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Clinical efficacy of *Rajanyadi Choornam* in Allergic Respiratory Disease in Children

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ABSTRACT

Allergic Respiratory Disease (ARD) is a frequent atopic condition manifesting through allergic rhino conjunctivitis and asthma, affecting up to 40% of the population world-wide. Though not viewed as a life-threatening condition, it is also recognized to impose a significant burden to the quality of life of sufferers and their caretakers. It is apparent from epidemiology studies that the Allergic Respiratory Disease in younger children below the age of 5 years is a relatively common problem. Many conventional managements provide only symptomatic relief resulting in recurrence of the disease. At the same time Ayurveda, aims at the elimination of the disease from its root cause rather than providing only a symptomatic relief that may cause recurrence of the condition. *Rajanyadi Choornam* is one such herbal formulation mentioned in the classics which would enhance the status of digestive fire (*Grahani Deepanam Sreshtam*) and helps in proper channelization of *Vata* (*Vataanulomana*), providing considerable relief to symptoms. A total of 32 children of age group 2-5 years satisfying the inclusion criteria were included in the study. The participants were given *Rajanyadi Choornam* in a dose of 2.5 gm twice daily with 5 ml of *Madhu* and *Ghritam* taken in unequal quantities. The severity of clinical symptoms and blood parameters (serum IgE, AEC) were assessed after 45 days of intervention. For clinical evaluation data regarding the severity of symptoms were collected and laboratory investigations like Serum Total IgE, AEC were done in the children both before and after drug intervention. The results were analysed statistically and reduction of symptoms was statistically significant.

Key words: *Allergic Respiratory Disease, AEC, Rajanyadi Choornam, Serum IgE*

INTRODUCTION

Allergic Respiratory Disease is a frequent atopic condition, manifesting through allergic rhino conjunctivitis and asthma.[1] An allergic condition which is a hypersensitivity disorder of the immune system, is one of the major causes of recurrent respiratory diseases among the pediatric population.

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Various air borne allergens can induce a variety of upper respiratory symptoms with a wide spectrum of severity, which includes nasal congestion, watery nasal discharge, paroxysmal sneezing, chest congestion, cough, sore throat etc. Allergic respiratory disorders are characterized by an increase of serum IgE levels. A serum total IgE higher than 100 IU/ml before the age of six years have a higher risk of being atopic.[2]

Need and significance of study

Allergic respiratory disease affects, up to 40% of the population worldwide and with a significant impact over the quality of life.[1] Allergic diseases in children have increased significantly in recent years and affect up to 35% of children. Various studies have quoted the prevalence of the same as 20% in children and 30% in adults.[3] The onset of allergic responses appears to be highest in the school going children, usually before 5 years of age. Allergy is confirmed in 35 to 38% of upper respiratory tract infections in children and pose an

ISSN: 2456-3110 ORIGINAL ARTICLE March 2023

important risk factor for the same.[2] These allergic disorders are often under diagnosed and under treated, creating considerable burden on children and families and is responsible for approximately 1% of all disability adjusted life years lost worldwide. Complications has also been reported to increase health care cost of the affected child.[3] Therefore, even though, mostly a nonlife threatening conditions, they can impair the person's ability to function. The probability to develop allergies to various allergens is largely genetically determined. The risk is increased from 25% in general population to about 75% when both the parents are atopic. Although there is a genetic predisposition, it is the exposure to environmental allergens, irritants and infections that will determine the sensitization to different allergens.

In Ayurvedic science, even though Allergic Respiratory Disease presents with a vivid symptomatology like rhinitis (*Pratisyaya*), cough (*Kasa),* sneezing (*Kshwathu*), dyspnea (*Swasa)* etc. the root cause of these symptoms remains the same, as one acts as the precipitating factor for other. Our science aims at the elimination of a disease from its root cause rather than providing only a symptomatic relief that may cause recurrence of the condition. In children the *Pranavaha Srotas* easily gets affected as their digestive fire (*Agni)* is unstable due to non-acclimatization with different states of food *(Aharasankaratwat*).[4] This digestive fire (*Agni*) is closely related to *Pitta Dosha* and thus resulting in the simultaneous vitiation of the same. Moreover, the site of *Pranavaha Srotas* is at *Kapha Sthana* and children are more in *Kapha* predominant stage. So mostly *Kaphaja* disease are encountered with *Pranavaha Srotas* in children. Vitiation of *Pranavaha Srotas* sequentially results in the vitiation of *Anna* and *Udakavaha Srotas*. Thus, the vitiation of *Kapha* and *Pitta Dosha* along with vitiation of *Prana, Anna, Udakavaha Srotas* gives rise to many symptoms pertaining to upper respiratory tract. So, managing at the root level i.e., correction of the deranged digestive fire (*Agni*) and maintaining its equilibrium prevents the subsequent *Dushti* of *Doshas* and *Srotas*. This helps in further recurrence of the condition. *Rajanyadi Choornam* is one such herbal formulation mentioned in the classics which would enhance the status of digestive fire (*Grahani Deepanam Sreshtam*), thereby alleviating *Pitta Dosha* and helps in proper channelization of *Vata* (*Vataanulomana*).[5] This formulation helps in establishing the enriched status of the different body tissues and imparts strength. It ultimately helps in preventing the recurrence of the condition in the child.

Aim and Objectives

The study intends to find the effect of *Rajanyadi Choornam* in improving the recurrent respiratory allergic symptoms in children between age group of 2 to 5 years. The aim was to reduce the severity and duration of exacerbations to the minimum providing quality life to these children.

