

## CLINICAL EVALUATION OF AGNIKUMARA RAS IN DUSHTA PRATISHYAYA

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## ABSTRACT

In *Ayurveda*, the disease sinusitis can be co-related with “*Dushta Pratishyaya*” which arises as a complication of the disease “*Pratishyaya*”. A detailed description of *Pratishyaya* has been mentioned in *Sushruta Samhita* (Su. Ut 24/4). While explaining the complication of *Pratishyaya*, *Dushta Pratishyaya* has been mentioned. The features of the disease *Dushta Pratishyaya*, in general, is similar to that of Chronic Sinusitis in modern science. In modern medicine, management of Sinusitis includes Antibiotics, analgesics, Nasal steroids, Nasal Irrigation, Surgery etc. Even then there is no complete cure for Chronic Sinusitis through modern management. Hence to find out a solution through *Ayurveda*, *Agnikumara Ras* has been selected for the present study. *Agni kumara Ras* has been selected from the text *Basavarajeeyam*. It consists of five ingredients- *Shuddha Vatsanabha*, *Maricha*, *Kushta*, *Mustha* and *Vacha*.

**Keywords:** *Dushta Pratishyaya*, *Agnikumara Ras*, Clinical evaluation

## INTRODUCTION

The clinical trial is a set of procedures in medical research and drug development that is conducted to gather data to check the efficacy of a drug or a procedure. Depending on the type of formulation, investigations healthy volunteers or patients are recruited and

prescribed with drug according to a predetermined protocol. Results are interpreted to conclude. *Dushta Pratishyaya* is mainly caused by the involvement of *Vata*, *Pitta*, *Kapha* and *Rakta Dosha*<sup>[1]</sup> *Agnikumara Ras* is mainly considered to be *Vata-Kapha Shamaka*,

Tridoshahara in action. Hence an effort is made to study the effect of Agnikumara Ras on Dushta Pratishyaya.

**Aim and Objectives:**

- To reintroduce effective oral medication for treating Dushta Pratishyaya from classics.
- To ensure safe and efficacious preparation of Agnikumara Ras<sup>[2]</sup>.
- To perform analytical studies on Agnikumara Ras.
- To assess the therapeutic efficacy of Agni Kumara Ras in Dushta Pratishyaya.

**Materials and Methods:**

- The patients having classical symptomatology of Dushta Prathishyaya have been selected from OPD of TTD's S.V. Ayurvedic Hospital, Tirupati, irrespective of Sex, Religion, and Occupation etc.
- A special detailed clinical proforma has been prepared to incorporate selected symptoms and signs based on Ayurvedic Classics. A detailed history has been taken and a complete physical examination has been carried out.

**Criteria for Inclusion of Patient:**

Patients with typical features narrated in the classics under the heading of Dushta Pratishyaya.

**Criteria for Exclusion of Patient:**

- The age group is below 16 years and after 60 years.
- Pregnant women and lactating women.
- Chronic debilitating infectious disease.
- Surgical diseases e.g.: DNS, Polyp etc.

**Investigations:** Absolute eosinophil count.

**Posology:**

- **Internal therapy:** Agnikumara Ras
- **Dose:** 125mg
- **Kala:** Twice a day after meals
- **Anupana:** Ardraka Swarasa
- **Duration:** 45 days

**Diet & Regimen:**

**Pathya:** Yava, Laghu Ushna Ahara

**Apathya:** Guru Madhura Ahara, Sita Ahara Sevana, Nava Madhya, Sitambu, Shoka.

**Advice is given to the patient:**

- Patients were strictly advised to follow the diet restrictions.
- Avoid sleep during the daytime.
- Put warm, wet towels on the face 3 to 4 times a day.

**Follow-up:** All the patients were reviewed after every 15<sup>th</sup> day for a total period of 45 days.

**Diagnostic Criteria:**

- Patients were examined clinically and details regarding disease starting from history taking, physical examination, signs and symptoms as mentioned in our classics and allied sciences were recorded in a specially prepared Clinical Proforma. This was prepared, based on Inclusive criteria.
- Informed consent of all the registered subjects was taken before starting the interventions. The patients were assessed clinically before and after treatment.

**Criteria for Assessment:**

**General parameters:**

A general assessment of patients is carried out based on various parameters like age, education, sex, location, religion, marital status, occupation etc.

**Subjective Parameters:**

- Criteria of assessment were kept based on relief in the sign and symptoms of Dushta Pratishyaya before and after the treatment. For this purpose, cardinal signs and symptoms were given scores.

