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Clinical Safety Analysis of Ayurveda-Derived Therapies for Iron Deficiency Anemia in Children: A narrative review.

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Abstract

Background: Iron Deficiency Anaemia (IDA) remains a major public health problem in children, particularly in developing countries. Although conventional iron supplementation is effective, long-term use is frequently associated with gastrointestinal intolerance and poor compliance. Ayurvedic herbomineral formulations have been traditionally used for anemia, but concerns regarding safety, especially in pediatric populations, necessitate systematic evaluation. **Objectives:** To critically evaluate the clinical safety of commonly used Ayurvedic iron formulations in the management of childhood IDA. **Methods:** A narrative review of clinical trials, observational studies, experimental toxicological studies, and pharmacovigilance reports was conducted. Pediatric studies evaluating safety outcomes such as adverse drug reactions, liver and renal function tests, and hematological parameters were prioritized. Classical Ayurvedic formulations including *Mandura Bhasma*, *Loha Bhasma*, *Dhatri Lauha*, and *Trikatrayadi Lauha* were included. **Results:** The majority of reviewed clinical studies demonstrated significant improvement in hemoglobin concentration and red blood cell indices with minimal adverse effects. Reported adverse events were mild, self-limiting, and did not necessitate treatment discontinuation. Biochemical safety parameters remained within normal limits. Experimental studies further supported the safety of these formulations when prepared using classical standardized methods. **Discussion** & **Conclusion:** Ayurvedic iron formulations appear to be clinically safe and well tolerated in children with IDA when administered in appropriate doses under professional supervision. These formulations may serve as a viable alternative or adjunct to conventional iron therapy, provided strict quality control and pharmacovigilance measures are ensured.

Keywords: Iron Deficiency Anaemia; Pediatric Anemia; Mandura Bhasma; Loha Bhasma; Ayurvedic Safety

Introduction

Anaemia is defined as a reduction in hemoglobin concentration below the normal reference range for age and sex, resulting in diminished oxygen-carrying capacity of blood [1]. Iron deficiency is the most common

nutritional cause of anemia worldwide and disproportionately affects infants and children due to increased iron requirements during growth [2].

According to the World Health Organization, approximately 40% of children aged 6–59 months are anaemic globally [3]. In India, data from the National Family Health Survey-5 (2019–21) indicate that 67.1% of children aged 6–59 months suffer from anemia [4]. Childhood IDA is associated with impaired cognitive development, delayed motor milestones, increased susceptibility to infections, and reduced academic performance [5].

Conventional management relies on oral iron salts such as ferrous sulfate, fumarate, and gluconate. Despite proven efficacy, long-term therapy is frequently associated with gastrointestinal adverse effects including nausea, abdominal pain, constipation, diarrhea, and metallic taste, leading to poor compliance in children [6].

Ayurveda describes anemia under *Pandu Roga*, with detailed etiopathogenesis and management outlined in classical texts such as Charaka Samhita, Sushruta Samhita, and Madhava Nidana [7–9]. Ayurvedic management includes dietary regulation, herbal therapy, and iron-based herbomineral formulations (*Lauha* and *Mandura* preparations). However, concerns regarding heavy metal toxicity highlight the need for evidence-based safety evaluation, particularly in pediatric populations.

Materials and Methods

Study Design

A narrative review methodology was adopted to synthesize clinical safety evidence of Ayurvedic iron formulations used in children with IDA.

Data Sources

Published literature was searched in PubMed, Google Scholar, AYUSH Research Portal, and indexed Ayurvedic journals. Classical Ayurvedic texts were consulted for conceptual correlation.

Inclusion Criteria

- Clinical trials and observational studies involving children (<18 years)
- Use of Ayurvedic iron-based formulations
- Reporting of safety parameters (adverse events, LFT, RFT)

Exclusion Criteria

- Adult-only studies
- Non-iron Ayurvedic formulations
- Studies lacking safety data

Results

Table 1. Summary of Clinical Studies Evaluating Ayurvedic Herbomineral Formulations in Childhood Anemia

