Research Article

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EFFICACY OF VACHADI SYRUP IN THE MANAGEMENT OF PRATISHYAYA IN CHILDREN

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ABSTRACT

Pratishyaya is one among the Nasagata roga & is a complex disease involving several symptomatology and diverse pathogenesis. It is one of the common disorders of children known for its recurrence and chronicity. It could lead to complications such as Kasa, Shwasa then Kshaya if not managed in time. Recurrence of this disease can be attributed to lower level of immunity in children due to Asampurna bala and hence we need such a drug to improve the immunity to prevent recurrence and complications. Vachadi syrup is one such medicine which serves the purpose, with this aim this trial has been taken up. It is an open labeled clinical trial where 30 children of age group 4-12 yrs with the signs and symptoms of Pratishyaya were enrolled. Vachadi syrup was given in a dose of 5ml 8th hourly for 4-8yrs and 10ml 8th hourly for 8-12yrs for 7 days, clinical assessment was done by grading both subjective and objective criteria. Vachadi Syrup shows highly significant results in clinical symptoms of Pratishyaya & laboratory investigations. Pratishyaya is the disease condition in which Vata and Kapha vitiation is observed, Vachadi sryup shows the dominancy of Tikta, Kashaya and Katu Rasa, Ushna Virya(hot potency), Katu Vipaka (post digestion) which helps in alleviating Vata & Kapha by breaking down the pathogenesis. The clinical trial suggested that the Vachadi syrup is effective and safe herbal formulation in reducing the signs and symptoms of Pratishyaya.

Keywords: Vachadi, Pratishyaya, rhinitis, syrup

INTRODUCTION

Ayurveda is a science which developed as a result of various discussions and researches. It gives equal importance to preventive and curative aspects of diseases. Ayurveda postulated the unique principles of Tridosha, Dhatu and Mala for the homeostasis of the body[1]. Good health is the base of achievements like Dharma (righteousness), Artha (prosperity), Kama (pleasure) and Moksha[2] (liberation). A lot of modern disease entities can be included under the heading of Pratishyaya (rhinitis). Every man should have suffered from this disease at least once in his life. Unless it is managed properly it can lead to several complications which may be life threatening or crippling. Pratishyaya(rhinitis) is such a disease in which running nose is the main clinical feature. Kaumarabhritya (Pediatrics), a branch of Ashtanga Ayurveda deals with the management of children beginning from their procreation[3]. Overall prevalence of rhinitis was 26.1% in school going children[4]. Harita Samhita has described the formulation Vachadi Kashaya[5] to overcome the Pratishyaya (rhinitis). Trial was conducted in pediatric age group hence for palatability purpose the Kashaya(decoction) is modified into syrup form.

Objectives of the study

To evaluate the efficacy of Vachadi syrup in Pratishyaya(rhinitis).

MATERIALS AND METHODS

Table 1: Ingredients of Vachadi Syrup

S.N	Drug	Botanical Name	Usable part
1.	Vacha[6]	*Acorus calamus* Linn.	Rhizome
2,	Yavani[7]	*Trachyspermum ammi* Linn.	Fruit
3.	Aamalaki[8]	*Phyllanthus emblica* Linn.	Fruit
4.	Vibhitaki[9]	*Terminalia bellirica* Roxb.	Fruit
5.	Haritaki[10]	*Terminalia chebula* Retz.	Fruit
6.	Shunti[11]	*Zingiber officinalis* Roscoe.	Rhizome

Collection and authentication of raw drugs

The raw drugs are collected from the SDM Pharmacy of Ayurveda, Udupi, Karnatka state, India. The drug analysis and standardization[12] of syrup was done at SDM centre for Research in Ayurveda and Allied Sciences, Udupi, Karnataka state, India.

Method of Vachadi syrup preparation

After thorough cleaning of each drug, they were powdered into a coarse form separately. 1.33 kg of the powder of each drug is soaked with 32 liters of water and kept for overnight. Next day the contents were boiled and reduced to 1/4th part and filtered. In the obtained mixture 5.6kg of sugar was dissolved and reboiled to obtain one thread consistency of the syrup and cooled to room temperature. Lastly it was filtered and sealed in sterilized 200ml bottle.