<b>Nasa srava (Nasal discharge)</b>	<b>Grade</b>
No discharge	0
Occasional	1
Frequent	2
Continuous heavy	3
<b>Agandha (Loss of smell)</b>	<b>Grade</b>
No loss of smell	0
Partial and unilateral	1
Partial and bilateral	2
Total loss of smell	3
<b>Shirashoola (headache)</b>	<b>Grade</b>
No headache	0
Occasionally with low intensity	1
Frequently with moderate intensity	2
Always with severe intensity	3

<b>Shirogurutwa (heaviness of head)</b>	<b>Grade</b>	>16 times/day	3
No heaviness	0	<b>Objective assessment:</b>	
Occasionally with low intensity	1	<b>Absolute Eosinophilic count</b>	<b>Grade</b>
Frequently with low intensity	2	Normal Count (0-6%)	0
Always with severe intensity	3	Count between 7-15%	1
<b>Mukha Daurgandhya (Halitosis)</b>	<b>Grade</b>	Count between 16-50%	2
No halitosis	0	Count 50% above	3
Occasionally bad smell in mouth	1	Statistical analysis was done with the help of a student	
Frequent bad smell in mouth	2	"t" test; based on this scoring pattern before starting	
Continuous bad smell in mouth	3	the treatment and after a course of treatment.	
<b>Kshavathu (sneezing)</b>	<b>Grade</b>	<b>Criteria for the overall effect of therapy:</b>	
No sneezing	0	The total effect of the therapy was assessed considering	
Occasionally <5/day	1	the following criteria.	
5-15times/day	2		

**Table 1:** Showing assessment on basis of percentage of relief obtained by the therapy

S. No	Effect	Percentage of relief
1.	Marked Improvement	76%-100%
2.	Moderate Improvement	51%-75%
3.	Mild Improvement	26%-50%
4.	No improvement	<25%

### Statistical Evaluation of results:

The obtained information was analysed statistically in terms of the mean score(x), Standard Deviation (S.D), Standard Error (S.E). Paired t-test was carried out at the level of 0.05, 0.01 and 0.001 of p levels. For the more effectiveness of therapy paired t-Test is carried out. The results were interpreted as

- Insignificant:  $p > 0.05$
- Significant:  $p < 0.05$
- Highly significant:  $p < 0.01, p < 0.001$
- Extremely significant:  $p < 0.0001$

Statistical analysis was carried out using “**Analysis tool pack Add-in of Microsoft Excel -2019**” and “**Graph pad Prism Version-7**” by applying Paired 't-Test.

### Presentation of data:

The data collected & analysed has been depicted in the following sequence:

1. General observations viz. age, religion, *desha* etc.
2. Result of therapy evaluated on the basis of improvement in symptomatology and laboratory investigations.

### Observations and Results:

A total of 30 patients were registered and had completed the treatment. In the present study maximum number of patients i.e., 14 (47%) were between 31-45 years age group, followed by 9 patients (30%) between 15-30 years age group, 7 patients (23%) were between 46-60 years age group and a maximum number of patients i.e., 16 (53%) were female and rest of the patients i.e., 14(47%) were male. *Nasasrava* and *Shirogurutwa* were observed in all patients i.e 100% followed by *Shiroruk* and *kshavathu* in 20 patients (86.6%), *Dourgandhya* in 12 patients i.e., 40% and *Agandha* in 15 patients i.e 50%. 25 patients (83.3%) had abnormal Absolute eosinophil count values. In the present study, *Agnikumara Ras* showed statistically Extremely significant relief ( $P < 0.0001$ ) in *Nasasrava*, *Shirogurutwa*, *Shiroruk*, *Kshavathu*, *Dourgandhya* and *Agandha*.

**Table 2:**

Cardinal symptoms	Number of Patients	% Of Distribution
<i>Nasasrava</i>	30	100%
<i>Shirogurutwa</i>	30	100%
<i>Shiroruk</i>	20	86.6%
<i>Kshavathu</i>	20	86.6%
<i>Daurgandhya</i>	12	40%
<i>Agandha</i>	15	50%

*Agnikumara Ras* showed maximum relief in *Kshavathu* (84.90%) followed by *Nasasrava* (83.09%), *Shiroruk* (80%), *Shirogurutwa* (75%), *Agandha* (75%) and *Daurgandhya* (68.6%). In the

present study, *Agnikumara Ras* showed Statistically Extremely significant improvement with 60.14% ( $P < 0.0001$ ) in Absolute Eosinophilic count.