Materials and Methods

Materials used in the study are

1. Trial Drug
2. Study tools

Trial drug

The drug Rajanyadi Choornam mentioned in Ashtanga Hrudaya Utharasthana *Balamaya Pratishedha* and exclusively used in the management general paediatric ailments.

Collection of materials

Raw drugs were collected from a reputed raw drug shop for genuine raw drugs in Thiruvananthapuram district. The authenticities of raw drugs were tested in the pharmacology department of the Government Ayurveda College Thiruvananthapuram. Drugs were washed, cleaned, and dried well.

Preparation of medicine

The medicine was prepared in the pharmacy of Govt. Ayurveda College, Thiruvananthapuram as per classical reference.

Ingredients

1. *Rajani / Haridra - Curcuma longa* Linn.
2. *Devadaru - Cedrus deodara*

ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

3. *Sarala - Pinus roxburghii* Sarg
4. *Sreyasi - Piper chaba* Linn.
5. *Brhati - Solanum indicum* Linn
6. *Kantakari - Solanum xanthocarpum* Schrad
7. *Prsniparni - Uraria picta* Desv
8. *Satahwa - Anethum sowa* Kurz

Method of preparation of *Rajanyadi Choornam*

The medicine was prepared as per the classical reference. The drugs mentioned in the formulation are taken in equal quantities. They were washed, cleaned, dried, powdered and mixed well. The prepared *Choornam* were stored in an airtight container. The raw drugs were purchased from GMP certified authorized raw drugs shop.

Study tools

- Subjective parameters: severity of 8 clinical symptoms sneezing, running nose, nasal congestion, cough, sore throat, scratchy throat, hoarseness, itching of eyes.
- Objective parameters: Serum IgE, AEC.

Table 1: Symptom Severity Grade

Symptom	None Grade 0	Mild Grade 1	Moderate Grade 2	Severe Grade 3
Sneezing	No sneezes	Few short episodes of sneezing	Occasional sneezes	Frequent sneezes
Runny Nose	No runny nose	Had to wipe (or blow) nose rarely	Had to wipe (or blow) occasionally	Had to wipe (or blow) frequently
Nasal congestion	No congestion	Breathing through slightly	Breathing through nose noisy, has nasal speech, breathes through mouth sometimes	Breathes through moth almost all the times because of nasal congestion, nasal speech
Cough	No cough	Few short episodes of coughing	Occasional cough / rare episodes of prolonged coughing	Frequent cough/at least occasional episodes of prolonged coughing
Sore throat	No sore throat	Mild pain with swallowing	Moderate pain with swallowing	Very painful to swallow
Scratchy throat	No throat pain	Infrequent complaint of pain in mouth or throat, discomfort mild	Occasional complaint of pain in mouth or throat, moderate discomfort	Frequent complains of pain in mouth or throat or severe discomfort
Hoarseness	No change in voice	Speech is slightly hoarse or husky	Speech is very hoarse or husky	Cannot speak above a whisper because of hoarseness
Itching of eyes	No itching	Steady symptoms but easily tolerable	Symptoms hard to tolerate, may interfere with sleep or activities of child	Symptoms are so bad; child cannot function all the time.

Table 2: Severity of clinical symptoms

SN	Symptoms	Before Treatment	After Treatment
1.	Sneezing		
2.	Runny nose		

ISSN: 2456-3110 ORIGINAL ARTICLE March 2023

3.	Nasal congestion		
4.	Cough		
5.	Sore throat		
6.	Scratchy throat		
7.	Hoarseness		
8.	Itching of eyes		

Table 3: Blood Investigations

Blood Parameters	Before Treatment	After Treatment
Serum IgE		
Absolute Eosinophil Count		

METHODOLOGY

Study design: Quasi experimental design, pre and post-test study, single group

Study setting: Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvanathapuram.

Study duration: 45 days

Study period: 18 months

Study population: Source population is children of both the sex of the age group of 2 to 5 years suffering from Allergic Respiratory Disease, attending the out-patient wing of Dept of Kaumarabhritya, Govt. Ayurveda College Hospital for Women & Children, Poojappura, Thiruvananthapuram.

Inclusion criteria

Children showing the clinical symptoms of allergic respiratory disease with serum total IgE 60 IU/ml - 1000 IU/ml.

Exclusion criteria

- Children with acute respiratory tract infection.
- Diagnosed case of bronchial asthma.
- Diagnosed case of any chronic systemic illness.
- Children on regular oral corticosteroids, decongestant, antihistamines, inhalers.
- Children who are known case of Deviated Nasal Septum, nasal polyp, adenoiditis.

Sample size: 32 patients were included in the study.

Sampling technique

All the consecutive cases, satisfying inclusion criteria coming to the OPD of Kaumarabhritya department were recruited to the study until the sample size is attained.

Methods of Data Collection

The qualitative data related to the clinical condition was collected as per the case proforma. The information included the were the data related to the patient such as name, age, domicile etc followed by chief complaints with history of present illness to reveal the gravity of the problem, past history to know any predisposing factors. Similarly, personal history to find out the diet, appetite, bowel and bladder habits, family history to know any relevant history of similar complaints in the family. Obstetric history and immunization history were also taken. General and systemic examination was also taken to know the severity of the condition or any associated diseases. For clinical evaluation, data regarding the severity of 8 symptoms - sneezing, running nose, nasal congestion, cough, sore throat, scratchy throat, hoarseness, itching of eyes was collected. Laboratory investigations like Serum Total IgE, AEC are also done in the children.

