

## Effect of Iron Supplementation on Haemoglobin Levels in Anaemic Children of 2–5 Years Age Group

\*Sattar S<sup>1</sup>, Quddus ASMR<sup>2</sup>

### Abstract

Iron-deficiency anaemia is a major health issue among young children in low-resource settings, contributing to developmental delays and increased morbidity. A randomized controlled trial was conducted at Community Based Medical College, Bangladesh (CBMC,B), Mymensingh, Bangladesh, from January 2022 to December 2023, to assess the effect of iron supplementation on haemoglobin levels in anaemic children of 2–5 years age group. A total of 60 anaemic children with haemoglobin <11 g/dL was selected for this study. Participants were randomly allocated to either an intervention group (n=30) receiving daily oral ferrous sulfate (3 mg elemental iron/kg/day) or a control group (n=30) receiving standard care without iron supplements. Haemoglobin levels were measured at baseline and post-intervention using standardized cyanmethemoglobin methods. Anthropometric measurements and adverse effects were monitored throughout the study period. The intervention group demonstrated a significant increase in mean haemoglobin levels from 8.7±0.8 g/dL to 11.0±1.1 g/dL (p<0.001). In contrast, minimal change was observed in control group (8.8±0.9 g/dL to 8.9±0.7 g/dL; p>0.05). Adherence to supplementation was observed in 86.7%; only 5(16.7%) mild transient side effects were reported. Children with severe anaemia (haemoglobin <8 g/dL) showed a greater response (2.8 g/dL increase) than those with moderate anaemia (1.9 g/dL increase). Serum ferritin levels increased significantly in the supplemented group (from 14.3±3.0 µg/L to 32.5±5.6 µg/L; p<0.001); however, no difference was observed in control group (from 15.0±2.8 µg/L to 15.8±3.1 µg/L; p>0.05). Our data suggests that adding an iron supplement for 12 weeks significantly improved haemoglobin levels in anaemic pre-school children, with good tolerability and adherence.

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### Introduction

Iron-deficiency anaemia (IDA) remains one of the most prevalent nutritional disorders globally, particularly affecting children in low- and middle-income countries (LMICs).<sup>1</sup> The World Health Organization (WHO) estimates that approximately 40% of preschool-aged children in developing nations suffer from anaemia, with iron deficiency being the leading cause.<sup>2</sup> In Bangladesh, the burden is even higher, with studies reporting anaemia rates of up to 50% among children under five years of age.<sup>3,4</sup> This condition impairs cognitive development, immune function, and physical growth, leading to long-term socioeconomic consequences.<sup>5</sup> Iron supplementation has been widely recommended as a primary intervention to combat IDA in pediatric populations.<sup>6</sup> Clinical trials in various settings have demonstrated their efficacy in raising haemoglobin levels and reducing anaemia prevalence.<sup>7,8</sup> However, the response to iron supplementation can vary based on

factors such as baseline iron status, dosage, duration of supplementation, and coexisting infections like malaria or helminthiasis.<sup>9,10</sup> While several studies have explored iron supplementation in school-aged children and pregnant women, data on its effectiveness in Bangladesh's preschool-aged children (2–5 years age group) remain limited.<sup>11,12</sup> Current national programs in Bangladesh, such as the National Nutrition Services (NNS), include iron-fortified foods and periodic supplementation campaigns.<sup>13</sup>

1. \*Dr. Shamima Sattar, Associate Professor, Department of Pharmacology and Therapeutics, Community Based Medical College Hospital Bangladesh.
2. Professor. Dr. A.S.M. Ruhul Quddus, Professor & Head, Department of Pediatrics, Community Based Medical College Hospital Bangladesh.

#### Address of Correspondence:

Email: [shamimacbmcb@gmail.com](mailto:shamimacbmcb@gmail.com)

However, adherence to these interventions is often suboptimal due to logistical challenges, lack of awareness, and side effects like gastrointestinal discomfort.<sup>14,15</sup> Moreover, existing studies in this region have primarily focused on population-level surveys rather than controlled trials evaluating Hb improvement post-supplementation.<sup>16</sup> A rigorous assessment of iron supplementation's impact in a hospital-based setting could provide actionable insights for clinical and public health strategies. Therefore, our study aims to assess the effect of iron supplementation on haemoglobin levels in anaemic children of 2–5 years age group in a tertiary level hospital in Bangladesh through a randomized controlled trial (RCT).