Study design
It is an open labeled clinical trial.

Selection of cases
Patients having sign & symptoms of Pratishyaya were selected from the Kaumarabhritya OPD of SDM College of Ayurveda &Hospital, Kuthpady, Udupi, Karnataka.

Inclusion criteria
1. Patients of either sex.
2. Patients between age group of 4 to 12 years.
3. Patients with signs and symptoms described in the context of Vataja, Pittaja and Kaphaja Pratishyaya (rhinitis).

Exclusion Criteria
1. Patients presenting with symptoms of Sannipataja, Raktaja and Dusta pratishyaya.
2. Patients suffering with other nasal diseases like deviated nasal septum, nasal polyps etc.
3. Pratishyaya associated with nasal malignancy.
4. Pratishyaya associated with systemic diseases.

Group: Single group minimum of 30 patients.

Plan of intervention
Dosage form: Syrup (sharkara)

Dose
4-8 year of age group -5ml
8-12 year of age group-10ml

Times of administration: In three divided doses (8th hourly) after food

Duration of treatment: 7 days

Detail history: Obtaining a detailed history is important in the evaluation of Pratishyaya (rhinitis). Important elements include Name, age, sex, socio-economic status, education, chief and associate complains, evaluation of the nature, duration and time, course of symptoms, possible triggers for symptoms, response to medications, social history, immunization history, personal history, family history of allergic diseases, and also examined anthropometry, general examination, systemic examination (Inspection, palpation, percussion, auscultation) was performed.

Lab Investigations conducted
1. Hemoglobin gram%
2. Total leukocyte count
3. Erythrocyte sedimentation
4. Absolute eosinophil count

Criteria for Assessment

Subjective
1. Nasavarodha(Nasal obstruction)
2. Nasasrava(Nasal discharge)
3. Shirashoola (Headache)
4. Kshavathu (Sneezing)

Objective
1.Swollen turbinates.
2.Total leukocyte count
3.Erythrocyte sedimentation rate
4.Absolute eosinophil count

Follow-up study: Evaluation for recurrence of the signs & symptoms of Pratishyaya (rhinitis), general health status & systemic examination were conducted during the follow up period.

Statistical Evaluation: Statistical analysis was carried out using the software SPSS 21.0.The frequency calculations along with parametric and non-parametric test procedure have been performed. Differences of paired samples (example comparison between before treatment and after treatment) were tested with dependent student T test with regard to significance.

After obtaining‘t’ value the corresponding ‘P’ value against particular degree of freedom was noted on the Table of ‘t’. P value <0.05 was considered as spastically significant, P<0.01 or <0.001 were considered as highly significant.

Ethical clearance: This trial has been cleared by institutional Ethical committees; vide Ref. SDMCAU/ACA-49/EC46/14-15

Table 2: Effect of Vachadi syrup on Nasasrava (Nasal discharge)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
30	BT	1.200			0.406	0.742		
	AT	0.566	53%	0.633	0.504	0.092	5.641	<0.001
	FU	0.166	86%	1.033	0.379	0.069	10.17	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 3: Effect of Vachadi syrup on Gandha-ajnana (Loss of smell sensation)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
21	BT	1.000			0.000	0.000		
	AT	0.3000	70%	0.700	0.470	0.105	6.658	<0.001
	FU	0.1500	85%	0.850	0.366	0.081	10.376	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 4: Effect of Vachadi syrup on Mukhashosha (Dryness of mouth)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.0476			0.218	0.047		
	AT	0.381	63%	0.666	0.497	0.108	6.325	<0.001
21	FU	0.190	82%	0.857	0.402	0.087	8.216	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 5: Effect of Vachadi syrup on Kshavathu (Sneezing)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.400			0.498	0.090		
	AT	0.500	64%	0.900	0.508	0.092	7.449	<0.001
30	FU	0.300	78.5%	1.100	0.466	0.085	8.462	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 6: Effect of Vachadi syrup on Ghranavarodha (Nasal obstruction)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	0.95			0.213	0.045		
	AT	0.271	71.5%	0.681	0.455	0.097	5.631	<0.001
22	FU	0.045	95%	0.909	0.213	0.045	14.49	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 7: Effect of Vachadi syrup on Shirovedana (Headache)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.000			0.00	0.00		
	AT	0.214	78.5%	0.785	0.425	0.113	6.904	<0.001
14	FU	0.071	92.8%	0.928	0.267	0.071	13.00	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 8: Effect of Vachadi syrup on Swarasada (Altered voice)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.000			0.00	0.00		
10	AT	0.400	60%	0.600	0.516	0.163	3.674	<0.005
	FU	0.400	60%	0.600	0.516	0.163	3.674	<0.005

