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Clinical evaluation of the efficacy of unani formulation sharbat ustukhuddus in the management of chronic rhinosinuitis

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Abstract

Aim: We undertook this study to find out the efficacy of unani drug sharbat ustukhuddus in the management of nazla muzmin (chronic rhinosinuitis).

Material & Methods: Study was conducted on 30 patients having various subjective and objective parameters, confirmed by comprehensive general, systemic examination as well as the local examination of nose and paranasal sinuses and diagnosis was confirmed on the basis of X-ray PNS (water's view), which was carried out before and after the treatment.

Study Design & duration: The study was designed as open, randomized clinical trial. Subjects were randomly allocated from AKTC Hospital, either from IPD or OPDs. The treatment period of test drug was six weeks. The study was divided into six visits (7th, 14th, 21th, 28th, 35th, 42th wks) of follow up which were made at an interval of one week.

Results: Test drug was found to be effective on subjective parameters as well as on objective parameters, it significantly reduce sinus tenderness & sinus opacity after treatment which were the main objective parameters.

Keywords: Nazla muzmin, chronic sinusitis, unani drug, sharbat ustukhuddus

Introduction

Sinusitis is the acute or chronic inflammation of the lining of the paranasal sinuses and possibly the underlying bone, which may be due to allergies, polyp, subtle immune deficiency states and dental diseases [1-4]. Sinusitis is one of the commonest allergic manifestations all around the world. Chronic sinusitis or *warm-e- tajaweef anf muzmin* is the term used when sinusitis has persisted for longer than 12 weeks. It is almost always accompanied by concurrent nasal airway inflammation and is often preceded by symptoms of rhinitis. Thus the term chronic rhinosinuitis (CRS) is more accurate than rhinitis or sinusitis [5]. Recent data have demonstrated that CRS affects approximately 5-15% of general population [6]. It remains extremely prevalent and has a significant socioeconomic impact. It is the second most common diagnosis resulting in the prescription of an antibiotic by physician in the United States. Despite its worldwide prevalence and substantial impact on the population, there is no satisfactory treatment [7].

In Unani literature there is no specific description of chronic sinusitis or *warm-e- tajaweef anf muzmin* but the features described by Unani physicians under *Nazla-e- haar* and *Nazla-e- barid* in various Unani books corresponds with signs & symptoms of *warm-e- tajaweef anf haad & muzmin* (acute & chronic sinusitis) respectively [8].

Clinical features of *nazla-e- barid* very closely resemble with the clinical features of chronic sinusitis described in modern medicine. Therefore, *nazla-e- barid* can be correlated to chronic sinusitis.

Most of the Unani physicians say that the phlegm or the morbid material dripping into the throat from brain is known as *Nazla* and to the nose is known as *Zukam* [9-14].

Unani physicians ascertain that the genesis of *nazla* is related with extrinsic and intrinsic causative factors. One or the other of these causes are *su-e-mizaj* (ill temperament) in the *ghisha-e-mukhati* (mucous membrane). The mucus membrane gets inflamed and produces secretions which may be *raqeef* (watery) or *ghaleez* (viscus), *garam* (hot), *laza* (irritative),

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barid (cold) and benign, distasteful or tasteless according to causative factors [15].

The sign and symptoms of *nazla muzmin* includes Nasal discharge [16, 17], Nasal congestion [16, 17] Sneezing [11, 16, 17], Redness of face and eyes [16, 18], Burning, irritation, and itching in the nose, eyes and throat [11, 17, 18], Mild headache [16, 18], Hot to touch [16, 18], Excessive thirst [16, 18], Fatigue [16, 18]

Therefore, holistic approach of Unani system of medicine may be much more beneficial in the cure of sinusitis. Unani drugs can be used for longer duration. The system provides abundance of single and compound drugs which can be given in chronic sinusitis. These drugs can be used for longer duration without any known side effects. Sharbat ustukhuddus is very useful compound unani drug, commonly prescribed in the management of chronic sinusitis.

