RESEARCH PAPER

A Randomized, Open-Labeled, Controlled Clinical Study of Shunthyadi Ghrita Nasya and Haridra Khanda in Vataja Pratishyaya with Special Reference to Allergic Rhinitis

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ABSTRACT

Allergic rhinitis is a chronic inflammatory disorder of the nasal mucosa that presents a significant global health burden. In Ayurvedic nosology, this condition correlates with Vataja Pratishyaya, a Nasagata Vyadhi characterized by the vitiation of Vata and Kapha Doshas lodging in the nasal passages. This prospective, randomized, open-labeled, controlled clinical study evaluated the therapeutic efficacy of Shunthyadi Ghrita Nasya combined with oral Haridra Khanda (Trial Group, n=35) compared to Shadbindu Ghrita Nasya with the same internal medicine (Control Group, n=35). A total of 70 patients were enrolled and administered Nasya therapy once daily for seven days, with follow-up assessments conducted on days 0, 7, and 15. Outcome measures included subjective clinical symptoms (nasal obstruction, rhinorrhea, and sneezing) and objective variables (turbinate hypertrophy and Absolute Eosinophil Count [AEC]). While both groups demonstrated statistically significant within-group improvements across most parameters, intergroup analysis revealed that the trial group achieved significantly superior resolution of nasal obstruction ($p = 0.013$), rhinorrhea ($p < 0.0001$), and sneezing ($p = 0.006$) by the final follow-up. Notably, 33 out of 35 patients (94.3%) in the trial group achieved complete improvement, compared to only 13 out of 35 (37.1%) in the control group. Both interventions were comparable in their effect on reducing turbinate hypertrophy and AEC. The study concludes that the combination of Shunthyadi Ghrita Nasya and Haridra Khanda is a statistically superior and clinically effective regimen for managing the core symptoms of Vataja Pratishyaya, offering a potent holistic alternative for the long-term management of allergic rhinitis.

Keywords: Vataja Pratishyaya, Allergic Rhinitis, Shunthyadi Ghrita, Haridra Khanda, Nasya Karma, Absolute Eosinophil Count, Controlled Clinical Study.

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1. Introduction

Allergic rhinitis is a chronic inflammatory disorder of the nasal mucosa induced by an IgE-mediated immunological response following allergen exposure [1]. As one of the most prevalent upper respiratory conditions, it affects approximately 10% to 30% of the global population, imposing a significant symptomatic, functional, and socioeconomic burden [2], [3]. The cardinal manifestations—paroxysmal sneezing (*Kshavathu*), watery rhinorrhea (*Nasagata Tanusrava*), nasal obstruction (*Nasaavarodha*), and pruritus—frequently interfere with sleep quality, cognitive performance, and overall psychological well-being [1], [2]. If left inadequately managed, the condition may progress toward chronic comorbidities, including recurrent sinusitis, Eustachian tube dysfunction, and lower airway hyperreactivity such as bronchial asthma [2].

While conventional pharmacotherapy, including second-generation antihistamines and nasal corticosteroids, provides effective symptomatic relief, these interventions often necessitate long-term administration and may not address the underlying susceptibility to recurrence [3], [4]. This limitation has sustained clinical interest in holistic medical systems like Ayurveda, which emphasize a dual approach of

localized treatment and systemic immunomodulation to achieve sustainable remission [5].

In Ayurvedic nosology, the clinical features of AR closely correspond to *Vataja Pratishyaya*, a type of *Nasagata Vyadhi* (nasal disease) [1]. The pathophysiology is characterized by the vitiation of *Vata* and *Kapha Doshas*, which lodge in the nasal passages, leading to obstructive and secretory symptoms [1]. This process is often underpinned by *Agni-Mandya* (impaired digestive fire) and the subsequent formation of *Ama* (metabolic toxins), which circulate through the *Srotas* (channels) and heighten the host's hypersensitivity to aeroallergens [3].

Nasya Karma, the intranasal administration of medicated oils or fats, is recognized as the premier *Shodhana* (purification) method for all disorders of the *Uttamanga* (head and neck) [1]. The nasal route provides direct mucosal contact and a plausible pathway for modulating local inflammation and hyperreactivity [1]. *Shunthyadi* preparations are traditionally indicated for managing chronic sneezing and nasal irritation, particularly when administered in a lipid base like *Ghrita* (clarified butter), which facilitates superior penetration across the blood-air barrier [1]. Concurrently, *Haridra Khanda* serves as a potent systemic intervention, utilized for its anti-allergic and immunomodulatory properties that address the underlying metabolic imbalances by improving *Agni* and promoting *Vata Anulomana* [3].

The present study evaluates the combined efficacy of *Shunthyadi Ghrita Nasya* and *Haridra Khanda* in managing the symptom triad of *Vataja Pratishyaya*. Utilizing a randomized, open-labeled, controlled design, the study compares this intervention against a control group receiving *Shadbindu Ghrita Nasya* alongside the same internal medicine [2]. By integrating localized *Snehana* (oleation) with systemic immune correction, this research seeks to determine if a seven-day protocol of eight drops of *Nasya* and twice-daily *Haridra Khanda* (5g) can provide statistically superior relief and reduce the frequency of allergic episodes compared to standard Ayurvedic protocols [1], [3], [6]. This investigation aims to establish a robust clinical evidence base for the integration of these traditional formulations into the contemporary management paradigm for allergic rhinitis.

2. Aim, Objectives, and Hypotheses

This section defines the primary research goal, specific clinical targets, and the statistical hypotheses used to evaluate the efficacy of the trial intervention.

