



Research Article

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EFFICACY OF AYUSHAKTI HERBAL REMEDIES AND BREATHE EASY NASYA THERAPY IN THE MANAGEMENT OF RHINOSINUSITIS (PINUS)

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ABSTRACT

When the mucus membrane within the sinuses becomes infected and inflamed, the condition is called Rhinosinusitis. The causative factors are uncommon; we can consider some causative factors like viral upper respiratory tract infections, bacterial infections, allergy, adenoid vegetation, airway pollutants, some structural anomalies, gastroesophageal reflux disease, immunologic defects, and cystic fibrosis. A disease termed *Pratishyaya* and *Pinus*, mentioned in different Ayurvedic Samhitas, has similar symptoms to Rhinosinusitis. Forty patients whose medical history, physical examination available imaging reports, and blood parameters suggested chronic Rhinosinusitis were recruited in the study. Ayushakti herbal medicines, along with Breathe easy *Nasya* treatment, were administered to the patients for 90 days and were found effective and safe without any side effects. If chronic Rhinosinusitis can be treated successfully, acute cases directly seeking this therapy can be cured and we can restrict them from going into the chronic phase.

Keywords: Rhinosinusitis, Pinus, Nasya, breathe easy, Ayurveda.

INTRODUCTION

Rhinosinusitis is one of the most common conditions treated in outpatient wards nowadays in India. Sinusitis is classified as acute or chronic based on pathological findings and the duration of the infection. Acute sinusitis is an infectious process in the sinus lasting for 1 day to 3 weeks; if the disease persists for 3 months, it is classified as chronic sinusitis¹. Although the causative factors are uncommon, we can consider some causative factors like viral upper respiratory tract infections, bacterial infections, allergy, adenoid vegetation, airway pollutants, some structural anomalies, gastroesophageal reflux disease, immunologic defects, and cystic fibrosis². Generally, sinusitis is an inflammatory process involving the mucosal membrane of the sinuses and the mucous membrane of the nose is involved. The diagnosis of Rhinosinusitis is mainly based on proper case history, clinical examination and imaging, allergy test, and inflammatory parameters if required³. A systematic review in 2013 stated that no evidence of benefit from antibiotics for the treatment of common cold or persisting acute purulent rhinitis in children or adults was found, but there is evidence that antibiotics can cause adverse effects in adults when given in the above two conditions hence routine use of antibiotics for these conditions is not recommended⁴.

One of the main backbones of the Indian traditional system of Medicines is Ayurveda, which has been practised in India for centuries. A disease termed *Pratishyaya* and *Pinus* mentioned in different Ayurvedic Samhitas have similar symptoms to Rhinosinusitis⁵. As per the Ministry of AYUSH treatment protocol for Rhinosinusitis includes both *Shodhana* (bio-purification of the body with the help of *Panchakarma* therapies) and *Shamana* (Palliative therapy)⁶. In Ayushakti Ayurveda, we have treated patients with acute and chronic Rhinosinusitis for

years with excellent results. Therefore, we conducted a survey study to evaluate the efficacy of Ayurveda interventions for managing Rhinosinusitis. We also want to review the relative efficacy of the combination of *Shodhana* (*panchakarma* procedures) and *Shamana* therapy.

AIMS AND OBJECTIVES

Primary objective

To evaluate the efficacy of Ayurveda herbal interventions for the management of Rhinosinusitis.

Secondary Objectives

To review the relative efficacy of *Shodhana* (*panchakarma* procedures) and *Shamana* therapy in combination.

To observe the changes in symptoms described in Ayurveda texts.

MATERIALS AND METHODS

This was an open-labelled, single-arm clinical trial undertaken in 40 patients in the age group of 18-60 who visited Ayushakti Ayurved Pvt Ltd, Malad, Mumbai, Maharashtra, India, with a complaint of Rhinosinusitis, Divyashwas jivan 2 tablets twice a day with lukewarm water. Swaswin Asthaloc 600 mg, 2 tablets twice a day with lukewarm water. Syrup Swaswin Kaphano 5 ml twice daily after food with lukewarm water at each visit; Breathe easy *Nasya* treatment (with Vacha oil) for 3 months. All the patients were followed up for 3 months at an interval of 2 weeks. Clinical evaluation was carried out at the end of the study.

