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A CLINICAL STUDY TO EVALUATE THE EFFECT OF *VYAGHRI HARITAKI* ORALLY 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 can be clinically correlated with Chronic Sinusitis. It is characterized by persistent symptoms such as nasal obstruction, nasal discharge, sneezing, headache, post-nasal discharge and impaired sense of smell. *Vyaghri Haritaki Avleha* was selected for the present study due to its potential therapeutic role in chronic sinonasal disorders. **Aim and Objectives:** To evaluate the clinical effect and safety of *Vyaghri Haritaki Avleha* in the management of *Dushta Pratishyaya w.s.r. to Chronic Sinusitis*. **Materials and Methods:** A clinical study was conducted on 10 patients fulfilling the diagnostic and inclusion criteria of *Dushta Pratishyaya w.s.r. to Chronic Sinusitis*. Patients were selected from the Department of Shalakya Tantra, Rajiv Gandhi Government Post Graduate Ayurvedic College and Hospital, Paprola, Kangra, Himachal Pradesh. Patients of either gender above 12 years were included. *Vyaghri Haritaki Avleha* was administered orally at a dose of 10 g twice daily with *Mandoshan Dugdha* for 30 days. Follow-up was conducted on the 15th day and at the end of treatment. Assessment was based on subjective and objective parameters. **Observations and Results:** Improvement was observed in the clinical manifestations of *Dushta Pratishyaya*. No adverse reactions were reported during treatment or follow-up. **Conclusion:** *Vyaghri Haritaki Avleha* demonstrated appreciable symptomatic improvement and was found to be safe and well tolerated in patients of *Dushta Pratishyaya w.s.r. to Chronic Sinusitis*.

KEYWORDS: Dushta Pratishyaya, Chronic Sinusitis, Vyaghri Haritaki Avleha, Ayurveda.

INTRODUCTION

Ayurveda provides a systematic understanding of diseases affecting the organs above the clavicle. Acharya Sushruta has described *Pratishyaya* in detail in *Uttaratantra* (Chapter 24), including its etiopathogenesis, types, clinical features, complications, and management.[1]

According to Acharya Sushruta, vitiation of *Kapha, Pitta,* and *Rakta* with abnormal movement of *Udana Vayu* leads to *Pratishyaya*.[2] Improper diet, lifestyle, and inadequate treatment may progress the disease into *Dushta Pratishyaya*.[3] When such a condition is inadequately managed, it progresses into a more severe and chronic form known as *Dushta Pratishyaya*. This advanced stage is difficult to treat and is associated with serious complications such as *Badhirya*, *Andhata* (blindness), and *Ghrananasha* (loss of smell), indicating its grave prognosis.[4]

Ayurvedic Acharyas have described various treatment modalities for *Pratishyaya* based on the stage of the disease, dominance of *Dosha*, strength of the patient, and chronicity of the condition. However, all classical texts unanimously agree that *Dushta Pratishyaya* represents a highly complicated state with poor prognosis if not managed appropriately at an early stage.[5]

From the modern perspective, persistent inflammation of the nasal and sinus mucosa may result in chronic rhinosinusitis. Increasing pollution, allergens, altered lifestyle, and recurrent nasal infections contribute to its growing burden.

Thus, considering the classical description of *Dushta Pratishyaya* and its clinical correlation with chronic rhinosinusitis, its proper understanding and management are essential.

AIMS AND OBJECTIVES

- To evaluate the effect of *Vyaghri Haritaki Avleha* in the management of *Dushta Pratishyaya* w.s.r. to Chronic Sinusitis.
- To assess the clinical safety of *Vyaghri Haritaki Avleha* in the management of *Dushta Pratishyaya* w.s.r. to Chronic Sinusitis.

PLAN OF STUDY

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

i.) Conceptual study

All the concerned Ayurvedic and Modern texts related to the disease undertaken for the trial will be reviewed in detail along with research papers and materials available in the department/college library and internet. The detailed review of the selected drugs from the trial will be done in this study section.

ii.) Clinical study

Clinical study will be carried out on 10 patients fulfilling the inclusion criteria which will be selected from OPD/IPD of Rajiv Gandhi Government Post Graduate Ayurvedic College and Hospital Paprola. Complete description regarding the detail of each research case will be recorded in a pre-prepared proforma.

