

## CLINICAL EVALUATION OF VYOSHADI GUTIKA IN VATAJA PRATISHYAYA (ALLERGIC RHINITIS)

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## ABSTRACT

The present clinical trial was carried out with the prime aim of assessing the effect of *Vyoshadi Gutika* on *Vataja Pratishyaya* in children between 5 and 16 years of age. It can affect any age group, but it is more prevalent in children. *Pratishyaya* is one of the most common diseases among *Nasa Roga*. This is defined as the condition where the secretion is produced due to the vitiation of *Vata* and *Kapha* at the root of the nose which flows down through the nose against the inspired air. *Vataja Pratishyaya* can be correlated with Allergic Rhinitis. Allergic rhinitis is caused by the inflammation of airway mucosa with hypersensitivity and is characterised by watery nasal discharge, nasal obstruction, sneezing, nasal dryness, hoarseness of voice and headache<sup>[1]</sup>. Managing the disease is essential as it can lead to the obstruction of *Prana Vayu*. The ancient *Acharya* developed various *Ayurvedic* formulations through continuous study, experiments, observation and judgements. *Vyoshadi Gutika* is one of the formulations mentioned in the *Sharangadhara Samhita Madhyam Khand* 7th chapter under *Kumar-Tantra* and has been chosen for the present study.

**Aim:** To evaluate the efficacy of *Vyoshadi Gutika* in *Vataja Pratishyaya*.

**Objectives:** -To provide an economical and safe herbal formulation for *Pratishyaya*. To observe the adverse effects of the drug during the clinical trial.

**Methods:** A total of 40 patients were registered between 5 and 16 years of age with classical symptoms of *Pratishyaya*. The drug *Vyoshadi Gutika* was administered in a daily dose fixed as per Young's rule. The trial lasted 35 days.

**Result:** Overall, the study revealed that *Vyoshadi Gutika* has a highly significant effect on the management of *Vataja Pratishyaya*.

**Keywords:** *Vataja Pratishyaya*, *Vyoshadi Gutika*, Allergic Rhinitis, *Ayurveda*.

## INTRODUCTION

The word *Pratishyaya* means continuous flow with recurrent attacks and can precipitate even due to minute etiological factors. *Vata* is the main *Dosha*, and *Kapha*, *Pitta* and *Rakta* are associated with it [2]. *Vataja Pratishyaya* can be correlated with Allergic rhinitis due to similar signs and symptoms.

Allergic rhinitis (AR), a Type 1, immunoglobulin E (IgE)-mediated, hypersensitivity reaction, is the most common chronic condition in children, afflicting up to 40% of pediatric population worldwide [3]. According to the World Allergy Organization (WAO), 400 million persons worldwide have allergic rhinitis [4]. Prevalence of allergic rhinitis is approximately 20% to 30% of the population of India, of which 15% develop asthma, and studies have shown that the prevalence of allergic rhinitis in India has increased in recent years [5]. In Uttarakhand, where the population is scattered due to hill areas, health facilities in these areas are also remote. The prevalence of allergic rhinitis is 24%, the most common cause of nasal obstruction and congestion among the Garhwal population [6]. *Pratishyaya* is more detailed as a separate chapter and clinical condition in *Uttaratantra of Sushruta Samhita*. It is classified into five types – *Pratishyaya*, *Vataja*, *Pit-taja*, *Kaphaja*, *Sannipataja*, and *Raktaja* [7]. Improper management of *Pratishyaya* leads to a severe and complicated condition called *Dushta Pratishyaya*, which is very difficult to treat and causes a lot of complications like *Badhira* (Deafness), *Anadhata* (Blindness), *Ghrananasha* (Anosmia) etc. [8]. *Vataja Pratishyaya* is characterised by *Anaddha nasa* (Nasal obstruction), *Tanu Srava pravartini* (Rhinorrhoea), *Kshavathu* (Sneezing), *Kandu* (Itching in the nose), *Shankhanistoda* (Pain in the temporal region)

*Swaropaghata* (Hoarseness of voice) *Galashosha* (Sore throat) [9]. So, the present study was conducted to find the efficacy of “*Vyoshadi Gutika*” in *Vataja Pratishyaya*.

