

CLINICAL COMPARITIVE STUDY ON THE EFFICACY OF GOMUTRA TAILA NASYA WITH CHITRAKA HARITAKI LEHYA INTERNALLY AND ANUTAILA NASYA WITH CHITRAKA HARITAKI LEHYA INTERNALLY IN THE MANAGEMENT OF CHRONIC RHINOSINUSITIS

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ABSTRACT

Chronic rhino sinusitis (CRS) is an inflammatory condition of mucous membrane lining the nasal cavity and para nasal sinuses, characterized by facial pain, nasal blockage, nasal discharge, hyposmia etc. It has prevalence rate as 1 in 8 individuals in India, which has a negative impact on quality of life and productivity. CRS resembles with *dushta pratishya* explained in *Ayurveda*, Acharya *Vagbhata* advocated *yakshma* and *krimi chikitsa* for the same. With the same idea *Gomutra taila* was selected for *nasya* and *chitraka haritaki lehya* as oral medication. This was a two armed controlled clinical trial. With *Gomutra taila nasya* for trial group (n=20) and *Anutaila nasya* for control group (n=20). Three sittings of seven days each with a gap of one week in between and *chitraka haritaki* internally for a total period of 35 days. There was marked regression of symptoms in group A after first sitting of *Nasya*, whereas in group B same is achieved after second sitting of *Nasya*, Changes in X ray findings were well appreciable in group A. Overall result of Group A was 88.31% and Group B 73.84%. The ingredients of *Gomutra Taila* by virtue of their properties helps in clearing the *Srotas*, acts as *shulaghna*, *shotahara* and *krimighna*. The *Rasayana* effect of *Chitraka Haritaki lehya* corrects *Agni*, *Dhatus*, *Doshas* and *Vyadhiksamatva Shakti* and helps in resolving the condition.

KEYWORDS: Chronic rhino sinusitis, *dushtapratishyaya*, *nasya*, *gomutra taila*, *anutaila*, *chitrakaharitak lehya*.

INTRODUCTION

Chronic rhinosinusitis (CRS) may be broadly defined as an inflammatory disorder of the paranasal sinuses and linings of the nasal passages that lasts 12 weeks or longer¹. Most important cause of chronic sinusitis is failure of acute infection to resolve. Acute infection destroys normal ciliated epithelium impairing drainage from

the sinus. Pooling and stagnation of secretions in the sinus invites infection. Persistence of infection causes mucosal changes, such as loss of cilia, oedema and polyp formation, thus continuing the vicious cycle². The medical management of CRS includes administration of antibiotics and decongestants. Surgical procedures like

Caldwell-Luc operation, Functional endoscopic sinus surgery etc.

The features of chronic rhino sinusitis can be correlated to that of *Dushta Prathishyaya*. *Dushta Prathishyaya*³ is a chronic condition occurring due to the improper management of *Prathishyaya*. It is characterised by *Nasavrada*, *Kshavathu*, *Nasavarodha*, *Shirashula*, *Ghranaviplava*, *Shirogaurava* and *Mukhadaurgandha*. Acharya *vagbhata* advocated *yakshma* and *krimichikitsa* for this condition.⁴ with this concept Gomutra taila⁵ nasya and '*Chitraka haritaki lehya*⁶ internally was taken for the study with Anutaila⁷ nasya and *Chitraka haritaki lehya* internally as control.

AIMS AND OBJECTIVES:

1. To evaluate the efficacy of *Gomutra taila Nasya & Chitraka hareetaki lehya* internally in chronic rhino sinusitis.
2. To evaluate the efficacy of *Anu taila Nasya & Chitraka hareetaki lehya* internally in chronic rhino sinusitis.
3. To compare the efficacy of *Gomutra taila nasya* and *Anutaila Nasya* in chronic rhino sinusitis.

MATERIALS AND METHODS:

1. Raw drugs required for Gomutra taila were procured from market and taila was prepared in bhaishajya kalpana department of Govt. Ayurveda medical college, Bengaluru.

2. Anutaila and Chitraka hritaki lehya of GMP standard company were procured from market.

A total of 40 patients having the features of chronic rhino sinusitis were selected for the study irrespective of gender, occupation, religion and socio-economic status from *Shalakyatantra* OPD & IPD of Sri Jaya

Chamarajendra Institute of Indian Medicine, Bangalore and allotted to the groups according to randomization table. The following criteria were adopted in selection of patients.

Inclusion criteria:

1. Cases with clinical features of chronic rhino sinusitis.
2. Patients between age group of 7 –80 yrs.

Exclusion criteria:

1. Patients with nasal polyps.
2. Patients with sphenoidal sinusitis.
3. Patients with other systemic illness.
4. Patients unfit for *nasya*.
5. Any acute or traumatic conditions of head.