SELECTION OF DISEASE

1. Availability of patients in good number.

2. Many treatment modalities are explained in Allopathic science like Corticosteroids, Antiallergic drugs, Antibiotics, Nasal decongestants, Inhalers and Antihistamines etc. But none of them are totally effective in curing the disease. Although innumerable preparations are available in modern science, no drug ensures complete relief without any side effects and the chances of recurrence are relatively high. Hence there is a need for more effective and safe treatment modality which is especially beneficial in chronic cases to treat this problem from root level.

MATERIAL AND METHODS

To fulfil the aims and objectives of the study following material and methods will be used-

(a) Selection of patient

1. Patient will be selected from OPD/IPD of Department of *Shalakya tantra* Rajiv Gandhi Government P.G. Ayurvedic College and Hospital Paprola, Kangra (H.P.) 176115. A detailed history will be obtained, physical examination will be conducted and relevant investigations will be carried out before enrollment of the patients.
2. A minimum sample of 30 patients will be assessed during the trial.

(b) Diagnostic criteria

The patients will be diagnosed on the basis of Ayurvedic and modern parameters. Clinical signs and symptoms as described in classical text will be considered for the diagnosis of *Dushta Pratishyaya*.

Inclusion Criteria

- Patients fulfilling the diagnostic criteria based on signs and symptoms of *Dushta Pratishyaya* (Chronic Sinusitis) in *Ayurveda* classics and modern science.
- Patient willing to participate.
- Patient of either gender in the age group above 12 years.

Exclusion criteria

- Patient not willing for the trial.
- Patients requires surgical treatment e.g. cases of nasal polyp.
- Patients with history of multiple episodes of epistaxis.
- Patients below age of 12 years.
- Patient suffering from diseases like Diabetes mellitus, Carcinoma, Tuberculosis.
- Pregnant and lactating women.

Investigations

- "X"-ray PNS waters view.
- Haematological investigations – CBC, ESR
- Biochemical investigation- Fasting Blood Sugar.

DOSE OF DRUG FORMULATON

(A) ***Vyaghri Haritaki***:

10gm BD with *Mandoshan Dugdha*

Route of administration - Oral

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 Haritaki 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

EFFECT OF THERAPY

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

Sr. no.	Variable	N	Mean				SD	SE	t	p	Sig
			BT	AT	Diff.	Change in % age					
1,	*Kshavathu*	7	2.71	1.14	1.57	57.89%	0.53	0.20	7.78	0.00024	HS
2.	*Nasavarodha*	10	2.50	1.10	1.40	56.00%	1.08	0.34	4.11	0.0026	MS
3.	*Nasa srava*	7	3.00	1.43	1.57	52.38%	0.90	0.34	4.62	0.0035	MS
4.	*Kasa*	3	2.33	0.33	2.00	85.84%	1.00	0.58	3.46	0.074	IS
5.	*Shirahshoola*	8	2.13	0.63	1.50	70.42%	0.76	0.27	5.58	0.0008	HS
6.	*Puyabha Satrav*	4	2.00	0.50	1.50	75.00%	0.58	0.29	5.17	0.014	S
7.	*Gandha Agyanata*	2	2.00	1.00	1.00	50.00%	0.00	0.00	-	-	IS
8.	*Mukha Daurgandha*	3	2.00	0.67	1.33	66.50%	0.58	0.33	4.00	0.057	IS
9.	*Jwara*	2	1.00	0.00	1.00	100.00%	0.00	0.00	-	-	IS
10.	*Swarabheda*	3	1.33	0.33	1.00	75.19%	0.00	0.00	-	-	IS

