Therapeutic evaluation of *Habb-e-shifa* and *Roghan banafsha* in Chronic Rhinosinusitis – A case series

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Abstract

OBJECTIVES: Chronic rhinosinusitis (CRS) is a chronic inflammatory disease of nasal and paranasal sinus mucosa where symptomatology has continued beyond 12 weeks. Sometimes there are acute exacerbations superimposed on chronic rhinosinusitis, where symptoms worsen but return to baseline of CRS after treatment. It is estimated that CRS has a prevalence of 15% in most urban communities. The common symptoms of CRS are nasal congestion and discharge. Pain and headache are usually mild or absent, and fever is uncommon. Bone erosion may be present in CRS. Medical treatment options for chronic rhinosinusitis should begin with topical nasal steroids along with aggressive treatment of any underlying cause or comorbid allergy.

The aim of present study is to assess the safety and efficacy of polyherbal unani formulations *habb-e-shifa* orally and *roghan banafsha* locally in the treatment of CRS.

METHODS: A case series was conducted on 10 diagnosed cases of CRS attending the Moalejat OPD – 4 at AKTCH, AMU Aligarh.

RESULTS: There was significant improvement in subjective and objective parameters after 45 days treatment with unani formulations. The result was analyzed using visual analogue scale (VAS) for subjective parameters and X- ray PNS (water's view) for objective parameter.

CONCLUSION: The preliminary findings indicate that these unani drug formulations are effective in CRS patients.

KEYWORDS: CRS, polyherbal, unani formulation, PNS, VAS.

INTRODUCTION:

The respiratory epithelium lining the nose is confluent with the mucosa of the paranasal sinuses. Inflammation of the nasal mucosa, or rhinitis, is often associated with some degree of sinus inflammation, or sinusitis. The two entities are therefore not distinct but are part of a clinical spectrum which is correctly referred to as rhinosinusitis.[1] The definition of chronic rhinosinusitis is nasal congestion or blockage lasting more than 12 weeks and accompanied by one of the following three sets of symptoms: facial pain or pressure; discoloured nasal discharge or postnasal drip; or reduction or loss of smell.[2] Symptoms are divided into major and minor factors. Major factors included facial pain or pressure, nasal obstruction or blockage, nasal discharge or purulence or discolored postnasal discharge, hyposmia or anosmia, purulence in nasal cavity. Minor factors were defined as headache, fever, halitosis, fatigue, dental pain, cough, and ear pain, pressure, or fullness.[3]

It is a prevalent inflammatory condition of the mucosa of the nose and paranasal sinuses, in the presence (CRSwNP) or absence (CRSsNP) of nasal polyps.[4] The most frequently affected sinus is maxillary sinus, followed in frequency by the ethmoid, frontal, and sphenoid sinus.[5] Sometimes, all the sinuses of one or both sides are involved simultaneously then it is termed as pansinusitis.[6] Prevalence rates are approximately 10% in the UK and data from the Clinical Practice Research Datalink estimate that 1% of UK adults receive treatment annually in primary care.

With an estimated 120000 outpatient consultations and 40000 sinus operations per year in England and Wales, CRS contributes a significant burden to National Health Service healthcare resources.[4] It affects 1 in 6 people, and 1 in 4 adolescents. It is extremely common and accounts for an increasing number of consultations with general practitioners in the United Kingdom.[1] It is a multifactorial disease caused by infection (bacterial) or inflammatory process (allergy, eosinophilic vasculitis or sarcoidosis).[7] Various genetic and environmental factors contribute to its pathogenesis. Predisposing factors can include allergic rhinitis, viral illness, gastroesophageal reflux, environmental illness such as cigarette smoking, anatomic obstruction, immune deficiency, cystic fibrosis, ciliary dyskinesia.[8] The incidence of rhinosinusitis is higher in patients with allergy (particularly those with IgE mediated allergic rhinitis (25% to 50%)) than in the general population, although a causal relation is difficult to show.8-10 Studies have shown a higher prevalence of atopy in patients with chronic rhinosinusitis.[2]

