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A Comparative Study on the efficacy of *Tryushanadi Vati* with and without *Pathya* in children suffering from *Pratishyaya* (~Allergic Rhinitis)

Research Article

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Abstract

Background: *Pratishyaya* is one of the most common disorders in the pediatric age group. The accumulated *Vatadi doshas* get to reside in the nose and produce various types of discharges from it which is called *Pratishyaya*. *Pratishyaya* is discussed under the 31 *Nasagataroga* by *Acharya Sushruta.* It is a disease of *KaphaVata* dominance characterized by *Nasasrava* (Nasal discharge)*, Nasanaha* (Nasal Congestion), *Shirogourava* (Heaviness), *Anadhvapihita Nasa* (Intermittent nasal Obstruction*) a*nd is difficult to cure. Aim: To study the effect of *Tryushanadi vati in Pratishyaya*. Material & Method: 30 children were randomly selected according to a computer-generated randomized chart and assigned to two groups. In which *Tryushanadi Vati* and *Tryushanadi Vati* with *Pathya* were given according to the age group of 7 days. The results are then interpreted and analyzed statistically. Results: There was a significant improvement in *Nasasrava, Nasanaha, Kshwathu* (sneezing)*,* and *Klama* (fatigue). It is the treatment principle that is effective in the *Sampraptivighatan (*breaking the pathogenesis) of *Pratishyaya* resulting in the alleviation of features. The overall result after treatment by statistical analysis was 46.87 % in the group of T vati and 57.51% in T vati+P. Statistically, both the groups T vati and T vati +P have shown significant results as per subjective and objective criteria but T vati+P has more efficacy owing to the synergistic effect of *Pathya*.

Key Words: *Pratishyaya*, Allergic Rhinitis, *Nasasrava, Nasanaha, Kshwathu, Klama.*

Introduction

Pratishyaya comes under the category of disease affecting the nasal cavity. The accumulated *humor* (*Kapha-Vata)* get resides and produces various types of discharges from it which is called *Pratishyaya* (Allergic Rhinitis). It is a disease of body humors dominance characterized by *Nasasrava* (Nasal discharge)*, Nasanaha* (Nasal Congestion), *Shirogourava* (Heaviness), *Anadhvapihita Nasa* (Intermittent nasal Obstruction*)* and is difficult to cure (1-2). These symptoms of *Pratishyaya* explained in Ayurveda classics show resemblance with the symptoms of allergic rhinitis (3). Allergic rhinitis is a diverse disorder that, despite its high prevalence, frequently goes undiagnosed. It affects 40% of children and 10 to 30% of adults and is characterized by one or more symptoms such as sneezing, itching, nasal congestion, and rhinorrhea. (4). In India, 20 to 26% of people suffer from allergic rhinitis and 80 % of asthmatic adults were presenting with the same symptoms (5). It is the most frequently troubling of all inflammatory diseases, and it necessitates special attention since growth and development may be hampered as a result of disrupted daily activities.

Several types of research have been conducted on Allergic rhinitis in the last five years as it is a common disease in pediatrics. But there is no data available on the selected drug, *Tryushanadi Vati* which would help in treating the disease. *Tryushanadi Vati* is explained in the context of *Pratishaya*. Treatment of *Pratishyaya* as per Ayurveda classics is the usage of hot potency of drugs. The drugs are acting as anti-inflammatory, immunomodulatory, antimicrobial, and anti-tussive. As the current formulation which has been selected for trial, possesses similar qualities. So, these qualities of drugs go hand in hand with the principle of treatment. *Pathya* milk and rice alleviate *Pratishyaya* ,especially *Kapha*; *Panchalavan*, *Vidarigandhadi Ganaa* processed *ghrita* help to pacify vitiated *dosha* in *Pratishyaya*; meat juice of the goat prepared with long pepper, barley, horse-gram with ginger-pomegranate or *Emblica myrobalan* and unctuous articles help to alleviates *Pratishyaya* (6). Thus, correction of body metabolism would correct the disease so, the present clinical study is an attempt to assess the effect of *Tryushanadi Vati* with *Pathya* in *Pratishyaya* with special reference to allergic rhinitis.

