



### Research Article

## Effect of *Bhaskarlavan Churna* in Patients with Allergic Rhinitis with a history of Habitual Suppression of Urges of Elimination: An Exploratory Single-Arm Open labelled Trial

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### Abstract

Context: Allergic rhinitis (AR) represents one of the most prevalent inflammatory disorders in clinical practice, frequently correlated with *Vataj Pratishyay* (VP) in *Ayurvedic* medicine. Aim: This single-arm interventional study investigated the therapeutic effect of *Bhaskarlavan Churna* (BLC) in the management of AR precipitated by suppression of natural physiological urges of flatulence, micturition and defecation. Settings and Design: Sixty subjects (aged 20-50 years) with established AR diagnoses and documented history of habitual suppression of micturition, defecation, and flatus evacuation for a minimum duration of six months were enrolled. Material and Methods: Therapeutic intervention consisted of oral administration of BLC for seven consecutive days. Clinical assessment utilized the Total Nasal Symptom Score (TNSS) to quantify rhinorrhea, nasal obstruction, and paroxysmal sneezing. Statistical Analysis: Statistical evaluation employed Wilcoxon signed rank testing and percentage improvement calculations. Results: Pre-intervention mean symptom scores for rhinorrhea, nasal obstruction, and paroxysmal sneezing were 2.12, 0.40, and 1.05, respectively, with post-intervention values demonstrating significant reduction to 0.65, 0.08, and 0.25 ( $p < 0.05$ ). Among participants with histories of flatulence suppression, the highest prevalence of symptomatology was observed for rhinorrhea (91.23%), followed by paroxysmal sneezing (73.68%), and nasal obstruction (21.05%). Following BLC administration, these symptoms demonstrated marked amelioration of 69.29%, 76.19%, and 79.17%, respectively. Conclusion: The findings suggest an association between voluntary suppression of natural physiological urges and the pathogenesis of AR. Furthermore, BLC demonstrates promising therapeutic potential for symptomatic management of AR associated with such suppressions.

**Keywords:** Allergic-Rhinitis, Urge-suppression, TNSS, *Bhaskarlavan churna*

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## Introduction

Allergic Rhinitis (AR), one of the most prevalent inflammatory conditions, affects approximately 18.1% of the global population. (1) It frequently remains undiagnosed despite its impact on quality of life. (2) The clinical presentation of AR includes paroxysmal sneezing, nasal pruritus, congestion, and rhinorrhea. (3)

According to *Ayurveda*, AR demonstrates concordance with *Vataj Pratishyay* (VP). (4) Its development involves gastrointestinal

dysfunction secondary to chronic suppression of physiological elimination reflexes, specifically flatulence (*Adhovata*), micturition (*Mutra*), and defecation (*Purisha*). (5) This is traditionally believed to adversely affect the balance of gastric microflora. (6) Research has demonstrated evidence linking AR pathogenesis to gut microbial dysbiosis. (7)

Although allergic rhinitis is commonly managed with conventional symptomatic therapies, the contribution of lifestyle-related factors such as Vegavidharana (suppression of natural urges) remains poorly explored in clinical research. Ayurvedic formulations like *Bhaskarlavan Churna* are traditionally indicated for correcting digestive dysfunction and Vata imbalance associated with such practices. (8) However, no clinical studies have specifically evaluated the effect of *Bhaskarlavan Churna* in allergic rhinitis patients with a history of habitual urge suppression. Therefore, this pilot study was undertaken to

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generate preliminary evidence on its therapeutic role in this subset of patients.

### Aim and Objectives

The primary aim of the single-arm interventional study was to comprehensively evaluate the therapeutic potential of BLC in managing AR, particularly in cases where the condition may be precipitated by the habitual suppression of natural physiological elimination reflexes. The study established two distinct objectives to achieve this aim: firstly, to assess the therapeutic effect of BLC for managing AR; and secondly, to investigate and analyze potential association between the manifestation of AR and the chronic behavioral suppression of fundamental physiological elimination processes.

