RESEARCH PAPER

"Evaluation of IgE-Associated Immune Modulation of Bal-Rasayana® Syrup in Pediatric Recurrent Respiratory Tract Infections with Type I Allergy"

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Abstract

Background: Recurrent respiratory tract infections (RRTIs) associated with Type I hypersensitivity represent a major cause of Pediatric morbidity and healthcare burden worldwide. Existing pharmacological interventions offer symptomatic relief but are often associated with adverse effects and limited immunomodulatory potential, highlighting the need for safe, long-term therapeutic options.

Objective:

To evaluate IgE-associated immunomodulatory effects of Bal-Rasayana® Syrup, a polyherbal formulation, in Pediatric patients with recurrent respiratory tract infections associated with Type I allergy.

Methods:

This open-label, non-comparative, prospective clinical study (CTRI Registration No. CTRI/2024/05/067252) was conducted at a tertiary care teaching hospital in Mumbai, India, in accordance with CONSORT guidelines. Thirty-two children aged 3–16 years with recurrent respiratory tract infections associated with Respiratory allergy and showing classical symptoms of *Vataja Pratishyaya* were enrolled. Bal-Rasayana ® Syrup was administered orally for 60 days, with dosage determined according to Young's formula. Clinical assessments were performed at baseline and at 15-day intervals, with a post-treatment follow-up on Day 90.

Results: All subjective clinical parameters showed statistically significant improvement after treatment ($p < 0.01$), with sneezing demonstrating a highly significant reduction ($p < 0.001$). Comparison of Before Treatment (BT) and After Treatment (AT) values in the trial group revealed highly significant changes in objective parameters, including serum IgE levels, absolute eosinophil count, and hemoglobin percentage ($p < 0.001$ for all). No treatment-related adverse events were reported during the study period.

Conclusion:

Bal-Rasayana® Syrup demonstrated significant IgE-associated immunomodulatory effects in children with recurrent respiratory tract infections and Type I allergy, with a favourable safety profile. The findings suggest that Bal-Rasayana® Syrup offers a holistic and sustainable therapeutic alternative to conventional management in Pediatric Recurrent respiratory tract infections.

Keywords:

Bal-Rasayana® Syrup; Ayurveda, Pediatric Allergy; Recurrent Respiratory Tract Infections; Type I Hypersensitivity; Immunomodulation.

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Introduction

Recurrent respiratory tract infections (RRIs) represent a major public health concern in Pediatric populations worldwide, accounting for substantial morbidity[i], healthcare utilization, and school absenteeism. Epidemiological studies report that up to 25% of children experience RRIs during early childhood.[ii] Immunological immaturity, characteristic of childhood (*Bālya avasthā*), predisposes children to frequent infections.[iii]

RRIs are strongly associated with allergic respiratory disorders such as allergic rhinitis and asthma. Type I

hypersensitivity leads to chronic airway inflammation, increased mucosal permeability, and impaired local immunity, facilitating recurrent infections. Conversely, repeated infections further exacerbate allergic inflammation, creating a self-perpetuating vicious cycle.[iv]

Details	Trial Group
Drug	Bal-Rasayana® syrup
Dosage	As per the Proposed Guidelines Calculated Based on Youngs Formula
Aushadhi sevan kala	Morning (Before breakfast), Evening (Before Snacks)
Duration	8 weeks
Route	Oral
Anupana	Lukewarm Water
Follow-up	During treatment- Baseline,15th, 30th, 45th, 60th, days. After 30 days, without medication

Ayurvedic literature describes similar symptomatology under *Pratishyaya*, particularly *Vataja Pratishyaya*, which is closely linked to impaired *Vyadhikshamatva* (disease resistance) and dysfunction of *Pranavaha srotas*. [v]Rasayana therapy, aimed at immune enhancement and tissue nourishment, offers a rational approach for breaking this cycle. Bal-Rasayana® syrup, a polyherbal formulation, has been selected for its immunomodulatory and Rasayana properties.[vi]

Aim and Objectives

Aim

To assess the IgE-associated immunomodulatory effects of Bal-Rasayana® syrup in Pediatric recurrent respiratory tract infections with Type I allergy.

Objectives

1. To evaluate efficacy of Bal Rasayana® syrup in children with RRIs.
2. To reduce the incidence and severity of recurrent respiratory tract infections.
3. To reduce school absenteeism associated with RRIs.

Materials and Methods

Study Design -Open-label, non-comparative, prospective clinical trial.

Ethical Considerations-The study was approved by the Institutional Ethics Committee (IEC approval no. RAPMC/V.V/Ethics/2024/292, dated 8 January 2024) and registered with the Clinical Trials Registry of India (CTRI/2024/05/067252).

Sample Size-Sample size was calculated using the prevalence-based formula[vii] and finalized as 32 participants.

