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A ranomized open comparative clinical study of sharbat ustukhuddus and sharbat banafsha in the management of chronic rhinosinusitis

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To compare the efficacy of sharbat ustukhuddus and sharbat banafsha in the management of *nazlamuzmin* (chronic rhinosinusitis). Study was conducted on 60 patients, divided in two groups i.e., test group A (sharbat ustukhuddus) and test group B (sharbat banafsha), 30 patients in each group 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 termination of drug therapy.

The study was designed as open, randomized-comparative clinical trial. Subjects were randomly allocated from Ajmal Khan Tibbiya College & Hospital, either from IPD or OPD. The treatment period of test drug was six weeks. The study was divided into six visits (7^{th}, 14^{th}, 21^{st}, 28^{th}, 35^{th}, 42^{th} wks) with weekly follow up. Both test drugs were found to be effective on subjective as well as on objective parameters, these drugs significantly reduced sinus tenderness & opacity after treatment which were the main objective parameters but sharbat banafsha was superior than sharbat ustukhuddus and better remedy for this illness as it effectively relieved most of the clinical features of chronic sinusitis.

Keywords. Chronic sinusitis, Sharbat banafsha, Sharbat ustukhuddus, Unani drugs
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Sinusitis refers to acute or chronic inflammation/ infection of the paranasal sinuses and possibly the underlying bone, which may be due to allergies, polyp, subtle immune deficiency states and dental diseases[1,2,3,4]. It is almost always accompanied by concurrent nasal airway inflammation and is often preceded by symptoms of rhinitis. Thus the term chronic rhinosinusitis (CRS) is more accurate than rhinitis or sinusitis.[5]

CRS is one of the most frequent otolaryngologic diseases encountered and affecting persons of all age groups. It accounts for substantial health care expenditure in-terms of office visit, antibiotic prescription filled, lost work days and missed school days[6]. Approximately one in eight persons are affected by the condition at least 35 million Americans suffer each year[7]. Sometimes patients often suffer significant morbidity or it can reduce quality of life, ability to get restful sleep and to do work. Despite its worldwide prevalence and substantial impact on the population, there is no satisfactory treatment. Continuous use of anti-allergic and anti-inflammatory drugs always leads to a number of hazardous side effects[1]. Unfortunately, sinusitis is often very frustrating and difficult to treat and medical failures often become surgical patients. Hence there is a strong need for greater understanding of the disease and for more effective treatment of CRS as well.[8]

In Unani literature there is no specific description of sinusitis but the features described by Unani physicians under *nazlahaar* and *nazlabarid* in various books corresponds with the signs and symptoms of acute & chronic sinusitis respectively[9].

Most of the Unani physicians said that the phlegm or the morbid material dripping into the throat from the brain is known as *Nazla* and to the nose is known as *Zukam*[10,11,12,13,14]. These humors are formed, circulated and absorbed in the brain. When brain gets affected by extreme cold or heat, these humors are not absorbed and they start dripping from the anterior two ventricles into throat[15,16].

The signs and symptoms of *nazlamuzmin* include Nasal discharge[17,18]. Nasal congestion[17,18] Sneezing[12,17,18]

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Redness of face and eyes[17,19]. Burning, irritation, and itching in the nose, eyes and throat[12,18,19]. Mild headache[17,19]. Hot to touch[17,19] excessive thirst[17,19] fatigue[17,19]

All Unani physicians unanimously ascertain that the genesis of *nazla* is related with extrinsic and intrinsic causative factors. One of these causes is *su-e-mizaj* (ill temperament) in the *ghisha-e-mukhati* (mucous membrane). The mucus membrane gets inflammed and produces secretions which may be *raqeeq* (watery) or *ghaleez* (viscous), *garam* (hot), *laze* (irritative), *barid* (cold) and benign, distasteful or tasteless according to causative factors[20].

Holistic approach of Unani system of medicine may be much more beneficial in the cure of sinusitis. The system provides abundance of single and compound drugs, these drugs can be used for longer duration without any known side effects. Both sharbat ustukhuddus and sharbat banafsha are two very useful compound unani drugs, commonly prescribed in the management of chronic sinusitis.

