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EFFECTIVENESS OF INTERMITTENT ORAL IRON THERAPY VERSUS CONTINUOUS ORAL IRON THERAPY IN TREATING IRON DEFICIENCY ANEMIA IN PATIENTS UP TO 5 YEARS OF AGE: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: *Iron deficiency anemia (IDA) is a prevalent nutritional deficiency in children, leading to impaired growth and development.*

Objective: *To compare the effectiveness of intermittent oral iron therapy versus continuous oral iron therapy in treating iron deficiency anemia in patients up to 5 years of age in terms of the mean change in hemoglobin and ferritin levels from the baseline.*

Methods: *This randomized controlled trial was conducted at University of Child Health Sciencs, The Children's Hospital Lahore, from October 2024 to March 2025. A total of 60 children diagnosed with IDA were randomly assigned to two groups: Group A (Continuous Oral Iron Therapy) and Group B (Intermittent Oral Iron Therapy). The primary outcomes, hemoglobin (Hb) and ferritin levels, were measured at baseline and after 2 months of treatment.*
Clinical Trial number TCTR20251128005 registered at ThaiClinicalTrialsRegistry (https://www.thaiclinicaltrials.org/show/TCTR20251128005)

Results: *The mean increase in Hb levels was significantly greater in Group A (3.1 ± 0.8 g/dL) compared to Group B (1.8 ± 1.2 g/dL) ($p \leq 0.001$). Similarly, the mean increase in ferritin levels was higher in Group A (13.1 ± 4.3 ng/mL) compared to Group B (8.7 ± 3.5 ng/mL) ($p \leq 0.001$). Group A also had more frequent gastrointestinal side effects, including nausea, gastric discomfort, and constipation, compared to Group B ($p \leq 0.05$). Adherence was significantly better in Group B (93%) compared to Group A (80%) ($p \leq 0.05$).*

Conclusion: *Continuous oral iron therapy was more effective in improving hemoglobin and ferritin levels than intermittent therapy. However, intermittent therapy showed fewer side effects and better adherence, making it a viable option for patients who experience discomfort with daily dosing. The choice of therapy should be personalized, considering both the efficacy and the patient's ability to tolerate and adhere to the treatment regimen.*

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INTRODUCTION

Anemia has comprehensive adverse effects on the growth and development of children [1]. Iron deficiency anemia (IDA) is the most common hematological disorder in adolescence and childhood and the most common form of anemia, with the figures standing at 20.1 percent in children 0-4 years of age, and 5.9 percent among those aged 5-14 (39 and 48.1 percent in developing countries) [2]. It is said that the prevalence rate of IDA in children between the ages of 5 is good of Pakistan is 40-70 percent. The National Nutritional Survey 2018 however found out that the prevalence of IDA in children is 28.6% The percentage of IDA in urban male and rural was 29.1 and 28.9 respectively [3]. Iron deficiency and IDA retard the mental and physical development of infants and children, suppress immune mechanisms and cause greater morbidity due to infectious diseases [4]. Those with iron deficiency will have the treatment options of oral and intravenous (IV) iron products. Oral iron can be used in the treatment of ID on stable patients but there are a lot of populations where IV iron is better [5]. Supplementation of iron in late infancy in term infants mainly fed on breast milk has been known to augment the hemoglobin by 0.7 g/dl after two months into iron supplementation [6]. There is however an unexplained clinical shortcoming of oral iron treatment namely that it can impose serious gastrointestinal (GI) side effects including constipation, abdominal pains, nausea and bloating. There is a high prevalence of oral iron as the pill of choice in the treatment of ID and IDA because of its cheap nature, high rate of bioavailability and efficacy [7]. In theory, administration of alternative doses and larger time between successive doses could limit the presence of unabsorbed iron on the gastrointestinal tract leading to less gastrointestinal side effects. Nevertheless, the primary issue of alternate day dosing is that the total dosage level of iron provided in one day is not given in a single unit as is the case in daily dose [8]. In India, Mehta et al. (2020) [9] said that there was a significant difference in mean hemoglobin increase between intermittent day oral iron therapy and continuous therapy groups (1.58 0.53 vs. 0.41 0.25 mg/dl; p-value < 0.05). Regarding the study above, intermittent oral iron therapy appears to be very appealing and the same should be promoted because of reduced side effects involved. However, prior to its promotion and abandoning of the persistent traditional continuous iron therapy oral therapy practice, it is critical to encounter another study where Pasupathy et al. (2023) [10] in India said that the mean changes in the hemoglobin were lower in the intermittent day iron therapy group than in the continuous therapy group (1.05 g/dL) 1.36 vs. 1.36 (g/dL) 1.51 g/dL, and the change was not significant (p-value=0.4 In addition, a negative correlation existed in China which Li et al. (2020) [11] have demonstrated, with the mean change in hemoglobin being significantly higher in continuous oral iron treatment group as compared to the intermittent group at p-value=0.037. In the above research, controversy exists concerning the mean change in hemoglobin level of baseline between oral intermittent iron therapy against continuous oral iron therapy. Also, as far as the resident is aware, there is still no other local or international research that has conducted the same comparison.

