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Research Article

COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *BRIHAT VASAVLEHA* AND *SHADBINDU TAIL NASYA* IN THE MANAGEMENT OF *PRANAVAHA SROTO DUSHTI* W.S.R. OF RESPIRATORY ALLERGIC DISORDERS IN CHILDREN

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ABSTRACT

Allergy is a rapid immune response classified as Type I hypersensitivity, which occurs when an individual is exposed to an allergen. When an allergic person inhales an allergen, such as pollen, animal dander, mold, or dust, the body releases chemicals that trigger an allergic response and cause various allergy symptoms. *Nasya Karma* is an important *Shodhana* (purificatory) therapy, that helps remove vitiated *Doshas* from the *Urdhvanga* (organs situated above the clavicle), thereby supporting the normal functioning of the brain and other bodily systems. The study was designed as a randomized comparative controlled clinical trial. In this study total of 60 children were randomly selected and equally allocated into two groups, namely Group A and Group B, comprising 30 children in each group**.** Subjective and Objective parameters were documented before and after the completion of treatment. It is concluded from the results that both treatment modalities showed improvement in the signs and symptoms of respiratory allergic disorders in children. However, *Brihat Vasavaleha* with *Shadbindu Taila Nasya* showed better therapeutic efficacy compared to *Shadbindu Taila Nasya* with placebo.

INTRODUCTION

Respiratory disorders represent a significant global health concern, with their prevalence being influenced by climatic variations, environmental pollution, and recurrent infections. Among the various respiratory ailments, *Pratishyaya* is a commonly encountered condition that significantly affects the health and well-being of individuals. The term "Allergy" is not directly described in classical Ayurvedic literature; however, its concept can be understood through the theory of *Ama*, which is formed as a result of *Mandagni* (impaired digestive and metabolic fire). According to Ayurveda, *Ama* is produced due to various dietary and lifestyle factors and plays an important role in the development of many diseases[1].

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The "*Pranavaha Strotas*" is connected to the "*Shwasa-prashwasa Kriya".* The word *Pratishyaya* refers to the continuous discharge or secretion from the nose. The term is made of two parts: "*Prati*", which means towards or facing, and "*Shyaya*", which means flowing. Therefore, *Pratishyaya* means the condition in which nasal discharge continuously flows outward from the nose[2]. One such common condition is characterized by continuous nasal discharge, which interferes with daily activities and affects the child's normal growth and development due to its recurrent nature. This condition occurs due to the vitiation of *Vata* and *Kapha Doshas* accumulated in the upper part of the body (*Uttamanga*). The disease in which *Kapha* and other *Doshas* are expelled through the nose is known as *Pratishyaya*[3]. *Acharyas* indicates that the majority are related to immediate triggering agents, such as exposure to dust (*Dhuli*), smoke (*Dhuma*), pollen (*Raja*), and excessive consumption of cold water (*Ati Shita Jala Sevana).* In contrast, conditions such as *Mandagni* (diminished digestive fire), *Ajirna* (indigestion) [4]. *Tamaka Shwasa* is characterized by respiratory distress manifested as *Pranavilomata*,

Hridaya Peedana, *Ruddha Shwasa*, *Ghurghuraka* and *Kasa*. The condition primarily involves vitiation of *Vata* and *Kapha Doshas*[5]. Aggravated *Vata*, following *Pratiloma Gati*, enters the *Pranavaha Srotas* and vitiates *Kapha*, resulting in *Margavarodha* and consequent bronchoconstriction. Thus, *Tamaka Shwasa* is predominantly regarded as a *Vata-Kaphaja Vyadhi.* It is considered as a *Yapya Vyadhi*, meaning a chronic condition that can be managed but not completely cured[6]. Allergy is a Type I hypersensitivity reaction triggered by exposure to a specific allergen and may involve multiple organ systems, especially the respiratory tract. Bronchial asthma and allergic rhinitis are among the most prevalent respiratory allergic disorders. The concept of "one airway, one disease" indicates that these two conditions are closely interconnected and may represent different manifestations of a common underlying pathological process[7]. An Indian study reported that prevalence of allergic rhinitis was 11·3% in children aged 6–7 years, and 24·4% in children aged 13–14 years. The prevalence of asthma varies between 2% and 23% (median 8%) among school going children[8].

