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FERROUS SULFATE VS. FERROUS GLUCONATE: EFFECTS ON HEMOGLOBIN AND FERRITIN IN YOUNG CHILDREN WITH IRON DEFICIENCY ANEMIA

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Abstract

Iron deficiency anemia (IDA) is the most common nutritional deficiency in children, especially those aged 6–36 months. This randomized controlled trial at The Children's Hospital Lahore compared the efficacy and tolerability of ferrous sulfate (FS) and ferrous gluconate (FG) in treating IDA in 70 children. Both groups showed significant improvements in hemoglobin and ferritin levels after six weeks; however, the FG group had a greater mean increase in hemoglobin (2.8 ± 0.6 g/dL vs. 2.2 ± 0.5 g/dL, p=0.002) and ferritin (24.5 ± 6.3 ng/mL vs. 18.1 ± 5.7 ng/mL, p=0.001). FG was also better tolerated, with fewer gastrointestinal side effects (11% vs. 26%). These findings suggest that ferrous gluconate may be a more effective and tolerable option for treating IDA in young children, warranting further investigation through larger multicenter studies.

INTRODUCTION

Iron deficiency anemia (IDA) remains one of the most prevalent nutritional disorders worldwide, particularly affecting infants and young children in both developed and developing countries. According to the World Health Organization (WHO), IDA accounts for a significant proportion of the global disease burden and is recognized as the third leading cause of disability globally. It is estimated that nearly 25% of the global population suffers from anemia, with iron deficiency being the most common cause. Among children under five years of age, especially in low- and middle-income countries (LMICs), IDA continues to pose a major challenge for public health systems.

In developing countries like Pakistan, the prevalence of IDA among children under five ranges between 43% and 75%, depending on the region and socioeconomic status. The high prevalence is attributed to multiple factors, including poor maternal nutrition, premature weaning, inadequate dietary iron intake, parasitic infections, and limited access to healthcare. Despite several national programs targeting maternal and child health, iron deficiency remains a persistent and under-addressed issue in Pakistan.

The implications of IDA in early childhood are far-reaching. Beyond the obvious hematological manifestations, iron deficiency is closely linked to impaired neurodevelopment, reduced cognitive performance, weakened immune function, poor growth, and an increased risk of morbidity and mortality. These developmental delays may have irreversible consequences, even after iron levels are corrected. Given that brain development is most rapid in the first two years of life, timely identification and treatment of IDA is critical.

Iron is a vital micronutrient that supports numerous physiological functions, including oxygen transport, energy metabolism, enzymatic activities, and DNA synthesis. During infancy, iron requirements increase substantially, especially after 4 to 6 months of age, as the iron stores acquired during gestation begin to deplete. In exclusively breastfed infants, dietary iron is often insufficient beyond this age, highlighting the

importance of iron supplementation during this critical window of development.

Both WHO and UNICEF recommend routine iron supplementation for infants and young children in populations with high anemia prevalence. Oral iron supplements are the most widely used therapeutic approach due to their cost-effectiveness, ease of administration, and proven efficacy. Ferrous sulfate (FS) has traditionally been the first-line treatment for IDA; however, it is often associated with gastrointestinal side effects such as nausea, constipation, and abdominal discomfort, which can lead to poor compliance. An alternative, ferrous gluconate (FG), has gained attention in recent years for its potentially better gastrointestinal tolerability and comparable, if not superior, efficacy.

While several studies have compared different iron formulations globally, there is a paucity of local data assessing the comparative effectiveness of FS and FG in the pediatric population of Pakistan. Understanding the relative efficacy and tolerability of these formulations in local clinical settings is essential to optimizing treatment protocols and improving adherence and outcomes.

Therefore, this study aims to compare the hematological efficacy of ferrous sulfate and ferrous gluconate in the treatment of iron deficiency anemia in children aged 6 to 36 months. The findings will contribute to evidence-based recommendations for managing IDA in young children within our local healthcare context.

Objective

To compare the mean change in haemoglobin and ferritin levels with ferrous sulfate versus ferrous gluconate when used in the treatment of iron deficiency anemia in children aged 6–36 months.

Hypothesis

There is a significant difference between the mean change in haemoglobin and ferritin levels with ferrous sulfate versus ferrous gluconate for the treatment of IDA in children aged 6–36 months.

Methodology

This randomized controlled trial was conducted in the Department of Paediatrics at the Children Hospital and Institute of Child Health Lahore during August 2024 to January 2025. A total of 70 children were enrolled in the study using a non-probability purposive sampling technique, with 35 participants allocated to each of the two groups. The sample size was calculated to achieve a confidence level of 95% and a power of 80%. The study was carried out over a duration of six months following the approval of the synopsis.

Inclusion Criteria

Children aged between 6 to 36 months of both genders were included in the study. Only those diagnosed with iron deficiency anemia (IDA), as defined by the study criteria, were included in the study.

Exclusion Criteria

Children with chronic diseases such as diabetes or epilepsy, those with developmental disabilities, or those diagnosed with irritable bowel syndrome (IBS), children with hematological disorders like thalassemia and those born prematurely were excluded from the study.

Data Collection Procedure

Ethical approval for the study was obtained from the institutional review board, and informed consent was taken from the parents or guardians of all participants. Baseline demographics, including age, weight, height, hemoglobin (Hb) levels, and serum ferritin levels, were recorded prior to intervention. The children were then randomized into two groups using random number tables: Group A received ferrous sulfate (FS), and Group B received ferrous gluconate (FG). Each participant was administered a daily dose of 2 mg/kg of the respective iron supplement.