Inclusion Criteria

- Children aged 3–16 years
- Diagnosed with *Vataja Pratishyaya* and RRIs
- Elevated serum IgE levels
- History of ≥3 RRI episodes in the last 6 months

Exclusion Criteria

- Severe or complicated respiratory disorders (e.g., pneumonia, tuberculosis, etc)
- Chronic asthma, nasal polyposis
- Congenital respiratory anomalies
- Children on systemic or inhaled corticosteroids

Intervention Details:

Assessment Criteria

Subjective Parameters: Nasal discharge, sneezing, nasal obstruction, nasal/ocular itching, epiphora (graded scoring).

Objective Parameters: Serum IgE, absolute eosinophil count, complete blood count.

Statistical Analysis-Data were analysed using paired statistical tests. Results were expressed as mean ± SD, and $p<0.05$ was considered statistically significant.

Trial Drug procurement and Preparation -The trial drug Bal-Rasayana® syrup was procured from GMP certified company which was prepared as per the classical method and standard protocol as explained in *Sharangdhar Samhita*.[viii]Analytical standards, safety and heavy metal screening was done through NABL approved Laboratory and found to be within the permissible limit of their standards. CONSORT Herbal Medicinal Interventions checklist[ix] was reviewed regarding Safety, Efficacy, and Standardization of Trial drug

Observation and Results

Demographic Profile

The study comprised 32 children diagnosed with recurrent respiratory tract infections associated with Type I allergy (*Vātaja Pratiśyāya*), with a male predominance (59.38%). The majority of participants (59.37%) were in the 3–7-year age group, suggesting increased susceptibility of younger children to recurrent respiratory tract infections. Participants were drawn from both urban (60.2%) and rural (34.20%)

settings, reflecting the widespread prevalence of the condition across populations.

A seasonal pattern of symptom exacerbation was observed in all participants (100%), while morning aggravation was reported in 81.3% of cases. These clinical features are consistent with the predominance of *Vāta* and *Vāta–Kapha Prakṛti* in children, supporting the Ayurvedic conceptual framework of the disease.

Table No.1: Statistical Presentation of overall improvement in subjective parameters in Trial group

Sr. No.	Morbidity Features	Mean Score			S.D.	S.E.	P Value	Significance
		B.T	A.T	Diff.				
1	Nasal Discharge	6.48	3.51	2.96	4.86	0.91	0.021	Significant
2	Sneezing	7.15	3.53	3.61	3.87	0.76	0.001	Highly Significant
3	Nasal obstruction	5.81	3.68	2.13	4.40	0.93	0.034	Significant
4	Itching (Nasal/Eye)	6.42	3.42	3.00	4.21	0.92	0.032	Significant
5	Epiphora	5.12	2.93	2.18	3.34	0.84	0.019	Significant

Significant improvement was observed in all subjective symptoms ($p<0.01$), with sneezing showing highly significant reduction ($p<0.001$).

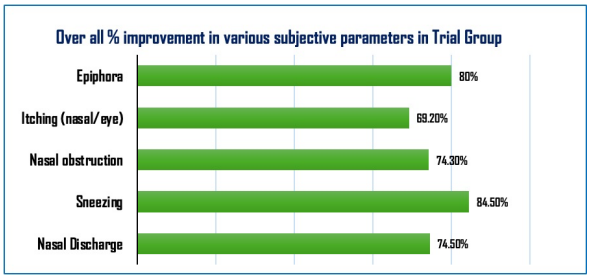
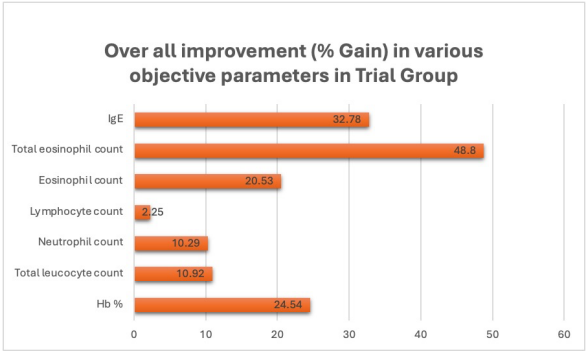


Table No.2: Analysis of Effect of treatment (BT and AT) in Trial Group

Objective Parameters	Paired Differences			t Value	P Value	Significance
	Mean	SD	SE Mean			
IgE	166.14	311.40	55.05	3.02	0.005	Highly Significant
Hb%	10.90	26.00	4.60	2.37	0.002	Highly Significant
AEC	0.16	0.36	0.06	2.47	0.001	Highly Significant
Platelet	0.26	0.77	0.14	1.88	0.070	Not Significant
WBC count	765.63	2830.78	500.42	1.53	0.013	Significant

When comparing the values before treatment with those after treatment for objective parameters, Highly significant difference was observed, with a p-value of less than 0.001 in IgE, Absolute Eosinophil and Hb%, whereas significant improvement noted in WBC count. Hence treatment in Trial Group in is effective in objective parameters.

