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Research Article

A CLINICAL STUDY ON THE EFFECT OF *ANU TAILA NASYA* AND *SHATYADI VATI* IN *VATAJA PRATISHYAYA* WITH SPECIAL REFERENCE TO ALLERGIC RHINITIS

Arti Panwar[1]*, Arun Kumar[2], Gunjan Sharma[3]

*[1]PG Scholar, [2]Assistant Professor, [3]Professor & HOD, Department of Shalakya Tantra, Rishikul Campus, Uttarakhand Ayurved University, Haridwar, Uttarakhand, India.

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ABSTRACT

Vataja Pratishyaya (Allergic Rhinitis) is well known for its recurrence and chronicity. Currently approximately 10-30% of adults and 40% of children are affected (feb 2023). A study 2022 revealed that COVID -19 could cause disturbances to the immune system, leading to unusual mast cell activation that may cause allergic flare-ups. Long term usage of nasal decongestants, causes Rhinitis Medicamentosa (RM). Keeping in view the limitations associated with long term usage of modern medications, there is a need to approach *Ayurveda* treatment for allergic rhinitis. So in present study *Anu Taila Nasya* and *Shatyadi Vati* were selected. The trial was conducted on 40 clinically diagnosed patients of *Vataja Pratishyaya* (allergic rhinitis). Study was carried out in a single group. *Anu Taila* in the form of *Nasya* therapy 8 drop of *Marsha Nasya* of 3 sitting and 2 drop of *Pratimarsha Nasya* in between 3 sitting of *Marsha Nasya* in both nostrils, once a day for 35 days along with *Shatyadi Vati* (500mg) 1 tab BD with lukewarm water for 35 days was given. Result was observed and data was statistically analysed before and after treatment. Highly significant results were found in subjective parameters as well as in objective parameters like sneezing (paroxysmal), nasal obstruction, running nose, itching in the nose, temporal headache, nasal congestion except IgE values (significant result).

INTRODUCTION

Acharya Sushruta described 31 *Nasagata Roga* in *Sushruta Samhita Uttartantra*. *Pratishyaya* is one of the *Nasagata Roga*[2] and a whole separate chapter is devoted by *Acharya Sushruta* in *Uttara Tantra* under *Pratishyaya Pratishedha Adhyaya*. It is classified into five types *Vataja, Pittaja, Kaphaja, Raktja, and Sannipataja*.[3] Among them *Vataja Pratishyaya* is *Vata Pradhana Tridoshaja Vikara*. Improper management of *Pratishyaya* leads to a severe and complicated condition called *Dushta Pratishyaya*.[4] The characteristic features of *Vataja Pratishyaya* mentioned by different *Acharayas* in different texts are as *Anaddhanasa* (nasal obstruction), *Pihitanasa* (foreign body sensation/itching inside the nose), *Tanusrava* (rhinorrhea), *Galtauoshthashosha* (dryness of oral cavity), *Shankhanistoda* (pricking pain in temporal region/temporal headache), *Swaraupghata* (hoarseness of voice).[5] On reviewing the clinical presentation of *Vataja Pratishyaya* nearly simulates with the disease Allergic rhinitis. Allergic rhinitis is certainly one of the prime diseases of Rhinology. Allergic rhinitis is an IgE mediated immunologic response of nasal mucosa to air-borne allergen and it is characterised by sneezing, itching in the nose, watery nasal discharge and nasal obstruction. This may also be associated with symptoms of itching in the eyes, palate and pharynx.[6] As *Nidana parivarjanam* is the first line of treatment in *Ayurveda.* Therefore, such type of negligence (*Praghyapradha*) push the diseases to recurrence and then to chronicity, which leads to a severe complication like *Badhirya* (deafness), *Andhata* (blindness), *Gandhanasha* (loss of smell) which is difficult to treat, even it becomes potential cause of *Kshaya Roga*.[7] Many emotional and climate changes in the human body which leads to vitiation of *Vata* and person who are unable to bear these changes suffer

