

A CLINICAL STUDY TO EVALUATE THE EFFECT OF *CHITRAKA HARITAKI* AND *HINGWADI TAIL NASYA* IN THE MANAGEMENT OF *DUSHTA PRATISHYAYA* W.S.R. TO CHRONIC SINUSITIS

^{1*}Dr. Manoj Sharma M.S., ²Dr. Vijayant Bhardwaj M.D., PhD., ³Dr. Satish Sharma M.D., PhD. and ⁴Dr. Swati Sharma M.D.(Final year)

¹Asst. Prof. Cum Dy. M.S. Shiva Ayurvedic Medical College & Hospital, Bilaspur HP.

²Sr. Lecturer, P.G. Deptt. of Shalaky Tantra, R. G. Govt. P. G. Ayurvedic College & Hospital Paprola, HP.

³Reader, P.G. Deptt. of Shalaky Tantra, R. G. Govt. P. G. Ayurvedic College & Hospital Paprola, HP.

⁴Research Scholar, P.G. Deptt. of Ras Shastra & Bhaishjya Kalpana, R. G. Govt. P. G. Ayurvedic College & Hospital Paprola, HP.

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***Corresponding Author**

Dr. Manoj Sharma

Asst. Prof. Cum Dy. M.S.
Shiva Ayurvedic Medical
College & Hospital, Bilaspur
HP.

ABSTRACT

Dushta Pratishyaya is explained in *Ayurvedic* system of medicine as on & off discharge from nose, stuffy nose, smelly breathe, absence of sense of smell etc. which are comparable to chronic sinusitis in modern system of medicine. The aim of clinical study was to evaluate the combined efficacy of *Chitraka Haritaki* & *Hingwadi Tail Nasya* and prevention of initial development of the disease along with exploration of ways to improve quality of life. Retained discharge should be drained out from the sinuses. As only local treatment is not enough to treat the disease, oral drug is also necessary which helps to remove the pathology and also improve the immune status of the patient. This

clinical study has been done with *Chitrak Haritaki* 10 gm B.D. with Luke warm water for 4 weeks and *Hingwadi Tail Nasya* 6 drops in each nostril every morning for 14 days in 2 cycles with seven days interval, which enhanced the pathogenesis of *Dushta Pratishyaya*. In total, 15 patients were eligible for inclusion in this analysis, out of which 60% markedly improved & 40% were moderately improved on subjective criterion and 20% were cured, 26.66% were moderately improved & 53.33% were slightly improved based on objective criterion. Non-

significant results in fever and on haematological values. No adverse effect of medicines was reported.

KEYWORDS: *Dushta Pratishyaya*, Sinusitis, *Chitraka Haritaki* and *Hingwadi Tail*.

INTRODUCTION

Ayurveda is time tested science with holistic principles of management. Principles laid down by our ancient 'Maharishies' are eternal as made up through thorough investigations and logics.

Around 134 million Indians suffer from chronic sinusitis which means 1 in every 8 is being suffered (*Times of India*).^[1] This disease is characterized by major and minor clinical features. Facial pain, nasal obstruction & post nasal discharge are included in major and headache, fever, halitosis, dental pain, fatigue, cough & ear pain are included in minor.^[2] Rhinosinusitis lasting longer than 12 weeks is classified as Chronic.^[3] Sinus infection lasting for months or year is called Chronic sinusitis.^[4] Once sinus is infected, improper management and dietary habits lead the disease into a chronic phase this chronic sinusitis is too difficult to drain out completely. It remains as a focus for infections and inflammations in all associated structures like tonsil, ear, pharynx, larynx etc. Finally it may lead to many complications like otitis media, rheumatic heart disease, poly arthritis etc. These symptoms can impact all activities (work, leisure and sleep) of C.S. (Chronic Sinusitis) patients. There is loss in worker productivity related to rhinosinusitis.^[5]

In modern medical system a wide range of antibiotics and decongestants are available. But these drugs have nothing to do with such a chronic condition. Antral puncture and antral irrigation is the commonest intervention, FESS (Functional Endoscopic Sinus Surgery), Caldwell-Luc operation, Haworth's operation etc.^[6] are the chief operative procedures to drain the sinus if conservative measures fail. All these costly surgical procedures will lead a lot of complications ranging from bleeding, oro-antral fistula, infra orbital anaesthesia leads to neuralgia and paraesthesia.