### ❖ STUDY DESIGN: -

- Grouping- A single group of *Vyoshadi Gutika*.
- Selected Drug: *Vyoshadi Gutika*
- No of patients: - 40
- Form of medicine: - *Vati*
- Type of study- Single open-arm clinical trial.
- Period of study 18 months.
- Level of study O.P.D level.
- Period of assessment- assessment will be done 4 times at 7-7 days.
- Follow-up – Follow-up will be done after 7 days of cessation of medicine.
- Duration of trial - 35 days.

### DETAILS OF THE GROUP:

Out of 40 patients, only 35 could complete their treatment. Five patients left against their medical advice. Hence, the final assessment of the result was done only in 35 patients.

**COLLECTION OF DATA:** For the clinical trial of the present study, 40 patients suffering from *Vataja Pratishyaya* were selected from O.P.D. Kaumarbharitya Department, Rishikul Campus, Uttarakhand Ayurveda University. The patients were selected based on inclusion, exclusion, and classical features of *Vataja Pratishyaya*.

### INCLUSION CRITERIA:

- Age between 5-16 years.
- Children have classical features of *Pratishyaya*.
- Patient with SFAR score > 7 [10][11]

**EXCLUSION CRITERIA:**

- Age below 5 years and above 16 years.
- Presenting symptoms other than *Vataja Pratishyaya*. (Malaise, fever, etc.)
- Patient with SFAR score < 7
- Known cases of nasal polyp, nasal tumor, DNS, bronchial asthma, serious otitis media & sinusitis.
- Patients with uncontrolled systemic diseases.
- Patient with a history of nasal surgery.
- Patient with other allergic disorders.

**CRITERIA FOR WITHDRAWAL:**

- Aggravation of symptoms
- Intercurrent illness
- Personal matters
- LAMA [Leave Against Medical Advice]

**DIAGNOSTIC CRITERIA:**

- Signs and Symptoms of *Vataja Pratishyaya*.
  1. *Anaddha nasa* (Nasal obstruction).
  2. *Tanu srava pravartini* (Rhinorrhea).
  3. *Kshavathu* (Sneezing).
  4. *Nasa shosha* (Nasal dryness)
  5. *Shirashoola* (Headache).
  6. *Swaropaghata* (Hoarseness of voice).
  7. *Galashosha* (Sore throat).

**ASSESSMENT CRITERIA:**

- Based on subjective and objective parameters, the following clinical findings will be assessed before, during and after treatment.

**SUBJECTIVE PARAMETERS** <sup>[12] [13]</sup>

Sr.No	Parameters	Grade 0	Grade 1	Grade 2	Grade 3
1	<i>Kshavathu</i> (Sneezing)	No sneezing/day	1-10 sneezing/day	11-15 sneezing/day	16-30 sneezing/day
2	<i>Nasa srava</i> (Nasal discharge)	No discharge	Occasionally, Rhinorrhea with a feeling of running nose without visible fluid	Rhinorrhea with the occasionally running nose with visible fluid	Rhinorrhea with a runny nose that needs moping but is controllable
3	<i>Nasa shosha</i> (Nasal dryness)	No symptoms	Only <i>shushkata</i> in nasa without <i>daha</i>	<i>Shushkata</i> is associated with mild <i>daha</i>	<i>Shushkata</i> in <i>Nasa</i> is associated with notable <i>daha</i>
4	<i>Nasa Anaha</i> (Nasal obstruction)	No obstruction	Inhalation and Exhalation with effort with a feeling of mild obstruction	The feeling of moderate obstruction. Inhalation and Exhalation are to be supplemented with mouth breathing	Sever blockage with complete mouth breathing
5	<i>Shirashoola</i> (Headache)	No headache	Occasionally present	Persistent <i>Shirashoola</i> but not sever	Severe and Persistent
6	<i>Galashosha</i> (Sore throat)	No sore throat	Sore throat with pain but no difficulty in food intake	Sore throat with pain and difficulty in food intake	Sore throat with pain which interferes with the intake of food along with water
7	<i>Swarabheda</i> (Hoarseness of voice)	Absent	Hoarseness of voice only at the time of cough	Hoarseness of voice present but no difficulty in speech	Can't make sound due to hoarseness of voice

**Table no. 1****OBJECTIVE PARAMETERS: -**

The objective assessment is done based on changes in clinical findings and relevant laboratory parameters before, during, and at the end of the trial: DLC, TLC, AEC, and ESR.