AIM

To evaluate and compare the efficacy of *Brihatvasavleh* with *Shadbindu Tail Nasya* and *Shadbindu Taila Nasya* along with placebo in the management of *Pranavaha Sroto Dushti* w.s.r. to respiratory allergic disorders in children.

Primary Objective

To evaluate and compare the efficacy of *Brihatvasavleh* with *Shadbindu Tail Nasya* and *Shadbindu Taila Nasya* along with Placebo in the management of *Pranavaha Sroto Dushti* w.s.r. to respiratory allergic disorders in children.

Secondary Objective

- To evaluate and compare the efficacy of *Brihatvasavleh* with *Shadbindu Tail Nasya* and *Shadbindu Taila Nasya* along with placebo in the management of *Pranavaha Sroto Dushti* w.s.r. to respiratory allergic disorders in children as per subjective criteria.
- To evaluate and compare the efficacy of *Brihatvasavleh* with *Shadbindu Tail Nasya* and *Shadbindu Taila Nasya* along with placebo in the management of *Pranavaha Sroto Dushti* W.S.R. to respiratory allergic disorders in children as per objective criteria (CBC, IgE, TEC, ESR).

MATERIAL AND METHOD

A randomized comparative controlled clinical trial was conducted at M.M.M. Government Ayurveda College and associated hospitals in Udaipur, including Rajved Premshankar Sharma Government Ayurved Hospital and Government Ayurvedic Hospital, Moti Chohatta, with additional participants recruited through school health check-up camps. Institutional Ethics Committee Clearance: The ethical approval was obtained from by the Institutional Ethics Committee of the Madan Mohan Malviya Govt. Ayurved College Ambamata, Udaipur with IEC Reference number IEC/ACA/2023/ 07-09 issued on July 10, 2025.Clinical Trial Registry of India Registration: The trial was registered to CTRI with Registration No. CTRI/2025/03/082008 in March 2025.

Study Plan

Group A: Children received *Brihat Vasavaleha* orally along with *Shadbindu Taila Nasya* for 8 weeks.

Group B: Children received Placebo orally along with *Shadbindu Taila Nasya* for 8 weeks.

Inclusion Criteria

- Children whose parents are willing to give consent/assent for clinical trial.
- Children having cardinal features of respiratory allergy.
- Children aged between 06 years to 14 years of either sex.
- Children with a history of three or more episode within the past year.

Exclusion Criteria

- Children cases of respiratory allergies that are severe and complicated.
- Children aged below 06 years and above 14 years of either sex.
- Children suffering from major systemic illness necessitating long term treatment.
- Children with evidence of malignancy, genetic or congenital anomaly.
- Children diagnosed with tuberculosis, plural effusion, emphysema, lung abscess.

H/o hypersensitivity to any of the trial drug or their ingredient.

Clinical Study

Assessment Parameters

Table 2: Subjective Criteria

Symptoms	Grade	Description
Shirahshoola (headache)	0	No headache

	1	Occasional headache only at the time of *Pratishyaya*
	2	Frequent headache but not severe
	3	Severe constant headache
Kshwathu (sneezing)	0	No sneezing per day
	1	Mild sneezing
	2	Occasional sneezing
	3	Always sneezing
Kasa (cough)	0	No cough
	1	Occasional cough
	2	Continuous cough with moderate pain
	3	Continuous cough with severe pain
Swarsada (hoarseness of voice)	0	No change in voice
	1	Hoarseness of voice at the time of *Pratishyaya*
	2	Hoarseness of voice present but no difficulty in speech
	3	Difficulty to sound
Nasa srav (rhinorrhea)	0	No *Nasa srav*
	1	*Nasa srav* only in morning
	2	*Nasa srav* both in the morning and evening
	3	Continuous *Nasa srav*
Jwara (fever)	0	No fever
	1	Fever only at night
	2	Mild fever throughout the day
	3	Moderate/severe fever throughout the day
Ghranoparodha (nasal obstruction)	0	No obstruction
	1	Obstruction only during sleep
	2	Intermittent obstruction throughout the day
	3	Complete obstruction throughout the day
Galashotha (throat inflammation)	0	No sore throat
	1	Sore throat with pain no difficulty in food intake
	2	Sore throat with pain and difficulty in food intake
	3	Sore throat with pain which interferes with intake of
Shwaskashtata (dyspnoea)	0	No dyspnoea
	1	Dyspnoea on cold exposure
	2	Dyspnoea present and pt. is forced to take medicine for relief
	3	Dyspnoea not relieved even with medicines