Material and methods

Drugs& Dosage form

The drugs for the trial were sharbat banafsha (composition in Table 1) and sharbat ustukhuddus (composition in Table 2) manufactured by Dawakhana Tibbiya College, Aligarh Muslim University. Both sharbat were given in the dose of 20 mL twice a day orally for six weeks. Patients were also advised to take steam inhalation twice a day.

Place of Study

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

Study Design

The study was designed as a randomized open comparative clinical trial on 60 patients. Subjects were randomly allocated from AKTC Hospital, either from IPD or OPD.

Study Duration

Duration of the study was 18 months.

Duration of protocol Therapy

The treatment period of both test drugs were six weeks. The study was divided into six visits (7^{th}, 14^{th}, 21^{st}, 28^{th}, 35^{th}, 42^{th} wks) with weekly follow up.

Criteria for Selection of Subjects:

A) Inclusion criteria:

i. Clinically diagnosed patients of chronic sinusitis of not more than 5 years duration.
ii. Patients of either sex.
iii. Patients in the age group of 20 to 50 years.
iv. Patients with involvement of any sinus.
v. Those who given written consent.

B) Exclusion criteria:

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

Method of assessment of the disease:

a) Subjective parameters:

i. Nasal obstruction
ii. Nasal discharge
iii. Anosmia
iv. Headache
v. Facial pain
vi. Halitosis
vii. Earache

Table 1 — Composition of sharbat banafsha[21]

S. No	Name of ingredient	scientific Name	Dose
1	Gul-e-banafsha	*Viola odorata*	120 g
2	Shakarsafaid	*Saccharum officinarum*	964 g

Table 2 — Composition of sharbat ustukhuddus[21]

S. No	Name of ingredient	Scientific Name	Dose
1	Ustukhuddus	*Lavandula stoechas*	60 g
2	Asl-us-soos	*Glycyrrhiza glabra*	60 g
3	Barg-e-Gaozaban	*Borago officinalis*	60 g
4	Badiyan	*Foeniculum vulgare*	60 g
5	Parsiaoshan	*Adiantum capillus veneris*	60 g
6	Tukhm-e-khatmi	*Althaea officinalis*	60 g
7	Tukhm-e-karafs	*Apium graveolens*	60 g
8	Sapistaan	*Cordia latifolia*	50 in number
9	Oodsaleeb	*Paeonia officinalis*	60 g
10	Gul-e-banafsha	*Viola odorata*	84 g
11	Gul-e-surkh	*Rosa Damascena*	84 g
12	Maveezmunaqqa	*Vitis vinifera*	240 g

viii. Dental pain
ix. Cough
x. Fatigue.

b) Objective parameters:
i. Local examination of nose and paranasal sinuses
ii. Transillumination Test
iii. AEC (Absolute eosinophil count)
iv. X- ray PNS (Water's view)
v. Above investigations were done before and after termination of drug therapy

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)

Blood urea (UV method), Serum creatinine (Picrate method)

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.

Withdrawal Criteria:
i. Right of the trial subject to withdraw consent at any time during the course of the trial.
ii. If the subject not willing to continue.
iii. The cases in which adverse drug reaction was noticed.
iv. Any acute systemic illness during the therapy.
v. Drug intolerance.
vi. Non-compliant with the study protocol.

Documentation of adverse effect

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

Statistical analysis:

Appropriate statistical tests were applied to analyze the data using Graph Pad In stat. For intra group comparison, paired t-test was used for qualitative analysis and chi square test was used for quantitative assessment.

OBSERVATIONS AND RESULTS

70 subjects were screened for the study as per the screening parameters, out of which only 60 subjects fulfilled the inclusion criteria and were enrolled for the study. The distribution of study subjects according to presenting symptoms is depicted in Table 1,2,3,4,5,6,7,8,9 & 10 which shows effect of sharbatustukhuddus & sharbatbanafsha on various subjective and objective parameters before and after the termination of drug therapy.

