml) at Baseline, 1 Month, 3 Months of Age shown in Table IV. Comparison of mean serum ferritin values revealed difference was statistically significant at 1 month with p value of 0.000 and the mean difference in the MCH at 3 months between both groups was  $6 \pm 0.73$  ng/ml which was statistically significant with p value of 0.000. There was no significant difference in terms of adverse effects

**Table I: Comparison of Mean Hemoglobin at Baseline, one Month and 3 Months**

Duration	Groups	Mean±SD	Difference Between Both Groups	T-Test	P Value
At baseline	A (Iron bisglycinate)	9±0.48	0.09±0.08	1.041	0.300
	B (Iron polymaltose)	8.9±0.49			
At 1 month	A (Iron bisglycinate)	9.4±0.48	0.3±0.09	3.502	0.001
	B (Iron polymaltose)	9.2±0.50			
At 3 months	A (Iron bisglycinate)	10±0.43	0.6±0.08	8.466	0.000
	B (Iron polymaltose)	9.4±0.48			



**Figure I: Gender Distribution of Patients**

between both groups with p value of 0.832. Data was stratified with respect to age and gender, and it was revealed there was no significant association between these effect modifiers and mean Hemoglobin levels, MCV, MCH and serum ferritin levels at 3 months as was indicated by a p--value of >0.05. Shown in Table V, VI.

**Table II: Comparison of Both Groups in Term of Mean MCV (fl) Baseline, 1 Month, 3 Months of Age.**

Duration	Group	Mean±Standard Deviation	Difference Between Both Groups	T-Test	P-Value
At baseline	A (Iron bisglycinate)	69±5.01	1±0.88	-0.895	0.372
	B (Iron polymaltose)	70±5.09			
At 1 month	A (Iron bisglycinate)	78.5±4	1±0.69	1.405	0.162
	B (Iron polymaltose)	77.5±3.9			
At 3 months	A (Iron bisglycinate)	87±2.53	6±0.47	12.364	0.000
	B (Iron polymaltose)	81±2.80			

**Table III: Comparison of Both Groups in Term of Mean MCH (Pg) at Baseline, 1 Month, 3 Months of Age.**

Duration	Group	Mean ± Standard Deviation	Difference Between Both Groups	T-Test	P Value
At baseline	A (Iron bisglycinate)	25.5±2.26	0.7±0.36	-1.858	0.065
	B (Iron polymaltose)	26.2±1.83			
At 1 month	A (Iron bisglycinate)	29.9±1.62	0.9±0.25	2.893	0.004
	B (Iron polymaltose)	29±1.24			
At 3 months	A (Iron bisglycinate)	33.3±1.07	2.3±0.19	11.505	0.000
	B (Iron polymaltose)	31±1.12			

Duration	Group	Mean ± Standard Deviation	Difference Between Both Groups	T-Test	P Value
At baseline	A (Iron bisglycinate)	9.1±1.31	0.7±0.39	1.535	0.127
	B (Iron polymaltose)	8.8±1.19			
At 1 month	A (Iron bisglycinate)	20±1.19	4±0.37	12.078	0.000
	B (Iron polymaltose)	16±2.49			
At 3 mont	A (Iron bisglycinate)	29±5.65	6±0.73	8.983	0.000
	B (Iron polymaltose)	23±1.87			

Side Effects	Groups		P-Value
	A (iron bisglycinate)	B (iron polymaltose)	
Vomiting	4 (6%)	5 (7.6%)	0.832
Epigastric pain	1 (1.5%)	0 (0%)	
Diarrhea	4 (6%)	4 (6%)	
Heartburn	0 (0%)	1 (1.5%)	
Colic	1 (1.5%)	1 (1.5%)	
Constipation	0 (0%)	0 (0%)	
No side effects	56 (84.8%)	55 (83.4%)	
Total	66 (100%)	66 (100%)	

Variables	Gender		P-Value
	Males	Females	
Hemoglobin levels (g/dl)	9.71±0.58	9.75±0.54	0.729
MCV (fl)	84±3.81	84.4±4.1	0.596
MCH (pg)	32.2±1.55	32.3±1.58	0.856
Ferritin (ng/ml)	25.5±5.46	26.3±5.18	0.074

Variables	Age Groups		P-Value
	≤6 years	>6 years	
Hemoglobin levels (g/dl)	9.72±0.55	9.74±0.58	0.829
MCV (fl)	84.3±3.73	84.2±4.23	0.828
MCH (pg)	32±1.61	32.4±1.46	0.365
Ferritin (ng/ml)	25±4.93	26.8±5.78	0.074

## Discussion

The current study revealed that in children with iron deficiency anemia, iron bisglycinate resulted in significantly more improvement in hemoglobin levels (10±0.43 g/dl versus 9.4±0.48 g/dl with significant p value of 0.000), MCV (87±2.53 fl and 81±2.8 fl with mean difference of 6±0.47 fl with significant p value of 0.000), MCH(33.3±1.07 pg versus 31±1.12 pg with mean difference of 2.3±0.19 pg with significant p value of 0.000) and serum ferritin levels(29±5.65 ng/ml versus 23±1.87 ng/ml with mean difference of 6±0.73 ng/ml which was statistically significant with p value of 0.000) compared to iron polymaltose after 3 months of treatment. The majority of the children in our study were males.

There were No Dropout rate in follow up examination.