## Methods

This randomized controlled trial was conducted in Community Based Medical College, Bangladesh (CBMC,B), Mymensingh, Bangladesh, from January 2022 to December 2023. We enrolled 60 anaemic children aged between 2 and 5 years with confirmed haemoglobin levels  $<11$  g/dL. Participants were randomly allocated into two groups using computer-generated randomization: an intervention group ( $n=30$ ) receiving daily oral ferrous sulfate (3 mg elemental iron/kg/day) and a control group ( $n=30$ ) receiving regular standard care without any iron supplements. Haemoglobin levels were measured at baseline and after 12 weeks using the cyanmethemoglobin method. Anthropometric measurements (weight, height) were recorded at both time points. Adherence was monitored through weekly follow-up visits and parental recall. Adverse effects were documented using standardized reporting forms.

Statistical analysis was performed using Statistical Package for Social sciences (SPSS) version 23.0 for

windows. Data was expressed as either mean and standard deviation or frequency and percentage as applicable. Normal distribution was confirmed using Shapiro-Wilk tests. Within the group, comparisons were done using paired t-tests, while between-group differences were analyzed using independent t-tests. Effect sizes were calculated using Cohen's  $d$ . A  $p$ -value  $<0.05$  was considered statistically significant.

The study was approved by the Ethical review Committee of Community Based Medical College, Bangladesh (CBMC,B), Mymensingh, Bangladesh.

## Results

Our study evaluated 60 anaemic children (30 in each group) with comparable baseline characteristics. No differences were found in age, gender, haemoglobin levels and severe anaemia between intervention group and control group (Table-I). After 12 weeks of intervention, the iron-supplemented group showed a significant increase in mean haemoglobin levels from  $8.7 \pm 0.8$  g/dL to  $11.0 \pm 1.1$  g/dL ( $p < 0.001$ ), while the control group demonstrated minimal change ( $8.8 \pm 0.9$  g/dL to  $8.9 \pm 0.7$  g/dL;  $p > 0.05$ ) (Table-II). The between-group difference in haemoglobin change was statistically significant ( $p < 0.001$ ). Stratified analysis revealed that children with severe anaemia (haemoglobin  $<8$  g/dL) experienced greater haemoglobin improvement ( $2.8 \pm 0.6$  g/dL) compared to moderately anaemic children (haemoglobin 8-10.9 g/dL) ( $1.9 \pm 0.5$  g/dL) (Table-III). Adherence to supplementation was excellent (86.7%); only 5 (16.7%) children reported mild side effects (Table-IV). Anthropometric measurements showed improvements in weight-for-age z-scores in the intervention group as compared to controls ( $+0.32 \pm 0.20$  vs.  $+0.06 \pm 0.10$ ;  $p < 0.05$ ) (Table-V). Serum ferritin levels increased significantly in the supplemented group (from  $14.3 \pm 3.0$   $\mu$ g/L to  $32.5 \pm 5.6$

µg/L;  $p < 0.001$ ); however, no difference was observed in control group (from  $15.0 \pm 2.8$  µg/L to  $15.8 \pm 3.1$  µg/L;  $p > 0.05$ ) (Table-VI).

**Table-I:** Baseline characteristics of the study participants (N=60)

Variables	Intervention (n=30)	Control (n=30)	p-value
Age (in years)	$3.5 \pm 0.7$	$3.4 \pm 0.8$	0.584
Male gender	16 (53.3%)	15 (50.0%)	0.796
Haemoglobin (g/dL)	$8.7 \pm 0.8$	$8.8 \pm 0.9$	0.653
Severe anaemia	9 (30.0%)	8 (26.7%)	0.776

**Table-II:** Changes in haemoglobin levels

Group	Baseline haemoglobin (g/dL)	Final haemoglobin (g/dL)	p-value
Intervention	$8.7 \pm 0.8$	$11.0 \pm 1.1$	$< 0.001$
Control	$8.8 \pm 0.9$	$8.9 \pm 0.7$	$> 0.05$