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Materials and Methods

30 diagnosed children of *Pratishyaya* as per the diagnostic criteria and fulfilling the inclusion criteria were randomly selected for the study from *Kaumarabhritya* OPD from May 2018 to January 2019. Ethical permission was taken for the conduction of the study (reference letter no – DMIMS (DU)/IEC/ 2017-2018/6373). Informed consent was taken from the parents/guardian.

Diagnostic criteria

Presence of minimum 2 classical features of *Pratishyaya* like

- *Nasasrava* (Nasal discharge)
- *Nasanaha/ Ghranoparodha* (Nasal congestion)
- *Kshavathu* (Sneezing)
- *Klama*

Inclusion Criteria

- Participants having classical signs and symptoms of *Pratishyaya* irrespective of their sex, religion, and socioeconomic status were included in the study.
- Subjects belong to the age group 4 to 14 years with or without cough and pharyngitis.

Exclusion Criteria

- Fever
- *Raktaj* and *Dushtaj Praitshyay* (Chronic Rhinitis)
- Any infection and chronic diseases like Tuberculosis, COPD, Pneumonia, DNS,
- Nasal polyp, Asthma, Sinusitis.
- Allergic rhinitis associated with immunodeficiency like HIV.
- Any other systemic illness and Chronic Rhinitis.

A present research study designed as randomized double-arm parallel clinical study. The study was conducted on 30 diagnosed children of *Pratishyaya* fulfilling the inclusion criteria. *Tryushanadi Vati* was administered in 15 children and *Tryushanadi Vati* with *Pathya* was administered in other 15 children for 7 days. Assessment of only subjective parameters was done on the 3rd day with the final assessment was done after the course of the trial i.e. on the 7th day. Hematological investigations were done only before and after the clinical trial.

Source of Drug

The polyherbal formulation was selected from the Ayurveda classic Vangasen Samhita which contained the following ingredients shown in Table no 1 which was prepared at Dattatraya Rasashala of the institute under expert supervision. Later analysis and standardization were carried out and then allowed for intervention in children.

Table No 1: Ingredients of *Tryushanadi Vati*

Sr.No	Ingredients	Botanical name	Part used	Quantity
1	*Sunthi*	*Zingiber officinalis* Roscoe	Rhizome	1 part
2	*Marich*	*Piper nigrum* Linn.	Fruit	1 part
3	*Pippali*	*Piper longum* Linn.	Fruit	1 part
4	Jaggery	*One of the sources is Saccharum officinaram* Linn.	--	6 parts

Method of Study

After taking the informed consent from the parents/guardian, 33 subjects were enrolled as per the inclusion criteria and divided into Group A-*Tryushanadi Vati* and Group B-*Tryushanadi Vati* with *Pathya*. Milk and rice were given as *Pathya* daily or 7 days at least once compulsorily. The whole day only rice and milk were not expected rather only once a day till 7 days as Acharya Vangsen suggested for the treatment of Pratishyaya as Pathya and Acharya Kashyap suggested Ahar as a great medicine- Mahaushadh hence it is a part of an intervention to check its adjuvant efficacy with *Tryushanadi vati*. The trial drug-*Tryushanadi Vati* was administered for 7 days during which assessment of both subjective and objective parameters and other observations were recorded on the 0^{th}, $3^{rd,}$ and the 7^{th} day in a specially prepared research proforma. Post-trial follow-up was done for 14 days. The withdrawal criteria were set as any worsening of symptoms or the onset of any such medical problem during treatment, for which subjects would be forced to withdraw from the study and a viable solution provided free of charge until the children get symptom-free.

Criteria for Assessment of Results

Statistical analysis was done by using descriptive and inferential statistics using the chi-square test, student's paired-unpaired t-test, Mann Whitney U test and Wilcoxon Signed Rank test, and software used in the analysis were SPSS 22.0 version and GraphPad Prism 7.0 version. $p<0.05$ is considered as the level of significance. Assessment of the clinical trial was done based upon the objective parameters and gradational changes in subjective (7) depicted in Table no.2

Before the study, an initial assessment was performed, followed by an assessment of only subjective parameters on the fourth day of the study. The final assessment was performed at the end of the trial, on the seventh day, with a follow-up of 14 days. Hematological tests were performed only before and after the clinical trial.

