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Research Article

Evaluating the Efficacy of Intramuscular Iron Treatment in Pediatric Patients with Severe Iron Deficiency Anemia: A Pilot Study

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ABSTRACT

Background: Iron deficiency anemia (IDA) is a common public health problem among children, particularly in low- and middle-income countries. Oral iron therapy is the conventional treatment for IDA; however, poor absorption, gastrointestinal side effects, and poor treatment adherence often limit its effectiveness. Intramuscular iron therapy may serve as an alternative treatment option in such cases. Nevertheless, evidence regarding the effectiveness of newer intramuscular iron formulations, such as iron isomaltoside 1000, remains limited.

Objective: To assess the effectiveness of intramuscular iron therapy in children with severe iron deficiency anemia.

Study Design: Pilot study.

Duration and Place of Study: This study was conducted at Shaheed Mohtarma Benazir Bhutto Medical College Lyari Karachi from April 2025 to April 2026.

Methodology: This pilot study included 50 children aged 6 months to 5 years diagnosed with severe iron deficiency anemia. Participants were recruited using a non-probability purposive sampling technique. The iron deficit was calculated using the Ganzoni formula, targeting a hemoglobin concentration of 12 g/dL. Iron isomaltoside 1000 was administered intramuscularly, with a maximum dose of 200 mg (2 mL) injected into the anterolateral thigh over a four-week period. Participants were monitored for adverse events following administration. Hemoglobin levels were reassessed four weeks after treatment. Data were analyzed using SPSS version 26. The Wilcoxon Signed-Rank Test was used to compare pre- and post-treatment outcomes,

and effect size was estimated using Cohen's d.

Results: A total of 50 children aged 6 months to 4 years were enrolled in the study. The mean age was 1.57 ± 0.63 years, and the mean weight was 9.60 ± 1.73 kg. The median increase in hemoglobin level was 4.40 g/dL, while the median weight gain was 0.80 kg. No adverse reactions were observed in 94% of participants.

Conclusion: Intramuscular iron isomaltoside therapy appears to be a safe, effective, and well-tolerated treatment option for children with severe iron deficiency anemia.

Keywords: Iron deficiency anemia, IDA, iron isomaltoside 1000, intramuscular iron therapy, parenteral iron, children

INTRODUCTION

Iron deficiency anemia (IDA) is one of the most common nutritional disorders worldwide, affecting approximately 269 million children globally [1]. The burden of the disease is particularly high in low- and middle-income countries, where nutritional deficiencies and limited access to healthcare remain significant challenges. The prevalence of anemia among young children in developing countries is estimated to be approximately 53.7% [2]. Iron deficiency during early childhood can have serious consequences, including impaired growth, delayed cognitive and psychomotor development, compromised immune function, and reduced physical activity. The most common causes of IDA include inadequate dietary iron intake, impaired iron absorption, and increased iron requirements associated with rapid growth during infancy and early childhood [3].

Oral iron supplementation remains the conventional first-line treatment for IDA because of its availability, low cost, and ease of administration [4]. However, its effectiveness is often limited by gastrointestinal side effects, poor intestinal absorption, prolonged treatment duration, and poor patient adherence. Consequently, many children fail to achieve an adequate hematological response with oral therapy alone. In such circumstances, parenteral iron administration may be considered as an alternative treatment option [5].

Although intravenous (IV) iron therapy has demonstrated efficacy in the treatment of IDA, its administration requires close monitoring because of the risk of hypersensitivity reactions and the need for healthcare resources and trained personnel [6]. Intramuscular (IM) iron therapy offers an alternative route of administration that enables rapid replenishment of iron stores while avoiding gastrointestinal adverse effects associated with oral iron preparations [7]. Furthermore, IM iron therapy may be particularly beneficial in children with malabsorption syndromes, intolerance to oral iron, or poor compliance with oral treatment. Nevertheless, pain at the injection site, skin staining, and iron deposition within tissues remain potential limitations of this approach.

Despite the widespread burden of severe IDA in children, there is limited evidence regarding the efficacy and safety of intramuscular iron therapy in the pediatric population, particularly in developing countries [8,9,10]. Previous studies have reported favorable outcomes with intramuscular iron sorbitol; however, data regarding newer intramuscular iron formulations, such as iron isomaltoside 1000, remain scarce [11,12,13]. Given the need for effective and well-tolerated alternatives to oral iron therapy, further evaluation of these newer formulations is warranted. Therefore, this study aimed to assess the effectiveness of intramuscular iron treatment in children with severe iron deficiency anemia.