## Methodology

### Study Design and Setting

This prospective, single-arm open labelled interventional clinical study was conducted at the ENT outpatient department of Dr. D. Y. Patil Ayurveda Hospital and Research Centre, Pimpri, Pune-18, India. The study protocol received approval from the Institutional Ethics Committee (IEC) with reference number IEC/553/2021 dated 14/06/21 and was registered with the Clinical Trials Registry of India (CTRI) under registration number CTRI/2022/02/040441 on 21<sup>st</sup> February 2022. Written informed consent was obtained from all participants following comprehensive disclosure of the research objectives, intervention protocols, and potential therapeutic effects.

### Participant Selection and Sample Size

A purposive sampling methodology was utilized to enroll 60 participants within the age range of 20-50 years with confirmed allergic rhinitis diagnosis from the outpatient department. Sample size calculation was based on an estimated disease prevalence of 18.1%, with a 95% confidence interval and acceptable margin of error of 10%.

This clinical investigation was conducted in strict compliance with Schedule Y of the Indian Drugs and Cosmetics Act (1945, amended 2005), ICMR ethical guidelines for human biomedical research, and Good Clinical Practice standards per the Declaration of Helsinki.

### Inclusion Criteria

Participants diagnosed with AR were enrolled if they presented with a documented history of habitual suppression of physiological elimination reflexes including micturition, defecation, and flatus evacuation for a minimum duration of six months concurrent with the rhinitis symptomatology.

### Exclusion Criteria

Participants were excluded if they presented with severe nasal obstruction, extensive intranasal adhesions, deviated nasal septum, nasal polyposis, or other structural nasal abnormalities that could confound symptom assessment or therapeutic response evaluation.

### Preparation of medicine

The powdered pharmaceutical ingredients were procured and subsequently authenticated at the institute's FDA-approved and GMP-certified pharmacy facility. All constituent powdered materials were proportioned according to specifications outlined in the Ayurvedic Formulary of India (AFI) and subjected to

thorough homogenization to achieve the final pharmaceutical preparation.(9)

### Intervention Protocol

All enrolled participants received BLC administered orally at a standardized dosage of 1.5 grams twice before meals daily with lukewarm water for seven consecutive days. A 7-day intervention was chosen to evaluate early symptomatic response.

### Assessment Parameters and Data Collection

This study employed the original 3-item TNSS validated by Tamasauskiene et al. (10), comprising nasal obstruction (*Ghranoprodh*), combined itching/sneezing (*Kshavathu*), and rhinorrhea (*Jalavatnasasrav*), each graded 0–3, yielding a total score range of 0–9. (See Table 1)

**Table 1: Total Nasal Symptom Score**

| Grade | Severity                                                            |
|-------|---------------------------------------------------------------------|
| 0     | No Symptoms                                                         |
| 1     | Mild (Symptoms clearly present but tolerated).                      |
| 2     | Moderate (Symptoms bothersome but Tolerable)                        |
| 3     | Severe (Symptoms difficult to tolerate -interfere with activities). |

### Follow-up Schedule

Systematic clinical evaluations were conducted at baseline (day 0), interim assessment (day 4), and final evaluation (day 8) to monitor therapeutic response and symptom progression. Interim Day 4 assessment was used only for monitoring of compliance and the symptom scores were formally analyzed at baseline and final evaluation. No adverse events or safety concerns were reported throughout the duration of the clinical trial.

### Data Analysis

Data was analysed using SPSS Version 20.00 software and the parameters were analysed with the Wilcoxon signed test.

## Results

A total of 78 patients were screened, and 60 patients were enrolled in the trial. All the participants completed the trial and thereby the data of total 60 patients were processed for statistical analysis.

