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A CLINICAL STUDY TO EVALUATE THE EFFECT OF VYAGHRI TAILA NASYA IN THE MANAGEMENT OF DUSHTA PRATISHYAYA W.S.R. TO CHRONIC SINUSITIS

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ABSTRACT

Background: *Dushta Pratishyaya* is described in Ayurvedic classics as a chronic and complicated form of *Pratishyaya*, which may be clinically correlated with Chronic Sinusitis. Chronic Sinusitis is characterized by persistent inflammation of the nose and paranasal sinuses, presenting with nasal obstruction, nasal discharge, sneezing, headache, post-nasal discharge and impaired sense of smell. *Nasya Karma* is an important therapeutic procedure for *Urdhvajatrugata Vyadhi*. **Aim and Objectives:** To evaluate the clinical efficacy and safety of *Vyaghri Taila Nasya* in the management of *Dushta Pratishyaya w.s.r. to Chronic Sinusitis*. **Materials and Methods:** A single-arm clinical study was conducted on 10 patients diagnosed with *Dushta Pratishyaya w.s.r. to Chronic Sinusitis* according to Ayurvedic and contemporary diagnostic criteria. Patients above 12 years of either gender were selected from the Department of Shalakya Tantra, R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Kangra, H.P. *Vyaghri Taila Nasya* was administered for 30 days as per the prescribed protocol. Clinical assessment was performed before and after treatment, with follow-up on

the 15th and 30th days. **Observations and Results:** Improvement was observed in clinical features including nasal obstruction, nasal discharge, sneezing, headache and post-nasal discharge, with reduction in associated sinonasal symptoms. No significant adverse effects were observed. **Conclusion:** *Vyaghri Taila Nasya* showed beneficial effects in the management of *Dushta Pratishyaya*. Larger controlled clinical studies are required to establish its efficacy conclusively.

KEYWORDS: *Dushta Pratishyaya*, Chronic Sinusitis, *Vyaghri Taila*, *Nasya Karma*, Ayurveda.

INTRODUCTION

The nose is an important organ of the respiratory system and plays a vital role in respiration, olfaction, humidification, filtration and regulation of inspired air. The paranasal sinuses, together with the nasal cavity, form an important part of the upper respiratory tract and contribute to the conditioning of inspired air, resonance of voice and mucociliary clearance[1] Disorders affecting the nose and paranasal sinuses are therefore associated with considerable morbidity and may adversely affect the quality of life.

Chronic inflammatory disorders of the nose and paranasal sinuses are common clinical conditions encountered in otorhinolaryngological practice. Chronic Sinusitis is characterized by persistent inflammation of the sinonasal mucosa and may manifest with symptoms such as nasal obstruction, nasal discharge, post-nasal discharge, headache or facial pressure, sneezing and impairment of the sense of smell.[2] The chronic and recurrent nature of the disease, along with its impact on daily activities and quality of life, makes its effective management an important clinical concern.[3]

In contemporary medicine, the management of Chronic Sinusitis includes pharmacological measures such as saline irrigation, intranasal corticosteroids, decongestants and, in selected cases, antimicrobial therapy. Surgical intervention may be considered in patients with persistent symptoms, anatomical obstruction or disease refractory to appropriate medical management.[4] However, prolonged or inappropriate use of certain conventional medications may be associated with limitations and adverse effects. This has encouraged increasing interest in complementary and traditional therapeutic approaches that may provide symptomatic relief with an acceptable safety profile.[5]

Ayurveda gives considerable importance to diseases affecting the *Urdhvajatru* region. The concept of *Pratishyaya* is described in detail in the classical Ayurvedic texts, with various clinical manifestations depending upon the predominance of *Dosha*. When the condition becomes chronic, neglected or improperly managed, it may progress to a complicated form referred to as *Dushta Pratishyaya.*[6] The clinical features described under *Dushta Pratishyaya*, including persistent nasal discharge, obstruction, headache, sneezing, alteration of smell and other associated manifestations, show clinical resemblance to the features observed in Chronic Sinusitis.[7]

The pathogenesis of *Dushta Pratishyaya* can be understood in terms of vitiation of *Dosha*, particularly *Vata* and *Kapha*, along with impairment of normal functioning of the nasal passages. Chronicity and improper management may further lead to persistence of *Dosha* and obstruction of the normal channels, resulting in recurrent or prolonged symptoms. Thus, treatment aimed at restoring the normal physiological functioning of the nasal passages and eliminating accumulated *Dosha* assumes particular importance.[8]