Procedure

Children with clinical features of Allergic Respiratory Disease was selected from the OPD of department of Kaumarabhritya as per the inclusion criteria. The child was assessed using the case proforma. Blood investigations were done to assess the objective parameters like serum IgE, Absolute Eosinophil Count. *Rajanyadi Choornam* was prepared as per the classical reference and properly packed. The participants were given *Rajanyadi Choornam* in a dose of 2.5 gm twice daily with 5 ml of *Madhu* and *Ghritam* taken in unequal

ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

quantities continuously for a period 45 days. Mode of administration was well explained to the parents. The patient was advised to maximum avoidance to various triggering factors such as dusts, mites, pollen etc. No strict diet restrictions were advised. The severity of clinical symptoms and blood parameters (serum IgE, AEC) were assessed after 45 days of intervention.

Assessment Criteria

- Improvement in the clinical symptoms of Allergic Respiratory Disease
- Blood parameters (IgE, AEC).

Statistical Analysis

Quantitative Variables were expressed as mean, SD, median and inter quartile range and qualitative variables were expressed as proportion. Paired comparison of qualitative variable was analysed by Wilcoxon signed rank test and quantitative variables were analysed by paired-t test. Data analysis was performed using SPSS ver 17.0.

OBSERVATION AND RESULTS

Data related to different quantitative and qualitative parameters were collected and calculated the mean and standard deviation before and after the treatment. The significance of effectiveness of the treatment on qualitative and quantitative parameters was statistically analysed by Wilcoxon Signed Rank test and Paired t test respectively. A calculated p value <0.05 was considered to be statistically significant.

1. Effectiveness of treatment on clinical assessment

Clinical assessment of ARD was done by grading the clinical features according to severity of attacks. They were graded as no symptom, mild, moderate and severe symptom. Since they are qualitative parameters, ranking with suitable score was given and statistical analysis was done using Wilcoxon Signed Rank test. The eight main features which are frequently seen in ARD were considered for the evaluation before and after the treatment.

Table 4: Effectiveness of treatment on Sneezing

Sneezing	BT		AT	
	n	%	n	%
No sneezing	0	0	4	12.5
Mild	5	15.6	20	62.5
Moderate	16	50	8	25
Severe	11	34.4	0	0
Total	32	100	32	100
			Z	p
Wilcoxon Signed Rank test			5.203	<0.001

Out of 32 participants, 50% of the children had moderate sneezing followed by severe sneezing in 34.4%. Mild sneezing was noted in 15.6% of children. After treatment around 12% of participants completely relieved from the symptom and majority (62%) had only mild sneezing. 25% of the group had moderate sneezing and none of the participants had severe sneezing. Since the p value <0.001, it is statistically highly significant.

Figure 1: Comparison of sneezing before and after treatment

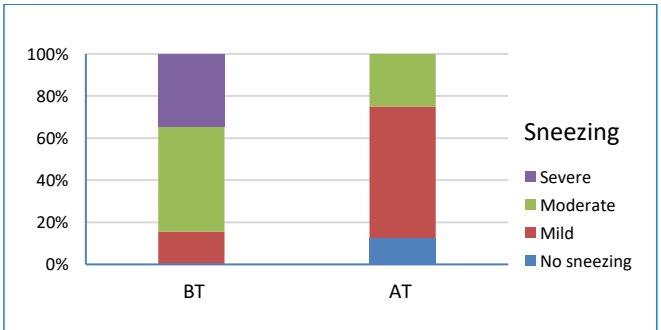


Table 5: Effectiveness of treatment Running Nose

Running Nose	BT		AT	
	n	%	N	%
No runny nose	1	3.1	4	12.5

ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

Mild	2	6.3	16	50
Moderate	16	50	12	37.5
Severe	13	40.6	0	0
Total	32	100	32	100
			Z	**p**
Wilcoxon Signed Rank test			5.416	<0.001

Half of the participants had moderate running nose (50%) and around 40% had severe running nose before the treatment. After the treatment it was noted that percentage of participants with moderate running nose reduced to 37% and none of them had severe running nose. Half of the participants had only mild running nose (50%) after treatment. Since the p value is <0.001, it is statistically highly significant.

Figure 2: Comparison of Running nose before and after treatment

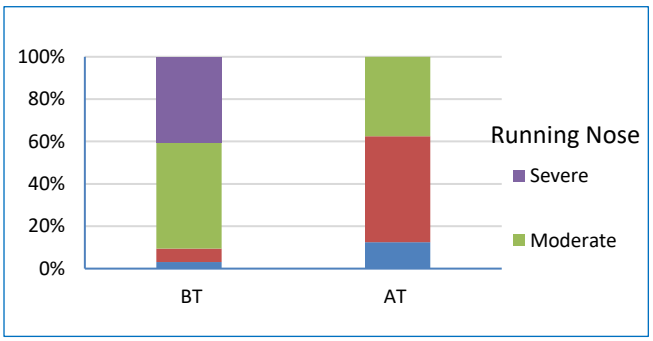


Table 6: Effectiveness of treatment on Nasal congestion

Nasal Congestion	**BT**		**AT**	
	n	**%**	**n**	**%**
No Nasal Congestion	1	3.1	5	15.6
Mild	5	15.6	20	62.5
Moderate	16	50	7	21.9
Severe	10	31.3	0	0
Total	32	100	32	100
			Z	**P**
Wilcoxon Signed Rank test			5.26	<0.001

50% of the children had moderate nasal congestion before treatment which changed to 21.9% after treatment. Severe nasal congestion was found in 31.3% of patients but after treatment none of them had severe nasal congestion. Around 15% got completely cured from the symptom. It was found to be statistically significant since the p value was<0.001. Since the p value is <0.001, it is statistically highly significant.