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 9: Effect of Vachadi syrup on Trishna (Thirst)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.100			0.316	1.00		
10	AT	0.200	81%	0.900	0.421	0.133	9.00	<0.001
	FU	0.200	81%	0.900	0.421	0.133	5.501	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 10: Effect of Vachadi syrup on Nasagra-paka (Nasal mucosa inflammation)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.000			0.00	0.00		
	AT	0.600	40%	0.400	0.547	0.244	1.633	<0.178
05	FU	0.600	40%	0.400	0.547	0.244	1.633	<0.178

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 11: Effect of Vachadi syrup on Kasa(Cough)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.233			0.430	0.785		
30	AT	0.433	66.6%	0.800	0.504	0.092	7.954	<0.001
	FU	0.233	83%	1.00	0.430	0.078	8.515	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 12: Effect of Vachadi syrup on Aruchi(Loss of appetite)

N	Mean		%	M.D	Paired t test			
30					SD	SE	T value	P value
	BT	1.033			1.825	0.333		
	AT	0.433	58%	0.600	0.568	0.103	6.595	<0.001
	FU	0.200	80%	0.830	0.406	0.074	12.042	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 13: Effect of Vachadi syrup on Nasal Congestion

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.066			0.258	0.666		
15	AT	0.400	62%	0.666	0.507	0.130	5.292	<0.001
	FU	0.133	87%	0.933	0.351	0.090	7.897	<0.001

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 14: Effect of Vachadi syrup on Shirogaurava (heaviness of head)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
	BT	1.000			0.00	0.00		
06	AT	0.333	66%	0.666	0.516	0.210	3.162	<0.025
	FU	0.333	66%	0.666	0.516	0.210	3.162	<0.025

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 15: Effect of Vachadi syrup on Nasal itching

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
05	BT	1.000			0.00	0.00		
	AT	0.600	40%	0.400	0.547	0.244	1.633	1.78
	FU	0.200	80%	0.800	0.447	0.200	4.000	1.78

BT: Before Treatment, AT: After Treatment, FU: Follow up

Table 16: Effect of Vachadi syrup on Total leukocyte count on Pratishyaya (rhinitis)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
30	BT	9576.6			3086.86	563.58	2.512	<0.018
	AT	8730.0	8.8%	846.66	1600.46	292.20		

BT: Before Treatment, AT: After Treatment

Table 17: Effect of Vachadi syrup on Absolute Eosinophil count on Pratishyaya (rhinitis)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
30	BT	404.366			112.81	20.597	2.706	<0.011
	AT	367.43	9%	36.93	81.98	14.96		

BT: Before Treatment, AT: After Treatment

Table 18: Effect of Vachadi syrup on Erythrocyte sedimentation rate on Pratishyaya (rhinitis)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
30	BT	21.700			8.052	1.470	3.954	<0.001
	AT	17.93	17%	3.766	4.184	0.764		

BT: Before Treatment, AT: After Treatment

Table 19: Effect of Vachadi syrup on Hemoglobin % on Pratishyaya (rhinitis)

N	Mean		%	M.D	Paired t test			
					SD	SE	T value	P value
30	BT	11.06			1.557	0.284	0.221	<0.827
	AT	11.04	0.2%	0.025	1.455	0.265		