Assessment criteria:

It was made based on following subjective and objective criteria conclusion was drawn based on paired T test method.

Subjective parameters:

1. *Nasa Srava* (Nasal discharge)
2. *Nasavarodha* (Nasal obstruction)
3. *Shirashula* (Headache)
4. *Ghrana viplava* (Loss of smell)
5. *Shirogaurava* (Heaviness in head)

Objective parameters:

1. Sinus tenderness
2. X-Ray/ CT PNS

STUDY DESIGN:

40 patients selected were randomly divided into 2 groups. Group A and Group B with 20 patients each. Three sittings of seven days madhyama rechana type of Nasya (dosage-6 bindu) were administered with gomutra taila in Group A and with anutaila in Group B. *Chitraka haritaki lehya* was given orally 12gms with warm water early morning in empty stomach for 35 days. Pathyapathya related to nasyakarma were

explained to the patient.

OBSERVATION:

Observations were made before, on 7th day, 21st day and 35th day of the treatment. All the observations were recorded in a specially

designed proforma prepared for the study.

Follow up period: A follow up period of 60 days was fixed to observe the possible recurrences.

Table no: 1 Showing Scoring criteria of Subjective and Objective Criteria

Sl. no	Grade Parameter	0	1	2	3
1	Headache	Absent	Mild	Moderate	Severe
2	Heaviness of head	Absent	Mild	Moderate	Severe
3	Nasal obstruction	Absent	Intermittent, unilateral	Intermittent, bilateral	Continuous, unilateral/bilateral
4	Loss of smell	Absent	Occasional	Frequent	Continuous
5	Nasal discharge	Absent	Watery, transparent	White, Thick	Mucoid, Purulent.
6	Sinus tenderness	Absent	Mild	Moderate	Severe
7	X ray	Well aerated antrum	Mucosal thickening	Haziness	Complete opaque antrum

Criteria for assessment of response:

Good response: > 75% relief of all signs and symptoms.

Moderate response: 51-75% relief of all signs and symptoms.

Mild response: 25-50% relief of all signs and symptoms

Poor response: < 25% relief of all signs and symptoms

No relief : below 25% relief of all complaints.

RESULTS:

Observations of both groups analysed by using Paired T test and the results are drawn.

Assessment of overall results:

The percentage of improvement in Group A on Headache is 98%, Heaviness of Head is 96%, Nasal Blockage is 95%, Loss of Smell is 100%, Nasal Discharge is 100%, sinus tenderness is 100% and X ray is 17%.

The percentage of improvement in Group B on Headache is 78%, Heaviness of Head is 85%, Nasal Blockage is 93%, Loss of Smell is 100%, Nasal Discharge is 92%, sinus tenderness is 75% and X ray is 3%.

Table no 2: Showing Comparison of effect of treatment on Parameters in Group A and Group B

Parameters	Group	Mean		%	SD	SE	T-Value	P-Value	Remarks
		BT	FU						
Headache	A	2.8	0.05	98	0.444	0.099	4.26	<0.001	S
	B	2.55	0.55	78	0.649	0.145			

Heaviness of Head	A	2.7	0.10	96	0.598	0.134	3.19	<0.001	S
	B	2.3	0.35	85	0.686	0.153			
Nasal Blockage	A	1.85	0.10	95	0.910	0.204	0.85	>0.05	NS
	B	2.1	0.15	93	0.510	0.114			
Loss of Smell	A	0.4	0.00	100	0.681	0.152	1.79	<0.05	S
	B	0.1	0.00	100	0.308	0.069			
Nasal Discharge	A	0.65	0.00	100	0.813	0.182	1.94	<0.05	S
	B	1.25	0.10	92	0.813	0.182			
Sinus Tenderness	A	2.8	0.00	100	0.410	0.092	5.28	<0.001	S
	B	2.55	0.65	75	0.641	0.143			
X Ray	A	1.5	1.25	17	0.444	0.099	1.79	<0.05	S
	B	1.55	1.50	3	0.224	0.050			

DISCUSSION

DRUG

Gomutra Taila

→**Gomutra** is effective as an antimicrobial and antifungal⁸, contains 20-200µg of corticosteroids⁹

→**Vidanga** possesses Antihistaminic property by blocking H1 receptors. Also attributed with anti-inflammatory, analgesic and antioxidant property¹⁰.

→**Pippali** – It is anti-inflammatory in nature. Studies have reported that piper longum showed marked inhibition of histamine release from mast cells¹¹. Immunomodulatory activity of Piper longum fruits and piperine are reported in mice¹².

→**Maricha** - Piper nigrum contains pungent alkaloid ‘Piperine’ that increases the bioavailability of many drugs and nutrients by inhibiting various metabolic enzymes. It acts as anti-inflammatory by inhibiting the synthesis of Prostaglandin E2 and possess antioxidant activity due to presence of flavonoids and phenolic compounds¹³.