Discussion

From the above clinical findings in both test groups A & B, the demographic data shows that maximum number of patients (65%) were found in the age group of 20-30 years, the incidence of disease was higher in females (63.3%) than males, higher incidence of disease was found among muslims (86.6%), unmarried patients (61.6%) were more than married (38.3%) patients, maximum number of patients were students (33.3%) followed by unskilled workers (21.6%), the higher incidence of chronic sinusitis was found in lower socioeconomic group (38.3%), maximum number of patients were having balghami (phlegmatic) mizaj (66.7%), out of 60 patients, 48.3% cases were found to have positive family history whereas , positive history of allergy was found in 76.7% cases, history of smoking was found in 14.9% of the patients, previous history of dental infections was found in 11.7% of the patients and maxillary sinusitis was found to be the commonest type (29.9%) Table 3. Effect of drugs on subjective and objective parameters shows that headache was relieved in 76% patients of group A, and 84% patients of group B. On comparing both the groups the test statistic, ψ^2=0.60,

p=0.43, shows non-significant difference between two groups Table 4 & Table 6. Nasal obstruction was relieved in 60% patients of group A while in group B it was relieved in 73% patients following treatment. On comparing both the groups test statistic, ψ^2=0.7, p=0.71, indicates non- significant difference between the two groups. Nasal discharge was relieved in 78% and 84% patients in group A and B respectively. On

Table 3 — Baseline characteristic / Demographic data (n=60)

S. No	CHARACTERISTIC	TEST GROUP A (No of Patients)	TEST GROUP B (No of Patients)	TOTAL (% age)
1	Age Group			
	20- 30	22	17	65
	30-40	4	6	16.66
	40-50	4	7	18.33
2	Sex			
	Male	10	12	36.65
	Female	20	18	63.3
3	Marital Status			
	Unmarried	20	17	61.6
	Married	10	13	38.33
4	Occupation			
	Student	9	11	33.3
	Professionals	2	3	8.33
	Unskilled workers	7	6	21.66
	Unemployed individuals	7	4	18.31
	Housewife	5	6	18.33
5	Religion			
	Muslim	27	25	86.65
	Non- Muslim	3	5	13.3
6	Socio-Economic Status			
	Upper	8	8	26.6
	Middle	10	11	34.95
	Lower	12	11	38.3
7	Temperament			
	Sanguineous(damvi)	5	6	18.3
	Phlegmatic (balgami)	21	19	66.65
	Bilious (safravi)	4	4	13.3
	Melancholic (saudawi)	0	1	1.65
8	Family History			
	Present	15	14	48.3
	Absent	15	16	51.7
9	History of allergy			
	Present	22	24	76.7
	Absent	8	6	23.3
10	History of smoking			
	Present	4	5	15
	Absent	26	25	85
11	Dental infection			
	Present	3	4	11.7
	Absent	27	26	88.3
12	Site of Infection			
	Maxillary	10	8	30
	Frontal	5	6	18.33
	Ethmoidal	1	0	1.66
	Ethmoidal+ Maxillary	3	4	11.66
	Frontal+Maxillary	9	8	28.33
	Pansinusitis	2	4	10

Table 4 — Effect of Test drug A on subjective parameters

Subjective Parameters	Durationin weeks														% age 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 5 — Effect of Test drug A on objective parameters

Objective Parameters	Duration in weeks														% age at 6 wks
	No. of Patients							No. of patients improved							
	0	1	2	3	4	5	6	0	1	2	3	4	5	6	
Tenderness over affected sinus	23	21	19	16	13	9	7	0	2	4	7	10	14	16	69.5
Translucency in affected sinus during transillumination 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 6 — Effect of Test drug B on subjective parameters

Subjective Parameters	Duration in weeks														% age 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	26	23	19	15	12	18	4	0	3	7	11	14	8	22	84.61
Nasal Obstruction	19	17	14	12	9	8	5	0	2	5	7	10	11	14	73.68
Nasal Discharge	26	23	19	15	11	7	4	0	3	7	11	15	19	22	84.6
Cough	24	21	18	14	9	5	2	0	3	6	10	15	19	22	91.6
Facial Pain	18	16	15	12	9	7	6	0	2	3	6	9	11	12	66.7
Halitosis	15	14	12	11	10	9	9	0	1	3	4	5	6	6	40
Earache	9	9	7	6	6	5	5	0	0	2	3	3	4	4	44.4
Dental Pain	7	7	6	6	6	5	5	0	0	1	1	1	2	2	28
Anosmia	7	6	5	4	3	2	2	0	1	2	3	4	5	5	71.4
Fatigue	21	20	17	16	11	7	5	0	1	4	5	10	14	16	76

