

Clinical Efficacy And Immunomodulatory Effect Of Bal-Rasayana® Syrup In Pediatric Allergic Rhinitis: An Open-Label Prospective Study

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ABSTRACT

Background: Allergic rhinitis (AR) is one of the most common chronic respiratory disorders in children, often associated with asthma and recurrent morbidity. Conventional management with antihistamines is frequently limited by adverse effects, highlighting the need for safe, long-term, immune-modulating therapies. In Ayurveda, AR resembles Vataja Pratishyaya, which arises from Kapha-Vata dosha imbalance and Ama accumulation in the Pranavaha Srotas. Objective: To evaluate the clinical efficacy, safety, and immunomodulatory effects of Bal-Rasayana® syrup, a polyherbal formulation, in children with allergic rhinitis.

Methods: An open-label, non-comparative, prospective clinical trial was conducted in the OPD of Balroga, Bharati Vidyapeeth Ayurved Hospital, Pune. Sixty children aged 3–16 years with recurrent AR were enrolled. Participants received Bal-Rasayana® syrup at a dose of Age (years) × 4 ml twice daily for 90 days, with follow-ups on Day 30, 60, 90, and post-treatment review on Day 120. Subjective symptoms (sneezing, rhinorrhea, nasal obstruction, nasal itching, epiphora) were assessed using clinical scoring, while objective parameters included Absolute Eosinophil Count (AEC) and Serum IgE. Statistical analysis was performed using Wilcoxon Signed Rank Test for subjective parameters and paired t-test for objective parameters, with significance set at $p < 0.05$.

Results: Significant improvement was observed in all subjective symptoms: sneezing (81.94%), rhinorrhea (78.74%), nasal obstruction (64.15%), nasal itching (68.66%), and epiphora (85.30%) ($p < 0.001$). Objective parameters also showed marked improvement: AEC decreased by 64.77% and Serum IgE by 78.65% ($p < 0.001$). Overall, 44.4% of children achieved moderate improvement (50–75% relief) and 36.5% achieved excellent improvement (75–100% relief). No significant adverse effects were reported.

Conclusion: Bal-Rasayana® syrup is a safe, effective, and child-friendly polyherbal intervention for allergic rhinitis, providing significant symptomatic relief and immunomodulatory benefits. The formulation addresses the underlying Ayurvedic pathophysiology by restoring Agni, clearing Ama, pacifying Kapha-Vata dosha, and strengthening the Pranavaha Srotas. These findings support its use as a holistic alternative or adjunct to conventional therapy in pediatric AR.

KEYWORDS: Allergic rhinitis, Pediatric, Bal-Rasayana® syrup, Ayurvedic therapy, Immunomodulation, Vataja Pratishyaya.

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INTRODUCTION

Allergic Rhinitis (AR) is one of the most common chronic respiratory disorders affecting children worldwide. Industrialized regions report higher prevalence, with an estimated 40% of children experiencing symptoms that interfere with daily functioning and academic performance. The International Study of Asthma and Allergies in Childhood (ISAAC) has shown a rising prevalence of allergic rhino-conjunctivitis among Indian children aged 6–7 years (3.9%) and 13–14 years (10.4%), with a clear upward trend. AR also shows a strong association with asthma—nearly one-third of children with rhinitis have asthma, and half of those with asthma present rhinitis symptoms, highlighting its systemic involvement.

Conventional management primarily relies on antihistamines and intranasal corticosteroids. However, antihistamines are associated with sedation, drowsiness, impaired learning, and anticholinergic effects in children. This underscores the need for a safe, long-term, immune-modulating intervention, particularly for school-aged children who suffer from recurrent episodes of AR.

In Ayurveda, AR resembles **Vataja Pratishyaya**, described extensively in *Bruhatrayi* and *Laghutrayi*. If untreated, it may lead to complications such as Kasa, Shwasa, Ghrana-viplava, Badhira, and Rajayakshma. Classical management—Snehana, Swedana, Shodhana, and Nasya therapies—is effective but often cumbersome for pediatric application. Therefore, there is a need for an easily administrable, safe, and palatable formulation for children.