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from *Vataja Pratishyaya*. According to WAO (World Allergy Organization) it is estimated that 400 million people suffer from allergic rhinitis across the world.[8] Young adults are more affected with co-morbidities of asthma, sinusitis, conjunctivitis etc.[9] It may increase because of allergen, irritants, pollutants (71.15%) and change in lifestyle (46.15%) mostly children (44.23%) and adolescents (42.31%).[10] Its symptoms are more prominent in the spring (51.92%) and autumn season (28.85%).[11] Long time use of modern drugs i.e., oral antihistamines, which are used in allergic rhinitis, has been limited due to sedative effect. Local irritation and epistaxis are the most frequent side effects of nasal corticosteroid. Intra-arterial injection of steroid into the inferior turbinate runs the risk of inducing blindness. Oral decongestants are beneficial in short term treatment but can have significant side effects such as hypertension, nervousness, insomnia, irritability and long term usage of nasal decongestants, causes Rhinitis Medicamentosa (RM).[12] Keeping in view the limitations associated with long term usage of modern medications, there is a need to approach *Ayurvedic* management for allergic rhinitis. So in present study *Anu Taila Nasya* and *Shatyadi Vati* were selected.

AIMS AND OBJECTIVES

1. To study conceptually *Vataja Pratishyaya* and Allergic rhinitis both *Ayurvedic* and Modern perspective.
2. To study the effect of *Anu Taila Nasya* and *Shatyadi Vati* in *Vataja Pratishyaya* (Allergic rhinitis).

MATERIAL AND METHODS

Patients were selected randomly on the basis of classical features of *Vataja Pratiyaya* and signs & symptoms of allergic rhinitis irrespective of sex, race and religion from O.P.D. (Department of *Shalakya Tantra)* Rishikul Campus, Haridwar (U.K.) India. For this study a total 40 patients were selected on the basis of inclusion and exclusion criteria. Informed and written consent were taken from all the patients. Approval was taken from Institutional Ethical Committee (UAU/RC/IEC/2022/PG/1-67) prior to patient's enrolment. The trial was registered Rg.no. CTRI/2022/07/044249 in the Clinical Trial Registry of India before commencement of patient's enrolment.

Inclusion Criteria

- Patient aged between 16-60 yrs.
- Patient suffering from *Vataja Pratishyaya* (Allergic rhinitis).
- Minimum 3 recurrent attacks of sign and symptoms of *Vataja Pratishyaya* (Allergic rhinitis)
- Chronicity of disease up to 2 years duration.

Exclusion Criteria

- Patient not willing for clinical trial.
- Any individual above 60 years and below 16 years of age either of any sex.
- Suffering from rhinitis other than allergic rhinitis, acute/chronic sinusitis, other nasal pathology like- DNS, nasal polyp, and nasal trauma.
- Known cases of chronic systemic diseases like- DM, HTN, tuberculosis, lower respiratory tract diseases.

Nasal Examination

Physical Examination of Nose

- Anterior Rhinoscopy
- Posterior Rhinoscopy

Functional examination of Nose

- Patency of the nose
- Sense of smell

Investigation- Hb%, TLC, DLC, ESR, RBS, AEC, IgE, X-RAY- PNS (Water's View with open mouth), Chest X-RAY (whenever required) was done.

Plan of Study

Clinical study was accomplished in three phases-

1-Diagnostic phase 2- Interventional phase 3-Assessment phase.

Diagnostic Phase

All the patients of *Vataja Pratishya* (Allergic rhinitis) were diagnosed on the basis of various clinical presentations, laboratory investigations and findings.

Subjective Parameter

- *Kshavathu* (Sneezing)
- *Anaddhanasa* (Nasal obstruction)
- *Pihitanasa* (Foreign body sensation/Itching in nose)
- *Tanusrava* (Running nose)
- *Sankhanistoda* (Temporal headache)

Objective parameter

- Nasal congestion
- Inferior turbinate hypertrophy
- AEC (Absolute eosinophil count)
- IgE

Interventional Phase

Study Design: The method adopted for the study was Simple Randomised Open Clinical Study.