**SELECTION OF DRUG:** “Vyoshadi Gutika” is described in *Sharangadhara Samhita Madhyam Khand* 7<sup>th</sup> chapter <sup>[14]</sup>. Vyoshadi Gutika yoga by the name of Vyosha (*Trikatu- Pippali, Maricha, Sunthi*), *Chavya, Chitraka, Jiraka, Talisa, Amlavetasa* (substitute-*Dolu*) *Tintidika, Tvak, Sukshma Ela*, and *Tvak patra* Ayurvedic drugs in the form of Vati has been highlighted as a drug of choice for the management of Vataja Pratishyaya.

**METHOD OF PREPARATION OF DRUG:**

- The contents of the selected medicine were identified by the Postgraduate **Department of Dravyaguna**, Rishikul Campus, Haridwar. U.A.U. Uttarakhand and medicine were prepared in Anamika Pharmacy (MFG LIC NO.UK AY-217/2010, GSTIN: 05AAPFA404002ZW) located in the Sidcul industrial area, Haridwar. Uttarakhand, under the guidance of related experts.
- The drug has been prepared according to the method of preparation of Vati as given in the *Sharangdhara Samhita* <sup>[15]</sup>.
- All the ingredients were collected and cleaned from dust, stone, and other impurities.
- Since *Amlavetasa* was unavailable, we used substitute *Dolu* (*Rhuem emodi*) instead of *Amlavetasa*.

- All the ingredients were taken according to their composition, as mentioned above, made into a fine powder, and then sieved (sieve size 85).
- That fine powder of composition mixes with jaggery, then makes *Gutika*. The weight of each *Gutika* has been kept at one gram.
- Storage of medicine: *Gutika* was stored in airtight containers with silica gel at normal room temperature and away from sunlight exposure.

**Dose of medicine:** Dose is calculated by using Young’s formula.

**Route of administration: -** Orally

**Procedure: -** The medicine was given in three divided doses.

**STATISTICAL ANALYSIS: -**

For comparing subjective criteria before and after treatment, the **Wilcoxon Signed Rank test** and the **Paired t-test** are applied.

**OBSERVATIONS & RESULTS:**

Of the 40 patients, 55% were aged 11-16, followed by 5-10 years (45%). Regarding religion, 75% were from the Hindu religion, whereas only 25% of patients were Muslim and other religions. In the present study, a maximum number of patients were male (65%), and 35% were female. The study shows slightly more prevalence in the male sex. 60% were from rural areas, followed by 40% from urban areas. The majority of the patients, i.e. 37% belonged to the upper lower, 45% from the lower middle class, and 18% from the upper middle class. 60% had a family history of allergic disease, but 40% had no family history of allergic disease. 50% of patients had regular bowel habits, 30% had irregular bowel habits, and 20% had constipated bowel habits.

**Table no. 2 shows the patients’ distribution** by the degree of *Kshavathu* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)
Grade 0	2.85%	77.14%
Grade 1	31.42%	17.14%
Grade 2	60%	5.71%
Grade 3	14.28%	0%

**Table no. 3:** Observation of *Nasa Srava* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)
Grade 0	11.42%	77.14%
Grade 1	25.71%	14.28%
Grade 2	20%	8.57%
Grade 3	42.85%	0%

**Table no. 4:** Observation of *Nasa Shosha* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)
Grade 0	42.85%	88.57%
Grade 1	37.42%	11.42%
Grade 2	20%	0%
Grade 3	5.71%	0%

**Table no. 5:** Observation of *Nasa Anaha* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)
Grade 0	31.42%	94.28%
Grade 1	60%	5.71%
Grade 2	8.57%	0%
Grade 3	0%	0%

**Table no. 6:** Observation of *Shirashoola* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)
Grade 0	34.28%	94.28%
Grade 1	54.28%	5.71%
Grade 2	11%	0%
Grade 3	0%	0%