→**Hingu** – it is antioxidant, antimicrobial, antiviral, antifungal.¹⁴ Asafoetida exhibited a

significant antinociceptive effect on chronic and acute pain in mice.¹⁵

→**Shunti** – It possesses multiple bioactivities, such as antioxidant, anti-inflammatory, and antimicrobial properties.¹⁶

→**Apamarga** – It is anti-inflammatory, antipyretic, anti-microbial, anti-oxidant.¹⁷

→**Haridra**: is anti-microbial, anti-histamine, anti-inflammatory to the mucous membrane¹⁸

→**Kshavaka** - The plant extract showed a good antitussive and expectorant activity on mice. The flavonoids, sesquiterpenes and amide exhibited significant anti-allergy activity in passive cutaneous anaphylaxis (PCA) test.¹⁹

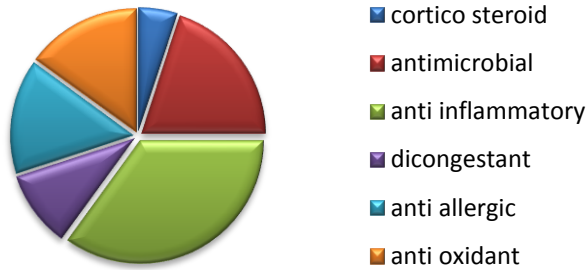
→**Tila taila**: Flavonoids and phenols give it antioxidant properties also saponins which are antioxidant, anti-cancer and immunity booster. Tannin present in oil makes it antibacterial, antiviral, and astringent.²⁰

These properties are very much in favour of clearing the *Srotas*. It dries up kleda and purulent discharge. *Katu vipaka* (70%), *Ushna veerya* (100%) and *Tikshna* (60%) properties produce *Draveekarana* (*Vilayana*) and *Chedana* of vitiated *Kapha*.

Tikta rasa (50%), rookshaguna (40%) dose shotha hara and shoola hara karma. Few drugs possess vishaghna and krimighna

properties which acts on infections. This medicine shows Tridosahara property when we analyse the Karma in detail.

Pharmacological activity of gomutra taila



Anutaila:

Majority of ingredients of Anutaila shows Tiktarasa (36.36%) and Laghu guna, properties. These properties are very much in favour of clearing the Srothases. It dries up kelda and purulent discharge. Katu vipaka (55.56%), Ushna veerya (51.85%) and Tikshna properties produce Draveekarana (Vilayana) and Chedana of vitiated Kapha. Madhura rasa (30.91%), Sheeta veerya (48.15%) and Snigdha properties helps to nourish the Dhatus. This medicine shows Tridosahara property when we analyse the Karma in detail.

Chitraka Haritaki Lehya

Deranged Agni, Dhatus, Doshas and Vyadhiksamatva Shakti of the person are responsible in production of the disease Pratishyaya, hence the aim of the treatment is to correct at all the stages. Chitraka Haritaki lehya had been selected for the treatment protocol because the major ingredients Chitraka have the basic property to digest the Ama and Haritaki is known for Rasayana effect. The other ingredients possess anti-inflammatory, anti-pyretic and anti-bacterial properties. Due to these

properties, the medicine prevents recurrent infections and reduces inflammatory process. It is also having the ability to alleviate the irritation particularly of mucous membrane of the nasal cavities and sinuses. Gomutra taila by its teekshna guna, ushna veerya and katu vipaka showed good result than anu taila nasya.

PROCEDURE

Madhyama matra of shirovirechana type of nasya- 6 bindu has been selected for the study. The age group of inclusion criteria 8-70 years was based on the age group eligible for nasya karma. The nasya dravya acts in this condition by local and systemic ways. Locally it acts as anti-microbial and cleanses the nasal mucosa aiding proper aeration of para nasa sinuses. The nasya dravya is absorbed into Olfactory blood vessels and reaches into the intracranial circulation by draining into the cavernous venous sinus of the brain and ultimately into the circulation. Hence does anti-inflammatory, immune modulatory actions.

CONCLUSION

This study was taken up to know the efficacy of Gomutra taila nasya in the

management of CRS, with *anu taila nasya* as control. *Chitraka haritaki lehya* was given to both groups. Both groups showed statistically significant result. But the trial group showed better result in subjective and objective parameters in comparison with control group. There were no adverse effects reported during treatment period

Limitations

This study should be done on larger sample

so that definite conclusions can be drawn, as the present study is limited to small sample of 40 patients. Majority of assessment was made on subjective parameters, so reduced accuracy in assessment.

Recommendations

Shodhana karma can be adopted before treatment.

Advanced investigative procedures may be incorporated for better assessment.

X ray PNS of a patient before and after treatment



BT



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