Table 1: Composition of sharbat ustukhuddus [19]

S.no	Name of ingredient	Scientific Name	Dose
1	Ustukhuddus	<i>Lavandula stoechas</i>	60 grams
2	Asl-us-soos	<i>Glycyrrhiza glabra</i>	60 grams
3	Barg-e-Gaozaban	<i>Borago officinalis</i>	60 grams
4	Badiyan	<i>Foeniculum vulgare</i>	60 grams
5	Parsiyaunshan	<i>Adiantum capillus</i>	60 grams
6	Tukhm-e-khatmi	<i>Althaea officinalis</i>	60 grams
7	Tukhm-e-karafs	<i>Apium graveolens</i>	60 grams
8	Sapistaan	<i>Cordia latifolia</i>	50 in number
9	Oodsaleeb	<i>Paeonia officinalis</i>	60 grams
10	Gul-e-banafsha	<i>Viola odorata</i>	84 grams
11	Gul-e-surkh	<i>Rosa damascena</i>	84 grams
12	Maveez munaqqa	<i>Vitis vinifera</i>	240 grams

Material and Methods

1. Study Drug & Dosage

The drug for the trial was sharbat ustukhuddus manufactured by Dawakhana Tibbia College, Aligarh Muslim University. It was given in the dose of 20 ml twice a day orally for 6 weeks. Patients were also advised to take steam inhalation twice a day.

2. Place of Study

The study was conducted in the department of Moalejat, Ajmal Khan Tibbiya College & Hospital, AMU, Aligarh. Started from January 2017 to June 2018.

3. Study Design

The study was designed as open, randomized clinical trial, 30 patients subjects were randomly allocated from AKTC Hospital, either from IPD or OPDs.

4. Study Duration

Duration of the study was 18 months.

5. Duration of protocol Therapy

The treatment period of test drug was six weeks. The study was divided into six visits (7th, 14th, 21th, 28th, 35th, 42th wks) of follow up which were made at an interval of one week.

6. Criteria for Selection of Subjects

A) Inclusion criteria

- Clinically diagnosed patients of chronic sinusitis of not more than 5 years duration.
- Patients of either sex.
- Patients in the age group of 20 to 50 years.
- Patients with involvement of any sinus.
- Those who give written consent.

B) Exclusion criteria

- Patients below 20 and above 50 years of age.
- Pregnant & lactating mothers.
- Patients who fail to follow up.
- Mentally retarded person.
- Patients suffering from any congenital or acquired structural abnormality of the nasal cavity.
- Any medical condition where physician feels that participation in the study could be detrimental to patient's well-being.
- Patients of diabetes mellitus.
- Patients who fail to give consent.

7. Method of assessment of the disease

a) Subjective parameters

- Nasal obstruction
- Nasal discharge
- Anosmia
- Headache
- Facial pain
- Halitosis
- Earache
- Dental pain
- Cough
- Fatigue.

b) Objective parameters

- Local examination of nose and paranasal sinuses
- Trans illumination Test
- AEC (Absolute eosinophil count)
- X Ray PNS (Water's view)

Above investigations were done before and after termination of drug therapy

8. Investigations

Following investigations were carried out as safety parameters before commencement of protocol therapy for the exclusion of any concomitant acute and chronic illness.

- 1) Haemogram: Hb% (Sahli's method), TLC (Wintrobe's method), DLC (Wintrobe's method), ESR (Wintrobe's method)
- 2) Urine for routine and microscopic examination
- 3) Stool- for ova and Cyst
- 4) Random Blood Sugar
- 5) Liver Function Test (LFT): Serum Total Bilirubin (Jendrassic & Grof method), SGOT-UV Kinetic(IFCC) method, SGPT-UV Kinetic(IFCC) method, Alkaline phosphatase (PNPP method)
- 6) Renal Function Test (RFT)
- 7) Blood urea (UV method), Serum creatinine (Picrate method)

9. Efficacy Assessment

The assessment of efficacy was based on subjective and objective parameters. The subjective parameters were assessed and local examination was done at every visit. Improvement or deterioration in symptoms was noted in the proforma and the results were compared.

10. Withdrawal Criteria

- Right of the trial subject to withdraw consent at any time during the course of the trial.
- If the subject not willing to continue.

- The cases in which adverse drug reaction was noticed.
- Any acute systemic illness during the therapy.
- Drug intolerance.
- Non-compliant with the study protocol.

11. Documentation of adverse effect

During the course of the study, no adverse event was reported by the patients and no adverse effect was detected by clinical examination or laboratory investigations. The formulation was well tolerated.

12. Statistical analysis

Appropriate Statistical tests were carried out to analyze the

data using Graph Pad Instat. For intra group comparison paired 't' test was used for qualitative analysis and chi square test was used for quantitative assessment.

Observations and Results

40 subjects were screened for the study as per the screening parameters, out of which only 30 subjects fulfilled the inclusion criteria and were enrolled for the study. The distribution of study subjects according to the presenting symptoms is depicted in table no 2, 3, 4, 5, 6 & 7 Shows effect of sharbat ustukhuddus on various subjective and objective parameters before and after the termination of drug therapy.