Proforma: A special proforma was prepared on the basis of classical features of *Vataja Pratishyaya* (Allergic rhinitis).

Informed Consent: The purpose of the study, nature of the study drugs, the procedure to be carried out and potential risk and benefits were explained to the patients in detail in non-medical terms. Thereafter their written consent was taken before starting the procedure.

Sample Size (No. of patients): 40 patients.

Period of study: Total period of study was 35 days.

Follow up study: After completion of the treatment, there were 2 follow-up at an interval of 30 days of two months.

Procedure

Deepan-Pachana: *Chitrakadi Vati* 2 *Vati* BD with lukewarm water according the *Kostha* for 3- 5 days prior to the therapy.

Oral Administration: *Shatyadi Vati* 1 tab 500mg BD with lukewarm water.

Local Administration: *Nasya* with *Anu Taila*
(*Marsha* and *Pratimarsha Nasya*).

Dose: 8 drops of *Marsha Nasya* in each nostril- once a day.

2 drops of *Pratimarsha Nasya* in each nostril- once a day.

Poorva Karma: *Snehana* with lukewarm *Tila Taila* (5-7 min, local)

Swedana Ushnambuchelika Vidhi (5-7 min)

Pradhana Karma: Patient lies down in supine position, keeping the head slightly down position (apx-45° bent). Elevated the tip of the nose by left hand and with the right hand poured the lukewarm *Anu Taila*, 8 drops in both the nostrils alternately. Then kept the patient in the same position for 2-3 min.

1st sitting	7 days	*Marsha Nasya*
	7days	*Pratimarsha Nasya*
2nd sitting	7 days	*Marsha Nasya*
	7 days	*Pratimarsha Nasya*
3rd sitting	7 days	*Marsha Nasya*

Pashchata Karma: Patient fomented again and again, gargle with lukewarm water, *Nasa dhumapana (haridra, neempatra, sarsapa, trikatu)* was given.

Assessment Phase

Criteria for Assessment of Result: Grading and Scoring system was adopted for assessing each clinical feature before the commencement of trial and after completion of trial as under.

Subjective parameters

***Kshavathu* (sneezing)**

Grade 0	No sneezing
Grade 1	1-10 times/day (paroxysmal sneezing)
Grade 2	10-20 times/day (paroxysmal sneezing)
Grade 3	>20 times/day (paroxysmal sneezing)

***Anaddhanasa* (nasal obstruction)**

Grade 0	No obstruction
Grade 1	Partially, occasionally and unilateral/bilateral or postural
Grade 2	Complete, frequently and unilateral/bilateral
Grade 3	Always complete and bilateral obstruction of nasal cavity

***Tanusrava* (running nose)**

Grade 0	No discharge from nose
Grade1	Occasional nasal discharge with a feeling of running nose with or without visible fluid
Grade 2	Discharge from nose which needs moping but controllable
Grade 3	Severe discharge from nose with copious fluid needs repeated mopping

***Phitanasa* (itching in the nose/foreign body sensation)**

Grade 0	No itching in the nasal cavity
Grade 1	Mild-moderate itching in nasal cavity
Grade 2	Moderate itching in nasal cavity
Grade 3	Severe itching in nasal cavity

***Sankhanistoda* (temporal headache)**

Grade 0	No headache
Grade 1	Mild headache does not hamper routine work
Grade 2	Moderate headache interferes with routine work
Grade 3	Severe headache, patients carry routine work with difficulty or need to rest

Objective Parameters

Nasal Congestion (nasal mucosa colour)

Grade 0	Pinkish colour of nasal mucosa
Grade 1	Pale colour of nasal mucosa
Grade 2	Yellow colour of nasal mucosa
Grade3	Purple/bluish colour of nasal mucosa