**Table 3:**

Parameters	n	Mean		Mean Difference	Relief %	SD		SE		t Value	p-Value
		B. T	A. T			B. T	A. T	B. T	A. T		
<i>Nasasrava</i>	30	2.13	0.37	1.77	83.09	0.78	0.76	0.14	0.14	13.2930	<0.0001
<i>Shirogurutwa</i>	30	2.07	0.47	1.61	77.77	0.69	0.51	0.13	0.09	11.3793	<0.0001
<i>Shiroruk</i>	20	1.37	0.27	1.10	80	1.19	0.45	0.22	0.08	6.80	<0.0001
<i>Kshavathu</i>	20	1.53	0.23	1.30	84.9	1.25	0.43	0.23	0.08	6.966	<0.0001
<i>Daurgandhya</i>	12	0.83	0.27	0.57	68.6	1.12	0.45	0.20	0.08	4.010	<0.0001
<i>Agandha</i>	15	1.10	0.27	0.83	75	1.21	0.45	0.22	0.08	5.000	<0.0001

**Table 4:**

Parameters	n-	Mean		Mean difference	% Relief	S. D		S. E		t value	p-value
		B. T	A. T			BT	AT	BT	AT		
Eosinophilic count	26	2.52	1.32	1.2	60.14	0.51	0.71	0.14	0.14	6.82	<0.0001

From this observation, it is clear that the patients who are treated with *Agnikumara Ras* have shown favourable responses regarding the clinical parameters of *Dushta prathishyaya*.

## DISCUSSION

### Subjective Parameters

**Effect on *Nasasrava*:** All the 30 patients were having *Nasasrava* with the mean initial score of 2.13 which was reduced to 0.36 after the treatment. The improvement is statistically extremely significant 83.09% ( $p < 0.0001$ ). It is known that *Nasasrava* occurs due to *Kapha dosha*. The significant relief in *Nasasrava* may be due to the *Vata-Kapha Shamaka* property of *Vatsanabha*, *Maricha*, *Kushta* and *Vacha*.

**Effect on *Shirogurutwa*:** All the 30 patients were

having *Shirogurutwa* with the mean initial score of 2.07 which was reduced to 0.46 after the treatment. Statistically, this improvement is extremely significant 77.77% ( $p < 0.0001$ ). It is known that *Shirogurutwa* occurs due to *Kapha dosha*. The significant relief in *Shirogurutwa* may be due to the *Vata-Kapha Shamaka* property of *Vatsanabha*, *Maricha*, *Mustha*, *Kushta* and *Vacha*.

**Effect on *Shiroruk*:** Among 30 patients, 20 patients were suffering from *Shiroruk* with the mean initial score of 1.37 which was reduced to 0.27 after the treatment. This improvement is statistically extremely significant 80% ( $p < 0.0001$ ). It is known that *Shiroruk* occurs due to *Tridosha* and *Rakta*. The significant relief in *Shiroruk* may be due to the *vedanasthapana* property of *Kushta*, *Vatsanabha* and *Shoola Prasamana*

property of *Vacha*.

**Effect on *Kshavathu*:** Among 30 patients, 20 patients were having *Kshavathu* with the mean initial score of 1.53 which was reduced to 0.23 after the treatment. Statistically, this improvement is extremely significant 84.9% ( $p < 0.0001$ ). It is known that *Kshavathu* occurs due to *Vata* and *Kapha dosha*. The significant relief in *Kshavathu* may be due to the *vata-kapha shamaka* properties of *Maricha*, *Vacha*, *Kushta*.

**Effect on *Dourgandhya*:** Among 30 patients, 12 patients were having *Dourgandhya* with the mean initial score of 0.83 which was reduced to 0.27 after the treatment. This improvement is statistically extremely significant 68.6% ( $p < 0.0001$ ). It is known that *Dourgandhya* occurs due to *Tridosha* mainly *Pitta dosha*. The significant relief in *Dourgandhya* may be due to the *seeta Veerya of Mustha*, *durgandha nashaka* property of *Kushta*, *madhura vipaka* and *Tridoshagna*

property of *Vatsanabha*.

**Effect on *Agandha*:** In this study among 30 patients, 15 patients were having *Agandha* with the mean initial score of 1.10 which was reduced to 0.27 after the treatment. This improvement is statistically extremely significant 75% ( $p < 0.0001$ ). It is known that *Agandha* occurs due to *Vata dosha*. The significant relief in *Agandha* may be due to the *Vata Kapha Samaka* property of *Vatsanabha*, *Mustha* and *Maricha*.