Table 2: Baseline characteristic / Demographic data (n=30)

S. No	Characteristics	Test Group (No of Patients)	Percentage (%)
1	Age Group		
	20- 30	22	73.3
	30-40	4	13.3
	40-50	4	13.3
2	Sex		
	Male	10	33.3
	Female	20	66.6
3	Marital Status		
	Unmarried	20	66.6
	Married	10	33.3
4	Occupation		
	Student	9	30
	Professionals	2	6.66
	Unskilled workers	7	23.33
	Unemployed individuals	7	23.33
	Housewife	5	16.66
5	Religion		
	Muslim	27	90
	Non- Muslim	3	10
6	Socio-Economic Status		
	Upper	8	26.6
	Middle	10	33.3
	Lower	12	40
7	Temperament		
	Sanguineous(damvi)	5	16.6
	Phlegmatic (balgami)	21	70
	Bilious (safravi)	4	13.3
	Melancholic (saudawi)	0	0
8	Family History		
	Present	15	50
	Absent	15	50
9	History of allergy		
	Present	22	73.3
	Absent	8	26.6
10	History of smoking		
	Present	4	13.3
	Absent	26	86.6
11	Dental infection		
	Present	3	10
	Absent	27	90
12	Site of Infection		
	Maxillary	10	33.33
	Frontal	5	16.6
	Ethmoidal	1	3.33
	Ethmoidal+ Maxillary	3	10
	Frontal+Maxillary	9	30
	Pansinusitis	2	6.66

Table 3: Effect of Test drug on subjective parameters

Subjective Parameters	Duration in weeks														% at 6 wks
	No. of Patients						No. of patients improved								
	0	1	2	3	4	5	6	0	1	2	3	4	5	6	
Headache	25	24	21	19	15	11	6	0	1	4	6	10	14	19	76
Nasal Obstruction	15	14	12	10	8	7	6	0	1	3	5	7	8	9	60
Nasal Discharge	23	22	20	15	13	9	5	0	1	3	8	10	14	18	78.2
Cough	22	21	20	15	12	7	4	0	1	2	7	10	15	18	81
Facial Pain	12	11	10	8	7	7	6	0	1	2	4	5	5	6	50
Halitosis	10	10	9	9	8	7	7	0	0	1	1	2	3	3	30
Earache	8	8	7	7	6	5	5	0	0	1	1	2	3	3	37
Dental Pain	5	5	5	5	4	4	4	0	0	0	0	1	1	1	20
Anosmia	10	10	9	7	7	6	6	0	0	1	3	3	4	4	40
Fatigue	18	18	16	14	13	10	8	0	0	2	4	5	8	10	55

Table 4: Effect of Test drug on objective parameters

Objective Parameters	Duration in weeks														% age at 6wks
	No. of Patients						No. of patients improved								
	0	1	2	3	4	5	6	0	1	2	3	4	5	6	
Tanderness over affected sinus	23	21	19	16	13	9	7	0	2	4	7	10	14	16	69.5
Translucency in affected sinus during trans illumination test	24	24	22	21	18	16	12	0	0	2	3	6	8	12	50
Mucosal Edema	17	16	15	13	12	10	8	0	1	2	4	5	7	9	52.9
Nasal Congestion	24	22	19	16	13	9	6	0	2	5	8	11	15	18	75
Sinus Opacity	23													16	69.5
Sinus haziness	24													16	66.6

Table 5: Effect of Test drug on Eosinophil count.

S. No.	Investigations	Test Group			
		Mean ± SEM		t value	p value
		BT	AT		
1	DEC	9.53 ± 0.238	8.43 ± 0.218	3.40	<0.001
2	AEC	647 ± 24.18	528 ± 19.47	3.8	<0.0003

Table 6: Effect of Test drug on Hematological parameters

S. No.	Investigations	Test Group			
		Mean ± SEM		t value	p value
		BT	AT		
1	Hbgm/dl	11.5 ± 0.20	11.8 ± 0.12	0.84	>0.05
2	ESR mm/hr	21.86 ± 0.69	22.33 ± 0.87	0.41	>0.05
3	TLC/cumm	6826 ± 154.2	6720 ± 174.2	0.45	>0.05
4	N/cumm	63.93 ± 1.17	64.36 ± 1.04	0.27	>0.05
5	L/cumm	29.9 ± 1.12	30.0 ± 1.23	0.03	>0.05