Among the therapeutic procedures described in Ayurveda, *Nasya Karma* holds a prominent position in the management of diseases affecting the region above the clavicle. The nasal route is considered an important route for administering medicines in *Urdhvajatru* disorders[6]. Administration of medicated oil through the nasal passages may help in alleviating aggravated *Dosha*, clearing obstruction and maintaining the normal function of the nasal and paranasal structures. Therefore, *Nasya Karma* may have particular therapeutic relevance in chronic sinonasal disorders.[9]

Vyaghri Taila is an Ayurvedic medicated oil traditionally indicated in disorders involving the respiratory and upper airway region. Its constituent drugs possess properties that may be beneficial in disorders associated with *Kapha* accumulation, obstruction and inflammation. When administered through *Nasya Karma*, the therapeutic properties of the formulation may act locally as well as through the systemic effects attributed to the nasal route of drug administration. Hence, *Vyaghri Taila Nasya* may provide a rational Ayurvedic approach for the management of chronic sinonasal symptoms.

AIM AND OBJECTIVES

Aim

To evaluate the clinical efficacy of *Vyaghri Taila Nasya* in the management of *Dushta Pratishyaya w.s.r. to Chronic Sinusitis*.

Objectives

To study the conceptual aspects of *Dushta Pratishyaya* with special reference to Chronic Sinusitis from Ayurvedic classical texts and contemporary literature.

PLAN OF STUDY

To fulfil the aims and objectives of the present study, the research work will be carried out under the following two headings:

i.) Conceptual Study

All the relevant Ayurvedic classical texts and contemporary literature related to the disease undertaken for the study will be reviewed in detail. Relevant research papers, journals and other authentic literature available in the department/college library and reliable internet sources will also be referred to. A detailed review of *Dushta Pratishyaya* with special reference to Chronic Sinusitis, including its etiopathogenesis, clinical features, diagnosis and management, will be carried out. The conceptual aspects of *Nasya Karma* and the pharmacological and therapeutic properties of *Vyaghri Taila* will also be reviewed in detail.

ii.) Clinical Study

The clinical study will be carried out on **10 patients** fulfilling the predefined inclusion and diagnostic criteria. Patients will be selected from the OPD/IPD of the Department of *Shalakya Tantra*, Rajiv Gandhi Government Post Graduate Ayurvedic College and Hospital, Paprola, Kangra, Himachal Pradesh. A detailed history will be obtained, general and systemic examinations will be conducted, and relevant investigations will be carried out before enrolment. Complete details of each research case will be recorded in a pre-prepared case proforma.

SELECTION OF DISEASE

The disease was selected on the basis of the following considerations.

1. *Dushta Pratishyaya* is a chronic condition affecting the *Urdhvajatru* region and shows considerable clinical resemblance to Chronic Sinusitis.

2. Chronic Sinusitis is a commonly encountered sinonasal disorder with persistent and recurrent symptoms that may adversely affect the quality of life.
3. Various treatment modalities are available in contemporary medicine, including corticosteroids, antihistamines, antibiotics, decongestants and other supportive measures. However, persistent or recurrent symptoms may occur in some patients, particularly in chronic cases.
4. Therefore, there is a need to explore safe and effective Ayurvedic treatment modalities for the management of chronic sinonasal disorders.
5. *Nasya Karma* is an important therapeutic procedure described in Ayurveda for disorders of the *Urdhvajatru* region. Hence, *Vyaghri Taila Nasya* was selected for the present clinical study to evaluate its therapeutic effect in *Dushta Pratishyaya w.s.r. to Chronic Sinusitis*.

MATERIAL AND METHODS

To fulfil the aims and objectives of the study, the following materials and methods will be used

(a) Selection of Patients

1. Patients will be selected from the OPD/IPD of the Department of *Shalakya Tantra*, Rajiv Gandhi Government P.G. Ayurvedic College and Hospital, Paprola, Kangra (H.P.) 176115.
2. A detailed history will be obtained and relevant clinical examinations and investigations will be carried out before enrolment of the patients.
3. A **minimum sample of 10 patients** will be assessed during the clinical trial.
4. All selected patients will receive ***Vyaghri Taila Nasya*** according to the prescribed therapeutic protocol.

(b) Diagnostic Criteria

The patients will be diagnosed on the basis of Ayurvedic and contemporary parameters. The clinical signs and symptoms described in the classical Ayurvedic texts for *Dushta Pratishyaya* will be considered along with relevant clinical features of Chronic Sinusitis.

INCLUSION CRITERIA

- Patients fulfilling the diagnostic criteria based on the signs and symptoms of *Dushta Pratishyaya* (Chronic Sinusitis) described in Ayurvedic classics and contemporary medical science.
- Patients willing to participate in the study and provide informed consent.