Statistical Presentation of overall improvement in objective parameters



Discussion

Pratishyaya has been described as an independent disease, as a symptom[x] or as a complication in the context of different diseases in Ayurvedic classics.[xi]

The symptoms of RRIs resemble with *Lakshanas* mentioned in *Pratishyaya* (*Vataja*) [xii]and if not managed even leads to severe diseases like *Rajyakshama* [xiii]establishing the relation to *vyadhi kshamatwa.*[xiv]

Childhood *(Bālya avasthā)* described as *Alpa Vyadhikshamatva*,[xv] Immature *Dhatu, Agni* & *Srotas*, Reduced disease resistance, and more *Pranavaha srotas* involvement.

Respiratory disorders, described in Ayurveda as vitiation of *Pranavaha Srotas*, primarily involve an imbalance of *Vata* and *Kapha Dosha*. The principal *Dushya* involved is *Rasa Dhatu*, while the affected *Srotas* include *Pranavaha*, *Annavaha*, and *Rasavaha*. Hence, the therapeutic agent should possess the ability to act simultaneously on these *srotas*, exhibiting *Deepana*, *Pachana*, *Vata–Kapha Shamaka*, and *Srotoshodhana* properties. More specifically, such a drug should predominantly possess *Laghu*, *Sukshma*, *Ushna*, and *Tikshna Guna*.

Bal Rasayana® Syrup is a polyherbal formulation[xvi] comprising drugs with *Amapachaka* properties (e.g., *Pippali, Ativisha, Musta*), *Rasayana* effects (e.g., *Amalaki, Pippali, Guduchi*), *Vishaghna* action (e.g., *Musta, Ativisha, Vidanga*), *Shothahara* activity (e.g., *Pippali, Vasa, Guduchi*), and *Vata–Shleshmahara* properties (e.g., *Vasa, Pippali, Ativisha, Musta*). The trial drug predominantly exhibits *Katu* and *Tikta Rasa*, *Laghu*, *Ushna*, and *Tikshna Guna*, *Katu Vipaka*, *Ushna Virya*, and *Kapha–Vata Shamaka* action.

Owing to these properties, the formulation demonstrates significant *Srotoshodhana* activity, which may assist in eliminating *Avarana* and sluggish *Dosha* from the affected *srotas*. The combined effect of *Katu* and *Tikta Rasa*, *Ushna Virya*, and *Laghu–Tikshna Guna* facilitates *Kapha Vilayana*, enhances *Pachana*, and promotes effective clearance of the

respiratory channels. This liquefaction and mobilization of *Kapha Dosha* aids in expectoration, resulting in improved airway patency and relief of respiratory symptoms, particularly during coughing.

Bal Rasayana® Syrup having a potential property of alleviating both *vata* and *kapha dosha* by virtue of *tikta, katu rasa* and *ushna virya, laghu tikshna* and *ushna* quality. Thus, *kaphashamaka* properties of drug help in breaking the *srothorodha* and digestion of *ama*, which leads to proper functioning of the *Agni*.

The trial drug contains several *Rasayana* ingredients known for their immunomodulatory properties, which help in qualitative and quantitative enhancement of *Dhatu*. Drugs such as *Piper longum* (Pippali), *Āmalakī*, *Guḍūcī*,[xvii] and *Harītakī* are classical *Rasayana* agents with well-documented effects on immune regulation and tissue nourishment. Among these, Pippali is regarded as a superior Rasayana for *Prāṇavaha Srotas*, the primary site of manifestation in allergic respiratory disorders.

The formulation appears to act at multiple levels of allergic pathogenesis. Certain ingredients exert effects on the **early (immediate) phase of Type I hypersensitivity**, primarily by inhibiting histamine release or mast cell degranulation[xviii]. Experimental evidence suggests that *Piper longum* possesses mast cell–stabilizing activity, while *Vāsa* (*Adhatoda vasica*)[xix] has been shown to deplete histamine from bronchial and lung tissues. These actions contribute to the reduction of acute allergic symptoms such as sneezing, nasal discharge, and itching.

Other components of the formulation act predominantly on the **late-phase allergic response**, either by inhibiting leukotriene pathways or by reducing eosinophil counts. Drugs such as *Musta*, *Vāsa*, and *Pippali*[xx] have demonstrated efficacy in attenuating eosinophilic inflammation, which is a hallmark of chronic allergic respiratory disorders. The combined anti-allergic effects of these ingredients likely account for the overall symptomatic relief observed in the study group.