2.1 Study Aim

The primary aim of this clinical investigation was to evaluate the therapeutic efficacy of a combined Ayurvedic protocol—*Shunthyadi Ghrita Nasya* and *Haridra Khanda*—in the management of *Vataja Pratishyaya*, particularly as it relates to the symptomatic presentation of Allergic Rhinitis [1].

2.2 Clinical Objectives

To achieve the primary aim, the study was structured around the following objectives:

- **Primary Objective:** To evaluate the clinical response following a seven-day treatment course consisting of *Shunthyadi Ghrita Nasya* (administered at a dose of 8 drops in each nostril, once daily) and oral *Haridra Khanda* (5 g, twice daily).
- **Secondary Objective 1:** To establish a diagnostic correlation between the Ayurvedic clinical entity of *Vataja Pratishyaya* and contemporary Allergic Rhinitis, based on shared clinical symptoms such as *Kshavathu* (paroxysmal sneezing), *Nasaavarodha* (nasal obstruction), and *Nasagata Tanusrava* (watery discharge) [1].
- **Secondary Objective 2:** To conduct a comparative analysis of therapeutic efficacy between the trial regimen (*Shunthyadi Ghrita Nasya* + *Haridra Khanda*) and a control regimen (*Shadbindu Ghrita Nasya* + *Haridra Khanda*).

2.3 Research Hypotheses

The study tested the clinical outcomes against the following statistical hypotheses:

- **Null Hypothesis (**H_0**):** There is no significant therapeutic role or clinical improvement attributable to the combined use of *Shunthyadi Ghrita Nasya* and *Haridra Khanda* in the management of *Vataja Pratishyaya* or Allergic Rhinitis.
- **Alternate Hypothesis (**H_1**):** The administration of *Shunthyadi Ghrita Nasya* in conjunction with *Haridra Khanda* provides a statistically significant therapeutic role in the clinical management and symptomatic relief of *Vataja Pratishyaya* and Allergic Rhinitis.

3. Review of Literature and Conceptual Framework

The conceptual framework of this study is grounded in an integrated review of Ayurvedic and contemporary medical literature, establishing a clinical equivalence between *Vataja Pratishyaya* and Allergic Rhinitis. This integration is necessitated by the high global prevalence of AR, which affects 10% to 30% of the

population and necessitates a multidimensional therapeutic approach [2], [3].

3.1 Ayurvedic Perspective on Nasal Physiology and Pathogenesis

In Ayurvedic literature, the nose (*Nasa*) is described as the seat of the *Ghranendriya* (olfactory sense) and is considered the gateway to the head (*Nasa Hi Shiraso Dwaram*) [1]. Normal nasal function is governed by the equilibrium of *Prana Vayu*, which regulates respiratory movement, and *Tarpaka Kapha*, which provides lubrication and protection to the nasal mucosa [1].

Vataja Pratishyaya is classified as a *Nasagata Roga* (nasal disease) primarily driven by the vitiation of *Vata* and *Kapha Doshas* [1]. Classical texts identify etiological factors such as exposure to *Raja* (dust), *Vata* (wind), *Hima* (cold/snow), and *Dhooma* (smoke), alongside lifestyle irregularities like the suppression of natural urges (*Vega-dharana*) [1], [3]. These factors resonate with modern environmental triggers of allergic inflammation. The resulting pathology involves the accumulation of *Ama* (metabolic toxins) due to *Agni-Mandya* (impaired digestion), leading to systemic hypersensitivity and local manifestations of *Kshavathu* (paroxysmal sneezing), *Nasaavarodha* (nasal obstruction), and *Nasagata Tanusrava* (watery discharge) [1], [3].

3.2 Contemporary Immunopathogenesis of Allergic Rhinitis

Modern medical discourse defines Allergic Rhinitis as a symptomatic disorder of the nose induced by IgE-mediated inflammation of the nasal membranes following allergen exposure [1], [2]. The immunopathogenesis involves a complex interplay of inflammatory cells, including mast cells and eosinophils [4], [7]. Upon exposure to aeroallergens, such as house dust mites or pollen, IgE-mediated mast cell degranulation releases mediators like histamine and leukotrienes [4]. This leads to vasodilation, mucosal edema, and glandular hypersecretion, characterizing the acute phase response [4]. The late-phase response is marked by eosinophilic infiltration, which sustains chronic inflammation and leads to turbinate hypertrophy and persistent nasal congestion [2], [7].

3.3 Rationale for Combined Ayurvedic Intervention

The therapeutic rationale for this trial utilizes a dual-action approach targeting both localized and systemic components of the disease. *Nasya Karma*—the intranasal administration of medicated fats—is the premier therapy for diseases affecting the *Urdhvajatrugata* (head and neck) region [1]. *Shunthyadi* preparations are traditionally indicated for managing *Kshavathu* (continuous sneezing) and chronic nasal discharge [1]. The use of *Ghrita* (clarified butter) as a vehicle facilitates superior mucosal penetration and provides essential *Snehana* (oleation) to counter the dryness and irritation caused by vitiated *Vata* [1].

Systemically, *Haridra Khanda* is employed for its potent anti-allergic and immunomodulatory properties [3]. As a turmeric-based formulation, it addresses the underlying metabolic disturbances by improving *Agni* and promoting *Vata Anulomana* (normal movement of Vata), thereby preventing the recurrence of allergic episodes [2], [3]. This combined protocol aims to provide immediate symptomatic relief through *Nasya* while achieving long-term immune stabilization through oral intervention [2], [5].

4. Materials and Methods

This clinical investigation utilized a prospective, randomized, open-labeled, controlled clinical design to evaluate the therapeutic role of *Shunthyadi Ghrita Nasya* in the management of *Vataja Pratishyaya*. The study was conducted at a specialized Ayurvedic teaching hospital, involving both Outpatient and Inpatient departments. The methodological framework was designed to compare the efficacy of a specific trial regimen against a standard control intervention, both of which were integrated with systemic oral treatment to address the underlying immunological components of allergic rhinitis [2], [5].