Figure 3: Comparison of nasal congestion before and after treatment

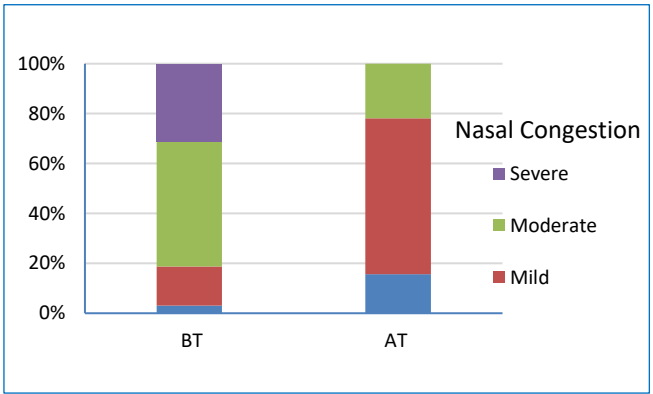


Table 7: Effectiveness of treatment on Cough

Cough	**BT**		**AT**	
	n	**%**	**n**	**%**
No Cough	3	9.4	6	18.8
Mild	10	31.3	19	59.4
Moderate	14	43.8	7	21.9
Severe	5	15.6	0	0
Total	32	100	32	100
			Z	**p**
Wilcoxon Signed Rank test			4.264	<0.001

ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

Moderate cough was present in nearly half of the children (43.8%) and mild cough in 31.3% of children before treatment. After treatment moderate cough was noted in 21.9% participants. None of them presented with severe cough after treatment and majority of children had only mild cough (59.4%). 18.8% of children had no episodes of cough after treatment which was only 9% before treatment.

Figure 4: Comparison of cough before and after treatment

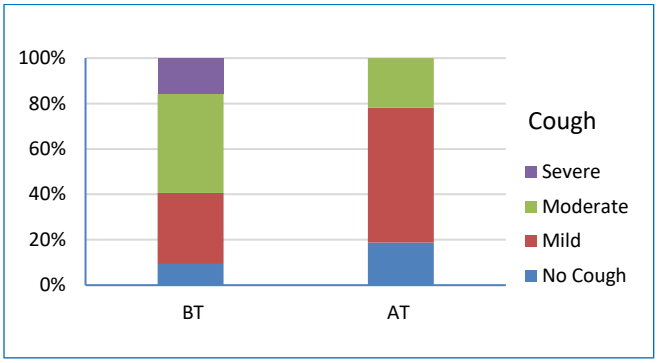


Table 8: Effectiveness of treatment on Sore throat

Sore Throat	BT		AT	
	n	%	N	%
No Sore throat	20	62.5	31	96.9
Mild	11	34.4	1	3.1
Moderate	1	3.1	0	0
Severe	0	0	0	0
Total	32	100	32	100
			Z	p
Wilcoxon Signed Rank test			3.464	<0.001

Only mild sore throat was present in 34.4% of the children and more than half of them had no sore throat (62.5%) before treatment. After treatment it was found that those with mild sore throat considerably reduced to 3.1% and 96.9% had no symptom. Since the p value is <0.001, it is statistically highly significant.

Figure 5: Comparison of sore throat before and after treatment

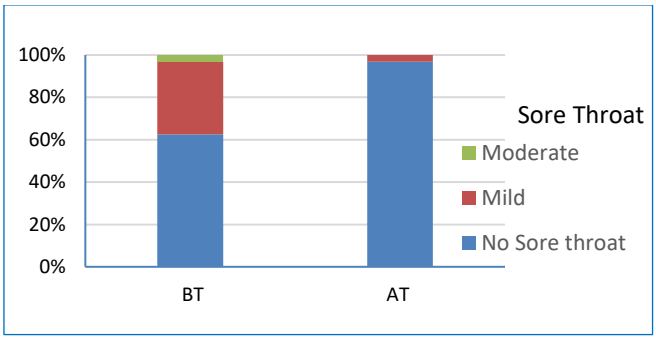
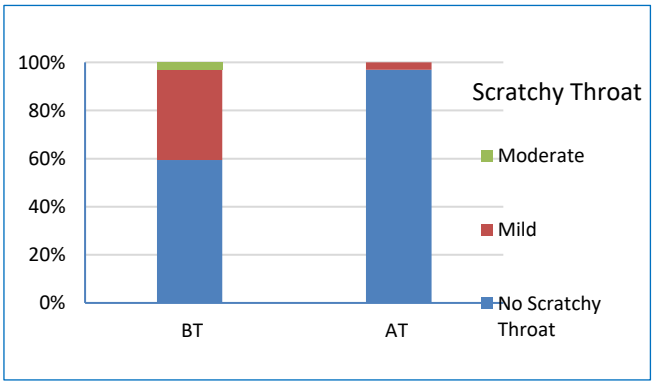


Table 9: Effectiveness of treatment on Scratchy throat.