In CRS, as pain or systemic symptoms are absent, the clinical diagnosis may be missed. Nasal obstruction (sometimes unilateral), purulent postnasal discharge, chronic cough, hyposmia, sore throat and unpleasant breath are the most common presenting symptoms. Physical examination will reveal an oedematous nasal mucosa bathed in mucopus.[9]

Most diagnoses are based on the clinical history and presentation, possibly supported by radiologic evaluations. Radiologic studies are essential in the diagnosis of severe, refractory, nosocomial, or complicated cases of sinusitis, but they are not necessary in routine cases.[10,11]

CRS has a significant impact on patients' quality of life, affecting their ability to work effectively, their social interactions and daily living. Poor or disrupted sleep associated with CRS was commonly reported, leading to tiredness and fatigue, and consequently affecting ability to concentrate and be fully effective at work.[4] Untreated, sinusitis may lead to a number of serious, life-threatening complications which may be intracranial (meningitis, brain abscess) or extracranial (orbital cellulitis, blindness, orbital abscess, osteomyelitis).[2,10,12]

Treatment for CRS may include self-management techniques, topical and oral medical treatments and surgery. However, patient expectations and experiences of CRS management have yet to be fully explored. Preliminary qualitative research identified patients' frustration with inadequate treatment and lack of coordinated care; hence, further work is required.[4]

Unani perspective:

Rhinusinusitis is translated as *Warm-e-tajaweef anaf* by unani scholars but it is not mentioned as such in classical literature.[13] There is description of *nazla wa zukam* in various books which can be correlated with *warm-e-tajaweef anaf.* Some unani scholars regarded *nazla wa zukam* as a single entity. But some scholars referred *nazla* and *zukam* as two different conditions. When morbid matter from the brain flows down towards throat or chest then it is featured as *nazla,* if it flows down towards nose then it is referred as *zukam*.[14,15,16,17] Nazla has been classified into *nazla-e-haar wa nazla-e-barid*.[14,18] And the clinical features mentioned under *nazla-e-barid* correspond with sign and symptoms of *warm-e-tajaweef anaf muzmin*. So *nazla-e-barid* can be correlated with *warm-e-tajaweef anaf muzmin.* There are various factors which are responsible for the development of *nazla-e-barid*. These factors may be extrinsic *(baroodat kharji),* intrinsic *(baroodat mizaji)* or both. Some scholars described that the people of cold temperament are more prone to develop this disease and exposure to cold in these people lead to production of excessive phlegm

or morbid matter which will not be able to utilize completely. This excessive or improper utilized morbid matter will become the reason for development of nazla-e-barid.[14,15] Improper digestion may lead to changes in the temperament of the body and then this condition plays the role of intrinsic factor for the development of disease.[14] Some scholars described that *sudda* (obstruction) in the nasal passage may lead to *ufoonat* (infection) which results in the development of *warm-e-tajaweef anaf muzmin.*[14,19]

A large number of single and compound drugs have been documented in the treatment of *nazla-e-barid* and these have also been testified for their efficacy in *warm-e-tajaweef anaf muzmin.* In addition to oral drugs, there are many drugs which have been used locally for the treatment of disease and they are effective as well. In this study there are two formulations which were given to the patients. One is an oral formulation which is given in tablet form and the other is for local use which is given in roghan form. The unani oral formulation is a polyherbal preparation of unani medicines namely *tukhm joz masil, rewand chini, zanjabeel* and *samagh-e-arbi* (all in equal quantity). Roghan comprises of *roghan banafsha and roghan kunjad.* So present case series was performed, with the aim to explore the effect of unani formulations on patients with *warm-e-tajaweef anaf muzmin.*

Material and Methods

Informed consent was taken from all the patients. The study was conducted on the patient attending Moalejat OPD – 4 at Ajmal Khan Tibbiya College & Hospital, AMU, Aligarh.