Table 7: Effect of Test drug on biochemical parameters

S. No.	Investigations	Test Group			
		Mean ± SEM		t value	p value
		BT	AT		
1	BU mg/dl	23.5 ± 0.74	23.4 ± 0.79	0.07	>0.05
2	SC mg/dl	0.85 ± 0.02	0.83 ± 0.01	0.53	>0.05
3	SB mg/dl	0.87 ± 0.01	0.85 ± 0.01	0.74	>0.05
4	AST U/L	25.5 ± 0.79	24.5 ± 1.1	0.70	>0.05
5	ALT U/L	25.7 ± 1.63	25.0 ± 1.21	0.35	>0.05
6	SAP U/L	106.9 ± 1.53	108.2 ± 0.99	0.67	>0.05
7	RBS mg/dl	80.1 ± 2.17	82.0 ± 2.05	0.60	>0.05

Discussion

In our study we observed that unani drug (sharbat ustukhuddus) effectively relieved the symptoms of chronic sinusitis. From the observations in the test group, it is evident that maximum effect was found on cough which were subsided in (81%) cases followed by nasal discharge (78.2%), headache (76%), nasal congestion (75%), tenderness over affected sinus & sinus opacity (69.5%), sinus haziness (66.6%), nasal obstruction (60%), fatigue(55%) mucosal edema (52%), translucency in affected sinuses during trans

illumination test & facial pain (50%), anosmia (40%), earache (37%), halitosis (30%), dental pain (20%).

The effect of test drug on eosinophil Table No (5). Mean AEC before the treatment was 647 ± 24.18/mm³, while after the treatment it was 528 ± 19.47/mm³, here test statistic (t=3.8, p<0.0003) shows significant difference by using paired t test. Mean DEC was 9.53 ± 0.23/cumm and 8.43 ± 0.21/cumm before and after the treatment respectively, (t=3.4, p<0.001) indicating significant difference statistically.

Insignificant difference was observed in haematological and

biochemical parameters studied before and after the treatment. (Table No 6 & 7)

The effectiveness of Sharbat ustukhuddus in the management of *nazla muzmin* may be attributed to the Anti-inflammatory (muhallil) activity of Ustukhuddus [20, 21, 23, 24], Asl-us-soos [20, 22, 23], Badiyan [21, 22, 23, 25], Banafsha [22, 24], Karafs [22, 24], Khatmi [20, 24, 25, 27, 32], Maveez Munaqqa [23], Ood saleeb [21-23], Parsiaoshan [20, 21, 23]. Demulcent (mulattif) activity of Ustukhuddus [24, 25], Asl-us-soos [22, 27], Badiyan [25, 27], Banafsha [24], Gaozaban [22], Gul-e-surkh [24], Khatmi [22, 27], Maveez Munaqqa [39], Ood saleeb [23], Parsioshan [20-38], Sapistaan [22]. Brain Tonic (Muqawwi-e-dimagh) Ustukhuddus [20, 21, 23, 27], Maveez munaqqa [25] and Brain Depurative (Munaqqi-e-dimagh) properties of Ustukhuddus [20, 21, 97, 23-25, 27], Asl us soos [20, 21, 23]. Expectorant (Munaffis-e-balgham) activity of Ustukhuddus [26], Asl-us-soos [22, 21, 31], Banafsha [22], Gaozaban [20, 22, 23], Gul-e-surkh [22], Khatmi [21], Maveez Munaqqa [39], Parsioshan [22, 38], Sapistaan [20, 21, 23]. Saleeb [21]. Concoctive of phlegm (Munziji-e-balgham) action of Ustukhuddus [24], Badiyan [20, 23, 27], Asl-us-soos [27], Karafs [27], Khatmi [20, 21], Ood saleeb [24], Parsiaohan [20, 21, 23, 25]. Purgative for phlegm (Mushil-e-balgham) activity of Ustukhuddus [20, 21, 23, 27], Asl us soos [23], Gul-e-surkh [23]. Antiseptic (Dafa e ufoonat) activity of Ustukhuddus [22], Karafs [22], Ood and Anti tussive (Dafa-e-sual) action of Asl us soos [28], Gul e surkh [29], Khatmi²⁸

Various pharmacological studies have also established the following properties of the constituents of Sharbat ustukhuddus which may also be helpful in the management of chronic sinusitis because of Anti-inflammatory activity of Ustukhuddus (flavonoids) [30], Asl-us-soos (glycyrrhizic acid, glycyrrhizin) [31], Gul-e-surkh (vitamin C) [29], Khatmi (polysaccharide, hypoletin 8-glucoside) [32, 33], Maveez Munaqqa (resveratrol, quercetin) [34]. Anti-histaminic activity of Asl us soos (liquiritoside, papaverine salt, glycyrrhizin) [35], Khatmi (Hypoletin 8-glucoside) [33]. Antiviral activity of Asl-us-soos (glycyrrhizin) [31, 35, 36]. Antibacterial activity of Asl-us-soos (isoprenoid phenols, glabridin, glabrin, glabrol, glabrin, hispaglabridin A, hispaglabridin B) [36], Maveez Munaqqa (gallic acid, hydroxycinnamic acid trans-resveratrol) [37]