**Table no. 7:** Observation of *Galashosha* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)
Grade 0	28.57%	71.42%
Grade 1	40%	14.28%
Grade 2	31.42%	14.28%
Grade 3	0%	0%

**Table no. 8:** Observation of *Swarabheda* before and after treatment.

Score (n=35)	BT	AT
	No. of cases (%)	No. of cases (%)

<b>Grade 0</b>	31.42%	82.85%
<b>Grade 1</b>	45.71%	11.42%
<b>Grade 2</b>	22.85%	5.71%
<b>Grade 3</b>	0%	0%

**Table No. 9: EFFECT OF THERAPY ON SUBJECTIVE CRITERIA**

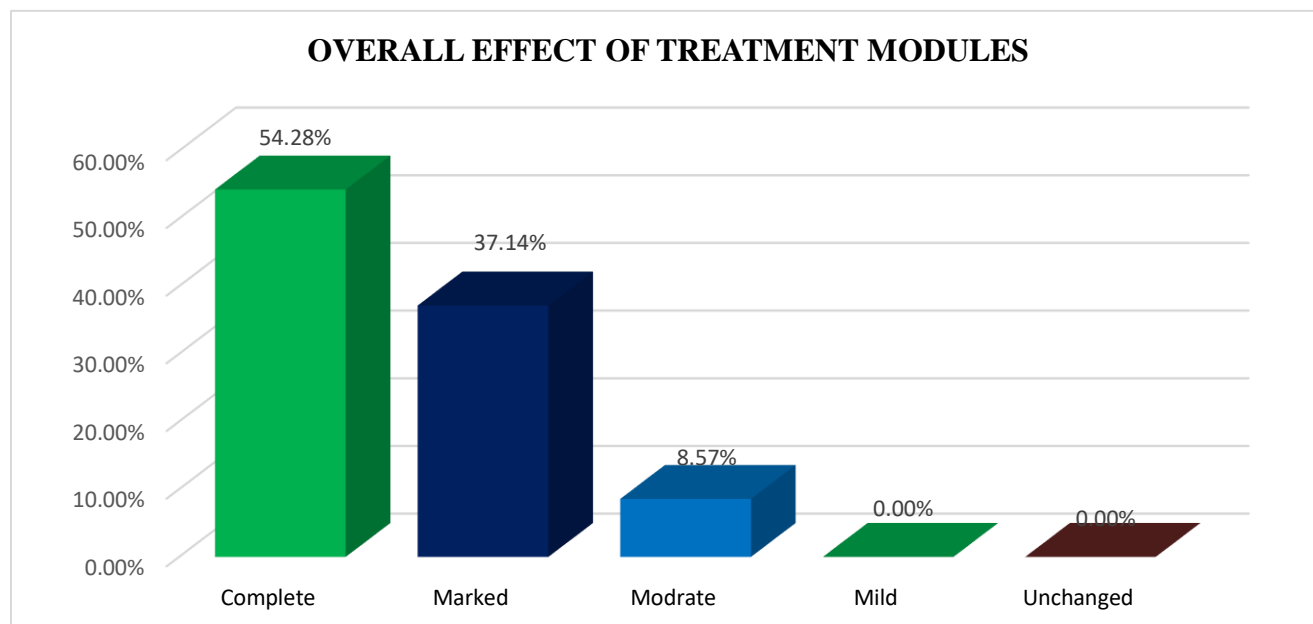
Parameter	No. of pat.	Mean score		SD	W	p-value	Significance
		BT	AT				
<i>Kshavathu</i>	34	1.82	0.29	0.50	-594	<0.001	HS
<i>Nasa Sarav</i>	31	2.17	0.36	1.05	-465	<0.001	HS
<i>Nasa Shosha</i>	19	1.57	0.42	0.06	-190	<0.001	HS
<i>Nasa Anaha</i>	24	1.12	0.25	0.45	-231	<0.001	HS
<i>Shirashoola</i>	23	1.17	0.17	0.42	-300	<0.001	HS
<i>Galashosha</i>	25	1.44	0.72	0.54	-171	<0.001	HS
<i>Swarabheda</i>	24	1.33	0.58	0.53	-171	<0.001	HS

In this study, 83.87% of relief was found in *Kshavathu*, 70.40% in *Nasa Srava*, 73.33% in *Nasa Shosha*, 77.29% in *Nasa Anaha*, 85.18% in *Shirashoola*, 50% in *Galashosha*, and 56.25% in *Swarabheda*.