Scratchy Throat	BT		AT	
	n	%	n	%
No Scratchy Throat	19	59.4	31	96.9
Mild	12	37.5	1	3.1
Moderate	1	3.1	0	0
Severe	0	0	0	0
Total	32	100	32	100
			Z	p
Wilcoxon Signed Rank test			3.606	0.001

59.4% of the children had no complaints of scratchy throat before treatment which increased to 96.9% after treatment. After treatment 3.1% had only mild scratchy throat. Since the p value is <0.05, it is statistically significant.

Figure 6: Comparison of Scratchy throat before and after treatment



ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

Table 10: Effectiveness of treatment on Hoarseness of voice

Hoarseness	BT		AT	
	n	%	n	%
No change in voice	31	96.9	32	100
Mild change	1	3.1	0	0
Total	32	100	32	100
			Z	p
Wilcoxon Signed Rank test			1	0.317

Majority of the participants showed no change in voice (96.9%) and only 3.1% had mild change in voice. After treatment none of them had the complaints of hoarseness of voice. Since the p value is greater than 0.05, it suggests no significant effect of study drug in curing hoarseness of voice.

Figure 7: Comparison of Hoarseness of voice before and after treatment

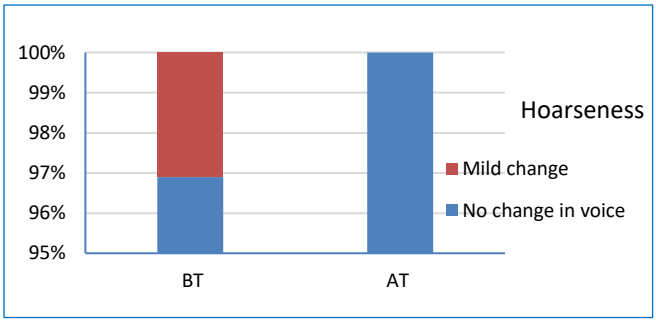


Table 11: Effectiveness of treatment on Itching of eyes.

Itching of eyes	BT		AT	
	n	%	n	%
No itching	15	46.9	24	75
Mild	16	50	8	25
Moderate	1	3.1	0	0
Total	32	100	32	100
			Z	p
Wilcoxon Signed Rank test			3.162	0.002

Half of the children presented with complaints of mild itching of eyes (50%) and moderate itching was present in 3.1% of participants. Around 46% had no complaints before the treatment. After treatment it was noted that children with mild itching of eyes reduced to 25%. 75% of children got completely cured with the symptom. Since the p value is <0.05 it is said to be statistically significant.

Figure 8: Comparison of Itching of eyes before and after treatment.

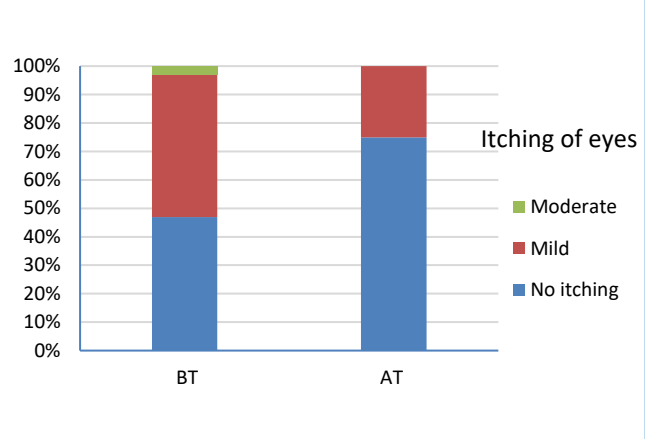


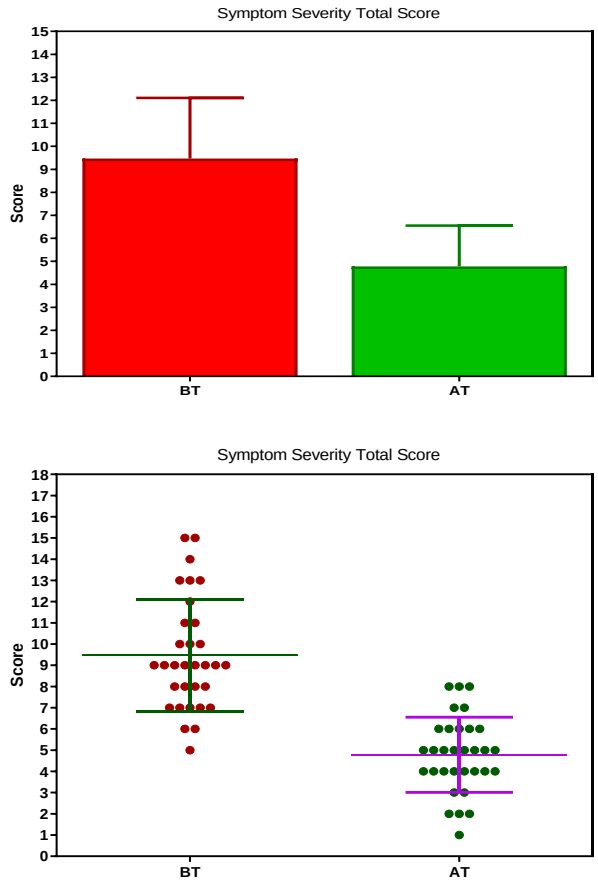
Table 12: Effectiveness of treatment on Symptom severity total score.