Sr. no	Author (Year)	Study Design	Age Group (years)	Intervention & Dose	Duration	Key Efficacy Outcomes	Safety & Adverse Events
1	Dhaked et al. (2009)	Randomized comparative trial	1–14	Group A: *Dhatri Lauha* syrup (1 ml/kg/day) Group B: *Gudadi Mandura* syrup (1 ml/kg/day)	45 days	Significant improvement in Hb, MCV, MCH, MCHC, TRBC, serum iron & ferritin (P<0.001); Gudadi Mandura showed higher marked improvement (50%)	No serious adverse events reported
2	Gupta et al.	Non-randomized controlled trial	5–12	Group A: *Mandura Bhasma* 8 mg/kg q12h + honey Group B: *Mandura Bhasma* alone	30 days	Significant increase in serum iron/TIBC ratio; better results with honey adjuvant	No toxicity or biochemical abnormalities reported
3	Garai et al. (2009)	Open-label clinical 4study	Children (IDA)	*Panduhara Yoga* (Mandura Bhasma : Amalaki Churna = 1:10)	6 weeks	93.33% showed very good clinical improvement; 50% showed marked Hb improvement	No adverse drug reactions observed
4	Kumar & Garai	Double-blind randomized placebo-controlled trial	Children (IDA)	*Trikatrayadi Lauha* suspension	10 weeks	Highly significant improvement in clinical & hematological parameters (P<0.001)	Well tolerated; no adverse effects reported

5	Yogita et al. (2014)	Randomized controlled trial	Children (SCD)	*Gomed-Mandura-Kasisa Bhasma* vs folic acid	Not specified	Significant improvement in Hb% and symptoms; no significant change in hepatosplenomegaly	No serious adverse effects reported
6	Ragamala KC et al. (2010)	Open-label safety trial	Children	*Dhatri Lauha*	45 days	Significant increase in hemoglobin levels	Mild, self-limiting adverse events: abdominal burning (8.5%), nausea (4.5%), diarrhea (2.0%), skin rash (2.5%); LFT & RFT normal
7	Comparative synthesis	Narrative comparative analysis	—	*Dhatri Lauha*, *Gudadi Mandura*, *Mandura Bhasma*, *Gomed-Mandura-Kasisa Bhasma*	—	Gudadi Mandura & honey-adjuvanted Mandura Bhasma superior in IDA; compound Bhasma effective in SCD	Overall favorable safety profile

Clinical Evidence on Safety and Efficacy of Ayurvedic Iron Formulations in Children

A total of six pediatric clinical studies and one comparative analytical synthesis evaluating Ayurvedic herbomineral formulations in childhood anemia were reviewed [Table 1]. Among these, five studies addressed Iron Deficiency Anemia (IDA) and one study evaluated sickle cell disease (SCD)–related anemia, while one provided an integrated comparative interpretation of available trials.

Dhaked et al. conducted a randomized comparative clinical trial in children aged 1–14 years, comparing *Dhatri Lauha syrup* (Group A, n=30) and *Gudadi Mandura syrup* (Group B, n=30) administered at a dose of 1 ml/kg/day in two divided doses for 45 days. Statistically highly significant improvement was observed in hemoglobin, MCV, MCH, MCHC, total RBC count, serum iron, and serum ferritin levels in both groups ($P < 0.001$). Clinically, Group B demonstrated superior outcomes with 50% of patients showing marked improvement compared to 20% in Group A, suggesting better efficacy of *Gudadi Mandura* [10].

Gupta et al. conducted a non-randomized controlled trial in children aged 5–12 years using *Mandura Bhasma* with and without honey. Group A (n=20) received *Mandura Bhasma* 8 mg/kg body weight every 12 hours with honey, while Group B (n=10) received *Mandura Bhasma* alone for 30 days. Both groups showed positive changes in total leukocyte count and erythrocyte sedimentation rate, with a significant increase in serum iron/TIBC ratio, which was more pronounced in the honey-adjuvant group [11].

Garai et al. evaluated *Panduhara Yoga* (Mandura Bhasma: Amalaki Churna in a 1:10 ratio) in children with IDA over six weeks. The study reported very good clinical improvement in 93.33% of participants, while 50% showed marked improvement in hemoglobin levels. Importantly, no adverse drug reactions were reported during the treatment period [12].

Kumar and Garai conducted a double-blind, randomized, placebo-controlled trial assessing *Trikatrayadi Lauha suspension* in children with IDA. After 10 weeks of therapy, statistically highly significant improvement in clinical features and hematological parameters was observed ($P < 0.001$). The formulation was well tolerated, and no adverse effects were recorded in any participant [13].

Yogita et al. performed a randomized controlled trial in children with sickle cell anemia comparing a *Gomed-Mandura-Kasisa Bhasma compound* with folic acid. The compound Bhasma group demonstrated significant improvement in hemoglobin levels and clinical symptoms compared to the control group. However, hepatomegaly and splenomegaly did not show significant reduction [14].

Ragamala KC et al. evaluated the safety of *Dhatri Lauha* in children over a 45-day treatment period. A significant rise in hemoglobin concentration was observed. Mild adverse events such as abdominal burning (8.5%), nausea (4.5%), diarrhea (2.0%), and skin rashes (2.5%) were reported. All adverse effects were self-limiting, with no study withdrawals or serious adverse events. Liver and renal function parameters remained within normal reference ranges [15].