4.1 Sample Size and Randomization

A total sample size of 70 patients was selected for the study, with 35 participants allocated to each treatment arm. This sample size was determined based on clinical feasibility and the logistical requirements of a specialized seven-day *Nasya* protocol [2]. To ensure baseline comparability and minimize selection bias, participants were allocated to either the trial group or the control group using a simple randomization lottery method [5]. Informed consent was obtained from all participants prior to their enrollment, following the ethical standards for clinical research [2].

4.2 Selection Criteria

Participants were screened based on a clinical diagnosis of *Vataja Pratishyaya*, which exhibits a high degree of symptomatic correlation with perennial allergic rhinitis [1], [8].

- **Inclusion Criteria:** The study recruited patients between the ages of 16 and 40 years, representing the demographic most frequently affected by chronic nasal hypersensitivity [1]. Eligibility required the presence of the classic symptom triad: recurrent paroxysmal

sneezing (*Kshavathu*), watery nasal discharge (*Tanustrava*), and nasal obstruction (*Aanadhapihita*) [1].

- **Exclusion Criteria:** Individuals with significant anatomical nasal obstructions, such as a severely Deviated Nasal Septum or nasal polyps, were excluded to ensure that symptomatic changes were attributable to the medicinal intervention [2]. Furthermore, the study excluded cases of infective rhinitis, congenital nasal anomalies, and patients with uncontrolled systemic diseases or those already undergoing immunotherapy [2], [3].
- **Withdrawal Criteria:** Participants were withdrawn if they developed serious adverse effects, protocol violations, or intercurrent illnesses that could potentially confound the interpretation of the therapeutic outcomes [5].

4.3 Intervention Protocol

The therapeutic regimen involved a dual approach targeting localized nasal inflammation and systemic allergic response:

1. **Trial Group:** Participants received *Shunthyadi Ghrita Nasya* at a dose of 8 drops in each nostril once daily for seven days [1]. The trial medication was prepared according to the classical guidelines of the *Vagbhata Samhita*, utilizing a *Kalka* (paste) of *Shunthi, Kushtha, Draksha, Vidanga,* and *Pippali* in a clarified butter base.
2. **Control Group:** Participants received *Shadbindu Ghrita Nasya* (8 drops per nostril daily for seven days), prepared as per the *Sharangadhara Samhita* [1].
3. **Supportive Therapy:** Both groups were concurrently administered oral *Haridra Khanda* (5 g) twice daily for seven days [3]. This turmeric-based formulation was utilized for its established anti-allergic and immunomodulatory properties, which address the systemic *Dosha* imbalance and improve *Agni* [2], [3].

4.4 Procedural Methodology (*Nasya Karma*)

The administration of *Nasya* followed a standardized three-phase protocol intended to maximize drug absorption and *Dosha* expulsion [1]:

- **Purvakarma:** Pre-procedural management involved local facial massage (*Abhyanga*) followed by mild steam inhalation (*Bashpa Swedana*) to liquefy the *vitiated Kapha* and facilitate mobilization [1].
- **Pradhana Karma:** The medicated *Ghrita* was instilled into each nostril while the patient remained in a supine position with the head slightly tilted, ensuring the medication reached the *Shringataka Marma* [1].
- **Pashchat Karma:** Following the instillation, patients underwent further steam inhalation and warm-water gargling (*Gandusha*) to cleanse the nasal and oral passages of excess secretions [1].

4.5 Evaluation and Statistical Analysis

Clinical assessment was performed at three specific intervals: Day 0 (baseline), Day 7 (completion of treatment), and Day 15 (follow-up) [2]. The study employed three subjective parameters—nasal obstruction, rhinorrhea, and sneezing—evaluated on an ordinal grading scale [1], [3]. Objective assessment included clinical observation of turbinate hypertrophy and laboratory measurement of the Absolute Eosinophil Count to monitor systemic inflammatory load [2], [3].

Statistical significance was set at $p = 0.05$. Baseline homogeneity was analyzed using the Chi-square test [2]. For within-group longitudinal changes, the Wilcoxon signed-rank test was applied, while the Mann-Whitney U test was used for intergroup comparative analysis of ordinal data [2]. Quantitative laboratory findings, specifically the AEC, were analyzed using the Z-test to determine the significance of immunological changes [2], [3].

Table M1. Study intervention schedule

Parameter	Trial Group A	Control Group B
Local therapy	Shunthyadi Ghrita Nasya	Shadbindu Ghrita Nasya
Dose	8 drops in each nostril	8 drops in each nostril
Time	Morning	Morning
Duration	7 days	7 days
Follow-up	0, 7th, 15th day	0, 7th, 15th day
Internal medicine	Haridra Khanda 5 g BD for 7 days	Haridra Khanda 5 g BD for 7 days

5. Results

The original dataset organized results into demographic and clinical domains. Baseline comparability was tested using chi-square statistics and found to be statistically non-significant across all demographic variables, indicating that both groups were homogeneous before treatment. Clinical efficacy was then assessed across repeated follow-ups and by intergroup comparison at relevant intervals[9], [10]. The primary efficacy endpoints included changes in the

subjective parameters of Aanadhapihita, Tanustrava, and Kshavathu, alongside objective assessments of turbinate hypertrophy and absolute eosinophilic count. [11]

5.1 Demographic profile

Table No. 1 - Age wise distribution of patient

Age	Trial n (%)	Control n (%)	Total n (%)	P value
16-28	22 (62.85714)	17 (48.57143)	39 (55.71429)	0.2289
29-40	13 (37.14286)	18 (51.42857)	31 (44.28571)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 2 - Gender wise distribution of patient