Demulcent activity of Asl-us-soos (glycyrrhizin) [31, 36] and Anti tussive activity of Asl-us-soos (liquiritin apioside) [36], Khatmi (uronic acid) [32, 33]

The complaint of nasal obstruction in most of the cases of *warm-e-tajaweef anf muzmin* is due to inflammation and secretion of nasal mucosa which produce obstruction in nasal passage. Due to Muhallil & Mulattif, Muqawwi-e-dimagh, Munaqqi-e-dimagh, properties of Ustukhuddus, Asl-us-soos, Badiyan, Banafsha, Gaozaban, Gul-e-surkh, Khatmi, Karafs, Maveez Munaqqa, Ood saleeb, Parsioshan, Sapistaan, helps to reduce the inflammation and dissolve the thick secretion to make nasal passage clear and thus reduce nasal obstruction.

Abnormalities of smell are restricted to less number of patients particularly in chronic infected cases of *warm-e-tajaweef anf muzmin* who develop thick, putrid and yellowish secretions, but after treatment revert to normal smell as soon as infected inflammatory condition of sinus mucosa is restored to normal. Again it is due to Muhallil & Mulattif, Munziji-e-balgham, Mushil-e-balgham, Muqawwi-e-dimagh, Munaqqi-e-dimagh, Dafa-e-ufoonat properties of Ustukhuddus, Asl-us-soos, Badiyan, Banafsha, Gaozaban, Gul-e-surkh, Khatmi, Karafs, Maveez Munaqqa, Ood saleeb, Parsioshan, Sapistaan which bring about changes in restoration of normal nasal mucosa.

Headache may be due to inflammation and collection of hot and irritative secretions in the sinus involved. Due to Muhallil, Mulattif, Munaffis-e-balgham, Munziji-e-balgham, Mushil e balgham, Muqawwi-e-dimagh, Munaqqi-e-dimagh actions of Ustukhuddus, Asl us soos, Badiyan, Banafsha, Gaozaban, Gul-e-surkh, Khatmi, Maveez Munaqqa, Ood saleeb, Parsioshan, Sapistaan which bring about changes in restoration of normal nasal mucosa and helps to reduce inflammation and clear sinus secretion and thus relieve headache.

Sharbat ustukhuddus is also helpful in alleviating nasal discharge by reducing inflammation and irritation of mucous membrane due to Muhallil, Mulattif, Munaffis-e-balgham, Munziji-e-balgham, Mushil-e-balgham, Dafa-e-ufoonat actions of this sharbat.

Tenderness over the involved sinus is a typical sign of *warm-e-tajaweef anf muzmin* and it is the testimony of ongoing inflammatory pathology in the sinus mucosa. Tenderness comes down as soon as the inflammatory pathology is reversed, restoring abnormal sinus to normal one due to properties of sharbat ustukhuddus like Muhallil, Mulattif, Munaffis-e-balgham, Munziji-e-balgham, Mushil-e-balgham, Dafa-e-ufoonat.

Opacity in sinuses is produced by accumulation of abnormal inflammatory fluid. This production and accumulation of abnormal fluid, like tenderness is also a byproduct of ongoing active process of chronic inflammation. As soon as inflammation is controlled by treatment, the opacity reduces itself accordingly and thus helps to resolve the opacity of sinuses due to Muhallil, Mulattif, Munaffis e balgham, Munaffis-e-balgham, Munziji-e-balgham, Mushil-e-balgham, Dafa-e-ufoonat action of sharbat ustukhuddus.

Hakeem Azam Khan described the overall efficacy of Sharbat ustukhuddus as demulcent, purgative for phlegm and black bile and general tonic which also act as broom of the brain by expelling morbid phlegm and black bile from the brain.⁴⁰ Because of these properties sharbat ustukhuddus is effective in treating chronic sinusitis.

Conclusion

The aim of this study was to explore chronic sinusitis in light of unani literature to evaluate the efficacy of unani drug sharbat ustukhuddus in chronic rhinosinusitis and to provide safe, easy available, easily tolerable and cost-effective drug. So, from this trial, we concluded that test drug was found to be effective on subjective parameters as well as on objective parameters, this drug significantly reduce sinus tenderness & sinus opacity after treatment which were the main objective parameters. Although no adverse effect of the drug was reported. Hence, it may be concluded that test drug is effective and safe in the management of chronic sinusitis.

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