Laboratory Investigations

The following laboratory parameters were assessed to evaluate the immunomodulatory effect of the intervention:

- CBC (Complete Blood Count)
- ESR (Erythrocyte Sedimentation Rate)
- Total Eosinophil Count (TEC)

- Allergen- specific IgE Antibody Test

Table 3: Drug Intervention

Group	A	B
Name of drug	*Brihat Vasavleha* and *Shadbindu Tail*	Placebo and *Shadbindu Tail*
No. of patients	30	30
Duration of drug trial	8 weeks	8 weeks
Dose	4 - 6 g/day & 2 drops per nostril	5ml per day & 2 drops per nostril
Route	Oral & nasal	Oral & Nasal

Drug Preparation

Preparation of *Brihat Vasavleha*

All raw materials were cleaned and authenticated. *Badi Kateri, Vasa,* and *Bharangi* were converted into *Yavakuta* (coarse powder) and used to prepare *Kwatha* (decoction). *Khanda (Mishri)* was added and heated to the required *Paka* stage. Subsequently, the fine powders (*Prakshepa Dravyas*), namely *Pippali, Kushta, Talish Patra, Kali Mirch, Tejpatra, Muramansi, Ushira, Lavanga, Nagkesar, Dalchini, Sugandhbala, Nagarmotha,* and *Abhrak Bhasma*, were added and mixed thoroughly. *Go-Ghrita* was incorporated, and heating continued until *Avaleha Paka Lakshana* appeared. After cooling to a lukewarm temperature, *Madhu* (honey) was added and mixed well. The finished *Brihat Vasavleha* was stored in clean, dry, airtight glass containers.

Preparation of *Shadbindu Tail*

Fresh *Bhringraj* (*Eclipta alba*) was cleaned, crushed, and its *Swarasa* (fresh juice) was extracted. *Tila Taila* (sesame oil) was heated mildly, and *Prakshepa Dravya Kalka* containing *Tagara, Vidanga, Yashtimadhu, Shunthi, Karkatashringi,* and *Saindhava Lavana* was added. Fresh *Aja Paya* (goat milk) was incorporated, and the mixture was cooked on mild heat with continuous stirring until *Taila Siddhi Lakshana* and *Mridu Paka* were achieved. The warm oil was filtered, cooled to room temperature, and stored in clean, airtight, dark-coloured containers.

RESULT

Table 5: Inter-group comparison of the effect of therapy on subjective parameters using the (Mann–Whitney U test)

S.No.	Symptoms	Group	Diff. of mean	SD+	SE+	U Value	P Value	Significance
1.	*Shirahshoola* (Headache)	A	.7333	0.7184	.1312	327	.0476	S
		B	0.4	0.4983	0.09097			
2.	*Kshwathu* (Sneezing)	A	1.433	.773	.1413	306	.0117	S
		B	1.04	0.4138	0.07556			
3.	*Kasa* (Cough)	A	1.167	.5307	.09689	307	.0111	S
		B	.76	0.7279	.1329			
4.	*Swarsada* (Hoarseness of Voice)	A	.63	0.5561	.1015	426.5	.7794	NS
		B	0.7	.5960	.1088			
5.	*Nasa srav* (Rhinorrhea)	A	0.9	.4807	.08776	408	0.4719	NS
		B	.8	0.8000	0.5509			
6.	*Jwara* (Fever)	A	0.4	.7701	.1406	364	.1805	NS
		B	0.2	.4068	0.074			
7.	*Ghranoparodha* (Nasal Obstruction	A	1.2	.7144	.1304	217.5	.0001	HS
		B	0.5	0.5085	0.09285			
8.	Galashotha (Throat Inflammation)	A	.7333	.5208	.09509	388	.3205	NS
		B	0.6	0.6215	.1135			
9.	*Shwaskashtata* (Dyspnea)	A	.4333	.5683	.1038	313.5	.0127	S
		B	0.1	0.3051	0.05571			

