

EFFICACY OF SHADBINDU TAILA AND AGASTYA HARITAKI IN CHRONIC SINUSITIS

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ABSTRACT

The Disease of Head (Headache) are caused by individual Doshas i.e. Aggravated Vata, Pitta and Kapha or By Simultaneous vitiation of all three Doshas together (Sannipataja) Among the Different types of shiroroga mentioned in Samhitas, Suryavarta is the One of the Common Disease in Day to Day life. The Symptoms of Suryavarta almost Resemble to Frontal Sinusitis. Sinusitis is a very Common Chronic illness with a Substantial Health Care impact. According to National Institute of Allergy and infectious Diseases (NIAID) An estimated 134 million Indians suffer from chronic Sinusitis. Among Indians, This Disease is more Widespread than Diabetes, Asthma or Coronary heart Disease. One in eight Indians suffer from chronic Sinusitis caused By the inflammation of the Nasal & Throat lining, which result in the Accumulation of mucus in the Sinus Cavity and Pressure Build-up in the face, eye and Brain. In this Clinical Research

Study, we will study the effect of 30 Patients suffering from Chronic Sinusitis were enrolled in Clinical Study to asses the efficacy of Shadbindu Taila and Agastaya Haritaki. The Dose of Agastya Haritaki is 10gm/day Divided in Two doses, Nasya of Shadbindu Taila 4 Drops each Nostrils was given. The duration of the Treatment is 2 months and follow up was done for 3 months. Radiological investigation was done periodically. The Patients examined Clinically in every week to asses the effect of Medicine. In the Present study Results obtained with Respect to all the Parameters were all Satisfactorily. Out of 30 Patient 25 (83%) got Marked Relief and 5 (16%) got moderate Relief from the parameters Considered for the study. Even

after Follow-up there was no recurrence. Hence this treatment could be Recommended for treatment of Chronic Sinusitis.

KEYWORD: Sinus, Suryavarta, Shiroroga Frontal Sinusitis, Nasya, Shadbindu Taila, AgastyaHaritaki.

INTRODUCTION

Chronic sinusitis can be defined as the chronic inflammation of the mucosa lining of the nose and paranasal sinuses, which is characterized by postnasal drip, nasal congestion, nasal blockage, etc. If the acute infection is not managed in time, it further damages nasal mucosa. Sinusitis is an infection of the Para nasal sinus and the nose, most commonly caused by *Streptococcus pneumoniae*, *Moraxella catarrhalis*. Accumulation of mucus in the sinus secondary to obstruction and inflammation facilitates pathogen growth. Approximately 30 million Americans develop sinusitis annually. Paranasal sinuses are a group of four paired air-filled spaces surrounding the nasal cavity. Those are lined with mucous membrane, which is a continuation of the nasal mucous membrane.

Inflammation of nasal mucosa by infection, allergic reaction, etc., will lead to inflammation of the paranasal sinuses due to the continuation of the mucosa. Symptoms of chronic sinusitis may include any combination.

The clinical features of sinusitis bear resemblance with “Suryavarta” as described in the Ayurvedic texts. According to Ayurveda, the main dosha involved is *vayu* and *kapha dosha*. Hence steam inhalation of *Dasamoola kwatha* was chosen for inhalation followed by *nasya* of *Shadbindu Taila*. The clinical features of sinusitis bear resemblance with “*Suryavarta*” as described in the Ayurvedic texts. According to Ayurveda, the main *dosha* involved is *vayu* and *kapha dosha*. Hence steam inhalation of *Dasamoola kwatha* was chosen for inhalation followed by *nasya* of *Shadbindu Taila*.

MATERIALS AND METHODS

Study design: This was a randomized non comparative trial performed in OPD of Shree Lakshmi Narayan ayurvedic hospital, designed to comply with current food and drug administration guidance for demonstrating clinical efficacy in the treatment of chronic uncomplicated sinusitis. Written informed consent was obtained from all the participating patients before study enrollment.

Eligibility and accrual: Patients who were eligible to participate in the study included adults (25yrs of age or, more) whose medical history, physical examination and radiographic findings suggested chronic uncomplicated sinusitis and in whom oral out patient therapy was indicated.

Inclusion criteria: Were facial pain, tenderness over one or both maxillary area, purulent discharge from back of throat, or, nose. Women of child bearing potential were required to have a documented negative serum or, urine pregnancy test before the start of therapy. They also had to sign an agreement pledging to use effective contraceptive throughout the trial. X-ray (Water's view) was done and read by a qualified radiologist and should have been positive at least for one of the following criteria- • Opacification or, haziness of sinus.

Key exclusion criteria: Included hyper sensitivity to any of the trial medicine, complicated sinusitis, cystic fibrosis or, an abnormality of the maxillary sinus ostium that impaired drainage, history of sinus surgery within 3 months, intake of a systemic antibiotic within 14 days of entry into the study, presence of significant hepatic disease, known renal insufficiency, pregnancy and lactation.