	N	Total score		Paired difference		Paired t test	
		Mean	SD	Mean	SD	T	P
BT	32	9.47	2.64	4.69	1.91	13.896	<0.001
AT	32	4.78	1.77				

The average symptom severity total score before treatment was 9.47±2.64 which after treatment changed to 4.78±1.77. Comparison between before and after treatment showed a significant reduction (p<0.001) suggestive of effectiveness of the study drug in reducing the symptoms.

ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

Figure 9: Comparison of Symptom Severity Total Score before and after treatment



2. Effectiveness of treatment on Haematological values

Table 13: Effectiveness of treatment on Serum IgE

	N	Serum IgE		Paired difference		Paired t test	
		Mean	SD	Mean	SD	T	p
BT	32	683.46	261.30	119.38	86.99	7.764	<0.001
AT	32	564.08	215.39				

The average serum IgE concentration before treatment was 683.46±261.30 which after treatment changed to 564.08±215.39. Comparison between before and after treatment showed a significant reduction (p<0.001) suggestive of effectiveness of the study drug in reducing the serum IgE levels.

Figure 10: Comparison of Serum IgE levels before and after treatment

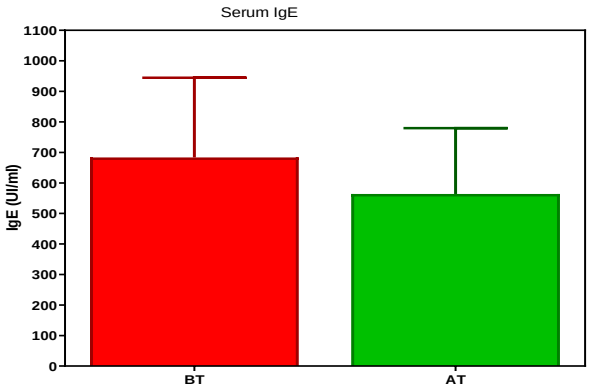
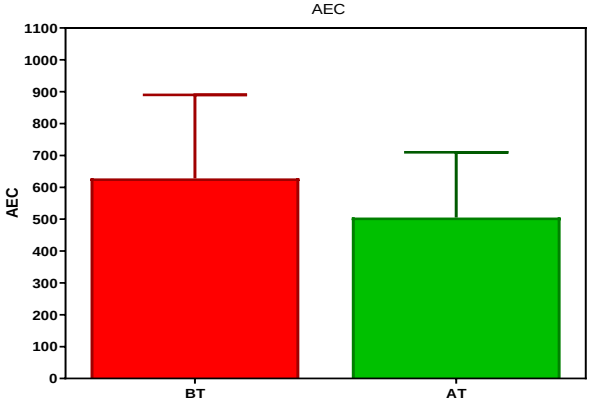


Table 14: Effectiveness of treatment on Absolute Eosinophil Count (AEC)

	N	AEC		Paired difference		Paired t test	
		Mean	SD	Mean	SD	t	p
BT	32	628.13	261.97	122.84	96.96	7.167	<0.001
AT	32	505.28	204.49				

The average AEC concentration before treatment was 628.13±261.97 which after treatment changed to 505.28±204.49. Comparison between before and after treatment showed a significant reduction (p<0.001) suggestive of effectiveness of the study drug in reducing the AEC levels.

Figure 11: Comparison of AEC levels before and after treatment.



ISSN: 2456-3110 ORIGINAL ARTICLE March 2023

DISCUSSION

Discussion on the study drug

The study drug "*Rajanyadi Choornam*" is a simple formulation mentioned in *Balaroga Adhikara* in *Ashtanga Hrudaya Uttarasthana*. *It* is a polyherbal ayurvedic classical formulation used in *Agnimāndya* (digestive impairment), *Atisāra* (diarrhea), *Jvara* (fever), *Kasa (*cough*), Kāmāla* (jaundice), *Pāṇḍu* (anemia) and *Śvāsa* (asthma).[5] Clinical experiences of many professionals have shown that the formulation is effective in managing respiratory allergies and recurrent infections by augmenting the immunity of the children. The drugs in the formulation have *Deepana* and *Pachana* properties which control the initial *Āma* formation which is very important in preventing the disease and this property is even mentioned in the indications of the formulation as *Grahani Deepanam Sreshtam*. The *Katu Vipaka* and *Ushna Veerya* of majority of drugs in the formulation eliminates the vitiated *Kapha Doshas* from the system clearing the obstruction in the channels. This ultimately helps in proper channelization of *Vata*. Apart from this, this classical preparation also offers a *Tridoshahara* action (pacifies *Tridoshas*). Hence this formulation stabilise the status of *Agni* (digestive fire) thereby clearing the vitiation of *Kapha* and *Pitta Doshas* in *Amasaya*, remove the *Utklishta Kapha* from air pathways, helps in proper channelization of *Vata* (*Vataanulomana*) and most importantly, it acts over the respiratory system to strengthen and revitalize the system and make it immune and less susceptible to future attacks.