The inter-group comparison of subjective clinical parameters using the Mann–Whitney U test revealed that Group A showed significantly better improvement than Group B in *Shirahshoola* (headache) (P=0.0476), *Kasa* (cough) (P=0.0111), *Ghranaparodha* (nasal obstruction) (P=0.0001), and *Shwasakashtata* (dyspnea) (P=0.0127) *Kshwathu* (p=0.0117). These findings indicate that the combined therapy administered in Group A was more effective than the therapy given in Group B for these symptoms.

However, the inter-group differences in *Kshwathu* (sneezing) (P=0.0117), *Swarasada* (hoarseness of voice) (P=0.7794), *Nasa Srava* (rhinorrhoea) (P = 0.4719), *Jwara* (fever) (P=0.1805), and *Galashotha* (throat inflammation) (P=0.3205) were statistically non-significant (P>0.05). These findings indicate that both treatment modalities were effective in alleviating the subjective symptoms of respiratory allergic disorders; however, Group A demonstrated superior efficacy in reducing *Shirahshoola* (headache), *Kasa* (cough), *Ghranaparodha* (nasal obstruction), and *Shwaskashtata* (dyspnea).

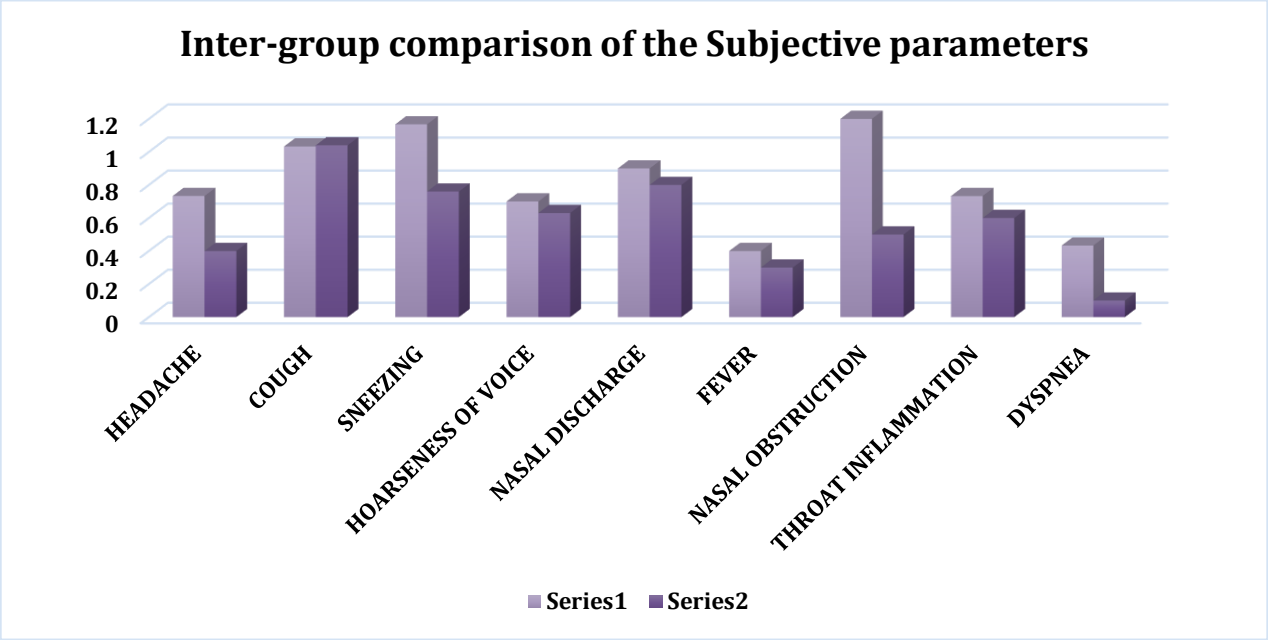

Figure 1. Mean Difference in Subjective Parameters in Both Groups

Table 6: Inter-group comparison of the effect of therapy on Objective parameters using the (Unpaired Student T- test)