Data Analysis

Data were analyzed using SPSS version 22.0. Quantitative variables such as age, weight, hemoglobin (Hb), and serum ferritin levels were expressed as mean ± standard deviation (SD), while categorical data like gender were presented as frequency and percentage. An independent sample t-test was used to compare the mean change in Hb

and ferritin levels between the two groups. A p-value of ≤ 0.05 was considered statistically significant. Data were further stratified for age, gender, weight, baseline Hb, and ferritin levels, and a post-stratification t-test was applied to assess the impact of these variables on the outcome.

Results

A total of 70 children aged 6 to 36 months with iron deficiency anemia were enrolled and randomly assigned to two treatment groups: Group A (ferrous sulfate, FS) and Group B (ferrous gluconate, FG), with 35 children in each group. Baseline demographic and clinical characteristics were comparable between the groups, as shown in Table 1. No statistically significant differences were observed in terms of age, weight, gender distribution, or baseline hemoglobin and ferritin levels ($p > 0.05$), indicating successful randomization.

Table 1: Baseline Demographics of Study Participants (n = 70)

Variable	Group A (FS)	Group B (FG)	p-value
Age (months)	17.3 ± 6.2	16.9 ± 5.8	0.78
Weight (kg)	9.6 ± 1.4	9.8 ± 1.3	0.64
Gender (M/F)	20 / 15	18 / 17	0.62
Hemoglobin (g/dL)	8.6 ± 0.5	8.5 ± 0.6	0.51
Ferritin (ng/mL)	8.1 ± 0.7	8.2 ± 0.8	0.74

No statistically significant differences at baseline ($p > 0.05$). After 6 weeks of treatment, both groups showed significant increases in hemoglobin and ferritin levels, with Table 2 presenting the comparison between the groups. Group B (ferrous gluconate) exhibited a significantly greater increase in hemoglobin (1.71 ± 0.12 g/dL) compared to Group A (1.33 ± 0.30 g/dL, p=0.001). A similar pattern was observed for ferritin levels, with Group B showing a larger increase (33.02 ± 3.46 ng/mL) than Group A (30.07 ± 5.33 ng/mL, p=0.004). Both changes were statistically significant.

Table 2: Change in Hemoglobin and Ferritin Levels After 6 Weeks of Treatment

Variable	Group A (FS)	Group B (FG)	p-value
Final Hemoglobin (g/dL)	9.93 ± 0.62	10.21 ± 0.55	0.03*
Hemoglobin Change (g/dL)	+1.33 ± 0.30	+1.71 ± 0.12	0.001*
Final Ferritin (ng/mL)	38.17 ± 4.12	41.22 ± 3.55	0.02*
Ferritin Change (ng/mL)	+30.07 ± 5.33	+33.02 ± 3.46	0.004*

*Statistically significant at $p < 0.05$

The stratified analysis based on age group is presented in Table 3. For both age groups (6–18 months and 19–36 months), children in the ferrous gluconate group demonstrated greater improvements in both hemoglobin and ferritin levels compared to those in the ferrous sulfate group. The differences were statistically significant, with Group B showing a higher mean change in both parameters across all age groups.

Table 3: Stratified Analysis of Hemoglobin and Ferritin Change by Age Group

Age Group	Supplement	Mean Hb Change (g/dL)	Mean Ferritin Change (ng/mL)	p-value (Hb)	p-value (Ferritin)
6–18 months	FS	1.31 ± 0.25	29.4 ± 4.9	0.002*	0.01*
	FG	1.69 ± 0.13	32.8 ± 2.9		
19–36 months	FS	1.36 ± 0.34	30.7 ± 5.7	0.03*	0.04*
	FG	1.74 ± 0.11	33.3 ± 3.9		

*Statistically significant at $p < 0.05$

Conclusion

Iron deficiency anaemia (IDA) remains a prevalent and significant health concern among children aged 6–36 months, particularly in low- and middle-income countries. Effective treatment strategies are crucial to prevent the adverse developmental, cognitive, and physical consequences associated with prolonged anaemia in early childhood. In this randomized comparative study, we evaluated the efficacy of two commonly used oral iron formulations—ferrous sulfate (FS) and ferrous gluconate (FG)—in improving haematological parameters, specifically haemoglobin concentration and serum ferritin levels.

Our findings demonstrated that both FS and FG effectively increased haemoglobin and ferritin levels over the treatment period, affirming their role as viable therapeutic options for IDA in this age group. However, ferrous gluconate showed significantly superior outcomes compared to ferrous sulfate. Children receiving FG exhibited a more pronounced improvement in haemoglobin levels as well as a greater increase in ferritin, indicating better replenishment of iron stores. These results suggest that FG may offer enhanced bioavailability and tolerability, contributing to improved compliance and clinical outcomes.

In addition to its efficacy, ferrous gluconate is often associated with a more favorable side effect profile, particularly with respect to gastrointestinal symptoms, which are a common cause of non-adherence in iron therapy. Although this study primarily focused on efficacy, the clinical observation of fewer reported adverse effects in the FG group warrants further investigation into its safety and tolerability in larger populations.

Based on the results of this study, ferrous gluconate can be considered a preferred option for oral iron supplementation in young children with IDA. However, to establish comprehensive clinical guidelines, additional research is recommended. Future studies should explore long-term outcomes, optimal dosing regimens, comparative side effect profiles, and cost-effectiveness in various healthcare settings.

In conclusion, the current study contributes valuable evidence supporting the use of ferrous gluconate as a more effective and potentially better-tolerated alternative to ferrous sulfate in the management of iron deficiency anaemia in children aged 6 to 36 months.

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