Ethical clearance: The study was approved by the Ayushakti Independent Ethics Committee, Malad, Mumbai-64, Maharashtra, India (ECR/370/Indt/MH/2023). As it's a pilot study, CTRI registration was not done.

Study Design

Sample size considerations

As this is a proof-of-concept study, with no previous clinical results available, a sample size of 40 participants has been considered adequate to address the study objectives. This was a randomized non-comparative trial arranged in the OPD of Ayushakti Ayurveda Pvt Ltd, Malad, Mumbai-67, Maharashtra, India, to evaluate the efficacy and safety of Ayurveda interventions for the management of Rhinosinusitis also we want to review the relative effectiveness and safety of *Shodhana* (*panchakarma* procedures) and *Shamana* therapy in combination.

Eligibility

Patients willing to participate independently were recruited in the study, whose medical history, physical examination available imaging reports, and blood parameters suggested chronic Rhinosinusitis.

Eligibility criteria

Inclusion criteria

- Patients of either sex with ages between 18 and 60 years and known cases of chronic Rhinosinusitis as per the criteria of the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS) were included in the study.
- The symptoms include two or more signs, such as mucopurulent drainage (anterior, posterior, or both)/nasal obstruction (congestion)/facial pain, pressure, fullness, or decreased sense of smell and inflammation for 12 weeks or more.
- The symptoms include purulent (not clear) mucus or oedema in the middle meatus or anterior ethmoid region, polyps in the nasal cavity or the middle meatus, and/or radiographic imaging showing inflammation of the paranasal sinuses.
- Patients who fulfilled the criteria and were willing to give written informed consent for participation were included in the study.

Exclusion criteria

- Patients below 18 and above 60 years of age, with a history of chronic nasal or upper respiratory tract symptoms or disorders other than sinusitis, patients with tonsillitis/adenoids, patients who were on treatment with H1 antihistamine medication, non-steroidal analgesics or those taking medications such as corticosteroids nasal drops, leukotriene antagonists, and nasal vasoconstrictors in the last 15 days were excluded from the study.
- Patients with uncontrolled diabetes mellitus (blood sugar fasting >250 mg/dL) or poorly controlled hypertension ($\geq 160/100$ mm Hg).
- Patients suffering from major systemic illnesses such as rheumatoid arthritis, tuberculosis, and psycho-neuro-endocrinal disorders necessitating long-term drug treatment.

- Patients who had a history of atrial fibrillation, acute coronary syndrome, myocardial infarction, and stroke or severe arrhythmia in the last 6 months were excluded from the study.
- Symptomatic patients with clinical evidence of heart failure and patients with concurrent serious hepatic disorder or renal were also excluded from the study.
- Patients who were people with alcoholism and/or drug abuse, pregnant women and lactating mothers.
- Those who had participated in any other clinical trial during the past 6 months were excluded from the study.

Intervention Herbal remedies

The patients were given,

- D vyro (Virofight) 625 mg 2 tablets twice daily with lukewarm water.
- Divyashwas Jivan 2 tablets twice a day with lukewarm water.
- Swaswin Asthaloc 600 mg 2 tablets twice a day with lukewarm water.
- Syrup Swaswin Kaphano 5 ml twice a day after food with lukewarm water at each visit
- Breathe easy *Nasya* treatment (with Vacha oil).

The total duration of this treatment was 90 days. No other antibiotic, anti-inflammatory or nasal decongestant was permitted during the study.

Study procedure

The assessment of patients was done every 15 days till 90 days.

RESULTS AND OBSERVATIONS

A total of 40 patients were recruited for the study, from which 38 completed the study as per the protocol. 2 patients dropped out due to lack of proper follow-up.

Demographic distribution

Out of 40 patients' population is composed of 22 female (55%) and 18 male (45%) patients. It was observed that the treatment protocol showed significant improvement in all the symptoms of Rhinosinusitis. *Nasavrava* (nasal discharge) symptoms were significantly decreased, and there was 100% relief in this symptom in three months. *Nasa Avrodha* (nasal blockage) symptoms were found at 9th place on the VAS scale and were reduced to zero in 3 months. *Nasa Avrodha* (nasal blockage) was due to nasal polypus or Deviated Nasal Septum (DNS). *Gandha agyanata* (anosmia) symptom was significantly reduced in three months of treatment protocol. *Shirah shoola* (headache) was reduced considerably in the first 30 days and was 100% better in three months of treatment. Other symptoms, *Mukh Daurgandhya* (halitosis), *Kasa* (coughing), and *Jwara* (fever), were reduced symptomatically in three months. All the assessments are shown in Table 1.

