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Original Article

Paediatrics Section

Oral Daily Iron Supplementation among Rural Children Aged 36-59 Months with Mild-to-moderate Anaemia: A Quasi-experimental Study from Central Karnataka, India

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ABSTRACT

Introduction: Anaemia is a serious concern for young children because it can result in impaired cognitive performance, behavioural and motor development, coordination, language development, and scholastic achievement, as well as increased morbidity from infectious diseases. While severe anaemia is typically addressed with urgency, mild-to-moderate anaemia is sometimes overlooked. However, even mild cases can have a significant impact on a child's health and development. Thus, oral iron supplementation, by reducing anaemia, can contribute to the development of a healthier and more productive population.

Aim: To assess the effect of daily Iron Folic Acid (IFA) supplementation among 36-59 month old children with mild-to-moderate anaemia.

Materials and Methods: This quasi-experimental study was conducted in the rural field practice areas of a tertiary care teaching hospital in central Karnataka, India from March 2022 to February 2023. After baseline assessment, 53 children aged between 36-59 months old in Anganwadi centres of the study area with mild-to-moderate anaemia (Haemoglobin - Hb: 10.9 – 7 g/dL) were recruited for the study after obtaining informed written consent from the parents. The IFA supplementation was administered under supervision for six months. The primary outcome was rise in the Hb concentration. The paired t-test was used to statistically analyse the data.

Results: Among the 53 study participants, the majority (27, 51%) were boys, and the mean age of the study participants was 46.6±8.4 months. The study showed that after six months of iron supplementation among 36-59 month old children with mild-to-moderate anaemia, there was a rise in the mean {Standard Deviation (±SD)} Hb by 0.71±0.32 gm/dL in the study participants, and it was found to be statistically significant (2.579, p=0.011). The increase in Hb was found in both girls (0.84±0.41 gm/dL) and boys (0.83±0.39 gm/dL).

Conclusion: The study concluded that supervised intervention for mild-to-moderate anaemia in preschool children has the potential to reduce the prevalence of iron deficiency anaemia among this vulnerable population, but it requires a joint effort from all stakeholders involved.

Keywords: Development, Early childhood, Elemental iron, Folic acid, Growth, Haemoglobin

INTRODUCTION

Anaemia is a condition where the Haemoglobin (Hb) concentration or red blood cell count is below the prescribed cut-off value [1]. If the body has abnormally low levels of red blood cells or insufficient Hb, the blood's ability to deliver oxygen to the body's tissues will be decreased. Worldwide, a total of 1.6 billion individuals suffer from anaemia, with 47.4% of them being preschoolers [2].

To effectively manage this problem, it is essential to address the root causes of anaemia in a multifaceted manner [3-5]. This includes increasing knowledge and education about anaemia and nutrition, promoting access to nutrient-dense food, bolstering the healthcare system, and tackling socio-economic inequities [6-8]. It also includes improving the implementation and coverage of iron and folic acid supplementation programs. Cooperation between the government, medical experts, community organisations, and other stakeholders is crucial in significantly reducing the prevalence of anaemia in India [9-11].

The recently released National Family Health Survey (NFHS 5) data shows an increase in the incidence of anaemia in under-5 children in India from 58.6% (NFHS 4) to 67%, and in Karnataka from 60.9% (NFHS 4) to 65.5% [12,13]. Iron deficiency typically starts manifesting around the age of six months, coinciding with the depletion of iron stores and the introduction of complementary foods. Many developing countries recommend iron supplementation for pregnant women and young infants [14-17]. The anaemia management protocol for children, as per the Government of India's Anaemia Mukth Bharath Abhiyan guidelines, recommends daily administration of 3 mg of iron/kg/day for two months among children aged 36-59 months (2 mL IFA syrup once a day) [18].

A study assessing the effectiveness of iron supplementation in improving Hb levels among children with anaemia can provide evidence of whether supplementation is a viable strategy for addressing this issue. With this background, the present study was undertaken to assess the feasibility, acceptance, and effectiveness of daily oral iron supplementation in reducing mild-moderate anaemia among children aged 36-59 months in rural areas of central Karnataka, India.

MATERIALS AND METHODS

A quasi-experimental study was conducted in the rural field practice area of JJM Medical College, a tertiary care teaching hospital in central Karnataka, India, for one year from March 2022 to February 2023. The study was initiated after receiving approval from the Institutional Ethical Committee (Reference No.: JJMMC/IEC-11-2022) prior to the study's commencement. Study participants were recruited after obtaining informed written consent from the parents.

Inclusion criteria: Children aged between 36-59 months with mild-to-moderate anaemia (Hb: 7-10.9 g/dL) [19], residing in the rural field practice area, and whose parents consented to their children's Hb estimation and intervention were included.