BT: Before Treatment, AT: After Treatment

OBSERVATION & RESULTS

Maximum number of patients i.e. 58.8% belongs to the age group 4-8 years. Majority of patients (55.9%) were female, 58.8% from BPL(below poverty level) socioeconomic class, 97.1% were having acute condition, recurrence were found in 73.5% patients, 73.5% belong to rural area, 21 children live in a closed area, 22 children had proper sanitary condition,26 children had Alpakshudha (Hunger), 23 children have Visamashana (unbalanced diet), 26 children have Avaraagni

(less digestion power), 25 children had avara jaranashakti (improper digestive capacity), 26 children have complained of disturbed sleep, 25 children have Krura kostha (constipated).

On parameter of Nasasrava (Nasal discharge) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.20 to 0.566, showing a reduction of 0.633 (53%) which is statistically significant (p <0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.20 to 0.166, showing a reduction of 1.033 (86%) which is statistically significant (p< 0.001). (Table 2)

On parameter of Gandha-ajnana (Loss of smell sensation) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.00 to 0.300, showing a reduction of 0.700 (70%) which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.00 to 0.150, showing a reduction of 0.850 (85%) which is statistically significant (p< 0.001). (Table 3)

On parameter of Mukhashosha (Dryness of mouth) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.0476 to 0.381, showing a reduction of 0.666 (63%), which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.0476 to 0.190, showing a reduction of 0.857 (82%) which is statistically significant (p< 0.001). (Table 4)

On parameter of Kshavathu (Sneezing) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.40 to 0.500, showing a reduction of 0.900 (64%) which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.40 to 0.300, showing a reduction of 1.10 (78.5%) which is statistically significant (p< 0.001). (Table 5)

On parameter of Ghranavarodha (Nasal obstruction) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 0.95 to 0.271, showing a reduction of 0.681 (71.5%) which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 0.95 to 0.045, showing a reduction of 0.909 (95%) which is statistically significant (p <0.001). (Table 6)

On parameter of Shirovedana (headache) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.00 to 0.214, showing a reduction of 0.785 (78.5%) which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.00 to 0.071, showing a reduction of 0.928 (92.5%) which is statistically significant (p< 0.001). (Table 7)

On parameter of Swarasada (altered voice) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.00 to 0.400, showing a reduction of 0.600 (60%) which is statistically significant (p< 0.001) and mean difference between BT &AF (on 14th Day) showed a change from 1.00 to 0.400, showing a reduction of 0.600 (60%) which is statistically significant (p< 0.001). (Table 8)

On parameter of Trishna (thirst) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.10 to 0.200, showing a reduction of 0.900 (81%) which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.10 to 0.200, showing a reduction of 0.900 (81%) which is statistically significant (p< 0.001). (Table 9)

On parameter of Nasagra-paka (nasal mucosa inflammation) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.00 to 0.600, showing a reduction of 0.400 (40%) which is statistically not significant (p <0.178) and that mean difference between BT & AF (on 14th Day) showed a change from 1.00 to 0.600, showing a reduction of 0.400 (40%) which is statistically not significant (p< 0.178). (Table 10)

On parameter of Kasa (cough) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.233 to 0.433, showing a reduction of 0.800 (66.6%) which is statistically significant (p <0.001) and mean difference of between BT & AF (on 14th Day) showed a change from 1.233 to 0.233, showing a reduction of 1.00 (83%) which is statistically significant (p< 0.001). (Table 11)

On parameter of Aruchi (loss of appetite) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.033 to 0.433, showing a reduction of 0.600 (58%) which is statistically significant (p< 0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.033 to 0.200, showing a reduction of 0.830 (80%) which is statistically significant (p <0.001). (Table 12)

On parameter of Nasal congestion statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.066 to 0.400, showing a reduction of 0.666 (62%) which is statistically significant (p <0.001) and mean difference between BT & AF (on 14th Day) showed a change from 1.066 to 0.133, showing a reduction of 0.933 (87%) which is statistically significant (p< 0.001). (Table 13)