Inferior Turbinate Hypertrophy

Grade 0	No hypertrophy of nasal turbinate
Grade 1	Mild enlargement of nasal turbinate with no obvious obstruction
Grade 2	Between grade 1 and 3
Grade3	Turbinate completely occluded the nasal cavity

A.E.C (Absolute eosinophil count)

Grade 0	100-450 cells/microl
Grade 1	451-500 cells/microl
Grade 2	501-750 cells/microl
Grade3	>750 cells/microl

IgE

Grade 0	150-300 IU/ml
Grade 1	301-600 IU/ml
Grade 2	601-900 IU/ml
Grade3	>900 IU/ml

Statistical Analysis

All information on various parameters was gathered and statistical study was carried out in terms of mean (X). Wilcoxon's signed rank-Test (W-value) before and after treatment was applied to the statistical data for evaluating the difference in the effect of therapy values and finally result were incorporated in terms of probability (p) as:

- ✓ $p > 0.05$ - Insignificant
- ✓ $p < 0.05$, $p < 0.01$ – Significant
- ✓ $p < 0.001$ - Highly significant

Overall Assessment

The assessment was done by adopting the following scoring pattern for signs and symptoms

Cured	>90% relief in sign and symptoms and no recurrence during follow up.
Marked improvement	76-90% improvement in signs and symptoms
Moderate improvement	51-75% improvement in signs and symptoms
Mild improvement	26- 50% improvement in signs and symptoms
No improvement	</=25% improvement in signs and symptoms

RESULT

Percentage Effect of Therapy on Subjective Parameters

Statistically highly significant result (p-value <0.001) were found in sneezing (78.33% relief), rhinorrhea (84.62% relief), nasal obstruction (81.08% relief), itching in nose (76.19% relief), temporal headache (82.14% relief).

Percentage Effect of Therapy on Objective Parameters

Statistically highly significant result (p-value <0.001) were found in nasal congestion (57.44% relief), inferior turbinate hypertrophy (37.96% relief), AEC (38.88% relief), significant relief (p<0.05) was found in IgE (18.18% relief).

Percentage Effect of Therapy on Subjective Parameters

Parameters	Sample size	Mean		Mean Difference	SD	% change	Wilcoxon signed rank test	P value	Result
		BT	AT						
Sneezing	40	1.575	0.325	1.175	0.636	78.33%	-630	<0.001	HS
Rhinorrhea	39	1.333	0.205	1.128	0.5703	84.62%	-630	<0.001	HS
Itching	37	1.135	0.27	0.865	0.6308	76.19%	-406	<0.001	HS
Temporal Headache	39	1.12	0.2	0.92	0.5715	82.14%	-210	<0.001	HS
Nasal obstruction	33	1.121	0.212	0.909	0.4585	81.08%	-378	<0.001	HS

Percentage Effect of Therapy on Objective Parameters

Nasal congestion	40	1.175	0.5	0.675	0.5723	57.44%	-325	<0.001	HS
ITH	35	1.114	0.657	0.423	0.5038	37.968	-136	<0.001	HS

Percentage Effect of Therapy on Haematological value

Haematological value	Sample size	Mean		Mean Difference	SD	% Changes	w	P value	Result
		BT	AT						
AEC	30	1.2	0.733	0.467	0.5074	38.88%	-105	<0.001	HS
IgE	28	1.571	1.286	0.286	0.5345	18.18%	-105	<0.05	S

Overall Effect of the Therapy

Overall effect	Frequency	Percentage
Marked Improvement	10	25%
Moderate Improvement	19	47.5%
Mild Improvement	10	25%
No Improvement	1	2.50%