**Table-III:** Response by anaemia severity

Baseline haemoglobin	Frequency	Increase in haemoglobin levels	p-value
$< 8$ g/dL	17	$2.8 \pm 0.6$	$< 0.001$
8-10.9 g/dL	43	$1.9 \pm 0.5$	$< 0.001$

**Table-IV:** Adverse effects

Adverse effects	Intervention	Control
Abdominal pain	3 (10.0%)	1 (3.3%)
Constipation	1 (3.3%)	-

**Table-V:** Anthropometric changes

Parameter	Intervention	Control	p-value
$\Delta$ WAZ	$+0.32 \pm 0.20$	$+0.06 \pm 0.10$	$< 0.05$

**Table-VI:** Changes in ferritin levels

Group	Baseline ferritin (µg/L)	Final ferritin (µg/L)	p-value
Intervention	$14.3 \pm 3.0$	$32.5 \pm 5.6$	$< 0.001$
Control	$15.0 \pm 2.8$	$15.8 \pm 3.1$	$> 0.05$

## Discussion

Our study demonstrates that a 12-week course of iron supplementation significantly improved haemoglobin levels in anaemic preschool children, with a mean increase of 2.3 g/dL in the intervention group compared to minimal change in controls. This finding aligns with previous RCTs in similar populations<sup>7,17</sup>, though our observed effect size was notably larger than the 1.4-1.8 g/dL improvements reported in recent meta-analyses.<sup>18,19</sup> The greater response may reflect our use of weight-adjusted dosing (3mg/kg/day) rather than fixed doses, as suggested by WHO guidelines for severe anemia.<sup>20</sup> The intervention's success was particularly marked in children with severe anaemia (haemoglobin  $< 8$  g/dL), who showed a 2.8 g/dL increase versus 1.9 g/dL in moderately anaemic children. This severity-dependent response mirrors findings from Gambia<sup>21</sup>, but contrasts with that of an Indian study reporting uniform efficacy across anemia grades.<sup>22</sup> The difference may relate to higher rates of concomitant infections in the latter setting, as inflammatory cytokines can blunt iron absorption.<sup>23</sup> Our hospital-based protocol likely minimized such confounders through active infection screening. Notably, the 86.7% adherence rate exceeded typical community-based program compliance (60-75%)<sup>24</sup>, attributable to our weekly follow-ups and structured counseling. While 16.7% of children reported mild gastrointestinal symptoms, none discontinued treatment which signifies a tolerability profile consistent with liquid formulations in this age group.<sup>25</sup> The parallel ferritin increase ( $+18.2$  µg/L) confirms robust iron store repletion, addressing concerns about transient haemoglobin responses without sustained iron deposition in anaemic children.<sup>26</sup> These findings carry important policy implications. First, they support expanding Bangladesh's National Nutrition Services<sup>27</sup>

to include structured preschooler supplementation, currently limited to school-age children. Second, the weight-adjusted dosing strategy warrants consideration in clinical guidelines, as fixed doses may under-treat severely anaemic children.<sup>28</sup> However, our single-center design and 12-week duration require cautious extrapolation to national programs. Future studies should evaluate longer-term outcomes and cost-effectiveness in decentralized settings.

This study was conducted at a single hospital, potentially limiting generalizability. The 12-week duration precluded assessment of long-term effects. Dietary iron intake was not monitored, and inflammatory markers were not measured, which could influence hemoglobin responses.

## Conclusion

Our data suggests that an iron supplement for twelve weeks significantly improved haemoglobin levels in anaemic preschool children with excellent adherence and tolerability profiles. The findings support weight-adjusted iron therapy as an effective intervention for managing pediatric iron-deficiency anaemia in Bangladesh. Future studies should evaluate long-term outcomes and cost-effectiveness to guide national policy decisions. Implement weight-based iron supplementation in clinical practice for anaemic pre-schoolers. We need further strengthening of counseling/health education, conducting multicenter studies to assess scalability and integrating anaemia screening with routine paediatric care while monitoring long-term growth and development.

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