### Participant Demographics and Urge Suppression Patterns (Table 2)

**Table 2: Distribution of patients based on Demographics and Suppressed urges**

| Sr. No. | Distribution of 60 participants based on baseline data | Category    | Frequency | Percentage |
|---------|--------------------------------------------------------|-------------|-----------|------------|
| 1       | Age                                                    | 21-30 years | 44        | 73.33%     |
|         |                                                        | 31-40 years | 7         | 11.67%     |
|         |                                                        | 41-50 years | 9         | 15.00%     |
| 2       | Religion                                               | Hindu       | 59        | 98.33%     |
|         |                                                        | Christian   | 1         | 1.67%      |
| 3       | Gender                                                 | Male        | 27        | 45.00%     |
|         |                                                        | Female      | 33        | 55.00%     |
| 4       | Occupation                                             | Business    | 4         | 6.67%      |
|         |                                                        | Doctor      | 6         | 10.00%     |
|         |                                                        | Homemaker   | 4         | 6.67%      |
|         |                                                        | Private Job | 18        | 30.00%     |
|         |                                                        | Student     | 28        | 46.67%     |

|   |                  |                                |    |        |
|---|------------------|--------------------------------|----|--------|
| 5 | Suppressed Urges | Defecation ( <i>purish</i> )   | 25 | 41.67% |
|   |                  | Micturition ( <i>mutra</i> )   | 27 | 45.00% |
|   |                  | Flatulence ( <i>adhovata</i> ) | 57 | 95.00% |

### Association Between Urge Suppression and Allergic Rhinitis Symptomatology

The association between specific types of urge suppression and allergic rhinitis manifestations demonstrated significant patterns, as presented in Table 3.

**Table 3: Type of Suppressed urges and its association with symptoms of AR**

| Suppressed Urges       | Sneezing ( <i>Kshavathu</i> ) |            | Rhinorrhea ( <i>Jalavatnasasrav</i> ) |            | Nasal Obstruction ( <i>Ghranoprodh</i> ) |            |
|------------------------|-------------------------------|------------|---------------------------------------|------------|------------------------------------------|------------|
|                        | No. of Patients               | Percentage | No. of Patients                       | Percentage | No. of Patients                          | Percentage |
| <b>Purish (n=25)</b>   | 16                            | 64.00%     | 23                                    | 92.00%     | 4                                        | 16.00%     |
| <b>Mutra (n=27)</b>    | 22                            | 81.48%     | 27                                    | 100.00%    | 4                                        | 14.81%     |
| <b>Adhovata (n=57)</b> | 42                            | 73.68%     | 52                                    | 91.23%     | 12                                       | 21.05%     |

### Therapeutic Effect of *Bhaskarlavan Churna*

The intervention with BLC demonstrated statistically significant improvement across all evaluated parameters as shown in Table 4 and Figure 1.

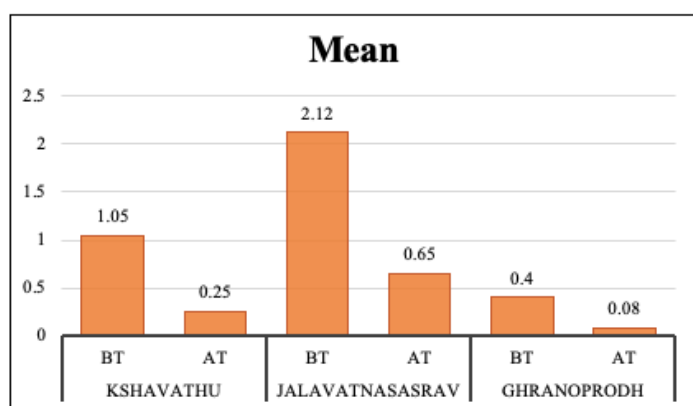
**Table 4: Effect of BLC on the chief complaints (nasal symptoms) of AR.**