Table no 2: Subjective Parameters

Grade Symptoms	Grade 1	Grade 2	Grade 3	Grade 4
Nasasrav (Nasal discharge)	No Discharge	Occasional watery/ mucoid discharge in a day	Frequent watery/mucoid discharge in a day	Continuous watery/ mucoid discharge in a day
Kshavathu (Sneezing)	Absent	<5 sneezing occasionally	5-10 Frequent Sneezing a day	>10 sneezing continuously a day
Ghranoprodha (Nasal congestion)	No Congestion	Occasional Congestion throughout the day	Frequent congestion throughout the day	Continuous congestion associated with mouth breathing during sleep
Klama (Fatigue)	No Fatigue	Not affecting daily activity	Affecting daily activity	Fatigue without any activity

Objective Parameters: Pre and post-intervention, these blood tests were done.

- Total leukocyte count
- Differential count
- Acute Eosinophil count
- Erythrocyte Sedimentation rate

The Wilcoxon Signed Rank Test and the Paired t-test were used for the statistical analysis of the obtained data. P value of < 0.05 was considered as statistically significant and pp-value< 0.01 and <0.001 were considered as highly significant. The level of significance was noted and interpreted accordingly. Overall assessment of the study was done by calculating the mean of parameters.

The assessment of progress was done after 7 days, that was, after completion of the course of treatment. An assessment scale was framed to assess the rate of improvement. At the end of treatment, the percentage of relief was calculated and classified under the maximum improvement > 75% improvement in both subjective and objective parameters, moderate: 50 – 75% improvement, Mild: 25 – 50% improvement, and no relief: 0 – 25% improvement of the above mentioned clinical subjective and objective parameters.

Observation and Results

A total of 33 subjects were registered for the study but 2 subjects had withdrawn due to medical advice. One child reported high high-grade fever soon after his registration for the trial and so he was forced to withdraw from the study and a suitable alternative was provided free of cost till he became symptom-free. So, the study was carried out on 30 participants.

The maximum number of children in Group A and Group B were 9 (60%) and 8(53.33%) aged between 5-8 years. Among 30 subjects, 27 Hindu and 3 Buddhist were enrolled of which 9 were from the middle class and 21 from lower class families. 15 children each had average, poor, and good personal hygiene respectively. Maximum numbers of children were given a history of a gradual mode of onset and intermittent time of occurrence. Vata-Kapha dosha was found dominant.

Assessment of Subjective Criteria

The numerical gradation was decided as per the severity of symptoms. The status of pre and post-treatment comparison of subjective criteria is reflected in tables no 3 to 6.

Table No. 3: Statistical Comparison of *Nasasrava* (Nasal Discharge) grade before and after treatment in two groups

Group	Day	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	BT	3.26	15	0.45	0.11	-	
	Day 3	2.46	15	0.51	0.13	0.80±0.41	3.46, p=0.001**
	Day 7	1.46	15	0.51	0.13	1.80±0.67 (55.21%)	3.48, p=0.0001***
	Day 21	1.06	15	0.25	0.06	2.20±0.56	3.53, p=0.0001***
Group B	BT	3.33	15	0.48	0.12	-	-
	Day 3	2.53	15	0.51	0.13	0.80±0.41	3.46, p=0.0001***
	Day 7	1.13	15	0.35	0.09	2.20±0.41 (66.06%)	3.62, p=0.0001***
	Day 21	1.00	15	0.00	0.00	2.33±0.48	3.54, p=0.0001***

*=Non-Significant, **=Significant, ***=Highly Significant

Table No.4: Comparison of *Kshavathu* (Sneezing) Level before and after treatment in two Groups