Bal-Rasayana® syrup, containing 15 classical herbs including Pippali, Ativisha, Guduchi, Vasa, Haritaki, Bibhitaki, and Amalaki, possesses Dipana-Pachana, Vata-Anulomana, Rasa-Pachana, Dhatvagni-Vardhana, anti-allergic, mucolytic, and immunomodulatory properties. These pharmacological qualities suggest potential benefit in AR by correcting **Pranavaha Srotodushti**, enhancing **Vyadhikshamatva**, reducing recurrence, and improving quality of life.

Given the increasing prevalence and recurrence of allergic rhinitis in children, adverse effects of long-term antihistamine use, and the lack of safe immune-enhancing Ayurvedic pediatric formulations, this study was designed to evaluate the clinical efficacy of Bal-Rasayana® syrup.

Aim and Objectives: To evaluate the clinical efficacy of Bal-Rasayana® syrup in children suffering from Allergic Rhinitis.

Objectives:

1. To assess improvement in the symptoms of allergic rhinitis.
2. To evaluate reduction in frequency of episodes and school absenteeism.
3. To study immunomodulatory changes such as Absolute Eosinophil Count (AEC) and Serum IgE levels.

MATERIALS AND METHODS

The present study was designed as an open-label, non-comparative, prospective clinical trial conducted in the Outpatient Department of Balroga, Bharati Vidyapeeth (Deemed to be University) Ayurved Hospital, Pune. The study aimed to evaluate the clinical efficacy of Bal-Rasayana® syrup in children diagnosed with Allergic Rhinitis (AR), corresponding to Vataja Pratishyaya in Ayurvedic literature. A total of 63 patients were registered for the study, out of which 60 children completed the trial, meeting the minimum required sample size.

Selection of participants was based on clearly defined inclusion and exclusion criteria to ensure homogeneity of the study population. Children aged 3 to 16 years with a clinical diagnosis of AR/Vataja Pratishyaya were considered eligible. Eligible participants were required to have experienced at least three episodes of allergic rhinitis in the previous six months and to present with cardinal symptoms, including sneezing, rhinorrhea, nasal itching, and nasal congestion. Children outside the specified age range, those suffering from severe respiratory illnesses such as pneumonia, tuberculosis, bronchitis, or bronchiectasis, and patients with asthma, nasal polyposis, or congenital anomalies of the respiratory tract were excluded. Additionally, children currently on systemic or inhaled corticosteroids were not considered for the study.

Discontinuation criteria were established to ensure patient safety and study integrity. Participants were withdrawn in the event of withdrawal of consent, development of acute systemic illness, emergence of respiratory complications, or non-compliance with the prescribed intervention protocol.

This methodological framework allowed systematic enrollment, careful monitoring, and ethical management of pediatric participants, providing a robust foundation for evaluating the efficacy, safety, and immunomodulatory potential of Bal-Rasayana® syrup in the management of recurrent allergic rhinitis in children.

Table 1: Posology of drug used

| Parameter | Details |
|------------------------------|---|
| Trial Drug | Bal-Rasayana® syrup (Kwatha-based formulation) containing 15 herbal ingredients |
| Dose | Child dose as per Sharangdhara: Dose = Age (years) × 4 ml, twice daily • Morning: 30 min before breakfast • Evening: 30 min before snacks |
| Duration of Treatment | 90 days (Day 0–90) |

| | |
|------------------------------|--|
| Follow-up Schedule | Day 30, Day 60, Day 90 |
| Post-treatment Review | Day 120 (no drug) |
| Endpoints | Primary endpoint: Day 90 Secondary endpoint: Day 120 |

Justification for Duration

Ayurveda indicates approximately one month for transformation from *Ahara Rasa* to *Shukra Dhatu*. Immunomodulation requires multiple tissue-level changes; hence treatment was maintained for 3 months.