Gender	Trial n (%)	Control n (%)	Total n (%)	P value
Male	9 (25.71)	15 (42.85)	24 (34.28)	0.130
Female	26 (74.28)	20 (57.14)	46 (65.71)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 3 - Religion wise distribution of patient

Religion	Trial n (%)	Control n (%)	Total n (%)	P value
Hindu	30 (85.71)	28 (80)	58 (82.85)	0.525
Muslim	5 (14.28)	7 (20)	12 (17.14)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 4 - Occupation wise distribution of patient

Occupation	Trial n (%)	Control n (%)	Total n (%)	P value
Student	16 (45.71)	11 (31.42)	27 (38.57)	0.326
Housewife	12 (34.28)	12 (34.28)	24 (34.28)	
Working	7 (20)	12 (34.28)	19 (27.14)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 5 - Literacy wise distribution of patient

Literacy	Trial n (%)	Control n (%)	Total n (%)	P value
Literate	27 (77.14)	24 (68.57)	51 (72.85)	0.420
Illiterate	8 (22.85)	11 (31.42)	19 (27.14)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 6 - Socioeconomic status wise distribution of patient

Status	Trial n (%)	Control n (%)	Total n (%)	P value
MC	22 (62.85)	20 (57.14)	42 (60)	0.625
P	13 (37.14)	15 (42.85)	28 (40)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 7 - Diet status wise distribution of patient

Diet	Trial n (%)	Control n (%)	Total n (%)	P value
Mix	19 (54.28)	19 (54.28)	38 (54.28)	1.000
Veg	16 (45.71)	16 (45.71)	32 (45.71)	
Total	35 (100)	35 (100)	70 (100)	

Table No. 8 - Prakruti status wise distribution of patient

Prakruti	Trial n (%)	Control n (%)	Total n (%)	P value
VK	12 (34.28)	10 (28.57)	22 (31.42)	0.8929
VP	10 (28.57)	10 (28.57)	20 (28.57)	
PV	2 (5.71)	3 (8.57)	5 (7.14)	
PK	3 (8.57)	6 (17.14)	9 (12.85)	
KV	4 (11.42)	3 (8.57)	7 (10)	
KP	4 (11.42)	3 (8.57)	7 (10)	
Total	35 (100)	35 (100)	70 (100)	

The demographic tables demonstrate that the enrolled population covered both younger and older adults within the defined range, with higher overall representation of females, students, and middle-class participants. None of these variables differed significantly between the two treatment arms, confirming that post-treatment differences are unlikely to be attributable to baseline imbalance.

5.2 Follow-up mean grades

Table No. 9 - showing nasal obstruction mean grade follow up

Group	0th	7th	15th
Trial	1.428571	0.771429	0.114286
Control	1.714286	0.971429	0.371429

Table No. 10 - showing rhinorrhea mean grade follow up

Group	0th	7th	15th
Trial	2.057143	1.2	0.057143
Control	2.228571	1.257143	0.828571

Table No. 11 - showing sneezing mean grade follow up

Group	0th	7th	15th
Trial	2.485714	1.285714	0.114286
Control	2.228571	1.285714	0.4

Table No. 12 - showing turbinate hypertrophy mean grade follow up

Group	0th	7th	15th
Trial	0.914286	0.771429	0.285714
Control	0.828571	0.771429	0.4

Table No. 13 - showing absolute eosinophile count mean grade follow up

Group	BT	AT
Trial	409.2286	234
Control	483.4286	271.5714286

Across all follow-up tables, both groups show downward movement in symptom mean grades, but the trial group demonstrates a distinctly sharper fall by day 15 for nasal obstruction, rhinorrhoea, and sneezing. Reduction in turbinate hypertrophy and absolute

eosinophilic count is present in both groups, with relatively closer values between groups.

5.3 Within-group statistical analysis

Table No. 14 - Nasal obstruction: 0th to 7th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	1.4286	2	-253	<0.0001
Trial Group	7th day	35	0.7714	1		
Control Group	0th day	35	1.714	2	-325	<0.0001
Control Group	7th day	35	0.971	1		

Table No. 15 - Nasal obstruction: 7th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	7th day	35	0.7714	1	-231	<0.0001
Trial Group	15th day	35	0.114	0		
Control Group	7th day	35	0.971	1	-210	<0.0001
Control Group	15th day	35	0.371	0		

Table No. 16 - Nasal obstruction: 0th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	1.4286	2	-325	<0.0001
Trial Group	15th day	35	0.114	0		
Control Group	0th day	35	1.714	2	-378	<0.0001
Control Group	15th day	35	0.371	0		

Table No. 17 - Rhinorrhea: 0th to 7th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	2.0571	2	-435	<0.0001
Trial Group	7th day	35	1.2	1		
Control Group	0th day	35	2.2285	2	-595	<0.0001
Control Group	7th day	35	1.2571	1		

Table No. 18 - Rhinorrhea: 7th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	7th day	35	1.2	1	-528	<0.0001
Trial Group	15th day	35	0.0571	0		
Control Group	7th day	35	1.2571	1	-105	0.000314
Control Group	15th day	35	0.8285	1		

Table No. 19 - Rhinorrhea: 0th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	2.0571	2	-561	<0.0001
Trial Group	15th day	35	0.0571	0		
Control Group	0th day	35	2.2285	2	-595	<0.0001
Control Group	15th day	35	0.8285	1		

Table No. 20 - Sneezing: 0th to 7th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	2.486	2	-630	<0.0001
Trial Group	7th day	35	1.286	1		
Control Group	0th day	35	2.23	2	-561	<0.0001
Control Group	7th day	35	1.29	1		