Study participants

In this case series 10 patients were enrolled as per the following criteria.

Inclusion criteria: 1) patient's age within the range of 18 to 60 years; 2) either gender; 3) ≥12 weeks of persistent symptoms; 4) Meet ≥2 of 5major symptoms criteria 5) X-ray of PNS (Water's view) shows haziness/opacity and may show free fluid level.

Exclusion criteria: 1) Pregnancy and Lactation patients; 2) known systemic and metabolic diseases; 3) Patients with the history of trauma and accidents

Study Intervention

The oral unani formulation was prepared in tablet form. First of all samagh arbi is dissolved in water and then *tukhm joz masil, rewand chini, zanjabeel* (all in equal quantity) are powdered and mixed with dissolved *samagh arbi*. From this mixture tablets of the size of a gram are prepared and 2 tablets are advised to the patients two times daily. Along with tablets patients are also advised to instill two drops of roghan banafsha in nasal cavity twice daily for a period of 45 days with the follow up on every 15th day. Diagnosis was made on the basis of clinical symptoms and X-ray PNS. Symptoms were graded as mild, moderate and severe according to severity on Visual analogue scale (VAS) (Table – 1). Patients were enrolled only after evidence of haziness in X ray PNS.

Case Presentations

Case – 1: A 22 year old male student visited AKTCH, Moalejat OPD with complaints of nasal congestion, headache and nasal discharge and feeling of lethargy from 3-4 months. He was given to use unani formulation as advised. Gradually he got relief in all the symptoms with clear X-ray PNS after 45 days of treatment.

Case – 2: A 30 year old married women came to OPD with complaints of headache, nasal congestion, facial pain and a weary feeling from 6 months. She was given unani formulations as elucidated. Eventually, she mitigated in her symptoms with clear X-ray PNS as well after 45 days of treatment.

Case–3: A 42 year old male patient, a shopkeeper visited OPD with complaints of nasal discharge, nasal congestion, headache from one year. He took various medicines for his illness but he did not get relief. He was advised to use unani formulations. After 45 days of treatment he got partial relief in symptoms and a slight reduction in haziness of PNS as documented by its X-ray.

Case – 4: A 21 year old female student came to OPD with complaints of nasal congestion, facial pressure, headache and ear pressure from 4 months. She was indicated to use unani formulations. After 45 days of treatment she got relief in the symptoms with a clear X-ray PNS and was found to have contentment with the unani formulations.

Case – 5: A 48 year female patient came to OPD with complaints of nasal congestion, ear pressure and a feeling of dullness from three and a half month. She was advised to use the formulations as indicated. After treatment there was subsequent diminution in her symptoms with improvement in X-ray PNS.

Case – 6: A 32 year old male patient, a business man came to OPD with complaints of headache, nasal discharge and congestion from seven months. He was given unani formulations. There was marked resolution in all the symptoms with clear X-ray PNS after complete treatment.

Case – 7: A 24 year female patient visited OPD with complaints of nasal congestion and headache from three months. She was advised the treatment and she got partial relief in the symptoms with mild improvement in X-ray PNS.

Case – 8: A 29 year old male patient, a labourer came to OPD with complaints of nasal congestion and fatigue with a sleepy feeling most of the times from four to five months. He was advised the same treatment. He was found to resolve all his symptoms with clear X-ray PNS after complete trial.

Case – 9: A 19 year old female student came to OPD with complaints of headache, nasal congestion, facial pressure and lassitude from 3 months. She was given the formulations as indicated. She did not get any relief in the symptoms after 45 days of trial.

Case – 10: A 38 year old female visited OPD with complaints of nasal discharge and headache from 9 months. She was advised to use unani formulations as explained. She got partial relief in her symptoms with mild improvement in X-ray PNS after complete treatment.