In *Ayurveda* a detailed description of *nasa roga* is available, *Dushta Pratishyaya* is mentioned in *Brihatrayi* (*Charaka Samhita* 26/11^[7], *Sushruta Samhita Utt.* 24/14-15^[8] & *Ashtanga Hridaya utt.* 19/10-12^[9]), *Madhava Nidana*^[10], *Yog Ratnakara*^[11] and *Bhava Prakasha*.^[12] *Dushta Pratishyaya* is described as the complication after *pratishyaya* if not

treated. All and lot of treatment modalities are also explained by *Acharya* for this disease according to condition of patient and progression of disease. For this clinical study two formulations were selected as *Chitraka Haritaki Avleha*^[13] for oral use & *Hingwadi Tail*^[14] for *Nasya karma*.

AIM

In general, clinical studies are designed to add to medical knowledge related to the treatment, diagnosis & prevention of diseases or conditions. Aims of study are as follows:

1. Clinical evaluation of combined therapy of *Chitraka Haritaki* orally and *Hingwadi tail nasya* on sinusitis
2. Finding ways to prevent the initial development or recurrence of a *Dushta Pratishtyaya*.
3. Exploring and measuring ways to improve the comfort and quality of life through supportive care for people with a chronic illness.

MATERIAL AND METHODS

Study Design

Open uncontrolled Study conducted in the E.N.T. Head & Neck O.P.D. of P.G. Department of *Shalaky Tantra*, Rajeev Gandhi Govt. P.G. Ayurvedic College & Hospital Paprola, Distt. Kangra, H.P.

Inclusion criteria

Fifteen patients of either sex in the age group of 10 to 65 years were enrolled in the study. A written informed consent was obtained from all these patients. All included patients had any of these clinical symptoms- facial pressure/pain, post nasal drip, headache, congestion/stuffy nose, nasal discharge, pain in upper teeth and sense of smell.

Exclusion Criteria

Patients with established Diabetes, Tuberculosis, Hypertension, Malignancy underwent and who need surgical intervention (e.g. polyp etc.) were excluded from the study.

Drug review

Drug *Chitraka Haritaki* (*Bhaishjya Ratnavali Nasa Roga*) contains *Plumbago zeylanica* Linn, *Emblica officinalis* Gaertn., *Tinospora cordifolia* Willd miers, *Aegle marmelos* Corr, *Premna mucronata* Roxb., *Oroxylum indicum* Vent., *Gmelina arborea* Linn., *Stereospermum suaveolens* DC., *Desmodium gangeticum* DC., *Uraria picta* Desv., *Tribulus terrestris* Linn.,

Solanum indicum Linn., *Solanum surattense* Burm., *Terminalia chebula* Retz., *Zingiber officinale* Roxb., *Piper nigrum* Linn., *Piper longum* Linn., *Cinnamomum zeylanicum* Breyn., *Elettaria cardamomum* Maton., *Cinnamomum tamala* Eberm. *Hordeum vulgare* Linn., Jaggery and honey as ingredients. Method of preparation for *Chitraka Haritaki Avleha* was adopted as in *Ayurvedic Formulary of India (A.F.I. part I)*.^[15]

The contents of *Hingwadi Tail (Yog Ratnakara Nasa roga)* are *Ferula narthex* Boiss., *Zingiber officinale* Roxb., *Piper nigrum* Linn., *Piper longum* Linn., *Embelia ribes* Burm., *Myrica esculata* Buch-Ham, *Acorus calamus* Linn., *Saussurea lappa* C.B. Clarke, *Elettaria cardamomum* Maton, *Laccifer laca* Kerr, *Boerhavia diffusa* Linn., *Cyperus rotundus* Linn., *Hollarhena antidysenterica* Linn., *Ocimum sanctum* Linn., *Brassica compestris* oil, cow urine. The drug has been prepared as per *Tail paka* procedure for *nasya*. *Sarshapa tail murchhana* done as per *Ayurved Sar Sangraha*.^[16]

Pratishyaya is a *Vata-kapha* predominant *Tridoshaja* disease in which *kapha etc dosha* show movement towards nose under the influence of *vata dosha*.