- Patients of either gender.
- Patients above 12 years of age.

EXCLUSION CRITERIA

- Patients unwilling to participate in the trial.
- Patients requiring surgical treatment, such as cases with significant nasal polyposis or other conditions requiring immediate surgical intervention.
- Patients with a history of recurrent/multiple episodes of epistaxis.
- Patients below 12 years of age.
- Patients suffering from serious systemic or debilitating diseases such as uncontrolled Diabetes Mellitus, Carcinoma or Tuberculosis.
- Pregnant and lactating women.

INVESTIGATIONS

The following investigations will be carried out wherever clinically indicated and as per the study protocol

- X-ray PNS – Waters' view.
- Haematological investigations:
  Complete Blood Count (CBC)
  Erythrocyte Sedimentation Rate (ESR)
- Biochemical investigation:
  Fasting Blood Sugar (FBS)

Vyaghri Taila

8 drops to be instilled each nostril in day time for seven days with 3 days interval, in 3 attempts.

Route of administration: Nasal

Duration: 30 days

GROUPING

The selected patients will be assigned to a single group consisting of 10 patients.

FOLLOW UP

Patient will be advised for follow up on 15th day and then at the end of trial.

CRITERIA FOR ASSESSMENT

Assessment of the effect of treatment will be done on subjective and objective criteria of *Dushta Pratishyaya*.

Overall effect of therapy

- Cured: 100% relief in signs and symptoms and no recurrence during the follow-up period
- Marked improvement: 76%–99% relief in signs and symptoms
- Moderate improvement: 51%–75% relief in signs and symptoms
- Mild improvement: 26%–50% relief in signs and symptoms
- Unchanged: Up to 25% reduction in signs and symptoms was noted as unchanged

Clinical Study

Group	Registered Pt.	Completed	Discontinued	Percentage
Vyaghri Taila Nasya Group	10	10	0	100%

Discussion of Demographic and Clinical Findings

The majority of patients (40%) belonged to the 31–40 years age group, followed by 18–30 years (30%) and 41–50 years (20%). Female patients predominated (60%) over males (40%). Rural residents constituted 60% of the study population, while 40% were from urban areas. A vegetarian diet was observed in 60% of patients, whereas 40% followed a mixed diet.

Among the presenting symptoms, *Nasavarodha* (nasal obstruction) was the most common complaint (100%), followed by *Kshavathu* (sneezing) and *Shirahshoola* (headache) in 70% each, and *Nasa Srava* (nasal discharge) in 60% of patients.

Regarding Ayurvedic parameters, *Vata-Kaphaja Prakriti* was predominant (50%), followed by *Vata-Pittaja* (30%) and *Pitta-Kaphaja* (20%). *Madhyama Satva* and *Madhyama Samhanana* were predominant, accounting for 80% each. *Madhyama Vyayama Shakti* was observed in 70% of patients. *Mandagni* was observed in 70% of patients, suggesting a possible association with *Ama* formation and *Kapha* aggravation in *Dushta Pratishyaya*.

RESULT

Subjective Criteria (On B.T./A.T.scale)

S no.	Variable	N	Mean				SD	SE	t	p	Sig
			BT	AT	Diff.	Change in %age					
1.	*Kshavathu*	6	2.67	0.67	2.00	74.91%	0.89	0.37	5.48	0.0028	MS

2.	*Nasavarodha*	10	2.40	0.90	1.50	62.50%	1.18	0.37	4.03	0.003	MS
3.	*Nasa sarva*	6	3.17	1.50	1.67	52.68%	0.82	0.33	4.99	0.004	MS
4.	*Kasa*	3	2.33	1.00	1.33	57.08%	0.58	0.33	4.00	0.057	IS
5.	*Shirahshoola*	6	2.00	0.33	1.67	83.50%	0.82	0.33	5.00	0.004	MS
6.	*Puyabha Satrav*	4	1.75	0.50	1.25	71.43%	0.50	0.25	5.00	0.015	S
7.	*Gandha Agyanata*	2	2.50	1.00	1.50	60.00%	0.71	0.50	3.00	0.205	IS
8.	*Mukha Daurgandhya*	3	2.00	0.33	1.67	83.50%	0.58	0.33	5.00	0.038	S
9.	*Jwara*	2	1.50	0.50	1.00	66.67%	0.00	0.00	NC	NC	IS
10.	*Swarabheda*	2	1.50	0.50	1.00	66.67%	0.00	0.00	NC	NC	IS