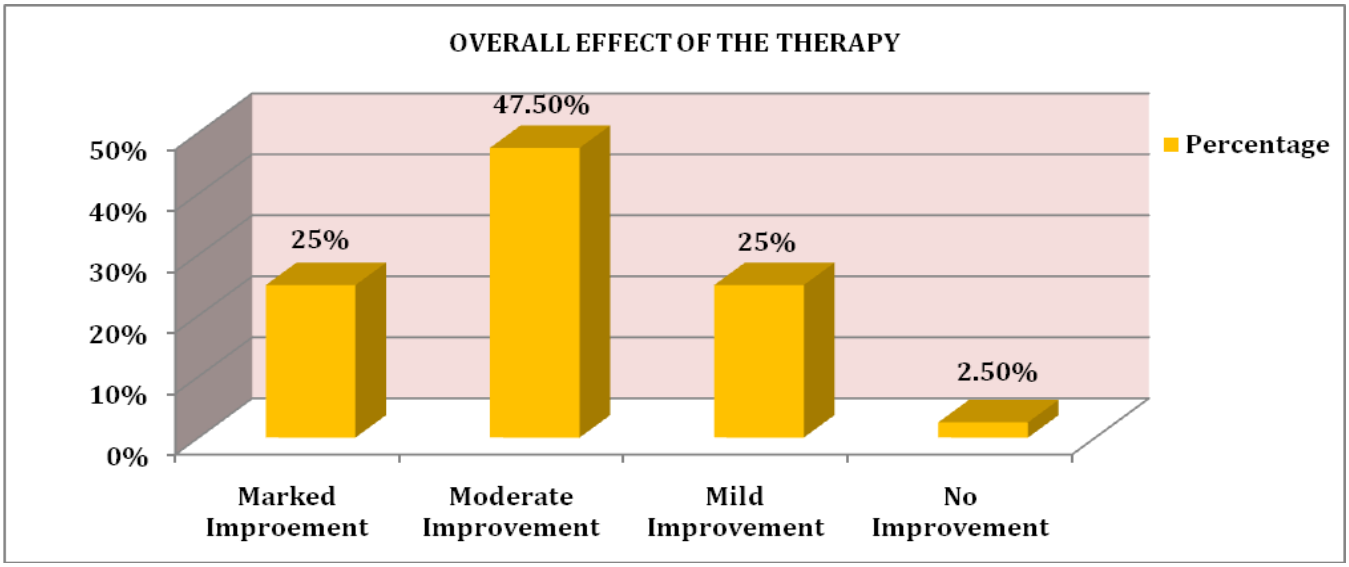

Table 1: Contents of *Anu Taila*

S.No.	*Dravya*	Latin Name	Family	Used Part	Ratio
1	*Bilwa*	*Aegle marmelos*	*Rutaceae*	*Bark*	1 Part
2	*Syonaka*	*Oroxylum indicum*	*Bignoniaceae*	*Bark*	1 Part
3	*Patla*	*Stereospermum suaveolens*	*Bignoniaceae*	*Bark*	1 Part
4	*Gambhari*	*Gmelina arborea*	*Verbenaceae*	*Bark*	1 Part
5	*Agnimantha*	*Premna mucronata*	*Verbenaceae*	*Bark*	1Part
6	*Brihati*	*Solanum indicum*	*Solanaceae*	*Bark*	1 Part
7	*Kantkari*	*Solanum surattense*	*Solanaceae*	*Bark*	1 Part
8	*Shalparni*	*Desmodium gangeticum*	*Leguminosae*	*Panchanga*	1 Part
9	*Prishniparni*	*Uraria picta*	*Leguminosae*	*Bark*	1 Part
10	*Gokshur*	*Tribulus terrestris*	*Zygophyllaceae*	*Bark*	1 Part
11	*Mulethi*	*Glycyrrhiza glabra*	*Leguminosae*	*Bark*	1/3 Part
12	*Tila*	*Sesamum indicum*	*Pedaliaceae*	*Bija Taila*	4 Part
13	*Saindhava*	Chloride of sodium			1/3 Part
14	*Rasna*	*Pluchea lanceolata*	*Compositae*	*Patra*	1/3 Part