Objective

To compare the effectiveness of intermittent oral iron therapy versus continuous oral iron therapy in treating iron deficiency anemia in patients up to 5 years of age in terms of the mean change in hemoglobin and ferritin levels from the baseline.

Methodology

This randomized controlled trial was conducted at The Children's Hospital & Institute of Child Health, Lahore, from October 2024 to March 2025. The sample size was calculated using the WHO sample size calculator, with 80% power of the test and a 5% level of significance. A total of 60 cases were enrolled (30 cases in each group). This calculation was based on the expected mean increase in hemoglobin levels of 1.58 ± 0.53 mg/dL in the intermittent oral iron therapy group and 0.41 ± 0.25 mg/dL in the continuous oral iron therapy group. Non-probability, consecutive sampling was used to select participants for the study.

Sample Selection Criteria:

Inclusion Criteria:

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- Patients of both genders, aged 0 to 60 months.
- Diagnosed with IDA according to the operational definition of the study.

Exclusion Criteria:

- Children who had received treatment for IDA within the last 2 months as per their history or clinical records.
- Children who had undergone a recent blood transfusion within the last 12 weeks.
- Children with chronic kidney disease, chronic liver disease, cardiac failure, or any concomitant malignancy.

Data Collection Procedure:

The data collection procedure began after obtaining ethical approval from the hospital's Ethical Review Board. A total of 60 patients, meeting the inclusion criteria, were recruited from the outpatient department. After providing a thorough explanation of the study, informed consent was obtained from the parents or guardians of all patients. Once consent was given, a detailed medical history was recorded. Hemoglobin (Hb) and ferritin levels were measured using venous blood samples, which were sent to the hospital's lab for analysis. These initial measurements were used to establish baseline levels. The patients were then randomly assigned to one of two treatment groups using a lottery method: Group A received continuous oral iron therapy, where they were administered 6 mg/kg/day of elemental iron (syrup ferrous sulphate) once daily for two months. Group B received intermittent oral iron therapy, where they were given the same dose of 6 mg/kg/day elemental iron, but only on three days a week for two months. At the end of the 2-month treatment period, patients were asked to revisit the hospital, where their haemoglobin and ferritin levels were rechecked. All procedures, including the collection of results, were conducted by the same hospital lab and consultant to minimize potential bias.