1. ***Kshavathu:*** Mean score reduced from 2.71 to 1.14, with **57.89% relief**, highly significant (p=0.00024).
2. ***Nasavarodha:*** Mean score reduced from 2.50 to 1.10, showing **56.00% relief**, moderately significant (p=0.0026).
3. ***Nasa Srava:*** Mean score reduced from 3.00 to 1.43, with **52.38% relief**, moderately significant (p=0.0035).
4. ***Kasa:*** Mean score reduced from 2.33 to 0.33, showing **85.84% relief**, statistically insignificant (p>0.05).
5. ***Shirahshoola:*** Mean score reduced from 2.13 to 0.63, with **70.42% relief**, highly significant (p=0.0008).
6. ***Puyabha Satrav:*** Mean score reduced from 2.00 to 0.50, showing **75.00% relief**, statistically significant (p=0.014).
7. ***Gandha Agyanata:*** Mean score reduced from 2.00 to 1.00, with **50.00% relief**; statistical significance could not be calculated.
8. ***Mukha Daurgandha:*** Mean score reduced from 2.00 to 0.67, showing **66.50% relief**, statistically insignificant (p>0.05).
9. ***Jwara:*** Mean score reduced from 1.00 to 0.00, showing **100% relief**; statistical significance could not be calculated.
10. ***Swarabheda:*** Mean score reduced from 1.33 to 0.33, with **75.19% 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	1.900	0.800	1.100	57.89%	0.738	0.233	10	4.714	0.001
Lt. Maxillary Sinus	1.500	0.600	0.900	60%	0.527	0.167	10	3.857	0.004
Rt. Frontal Sinus	0.800	0.300	0.500	62.5%	1.135	0.359	4	2.236	0.052
Lt. Frontal Sinus	0.500	0.1000	0.400	80%	0.707	0.224	4	2.449	0.037

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

Right Maxillary Sinus- Mean score of before treatment was 1.900 which reduced to 0.800 after treatment. Thus 57.89% 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 0.600 after treatment. Thus 60% relief was statistically significant at the level of 0.004.

Right Frontal Sinus- Mean score of before treatment was 0.800 which reduced to 0.300 after treatment. Thus 62.5% relief was statistically significant at the level of 0.052.
Left 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.

DISCUSSION

Selection of the Problem

The increasing prevalence of upper respiratory tract disorders is associated with environmental pollution, urbanization, changing dietary and lifestyle patterns, and recurrent infections. *Pratishyaya* is a common nasal disorder which, when persistent or inadequately managed, may progress to *Dushta Pratishyaya*, clinically comparable to chronic sinusitis.

Conventional management includes antibiotics, decongestants, and surgical interventions. Recurrent or prolonged antibiotic use may contribute to antimicrobial resistance, while surgery may not be suitable for all patients. Hence, there is a need for safe and effective therapeutic alternatives.

Therefore, the present study was undertaken to evaluate the efficacy of *Vyaghri Haritaki Avleha* in the management of *Dushta Pratishyaya* w.s.r. to chronic sinusitis.

Justification for Selection of Drug

Ayurvedic literature describes several formulations for the management of *Pratishyaya*. In the present study, *Vyaghri Haritaki Avleha* was selected as an oral formulation because of its *Rogaghna* and *Vyadhikshamatvakara (Rasayana)* properties.

The chronic stage of *Pratishyaya* may be correlated with chronic sinusitis, where persistent inflammation and impaired sinus drainage play important roles. The therapeutic properties of *Vyaghri Haritaki Avleha* may therefore help in reducing symptoms and improving the overall clinical condition.

Observations

Overall, the results of the *Vyaghri Haritaki Avleha* group revealed that

Complete remission was observed in 1 (10%) patient, marked improvement was seen in 3 (30%) patients, moderate improvement in 5 (50%) patients and mild improvement in 1 (10%) patient. No patient remained unchanged.

Adverse reactions

No adverse reactions were reported in any of the patients during the entire study period and follow up.

CONCLUSION

The conclusions drawn from the study are summarized as follows:
The symptomatology of *Dushta Pratishyaya* described in *Ayurveda* resembles that of Chronic Sinusitis. Hence, there exists a correlation between *Dushta Pratishyaya* and Chronic Sinusitis.

In the present study, the treatment administered proved to be economical, safe, and effective without any complications in the management of this disease. Although a wide range of medicines is available in the modern system of medicine, satisfactory results are often not achieved in chronic conditions. *Vyaghri Haritaki Avaleha* provided appreciable

symptomatic relief to the patients without producing any adverse effects and can be effectively used in routine OPD practice.

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