#### ➤ OVERALL EFFECT ON OBJECTIVE PARAMETERS

In this study, 3.98% of relief was found in TLC, 0.97% in Neutrophils, 17.87% in Eosinophils, 10.70% in Basophils, 4.57% in Monocytes, -0.28% in Lymphocytes, 10.53% in AEC, and 27.65% in ESR.

#### ➤ OVERALL EFFECT OF TREATMENT MODULES



In this trial, Complete improvement was found in 19 (54.28%) patients, marked improvement was found in 13 (37.14%) patients and Moderate improvement was seen in 3 (8.57%) patients.



## DISCUSSION

Pratishyaya is the most common disease encountered in general practice. Vataja Pratishyaya can be compared with allergic rhinitis of modern science, based on the literary discussion of etiopathogenesis and clinical features. The prevalence of allergic rhinitis is rising worldwide, and the incidence of allergic rhinitis in India ranges between 20% and 30%. Pratishyaya affects routine activities and academic performance in children and adolescents.

The trial drug **Vyoshadi Gutika**, with Predominance of *Laghu*, *Tikshana Guna*, *Katu*, *Tikta Rasa*, *Ushna Veerya* have the property of *Agnideepana*, *Amapachana* and *Deepana-Paachana Karma* increases the *Jatharagni* as well *Dhatwagni* by which *Aama* is digested, hence provide proper metabolism, increased dietary substance absorption, increase the function of senses, most of drugs has anti-inflammatory, anti-microbial properties through which *Samprapti Vighatana* can be attained to cure *Vataja Pratishyaya* and its associated symptoms.

Relief in **Kshavathu** was found to be 83.87%. This data shows statistically high significance with a p-value <0.001. As per *Ayurveda*, *Kshavathu* manifests when *Kapha* contaminates *Shringataka Marma* along with vitiated *Vata* or any substance which irritates. *Vata Kapha Shamaka*, properties of *Pippali*, *Maricha*, *Sunthi*, *Chavya*, *Chitraka*, *Jiraka*, *Talisa*, *Amlavetasa*, *Tintidika*, *Sukshma Ela*, and *Tvak patra*, help to resolve the *Kshavathu* by resolving *Vata* and *Kapha doshas*. *Pippali*, *Sunthi*, *Talisa*, *Sukshma ela*, and *Guda* help smooth the functioning of the membrane, which may be due to *Snigdha Guna*. The percentage of relief in **Nasa Srava** was found to be 70.40 %. This data shows statistically high significance with a p-value <0.001. *Amlavetasa*, *Maricha*, *Chavya*, *Chitraka*, *Tvak*, and *Jiraka* have *Ruksha* and, *Tikshna Guna*, & *Ushna veerya* properties because of these properties. The trial drug helps to relieve nasal discharge. Relief in **Nasa Shosha** was found to be 73.33 %. This data shows statistically high significance with a p-value <0.001. Nasal dryness is a symptom mainly caused by *Vata Dosha* imbalance. *Snigdha Guna* & *Vatanulomaka karma* of

*Sukshma Ela*, *Snigdha Guna*, & *Vata-pittaghna Doshakarma* of *Guda*, with the help of these properties of dug, helps to decrease the nasal dryness. The percentage of relief in **Nasa Anaha** was found to be 77.29%. This data is statistically highly significant. *Pramathi Karma* of *Maricha* and *Bhedana Karma* of *Chavya*, *Katu* and *Tikta Rasa* of *Jiraka*, *Tvak* and *Tvak patra* help to open the channels and remove *Srotoavarodha*. From a modern perspective, all the foresaid drugs of *Vyoshadi Gutika* contain anti-inflammatory properties, which alleviate nasal congestion by reducing inflammation.