| Symptoms                                 |    | Mean | Median | SD   | SE   | Wilcoxon W          | P Value   | % Effect | Result |
|------------------------------------------|----|------|--------|------|------|---------------------|-----------|----------|--------|
| Sneezing ( <i>Kshavathu</i> )            | BT | 1.05 | 1.00   | 0.81 | 0.10 | -5.929 <sup>b</sup> | 0.0000003 | 76.19    | Sig    |
|                                          | AT | 0.25 | 0.00   | 0.44 | 0.06 |                     |           |          |        |
| Rhinorrhea ( <i>Jalavatnasasrav</i> )    | BT | 2.12 | 2.00   | 0.99 | 0.13 | -6.483 <sup>b</sup> | 0.0000001 | 69.29    | Sig    |
|                                          | AT | 0.65 | 0.00   | 0.76 | 0.10 |                     |           |          |        |
| Nasal Obstruction ( <i>Ghranoprodh</i> ) | BT | 0.40 | 0.00   | 0.81 | 0.10 | -3.153 <sup>b</sup> | 0.0016162 | 79.17    | Sig    |
|                                          | AT | 0.08 | 0.00   | 0.28 | 0.04 |                     |           |          |        |

(BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard error).

Statistical analysis using the Wilcoxon signed-rank test confirmed significant therapeutic effect ( $p < 0.05$ ) for all assessed parameters.

**Figure 1: Effect of Treatment on AR Chief Complaints (Nasal Symptoms)**



### Overall Treatment Response Assessment

Based on the treatment outcomes assessed based on the TNSS score, 40% (24 patients) experienced marked improvement in their AR symptoms, while an equal proportion of 40% (24 patients) showed moderate improvement. Additionally, 20% (12 patients) demonstrated mild improvement in their condition. Notably, all patients in the study showed some degree of positive

response to the treatment, with no cases reporting lack of improvement or deterioration.

### Discussion

AR represents a complex inflammatory disorder that significantly impacts quality of life, with conventional treatment approaches primarily focusing on symptomatic management through antihistamines, corticosteroids, and immunotherapy.(11) While these interventions address the immediate inflammatory cascade, they often fail to target the underlying etiological factors that predispose individuals to develop AR. The present study investigates the previously unexplored connection between chronic suppression of natural physiological urges and the development of AR, establishing a novel therapeutic pathway through gastrointestinal restoration.

Literature documents the immunological mechanisms underlying AR, including IgE-mediated hypersensitivity responses.(1) However, a gap exists in understanding why certain individuals develop heightened susceptibility to these allergic responses while others remain unaffected despite similar environmental exposures. The findings demonstrate that 95% of AR patients exhibited chronic suppression of flatulence urges, while 45% and 41.67% suppressed micturition and defecation urges, respectively, suggesting a strong etiological correlation that can be further explored.

### The Gut-Airway Axis

The *Ayurvedic* concept of *Vegavidharan* (urge suppression) provides a framework for understanding this phenomenon.

According to traditional texts, voluntary suppression of natural elimination reflexes disrupts the normal functioning of *Apana Vata*, the physiological force governing downward elimination. (12) This disruption creates a pathological reversal of this force, affecting the upper respiratory tract and manifesting as *Pratishyay* (rhinitis).

Recent advances in microbiome research have revealed the existence of a gut-nasal axis, supporting the *Ayurvedic* understanding.

Prolonged retention of flatus, faeces, and urine is considered to cause intestinal dysbiosis. is associated with an increased risk of AR via gut-airway axis.(13)

The suppression of elimination prevents the natural detoxification. Accumulated metabolic waste products create a state of chronic low-grade inflammation that primes the immune system for hyperreactive responses to environmental allergens.(14)

Chronic urge suppression creates persistent stress on the autonomic nervous system, leading to sympathetic dominance and compromised parasympathetic function.(15) This imbalance affects immune regulation and increases susceptibility to allergic inflammatory responses.(16)

### **Therapeutic Rationale: Addressing Root Cause Through Digestive Restoration**

The significant therapeutic effect observed with BLC validates that addressing digestive dysfunction can resolve upper respiratory symptoms.