**Objective Parameter:** Among 30 patients, 25 patients were having abnormal Absolute eosinophil values with the mean initial score of 2.52 which was reduced to 1.32 after the treatment. This improvement is statistically extremely significant 60.14% ( $P < 0.0001$ ).

**Overall assessment of *Agnikumara Ras*:** *Agnikumara Ras* had shown marked improvement in 10 patients, moderate improvement in 17 patients and mild improvement in 3 patients.

**Table 5:**

Result	Number of Patients	% Patients
Marked Improvement	10	33%
Moderate Improvement	17	57%
Mild Improvement	3	10%
No improvement	0	0%

**Probable mode of action of drug:** *Acharya Charaka* has mentioned that the drugs show their actions due to their five properties viz. *Rasa*, *Guna*, *Viry*, *Vipaka* and *Karma*. The action of a compound formulation is decided by the action of a major ingredient or by the synergistic action of all the ingredients. The actions of ingredients of *Agnikumara Ras* are as follows:

**Table 6:** Showing *Rasa Panchaka* of *Agnikumara Ras*

Ingredient	Rasa	Guna	Viry	Vipaka	Karma	Biological Action
<i>Vatsanabha</i>	<i>Madhura</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Vedanasthapana, sothahara, swedajanaka, deepana, pachana</i>	Anti-inflammatory, Analgesic, Diaphoretic <sup>[3]</sup>
<i>Maricha</i>	<i>Katu</i>	<i>Ruksha, tikshna, laghu</i>	<i>Ushna</i>	<i>Katu</i>	<i>Deepana, Sulahara, Swedajanaka, Grahi, Krimighna, Lekhana</i>	Antioxidant, Anti-inflammatory, Analgesic, anti-microbial <sup>[4]</sup>
<i>Mustha</i>	<i>Tikta, Katu, Kashaya</i>	<i>Laghu, ruksha</i>	<i>Sita</i>	<i>Katu</i>	<i>Kaphaghna, deepana pachana, grahi, krimighna, lekhana</i>	Anti-bacterial, Anti-inflammatory, Antipyretic <sup>[5]</sup>
<i>Kushta</i>	<i>Tikta, Katu, Madhura</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>	<i>Vedanasthapana, Durgandhga nashana, deepana, pachana, Sulahara, kaphaghna</i>	Anti-inflammatory, Anti-bacterial <sup>[6]</sup> , immunomodulatory

Vacha	Katu, tikta	Laghu, ruksha, tikshna	Ushna	Katu	Vedanasthapana, Sothahara, krimighna, lekhana, deepana	Analgesic, anti-inflammatory, anti-microbial, anti-bacterial [7]
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- Based on this, the probable *Rasa Panchaka* for Agnikumara Ras is

*Rasa: Katu, tikta Guna: Laghu, Ruksha, Tikshna. Virya: Ushna Vipaka: Katu, Karma: Kaphavata shamaka, Sulaprashamana, Lekhana, Krimighna, Deepana*

**Properties of Agnikumara Ras:** *Katu rasa* is *chedaka, marga vivaraka and kapha shamaka*. *Tikta rasa* is *vishaghna, lekhana, amapachaka, sroto mukha vishodhaka*. *Tikta* and *katu rasa* have *laghu, ushna* and *tikshna* properties, which are very useful for *ama pachana*. These also have *deepana* and *pachana* properties, which help in, restoration of *agni*, removal of excessive *kledaka kapha*. *Laghu, ruksha* and *tikshna guna* are *kapha Shamaka*. *Ushna virya* is *kaphavata Shamaka*. *Katu vipaka* is *laghu* and *kaphaghna*. *Shulaghna* relieves pain and *sothahara* relieves inflammation. The components of *Agnikumara Ras* help in *Samprapti Vighatana* by acting on causative factors of *Dushta Pratishyaya*.

## CONCLUSION

*Agnikumara Ras* showed statistically extremely significant relief in subjective parameters like *Nasavrava, Shirashoola, Kshavathu, Shirogurutwa, Agandha, Dourgandhya* and objective parameter like absolute eosinophil count. No complications or side effects were seen in the patients during or after the treatment. Hence *Agnikumara Ras* proved to be a beneficial drug in the management of *Dushta Pratishyaya*.

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