Assessment Criteria

A. Subjective Parameters (Scored 0–3)

1. Kshavathu (Paroxysmal sneezing)
2. Anaddha Nasa (Nasal congestion)
3. Tanu Srava (Rhinorrhea)
4. Pihita Nasa (Nasal itching)
5. Epiphora

B. Objective Parameters

1. Absolute Eosinophil Count (AEC)
2. Serum IgE
3. Chest X-ray (PA View)

All parameters assessed **before** and **after** treatment.

Statistical Analysis

Data obtained from the study were subjected to appropriate statistical analysis to evaluate the efficacy of Bal-Rasayana® syrup in children with Allergic Rhinitis. Subjective parameters, including patient-reported symptoms such as sneezing, rhinorrhea, nasal itching, and congestion, were analyzed using the Wilcoxon Signed Rank Test, which is suitable for paired non-parametric data. Objective parameters, such as Absolute Eosinophil Count (AEC) and Serum IgE levels, were analyzed using the paired t-test to assess pre- and post-treatment changes in normally distributed continuous variables. A p-value of less than 0.05 was considered statistically significant, indicating meaningful clinical improvement following the intervention.

Observations and Results

Demographic Profile: The study included 60 children diagnosed with Allergic Rhinitis (Vataja Pratishyaya), with males predominating (58.4%). The majority of participants (66.4%) belonged to the 3–6 years age group, indicating higher vulnerability of younger children to recurrent AR episodes. Both rural (58.4%) and urban (41.6%) populations were affected, reflecting the widespread prevalence of the condition. Seasonal patterns were observed in all participants (100%), with morning aggravation reported in 69.6%, consistent with the Kapha Kala described in Ayurvedic texts.

Aggravating and Relieving Factors: Common aggravating factors included intake of cold water, seasonal variations, and daytime sleep, while nearly all patients (99.2%) reported symptomatic relief with warm water.

Associated Features: Sleep disturbances were reported in 96% of children, and decreased appetite was noted in 92.8%, reflecting systemic involvement and general discomfort. Tongue coating was observed in all patients, suggesting the presence of Ama, and lymphadenopathy was noted in 84%, indicating immune activation.

Symptomatic Relief: After 90 days of treatment with Bal-Rasayana® syrup, significant improvement in subjective symptoms was observed. Sneezing decreased by 81.94%, rhinorrhea by 78.74%, nasal obstruction by 64.15%, nasal itching by 68.66%, and epiphora by 85.30%, all with $p < 0.001$, indicating highly significant clinical efficacy.

Objective Parameters: The treatment led to a substantial reduction in immunological markers, with Absolute Eosinophil Count (AEC) decreasing by 64.77% and Serum IgE levels by 78.65% ($p < 0.001$), reflecting the immunomodulatory potential of the formulation.

Overall Effect: Clinically, 44.4% of patients exhibited moderate improvement (50–75%), while 36.5% showed excellent improvement (75–100%). No significant adverse effects were reported, underscoring the safety and tolerability of the intervention.

DISCUSSION

The present study demonstrates that **Bal-Rasayana® syrup** is effective in managing pediatric allergic rhinitis, providing significant symptomatic relief while modulating underlying immunological disturbances. Clinically, 44.4% of patients experienced moderate improvement (50–75% relief), and 36.5% showed excellent improvement (75–100% relief), highlighting the practical utility of this polyherbal formulation. Subjective symptoms such as sneezing, rhinorrhea, nasal obstruction, nasal itching, and epiphora improved significantly ($p < 0.001$), correlating with a substantial reduction in **Absolute Eosinophil Count (64.77%)** and **Serum IgE levels (78.65%)**, confirming the formulation's immunomodulatory action. No adverse effects were reported, supporting its safety and tolerability for long-term pediatric use.