Results:

All the 10 cases of CRS were analyzed on the basis of clinical symptoms. It was found that nasal obstruction, headache and facial pain were the prominent symptoms in all the cases. Whereas nasal discharge, ear pressure, and fatigue were present as mild symptoms. After 45 days of treatment, it was observed that the unani formulations were effective in improving the overall severity of symptoms which were analyzed by VAS and resolving the haziness of X-ray PNS.

Table : Grading of symptoms on Visual analogue scale

No.	Nasal obstruction		Nasal discharge		Facial pain		Headache		Fatigue		Ear pressure	
	P_1	P_2	P_1	P_2	P_1	P_2	P_1	P_2	P_1	P_2	P_1	P_2

1.	5	0	4	0	0	0	2	0	2	0	0	0
2.	4	0	0	0	1	0	5	0	4	0	0	0
3.	5	2	3	1	0	0	4	2	0	0	0	0
4.	8	2	0	0	3	0	8	1	0	0	2	0
5.	6	3	0	0	0	0	0	0	3	1	1	0
6.	7	0	5	1	0	0	3	0	0	0	0	0
7.	3	1	0	0	0	0	6	2	0	0	0	0
8.	5	0	0	0	0	0	0	0	1	0	0	0
9.	6	5	0	0	2	2	5	5	2	1	0	0
10.	4	0	3	0	0	0	7	0	0	0	0	0
0-3 = Mild, 4-7 = Moderate, 8-10 = Severe P1 = Pre-treatment, P2 = Post-treatment												

Discussion:

The impact of CRS on patients' quality of life is so pronounced that it reduces their ability to work effectually and it also interferes with their social interactions and daily living. So this case series was designed to determine the effect of these unani formulations in the treatment of CRS. The influence of unani formulations on various subjective parameters were assessed at baseline and 45th days. Patients were instructed to report in case of any adverse effects or exacerbation of disease. The study proclaimed that the most common presenting symptom in CRS was nasal congestion in 9 cases followed by headache in 8 cases. It was also noted that the frontal sinus was involved in 5 out of 10 cases. Almost all the patients exhibited a good response to the treatment which was analyzed and shown on VAS score (Table).

The extensive resolution in symptoms was noted in 6 patients, in which symptoms of 5 patients reduced to mild from moderate and 1 from severe to mild with complete resolution in haziness of X-ray PNS. While there were partial improvement in symptoms of 3 patients with mild changes in X-ray. One case was reported who did not get any relief in symptoms and changes in X-ray.

There were no adverse effects or provocation in symptoms reported, thus affirming the safety and efficacy of test formulations in the ailment of CRS.

The resolution in nasal congestion might be due to *mukhrij balgham* (expectorant) action of *zanjabeel, rewand chini* and *samagh arbi, munaqqi dimagh* and *mulattif* (demulcent) actions of *rewand chini* and *banafsha, muhallil* (resolvent) action of *rewand chini, roghan kunjad* and *gul banafsha, mujaffif* (absorbtive) property of *rewand chini.* The improvement in headache might be due to *musakkin* and *munawwim* properties of *tukhm joz masil, gul banafsha, roghan kunjad* and *rewand chini.* The relief in headache might be due to resolution in nasal congestion. The alleviation in facial and ear pain and fatigue might be due to *musakkin* action of *tukhm joz masil, rewand chini, gul banafsha* and *kunjad.* The improvement in nasal discharge might be due to *mujaffif* and *qabiz* properties of *tukhm joz masil* and *rewand chini.*

The resolution of haziness of X-ray PNS might be due to *mukhrij balgham* (expectorant) property of *rewand chini, zanjabeel* and *samagh arbi, mulattif* (demulcent) property of *banafsha* and *rewand chini.*[20,21]

Conclusion:

The present study illustrated that test drug formulations can be used efficiently for the ailment of *Warm-e-Tajaweef Anaf Muzmin* (Chronic Rhinosinusitis) without having any known adverse effects. There is necessity of further studies on efficacy of different doses and treatment duration of test drug formulations with larger sample size.

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