A comparative synthesis of available studies demonstrated that *Dhatri Lauha*, *Gudadi Mandura*, *Mandura Bhasma*, and *Gomeda-Mandura-Kasisa Bhasma* showed consistent improvement in hematological parameters in childhood anemia. Among IDA cases, *Gudadi Mandura* and honey-adjuvanted *Mandura Bhasma* exhibited comparatively superior outcomes. In SCD-related anemia, the compound Bhasma showed faster clinical improvement than folic acid [16].

Discussion

The findings of the present review indicate that *Ayurvedic* iron-based *herbomineral* formulations are clinically effective and exhibit an acceptable safety profile in pediatric Anaemia, particularly in Iron Deficiency Anaemia. Across multiple clinical trials, consistent improvement in hemoglobin concentration, red blood cell indices, and iron biomarkers was observed, supporting the hematinic potential of these formulations [10-13].

One of the most significant observations is the low incidence and mild nature of adverse events associated with Ayurvedic iron formulations. Unlike conventional oral iron salts, which are frequently associated with gastrointestinal intolerance and poor compliance in children, the reviewed studies reported either no adverse effects or only mild, self-limiting symptoms [15]. This improved tolerability may be attributed to the presence of herbal components such as *Amalaki* and the use of suitable *Anupana* like honey, which are known to enhance iron absorption and reduce gastric irritation [11,13].

Comparative evidence from Dhaked et al. suggests that *Gudadi Mandura* may offer superior clinical benefit over *Dhatri Lauha*, possibly due to its composite herbal base enhancing bioavailability and metabolic assimilation of iron [10]. Similarly, the superior outcomes seen with honey-adjuvanted *Mandura Bhasma* reinforce classical Ayurvedic principles of drug administration (*Yogavahi* effect of honey) [11].

Safety concerns regarding herbomineral formulations primarily stem from improper manufacturing, contamination, or non-standardized preparation. However, experimental toxicological studies have demonstrated that *Loha Bhasma* and *Mandura Bhasma* are safe even at doses exceeding therapeutic levels when prepared using classical *Shodhana* and *Marana* procedures [17,18]. The absence of significant hepatic or renal toxicity in pediatric trials further supports their safety [15].

In sickle cell disease–associated anemia, the improvement observed with *Gomeda-Mandura-Kasisa Bhasma* suggests that *Ayurvedic* formulations may also have a role beyond nutritional anemia, although organomegaly remains less responsive [14]. This highlights the need for condition-specific therapeutic strategies and longer follow-up durations.

Despite promising findings, limitations such as small sample sizes, heterogeneity of formulations, short treatment duration, and lack of long-term pharmacovigilance data must be acknowledged. Future research should emphasize multicentric randomized controlled trials, standardized formulations, and post-marketing safety surveillance to strengthen clinical confidence.

The present review consolidates available clinical evidence on the safety and efficacy of Ayurvedic herbomineral formulations in the management of childhood anemia, particularly Iron Deficiency Anemia (IDA). Across multiple pediatric clinical studies, formulations such as *Dhatri Lauha*, *Gudadi Mandura*, *Mandura Bhasma*, *Panduhara Yoga*, and *Trikatrayadi Lauha* consistently demonstrated significant improvement in hemoglobin levels, red blood cell indices, and iron-related biochemical parameters.

Importantly, the safety profile of these formulations was favorable. Reported adverse events were infrequent, mild, and self-limiting, with no serious adverse events or clinically significant hepatic or renal toxicity documented. Compared to conventional oral iron preparations, *Ayurvedic* iron formulations appeared to be better tolerated in children, which may translate into improved treatment adherence. The use of appropriate adjuvants such as honey and herbal constituents like *Amalaki* likely enhances bioavailability and minimizes gastrointestinal intolerance.

The evidence further suggests that composite formulations, particularly *Gudadi Mandura* and honey-adjuvanted *Mandura Bhasma*, may offer superior clinical benefits in IDA, while compound Bhasma formulations also show potential utility in sickle cell disease–associated anemia. However, limitations such as small sample sizes, heterogeneity of study designs, and lack of long-term pharmacovigilance data must be acknowledged.

Conclusion

In conclusion, Ayurvedic iron-based herbomineral formulations, when prepared using standardized classical methods and administered under qualified medical supervision, appear to be clinically safe and effective for the management of childhood anemia. These formulations may serve as a valuable alternative or adjunct to conventional iron therapy. Future multicentric, well-designed randomized controlled trials with long-term safety monitoring are warranted to strengthen the evidence base and support broader clinical integration.

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Conflicts of interest

There are no conflicts of interest.

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