S.No.	Investigation	Group	Diff. of mean	SD+	SE+	T Value	P Value	Significance
1.	HB	A	.246667	.2543	.04642	0.7200	0.4744	NS
		B	.2833	.1147	.02095			
2.	RBC	A	0.128333	0.3335	.06089	0.1248	.9011	NS
		B	.1288	.0435	.0079			
3.	MCV	A	1.446667	1.716	0.3133	2.022	.0478	S
		B	.583	.5331	0.097			
4.	MCH	A	1.246667	.0435	.0079	2.022	.0478	S
		B	1.446667	4.223	.7711	.3566	.7227	NS
5.	MCHC	A	1.0333	.8222	.1501	.6404	.5244	NS
		B	.87	1.129	.2062			
6.	RDW	A	.5	0.775	.1415	.0711	.9433	NS
		B	.487	.6937	.1266			
7.	PCV	A	.693	2.597	.4741	.5298	.5983	NS
		B	1.013	2.050	.3743			
8.	Neutrophil	A	2.69	3.496	.6383	1.325	.1904	NS

		B	1.5	3.462	.6320			
9.	Eosinophil	A	1.9	.8030	.1466	2.327	.0235	S
		B	1.46	.6288	.1148			
10.	Basophil	A	.00333	.01826	0.00333	2.057	.0442	S
		B	.133	.3457	.063			
11.	Monocyte	A	.57333	1.890	.3450	1.477	.1452	NS
		B	.067	1.431	.2623			
12.	Lymphocyte	A	.2066	3.754	.6854	1.798	.0773	NS
		B	1.9	3.537	0.645			
13.	Platelet Count	A	.142	.1702	.03107	.4036	.6880	NS
		B	.1646	.2562	.04678			
14.	IgE	A	98.4	107.5	19.62	1.272	.2086	NS
		B	72.7	26.53	4.844			
15.	ESR	A	6.46667	4.305	.7860	3.025	.0037	S
		B	9.27	2.677	.488			
16.	TEC	A	73.0667	46.71	8.528	1.204	.2336	NS
		B	61.8	21.14	3.86			

The above table presents the inter-group comparison of the effect of *Brihat Vasavleha* along with *Shadbindu Tail Nasya* (Group A) and *Shadbindu Tail Nasya* with placebo (Group B) on the objective clinical parameters of children with respiratory allergic disorders using the Unpaired Student's t-test.

The comparison revealed that MCH showed a statistically significant difference between the two groups (t=2.022, P=0.0478), indicating greater improvement in Group A than in Group B. Similarly, Eosinophil count demonstrated a statistically significant difference (t=2.327, P=0.0235), suggesting superior reduction in eosinophilic inflammation in Group A. Basophil count also showed a statistically significant difference (t=2.057, P=0.0442), favouring Group A. Furthermore, ESR exhibited a statistically significant difference between the two groups (t=3.025, P=0.0037), indicating a greater reduction in systemic inflammatory activity in Group A.