Elkhouly et al revealed that in patients with Iron deficiency anemia patients who received iron bisglycinate the mean hemoglobin levels at baseline were  $8.9 \pm 0.67$  gm/dl and at 12 weeks after treatment were  $11.5 \pm 0.91$  gm/dl and in the group which received iron polymaltose the mean hemoglobin levels at baseline were  $8.6 \pm 0.72$  and at 12 weeks after treatment were  $10.48 \pm 0.81$  gm/dl and this difference was found to be statistically significant with p value of less than 0.001. Regarding ferritin levels at baseline in bisglycinate group was  $39.2 \pm 8.31$  and at 12 weeks it was  $43.7 \pm 8.32$  ng/dl and in patients who received iron polymaltose, the mean serum ferritin levels at baseline was  $39.2 \pm 8.4$  and at 12 weeks was  $44 \pm 8.41$  fl and this difference between the two groups was statistically significant with p value less than 0.001.<sup>11</sup> These findings support our study findings that iron bisglycinate is significantly associated with more improvement in hemoglobin and ferritin levels compared to iron polymaltose.

JoãoName et al in a study revealed that both iron polymaltose and iron bisglycinate resulted in significant improvement in hemoglobin levels along with mean corpuscular volume, red cell distribution width and reduction in transferrin but iron bisglycinate has superior efficacy in increasing significant mean corpuscular hemoglobin and ferritin at follow up period. Regarding MCH they found that mean MCH in iron bisglycinate group was increased from  $24.4 \pm 1$  to  $24.9 \pm 0.9$  and this increase was statistically significant with p value less than 0.05, however, in the iron polymaltose group there was no significant increase in the MCH levels. They also noted a significant increase in the serum ferritin levels in iron bisglycinate from baseline to follow up from 21 ng/ml to 37ng/ml, whereas in the iron polymaltose group there was no significant improvement i.e. from 25ng/ml to 34 ng/ml. These findings are consistent with our study results.<sup>12</sup> Cheng et al carried study on iron bisglycinate role in

chronic kidney disease patients and results showed that if given for 4 months, it resulted in increase in both serum iron and transferrin levels in patients with restoration of iron stores and maintenance of hemoglobin levels with no significant documented gastrointestinal upset.<sup>13</sup> Bumrungpert et al carried study on efficacy of iron bisglycinate. Patients were given iron bisglycinate and ferrous fumarate formulations. Iron absorption with measurement of serum iron level after 2 hours of intake and hematological markers at 3<sup>rd</sup> and 6<sup>th</sup> months was assessed. They found that bisglycinate had superior efficacy with good absorption and better tolerability with few side effects of bloating, constipation and pain abdomen with p value less than 0.001. All these are consistent with our results findings.<sup>14</sup>

Perveen A et al carried study in 136 children on comparison of different iron formulations. They gave iron bisglycinate and ferrous sulphate and observed rise of hemoglobin. Mean hemoglobin in bisglycinate and ferrous sulphate group was  $2.5 \pm 1.31$  and  $1.8 \pm 1.59$  gm/dl respectively with significant p value of 0.003. They concluded that bisglycinate is superior to rest of Iron formulations in treating iron deficiency anemia.<sup>15</sup> Abass AM et al carried study on patients with iron deficiency anemia. They found that in patients who took iron bisglycinate mean increase of hemoglobin was  $2.48 \pm 0.12$  gm/dl with hemoglobin of more than 11gm/dl after 8 weeks of treatment. They concluded that iron bisglycinate has superior efficacy with more tolerability and good compliance with tolerable side effects.<sup>16</sup> All these are consistent with our results that show iron bisglycinate superiority.

Jordie A et carried out a systemic review and meta - analysis on iron bisglycinate. They included 17 randomized control trials and found that there was rise in mean hemoglobin with minimal side effects observed with bisglycinate when compared to other formulations with significant p value of 0.01.<sup>17</sup> Pai Raiturker et al carried retrospective study on iron

biglycinate and compared it to rest of Iron formulations and found that it's usage led to rise of mean hemoglobin of 2.41 gm/dl after 2 months usage with no side effects. 97.6% patients reported no side effects and 2.4 % only had mild gastrointestinal disturbances with excellent tolerability of more than 98% and compliance rate of more than 80%.<sup>18</sup> All these findings are consistent with our study results.

Singhal SR et al carried randomized control trials on 250 patients with Iron deficiency anemia and compared efficacy of different iron formulations. They divided patients in 5 groups with each group receiving different formulations. They concluded that the group who received iron biglycinate showed better results when compared to rest of iron formulations with mean hemoglobin & ferritin rise of 11+0.27 gm/dl and 13.47+7.03ng/dl respectively in 60 days of treatment with significant p value of 0.001. Also, minimal side effects were seen with biglycinate when compared to rest of formulations. All these findings are consistent with our study results that biglycinate has superior efficacy in treating iron deficiency anemia.<sup>19</sup>

The current study findings support the use of iron biglycinate in children with iron deficiency anemia as it was found to be significantly effective in terms of more improvement in the levels of hemoglobin, MCV, MCH and serum ferritin and was associated with similar safety profile as iron polymaltose and the side effects were low. Iron biglycinate in iron deficiency anemia can help in improving anemia quickly and will help in reducing further morbidity associated with the condition and improved parental satisfaction. Further studies must be carried out on a larger sample size for validation of current study findings.

The current study had certain limitations. Firstly, the sample size was small and the study was carried out at a single center so there is an issue of generalizability of the results. Secondly, comparison

with other available options was not made so the findings cannot be validated when other treatment options are used. Lastly, patients were not assessed over a long term follow up.

## Conclusion

In children with iron deficiency anemia, iron biglycinate showed a significant improvement in hemoglobin levels, MCV, MCH and serum ferritin levels compared to iron polymaltose.

### Recommendations:

Iron biglycinate is a better treatment agent that can help in improving hemoglobin levels of the children. It is tolerated well and is associated with lesser side effects, thus helping in better treatment among such children and decreased anxiety of the parents.

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