Table No. 21 - Sneezing: 7th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	7th day	35	1.286	1	-595	<0.0001
Trial Group	15th day	35	0.114	0		
Control Group	7th day	35	1.29	1	-351	<0.0001
Control Group	15th day	35	0.4	0		

Table No. 22 - Sneezing: 0th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	2.486	2	-630	<0.0001
Trial Group	15th day	35	0.114	0		
Control Group	0th day	35	2.23	2	-630	<0.0001
Control Group	15th day	35	0.4	0		

Table No. 23 - Turbinate hypertrophy: 0th to 7th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	0.9143	1	-15	0.03
Trial Group	7th day	35	0.7714	1		
Control Group	0th day	35	0.829	1	-3	0.34577

Control Group	7th day	35	0.771	1		

Table No. 24 - Turbinate hypertrophy: 7th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	7th day	35	0.7714	1	-180	0.000106
Trial Group	15th day	35	0.28571	0		
Control Group	7th day	35	0.771	1	-91	0.000363
Control Group	15th day	35	0.4	0		

Table No. 25 - Turbinate hypertrophy: 0th to 15th day

Group	Comparison	N	Mean	Median	W	P
Trial Group	0th day	35	0.9143	1	-253	<0.0001
Trial Group	15th day	35	0.28571	0		
Control Group	0th day	35	0.829	1	-120	0.000123
Control Group	15th day	35	0.4	0		

Table No. 26 - Absolute eosinophil count in trial group

Group	BT/AT	N	Mean	SD	Mean diff	SE mean	Z	P
Group A	BT	35	409.22	269.5669	175.22	47.05	3.72	0.000709
Group A	AT	35	234	167.132				

Table No. 27 - Absolute eosinophil count in control group

Group	BT/AT	N	Mean	SD	Mean diff	SE mean	Z	P
Group B	BT	35	483.4286	357.4806	211.8571	56.21058	3.768991	0.000624
Group B	AT	35	271.5714	220.2455				

Within-group analysis shows robust improvement in both treatment arms. Nasal obstruction, rhinorrhoea, and sneezing improved with highly significant p values in almost every interval. For turbinate hypertrophy, the trial group showed significant improvement as early as 0th to 7th day, whereas the control group did not show significance in that early interval, though both improved significantly by day 15. Absolute eosinophilic count showed statistically significant reduction in both groups by z test.[12] However, these within-group improvements do not inherently indicate superiority of one treatment over the other.

5.4 Between-group statistical analysis

Table No. 28 - Nasal obstruction comparison (0-7th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	0.7714	1150	520	0.232854
Group B	35	0.971	1335		

Table No. 29 - Nasal obstruction comparison (0-15th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	0.114	1085	455	0.013039
Group B	35	0.371	1400		

Table No. 30 - Rhinorrhea comparison (0-7th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	1.2	1221	591	0.760996
Group B	35	1.257	1264		

Table No. 31 - Rhinorrhea comparison (0-15th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	0.0571	819.5	189.5	<0.0001
Group B	35	0.8285	1665.5		

Table No. 32 - Sneezing comparison (0-7th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	1.286	1242.5	612.5	0.994012
Group B	35	1.29	1242.5		

Table No. 33 - Sneezing comparison (0-15th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	0.114	1067.5	437.5	0.006782
Group B	35	0.4	1417.5		

Table No. 34 - Turbinate hypertrophy comparison (0-7th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	0.7714	1242.5	612.5	0.993558
Group B	35	0.771	1242.5		

Table No. 35 - Turbinate hypertrophy comparison (0-15th day)

Group	N	Mean	Sum of Rank	U	P
Group A	35	0.28571	1172.5	542.5	0.32078
Group B	35	0.4	1312.5		

Table No. 36 - Absolute eosinophil count between trial and control group

Group	Mean	Difference in Mean	SD	SEM	Z	P	Sig
Trial	234	37.57	167.132	46.73365	0.803948	0.424229	No
Control	271.5714		220.2455				

Table No. 37 - Overall assessment of treatment in both groups

Improvement Criteria	Definition	Trial Group	Control Group
No Improvement	No improvement in any subjective and objective criteria	0	0
Moderate Improvement	Partial improvement in all or some criteria	2	22
Complete Improvement	Improvement in subjective and objective criteria	33	13

Intergroup comparison indicates that the trial therapy was not significantly different from control during the early 0-7 day interval for nasal obstruction, rhinorrhoea, or sneezing, but demonstrated significant superiority by final follow-up for nasal obstruction ($p = 0.013039$), rhinorrhoea ($p < 0.0001$), and sneezing ($p = 0.006782$).

For turbinate hypertrophy, between-group differences were not significant either at 0-7 days or at 0-15 days, suggesting comparable benefit of both regimens for this parameter. Likewise, final absolute eosinophilic count did not differ significantly between groups ($p = 0.424229$), even though both arms showed meaningful within-group reduction.

The most clinically striking result is the overall assessment: 33 of 35 patients in the trial group achieved complete improvement, compared with 13 of 35 in the control group. Moderate improvement was seen in only 2 patients in the trial group but in 22 patients in the control group. No patient in either group remained unchanged. This distribution strongly favors the Shunthyadi Ghrita Nasya regimen.

6. Discussion

The clinical synthesis of this randomized, open-labeled, controlled study provides an internally consistent picture of the therapeutic landscape for *Vataja Pratishyaya*. The findings indicate that while both Ayurvedic regimens are effective, the protocol centered on *Shunthyadi Ghrita Nasya* yields significantly greater symptomatic relief. This is particularly evident in the resolution of the three core symptoms that define the patient experience in allergic rhinitis: nasal obstruction (*Aanadhapihita*), rhinorrhea (*Tanustrava*), and paroxysmal sneezing (*Kshavathu*) [1], [2]. Because baseline homogeneity was maintained across demographic and *Prakruti* variables, the observed superiority of the trial group gains substantial interpretive strength.

