

## EFFICACY OF AYURVEDIC MEDICINE IN THE TREATMENT OF UNCOMPLICATED CHRONIC SINUSITIS.

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**Abstract-** *Thirty patients suffering from uncomplicated chronic Sinusitis were enrolled in a clinical study to assess the efficacy of Ayurvedic medicine comprising of Tribhuvan kirti rasa (Tablet) along with inhalation of steam of Dasamulakwath (Decoction) followed by nasya (intranasal instillation) with Anu tailam. The Tribhuvan kirti rasa was administered at a dose of 250mg b.d with Adrak swaras ( Juice of Ginger). Steam inhalation of Dasmula kwath was given two times a day followed by nasya of Anu tail at a dose of 4 drops in both nostrils. The duration of the treatment varied from 45 days to 90 days. Radiological tests were done periodically. The patients were examined clinically in every week to assess the effect of medicine. The overall clinical efficacy was 96.6%. This medicine along with steam inhalation followed by Nasya was found to be well tolerated in general and no side effects were reported. Hence this treatment could be recommended for treatment of chronic Sinusitis.*

### INTRODUCTION

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. Clinical symptoms include mucopurulent nasal discharge, nasal congestion, and facial pain or, tenderness lasting 7 to 28 days during attack. Diagnosis is therefore often presumptive, being based on clinical presentation and diagnostic interpretation, and may include culturing. Diagnostic technique includes sinus radiography, sinus transillumination, sonography, and computerized tomography.

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 *Anu taila*.

The present study is confined to uncomplicated maxillary and frontal sinusitis. *Tribhuvan kirti rasa*, a medicine described in *Bhaisajya Ratna vali* written by Govinddas (B.S2033) was selected. For steam inhalation *Dasamoola Kwatha* was selected followed by *Anu tail nasya*.

### **Procurement of Medicines:**

The medicines were procured from IMPCL (LTD) and dispensed at Central Research Institute, New Delhi.

## **MATERIALS AND METHODS:**

### **Study Design:**

This was a randomized non comparative trial performed in OPD of Central Research Institute Delhi, 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 (18yrs 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.
- >6mm. of mucosal thickening.
- Air fluid level.

**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 Central Research Institute New Delhi.

Initially the patients were given Tribhuvan Kirti Rasa 250mg with adrak swaras (juice of ginger) twice a day. The patients were then advised to inhale 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 *Anu tail* in a dose of 4 drops in both the nostrils and lay flat with slightly extended head for 10 minutes. During this period the patients were advised not to take curd, rice, and banana. The total duration of this treatment was 90 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 60 to 90 day.

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.

## **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 2/3<sup>rd</sup> of all the patients were from Delhi city. The median age was 39 years (range 18-62). The study population composed of 60% of women.

**Clinical Findings:** The most frequently noted symptoms of sinusitis were purulent nasal discharge (96.66% of patients), nasal congestion (93.33%), sinus pain (90%) facial pain (80%) post nasal drip (83.33%), head ache (90%) and sinus tenderness (80%)

In 84% of the patients, both maxillary sinus were involved and in 16% of cases it involves only one sinus.

In 90% of cases, X-Ray on Water's projection showed opacity in the sinus, mucosal thickening, or, air-fluid levels. However in 10% 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 2 onwards in the following signs and symptoms like frontal headache, pain over jaw, tenderness and nasal discharges. 13 patients were completely free from symptoms in 25 days, 7 patients on 35<sup>th</sup> day, and 8 patients on 47<sup>th</sup> day.

But all the patients were advised to continue same treatment upto 90 days. The minimum time required for relief of symptoms was the 25<sup>th</sup> day. Maximum duration required for relief of symptoms was observed to be 46<sup>th</sup> 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**  
**Showing Age distribution in studied cases**

<b>Age in year</b>	<b>No. of Patients</b>	<b>%</b>
18-28	1	3.34
29-39	21	70
40-50	6	20
50-60	2	6.66
Total	30	100

**Table No-2**  
**Showing Sex incidence**

<b>Sex</b>	<b>No of patients</b>	<b>%</b>
Male	12	40
Female	18	60
Total	30	100

**Table No-3**  
**Duration of present illness**

<b>Duration</b>	<b>No. of patients</b>	<b>%</b>
6month-1yrs.	17	56.6
1-2yrs.	12	40
2-4yrs.	1	3.33
More then 4 yrs.	nil	00
Total	30	100

**Table No-4**  
**No. of Sinusitis Episode in 12 months**

<b>No. of attack</b>	<b>No. of Patients</b>	<b>%</b>
2 to 3	18	60
4 to 6	12	40
More then 6	Nil	00
Total	30	100

**Table No. 5 (History of Prior treatment)**

<b>Prior medication</b>	<b>No. of Patients</b>	<b>%</b>
Systemic Antibiotic	27	90
Surgery	Nil	00
No prior Medication	03	10
Total	30	100

**Table No-6**  
**Involvement of Sinus**

<b>Site</b>	<b>No of Patients</b>	<b>%</b>
Unilateral	12	40
Bilateral	18	60
Total	30	100

**Table NO-7**  
**Radiological Findings**

<b>Radiological Findings</b>	<b>BT</b>	<b>%</b>	<b>AT</b>	<b>Relief %</b>
Haziness in Sinus	30	100	0	100
Mucosal thickening	27	90	0	100
Air-Fluid level	30	100	0	100

**Table No-8**  
**Overall assessment of Symptoms**

Symptoms	BT(No of pts)	%	AT(No. of pts.)	Relief %
Pain over Sinus	27	90	0	100
Tenderness over sinus	24	80	0	100
Purulentnasal discharge	29	96.66	0	100
Frontal headache	27	90	0	100
Post nasal drip	25	83.33	0	100
Nasal congestion	28	93.33	0	100
Facial pain	24	80	0	100

**Table No-9**  
**Overall assessment of efficacy recorded after 3months of Treatment**

Degree	No. of patients	%
Clinical success	29	96.6
Failure	0	0
Unable to determine	1	3.4
Total	30	100

### CONCLUSION:

Sinusitis is a common respiratory tract infection which often goes undiagnosed and untreated. A delay in diagnosis and failure to institute effective therapy may lead to development of complications like abscess, cellulitis, epidural empyema, osteomyelitis, and meningitis. This study confirms the anti-inflammatory effect of Dasmoola kwatha, Tribhuban kirti rasa and steam inhalation which potentially sooth the mucous and facilitate sinus drainage. Anu tail helps to decongest the sinus ostium.

A 90 day course of Ayurvedic medicine was well tolerated, safe, and effective clinically in adult with uncomplicated sinusitis. The overall clinical success rate was 96.6%.

On the basis of clinical and radiological findings, it is inferred that indigenous medicine like Tribhuban kirti Rasa, Dasamoolakwatha inhalation, Anu tail Nasya proves to be an effective treatment of choice in chronic uncomplicated Sinusitis.

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