Treatment and Compliance

Subjects were assigned randomly from OPD of Shree Lakshmi Narayan ayurvedic hospital, Initially the patients were given. Steam of Dasmoola kwatha by a steam inhaler for 15 minutes twice a day. After the inhalation of steam, the patients were advised to take nasya of *Shadbindu tail* in a dose of 4 drops in both the nostrils and lay flat with slightly extended head for 10 minutes along with *Agastya Haritaki Rasayan* 10gm/day divided into two doses. During this period the patients were advised not to take curd, rice, and banana. The total duration of this treatment was 60 days. No other systemic antibiotic, anti-inflammatory or, nasal decongestant were permitted during the course of the study. Compliance was measured by noting the exact dose taken, reason for missed dose and the amount of study medication returned by the subjects at the end of treatment.

Study procedure

The assessment of patients was conducted 4 times

- Within 48 hours of dosing.

- Day 7 to 15day.
- Day 30 to 45 day.
- Day 46 to 60day.

At base line, after subject provides written consent, the inclusion criteria and exclusion criteria were reviewed. Then demographic, medical history, and drug and non drug therapy were collected. A targeted physical examination, clinical assessment of sign and symptoms was also done. X-Ray PNS and routine examination were the investigation procedures. Pregnancy test was done for women of child bearing potential. At the end of the study, X-Ray was taken and compared with base line.

Criteria for evaluation

Clinical response were classified in to three category.

Clinical success: Resolution or, improvement of three cardinal signs and symptoms (Sinus pain, sinus tenderness, purulent discharges) with clear X-Ray PNS, without any additional therapy.

Failure: Persistence or, worsening of signs and symptoms.

Unable to determine: Not taken medicines or fewer than 7 days, received an additional therapy before evaluation or, lack of follow up.^[4]

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RESULTS AND DISCUSSION

Disposition of the patients: All 30 patients completed the study according to protocol. In a patient, proper follow up was not done however he has completed the treatment regimen.

Demography: Approximately all the patients were from amritsar city. The median age was 36 years (range 18-62). The study population composed of 50% of women.

In 2/3rd of the patients, both maxillary sinus were involved.

In 83% of cases, X-Ray on Water's projection showed opacity in the sinus, mucosal thickening, or, air-fluid levels. However in 17% of cases, only mucosal thickening was noted.

Therapeutic efficacy: Data of all the 30 patients who completed the study was eligible for analysis. Treatment with Ayurvedic medicine resulted in significant improvement from week 3 onwards in the following signs and symptoms like frontal headache, pain over jaw, tenderness and nasal discharges. 3 patients were completely free from symptoms in 25 days.

But all the patients were advised to continue same treatment upto 60 days. The minimum time required for relief of symptoms was the 25th day. Maximum duration required for relief of symptoms was observed to be 46th day.

At endpoint, the radiological examination showed no opacity or haziness in the sinus which suggested good sinus drainage and proper sinus ventilation. No evidence of mucosal thickening was found. No signs of ostial edema was found after treatment.

Safety evaluation

No adverse effects or side effects were found during the study.

Table No. 1: Radiological findings.

Radiological findings	BT	%	AT	Relief %
Haziness in Sinus	27	19	0	100
Mucosal thickening	25	83	0	100
Air-Fluid level	28	93	0	100

Table No. 2: Overall assessment of symptoms.

Symptoms	BT(No of pts)	%	AT(No. pts.) of	Relief %
Pain over Sinus	25	83	0	100
Tenderness over sinus	27	90	0	100
Purulent nasal discharge	27	90	0	100
Frontal headache	28	93.33	0	100
Post nasal drip	24	80	0	100
Nasal congestion	24	80	0	100
Facial pain	24	80	0	100

Table No. 3: Overall assessment of efficacy recorded after 3months of Treatment.

Degree	No. of patients	%
Clinical success	25	83
Failure	2	6
Unable to determine	3	11
Total	30	100

CONCLUSION

Chronic Sinusitis is long lasting swelling or infection in your sinus treatment. The most common malady mistaken for Sinusitis is Rhinitis or an Upper Respiratory Tract infection Treatment Focus on controlling and easing inflammation and open block sinuses. The main treatment which can drain the retained mucus discharge from the sinuses is shodhana nasya. In the present study nasya with Shadbindu Taila which is Teekshna, Anti-inflammatory, Anti microbial, Anti viral and Anti bacterial properties. This study confirms so it is helpful in all types of nasal, sinus infection and reduce inflammation in sinusitis along with Agastya Haritaki Rasayan are having Kapha-Vatta shamak properties showed good result in alleviating the symptoms of sinusitis. The overall clinical success rate was 83%. This prove that Shadbindu Taila Nasya and Agastya Haritaki Rasayan to be given in an effective treatment of choice in Chronic Uncomplicated Sinusitis.

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