Group	Day	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	BT	3.20	15	0.56	0.14	-	-
	Day 3	2.53	15	0.51	0.13	0.66±0.48	5.29, p=0.0001**
	Day 7	1.46	15	0.51	0.13	1.73±0.59 (54.37%)	11.30, p=0.0001**
	Day 21	1.46	15	0.51	0.13	1.73±0.79	8.40, p=0.0001**
Group B	BT	3.06	15	0.45	0.11	-	-
	Day 3	2.40	15	0.50	0.13	0.66±0.61	2.88, p=0.004**
	Day 7	1.20	15	0.41	0.10	1.86±0.63 (60.78%)	3.50, p=0.0001***
	Day 21	1.53	15	0.51	0.13	1.53±0.74	3.37, p=0.001**

Table No. 5: Comparison of *Klama* (Fatigue) level before and after treatment in two groups

Group	Day	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	BT	1.66	15	0.97	0.25	-	-
	Day 3	1.33	15	0.48	0.12	0.35±0.48	2.23p=0.025**
	Day 7	1.13	15	0.35	0.09	0.53±0.83 (31.92%)	2.07p=0.038**
	Day 21	1.00	15	0.00	0.00	0.66±0.97	2.23p=0.025**
Group B	BT	1.73	15	0.88	0.22	-	
	Day 3	1.33	15	0.61	0.15	0.40±0.50	2.44p=0.014**
	Day 7	1.06	15	0.25	0.06	0.66±0.81 (50.32%)	2.42p=0.015**
	Day 21	1.00	15	0.00	0.00	0.73±0.88	2.42p=0.015**

Table 6: Comparison of *Ghranaprodha* (nasal congestion) level before and after treatment in two groups

Group	Day	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	BT	2.66	15	0.72	0.18	-	-
	Day 3	2.13	15	0.74	0.19	0.53±0.63	3.22 p=0.006**
	Day 7	1.33	15	0.48	0.12	1.33±0.48 (50%)	10.58 p=0.0001***
	Day 21	1.00	15	0.00	0.00	1.65±0.72	8.91 p=0.0001***
Group B	BT	2.40	15	0.82	0.21	-	
	Day 3	1.80	15	0.86	0.22	0.60±0.50	4.58 p=0.0001***
	Day 7	1.13	15	0.35	0.09	1.26±0.70 (52.91%)	6.97 p=0.0001***
	Day 21	1.00	15	0.00	0.00	1.40±0.82	6.54 p=0.0001***

Hematological Parameters**:** TLC, AEC, and ESR showed significant results while all other hematological parameters showed no significant results. The status of pre and post-treatment statistical comparison of objective criteria is reflected in tables no 7 to 9.

Table 7: Comparison of TLC before and after treatments in two groups

Group	Day	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	BT	7680.00	15	2164.38	558.84	106.66± 1444.92	0.28, p=0.77*
	AT	7573.33	15	1726.04	445.66		
Group B	BT	7660.00	15	1779.96	459.58	406.66± 1511.60	1.04, p=0.31*
	AT	7253.33	15	2008.15	518.50		

Table 8: Comparison of ESR levels before and after treatment in two groups

Group	Day	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	BT	21.80	15	4.87	1.25	5.26±3.57	5.70, p=0.0001***
	AT	16.53	15	4.73	1.22		
Group B	BT	21.53	15	7.12	1.83	3.46±5.30	2.53, p=0.024***
	AT	18.06	15	6.43	1.66		

Table 9: Comparison of AEC levels before and after treatment in two groups

Group	Day	Mean	N	Std. Deviation	Std. Error	Mean Difference	t-value
Group A	BT	191.33	15	125.10	32.30	62.33±101.65	2.37 p=0.023*
	AT	129.00	15	86.22	22.26		
Group B	BT	196.73	15	95.18	24.57	62.33±101.65	2.37 p=0.023*
	AT	152.80	15	106.85	27.58		

Discussion

In this study, school-aged children were more likely to develop allergic rhinitis, which could be related to exposure to the outside environment and contact with infectious children. In addition to the fact that boys have a higher prevalence of respiratory infections throughout childhood, it is inherited independently. In terms of religion, the Hindu group had the greatest number of children, followed by the Buddhist community. This could be related to the geographic distribution of the specific set in the study location. Due to the environment in which they live, poor personal and social cleanliness, and a lack of health awareness, the prevalence of *Pratishyaya* belonging to lower middle- and lower-class families can be deemed an acceptable conclusion (8,9). The same was observed in the trial. 100% of patients were accurately immunized up to their age by routine vaccines, suggesting the lack of relation between the disease and immunization. As vaccines only stimulate

specific immunity to disease-specific and they are not directly associated with preventing routine infections which depends on the general immunity of children (10).