Table 2: Contents of *Shatyadi Vati*

S.No.	*Dravya*	Latin Name	Family	Used Part	Ratio
1	*Karchur*	*Curcuma zedoaria*	*Zingiberaceae*	*Rhizome*	1 part
2	*Bhumyamalaki*	*Phyllanthus urinaria*	*Euphorbiaceae*	*Panchanga*	1 part
3	*Shunthi*	*Zingiber officinale*	*Zingiberaceae*	*Rhizome*	1 part
4	*Pippali*	*Piper longum*	*Piperaceae*	*Fruit*	1 part
5	*Maricha*	*Piper nigrum*	*Piperaceae*	*Fruit*	1 part

- *Karchur* is a substitute of *Shati*.[13] So due to unavailability of *Shati*, *Karchur* was taken in place of *Shati*.
- The selected formulation mentioned in the text in the form of *Churna*.[14] For better compliance and self-life of this herbal formulation without affecting the potency, this formulation has been modified into *Vati* form by adding *Sarpi* and *Guda* as given in classical text.

DISCUSSION

All the factors, which aggravate *Tridosha*, are responsible for the accumulation and vitiation of *Doshas* called *Kalantarajanaka Nidanas,* while *Sadhyojanaka Nidanas* act like trigger factors. The complete description of allergy in Ayurveda can be understood under the concept of *Asatmya* and various factors like *Tridosha*, Heredity, *Asatmyaindriyartha Samyog, Dushi Visha* also related to it. Any substance which altered the response in the body is known as *Asatmya.* It can also understand by this way that those substances which are not *Satmya* or not suitable for a particular person, sometimes it may cause react, is called *Asatmya. Anu Taila* is mentioned in *Charaka Samhita Chikitsasthana* under "*Trimarma chikitsa adhyaya"* for *Nasya* therapy in the context of *Pratishyaya*.[15] The content of *Anu Taila* has mainly *Katu, Tikta, Madhura, Kashaya Rasa, Laghu, Tikshna, Snigdha, Ruksha Guna, Ushna Virya, Katu Vipaka, Kaphanihsaraka, Vatanulomaka, Deepana, Pachana, Lekhana, Jantughna, Agnideepaka, Shothahara, Vedanasthapana, Balakaraka*, anti-inflammatory, antifungal, anti-bacterial, anti-asthmatic, anti-allergic, analgesic, antispasmodic, stimulant and antioxidant properties. All these properties help to remove the pathology and promote local immunity. Hence *Anu Taila* was selected for *Nasya* therapy. *Shatyadi Churna* mentioned by *Yogratnakara* and stated that these are beneficial for the treatment of *Pratishyaya.*[16] *Acharya* also recommended that according to specific properties of individual drugs, they should be used in suitable form. Keeping this in present study, 5 drugs were made in tablet form for oral administration. Most of the drug of *Shatyadi Vati* have *Katu, Tikta*, *Kashaya Rasa, Laghu, Tikshna, Snigdha Guna,Ushna Virya, Katu Vipaka, Vata-Kapha Shamaka, Deepana, Pachaka, Rasayana, Rakta shodhaka, Krimihara, Sothahara, Lekhana*, antioxidant, anti-inflammatory, antiallergic, immunomodulator. Because having these properties

drugs have systemic effects. *Vataja Pratishyaya* is *Vata* dominant *Tridoshaja Vyadhi* and all the drugs have *Vata-Kapha samaka* properties.

CONCLUSION

Based upon the detailed conceptual description, it can be concluded that *Vataja Pratishyaya* and Allergic rhinitis both are nearly the same entities. This study showed that statistically highly significant results in subjective parameters as well in objective parameters except IgE values which showed significant results. No adverse effect was observed during the trial, after completion of the trial and while follow-up.

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***Address for correspondence**
Dr Arti Panwar
PG Scholar
Department of Shalakya Tantra,
Rishikul Campus,
Uttarakhand Ayurved University,
Haridwar, Uttarakhand.
Email:
artipanwarsep07@gmail.com