The percentage of relief in **Galashosha** was found to be 50%. This data is statistically highly significant. As per *Ayurveda*, *Galashosha* refers to the inflammation of throat tissues due to the accumulation of *Pitta* and *Kapha Doshas* in *Gala Pradesha*. Here, the *Tridosha shamaka* and *Shwasa-Kasahara* properties of *Trikatu*, *Chavya*, *Tlisa*, *Amlavetasa*, *Sukshma Ela* and *Twakpatra* and most of these drug contents have anti-inflammatory action, which give relief in the sore throat. The percentage of relief in **Swarabheda** was found to be 56.25%. This data is statistically highly significant. As per *Ayurveda*, *Vata Dosha* leads to *Swarabheda*. *Sunthi* provides relief in *Swarabheda* due to *Laghu*, *Snigdha Guna*, *Katu Rasa*, *Ushna veerya*, *Katu Vipaka*, and *Kapha-Vatashamaka Doshakarma* properties. The percentage of relief in **Shirashoola** was found to be 85.18%. This data is statistically highly significant. Accumulation of vitiated *Dosha* in *Shiraha Pradesha* causes headaches. *Vata* is the main causative factor of pain. Here, *Vatanulomaka* (*Talisa*, *Sukshma Ela*) and *Tridoshahara* properties of *Sukshma Ela* and, from a modern perspective, analgesic properties of *Maricha* and *Sukshma Ela* suppress the pain.

## PROBABLE MODE OF ACTION OF DRUG (AYURVEDIC)

*Pippali*, *Sunthi*, & *Talish* have *Snigdha Guna* & *Ushna Veerya*, *Sukshma Ela*, *Tvak* & *Tvakpatra* have *Vatanulomaka* with the help of these properties. The drug may resolve the *Vata Dosha*. *Tvak* & *Talisa* has *Madhur Tikta Rasa*, and *Guda* & *Sukshma Ela* has

Sheet Veerya. These properties of the drug may help to resolve the Pitta Dosha. Pippali, Sunthi, Chavya, Chitraka, and Tvak have Ushna Veerya, Laghu, Tikshna, Ruksha Guna, and Tikta rasa; with the help of these properties, the drug pacifies the Kapha Dosha and also helps to Rasa and Raktavaha Srotoshodana. Tvak patra, Tvak, Talisa, Chavya, Chitraka, Sunthi, Maricha has Deepan Paachana & Srotoshodana karma may be its due to Laghu Guna, Katu Rasa, Katu Vipaka & Ushna Veerya. Deepan-Paachana helps to Aama digestion. After Tridosha shamana, srothoshodhana, and Aama digestion, Dosha-Dushya comes in Samavastha.

## CONCLUSION

Vyoshadi Gutika provided relief in all symptoms of Pratishyaya. A statistically highly significant result was found in Anaddha Nasa (Nasal obstruction), Tanu srava (Nasal discharge), Kshavathu (Sneezing), Nasa shosha (Nasal dryness), Shirashoola (Headache), Swaropaghata (Hoarseness of voice), & Galashosha (Sore throat), in subjective parameter.

Among objective parameters, such as total leukocyte count (TLC), which showed significant results, neutrophils, basophils, monocytes, and lymphocytes showed non-significant results. Other than that, Eosinophil, Absolute Eosinophil Count (AEC), and Erythrocyte Sedimentation Rate (ESR) showed highly significant results.

The overall effect of the drug was highly significant. Complete improvement was found in 19 patients, marked improvement in 13 patients, Moderate improvement in 3 patients, and the number of patients remaining unchanged was 00.

Evaluating all the study's results, it can be concluded that Vyoshadi Gutika has a highly significant effect on the management of Vataja Pratishyaya. No patient has reported any adverse drug reaction during treatment and follow-up.

**No patient has reported any adverse drug reaction during the treatment and follow-up.**

## RECOMMENDATIONS OF FURTHER STUDIES:

✓ The study should be carried out in a large

sample size with a longer duration to see more accurate results and the recurrence of the disease in follow-ups.

- ✓ Maximum objective parameters and higher investigations, e.g. IgE, skin prick test, nasal smear test, etc., should be incorporated into the study. They would make the study more specific and the judgment of the effect of therapy more accurate.
- ✓ Experimental study to evaluate the effect of the drug on immunoglobins.

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