Exclusion criteria: Children with any chronic illness and a history of regular consumption of IFA tablets in the past three months were excluded from the study.

Sample size: The study setting included three villages with an approximate population of 9,300 as per the 2011 census [20]. The study population comprised all 281 children aged 36-59 months registered in the 10 anganwadi centres of the three villages covered under the rural field practice area.

Study Procedure

The study was conducted in stages as described below:

Stage 1: Community engagement

During the preinitiation stage, various stakeholders in the public health sector and the community were engaged using a participatory approach to understand their perceptions towards preventing anaemia in children. These stakeholders included medical officers in charge of Primary Health Centres in the three villages, Auxiliary Nurse Midwives (ANMs), Accredited Social Health Activists (ASHAs), Community Development Project Officers (CDPOs), Anganwadi Teachers (AWTs), village panchayat members, village leaders, and parents/primary caregivers of children aged 36-59 months.

Stage 2: Identification of children with mild-to-moderate anaemia

The rural field practice area of the tertiary care teaching hospital provides services to three villages comprising 2,660 households and a population of 9,300. Children aged 36-59 months were screened for anaemia at anganwadi centres in a phased manner.

A situational analysis was conducted in phases to understand the anaemia status of children aged 36-59 months. The selection criterion was children with mild-to-moderate anaemia (Hb: 7-10.9 g/dL) [19]. All children in the age group 36-59 months were line-listed anganwadi-wise in the study area. Blood samples were collected from the children at the designated anganwadi centres, with prior intimation of the date and time and written consent from the parents.

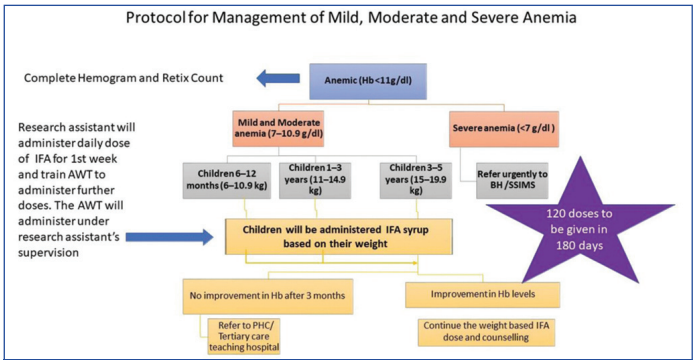
Collection of blood sample: Under aseptic precautions, 2.5 mL of blood was drawn from the antecubital vein for a Complete Blood Count (CBC). The grading of anaemia was based on the concentrations of Hb in the blood [19]:

- Mild anaemia: Hb of 10-10.9 g/dL
- Moderate anaemia: Hb of 7-9.9 g/dL
- Severe anaemia: Hb of <7 g/dL

Stage 3:

Intervention: The children received daily oral supplementation of IFA syrup based on their weight. The intervention consisted of IFA syrup containing a combination of elemental iron (80 mg) and folic acid (200 micrograms) [21].

All children aged 36-59 months who were found to have mild-to-moderate anaemia (Hb level of 7-10.9 g/dL) were offered intervention. The intervention involved daily observed oral iron supplementation (weight-based) given five days a week (Monday to Friday) for six months, ensuring that each child would receive at least 120 doses within 180 days. The study protocol is discussed in [Table/Fig-1].



[Table/Fig-1]: Study protocol.

Regular monitoring was conducted by trained local female research assistants who visited the anganwadi centres. Additionally, weekly visits were made to the households of the mothers of the beneficiary children. During these visits, a pretested semi-structured questionnaire was used to monitor adverse effects, address any concerns the mothers had regarding the supplementation, and improve awareness of the signs and symptoms of anaemia and its complications. Hb estimation was performed every three months to monitor the improvement in the children's Hb levels.

Postintervention: Postintervention, Hb estimation was repeated after three and six months to assess the changes in Hb levels among the beneficiaries.

Quality control: Quality control measures were implemented. Daily examination and plotting of all three levels of Internal Quality Control (IQC) samples (normal, low, and high) were conducted using a Levy Jennings plot. All data were found to be within a 2 SD range, without any patterns that could be interpreted as an IQC fault.

STATISTICAL ANALYSIS

The data analysis was performed by comparing means using International Business Machines (IBM) Statistical Package for Social Sciences (SPSS) v25.0, with the treatment effect (before vs after supplementation) as a within-subject factor. The paired t-test and Fisher's-exact test were used to assess the mean difference (after-before). A p-value <0.05 was considered statistically significant. The results are presented in tables and figures, as appropriate.