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METHODOLOGY

This pilot study was conducted in the Department of Pediatrics and included a total of 50 children. Participants were selected using a non-probability purposive sampling technique. Children aged 6 months to 4 years who were diagnosed with severe iron deficiency anemia (IDA) were enrolled in the study. Severe IDA was defined as a hemoglobin level of less than 7 g/dL and a serum ferritin level of less than 12 µg/L. Parents or legal guardians of all participants were informed about the study, and written informed consent was obtained prior to enrollment. Ethical approval for the study was obtained from the Institutional Ethical Review Committee.

Exclusion Criteria

Children with chronic illnesses, congestive cardiac failure, septicemia, or any condition known to interfere with iron metabolism were excluded from the study. In addition, participants who failed to complete the follow-up assessment were excluded from the final analysis.

Data Collection and Intervention

Baseline demographic characteristics, hemoglobin levels, and serum ferritin concentrations were recorded for all participants. Intramuscular iron supplementation was administered using iron isomaltoside 1000. The total iron deficit was calculated using the Ganzoni formula, with a target hemoglobin concentration of 12 g/dL. A maximum dose of 200 mg (2 mL) was administered intramuscularly into the anterolateral aspect of the thigh over a period of four weeks.

All participants were observed for one hour following each injection for the detection of immediate adverse reactions. Follow-up assessments were conducted throughout the study period to monitor treatment-related adverse events. Hemoglobin concentration and body weight were reassessed four weeks after initiation of therapy to evaluate treatment effectiveness.

Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 26. Categorical variables were summarized as frequencies and percentages, whereas continuous variables were presented as mean ± standard deviation (SD) or median and interquartile range (IQR), as appropriate. Changes in hemoglobin concentration and body weight before and after treatment were evaluated using the Wilcoxon Signed-Rank Test. Effect size was estimated usingCohen's d. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 50 children with severe iron deficiency anemia were enrolled in the study. The age of the participants ranged from 6 months to 4 years, with a mean age of 1.57 ± 0.63 years. The mean body weight was 9.60 ± 1.73 kg. Baseline hemoglobin and serum ferritin levels were 6.34 ± 0.61 g/dL and 5.10 ± 3.60 µg/L, respectively. The baseline demographic and clinical characteristics of the study participants are presented in Table 1.

Table 1. Baseline demographic and clinical characteristics of study participants (n = 50)

Variable	Mean	±	SD
Age (years)	1.57	±	0.63
Weight (kg)	9.60	±	1.73
Hemoglobin level (g/dL)	6.34	±	0.61
Serum ferritin level (µg/L)	5.10 ± 3.60		

The age distribution of the study participants is shown in Table 2. The majority of children (76.0%) were between 1 and 2 years of age. Children younger than 1 year accounted for 12.0% of the study population, while 10.0% were between 3 and 4 years of age.

Table 2. Age distribution of study participants (n = 50)

Age Group (years)	n	%
Up to 1 year	6	12.0
1.1 – 2.0 years	38	76.0
2.1 – 3.0 years	1	2.0
3.1 – 4.0 years	5	10.0
Total	50	100.0

Following intramuscular iron therapy, a marked improvement in hematological parameters was observed. Hemoglobin levels increased substantially after treatment, with a median increase of 4.40 g/dL. Body weight also improved following therapy, with a median gain of 0.80 kg. The minimum and maximum values of hemoglobin concentration and body weight before and after treatment are presented in Table 3.

Table 3. Hemoglobin concentration and body weight before and after intramuscular iron therapy (n = 50)

Parameter	Minimum	Maximum
Hemoglobin before treatment (g/dL)	4.2	7.0
Hemoglobin after treatment (g/dL)	8.3	11.0
Weight before treatment (kg)	6.5	16.9
Weight after treatment (kg)	8.0	18.1

Intramuscular iron therapy was well tolerated by most participants. No adverse reactions were observed in 47 (94.0%) children. Mild adverse events were reported in only three participants. Swelling at the injection site occurred in two (4.0%) children, while one (2.0%) child experienced nausea. No serious adverse events were reported during the study period.