comparing both the groups test statistic, ψ^2=0.32, p=0.56, indicates non-significant difference between the two groups. Anosmia/hyposmia was subsided in 40% patients of group A and 71.4% patients of group B. Facial pain was relieved in 50% patients of group A and 66% patients of group B. On applying chi square test for comparing both the groups statistic, ψ^2=1.6, p=0.20, indicates non-significant difference between the two groups. Halitosis was relieved in 30% patients of group A and 40% patients in group B. On comparing both the groups using chi square test statistic, ψ^2=0.26, p=0.60, indicates non-significant difference between the two groups. Earache was relieved in 37% patients of group A and 44.4% patients of group B. On comparing both the groups using chi square test statistic, ψ^2=0.08, p=0.77, indicates non-significant difference between the two groups. Dental pain was relieved in 20% patients of group A and 28% of group B. Cough was relieved in 81% and 91% patients in group A and B respectively. On comparing both the groups using chi square test statistic, ψ^2=0.98, p=0.32, indicates non-significant difference between the two groups. Fatigue was subsided in 55% patients of group A and 76% patients in group B. on comparing both the groups test statistic, ψ^2=1.8, p=0.17, indicates non-significant difference between the two groups Table 4 & Table 6. As far as tenderness over the sinuses is concerned, 85% patients

had tender sinuses. After 6 weeks of complete treatment 69% patients in group A and 82% in group B reported no tenderness. On comparing both the groups using chi square test statistic, ψ^2=1.1, p=0.28, indicates non-significant difference between the two groups. At the beginning of the study transillumination test came out to be negative in 81.6% of the patients. After 6 weeks of treatment transillumination test was observed positive in 50% of the patients in group A and 72% in group B. On comparing both the groups using chi square test statistic, ψ^2=2.49, p=0.11, indicates non-significant difference between the two groups. Before starting the treatment, 61.6% patients were observed as having nasal mucosal edema**.** On comparing both the groups using chi square test statistic, ψ^2=1.13, p=0.28, indicates non-significant difference between the two groups. After six weeks of treatment in 52.9% patients of group A and 70% patients of group B no mucosal edema was observed. Nasal congestion was relieved in 75% patients of group A and 92% patients of group B. On X-ray PNS (water's view**)** haziness was found in 83% of patient's X-rays. After complete 6 week follow ups this haziness disappeared in 66% patients of group A and 76% of group B. On comparing both the groups using chi square test statistic, ψ^2=3.16, p=0.75, indicates non-significant difference between the two groups Opacity in sinuses was disappeared in 69.5% patients of group A and 79% of group B after treatment. On comparing using chi square test, ψ^2=0.56, p=0.45, indicates non-significant difference between two groups Table 5 & Table 7.

Mean DEC in group A before treatment was 9.53±0.23/cumm and after treatment it was 8.43±0.21/cumm (t=3.4, p<0.001) showing significant difference. While in group B, it was 9.46±0.25/cumm and 8.13±1.07/cumm before and after treatment respectively (t=4.125, p=0.0001) indicating significant difference statistically. On comparing both the groups using unpaired t test test statistic (t=0.49, p=0.62) indicates non-significant difference between the two groups. (Table 8)

Mean AEC in patients of group A before the treatment was 647±24.18/mm^3, while after the treatment it was 528±19.47/mm^3, test statistic (t=3.8, p<0.0003) shows significant difference. In group B, mean AEC was 691±14.0/mm^3 before the treatment and 548±14.79/mm^3 after the treatment, here the test statistic (t=7.9, p=0.0001) reported significant difference. On comparing both the groups using unpaired t test test statistic (t=1.13, p=0.26) indicates non-significant difference between the two groups. (Table 8)

Non-significant difference was observed in haematological and biochemical parameters studied before and after the treatment. (Table 9 & Table 10)