Data Analysis Procedure:

The collected data was analyzed using SPSS version 25. Numerical variables such as age, BMI, hemoglobin levels at admission, ferritin levels, and the change in hemoglobin levels from baseline to after two months of treatment were presented as mean ± standard deviation (SD). Categorical variables, including gender, nausea, vomiting, gastric discomfort, and altered bowel habits, were summarized as frequencies and percentages. For comparisons between the groups, the Chi-square test was applied, and a p-value of ≤ 0.05 was considered statistically significant. To compare the mean change in hemoglobin levels between baseline and after treatment, a paired sample t-test was used within each group. Additionally, the mean change in hemoglobin levels between the two groups was compared using an independent sample t-test. The mean change in hemoglobin levels was further stratified by age, gender, and BMI to evaluate potential effect modifiers. After stratification, the Chi-square test was applied to identify any significant differences, with a p-value of ≤ 0.05 regarded as significant. Confounding variables, such as recent treatments or comorbidities, were controlled for through exclusion criteria, ensuring that the results were not influenced by these factors.

Results

Group A (Continuous Oral Iron Therapy) had a mean age of 24.5 ± 12.3 months, while Group B (Intermittent Oral Iron Therapy) had a mean age of 25.1 ± 12.7 months. Gender distribution was also similar, with 15 males and 15 females in Group A, and 16 males and 14 females in Group B. The mean BMI was 16.5 ± 3.2 kg/m² in Group A and 16.3 ± 3.1 kg/m² in Group B. Baseline Hb levels were 7.2 ± 1.1 g/dL in Group A and 7.3 ± 1.2 g/dL in Group B, while baseline ferritin levels were 9.3 ± 3.5 ng/mL in Group A and 8.9 ± 3.2 ng/mL in Group B (Table 1).

Table 1: Baseline Characteristics of Participants

Characteristic	Group A (Continuous Oral Iron Therapy)	Group B (Intermittent Oral Iron Therapy)	p-value
Age (months)	24.5 ± 12.3	25.1 ± 12.7	0.82
Gender (Male/Female)	15/15	16/14	0.82
BMI (kg/m²)	16.5 ± 3.2	16.3 ± 3.1	0.85

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Hb at baseline (g/dL)	7.2 ± 1.1	7.3 ± 1.2	0.78
Ferritin at baseline (ng/mL)	9.3 ± 3.5	8.9 ± 3.2	0.65

At 2 months, the mean hemoglobin level in Group A was 10.3 ± 0.8 g/dL, compared to 9.1 ± 1.0 g/dL in Group B (p = 0.001). The mean change in hemoglobin was 3.1 ± 0.8 g/dL in Group A, significantly greater than the 1.8 ± 1.2 g/dL change observed in Group B (p = 0.001). For ferritin levels, Group A showed a mean increase of 13.1 ± 4.3 ng/mL, while Group B showed a mean increase of 8.7 ± 3.5 ng/mL (p = 0.001) (Table 2).

Table 2: Change in Hemoglobin and Ferritin Levels After Treatment

Outcome	Group A (Continuous Oral Iron Therapy)	Group B (Intermittent Oral Iron Therapy)	p-value
Hemoglobin (g/dL) at 2 months	10.3 ± 0.8	9.1 ± 1.0	0.001
Mean Change in Hemoglobin (g/dL)	3.1 ± 0.8	1.8 ± 1.2	0.001
Ferritin (ng/mL) at 2 months	22.4 ± 5.4	17.6 ± 4.3	0.001
Mean Change in Ferritin (ng/mL)	13.1 ± 4.3	8.7 ± 3.5	0.001

Nausea was reported by 12 patients (40%) in Group A, compared to 4 patients (13%) in Group B (p = 0.03). Gastric discomfort was reported by 9 patients (30%) in Group A and 3 patients (10%) in Group B (p = 0.04). Constipation occurred in 7 patients (23%) in Group A and 2 patients (7%) in Group B (p = 0.05). Altered bowel habits were reported by 5 patients (17%) in Group A and 2 patients (7%) in Group B (p = 0.11). Adherence to treatment was better in Group B, with 28 out of 30 patients (93%) completing the full treatment, compared to 24 out of 30 patients (80%) in Group A (p = 0.05) (Table 3, Figure 1).