The results demonstrate improvement rates: 79.17% for nasal obstruction, 76.19% for sneezing, and 69.29% for rhinorrhea. These outcomes are significant given that patients with histories of flatulence suppression showed the highest symptom prevalence yet responded to treatment. This correlation strongly supports the hypothesis of correcting digestive dysfunction through urge management can effectively treat AR.

### **Mechanistic Analysis of Bhaskarlavan Churna's Therapeutic Action**

The multi-targeted therapeutic approach of BLC addresses the complex pathophysiology of urge suppression-induced allergic rhinitis.

The primary action involves correcting the pathological upward movement of *Apana Vata* through *Anulomana* (restoration of normal downward flow). The four *Lavanas* (salts) in the formulation *Saindhava*, *Vida*, *Sauvarchala*, and *Samudra* are believed to play a crucial role in this process.(17) They also exhibit mucolytic action explaining the superior response observed in nasal obstruction.(18)

The predominant *Deepana* (appetizer) and *Pachana* (digestive) properties of ingredients like *Pippali* (*Piper longum*, Fr.), *Shunthi* (*Zingiber officinale*, Rz.) and *Marich* (*Piper nigrum*, Fr.) restore optimal digestive function. These present a greater diversity of glycan substrates with commensurately larger effects on gut microbiota.(19)

The antimicrobial and prebiotic properties of *Amlavetasa* (*Garcinia pedunculata*, Fr.)(20), *Dhanyaka* (*Coriandrum sativum*, Fr.)(21) and *Dadima* (*Punica granatum*, Dr. Sd.)(22) are hypothesized to restore healthy gut microflora balance.

Constituents like *Pippali mula* (*Piper longum*, St.)(23), *KrishnaJeerak* (*Carum carvi*, Fr.)(24), *Twak* (*Cinnamomum*

*zeylanicum*, St. Bk.)(25), *Twakpatra* (*Cinnamomum tamala*, Lf.)(25), *Talispatra* (*Abies webbiana*, Lf.)(26), *Nagkeshar* (*Mesua ferrea*, Smn.)(27), *Jeerak* (*Cuminum cyminum*, Fr.)(24) and *Ela* (*Elettaria cardamomum*, Fr.)(28) exhibit anti-inflammatory and antioxidant properties that may have address both local nasal inflammation and systemic inflammatory burden.

The standardized dosage of 1.5 grams twice daily was selected based on classical texts which recommend this quantity for optimal *Deepana* (appetizer) and *Pachana* (digestive) effects without causing digestive irritation. Pre-meal administration ensures maximum bioavailability before food intake.

### **Limitations and Scope of Further Research**

This exploratory single-arm open-label trial lacked a control group; hence placebo effects and natural symptom variability cannot be excluded. The intervention period was limited to seven days, so long-term effect and recurrence could not be assessed. Outcomes were mainly based on subjective TNSS scoring without objective biomarkers, and urge suppression history was self-reported, which may introduce recall bias. Future research should include larger multicentric randomized controlled trials with longer follow-up, objective outcome measures (e.g., inflammatory markers, IgE, nasal cytology), and comparative evaluation against standard therapies to confirm effect and explore the proposed gut-airway mechanism.

### **Conclusion**

This study found a strong link between chronic suppression of natural urges of elimination (flatulence, urination, and defecation) and the development of AR, pointing to a previously overlooked lifestyle factor behind the condition. This association led to testing *Bhaskarlavan Churna*, which significantly reduced key symptoms of AR (sneezing, rhinorrhea, and nasal obstruction) within just seven days. Together, these findings support a promising, low-cost therapeutic approach rooted in digestive correction, while opening the door to larger controlled trials that can validate this novel gut-airway connection in the management of allergic rhinitis.

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### **Data Availability Statement**

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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**Conflicts of Interests:** None

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