The effectiveness of Sharbat ustukhuddus in the management of *nazlamuzmin* may be attributed to the Muhallil (Anti-inflammatory activity) of Ustukhuddus[22,23,25,26], Asl-us-soos[22,24,25], Badiyan[23,24,25,27], Banafsha[24,26], Karafs[24,26], Khatmi[22,26,27,29], Maveez Munaqqa[25], Ood saleeb[23,24,25], Parsiaoshan[22,23,25] Mulattif (Demulcent activity)of Ustukhuddus[26,27], Asl-us-soos[24,29], Badiyan[27,29], Banafsha[26], Gaozaban[24], Gul-e-surkh[26], Khatmi[24,29], Ood saleeb[25], Parsioshan[22,23,24,25,26], Sapistaan[24]. Muqawwi-e-dimagh (Brain Tonic) Ustukhuddus[22,23,25,29] Maveez munaqqa[27]

Table 7 — Effect of Test drug Bon objective parameters

Objective Parameters	Duration in weeks														% age at 6 wks
	No. of Patients							No. of patients improved							
	0	1	2	3	4	5	6	0	1	2	3	4	5	6	
Tenderness over affected sinus	28	24	22	16	13	10	5	0	4	6	12	15	18	23	82
Translucency in affected sinus during transillumination test	25	25	22	18	14	11	7	0	0	3	7	11	14	18	72
Mucosal Edema	20	20	18	15	11	8	6	0	0	2	5	9	12	14	70
Nasal Congestion	28	28	24	20	13	10	2	0	0	4	18	15	18	26	92
Sinus Opacity	24													19	79
Sinus haziness	26													20	76.9

Table 8 — Effect of Test Drugs A & B on Eosinophil Count

S. No	Investigations	Test Group A				Test Group B			
		Mean ±SEM		t value	p value	Mean ±SEM		t value	p value
		BT	AT			BT	AT		
1.	DEC	9.53 ± 0.238	8.43± 0.218	3.40	<0.001	9.46± 0.257	8.13± 1.074	4.12	0.0001
2.	AEC	647± 24.18	528 ± 19.47	3.8	<0.0003	691 ± 14.00	548 ± 14.79	7.99	<0.0001

Table 9 — Effect of Test Drugs A & B on Hematological Parameters

S. No	Investigations	Test Group A Mean±SEM BT	Test Group A Mean±SEM AT	t value	p value	Test Group B Mean±SEM BT	Test Group B Mean±SEM AT	t value	p value
1	Hbgm/d	11.5±0.20	11.8±0.12	0.84	>0.05	12.1±0.35	12.3±0.30	0.49	>0.05
2	ESR mm/hr	21.86±0.69	22.33±0.87	0.41	>0.05	25.4±1.23	24.9±1.33	0.25	>0.05
3	TLC/cumm	6826±154.2	6720±174.2	0.45	>0.05	6690±99.0	6733±126	0.26	>0.05
4	N/cumm	63.93±1.17	64.36±1.04	0.27	>0.05	66.5±0.97	66.3±0.77	0.16	>0.05
5	L/cumm	29.9±1.12	30.0±1.23	0.03	>0.05	32.6±1.45	31.5±1.49	0.55	>0.05

Table 10 — Effect of Test Drugs A & B on Biochemical Parameters

S. No	Investigations	Test Group A Mean±SEM BT	Test Group A Mean±SEM AT	t value	p value	Test Group B Mean±SEM BT	Test Group B Mean±SEM AT	t value	p value
1	BU mg/dL	23.5±0.74	23.4±0.79	0.07	>0.05	21.7±0.50	20.7±0.53	1.38	>0.05
2	SC mg/dL	0.85±0.02	0.83±0.01	0.53	>0.05	0.88±0.02	0.88±0.02	0.23	>0.05
3	SB mg/dL	0.87±0.01	0.85±0.01	0.74	>0.05	0.83±0.04	0.81±0.03	0.29	>0.05
4	AST U/L	25.5±0.79	24.5±1.1	0.70	>0.05	26.6±1.1	25.8±0.95	0.55	>0.05
5	ALT U/L	25.7±1.63	25.0±1.21	0.35	>0.05	27.7±1.63	27.2±1.52	0.22	>0.05
6	SAP U/L	106.9±1.53	108.2±0.99	0.67	>0.05	114.5± 1.76	113.2±1.67	0.53	>0.05
7	RBS mg/dL	80.1±2.17	82.0±2.05	0.60	>0.05	84.9±2.33	83.5±2.21	0.45	>0.05