On parameter of Shirogaurava (heaviness of head) statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.00 to 0.333, showing a reduction of 0.666 (66%) which is statistically significant (p< 0.025) and mean difference between BT & AF (on 14th Day) showed a change from 1.00 to 0.333, showing a reduction of 0.666 (66%) which is statistically significant (p< 0.025). (Table 14)

On parameter of Nasal itching statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 1.000 to 0.0.600, showing a reduction of 0.400 (40%) which is statistically insignificant and mean difference between BT & AF (on 14th Day) showed a change from 1.000 to 0.200, showing a reduction of 0.800 (80%) which is statistically insignificant. (Table 15)

On parameter of Total leukocyte count statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 9576.6 to 8730, showing a reduction of 846.6 (8.8%) which is statistically significant (p <0.018). (Table 16)

On parameter of Absolute Eosinophil count statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 404.36 to 367.4, showing a reduction of 36.9 (9 %) which is statistically significant (p< 0.011). (Table 17)

On parameter of Erythrocyte sedimentation rate statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 21.7 to 17.9, showing a reduction

of 3.766 (17%) which is statistically significant ($p< 0.001$). (Table 18)

On parameter of Hemoglobin % statistical analysis revealed that mean difference between BT & AT (on 7th Day) showed a change from 11.06 to 11.04, showing a marked increase of 0.025 (0.2%) which is statistically insignificant ($p <0.827$). (Table 19)

DISCUSSION

Pratishayaya had got simulation with allergic rhinitis which is the burning problem in the present generation and as there was no successful management for these conditions in allied science[13]. Hence, present clinically study was designed. Vachadi syrup shown statistically significant results in reducing symptoms of Pratishyaya (rhinitis)such as NasaSrava (nasal discharge), Mukhashosha (dryness of mouth), Shirovedana (headache), Gandhaajnana (loss of sense of smell), Ghranavarodha (nasal obstruction), Kshavathu(sneezing), Aruchi (loss of appetite), Kasa (cough).Whereas Vachadi syrup did not show statistically significant result in symptoms nasagrapaka (nasal mucosa inflammation), nasal itching and ulceration of Pratishyaya (rhinitis). The reason behind this could be probably there was not sufficient number of children exhibiting with these symptoms. All the symptoms were seen to reduce effectively within the first week in most of the children. But whoever persisted with those symptoms were completely reduced by the third week. During follow up, few children got recurrence of few symptoms but the intensity was reduced compared to that of before treatment.

Mode of action of Vachadi syrup: The Vachadi syrup contains Vacha, Yavani, Amalaki, Vibhitaki, Haritaki and Shunthi. Here, Vacha, Yavani, Haritaki and Shunthi by their properties of Ushna Veerya (hot potency), Laghu (lightness), Teekshnaguna (sharp in property) does Amapachana (digestive), Vatanulomana (proper movement of Vata) and are VataKapha hara. Whereas Amalaki and Vibhitaki by their Madhura vipaka (post digestion) acts as Tridoshahara. Altogether, this drug acts on Tridosha, corrects Agnimandya (digestive fire), relieves Srotodushti (clears obstruction in the channels), does Vatanulomana and thereby helps in samprapti vighatana(reverse the pathology).

CONCLUSION

Pratishyaya is a disease related to Pranavahasrotas (respiratory tract) associated with the vitiation of Tridoshas. Rhinitis is common in URTI according to the modern science and research articles; the same observation is also seen in the present study. Majority of the patients were found exposed to the Nidanas (causes) of Pratishyaya (rhinitis) explained in Ayurvedic classics which again justify those explanations even in present era. Pathogenesis of Pratishyaya (rhinitis) mainly points toward the inflammatory process of upper airway resulting in obstruction of Vata and resulting hyper secretion of mucus leading to nasal discharge. After revalidating the Vachadi Kashaya, the study proved that Kashaya in the form of syrup also gives relief in Pratishyaya(rhinitis).

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