Study procedure

At the randomized visit, a detailed medical history was obtained from all the enrolled patients. Subsequently, all the patients a thorough systemic clinical examination, along with the routine biochemical investigations (Hb., T.L.C., D.L.C., E.S.R. & F.B.S.) and radiological analysis (X-ray PNS water's view^[17]). All the patients underwent, at baseline & at the end of study. All the enrolled patients were taken in single group.

The patients were advised to consume the medicines as follows.

Chitraka Haritaki 10 gm twice a day for 4 weeks with hot water & *Hingwadi Tail Nasya* - 6 drops in each nostril every morning for 7 days. 2 cycles of *nasya* (7 days interval).

Monitoring and follow-up

All the patients were monitored at two weeks interval for clinical assessment as per subjective and objective criteria. All the patients underwent with biochemical investigation and radiological analysis at the end of clinical study.

All the patients were assessed for the following parameters.

Subjective parameters- Facial pressure/pain, post nasal drip, headache, congestion/stuffy nose, nasal discharge, pain in upper teeth and sense of smell.

Objective parameters- Haziness in X-ray P.N.S.(water's view).

Response to treatment was evaluated on a predefined symptom score scale, from 0 to 3 (3, maximum; 0, nil) for the clinical features and radiological investigation mentioned.

Assessment of effect of therapy: The effect of the therapy was assessed in terms of cured, moderately improved, improved and unchanged.

The details are as follows

- 1. Cured:** 100% relief from all signs & symptoms was considered as totally cured.
- 2. Markedly improved:** 76% to 99.99% relief from the signs & Symptoms was considered as markedly improved.
- 3. Moderately improved:** 51% to 75.99% relief from the signs & Symptoms was considered as moderately improved.
- 4. Improved:** 26% to 50.99% relief from the signs & Symptoms was considered as improved.
- 5. Unchanged:** Less than 26% or no relief from the signs & Symptoms was considered as unchanged.

Statistical analysis

Statistical analysis was done accordance to intent-to-treat principles. Baseline comparison for subjective and objective criteria was done by using paired *t* test in terms of B.T.(Before Treatment), A.T. (After Treatment), X (B.T.-A.T.), S.D. (Standard Deviation), S.E. (Standard Error). Paired *t* test was carried out at the level of $p<0.05$ and $p<0.001$. The efficacy of *Chitraka Haritaki & Hingwadi Taila Nasya* was studied in 15 patients on various parameters and results were derived after execution of statistical methodology.

OBSERVATION AND RESULTS

In the present study of 15 patients, incidences of signs and symptoms were follow as headache in 100%, congestion or stuffy nose in 93.33%, facial pains in 86.66%, nasal discharge in 86.66%, pain in upper teeth in 73.33%, post nasal discharge in 66.66%, sense of smell was altered in 53.33%, bad breathe in 40% and fever in 26% of the patients under trial.

The effect of therapy on subjective & objective criteria assessed has been presented as under:

A. Subjective criterion: (on B.T./A.T. scale)

(After completion of trial i.e. after four weeks)

Sr. No.	Signs and Symptoms	N	Mean		X (d) BT-AT	%age relief	SD ±	SE ±	t	P
			BT	AT						
1.	Facial pressure or pain	13	1.61	0.38	1.23	76.22	0.44	0.12	10.12	<0.001
2.	Post nasal drip	10	1.30	0.20	1.10	84.61	0.74	0.23	4.71	=0.001
3.	Headache	15	2.07	0.80	1.27	61.29	0.70	0.18	6.97	<0.001
4.	Congestion or stuffy nose	14	1.93	0.43	1.50	77.76	0.85	0.23	6.56	<0.001
5.	Nasal discharge	13	1.69	0.31	1.38	81.85	0.77	0.21	6.50	<0.001
6.	Fever	4	1.00	0.25	0.75	75	0.50	0.25	3.00	=0.058
7.	Bad breath	6	1.83	0.33	1.50	81.83	0.55	0.22	6.71	<0.001
8.	Pain in upper teeth	11	1.27	0.18	1.09	85.70	0.30	0.09	12.00	<0.001
9.	Sense of smell	8	1.62	0.12	1.50	92.30	0.76	0.27	5.61	<0.001

B. Objective criterion.

Sr. No.	X Ray Findings (Involvement of sinuses)	n	Mean		X (d) BT-AT	%age Change	SD ±	SE ±	t	p
			BT	AT						
1.	Haziness of sinuses	15	2.73	1.33	1.40	51.22	0.51	0.13	10.69	<0.001

X-ray P.N.S. w/v: The initial mean score of haziness in maxillary sinus was 2.73 B.T., which was reduced to 1.33 after treatment. The percentage relief was 51.22% which is highly significant at the level of $p < 0.001$ ($t = 10.69$).