and Munaqqi-e-dimagh (Brain Depurative properties) of Ustukhuddus[22,23,25,26,27,29], Asl us soos[22,23,25]. Munaffis-e-balgham (Expectorant activity) ofUstukhuddus[28], Asl-us-soos[23,24], Banafsha[24], Gaozaban[22,24,25], Gul-e-surkh[24], Khatmi[23], Parsioshan[24], Sapistaan[22,23,25]. Munzij-e-balgham (Concoctive of phlegm action) of Ustukhuddus[26], Badiyan[22,25,29], Asl-us soos[29], Karafs[29], Khatmi[22,23], Ood saleeb[26], Parsiaohan[22,23,25,27]. Mushil-e-balgham (Purgative for phlegm action) of Ustukhuddus[22,23,25,29], Asl us soos[25], Gul-e-surkh[25]. Dafa-e-ufoonat (Antiseptic activity) ofUstukhuddus[24], Karafs[24], Ood Saleeb[23] and Dafa e sual **(**Anti tussive action) of Asl us soos[30], Gul e surkh[31], Khatmi[30]

The effectiveness of Sharbat Banafsha in the management of *Nazla Muzmin* may be due to the following actions of Banafsha which have been described in Unani literature i.e., Muhallil (Anti-inflammatory activity)[24,26,34], Mulattif (Demulcent activity)[26,32,34], Munaffis-e-balgham (Expectorant)[24,32,33,34,38], Anti tussive (Dafa-e-sual)[22,26,32,33,36,,37,38] Mushil-e-safra (Purgative for bile)[26,34,35,36,38], Muaddilsafrawa dam[26,34,35,36] Musaffi-e-dam (blood purifier)[22,26,32], Musakkin-e-auja (Sedative)[35], Munawwim (Hypnotic)[22,36], Mulayyan-e-halaqwa-seena[22], Murattib (Homectant)[22], Mughazzi (Nutritive)[36], Muarriq (Diaphoretic)[24,32,34], Daf-e-humma (Antipyretic)[24,32,33,34,35], Jazib (Absorbent)[26], Muzalliq (lubricant)[26]

The above mentioned properties present in Banafsha helps to reduce the sign and symptoms of chronic sinusitis.

The complaint of nasal obstruction in most of the cases of *warm-e- tajaweefanfmuzmin* is due to inflammation and secretion of nasal mucosa which produce obstruction in nasal passage. Due to Muhallil (emollient)[24,26,34], Mulattif (demulcent)[26,32,34], properties of banafsha which 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- tajaweefanfmuzmin* 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 (emollient)[24,26,34], Mulattif (demulcent)[26,32,34], properties of banafsha 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 (emollient)[24,26,34], Mulattif (demulcent)[26,32,34], Munaffis-e balgham (Expectorant)[24,32,34], Mushil-e-safra (Purgative for bile)[26,34,35,36], Musakkin-e-auja (Sedative)[35], Munawwim (Hypnotic)[22,36] actions of banafsha helps to reduce inflammation and clear sinus secretion and thus relieve headache.

Banafsha is also helpful in alleviating nasal discharge by reducing inflammation and irritation of mucous membrane due to Muhallil (emollient)[24,26,34], Munaffis-e-balgham (Expectorant)[24,32,34], Mushil-e-safra (Purgative for bile)[26,34,35,36], Muaddilsafrawa dam[26,34,35,36], Mulayyan[22,26,32,34,35] actions of banafsha.

Tenderness over the involved sinus is a typical sign of *warm-e- tajaweefanfmuzmin* 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, properties like Musaffi-e-dam (blood purifier)[22,26,32], Mulattif (demulcent)[26,32,34,] Muhallil (Anti-inflammatory activity)[24,34] Musakkin (Sedative)[35] properties of banafsha.

Opacity in sinuses is produced by accumulation of abnormal inflammatory fluid. This production and accumulation of abnormal fluid, like tenderness is also a by-product of ongoing active process of chronic inflammation. As soon as inflammation is controlled by treatment, the opacity reduces itself accordingly. Banafsha helps to resolve the opacity of sinuses due to properties like Muhallil (emollient)[24,26,34] Mulattif (Demulcent activity)[26,32,34], Munaffis-e-balgham (Expectorant)[24,32,34], Mushil-e-safra (Purgative for bile)[26,34,35,36], Musaffi-e-dam (blood purifier)[22,26,32] Musakkin-e-auja (Sedative)[35]

Various pharmacological studies have also established the following properties of the constituents of Banafsha which may also be helpful in the management of Chronic Sinusitis: Phytochemical analysis of *n*-hexane, butanol, methanol, and aqueous extracts of V. odorata aerial parts showed the presence of flavonoids, tannins, alkaloid, glycoside, and saponins. These metabolites are responsible for numerous pharmacological activities of different preparations.