Table 3: Side Effects and Adherence to Treatment Protocol

Side Effect / Outcome	Group A (Continuous Oral Iron Therapy)	Group B (Intermittent Oral Iron Therapy)	p-value
Nausea	12 (40%)	4 (13%)	0.03
Gastric Discomfort	9 (30%)	3 (10%)	0.04
Constipation	7 (23%)	2 (7%)	0.05
Altered Bowel Habits	5 (17%)	2 (7%)	0.11
Adherence to Full Treatment	24/30 (80%)	28/30 (93%)	0.05

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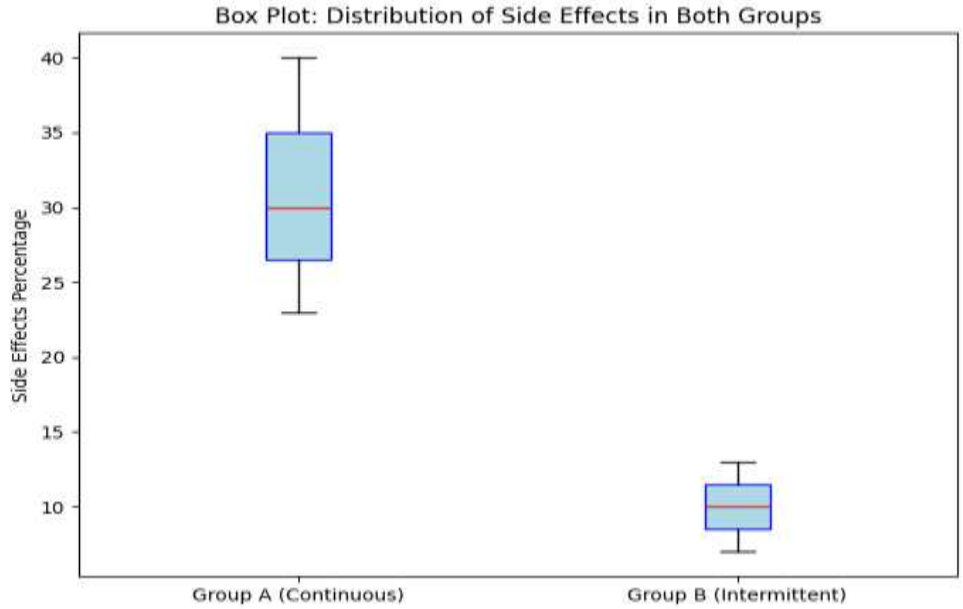

For children aged <24 months, the mean change in hemoglobin was 3.2 ± 0.7 g/dL in Group A versus 1.9 ± 1.1 g/dL in Group B (p = 0.01). In children aged ≥24 months, the mean change in hemoglobin was 3.0 ± 0.9 g/dL in Group A compared to 1.7 ± 1.2 g/dL in Group B (p = 0.02). Males in Group A experienced a mean hemoglobin change of 3.2 ± 0.8 g/dL, while males in Group B had a mean change of 1.9 ± 1.0 g/dL (p = 0.03). For females, Group A showed a mean change of 3.0 ± 0.7 g/dL, while Group B showed 1.6 ± 1.3 g/dL (p = 0.04). For children with BMI <16 kg/m², the mean hemoglobin change was 3.1 ± 0.9 g/dL in Group A and 1.8 ± 1.1 g/dL in Group B (p = 0.02), and for children with BMI ≥16 kg/m², Group A showed a mean change of 3.0 ± 0.8 g/dL, while Group B showed 1.7 ± 1.2 g/dL (p = 0.05) (Table 4).