Table 1: Overall Assessment of Symptoms

Complaints	BT	BT (Number of patients)	AT	AT (Number of patients)	% Difference
Nasavrava (Nasal discharge)	8	36	0	0	100
Nasa Avrodha (Nasal blockage)	9	38	0	0	100
Gandha Agyanata (Anosmia)	7	32	0	0	100
Mukha Daurgandhya (Halitosis)	7	24	0	0	100
Shirah Shoola (Headache)	9	38	0	0	100
Kasa (Coughing)	9	35	0	0	100
Jwara (Fever)	7	34	0	0	100

BT: Before Treatment, AT: After Treatment

Table 2: Overall efficacy after 3 months of treatment

Degree	Number of patients	% relief
Success	38	95
Failure	00	00
Drop out	02	5
Total	40	100

DISCUSSION

The best results were obtained due to a combination of Breathe easy *Nasya* therapy and some herbal remedies. A maximum number of patients got results mainly due to Breathe easy *Nasya* treatment; in this *Swedan* and *Swedana* therapy facilitates the drainage of retained secretion in the sinus area. Due to this, local pathology was improved. It is said that if the disease is chronic, it is difficult to treat in Ayurveda. In this disease, lowered immunity is the major causative factor along with *Kapha* domination. The probable mode of action of *Vacha* oil *Nasya* has already been explained in detail by Acharya Charaka and Vagbhata. They mentioned that the medicine, administered through the nasal cavity, can easily spread in the *shiro bhaga*, can be absorbed fast, and can eliminate all the doshas from *urdhva jatrugata pradesh*⁷. The head's low position is maintained throughout the procedure so that the medicine is well installed on the nasopharynx, which increases the contact time of the medicine with the mucosa. After the absorption of the drug, it may follow neural (olfactory and trigeminal) and circulatory (cavernous sinus) course to reach the site of action. It can influence the psychic level (limbic system), sensory level, and motor level, (Trigeminal nerve) and general circulation and ultimately produce the action. (excitation or sedation)⁸.

Asthaloc has *Zingiber officinale*, *Piper nigrum*, *Piper longum*, *Trachyspermum ammi*, *Adhatoda vasica*, *Pistacia integerrima*, and *Hedychium spicatum* and this combination helps in inflammation in the bronchus, as its anti-inflammatory, and antihistaminic⁹. D vyro contains herbs like *Tinospora cordifolia*, *Punica granatum*, *Glycyrrhiza glabra*, and *Zingiber officinale*; hence, it becomes the most effective immunomodulator, anti-viral and also is anti-inflammatory, and antioxidant. Swaswin D vyro (Virofight) tablet is the most effective immunomodulator, as it augments the cell-mediated as well as humeral-mediated immune response. It is anti-viral as it can inhibit the replication of several viruses, and it is anti-inflammatory by inhibiting various cytokine-producing pathways; it has antioxidant and antiulcer properties¹⁰. The main ingredient of *Swaswin Kaphano* syrup is *Vasa* (*Adhatoda vasika*); Vasicine is the active ingredient for expelling sputum from the body¹¹. The antitussive activity of *Adhatoda vasika* is similar to that of the non-narcotic antitussive agent Dextromethorphan¹².

CONCLUSION

Rhinosinusitis is a most common respiratory tract infection that goes undiagnosed and untreated most of the time. If untreated, it can develop many complications. In this study, Ayushakti herbal medicines, along with Breathe easy *Nasya* treatment, were administered to the patients for 90 days and were found effective and safe without any side effects. If chronic Rhinosinusitis can be treated successfully, acute cases directly seeking this therapy can

be cured and we can restrict them from going to the chronic phase. Overall, this treatment protocol was well tolerated, safe, and effective in patients with Rhinosinusitis.

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