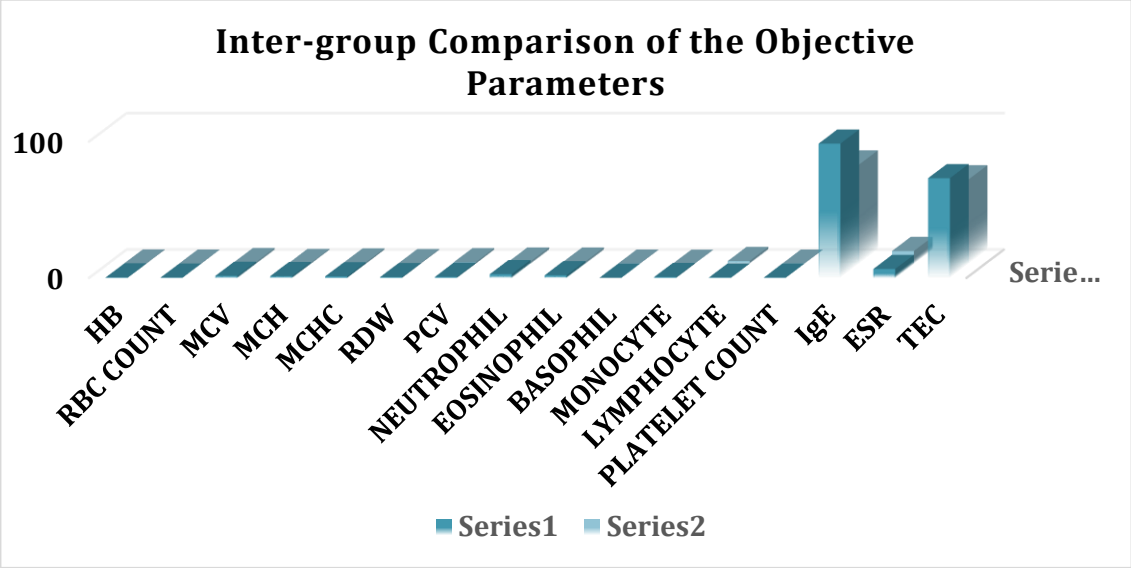

Figure 2. Mean Difference in Objective Parameters in Both Groups

Table 7: Percentage of relief in objective parameters of both groups

S.No.	Objective Parameter	Result in Percentage		
		Group A	Group B	Total
1.	HB	2.052705	2.357182	2.205

2.	RBC Count	2.896261	3.09	2.993
3.	MCV	1.758865	1.39	1.574
4.	MCH	4.623563	2.167	3.395
5.	MCHC	3.216101	2.70	2.958
6.	RDW	3.53523	3.43	3.483
7.	PCV	1.887477	2.76	2.324
8.	Neutrophil	5.14242	2.72	3.931
9.	Eosinophil	39.5833	26.82	33.202
10.	Basophil	4.7619	57.1429	30.952
11.	Monocyte	11.0825	1.28	6.181
12.	Lymphocyte	0.561188	5.36	2.961
13.	Platelet Count	4.714997	5.013	4.864
14.	IgE	13.1008	8.938	11.019
15.	ESR	27.2472	38.61	32.929
16.	TEC	11.8218	9.931	10.876
17.	The Average percentage of relief	9.80	9.68	9.74