Anti-inflammatory activity:[39,41,42] Aqueous extract of viola odorata contains combination of different essential oils (methy ester, salicylic acid, flavonoids, saponin, alkaloid, anthocyanin, gamma sitosterol, phytol, octadecanoid acid) causing good anti-inflammatory and antibacterial effect.

Antimicrobial activity[39,40,41,42]**:** Methanol and ethanol extract of Viola odorata leaves showed significant zone of inhibition against two Gram positive bacteria, *Bacillus subtilis*, Staphylococcus *aureus* and two Gram negative bacteria *Escherichia coli*, *Pseudomonas aeruginosa*. Composition of methanol fraction of V. odorataL. leaves contain N-Hexadecanoic acid, Pentadecanoic acid and 10-Undecyn-1-ol, ethy & methy ester, sitosterol, phytol, cyclotide reported to have antimicrobial activity.

Anti-histaminic activity: (octadecanoic acid, methy ester)[42] has property of antihistimic. Viola considerably inhibited the total serum level of IgE and cytokines such as IL-3 and IL-4. It also effectively decreased over response of the airways and eosinophilia and excessive secretion of mucus.[41]

Antiviral activity: gamma-sitosterol, eugenol has the characteristic of an antiviral[42].

Antifungal activity: peptides (cyclotides) including cycloviolacin Octadecanoic Acid, methyl ester has the property of antifungal[41,42].

Expectorant & Anti tussive activity (violin, rutin) which is used as an expectorant and saponinused as liquidator, expectorant, antispasm and bronchodilator[39,41].

Analgesic Activity: Metanol and Aqueous extract of arial part of viola odaorata (salicylic acid, alkaloid, steroid, flavonoid, tannin, saponin, n- hexane, butanolic, methanolic[39,40,41].

Sedative & Pre anaesthetic: Mixture of methanol and chloroform has sedative and preanaesthetic[39,40].

Antioxidant Activity peptides (cyclotides), eugenol, phytol, tetradecanoic, hexadecanoic, methyl ester, dichlormethane. All extract of viola odorata established potent antioxidan[40,41,42]

Antipyretic Activity: The antipyretic effect of (eugenol, *n*-hexane fraction)of Viola odorata was reported[39,42].

Allama Mohd Kabirduudin in bayaz-e-kabir has described the efficacy of Sharbat Banafsha in coryza, cough, fever, headache and chest pain[21].

Viola odorata has been used traditionally in different forms for curing different medical conditions. Viola flower syrup was also suggested by traditional Persian healers such as Avicenna (980-1037 AD) and Haly Abbas (930-994 AD) for cough control and asthma[41]. In Iranian traditional medicine, it was known as a plant with cold and wet temperament and has been used in hot and dry temperament diseases such as fever, excessive thirst, and uremic pruritus. It also widely recommended in Iranian traditional medicine for pulmonary diseases such as cough, pneumonia, and pleurisy[41]. So, by virtue of these properties Sharbat Banafsha is effective in treating chronic sinusitis.

As far as safety parameters are concerned, the difference in the hematological and biochemical parameters studied, before and after treatment, was

found to be statistically insignificant in both groups. This signifies that Sharbat Banafsha is safe with the given dose.

Conclusion

The aim of the study was to compare the efficacy of unani drugs sharbatustukhuddus and sharbatbanafsha in the management of chronic rhinosinusitis and to provide safe, easy available, easily tolerable and cost-effective drug. So, from this trial, we concluded that both test drugs were found to be effective on subjective as well as on objective parameters, Although no adverse effect of the drugs were reported, but sharbat banafsha is superior than sharbat ustukhuddus or better for this illness as it effectively relives most of the complaints due to chronic Sinusitis. However, authors recommend that more advanced studies need to be carried out .The study needs to be extra polated further on lager sample size.

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