RESULTS

A total of 281 children in the age group of 36-59 months were screened for anaemia. Among them, 55 children (19.6%) were diagnosed with anaemia. Two children had Hb levels below 7 gm/dL (severe anaemia) and were referred to a tertiary care teaching hospital for further evaluation and management.

Among the children with mild-to-moderate anaemia, 53 (18.9%) were included in the study after obtaining informed written consent from their parents. Of the study participants, 27 (50.9%) were boys, and 32 (60.3%) belonged to the age group of 36-47 months. The mean age of the study population was 46.6±8.4 months. The majority of children were of Hindu religion 36 (67.9%). Among the 53 children, 32 (60.4%) had mild anaemia, and 21 (39.6%) had moderate anaemia [Table/Fig-2].

Characteristics	Number (N=53)	Percentage (%)
Gender		
Boys	27	50.9
Girls	26	48.1
Age (months)		
36-47	32	60.3
48-59	21	39.6
Religion		
Hindu	36	67.9
Muslim	17	32.1
Education of mother		
Upto 7th Std	12	22.6
Upto 10th Std	19	35.8
Upto 12th Std	19	35.8
Uneducated	03	5.8
Education of father		
Upto 7th Std	13	24.5
Upto 10th Std	23	43.4
Upto 12th Std	15	28.3
Uneducated	02	3.8

Occupation of mother		
Homemaker	11	20.8
Working woman	42	79.2
Socio-economic status (As per modified BG Prasad SES classification updated for January 2022)		
Class-III	11	20.8
Class-IV	19	35.8
Class-V	23	43.4
Anaemia		
Mild (Hb: 10.0-10.9 g/dL)	32	60.4
Moderate (Hb: 7.0-9.9 g/dL)	21	39.6

[Table/Fig-2]: Clinico-socio-demographic characteristics of study participants.

During the intervention, the compliance with daily IFA supplementation among children was found to be 78%. The reasons given by the AWTs for non compliance were travel and/or absence of children from the anganwadi due to illnesses and local festivals/fairs. A total of 12 children (22.6%) were lost to follow-up after 3 months, and another 8 children (15.1%) were lost to follow-up after 6 months of intervention. Therefore, a total of 20 children (37.7%) were excluded from the postintervention evaluation. The reasons for loss to follow-up were migration of families out of the study area and children being sent to residential schools.

There was also an improvement in the grading of anaemia among the children from pre- to postintervention. At baseline, the majority of children 32 (60.4%) had mild anaemia. Six months postintervention, 11 children (33.3%) showed improvement in Hb levels above 11 gm/dL. The improvement in the grading of anaemia among the study participants was found to be statistically significant [Table/Fig-3].

Parameters	Mild N (%)	Moderate n (%)	Normal n (%)	p-value
Baseline/pre-intervention (n=53)	32 (60.4)	21 (39.6)	----	<0.0001
3-month postintervention (n=41)	27 (65.9)	14 (34.1)	----	
6-month postintervention (n=33)	12 (36.4)	10 (30.3)	11 (33.3)	

[Table/Fig-3]: Pre- and postintervention anaemia status of study participants. Fisher-exact test

After six months of daily IFA supplementation, there was an increase in the mean Hb from 9.79±1.11 gm/dL to 10.02±0.21 gm/dL (at 3-month postintervention) and 10.5±1.43 gm/dL (at 6-month postintervention). The improvement in Hb from baseline to 6-month postintervention was found to be statistically significant (2.579, p=0.011). The improvement in mean Hb at 6-month postintervention was statistically significant among both girls and boys [Table/Fig-4].

Eighteen children (33.9%) reported common side effects of IFA syrup, with 12 children (22.6%) experiencing constipation, 4 children (7.5%) experiencing heartburn, and two children (3.9%) experiencing stomach cramps.

Parameters	Girls (Mean±SD)	t, p-value	Boys (Mean±SD)	t, p-value	Total (Mean±SD)	t, p-value
Baseline/Pre-intervention (n=26*, 27#)	9.88±0.922		9.47±1.264		9.79±1.11	
3-month postintervention (n=21*, 20#)	10.31±0.35	2.019, p=0.049	9.92±0.89	1.360, p=0.180	10.02±0.21	1.307, p=0.194
6-month postintervention (n=16*, 17#)	10.71±1.658	2.090, p=0.043	10.31±1.196	2.191, p=0.034	10.5±1.43	2.579, p=0.011

[Table/Fig-4]: Pre and Postintervention Haemoglobin (Hb) status of study beneficiaries. Paired t-test *Girls, #Boys

DISCUSSION

In the present study, one-fifth (19.6%) of the children aged 36-59 months were found to be anaemic. Among the children who started on IFA supplementation, 20 (37.7%) children were lost to follow-up during the intervention as they moved out of the study area. Among the children who completed six months of supplementation, 11 (33.3%) children became non anaemic, and 12 (36.4%) children improved their status from moderate to mild anaemia.