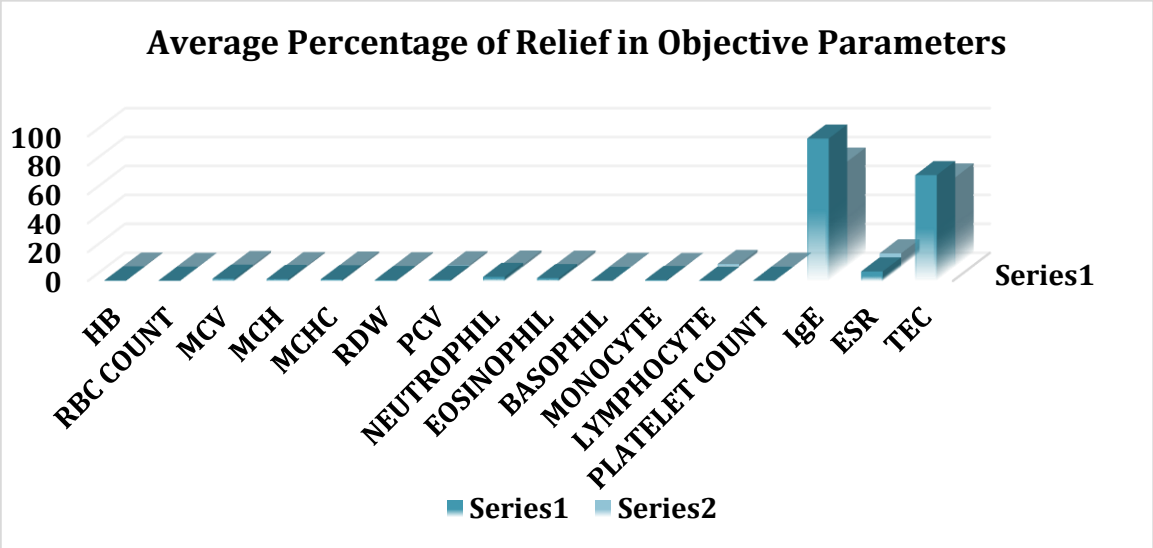

Figure 3. Relief in Objective Parameters in Both Groups

Table 8: Percentage of relief in Subjective parameters of both groups

S.No	Subjective Parameter	Result In Percentage		
		Group A	Group B	Total
1.	*Shirahshoola* (headache)	75.86207	41.37931	58.621
2.	*Kshwathu* (sneezing)	70.49	49.20635	59.85
3.	*Cough (Kasa)*	79.54545	56.09756	67.822
4.	*Swarsada* (hoarseness of voice)	59.375	56.75	58.06
5.	*Nasa srav* (rhinorrhea)	49.09091	46.15385	47.622
6.	*Jwara* (fever)	63.15789	53.84	58.50
7.	*Ghranoparodha* (nasal obstruction)	85.71429	51.72414	68.719
8.	*Galashotha* (throat inflammation)	78.57143	56.25	67.411

9.	*Shwaskashtata* (dyspnea)	76.47059	50	63.235
10.	Average percentage of relief	70.92	51.27	61.09

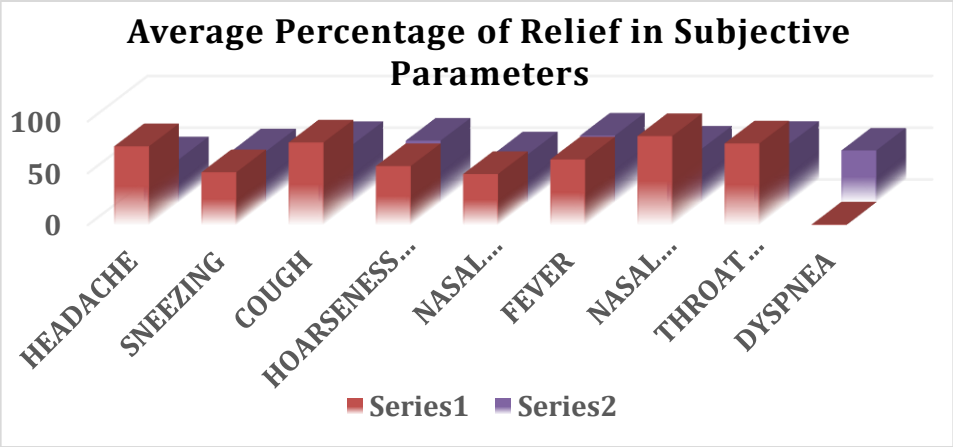

Figure 3. Relief in Subjective Parameters in Both Groups

DISCUSSION

Respiratory allergic disorders are among the most common chronic diseases affecting children worldwide and have shown a steadily increasing prevalence over recent decades. The rise in these disorders is closely associated with rapid urbanization, environmental pollution, industrialization, changing lifestyle patterns, and increased exposure to indoor and outdoor allergens.

Inter-group comparison using the Mann–Whitney U test showed that Group A had better improvement than Group B in most subjective parameters. A statistically significant difference was observed in *Shirashoola* (headache, p=0.0476), *Kshawthu* (sneezing, p=0.0117), *Kasa* (cough, p=0.0111), and *Shwaskashtata* (dyspnea, p=0.0127). A highly significant difference was observed in *Ghrana-prodha* (nasal obstruction, p=0.0001), indicating marked superiority of Group A. Inter-group comparison showed that Group A was significantly better than Group B for MCH, eosinophil count, basophil count and ESR. Overall, Group A showed better improvement in selected laboratory parameters.