6.1 Demographic and Etiological Interpretations

The demographic observations align with the known epidemiology of allergic rhinitis, which frequently affects young adults and imposes a high functional burden [2], [3]. The study's higher representation of females (65.71%) and students/housewives suggests that environmental triggers, such as household dust exposure and seasonal allergens, play a significant role in triggering *Vataja Pratishyaya* [1]. Within the Ayurvedic framework, the prevalence among students may be linked to stress, irregular routines (*Vishamashana*), and dietary indiscretions, which lead to the vitiation of *Vata* and the formation of *Ama*, thereby heightening systemic sensitivity [3].

6.2 Symptomatic Trajectory and Sustained Relief

The symptomatic trajectory across the 15-day period reveals critical insights into the drug's action. Both treatment arms demonstrated significant improvement by Day 7, indicating that *Nasya* combined with systemic immunomodulation can deliver early relief [2]. However, by Day 15, the trial group demonstrated a sharper and more sustained decline in mean symptom grades, whereas the control group retained higher residual scores for sneezing and discharge [1]. This suggests that the *Shunthyadi Ghrita* formulation may provide a "carry-over" effect, sustaining physiological resolution beyond the active seven-day administration period [1].

6.3 Procedural Logic and Formulation Rationale

The procedural logic of *Nasya Karma* is central to these results. The use of *Purvakarma* (local *Abhyanga* and *Swedana*) facilitates the liquefaction of *vitiated Kapha* and improves local tissue receptivity, ensuring better mucosal contact for the instilled medicine [1]. Furthermore, the choice of *Ghrita* (clarified butter) as a vehicle is significant; it acts through *Sanskaranuvartana*, enhancing the medicinal qualities of the incorporated herbs while providing superior lipid-mediated penetration of the blood-air barrier [1]. *Shunthyadi Ghrita* possesses *Katu, Tikta,* and *Madhura Rasa* and *Ushna Virya*, attributes specifically suited for *Vata-Kapha Shamana* and *Srotoshodhana* [1]. In contrast, *Haridra Khanda*—administered to both groups—provides essential systemic support. Its anti-inflammatory and antiallergic properties address the underlying immunological markers, such as IgE and eosinophil counts [2], [3]. The superior performance of the trial arm therefore likely reflects the incremental local potency of the *Shunthyadi* formulation in modulating the neurovascular and mucosal hyperreactivity of the nasal passages [1], [4].

6.4 Interpretation of Objective Markers and Limitations

The objective data require a nuanced interpretation. While both groups achieved significant reductions in turbinate hypertrophy and Absolute Eosinophil Count,

the intergroup differences were not statistically significant [2], [3]. This suggests that both local *Ghrita* formulations, when paired with systemic *Haridra Khanda*, are capable of reducing mucosal edema and systemic inflammatory load [3], [7]. It may also indicate that tissue-level changes or hematological shifts require a longer treatment duration or larger sample size to manifest discriminative intergroup differences [2].

Despite the high clinical success rate—where 94.28% of the trial group achieved complete improvement—this study has recognized limitations. The open-label design, relatively small sample size (n=70), and short follow-up period limit the generalizability of the findings regarding long-term recurrence [5]. Furthermore, the study did not stratify participants based on specific allergen exposure or seasonal variations [13]. Nevertheless, the results successfully present a reproducible clinical protocol and a coherent Ayurvedic rationale that aligns with modern symptomatic management, justifying the role of *Shunthyadi Ghrita Nasya* as a potent therapeutic option for allergic rhinitis [1], [3], [6].

7. Future Scope

The encouraging clinical results observed in this trial—particularly the 94.28% complete improvement rate in the trial group—provide a foundational evidence base for the use of *Shunthyadi Ghrita Nasya* and *Haridra Khanda* in managing *Vataja Pratishyaya* [1], [3]. However, to facilitate the broader integration of these Ayurvedic interventions into standard respiratory care, several avenues for future research must be pursued.

7.1 Longitudinal Assessment and Recurrence Prevention

The current study utilized a short-term evaluation period with a final follow-up on Day 15 [1]. Given that Allergic Rhinitis is characterized by a tendency toward chronicity and seasonal exacerbations, future investigations should implement extended longitudinal follow-up protocols ranging from six months to one year [5], [8]. Such studies are critical to determine whether the observed symptomatic remission translates into long-term disease modification or "sustained relapse reduction." Evaluating the frequency and severity of recurrences across different seasons would clarify if the treatment provides a lasting reset of the host's hyperreactive immune state or requires periodic maintenance cycles [2].

7.2 Integration of Advanced Immunological Biomarkers

While the reduction in Absolute Eosinophil Count and serum IgE levels provides a quantitative measure of systemic allergic response, future studies should incorporate more granular immunological markers [3], [7]. Investigating the role of inflammatory and tolerogenic myeloid cells could provide deeper insights into how *Nasya* and *Haridra Khanda* modulate the immune outcome following allergen challenge [7]. Additionally, exploring the association between therapeutic interventions and markers such as telomerase reverse transcriptase expression in dendritic cells may reveal the cellular mechanisms underlying the disruption of immune tolerance in AR patients [14].

7.3 Methodological Rigor and Multi-centric Scaling

To enhance the external validity of these findings, future research must transition from single-center studies to large-scale, multi-centric randomized controlled trials [2], [6]. Increasing the sample size significantly beyond the current cohort of 70 patients will provide the statistical power necessary to detect subtle differences in efficacy across diverse demographic and environmental variables [2]. Implementing double-blind protocols where feasible, perhaps through standardized placebos for oral medications, would further minimize observer bias and strengthen the evidence grade [5].