Table 4. Adverse reactions following intramuscular iron therapy (n = 50)

Adverse Reaction	n	%
Swelling at injection site	2	4.0
Nausea	1	2.0
No adverse reactions	47	94.0
Total	50	100.0

DISCUSSION

The present pilot study evaluated the effectiveness and safety of intramuscular iron therapy in children with severe iron deficiency anemia (IDA). The findings demonstrated a substantial improvement in hemoglobin levels following treatment, with a median increase of 4.40 g/dL after four weeks of therapy. In addition, a significant increase in body weight was observed, while adverse effects were minimal and limited to mild reactions in a small proportion of participants. These findings suggest that intramuscular iron therapy may represent an effective and well-tolerated treatment option for children with severe IDA.

Recent literature has highlighted the advantages of parenteral iron therapy over conventional oral iron supplementation in selected patients with iron deficiency anemia. A meta-analysis conducted by Neogi et al. (2019), which included 13 studies involving 1,475 participants, demonstrated that intramuscular iron therapy was superior to oral iron supplementation in improving hemoglobin levels and replenishing iron stores [14]. The authors reported a mean increase in hemoglobin concentration of 2.1 g/dL in the intramuscular iron group compared with 1.5 g/dL in the oral iron group. The findings of the present study are consistent with these observations and further support the effectiveness of intramuscular iron therapy in correcting anemia.

Similarly, Saha et al. (2021) conducted a randomized controlled trial involving 120 children with severe anemia and reported that intramuscular iron therapy produced a more rapid and sustained improvement in hemoglobin concentration compared with oral iron supplementation [15]. In their study, the mean increase in hemoglobin concentration was 3.2 g/dL in the intramuscular iron group compared with 2.1 g/dL in the oral iron group. The substantial improvement in hemoglobin levels observed in the current study further reinforces the therapeutic potential of intramuscular iron

therapy in pediatric patients with severe IDA.

The favorable response to intramuscular iron therapy may be attributed to its ability to bypass the gastrointestinal tract, thereby avoiding limitations associated with oral iron therapy, such as poor intestinal absorption, gastrointestinal adverse effects, and poor treatment adherence [16]. Furthermore, intramuscular administration enables direct replenishment of iron stores, resulting in improved hematological recovery. This route of administration may be particularly beneficial in children who are unable to tolerate oral iron preparations or who have conditions associated with impaired iron absorption.

An additional finding of the present study was the significant increase in body weight following treatment. This observation is clinically important because iron deficiency anemia has been associated with impaired growth and developmental delays during early childhood [18,19,20]. Improvement in iron status may contribute to enhanced appetite, increased physical activity, and better overall growth, which may explain the observed weight gain among study participants. Although the study was not specifically designed to assess growth outcomes, these findings suggest a potential positive effect of iron repletion on nutritional status and physical development.

The safety profile observed in this study was favorable, with no serious adverse events reported. Only a small proportion of participants experienced mild adverse reactions, including swelling at the injection site and nausea. The high proportion of children without adverse effects indicates that intramuscular iron isomaltoside therapy was generally well tolerated. These findings are encouraging and support the feasibility of using intramuscular iron therapy in clinical settings where oral treatment is ineffective or poorly tolerated.

Despite the promising findings, several limitations should be acknowledged. The study was conducted with a relatively small sample size and lacked a control group, which limits the generalizability of the results and precludes direct comparison with other treatment modalities. In addition, the short follow-up period did not allow assessment of long-term hematological outcomes or recurrence of anemia. Therefore, larger randomized controlled trials with longer follow-up periods are required to further evaluate the efficacy, safety, and optimal dosing strategies of intramuscular iron therapy in children with severe iron deficiency anemia.

CONCLUSION

This pilot study demonstrated that intramuscular iron therapy is a safe, effective, and well-tolerated treatment option for children with severe iron deficiency anemia. Significant improvements in hemoglobin levels and body weight were observed following treatment, while adverse effects were minimal. Intramuscular iron therapy may serve as a valuable alternative for children who are unable to tolerate or adequately respond to oral iron supplementation. However, larger controlled studies are required to confirm these findings and establish long-term safety and efficacy.

Funding Source

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Conflict of Interest

The authors declare that there are no conflicts of interest related to this study.

Ethical Approval

Ethical approval was obtained from the Institutional Ethical Review Committee prior to the commencement of the study.

The study was conducted in accordance with established ethical principles and guidelines.

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