The pharmacological studies on the drugs in the formulation revealed all of them has an anti-inflammatory and anti-microbial action helping in recurrent respiratory infection. *Haridra/Rajani* is a well-known herb to the world for its therapeutic exhibits in terms of immune boosting, antihistamine, anti-inflammatory and antioxidant properties. Various studies have shown that hydroxy groups of curcumin play a significant role in exerting both the anti-oxidative and anti-allergic activities.[6] Himachalol is one of the important chemical constituents in *Devadaru* has anti-allergic property. The volatile oils of Cedrus known to inhibit type ш hypersensitivity reaction and have immune-modulatory action.[7] The spasmolytic and antioxidant action of *Sarala* helps in treating diseases of the eyes, ears, throat, blood and skin, bronchitis, inflammations, and itching. The alcoholic extract of the same has demonstrated significant anti-asthmatic activities in the tested models.[8] *Chavya* belonging to the *Panchakola* group acts as an excellent digestive and appetizer along with its immune-modulatory, anti-tussive, expectorant properties. The drug also showed promising mast cell stabilizing activity reducing allergic symptoms.[9] *Brhati* and *Kantakari* belongs to *Laghu Panchamula* group and has excellent action on inflammatory conditions. Both the drugs act effectively on respiratory conditions and has significant inhibition of all asthmatic reactions.[10] Apigenin obtained from the extract of *Solanum xanthocarpum* (*Kantakari*) is having anti-allergic effects. Administration of apigenin before the last airway OVA challenge resulted in significant inhibition of all asthmatic reactions.[11] *Prisniparni* has a significant role in managing upper respiratory conditions by virtue of its *Vata Kaphahara* property. *Satahwa* is also known for its digestive and carminative action and the pharmacological studies showed that the drug induced antimicrobial, anti-inflammatory, analgesic, antisecretory effects, smooth muscle relaxant effect and many other effects.[12] Most of the drugs in the formulation possess antihistaminic action and hence possess potential role in the treatment of asthma and allergic disorders. They also have antioxidant and immune-modulatory actions which is significant in boosting the immune system, thereby preventing recurrent attacks.

Ayurveda pharmaco-dynamic properties of ingredients of *Rajanyadi Choornam* are tabulated below.

Table 15: Ayurveda pharmaco-dynamic properties of ingredients of *Rajanyadi Choornam.*

Name of ingredient	*Rasa*	*Guna*	*Veerya*	*Vipaka*	*Karma*
Rajani (Curcum	*Katu, Tiktha*	*Rookshа*	*Ushna*	*Katu*	*Krimighna, Vishaghna, Pramehanas*

ISSN: 2456-3110 ORIGINAL ARTICLE March 2023

a longa Linn.*)*					*aka, Kaphapittanut*
Devadaru (Cedrus deodara Roxb.*)*	*Tiktha*	*Laghu, Snigdha*	*Ushna*	*Katu*	*Vatahara, Kaphahara*
Sarala (Pinus roxburghii Sargent*)*	*Katu, Tiktha, Kashaya*	*Laghu, Snigdha, Teekshna*	*Ushna*	*Katu*	*Dipana, Kaphahara, Raksoghna, Vatahara, Visaghna*
Sreyasi (Piper chaba)	*Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha Vatahara, Pittavardhana, Deepaniya*
Brhati (Solanum indicum Linn.*)*	*Katu, Tiktha*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kaphavatahara, Amadoshahara*
Kantakari (Solanum surattense Burm*)*	*Katu, Tiktha*	*Laghu, Ruksha, Teekshna*	*Ushna*	*Katu*	*Deepana, Pachana, Amadoshahara, Kapha Vatahara, Pitha Vardhaka*
Prishniparni (Uraria picta)	*Madhura,* *Tiktha,* *Amla, Katu*	*Laghu, Sara*	*Ushna*	*Madhura*	Balances *Vata* and *Kapha, Deepaniya*
Satahwa (Anethum sowa Roxb.*)*	*Katu, Tiktha*	*Laghu, Teekshna*	*Ushna*	*Katu*	Balances *Vata, Kapha, Deepaniya*

Another important feature of the formulation is the adjuvant mentioned for its administration. Combination of *Madhu* and *Grta* is included under the group of incompatible foods (*Virudha Ahara*) and *Acharya Charaka* has quoted that heated honey and honey mixed with equal ghee produce deleterious effects in the body and may cause death also. But in unequal proportions they can be taken. *Madhu* has a scraping effect removing the morbid *Kapha Dosha* from the channels and also pacifies *Tridoshas*. It also has *Yogavahi* property which helps in enhancing the properties and action of the drugs with which it combines without losing its innate properties. Studies have shown that ingestion of honey in patients with respiratory allergies, there is a marked improvement in the symptoms with significant reduction in the total symptom severity score.[13] It also has antioxidant activity and stimulates immunity.

Similarly, ghee in proper quantity considered as best *Rasayana*. It promotes lifespan and protects from many diseases. It enhances digestive power, absorption, and assimilation in the body. It alleviates *Vata, Pitta* and acceptable for *Kapha Prakriti*. It is an excellent *Anupana* (vehicle) for transporting herbs to the deeper tissue layers of the body. Proper digestion, absorption, and delivery to a target organ system are crucial in obtaining the maximum benefit from any therapeutic formulation; the lipophilic action of ghee facilitates transportation to a target organ and final delivery inside the cell since the cell membrane also contains lipid.[14]

Discussion on data related to effectiveness of treatment on clinical symptoms

Data related to the effectiveness of treatment, showed that the drug was effective in reducing the severity of clinical symptoms after 45 days of intervention.

The group analysis of severity of sneezing by Wilcoxon Signed Rank test showed that there was highly significant response after treatment ($p<0.001$). After treatment it was noted that none of the subjects had severe sneezing and majority was under mild form of sneezing.

A highly significant response was noted in reducing severity of nasal discharge and nasal congestion ($p<0.001$) after treatment. None of the participants had complaints of severe nasal discharge and nasal congestion after treatment. Majority of the children had only mild symptoms. Around 12% and 15% of the

ISSN: 2456-3110 ORIGINAL ARTICLE March 2023

total subjects were completely free from the symptoms after the treatment.