7.4 Quality of Life and Pharmacoeconomic Analysis

Beyond physiological markers, the impact of AR on daily functioning necessitates the use of validated Quality-of-Life instruments, such as the Rhinoconjunctivitis Quality of Life Questionnaire or visual analog scales tailored for specific populations, including athletes [15]. Future studies should also include pharmacoeconomic evaluations to assess the cost-effectiveness of this Ayurvedic regimen compared to chronic conventional pharmacotherapy, such as daily intranasal corticosteroids [13].

7.5 Exploration of Formulation Variables

Finally, comparative studies investigating different media for *Nasya*—such as the efficacy of *Taila* (oil) versus *Ghrita* (clarified butter) or the development of long-acting, sustained-release formulations—could optimize the delivery of active principles to the nasal mucosa [1], [16]. By addressing these research gaps, future studies can move toward a truly integrated management paradigm that combines the symptomatic precision of modern medicine with the holistic stability offered by traditional Ayurvedic interventions [3], [5].

8. Conclusion

The findings of this clinical investigation confirm that *Vataja Pratishyaya* can be accurately correlated with Allergic Rhinitis based on its shared symptomatic profile, etiological triggers, and chronic recurrent

nature. The study demonstrates that both the trial and control regimens—utilizing *Shunthyadi Ghrita* and *Shadbindu Ghrita Nasya* respectively, in conjunction with oral *Haridra Khanda*—produced statistically significant improvements in subjective and objective parameters within each group.

However, the trial regimen demonstrated marked superiority in achieving final symptomatic relief. Specifically, *Shunthyadi Ghrita Nasya* proved significantly more effective in resolving the core symptom triad of nasal obstruction, rhinorrhea, and paroxysmal sneezing. In terms of objective laboratory and physical markers, both groups were found to be comparable in reducing turbinate hypertrophy and Absolute Eosinophil Count, suggesting that both lipid-based nasal interventions paired with systemic turmeric-based therapy contribute effectively to reducing local edema and the overall inflammatory load.

The overall therapeutic assessment strongly favors the trial intervention, with 33 of 35 patients (94.3%) achieving complete improvement, compared to 13 of 35 patients (37.1%) in the control group. Consequently, the null hypothesis is rejected, and the alternate hypothesis is accepted. The combination of *Shunthyadi Ghrita Nasya* and *Haridra Khanda* provides a significant and statistically superior therapeutic role in the management of *Vataja Pratishyaya*. This integrated Ayurvedic protocol offers a potent and effective approach for the clinical management of Allergic Rhinitis, successfully addressing both localized mucosal hyperreactivity and systemic immunological sensitivity.

9. Appendix: Labeled Visuals Retained from the Study Record

The following visual pages retain the original figure, graph, and flow-chart labels as presented in the study material. They are reproduced here to preserve the original visual dataset and numbering sequence associated with the study record.

Study Design Flow Chart

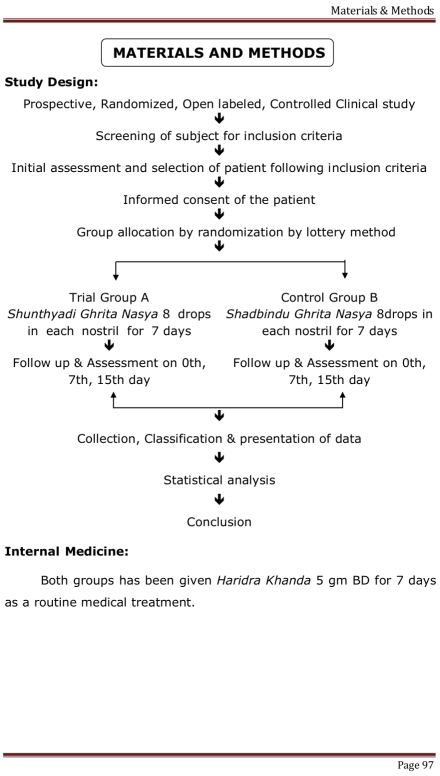


Fig. Lateral wall of right nasal cavity

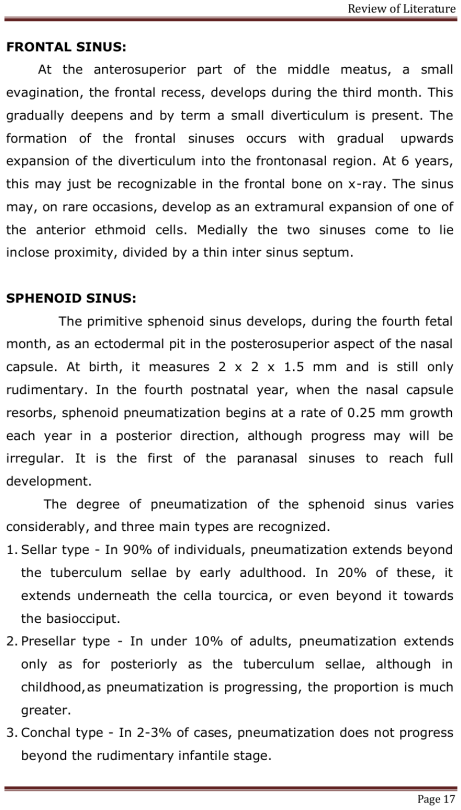


Fig.Shuthyadi Ghrita

ANATOMY:

Paranasal sinuses are air-containing cavities in certain skull bones. They are four on each side. Depending upon their drainage into the nasal cavity, the sinuses have been divided into 2 groups.