Table 4: Stratified Analysis of Mean Change in Hemoglobin by Age, Gender, and BMI

Subgroup	Group A (Continuous Oral Iron Therapy)	Group B (Intermittent Oral Iron Therapy)	p-value
Age (Months)			
<24 months	3.2 ± 0.7	1.9 ± 1.1	0.01
≥24 months	3.0 ± 0.9	1.7 ± 1.2	0.02
Gender			
Male	3.2 ± 0.8	1.9 ± 1.0	0.03
Female	3.0 ± 0.7	1.6 ± 1.3	0.04
BMI (kg/m²)			
<16 kg/m²	3.1 ± 0.9	1.8 ± 1.1	0.02
≥16 kg/m²	3.0 ± 0.8	1.7 ± 1.2	0.05

For children aged <24 months, the mean change in ferritin was 13.5 ± 4.1 ng/mL in Group A compared to 8.3 ± 3.6 ng/mL in Group B (p = 0.02). In children aged ≥24 months, the mean change was 12.8 ± 4.4 ng/mL in Group A versus 8.9 ± 3.5 ng/mL in Group B (p = 0.04). For males, Group A had a mean ferritin increase of 13.2 ± 4.3 ng/mL, compared to 8.5 ± 3.7 ng/mL in Group B (p = 0.03), while for females, Group A showed a mean increase of 13.0 ± 4.2 ng/mL, compared to 8.9 ± 3.3 ng/mL in Group B (p = 0.05). For children with BMI <16 kg/m², Group A had a mean ferritin change of 13.3 ± 4.2 ng/mL, compared to 8.4 ± 3.5 ng/mL in Group

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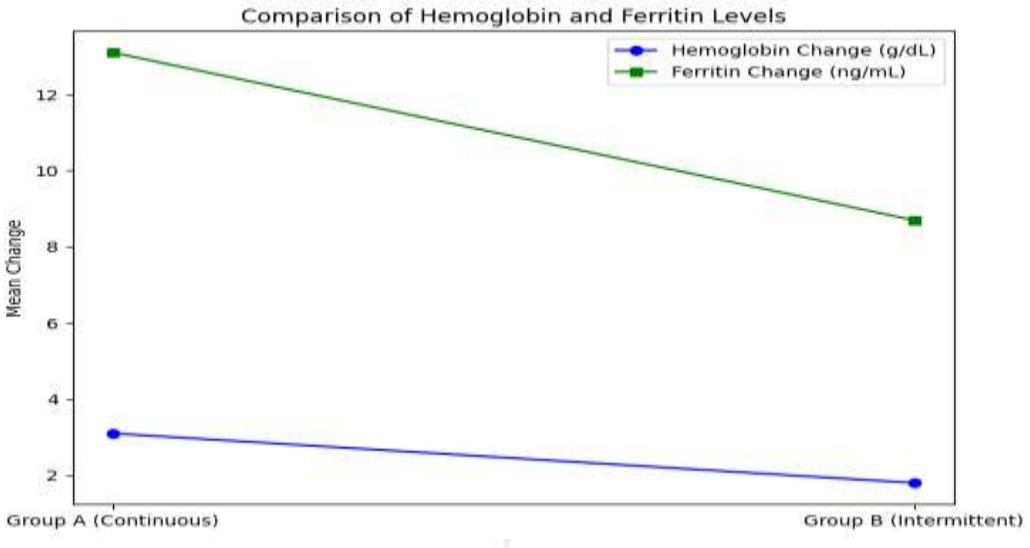
B (p = 0.03), and for those with BMI ≥16 kg/m², the mean change was 12.9 ± 4.4 ng/mL in Group A versus 9.0 ± 3.6 ng/mL in Group B (p = 0.04) (Table 5, figure 2).

Table 5: Comparison of Mean Ferritin Change by Age, Gender, and BMI

Subgroup	Group A (Continuous Oral Iron Therapy)	Group B (Intermittent Oral Iron Therapy)	p-value
Age (Months)			
<24 months	13.5 ± 4.1	8.3 ± 3.6	0.02
≥24 months	12.8 ± 4.4	8.9 ± 3.5	0.04
Gender			
Male	13.2 ± 4.3	8.5 ± 3.7	0.03
Female	13.0 ± 4.2	8.9 ± 3.3	0.05
BMI (kg/m²)			
<16 kg/m²	13.3 ± 4.2	8.4 ± 3.5	0.03
≥16 kg/m²	12.9 ± 4.4	9.0 ± 3.6	0.04