1. Effect on *Kshavathu*: Mean score reduced from 2.67 to 0.67, with 74.91% relief (p=0.0028, t=5.48), showing statistically significant improvement.
2. Effect on *Nasavarodha*: Mean score reduced from 2.40 to 0.90, with 62.50% relief (p=0.003, t=4.03), showing statistically significant improvement.
3. Effect on *Nasa Srava*: Mean score reduced from 3.17 to 1.50, with 52.68% relief (p=0.004, t=4.99), showing statistically significant improvement.
4. Effect on *Kasa*: Mean score reduced from 2.33 to 1.00, with 57.08% relief (t=4.00), showing improvement but statistically insignificant (p>0.05).
5. Effect on *Shirahshoola*: Mean score reduced from 2.00 to 0.33, with 83.50% relief (p=0.004, t=5.00), showing statistically significant improvement.
6. Effect on *Puyabha Srava*: Mean score reduced from 1.75 to 0.50, with 71.43% relief (p=0.015, t=5.00), showing statistically significant improvement.
7. Effect on *Gandha Agyanata*: Mean score reduced from 2.50 to 1.00, with 60.00% relief (t=3.00), showing improvement but statistically insignificant (p>0.05).
8. Effect on *Mukha Daurgandhya*: Mean score reduced from 2.00 to 0.33, with 83.50% relief (p=0.038, t=5.00), showing statistically significant improvement.
9. Effect on *Jwara*: Mean score reduced from 1.50 to 0.50, with 66.67% relief; statistical significance could not be calculated.
10. Effect on *Swarabheda*: Mean score reduced from 1.50 to 0.50, with 66.67% relief; statistical significance could not be calculated.

Effect of therapy on radiological investigation of PNS

Paranasal Sinus	Mean		Diff	% of relief	SD	SE	n	t	p
	BT	AT							
Rt. Maxillary Sinus	1.500	0.600	0.900	60%	0.527	0.167	10	5.014	<0.001
Lt. Maxillary	1.500	0.700	0.800	53.33%	0.527	0.167	10	4.000	0.003

Sinus									
Rt. Frontal Sinus	0.500	0.1000	0.400	80%	0.707	0.224	10	2.449	0.037
Lt. Frontal Sinus	0.500	0.1000	0.400	80%	1.080	0.342	10	1.309	0.223

Evaluating the effect of treatment on radiological finding of Paranasal sinuses among the patients in Group B-

Right Maxillary Sinus- Mean score of before treatment was 1.500 which reduced to 0.600 after treatment. Thus 53.33% relief was statistically highly significant at the level of <0.001.

Left Maxillary Sinus- Mean score of before treatment was 1.500 which reduced to 0.700 after treatment. Thus 60% relief was statistically significant at the level of 0.003.

Right Frontal Sinus- Mean score of before treatment was 0.500 which reduced to 0.100 after treatment. Thus 80% relief was statistically significant at the level of 0.037.

Left Frontal Sinus- Mean score of before treatment was 0.500 which reduced to 0.100 after treatment. Thus 80% relief was statistically insignificant at the level of 0.223.

DISCUSSION

Selection of the Problem

The increasing prevalence of upper respiratory tract disorders may be attributed to changing lifestyles, environmental pollution, urbanization, and the growing problem of antimicrobial resistance. *Pratishyaya* is a common upper respiratory tract disorder which, when persistent or inadequately managed, may progress to *Dushta Pratishyaya*, correlating clinically with chronic sinusitis.

Although modern management includes antibiotics, decongestants, and surgical interventions, prolonged or recurrent antibiotic use may contribute to antimicrobial resistance, while surgical management may be associated with complications and increased treatment burden. These limitations highlight the need for safe and effective therapeutic alternatives.

Overall result which was on *Vyaghri Taila Nasya* revealed that-

Complete remission was noted in 1(10%) patients, 5 (50%) were markedly improved, 3 (30%) moderately improved and 1 (10%) were mildly improved.

Therefore, the present study was undertaken to evaluate an Ayurvedic treatment approach aimed at reducing sinonasal pathology, facilitating sinus drainage, and improving the overall clinical condition in patients of *Dushta Pratishyaya* w.s.r. to chronic sinusitis.

CONCLUSION

The conclusions drawn from the present study are summarized as follows:

The clinical features of *Dushta Pratishyaya* described in Ayurvedic classics show considerable resemblance to those of Chronic Sinusitis. Thus, a clinical correlation can be established between *Dushta Pratishyaya* and Chronic Sinusitis.

The treatment administered in the present study was found to be economical, safe, and effective in reducing the major symptoms of the disease, without any reported adverse effects or complications. *Vyaghri Taila Nasya* demonstrated appreciable symptomatic improvement in patients with *Dushta Pratishyaya* and may be considered a safe and useful therapeutic approach for its management in routine clinical practice.

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