Anterior group:

Draining into the middle meatus and their ostia lieanterior to basal lamina & it includes-

1. maxillary sinus,
2. frontal sinus
3. anterior
4. middle ethmoidal sinuses

Posterior group:

Draining into superior meatus & it includes-

1. posterior ethmoidal sinuses
2. sphenoidal sinus draining into the sphenoethmoidal recess

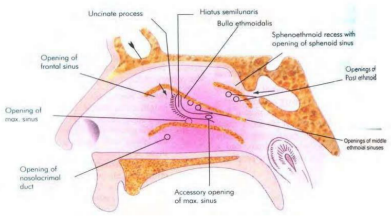


Fig.Diagrammatic representation of lateral wall of nose.

Graph No. 1 - showing Age wise distribution of patient

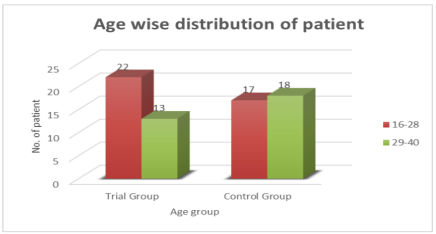
A) Demographic Data:

Table No. 1 – showing Age wise distribution of patient

SR.	Age	Trial Group		Control Group		Total	
		No. of Patient	%	No. of Patient	%	No. of Patient	%
1	16-28	22	62.85714	17	48.57143	39	55.71429
2	29-40	13	37.14286	18	51.42857	31	44.28571
	Total	35	100	35	100	70	100

Chi.Sq = 1.44 P Value = 0.2289 (p>0.05)

Graph No. 1 – showing Age wise distribution of patient



In Trial Group:

Age wise distribution of patients showing that 22(62.85714%) patients were in age group of 16-28 years, 13(37.14286%) patients were in age group of 29-40years.

In control group:

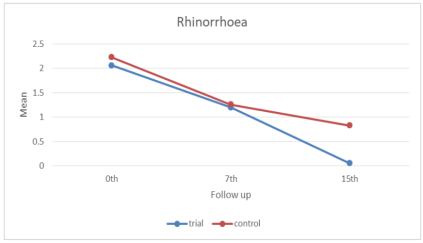
Age wise distribution of patients showing that 17(48.571%) patients were in age group of (16-28 years), 18(51.428%) patients were in age group of 29-40years.

Graph No. 10 - showing rhinorrhea mean grade follow up

Table no 10. showing rhinorrhea mean grade follow up

F/U	0th	7th	15th
Trial	2.057143	1.2	0.057143
Control	2.228571	1.257143	0.828571

Graph no 10 showing rhinorrhea mean grade follow up



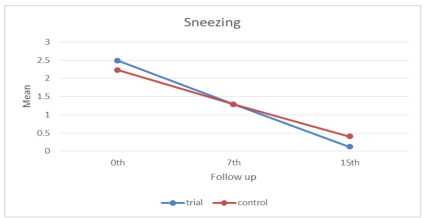
Above line chart shows follow up wise improvement in rhinorrhoea. On 0th day or before treatment the mean of rhinorrhoea was 2.057143 in trial group and 2.228571 in control group. After the treatment i.e on last follow up on 15th day it was seen that it decreases to 0.057143 in trial group and in 0.828571 in control group.

Graph No. 11 - showing sneezing mean grade follow up

Table no 11) showing sneezing mean grade follow up

F/U	0th	7th	15th
Trial	2.485714	1.285714	0.114286
Control	2.228571	1.285714	0.4

Graph no 11 showing sneezing mean grade follow up



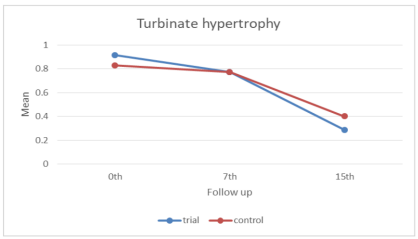
Above line chart shows follow up wise improvement in Sneezing. On 0th day or before treatment the mean of sneezing was 2.485714 in trial group and 2.228571 in control group. After the treatment i.e on last follow up on 15th day it was seen that it decreased to in 0.114286 trial group and 0.4 in control group.

Graph No. 12 - showing turbinate hypertrophy mean grade follow up

Table no 12) showing turbinate hypertrophy mean grade follow up

Group	0th	7th	15th
Trial	0.914286	0.771429	0.285714
Control	0.828571	0.771429	0.4

Graph no 12 showing turbinate hypertrophy mean grade follow up



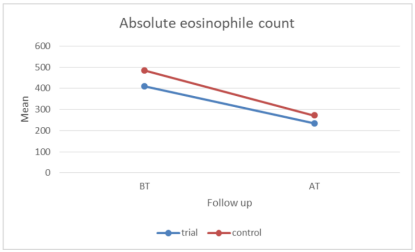
Above line chart shows follow up wise improvement in Turbinate hypertrophy. On 0th day or before treatment the mean of Turbinate hypertrophy was 0.914 in trial group and 0.828 in control group. After the treatment i.e on last follow up on 15th day it was seen that it decreased to 0.285 in trial group and 0.4 in control group.

Graph No. 13 - showing absolute eosinophile count mean grade follow up

Table no 13) showing absolute eosinophile count mean grade follow up

Group	BT	AT
Trial	409.2286	234
Control	483.4286	271.5714286

Graph no 13) showing absolute eosinophile count mean grade follow up



Above line chart shows follow up wise improvement in Absolute eosinophilic count. On 0th day or before treatment the mean of Absolute eosinophilic count was 409.2286 in trial group and 483.4286 in control group. After thetreatment i.e on last follow up on 15th day it was seen that it decreased to 234 in trial group and 271.571 in control group.

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