Previous national and sub-national surveys in India, including the National Family Health Survey (NFHS 4 and 5) [12,13], District Level Household Survey (DLHS) [22], National Nutrition Monitoring Bureau Survey (NNMB) [23], and Comprehensive National Nutrition Survey (CNNS) [24], have provided some but not adequate information on the prevalence of anaemia among children under six years of age over the years. The NFHS 4 and 5, NNMB survey, DLHS 4, and CNNS survey all conducted Hb estimation among preschool children between 2010 and 2020. The data from the NFHS surveys show a 10% increase in the prevalence of anaemia between NFHS 4 and 5. This increase may be partly attributed to the change in the method (Haemocue) used for Hb estimation. However, in the present study, the authors used venous blood for Hb estimation, and the prevalence of anaemia among 36-59 month old children was found to be 19.6%, which is much lower compared to the national survey results.

The World Health Organisation (WHO) expert groups recommend oral iron supplementation as a public health intervention for reducing the prevalence of anaemia in preschool children. Studies on IFA supplementation in preschool children have shown that daily IFA supplementation for three months or longer has resulted in an improvement in mean Hb levels (~0.5-1 g/dL) and ferritin levels [21].

In the present study, the children received 6 months of daily weight-based IFA supplementation. A systematic review and meta-analysis of studies assessing the effects of daily iron supplementation in 2 to 5-year-old children also found that daily iron supplementation increases Hb levels [25]. Studies have also documented that the improvement in Hb levels was higher with daily supplementation compared to biweekly or weekly supplementation, but maintaining compliance with daily supplementation on a long-term basis was more challenging [26,27]. The current WHO guidelines recommend daily IFA supplementation for three months every year in settings where the prevalence of anaemia is 40% or higher [21].

In the present study, at 6 months postintervention, 33.3% of the children improved their Hb levels to normal values. This finding is consistent with a randomised double-blind trial conducted to assess the effects of iron supplementation among iron-deficient infants, which showed an increase in Hb values at 4 months postintervention [28].

The compliance with daily IFA supplementation was 78%, and the authors observed a loss to follow-up of 20 children (37.7%). This observation is also consistent with studies that reported iron with multi-micronutrient fortification resulting in a clear reduction in anaemia and an increase in Hb levels [29]. The authors also found that adherence was better among children whose mothers were supportive of the intervention and attended the monthly health awareness group discussions. This finding is similar to another study conducted among children aged 12 to 59 months in rural southern India, which found that adherence to iron treatment improved through a combination of trial participation, improved maternal anaemia awareness, and close follow-up by lady health workers [30].

The postintervention results showed an improvement in anaemia and an increase in Hb levels among both boys and girls. This demonstrates that the use of an iron supplementation program for

children with mild-to-moderate anaemia, through an intervention that is easy to operate and reproduce with active involvement of mothers, can make a huge difference in reducing anaemia among preschool children [31,32].

In the present study, the daily intervention was administered at the anganwadi centre, and at 6 months postintervention, there was a significant rise in Hb levels ($p<0.011$). Another study found a greater increase in Hb levels among children receiving weekly intervention at home compared to the healthcare clinic, and this difference was also statistically significant ($p<0.00005$) [33]. A few studies that have used intermittent supplementation have noted improvements in Hb levels when larger iron dosages, longer intervention times, and concurrent administration of vitamins and minerals are employed [34,35].

The involvement of AWTs, support from local public health workers, and a locally trained woman acting as a research assistant in monitoring the supplementation and engaging mothers through home visits contributed to an adherence rate of over 50%. This finding aligns with a similar study conducted in the Empowered Action Group (EAG) states of India, which stated that interventions targeting only IFA supplements will not be sufficient. There is a need for policymakers to implement multiple interventions and approaches targeting the major preventable causes of anaemia among children aged 36-59 months [36].

Limitation(s)

The present research has some limitations. The diagnosis of anaemia was based solely on Hb levels, which restricted the classification of additional etiological categories of anaemia. Information on the duration of exclusive breastfeeding, the introduction of complementary foods, dietary patterns, parasite infestations, and genetic Hb abnormalities was not included in the present study. As a result, these factors were not assessed in the final analysis.

CONCLUSION(S)

The compliance with daily IFA supplementation was 70-80%, and there was an increase in Hb levels among children postintervention. The increase was observed in both girls and boys. The grading of anaemia also showed improvement. A three-pronged strategy of supplementation, improving maternal anaemia awareness, and regular follow-ups by a local research assistant was employed in the present study. This emphasises the need for collaborative efforts between the public health sector, community organisations, and other stakeholders for the health of children.

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