Comparison of the symptomatic improvement between the two groups revealed that the mean percentage of relief was higher in Group A i.e., 70.63 than in Group B i.e., 51.27, indicating that the therapeutic effect was more pronounced in Group A.

Probable Mode of Action of *Brihat Vasavleha* [13-26]

Badi Kateri, Vasa, Bharangi, Pippali, Kushtha, Kali Maricha, Tejpatra, Dalchini, Lavanga and *Nagarmotha,* with their predominantly *Katu, Tikta* and *Kashaya Rasa, Laghu* and *Tikshna Guna*, and mainly *Ushna Virya*, help in *Kapha Vilayana, Deepana-Pachana, Ama Pachana* and *Srotoshodhana*, thereby reducing mucus, congestion and inflammation in the respiratory tract. *Abhraka Bhasma* provides *Rasayana* and tissue-strengthening effects, while *Ushira*, *Sugandhabala, Madhu* and *Goghrita* provide soothing and balancing effects. Thus, the overall formulation helps in *Kapha-Vata Shamana*, clearing *Pranavaha Srotas* obstruction and relieving sneezing, nasal discharge, nasal obstruction, cough and dyspnea.

Probable Mode of Action of *Shadbindu Tail* [27-43]

Overall, *Shadbindu Taila* possesses predominantly *Katu, Tikta* and *Kashaya Rasa*, along with *Laghu, Ruksha, Snigdha* and *Tikshna Guna, Ushna Virya* and mainly *Katu-Madhura Vipaka.* These properties collectively promote *Kapha Vilayana, Ama Pachana* and *Srotoshodhana*, while *Ushna Virya* helps to alleviate *Kapha-Vata* and clear obstruction in the *Pranavaha* and *Urdhvajatrugata Srotas*. The *Snigdha* and *Madhura* components provide nourishment and counteract excessive dryness and irritation of the mucosa. Thus, through the combined action of *Rasa, Guna, Virya* and *Vipaka, Shadbindu Taila* helps to reduce *Kshawthu, Nasa Srava, Ghranoprodha, Kasa* and *Shwasa* and supports restoration of normal respiratory function.

Probable Mode of Action of *Nasya* [44]

According to *Acharya Vagbhata* the mode of action of *Nasya Karma*. According to him, the nose acts as the gateway to the head (*Shirah*); therefore, medicines administered through the nostrils reach the *Shringataka Marma*, a vital junction associated with the *Sira* and *Srotas*, through the *Nasa Srotas*. From *Shringataka*, the medicine spreads throughout the *Murdha* (head/brain) and reaches the *Netra* (eyes), *Shrotra* (ears), and *Kantha* (throat). It helps liquefy and mobilize the vitiated *Doshas* accumulated in the *Urdhvajatru* region (above the clavicle), thereby facilitating their elimination from the *Uttamanga* (head). *Shringataka* is described as the meeting point

of the *Srotas* associated with the *Jihwa* (tongue), *Ghrana* (nose), *Netra* (eyes), and *Shrotra* (ears).

CONCLUSION

Respiratory allergic disorders are predominantly *Kapha-Vata* dominant disorders involving *Pranavaha Srotas*, with *Agnimandya* and *Ama* playing an important role in their pathogenesis. *Shadbindu Taila Nasya* with placebo (Group B) also showed beneficial effects, indicating the therapeutic importance of *Nasya Karma* in respiratory allergic disorders. Significant improvement was observed in subjective symptoms such as nasal obstruction, cough, sneezing, nasal discharge, throat inflammation, headache, hoarseness of voice, dyspnea, and fever following treatment. Objective parameters including Serum IgE, Total Eosinophil Count (TEC), ESR and other hematological indices showed significant improvement after treatment, indicating reduction in allergic inflammation. *Brihat Vasavaleha* along with *Shadbindu Taila Nasya* (Group A) produced significant improvement in both subjective and objective parameters of respiratory allergic disorders. No adverse drug reactions or significant complications were observed during the study, suggesting that the treatment regimen is safe and well tolerated in children under the prescribed protocol.

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