Effect of therapy on haematological values

Sr. No.	Haematological Findings	n	Mean		X (d) BT-AT	%age Change	SD ±	SE ±	t	P
			BT	AT						
1.	Hb.	15	12.25	12.27	0.02	0.16	0.76	0.20	0.14	0.90
2.	T.L.C.	15	6433.33	6473.33	40.00	0.61	1226.96	316.80	0.13	0.90
3.	E.S.R.	15	12.00	14.44	2.4	16.62	7.87	2.03	1.18	0.26
4.	F.B.S.	15	90.73	88.27	2.46	2.71	14.95	3.86	0.64	0.53

RESULTS

Overall effect of treatment on 15 patients under clinical study.

Sr. No.	Assessment	No. of Patients (Subjective criteria)	%age	No. of Patients (Objective criteria)	%age
1.	Cured	0	00	3	20
2.	Markedly Improved	9	60	0	00
3.	Moderately Improved	6	40	4	26.66
4.	Slightly Improved	0	00	8	53.33
5.	Unimproved	0	00	0	00

In total, out of 15 patients as per subjective criteria, 60% patients were markedly improved, and remaining 40% were moderately improved.

On the basis of objective criteria, out of 15 patients 53.33% patients were slightly improved, 26.66% patients were moderately improved and 20% patients were cured.

DISCUSSION

Probable mode of action of drug

The drug formulations *Chitraka Haritaki (B.R. Nasa Roga)* and *Hingwadi Taila (Y.R. Nasa Roga)* were selected with their valid classical reference which is described in context of *chikitsa* of *Dushta Pratishyaya*.

Pratishyaya is a *Vata-kapha* predominant *Tridoshaja* disease in which *kapha etc dosha* show movement towards nose under the influence of *vata dosha*.

The trial drug ***Chitraka Haritaki*** is having *Tikta, Madhura rasa* (26.92% each) predominance followed by *katu rasa* (23.07%). The rest of indices there is predominance of *laghu guna* (28.07%), *ushana veerya* (69.56%), *madhura vipaka* (56.53%) and *vata-kaphashamaka* properties^[18] which are counteracting the *samprapti* (pathogenesis) of *dushta pratishyaya*.

The drug *Chitraka Haritaki* is having *tikta & madhura rasa* predominance. *Tikta rasa* as per *Ch.Su.26* has been credited with *krimighana & jwaraghna* properties which help to reduce infection & fever respectively. In the same context *lekhana, shleshma-upshoshana* etc. properties help to reduce *kapha* i.e. discharge in the sinuses. The *madhura rasa* being *marutaghana* helps to reduce excessive discharge tendency. Similarly *madhura vipaka* acts. Third dominant *rasa* is *katu* i.e. 23.07% having properties like *ghranam asravayati, shwayathu anupahanti, krimi hinasti, marga vivrinoti* as per *Ch.Su.26* helps a lot in reduction of signs & symptoms of chronic sinusitis, which will be discussed under following mode of action of *Hingwadi tail*. The dominant *Guna* of the annexed drug *Chitraka Haritaki* is *laghu*, that helps in relieving symptoms like heaviness around the area of paranasal sinuses. As the *Pratishyaya* is aggravated or initiated with cold food habits & environmental conditions, *ushana veerya* predominance leads to combating with this precipitating factor. Also *ushana veerya* affects in reducing *kapha* i.e. discharge or over secretions & helps to reduce *kapha* and *vata*, so acts against the *vata kaphaja* predominance of *Dushta Pratishayaya*.

The other trial drug i.e. **Hingwadi Tail** as *Nasya* is having predominance of *Katu rasa* (37.83%), *laghu guna* (36.58%), *ushana veerya* (77.78%), *katu vipaka* (77.78%) and *kapha-vata shamaka dosha karma*^[19] which is also counteracting the *samprapti* of *Dushta Pratishyaya*.