The analysis of severity of cough showed that there was a highly significant response ($p<0.001$) after the treatment, which proved the effectiveness of the study drug in reducing cough. Majority of the study subjects had moderate (43%) and mild cough (31%). After treatment 59% of the study subjects had only mild form of cough. Subjects under the category of moderate cough also nearly reduced to half.

A highly significant response to sore throat was noted ($p<0.001$) after the treatment. Even though majority of the participants had no complaints of sore throat even before the treatment nearly 34% had mild sore throat. After treatment, it was noted that 96.9% of the participants got completely cured from the symptom.

A significant response in reducing the complaints of scratchy throat was seen after the treatment ($p<0.05$). Majority had no complaints and none of them had severe scratchy throat. 37% of the participants had mild symptom and after treatment it was found that 96.9% got completely cured.

No significant effect in reducing the hoarseness of voice was noted in the study after the treatment ($p>0.05$). Only 1 among the 32 subjects presented with symptom and remaining subjects had no symptom even before the treatment. As there were no adequate positive cases, it is insignificant to interpret statistically the effect of drug in reducing hoarseness of voice.

The analysis of severity of itching of eyes showed that there was significant response ($p<0.05$) after the treatment. Half of the subjects had mild itching and in 3% had moderate itching before the treatment. After treatment it was noted that children with mild itching of eyes reduced to 25%. 75% of children got completely cured with the symptom.

There was significant reduction in the severity of most of the symptoms after the treatment. The average symptom severity total score after treatment has also significantly reduced. Comparison between before and after treatment showed a significant reduction ($p<0.001$) suggestive of effectiveness of the study drug in reducing the symptoms.

Discussion on data related to effectiveness of treatment on haematological values

The analysis of serum IgE levels and AEC levels showed significant response ($p<0.001$) in the comparison of values before and after treatment. The serum IgE levels which were included in the study was in a range of 60-1000 IU/ml. The drug is found to be more effective in reducing the values which is around 1000 IU/ml. This suggested that the study drug is effective in reducing the concentration of IgE and AEC in blood.

Rajanyadi Choornam is found effective in reducing most of the symptoms of Allergic Respiratory Disease. The concept of allergy is possibly explained under the concept of *Ama* and it has been already discussed the involvement of *Agnimandya* (hypo-functioning of *Agni*), *Ama/Ama Visha*, subsequently vitiated *Doshas* and *Dushyas, Srotovaigunya* (vitiation of body channels), *Pratiloma Gati* of *Vata* (movement of *Vata* in opposite direction) in the pathogenesis of both *Pratisyaya* and *Swasa*. Again, children are susceptible for easy vitiation of *Agni* as they have a *Kapha* predominance and their affinities are naturally in favour of increasing *Kapha*, resulting in formation of *Ama* more easily. This persistent state of *Mandagni* and unaddressed already formed *Ama* can be attributed as the sole factors behind the onset and recurrence of the symptoms. So, improving or strengthening the status of *Agni* along with proper channelization of *Vata* and correction of deranged *Srotas* helps not only in controlling of symptoms but also recurrent onset of symptoms. Again, *Prakruta Sleshma* is considered as *Bala/Ojas* (immunity)[15] and when the *Sleshma* gets vitiated with increased production of *Rasa Mala Kapha* because of impaired *Agni*, the *Sahaja Bala* of the child is compromised leading to recurrent infections. The impaired transformation of *Dhatus* also reduces the *Bala* (immunity) of the child. Thus, strengthening the *Agni* with proper transformation of *Dhatus* helps in improving the immune system of the child. The drugs in the formulation have *Deepana* and *Pachana*

ISSN: 2456-3110 **ORIGINAL ARTICLE** March 2023

properties which can effectively handle the pre-existing *Ama Dosha* and even prevents the further formation of *Ama* by stimulating and strengthening *Agni*. The vitiation of *Vata* and *Kapha Dosha* in the manifestation of the disease is evident from the various etiological factors mentioned in the classics. The *Katu Vipaka* and *Ushna Veerya* of the formulation eliminates the vitiated *Kapha Doshas* from the system clearing the obstruction in the channels. This ultimately helps in proper channelization of *Vata.* The *Seeta* nature of both *Vata* and *Kapha Dosha* is also addressed by the *Usna Veerya* of the formulation. Hence *Rajanyadi Choornam* can effectively control respiratory allergies by virtue of its *Agni Deepana, Vata Kapha Hara, Vatanulomana* action.

The various published data on the anti-allergic, anti-asthmatic, anti-tussive, anti-inflammatory and immune modulatory actions of the individual drugs in the formulation also substantiates the indications mentioned in the formulation.

Conclusion

The study drug, *Rajanyadi Choornam* was effective in reducing the severity of symptoms of ARD in children. *Rajanyadi Choornam* was effective in improving the biochemical parameters measured such as serum IgE and AEC. *Rajanyadi Choornam* was a simple and cost-effective formulation. *Rajanyadi Choornam* was effective in reducing the signs and symptoms of ARD even with small doses within a short period of time. The drug was safe and hence no adverse effects were observed during the study period. The patients were strictly advised to follow the dietary restrictions and specific recommendations to avoid the etiological factors. The hypothesis of the study, *Rajanyadi Choornam* is effective in controlling symptoms of ARD was proved.

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