Nasasrav

Nasasrav was present in all the 30 children divided into two groups before treatment. In Group A there was a complete cure in 8 children by the 7th day i.e after the treatment and 7 children remained in the improved category. There was a reduction rate of 55.21% in the mean score with a 'p-value of < 0.0001 showing a highly significant effect and in Group B there was a complete cure in 13 children by the 7th day i.e after the treatment and 2 children remained in the improved category. There was a reduction rate of 66.06% in the mean score with a 'p-value of < 0.0001 showing a highly significant effect. *Tryushanadi Vati* has *s*hown more improvement in Group B as compared to Group A. As *Tryushnadi Vati* has *Vatakaphahar* action because of its *ushna-tikshna guna*, it helped to reduce nasal discharge as *Shunthi is* having antiallergic, immune-stimulatory properties (11, 12). *Pippali* is having an antimicrobial effect on the respiratory system (13, 14). *Marich* is having known anti-inflammatory (15) immunomodulatory activity which combinedly acts on the pathology of nasal discharge. A significant result was seen in both groups but a more effective result was found in Group B which shows *Pathya* has enhanced the activity of *Tryushnadi Vati* in Pratishyaya.

Kshvathu

Kshvathu was present in all the 30 children of both groups. In Group A, there was a complete cure in 8 children by the 7th day i.e after the treatment, and 7 children remained in the improved category. There was a reduction rate of 54.37% in the mean score with a 'p-value of < 0.0001 showing a highly significant effect and in Group B there was a complete cure in 12 children by the 7th day i.e after the treatment and 3 children remained in the improved category. There was a reduction rate of 60.78 % in the mean score with a 'p-value of < 0.0001 showing a highly significant effect. *Tryushnadi Vati* has shown more improvement in Group B with *Pathya* as compared to Group A. As Sneezing is responding to allergic stimuli, anti-allergic, anti-inflammatory properties of *Shunthi, Marich,* and *Pippali have* shown significant results in *Kshavthu* (16-17). As compared to Group A, group B demonstrated more significant results when given along with *Pathya*. It shows that *Pathya* has a good role in treating symptoms of *Kshvathu.*

Klama

It was present in 11 participants among a total of 30 patients. Group A showed, that there was a complete cure in 3 children by the 7th day i.e. after the treatment and 2 children remained in the improved category. There was a reduction rate of 31.92% in the mean score with a 'p-value of < 0.0001 showing a highly significant effect and in Group B there was a complete cure in 5 children by the 7th day i.e after the treatment and 1 child remained in the improved category. There was a reduction rate of 50.32 % in the mean score with a 'p-value of < 0.0001 showing a highly significant effect. *Tryushanadi Vati* has shown more improvement in Group A +P as compared to Group A. All the contents of the trial drug having *Vatahar* property help to reduce *Klama*. The Pharmacological action of the trial drug has anti-inflammatory, antioxidant (18) properties, analgesic, and antipyretic activity (19) which help to reduce the symptom *Klama*. The result showed that Group B has more improvement rate as compared to Group A due to the *Vatahar* properties of *Pathya* (milk& rice) and *Pratishyaya* is mainly vata dominant disease.

Ghranoparodha

It was present in all the 30 children divided into two groups. In Group A, there was a complete cure in 9 children after the treatment, and 6 children remained in the improved category on the 7th day. There was a reduction rate of 50% in the mean score with a 'p-value of < 0.0001 showing a highly significant effect and in In Group B, there was a complete cure in 13 children by the 7th day i.e after the treatment and 2 children remained in the improved category. There was a reduction rate of 52.91%in the mean score with a 'p-value of < 0.0001 showing a highly significant effect. *Tryushnadi Vati has* shown more improvement in Group B as compared to Group A. The Trial drug *Shunthi*, *Marich*, and *Pimpali* have *Ushna tikshna guna* which directly reduces the Kapha dosha in the nasal pathway. The *Ushna tikshna guna* of the trial drug *Tryushanadi Vati* helps in removing the obstruction of *strotasa* which ultimately affects the *Ghranoprodha* by removing the obstruction by anti-inflammatory, anti-allergic properties of the drug help in curing the nasal congestion.