The drug *Hingwadi Tail* was used as *nasya* (nasal drops). There is *katu rasa* predominance, the actions of which like *ghranam asravayati*, *shwayathu anupahanti*, *krimi hinasti*, *marga vivrinoti* as per *Ch. Su. 26* help a lot in reduction of signs & symptoms of chronic sinusitis. *Ghranam asravayati* property acts as mucolytic i.e. thinning of secretions, *shwayathu anupahanti* property reduces regional oedema around ostia and *marga vivrinoti* helps to opening of channels i.e. ostia of sinuses. Along with *krimighana* i.e. action of contents of *Hingwadi Tail nasya* helps to clearance of sinuses through their respective ostia. Again *laghu guna* relieves the oedema of nasal mucosa and clears the osteo-meatal complex. *Ushana veerya* affects in reducing *kapha* i.e. discharge or over secretions. *Katu vipaka* also serves same functions as explained in *katu rasa* actions.

Apart from this, various pharmacological actions like anti-inflammatory, analgesic, anti-pyretic, antioxidant, immuno-modulatory etc. also endorsed by the annexed drugs in these formulations.^[20]

As the disease *Pratishyaya* is *vata kaphaja* predominant disease, and if it is not treated then develop into *Dushta Pratishyaya*. So the management of *Pratishyaya* in early phase improves the prognosis and the disease & it does not turn into *Dushta pratishyaya* i.e. in chronic phase. The principle of *kriyakala* explains the same, to treat the disease in its early phase.

Dushta Pratishyaya i.e. chronic sinusitis hampers day to day life and decreases quality of life. So following measures or ways to improve quality of life during the course of illness.

- ❖ Follow use of *pathya* and discontinue *apathya* as explained in *Su.Ut.24/21*; *As.H.Ut.20/1-4*.
- ❖ Steam inhalation during chronic sinusitis plays an important role.
- ❖ Environmental conditions also affect patients with sinusitis, so a stress free & devoid of pollution is recommended.
- ❖ Cold atmosphere aggravates the signs & symptoms of chronic sinusitis, so should be avoided.

- ❖ Rest in broad as explained '*Nidana Parivarjana*'^[21] principle of treatment in *Ayurveda* should be adopted.

So by using above mentioned ways to prevent the development or recurrence of *Dushta Pratishyaya* i.e. Chronic Sinusitis, there will be improvement in comfort & quality of life.

CONCLUSION

If we see the symptomatology of *Dushta pratishyaya* in *Ayurveda* we find the same symptomatology of Chronic Sinusitis.

The following conclusions can be drawn.

- ❖ It was observed that decongestant effects produced in modern drug treated patients are witnessed early. The duration of antibiotic therapy in chronic sinusitis is not clearly defined, but is typically on the order of 4 to 8 weeks.^[22] The results obtained by the administration of Annexed formulations were comparatively late in onset but were found to be more pronounced and sustained.
- ❖ All the *Dushta Pratishyaya* patients who received proposed formulations tolerated very well and no un-toward effects were reported by the patients registered for the current trial.
- ❖ Therefore, it can be concluded that the annexed trial drugs are good, safe, effective and dependable remedy for the management of *Dushta Pratishyaya* as these not only lowers down the symptoms but also imparts a feeling of well being and provide significant symptomatic relief.

Scope for further research work on the project

Although the present study gave satisfactory results, which proves the logical and practical explanation of this *Ayurveda* Science, some humble submissions of recommendations are as follows.

- ❖ The number of trial patients (sample size) should be increased to analysis of the data in more descriptive way.
- ❖ As the study was based on subjective criteria and objective criteria (only X-ray PNS w/v). It could be confirmed on better and more reliable objective criteria like assessment of reduction in mucosal thickening, clearance of sinuses by C.T. or M.R.I. scans and culture of nasal secretions/discharge before and after treatment to check the role of drugs in controlling the infection.

- ❖ Diagnostic sinus endoscopy should be performed before and after treatment to know what is actually going on inside sinus antrum, because radiographic techniques were particularly poor in identifying inflammatory disease, infected antrum and may produce false positive and false negative findings.
- ❖ Culture sensitivity should be done. This will help in appropriate drug action on the basis of microbiology.

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