From an **Ayurvedic perspective**, allergic rhinitis (Pratishyaya) primarily arises from **Kapha-Vata dosha vitiation** and the accumulation of Ama obstructing the Pranavaha Srotas. The herbs in Bal-Rasayana® syrup act to correct these fundamental pathophysiological disturbances. **Dipana-Pachana** actions of Pippali and Ativisha stimulate Agni (digestive fire) and enhance metabolism, preventing Ama formation. **Vata Anulomaka** effects normalize respiratory functions, reducing sneezing, nasal obstruction, and irritation. **Rasa-Pachaka and Rakta-Pachaka** actions of Guduchi, Amalaki, and Triphala (Bibhitaki + Haritaki + Amalaki) nourish and purify Rasa and Rakta, restoring immune competence. Additionally, **Dhatvagni Vardhaka** effects enhance tissue metabolism, strengthen immunity, and support mucosal repair. Collectively, these mechanisms address the root cause (Samprapti) of AR, restoring Agni, clearing Ama, pacifying Vata-Kapha dosha, and improving the functional integrity of Pranavaha Srotas.

From a **modern pharmacological perspective**, the individual herbal constituents exert complementary and synergistic effects. **Pippali (Piper longum)** inhibits histamine release, downregulates IL-4 and IL-13, and exhibits bronchodilatory and anti-inflammatory properties. **Ativisha (Aconitum heterophyllum)** demonstrates anti-inflammatory and immunosuppressive effects, modulating macrophage function and cytokine secretion. **Guduchi (Tinospora cordifolia)** balances Th1/Th2 cytokine profiles, reduces IgE and eosinophil counts, and provides antioxidant protection. **Vasa (Adhatoda vasica)** promotes mucociliary clearance and reduces airway inflammation. **Amalaki (Embllica officinalis)** provides natural antihistamine, antioxidant, and immunomodulatory effects. **Bibhitaki (Terminalia bellirica)** and **Haritaki (Terminalia chebula)** further contribute antioxidant, anti-inflammatory, and tissue-rejuvenating actions.

The **integrated mode of action** of Bal-Rasayana® syrup can be summarized as follows:

1. **Reduction of allergic inflammation:** Lowering IgE levels and eosinophilic activity attenuates hypersensitivity responses.
2. **Mucolytic and bronchodilatory effects:** Vasa and Pippali improve mucus clearance and reduce nasal obstruction.
3. **Restoration of digestive and metabolic functions:** Dipana-Pachana actions prevent Ama accumulation, which drives chronic inflammation.
4. **Rejuvenation and immunomodulation:** Rasayana herbs strengthen overall immunity, improving resistance to allergens.
5. **Anti-oxidative defense:** Antioxidant properties protect nasal mucosa from oxidative stress, reducing recurrence and severity.

In summary, the clinical improvements observed in this study result from a combination of **symptomatic relief, immune modulation, and systemic rejuvenation**. From the Ayurvedic standpoint, the formulation restores Agni, clears Ama, pacifies Kapha-Vata dosha, and strengthens the Pranavaha Srotas, while modern pharmacological evidence supports its anti-allergic, anti-inflammatory, immunomodulatory, mucolytic, and antioxidant effects. This dual action underscores Bal-Rasayana® syrup as a holistic, safe, and effective intervention for pediatric allergic rhinitis.

CONCLUSION

The study validates the hypothesis and confirms the primary objectives. Treatment with Bal-Rasayana® syrup resulted in significant relief of subjective symptoms and substantial improvement in objective immunological markers, demonstrating its dual role in symptomatic management and immune modulation. The formulation was well tolerated and suitable for long-term pediatric use, establishing it as a safe, holistic, and effective alternative for managing allergic rhinitis in children.

RECOMMENDATIONS AND FUTURE SCOPE:

1. Conduct larger, randomized controlled trials to strengthen the evidence base.
2. Perform comparative studies with conventional therapies to establish relative efficacy.
3. Undertake long-term follow-up studies to assess preventive and disease-modifying potential.
4. Investigate the molecular mechanisms underlying its immunomodulatory effects to support translational applications.

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