Hematological parameters

In this study, TLC, AEC, and ESR showed significant results. All of the other blood tests have a negligible relationship with the obtained p-value. Because the levels of hemoglobin and DLC (differential leukocyte count) were not significantly disordered before the treatment, only minor alterations in the values were seen.

Probable Mode of Action of drug *Tryushanadi Vati*

Shunthi is having anti-inflammatory, anti-tussive, immuno-modulatory effects with antimicrobial activities. *Pippali is* having analgesic, anti-inflammatory, immunomodulatory and anti-microbial activity. *Pippali* and *Maricha* are tannin-rich medicines that have a surface effect on the pharyngolaryngeal mucosa and regulate it to reduce exudation. In addition to providing a barrier against the interaction of any antigen (pathogen/allergen), tannins also have a local antibacterial effect, destroying any microbes that come into contact. *Maricha*, *Pippali*, and systemic anti-bacterial and anti-microbial (20) actions help in controlling systemic infection of different origins along with properties of *Vata*, and *Kapha* suppression (21).

Pathya means a dietary suggestion to take rice and milk in this disease as *Vangsen* has advised mainly due to *Vata-Pitta* suppressing action and hence act in *Pratisyaya* very well (6,22,23). Rice and milk suppress Vata and Pitta due to their properties. Pratishyaya with special reference to allergic rhinitis is a Vata dominant ailment hence Vata shaman is important for management. Sushrut, Charak and Vagbhat all have suggested medicated ghrit due to presence of pitta vitiation and feverish tendency found in pratishyaya, but many children do not want to have it. (24, 25). Lolimbaraj described the importance of Pathya in treatment as if someone follows a wholesome diet means Pathya then there is no role of medicines and if not at all followed then despite treatment no use of medicines. Also, Acharya Kashyapa described Aahar as a great medicine hence taken for this study to check its adjuvant efficacy with *Tryushanadi vati*. Rice and milk have not been given alone but adjuvant to T. vati, mainly advised during the evening which is a vatakala once only. We have not found any aggravation due to milk but rather the suppression of symptoms occurred more than in group A, i.e. only vati group.

Discussion on Overall Results

After assessing all the subjective and objective criteria in Trayushanadi vati and T vati +P groups, the total number of cured children in the T vati group was 46.66%, Partial relief in 36.66% and no changes were seen in 16.66%. In the *Tryushanadi vati + Pathya* group, the total percentage of cured children was 71.66%, Partial relief in 13.33%, and no changes seen in 15%. The overall result after treatment by statistical analysis was 46.87 % in T vati and 57.51% in T vati+P. Statistically, both the groups T vati and T vati +P have shown significant results as per subjective and objective criteria but T vati+P has more efficacy owing to the synergistic effect of Pathya.

The limitation of the study was the small sample size with no daily monitoring till duration i.e one week for the suggested diet taken by group B participants.

Conclusion

The prevalence of *Pratishyaya* was present more in poor and lower-middle-class families due to less hygiene and health awareness(26). Maximum numbers of children were showing *Vat-Kaphaj* Dominance. The drug *Tryushnadi Vati* with *Pathya* is effective in treating all types of *Pratishyaya* irrespective of Dosha dominance. *Tryushanadi vati* has shown highly significant results in all the subjective and objective criteria except DLC, RBC, and Hb % as not deranged in initial condition also. The overall effect was statistically significant in TLC, AEC, and ESR as well as in all the subjective criteria like Nasastrav, *Nasanaha, Kshwathu,* and *Klama*. The effect was marginally better in Group B (with *Pathya*) as compared to Group A without *Pathya*. The present study revealed the efficacy of the polyherbal tablet-*Tryushanadi vati* as a safe and effective preparation to treat *Pratishyay* (Allergic Rhinitis) without any reported adverse reaction.

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