Discussion

Iron deficiency anemia (IDA) remains one of the most common nutritional deficiencies worldwide, particularly in children. The results of this study suggest that continuous oral iron therapy is more effective than intermittent oral iron therapy in treating IDA in children up to 5 years of age. Although both types of therapies were claimed to be related to prominent changes in hemoglobin (Hb) and ferritin levels, continuous therapy resulted in even more pronounced growth in the levels of these indicators, which is why it can be judged as more effective in alleviating iron deficiency [12]. The corresponding rise in Hb levels in Group A (continuous Oral Iron Therapy) was 3.1 0.8 g/dL compared to that of Group B that showed 1.8 1.2 g/dL rise in Hb after completion of intervention (p <= 0.001). In the same way, the mean ferritin levels increased in Group A (13.1 4.3 ng/mL) than in Group B (8.7 3.5 ng/mL) (p 0.001). These results agree with other works previously carried out which have reported that sustained iron supplementation was effective in restocking of iron stores as well as in enhancement of hematologic values especially in severe cases of IDA [13]. There is also a fact that daily iron supplement offers greater stability of iron provision and consequently better absorption and more prominent benefits in iron stores. Although continuous therapy was superior in efficacy, there were other benefits of intermittent therapy. Side effect frequencies of nausea, gastric discomfort, and constipation were less occurring

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in Group B (Intermittent Oral Iron Therapy) than in Group A (Daily Oral Iron Therapy) [14]. This aspect raises a significant point on the pill intervener long-term treatment ability to comply with compliance. Group B children (13 percent) complain of nausea as opposed to 40 percent of the children in Group A. On the same note, gastric discomforts were identified as affecting 10% of children in Group B compared to 30% of children in Group A. These results are in line with those that indicated the tolerability attributed to children using intermittent therapy as a method to enhance the course of the overall adherence to the course of treatment [15]. Also decreased gastrointestinal side effects can bring about patient comfort and reduced incidences of halting the treatment, which is quite a problem when it comes to continuous iron treatment. The last issue which plays an important role in the effective treatment of IDA is the treatment adherence. Group B (Intermittent Oral Iron Therapy) had a much higher percentage of completion of the treatment regimen of 93% as compared to 80% Group A. This implies that children who have intermittent treatment can manage without considerably paralyzing their daily activities, hence resulting in increased compliance. The study by other researchers has pointed out the significance of adherence to treatment as a factor that guarantees success in iron supplementation, and the avoidance of the burden that comes with repetitive dosing can work towards a more effective adherence pattern in the real life [16]. Stratified analysis according to age, gender, and BMI showed a convergent trend of all subgroups, indicating continuous therapy shows superior positive changes in Hb and ferritin levels [17]. It emphasizes the fact that the success rates of continuous oral iron therapy do not depend on these demographic determinants very much, which implies that the method of treatment can be widely used among various patient populations [18]. Nevertheless, the demonstration that there were no interaction effects between treatment regimens and age, gender, or BMI indicates that the former factor of the study defined the success of the treatment most clearly, and not one of the mentioned demographic variables. Although the information in the study is of great value, it has weaknesses [19]. Since the sample size, though large enough to detect significant differences, is rather small, the study was performed in a single center. Larger, multicenter studies need to be conducted with a view toward validating these results, and answering the long-term impact of both treatment modalities on clinical outcomes, including growth and development, of a child. In addition, the research combined hemoglobin and ferritin as main results meaning other vital variables with regards to the study process like effects of the process on the cognitive development and the quality of life were not captured. The further investigations should consider these wider considerations of the IDA treatment.

Conclusion

It is concluded that continuous oral iron therapy is more effective than intermittent oral iron therapy in improving hemoglobin and ferritin levels in children with iron deficiency anemia (IDA). The results showed a significantly greater increase in both hemoglobin and ferritin levels in the continuous therapy group compared to the intermittent therapy group. However, intermittent therapy was associated with fewer gastrointestinal side effects and better adherence, making it a more tolerable treatment option for some patients.

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