Nasal obstruction and epiphora are clinical manifestations of mucosal edema and chronic inflammatory changes in target organs. The significant improvement observed in these symptoms suggests a potent **anti-inflammatory effect** of the study drug. Ingredients such as *Vāsa*, *Ativiṣā*, and *Pippali* are known for their anti-inflammatory activity. The observed normalization of leukocyte counts further supports the anti-inflammatory[xxi] and immunomodulatory actions of the formulation, which may be attributed to constituents like *Guḍūcī*, *Pippali*, and *Ativiṣā*.

Eosinophils play a central role as effector cells in Type I allergic hypersensitivity disorders. The significant reduction in eosinophil count and serum IgE levels observed in the study group is indicative of effective modulation of allergic inflammation.[xxii] This biochemical improvement correlates well with clinical outcomes, suggesting that the study drug not only provides symptomatic relief but also addresses the underlying immunopathology of recurrent respiratory infections (RRIs).

Importantly, sustained improvement in clinical symptoms and quality of life was observed during the one-month follow-up period after completion of therapy, suggesting a potential disease-modifying effect rather than mere symptomatic control. Additionally, parent-reported outcomes indicated a reduction in school absenteeism, reflecting functional improvement and enhanced daily activity in affected children.

Psychological stress is recognized as an important environmental factor that exacerbates oxidative stress and immune dysregulation in allergic disorders. Ingredients such as *Pippali* and *Guḍūcī*, owing to their anti-stress and antioxidant properties[xxiii], may have contributed to symptom regression by mitigating stress-induced immune dysfunction.

From an Ayurvedic perspective, RRIs and recurrent allergic respiratory disorders can be conceptualized as manifestations of impaired *Vyādhikṣamatva* and dysfunction of *Prāṇavaha Srotas*. *Bal Rasayana*® syrup contains classical Rasayana formulations such as *Balacaturbhadra*[xxiv] and *Triphala*[xxv], which are known for their immunomodulatory, anti-allergic, antioxidant, and anti-inflammatory properties.

The observed reduction in serum IgE and eosinophil counts reflects modulation of Type I hypersensitivity responses, thereby interrupting the vicious cycle of allergen exposure, inflammation, immune dysfunction, and recurrent infection. Improvement in clinical symptoms further corroborates the Ayurvedic rationale of *Rasayana* therapy in Pediatric allergic respiratory disorders, emphasizing its multidimensional role in restoring immune balance and enhancing host resistance.

Thus, recurrent respiratory infections associated with Type I allergy in children can be conceptualized as manifestations of impaired *Vyādhikṣamatva* and dysfunction of *Prāṇavaha Srotas*, wherein *Kapha–Vāta śāmaka* drugs and *Rasayana*-based interventions provide a rational and holistic therapeutic approach.

Conclusion-

Bal Rasayana® syrup demonstrated significant clinical efficacy in reducing symptom severity and modulating IgE-mediated immune responses in children with recurrent respiratory infections associated with Type I allergy. The findings support the role of *Rasayana*-based Ayurvedic interventions as a rational integrative approach for the long-term management of Pediatric allergic respiratory disorders. Further well-designed studies with larger sample sizes, longer follow-up durations, and detailed mechanistic evaluations are warranted to substantiate these findings.

Conflict of Interest- None declared.

Figures

Figure 1. CONSORT flow diagram of participant enrolment, allocation, follow-up, and analysis.

This figure illustrates the screening of 32 eligible Pediatric participants, allocation to the intervention group, completion of treatment, and follow-up analysis.

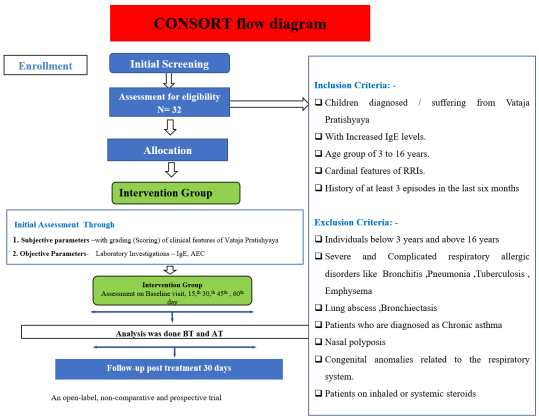
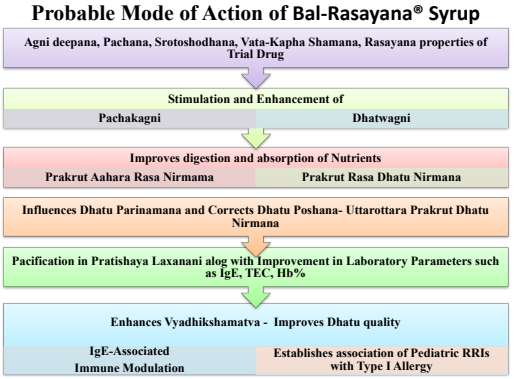


Figure 2. Mode of action of Trial Drug



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